Prospective Evaluation of 1-Day Polyethylene Glycol-3350 Bowel Preparation Regimen 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: The aim of the present study was to evaluate efficacy, safety, and tolerability of a pediatric colonoscopy bowel preparation regimen composed of polyethylene glycol-3350 (PEG-3350) and a sports drink completed in a few hours.

Methods: A prospective, open-label trial of a colonoscopy bowel preparation in children ages 8 to 18 years that included 238 g of PEG-3350 mixed with 1.9 L of Gatorade completed in a few hours. Efficacy was determined using the Boston Bowel Preparation Scale. Basic metabolic profiles and questionnaires were obtained that assessed for safety, adverse effects, tolerability, and patient acceptability.

Results: Forty-six patients completed the study. Patients were predominately boys (56.5%) with a mean age of 14.50 years (SD ±2.9 years). Forty-three (93.5%) were able to complete the regimen. All of the colonoscopies were completed to the cecum and 84% had terminal ileum visualization. Seventy-seven percent were found to be effective preparations. Nausea/vomiting were the most common reported adverse effect (60%) followed by abdominal pain/cramping (44%) and fatigue/weakness (40%). Overall, the regimen was acceptable with 1 exception being the large volume to drink. There were no clinically significant changes in basic metabolic profiles, although there was a statistically significant decrease in the mean potassium (0.16 mEq/L; $P = 0.016$), blood urea nitrogen (2.68 mg/dL; $P < 0.0001$), and carbon dioxide (1.89 mmol/L; $P < 0.0001$).

Conclusions: This study demonstrated that PEG-3350 + Gatorade administered in a few hours is an effective, safe, and moderately tolerable bowel preparation regimen for colonoscopy in children.

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

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Colonoscopy is an important procedure to evaluate the large intestine of children who present with diarrhea, hematochezia, melena, or abdominal pain. Bowel preparation is an essential part of the procedure. Incomplete colonic cleansing can result in poor colonic visualization, missed lesions, increased procedure time, potentially more procedure complications, difficult terminal ileum visualization, and added costs for patients including the inconvenience of a repeat procedure (1,2). Barriers to a good bowel preparation in children include poor palatability, large preparation volumes, poor compliance with multiple day regimens, strict dietary requirements, adverse effects, and potential safety concerns.

Standard pediatric bowel preparation regimens do not exist, although multiple studies have found that adult regimens are adequate for children. Preparations have included using high-dose polyethylene glycol with electrolytes (PEG-ELS) that frequently required nasogastric administration (3,4), magnesium citrate, or combinations with stimulants (ie, bisacodyl) that had poor palatability (3,5), prolonged polyethylene glycol-3350 (PEG-3350) over 4 days, which was too long of a regimen (6,7), oral sodium phosphate with risks of hyperphosphatemia and calcium fluxes (5,8,9), and enemas alone or in combination with stimulants that required anal insertion (9,9a).

PEG-3350 has been studied extensively and found to be safe and efficacious with very good tolerability in treatment of childhood constipation and for bowel preparation as a stand-alone medication (MiraLAX; Schering-Plough Healthcare Products Inc, Kenilworth, NJ) or when combined with an electrolyte-containing solution (10–17). Compared with lactulose and magnesium hydroxide, PEG-3350 has been shown to be both safe and effective, but better tolerated by patients (18–20). Kinservik and Friedhoff (21), in a review of PEG-3350 in children, concluded that there were no significant adverse effects and good acceptability. Another four studies have demonstrated that PEG-3350 is effective, safe, and well-tolerated for bowel preparation in children when given at a dose of 1.5–2 g/kg/day for 2–4 days before colonoscopy either alone (6,7,22), or in combination with bisacodyl (23).

