Polyethylene Glycol Powder Solution Versus Senna for Bowel Preparation for Colonoscopy in Children

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See ''Bowel Preparation in Children: Is Polyethylene Glycol an Answer?'' by Patel and Pashankar on page 115.

ABSTRACT

Objectives: Safety and effectiveness of large-volume polyethylene glycol-based solution (PEG-ES) have been documented, but the taste and volume can be barriers to successful colonoscopy preparation. Efficacy and safety of small-volume electrolyte-free (PEG-P) preparation (Miralax) for colonoscopy preparation have been rarely studied, although presently used at many pediatric centers. The primary objective of the present study was to determine whether PEG-P results in a more efficacious and safe colonoscopy preparation as compared with senna.

Methods: The study design was prospective, randomized, and single-blinded. Patients ages 6 to 21 years were randomized to a 2-day clean-out regimen of PEG-P at a dose of 1.5 g/kg divided twice per day for 2 days versus senna 15 mL daily (ages 6–12) or 30 mL daily (ages 12–21) for 2 days. Both preparations required 1 day of clear liquids whereas senna preparation required an additional day of full liquid diet. A blinded endoscopist graded the quality of preparation with a standardized cleanliness tool (Aronchick scale). Serum chemistry panels were obtained. Patients or parents rated symptoms and ease of preparation. The anticipated number of subjects was 166; however, the interim analysis demonstrated inferiority of senna preparation.

Results: Thirty patients were evaluated in the present study. Of the patients in the PEG-P arm, 88% (14/16) received an excellent/good score compared with 29% (4/14), with the senna preparation ($P = 0.0022$). Both preparations were well-tolerated by patient-graded ease of preparation. Demographics and laboratory values did not differ significantly across the 2 groups. No serious adverse events were noted.

Conclusions: PEG-P is an effective colonoscopy preparation whereas senna preparation was insufficient. Both were well-tolerated and appear safe in a pediatric population.

Key Words: bowel preparation, children, polyethylene glycol, senna

(*JPGN* 2013;56: 215–219)

The role of colonoscopy is crucial to the diagnosis and management of gastrointestinal disorders. To perform such a procedure, the colon must be as clean as possible for appropriate detection of bowel pathology such as in inflammatory bowel disease or for polyp removal. In a pediatric population, it is also likely the most difficult part of the entire procedure from a patient perspective.

There is a wide variability in the type and length of bowel preparations at different institutions. Ideally, the preparation would be low volume, palatable, inexpensive, and effective without electrolyte abnormalities or major life disruption. Pediatric preparations were recently reviewed (1). Most preparations use either stimulant laxatives to promote peristalsis and water secretion or isosmotic laxatives that are nonabsorbable and promote large-volume lavage. A 2-day preparation with senna has been the primarily used preparation at our institution (2); however, providers were increasingly dissatisfied with this preparation resulting in liquid stool remaining that required clearing and limited mucosal visibility. The use of polyethylene glycol with electrolytes (PEG-ELS, Go-lytely, Braintree Laboratories, Braintree, MA) was first described in children in 1984 (3). Although safe and effective, most pediatric patients require nasogastric (NG) tube placement owing to the large volume required and the salty taste (4). Low-volume PEG-ELS preparation (HalfLytely, Braintree Laboratories) has also been used, but in our experience its taste often precludes successful completion of preparation. PEG-3350 without electrolytes (PEG-P; Miralax, Schering-Plough HealthCare Products, Memphis, TN) has been used successfully and safely in the long-term management of constipation in children (5–7). Two studies have demonstrated that this medication can be used as a safe and effective preparation in children with a dose of 1.5 g/kg for 4 days (8,9). This regimen was condensed to a 2-day preparation using a 2-g/kg dose of PEG-P with bisacodyl and still yielded excellent and good colon preparation scores in approximately 90% of patients (10).

The primary objective of the present study was to compare the efficacy of PEG without electrolytes (PEG-P) and senna using the Aronchick scale to assess preparation quality. The secondary

Received February 6, 2012; accepted May 30, 2012.

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Supplemental digital content is available for this article. Direct URL citations appear in the printed text, and links to the digital files are provided in the HTML text of this article on the journal's Web site (*www.jpgn.org*).

www.clinicaltrials.gov registration number: NCT01140295.

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N.A.T. is supported by training grant NIH-T32-DK007066.

The authors report no conflicts of interest.

DOI: 10.1097/MPG.0b013e3182633d0a

objectives were to investigate safety by measuring serum electrolytes and to judge patient tolerability.

METHODS

Patients

Patients ages 6 to 21 having an outpatient colonoscopy at the Endoscopy Suite at the Children's Hospital of Philadelphia (CHOP) for the first time were eligible for this study. Based on criteria, eligible patients were identified and an informational letter about the study was sent via mail. Verbal consent was obtained by phone. Patients and/or their parents who consented to participate were counseled by a nurse over the phone using a packet containing a randomly chosen preparation (PEG-P or senna). Each packet contained a questionnaire and preparation instructions that the nurses administered and a residual stool survey for the endoscopist. The endoscopist was blinded to the type of preparation. When the principal investigator (P.M.) was performing the colonoscopy, a second endoscopist was asked to grade the preparation. All colonoscopies were performed under general anesthesia.

Patients were excluded from the study if they had chronic renal, liver, or heart failure, chronic constipation, or were presently hospitalized. Patients were not eligible for the study if they had a prior colonoscopy. Patients taking senna or PEG-P on a regular basis for laxative reasons were also excluded. Pregnant or lactating patients could not participate. For the PEG-P group, patients had to weigh <70 kg as not to exceed the maximum 51 g/dose, established by the institutional review board who approved the study.

Medication Dosing

Senna dosage was as follows: age 6 to 12 years: 3 teaspoons (26.4 mg sennosides) or 3 tablets (25.8 mg sennosides) by mouth 2 nights before endoscopy and 1 night before endoscopy. Age >12 years: 6 teaspoons (52.8 mg sennosides) or 6 tablets (51.8 mg sennosides) by mouth 2 nights before endoscopy and 1 night before endoscopy. Full liquid diet was to be maintained 2 days before endoscopy. Clear liquid diet was to be maintained on the day before endoscopy up until 3 hours before procedure. Patients were instructed to have nothing to eat or drink by mouth 3 hours before endoscopy procedure. A Fleet rectal adult-size enema (saline laxative, C.B. Fleet Co, Inc, Lynchburg, VA) was administered on the morning of the procedure.

PEG-P dosage was 1.5 g/kg divided twice a day for 2 days; maximum of 51 g/dose. Patients were instructed to dissolve each 17 g (1 capful) of PEG-P in 240 mL of water or another beverage according to the manufacturer's direction. A regular diet was to be maintained 2 days before endoscopy. Clear liquid diet was to be maintained on the day before colonoscopy up until 3 hours before procedure. Patients were instructed to have nothing to eat or drink by mouth 3 hours before colonoscopy procedure.

Electrolyte serum levels, including a standard chemistry 7 panel in addition to magnesium, calcium, and phosphate, were obtained before colonoscopy and evaluated by the principal investigator for any significant abnormalities on the day of colonoscopy. GFR was calculated with the Schwartz formula of $0.41 \times$ height (cm) $\times$ serum Cr (mg/dL) (11). The funding for the laboratory analysis was provided by the Division of Gastroenterology, Hepatology, and Nutrition and the Department of Pathology at CHOP.