A new short-course regimen is becoming more accepted among pediatric and adult gastroenterologists. This regimen utilizes a single, high-dose (200–255 g) of PEG-3350 mixed in 1.9 L of a sports drink. This dosage is comparable to the polyethylene glycol administered in PEG-ELS. The addition of sports drinks such as Gatorade (Pepsico Inc, Purchase, NY) provides electrolytes in a lower, more palatable amount, and theoretically would be more acceptable in the pediatric population. Two prospective adult studies have evaluated this regimen, and both found it to be less

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efficacious but more tolerable than other preparations such as PEG-ELS (24,25). Only one study has evaluated a similar regimen in children, and this retrospective study lacked a standardized method of evaluating bowel preparation (26). We conducted a prospective, open-label study to evaluate the efficacy, tolerability, acceptability, and safety of PEG-3350 + Gatorade administered over a few hours.

METHODS

Patient Selection

All of the 8- to 18-year-old patients scheduled for colonoscopy at Walter Reed Army Medical Center (WRAMC, Washington, DC) between September 1, 2010 and August 31, 2011 were eligible to enroll in the study. Exclusion criteria were aspiration risk, oral aversion, history of preexisting metabolic or renal disease, cardiovascular disease, or colonic surgeries, allergies to food coloring or PEG, inpatient or emergency colonoscopy, current nasogastric tube, or known pregnancy. The main indications for colonoscopy were abdominal pain, diarrhea, hematochezia, or growth failure.

The study received approval from the institutional review board of WRAMC. Written informed consent (and written assent for all of the children 11 years or older) was obtained for all of the patients and included a discussion of the expected volume needed to be ingested to complete the study.

Bowel Preparation Regimen

Patients were given a standardized regimen that included mixing 238 g of PEG-3350 with 1.9 L (64 ounces) of Gatorade. Detailed instructions on the bowel preparation regimen and the colonoscopy were provided by e-mail or in person. On the day of the preoperative appointment, patients and their parents received instruction on the completion of the regimen, and were provided with the 238 g of PEG-3350 and Gatorade. The Gatorade (1.9 L blue-flavored bottle) was provided at no expense to the family. Patients were instructed to mix 14 capfuls (238 g) into the bottle 1 day before the procedure. On that day, they were also expected to maintain a clear-liquid diet starting no later than 12:00 hours. At 18:00 hours, patients were instructed to start drinking 240 mL of the cleanout every 15 to 30 minutes until the full bottle was consumed. If they were unable to complete more than 75% of the regimen in 4 to 6 hours, families were instructed to call the on-service pediatric gastroenterology fellow, who would provide further instruction.

Safety and Efficacy Assessment

Bowel preparation efficacy was evaluated utilizing the Boston Bowel Preparation Scale (BBPS). This scale was found to be a valid and reliable measure of bowel preparation efficacy in adult patients (27). It proved to be a suitable research instrument for the present study because it accounted for the colon's cleanliness during the inspection phase of the colonoscopy and, thus, it did not penalize for the cleaning/suctioning process before inspection. Another benefit of utilizing this scale was the availability of a teaching video, which permitted intradepartmental consensus on scoring. The BBPS uses a 10-point cleanout efficacy scale, based on a rating of 0 to 3 in 3 sections of the colon (right side, transverse, and left side), where 0 = ''unprepared colon due to solid stool,'' 1 = ''portion of mucosa not seen,'' 2 = ''minor amount of residual staining,'' and 3 = ''entire mucosa seen well with no staining.'' The sum of all 3 sections was calculated to give a total score from 0 to 9. The BBPS was scored by the on-service fellow, in conjunction with the staff endoscopist at the completion of the colonoscopy. Another marker for efficacy was to determine whether cecal visualization or terminal ileum intubation was successful, and this was annotated at time of the completion of the BBPS. All WRAMC pediatric gastroenterology staff and fellows completed the training for the BBPS. By departmental consensus a BBPS score of at least 5 was believed to be an acceptable bowel preparation, whereas a score of $\geq$7 was established to be an excellent preparation.

Thirty-seven patients had serum electrolytes (sodium, potassium, calcium, and chloride), serum creatinine, blood glucose, and blood urea nitrogen obtained before preparation (<30 days from colonoscopy) and after cleanout (immediately before the colonoscopy). On the day of the procedure, 45 of the 46 patients and their parents completed a questionnaire that collected the following information: start and stop time of bowel preparation, total volume completed, stool consistency based on the Bristol stool scale (28), missed days from school or parent from work because of the bowel preparation, adverse effects, and rating scale for acceptance of volume, palatability, adverse effects, and overall. Rating was on a Likert scale from 1 to 5 with 1 = ''hated it,'' 2 = ''didn't like it,'' 3 = ''ok,'' 4 = ''good,'' and 5 = ''excellent.''

Statistical Analysis

Data were inspected for normality utilizing univariate techniques. Laboratory values before/after bowel preparation were assessed using a paired, Student *t* test or Wilcoxon signed rank test when data were not normally distributed. BBPS scores were categorized into a binary variable, at least 5, and <5. This variable was compared to age, sex, dose of PEG-3350 ingested (g/kg), patient height, time from cleanout initiation to time of scope, reported cleanout adverse effects using the Fisher exact test, Student *t* test, or Wilcoxon rank sum test. All statistical tests were 2-tailed, and an alpha of 0.05 was used in determining significance. All study data were analyzed using SAS 9.2 (SAS Institute, Cary, NC).

RESULTS

A total of 50 patients were recruited for the study and 46 were able to participate. Forty-three patients (93.5%) were able to complete the study bowel preparation regimen and 37 patients had laboratory evaluations performed. Two of the three patients who failed to complete the study regimen required an alternate bowel preparation but were able to complete the questionnaire and had their colonoscopies performed (although they were not included in efficacy and laboratory assessments). The third patient had her procedure cancelled because she was unable to complete the regimen in time for fasting requirements. Demographic and timing data are presented in Table 1. There were 26 boys and 20 girls with a mean age of 14.5 years (SD $\pm$ 2.9 years). The mean time for completion of the study regimen was 172 minutes (SD $\pm$57 minutes), and average time to start of the colonoscopy from start of the bowel preparation was 16 hours 43 minutes (SD $\pm$1 hour 30 minutes).

All of the patients had completed colonoscopies with the cecum visualized in 100% or the terminal ileum intubated in 84% of the procedures. Efficacy data distribution is presented in Figure 1. The mean total BBPS score was 6.16 (SD $\pm$1.66). Not unexpectedly, the right colon had the worst mean BBPS score of 1.86 (SD $\pm$0.68) compared with a transverse colon score of 2.21 (SD $\pm$0.6, and a left colon score of 2.07 (SD $\pm$0.70). The primary endpoint of our study for an acceptable preparation BBPS score of least 5 was met in 33 (77%) of the patients. Excellent bowel preparations were noted in 44% with BBPS scores of $\geq$7. Only 1 of the colonoscopies received a score <4 and was deemed ''poor.'' No predictive

TABLE 1. Patient demographics and bowel preparation timing

n = 46	No. (%)	
Female	20 (43.5)	
Male	26 (56.5)	
n = 46	Mean (±SD)	
Age, y	14.50 (±2.9)	
Weight, kg	55.4 (±19.1)	
n = 43*	Time (±SD)	IQR†
Bowel preparation completion time	2 h 52 min (±57 min)	120–219 min
Time to colonoscopy‡	16 h 43 min (±90 min)	15 h 46 min–17 h 30 min

IQR = interquartile range.
*Three patients who did not complete cleanout were not included in timing. †IQR (25%–75%). ‡Time from start of cleanout as reported on patient questionnaire to start of colonoscopy as reported by endoscopist.