Blinding

Endoscopists were blinded by instructing the nurse, patients, and patients' families to not discuss the specifics of the preparation. The endoscopist assessed the quality of the preparation by the Aronchick scale (12). A database was maintained by another member of the investigative team who was also blinded to the preparation but entered the corresponding packet number, questionnaire results, and result of residual stool survey. The Aronchick score uses stool coverage to measure adequacy of bowel preparation (12). A score of excellent is given for $>95\%$ of surface seen, good for liquid stool covering $<25\%$ or 90% of surface seen, fair for semisolid stool and $>90\%$ surface seen, poor if semisolid stool and $<90\%$ of surface seen, and inadequate if repeat procedure is required.

Patient Questionnaire

The patient questionnaire was completed by the parent on the day of the colonoscopy after the preparation was completed but before the start of the procedure. Six questions were asked (Appendix 1, *http://links.lww.com/MPG/A133*). Two questions pertained to completion of the patient preparation. Three questions queried symptoms of abdominal pain, nausea, and vomiting. Finally, the last question had the preparation rated on a scale of 0 to 10, with 0 being worst preparation possible and 10 being completely pain-free and easy.

Patient Population

During the study period, 835 colonoscopies were performed at CHOP and its satellite offices. Approximately 90% of children during this period received colon preparation with senna. Thirteen different physicians participated as the endoscopist based on availability at the time of the procedure. During the study, 365 patients were screened. Ninety-eight patients were eligible. Thirty-three patients enrolled, 41 declined, and 24 were either not contacted or pending at the time the study was closed for enrollment.

Statistical Analysis

Based on preliminary data obtained from CHOP on 25 consecutive patients undergoing colonoscopy in 2005, 80% of patients who received the senna preparation had a score of excellent or good. A score of excellent or good was considered an effective cleansed colon for colonoscopy. We postulated that the PEG-P preparation would yield a score of excellent or good in 90% of our patients. When sample size is 83 in each group, 2-sided 95% continuity corrected confidence interval (CI) for the difference between group 1 proportion of 0.8 and group 2 proportion of 0.9 based on the large sample normal approximation will extend 0.12 from the observed difference in proportion.

Interim analysis was planned after 25% of study patients were enrolled. Criteria for stopping the study included consistently poor colon preparation or life-threatening or serious complications. Poor colon preparation was defined as patients needing to undergo repeat colonoscopy owing to incomplete preparation or low proportion of patients with satisfactory rate of cleanliness. Poor colon preparation conditions were met by senna in the interim analysis, so the study was prematurely stopped.

The outcome of interest was the proportion of colon cleanliness rated as good (score 2) or excellent (score 1). 95% CI of the differences in proportions of outcome were estimated based on comparing PEG-P group to senna group. Vital signs and electrolyte values on the day of endoscopy were compared between the PEG-P and senna treatment group using a 2-sample t test. Chi-square test was performed to examine whether there was significant

association. Demographic, colonoscopy indication, and questionnaire variables were evaluated by Wilcoxon 2-sample tests.

RESULTS

Thirty-three patients were enrolled in the study and 30 patients completed the study. There was no significant difference in age, sex, race, or ethnicity between the 2 groups (Table 1). Several different indications were listed for each patient undergoing colonoscopy. Most common were abdominal pain and diarrhea (Table 1). There was no significant difference between study groups for colonoscopy indication. Of the 3 patients who did not complete the study, 1 patient canceled the procedure and 2 patients withdrew owing to preference for the nonassigned preparation after receiving the information.

Efficacy

The interim analysis was conducted after 30 patients were enrolled in the study. In evaluating the primary outcome it was clear that PEG-P was significantly more effective than the senna preparation (Fig. 1). The poor preparation outcome in the senna arm met conditions to stop the study prematurely.

Separated into discrete categories of excellent, good, fair, poor, or inadequate, the PEG-P preparation was superior. Although only 25% of patients received a score of excellent, 63% received a score of good in the PEG-P arm compared with 7% and 21% in the senna arm, respectively ($P = 0.0052$). When combining the excellent and good scores, 88% of patients in the PEG-P group achieved this level of preparation compared with 29% of patients in the senna group ($P = 0.0022$).

The type of preparation did not significantly affect the ability to complete the colonoscopy and reach the terminal ileum. The terminal ileum was reached in 16 of 16 patients in the PEG-P arm as opposed to 11 of 14 patients in the senna arm ($P = 0.089$). In the failed completions, the procedure was only completed to the hepatic flexure once and ascending colon once owing to the amount of stool present. In the third patient, the cecum was reached but the terminal ileum was not intubated. The preparation was poor and technical difficulties required the assistance of multiple endoscopists. From the records, it was not clear if intubating the terminal ileum was difficult owing to the preparation or whether a decision was made that the terminal ileum did not need to be visualized because it was a screening colonoscopy for colon cancer. No repeat colonoscopy was necessary in any of the procedures. One patient in the senna arm did receive a score of inadequate because no bowel movement was generated by the senna preparation and instructions were given by the overnight on-call physician for PEG-P to be given.

TABLE 1. Demographics of patient population and indications for colonoscopy

Demographics	PEG-P	Senna	Totals	*P*
Average age, mo	148.1	159.9	154.6	0.3150
Ethnicity				
Non-Hispanic	16 (100)	12 (86)	28	0.2092
Unknown	0 (0)	2 (14)	2	
Sex				
Male	10 (63)	7 (50)	17	0.7131
Female	6 (38)	7 (50)	13	
Race				
Asian	1 (6)	0	1	1.000
Black/AA	3 (19)	2 (14)	5	
White	12 (75)	12 (86)	24	
Average weight, kg	44.8	49.0	46.8	0.3564
Indications for colonoscopy				
Abdominal pain (N)	11	9	20	0.7992
Diarrhea (N)	7	6	13	0.9614
Rectal bleeding (N)	5	1	6	0.1054
Family history of colon cancer (N)	1	3	4	0.2303
Weight loss (N)	3	3	6	0.8572
Imaging concerning for IBD (N)	1	1	2	0.9234

AA = African American; IBD = inflammatory bowel disease; PEG = polyethylene glycol.

Safety

There was no significant difference in the serum electrolyte levels between the 2 groups (Table 2; *P* values 0.25–0.93). Values were recorded outside of the normal range in 28 of the 30 patients in the study; however, the abnormal values never deviated >1 or 2 units below normal and were deemed to be clinically insignificant by the principal investigator. For example, the lowest potassium value recorded was 3.5 mmol/L. The electrolytes that were altered most frequently were potassium, creatinine, and carbon dioxide. We did not have a previous set of laboratory values for all patients for comparison.

All of the abnormal creatinine values were 0.6 and 0.7 mg/dL for patients younger than 13 years except for 1 value of 0.9 mg/dL in a 15-year-old boy assigned to the senna preparation. A previous set of laboratory values demonstrated a creatinine of 0.8 mg/dL for this patient. The calculated GFR was >75 mL/min/1.73 m^2 in all patients, suggesting that renal function was not compromised with the preparations.

No significant adverse events were recorded. One patient had a small amount of emesis after general anesthesia.

Ease of Preparation

Patients or their families recorded the ease of preparation based on a 0–10 scale with 0 being the worst prep and 10 being a pain-free easy prep. The average score for the senna group was 6.7. The PEG-P arm yielded a slightly higher average rating of 7.9 ($P = 0.0839$). When questioned about abdominal pain, nausea, and vomiting, there was no significant difference between the 2 groups (Table 3). The 1 major difference between the groups was telephone calls made to the on-call care providers, 5 telephone calls in the senna group and 0 phone calls in the PEG-P group. Three of the calls were in reference to the senna prep not yielding any bowel movements and additional recommendations were made for further therapy.

Patients in both arms did not have trouble completing the preparation with all but 1 patient in each group taking 100%. One patient in the senna arm only completed 50% for unknown reasons and the cleanliness score was good. One patient in the PEG-P group that only completed 75% of the preparation owing to nausea and abdominal pain received a score of poor. An additional enema was required for 2 patients in the senna arm and 1 patient in the PEG-P arm ($P = 0.586$).