TABLE 2. Patient questionnaire responses

Bristol stool type (n = 45)	No. (%)
Type 1–5	0 (0)
Type 6	3 (6.7)
Type 7	40 (88.9)
Not rated*	2 (4.4)
Adverse effects (n = 45)	No. (%)
Nausea/vomiting	27 (60)
Abdominal pain/cramping	20 (44)
Fatigue/weakness	18 (40)
Other†	4 (8.9)
Called on-call provider‡	5 (11.1)

*Did not include 2 patients who had alterations to the bowel preparation regimen. †Headache (2), burping, chills, and chest pain. ‡Vomiting (2), unable to complete, took Dulcolax, and diet question.

variables (age, sex, height, dose per patient weight, timing, and reported adverse effects) because of bowel preparation efficacy were identified.

Of the 45 patients who completed the questionnaire (Table 2), 43 reported that they were able to complete 75% or more of the regimen with 37 patients completing the full 1.9 L. Of the other 2 patients, 1 drank only 460 mL and the other 600 mL. Their preparations were supplemented with bisacodyl or magnesium citrate before their colonoscopies. The median ingestion dose amount for all of the patients was 33.9 mL/kg (25%–75% interquartile 25.7–43.3). By the completion of the bowel preparation, 40 patients (93%) described their stool as a type 7 (''entirely liquid'') on the Bristol scale and the remaining patients reported Bristol type 6 (''mushy stool''). Thirty-four (76%) reported missing no days from school because of the bowel preparation, whereas 38 (84%) reported no parental missed days from work.

There were no clinically significant changes in basic metabolic profiles in the 37 patients who had labs drawn. There were statistically significant decreases in mean potassium (0.16 mEq/L, $P = 0.016$), blood urea nitrogen (2.68 mg/dL, $P < 0.0001$), and carbon dioxide (1.89 mmol/L, $P < 0.0001$) (Table 3). Six post-bowel preparation laboratory results were outside of normal, but none were deemed clinically significant by the study medical safety monitor.

Of the 45 patients who completed the questionnaire, 27 (60%) reported nausea or vomiting related to the regimen, whereas another 20 (44%) reported abdominal pain or cramping and 18 (40%) reported fatigue or weakness. However, only 5 of the 46 (11%) patients called the on-call provider due to adverse effects. Of these 5 patients, 2 required additions to their bowel preparation regimen as described above, and 1 had their colonoscopy cancelled and did not complete the questionnaire.

Ratings of the bowel preparation were completed by 45 patients via the questionnaire. Overall, 29 patients (64%) rated the regimen as acceptable; giving it a score of at least 3 (mean 2.91, SD ±1.08). Palatability of the regimen received high ratings (73% rating ≥3; mean 3.09, SD ±1.16), whereas volume received the lowest rating (62% rating ≤2; mean 2.38, SD ±1.11). Despite the reported adverse effects as discussed previously, only 31% of patients found them to be unacceptable with a score of ≤2 (mean 2.96, SD ±1.21).

DISCUSSION

The present study demonstrates that PEG-3350 with Gatorade administered in a few hours is effective, is safe, and has moderate tolerability and patient acceptance as a bowel preparation regimen in children. This regimen provides a reasonable alternative to existing 1-day PEG-ELS regimens, in urgently needed colonoscopies or for patients unwilling to complete a longer PEG-3350 preparation.

All of the patients who completed the study regimen had a complete colonoscopy with cecal visualization and/or terminal ileum intubation, making it an acceptable regimen for

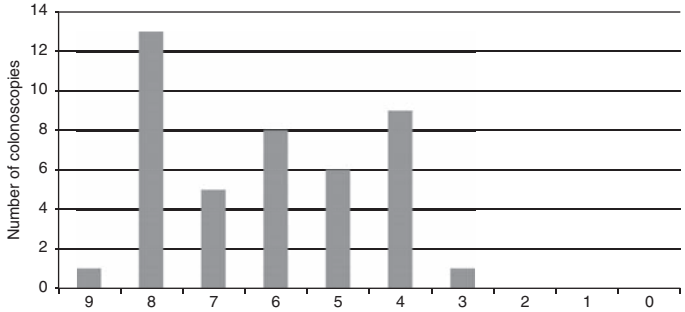

FIGURE 1. Distribution of Boston Bowel Preparation Scores (BBPS).