DISCUSSION

Bowel preparation for colonoscopy is a critical component for diagnosis and therapy of pediatric gastrointestinal disorders. Finding a preparation for children that is safe and tolerable can be difficult. The 2-day senna preparation has been used at our

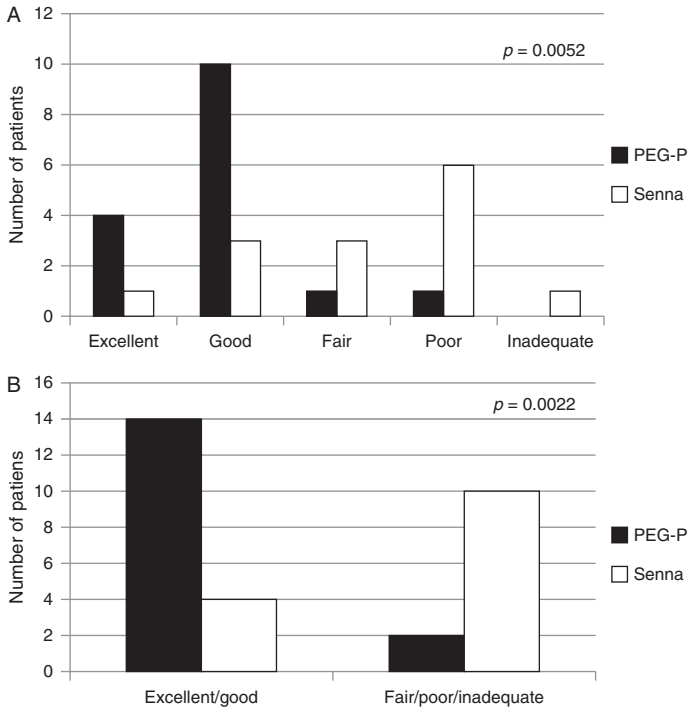

FIGURE 1. Aronchick scores for polyethylene glycol (PEG)-P and senna arms. A, Scores were separated into 5 distinct categories. B, Excellent/good scores were combined and compared with fair/poor/inadequate combined score.

institution for more than a decade (2). However, the efficacy of this preparation was found to be poor in our trial. Although the number of patients enrolled was rather small, the results prompted us to discontinue the use of a senna preparation and institute a PEG-P regimen, which was successful in almost 90% of patients. Separating the results into distinct categories, an excellent preparation, defined by >95% of the colon visualized, was achieved in only a quarter of patients using this PEG-P regimen emphasizing a need to continue to search for the appropriate dose and dietary restriction duration.

It is unclear why senna was associated with a poor outcome. The study data were different than our preliminary data acquired in 2005. However, 1 of the main reasons to perform this study was based on the subjective feeling of our endoscopists that the senna preparation provided poor results. Furthermore, looking back on the Trautwein et al's study on which our senna preparation is based, the preparation frequently yielded large amounts of liquid stool, although the Aronchick score was not used at that time. Senna does provide an effective bowel preparation in adults compared with PEG-ES (13). Using the same Aronchick scoring system,

TABLE 2. Electrolyte values on day of colonoscopy after preparation

	Ages	Normal range	PEG-P patient range	Senna patient range	P^*
Sodium	Age <15 years	136–145 mmol/L	135–141 mmol/L	134–142 mmol/L	0.5862
	Age >15 years	135–145 mmol/L	137–140 mmol/L	135–140 mmol/L	
Potassium	Age <10 years	4.1–5.8 mmol/L	4.0–4.4 mmol/L	4.4 mmol/L	0.7000
	10–15 years	3.8–5.4 mmol/L	3.7–4.9 mmol/L	3.6–4.2 mmol/L	
	Age >15 years	3.6–5.0 mmol/L	3.5–4.0 mmol/L	3.6–5.2 mmol/L	
Chloride	All ages	98–106 mmol/L	100–109 mmol/L	97–106 mmol/L	1.0000
Bicarbonate	All ages	20–26 mmol/L	23–29 mmol/L	22–29 mmol/L	0.4171
BUN	3–12 years	5–17 mg/dL	4–12 mg/dL	6–14 mg/dL	0.6015
	13–19 years	7–18 mg/dL	6–15 mg/dL	6–12 mg/dL	
Creatinine	Age <13 years	0.2–0.5 mg/dL	0.4–0.7 mg/dL	0.4–0.6 mg/dL	0.6944
	Age >13 years	0.3–0.8 mg/dL	0.6–0.8 mg/dL	0.5–0.9 mg/dL	
Magnesium	All ages	1.5–2.5 mg/dL	1.6–2.2 mg/dL	1.6–2.2 mg/dL	0.7565
Phosphorus	Age <12	3.7–5.6 mg/dL	3.8–5.7 mg/dL	4.6–5.4 mg/dL	1.0000
	Age 12–13	3.3–5.4 mg/dL	4.4–4.6 mg/dL	4.3–5.2 mg/dL	
	Age 14–15	2.9–5.4 mg/dL	3.6–4.9 mg/dL	4.4–5.8 mg/dL	
	Age >16 years	2.7–4.7 mg/dL	2.9–4.1 mg/dL	3.6 mg/dL	

BUN = blood urea nitrogen; PEG = polyethylene glycol.
* *P*-value based on values outside of range.

TABLE 3. Ease of preparation evaluation by patient/parent questionnaire

	PEG-P, N = 16 (%)	Senna, N = 14 (%)	*P*
Abdominal pain	5 (33)	9 (64)	0.143
Unable to finish prep	1 (6)	1 (7)	1
Nausea	3 (19)	6 (43)	0.236
Vomiting	1 (6	3 (21)	0.315

PEG = polyethylene glycol.

>90% of adults received an excellent/good score with the senna preparation. The difference from our pediatric population is considerable in which only 29% of patients received a score of excellent or good. The difference could be because of different dietary restrictions, senna dosing, or small sample size.

Studies have demonstrated the safety and efficacy of a 4-day PEG-P preparation (8,9); however, that length of preparation is not feasible in everyday practice. With the same daily dose of PEG-P ($1.5\ g \cdot kg^{-1} \cdot day^{-1}$), our study was able to show similar effectiveness of only a 2-day preparation (91%, 89%, and 88%, respectively, for the equivalent of excellent/good score). To establish an effective dose of PEG-P, a recent prospective study determined $1.9\ g \cdot kg^{-1} \cdot day^{-1}$ for 2 days with clear liquid diet resulted in clear stools and >90% of patients with the equivalent of an excellent/good Aronchick score (14). Finally, another recent prospective study evaluated a 2-day PEG-P preparation with $2\ g \cdot kg^{-1} \cdot day^{-1}$ PEG-P with bisacodyl supplementation (10). Although demonstrating efficacy (92% excellent/good cleanliness), the study was not blinded, lacked a comparison arm, and did not assess safety through electrolyte measurement. One retrospective study has evaluated a 1-day PEG-P preparation, which seems to be a commonly used regimen. With a common dose used for all ages and a large volume required (255 g PEG-P/1.9 L), the safety of this preparation has not been established and the patient tolerability has not been compared (15). Therefore, performing further studies in children will be necessary to establish both efficacy and safety of a 1-day regimen.

A limitation of this study is its small size. Although the study was powered for >160 children, the early results justified stopping the study prematurely. Despite the small size, the results were still significantly different for efficacy of the preparation. Another limitation of the small study size is the interpretation of electrolyte imbalances. Although many patients had a value determined outside of the normal range, none of these values were clinically significant.

Two-day PEG-P was found to be an effective colonoscopy preparation, whereas senna preparation was insufficient in this small, randomized clinical trial. Both preparations were well-tolerated and appeared safe in a pediatric population.

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