TABLE 3. Laboratory results before and after bowel preparation

Lab (n = 37)	Prepreparation (mean [±SD])	Postpreparation (mean [±SD])	Difference (mean [±SD])	$P^{*,\dagger}$
Sodium (mmol/L)	141.30 (±2.50)	140.65 (±3.00)	−0.65	0.178
Potassium (mEq/L)	4.44 (±0.26)	4.28 (±0.36)	−0.16	**0.016**
Chloride (mmol/L)	102.84 (±2.76)	103.41 (±2.76)	0.57	0.166
Carbon dioxide (mmol/L)	27.08 (±2.19)	25.19 (±2.59)	−1.89	**<0.0001**
Blood urea nitrogen (mg/dL)	11.92 (±3.83)	9.24 (±2.50)	−2.68	**<0.0001**
Creatinine (mg/dL)	0.71 (±0.17)	0.69 (±0.17)	−0.02	0.265

* Values in bold represent statistically significant values. † *P* values based on paired, 2-tailed Student *t*-test or sign rank test when data were not normally distributed.

the pediatric gastroenterologist. This result is comparable to the 98% to 100% cecal visualization rate that was reported for a 4-day PEG-3350 regimen and a 2-day PEG-3350 + bisacodyl regimen (6,7,22). Furthermore, according to our study criteria, 77% of the patients were found to have an effective preparation when assessed by a validated bowel preparation scale, which is comparable to previous studies that assessed PEG-based solutions (22,29).

Compared with the 4-day PEG-3350 regimens, the low number of missed school days and workdays with regards to this short-course regimen resulted in a comparable compliance rate (93.5%) vs 89% as reported by Pashankar et al (7). Additionally, stool frequency and consistency have been reported to be good predictors for adequate bowel preparations (6). We found that 100% of the patients in our study reported Bristol scale type 6 or 7 by the completion of the study regimen, although we were unable to assess frequency accurately.

Multiple studies have demonstrated that PEG-3350 is safe in children when used for constipation management or for bowel preparation. Our study demonstrated that there were no clinically significant adverse effects detected through electrolytes obtained before/after preparation, although there was a statistically significant decrease in potassium, carbon dioxide, and blood urea nitrogen. These laboratory results were comparable to the study of the 4-day PEG-3350 regimen that also found similar statistical electrolyte changes (7). Up to 60% of patients reported having some adverse effects during the preparation phase, although 69% of the patients rated adverse effects as acceptable, and only 2 patients were unable to complete the regimen due to these effects. The percentage of adverse effects identified was higher than lower-dosed PEG-3350 studies but comparable to PEG-ELS regimens as reported in multiple pediatric trials (3,4). Safder et al (6) reported 36% rate of reported adverse effects/symptoms for the 4-day PEG-3350 regimen, whereas Phatak et al (23) reported up to 19% of their patients experienced nausea with the 2-day PEG-3350 + bisacodyl regimen (22). Hunter and Mamula (29), in a 2010 review of pediatric bowel preparations, expressed concern about the safety of using large volumes of sports drinks mixed with PEG-3350. Specifically, they pointed out that sports drinks have significantly fewer electrolytes and increased carbohydrates or flavorings that alter osmolarity. They also pointed out the potential for increased bacterial fermentation related to the higher carbohydrate load, which could lead to combustible gas production in the colon; however, to date, there are no reported major adverse events in the pediatric literature with the use of PEG-3350 with Gatorade. We also did not find any major adverse effects or clinically significant electrolyte shifts in our population, although we excluded potentially vulnerable populations such as those with renal disease.

Overall, the study regimen had moderate acceptability by our patient population, although 93.5% of the patients were able to complete ≥75% of the regimen. The large volume required to be consumed was rated poorly by the study population. This requirement to drink a large volume during a short period is a major limitation to this regimen and most likely contributed to the increase in adverse effects. Furthermore, it also may not be acceptable in younger children or those with significant preexisting symptoms such as nausea or vomiting. In spite of this shortcoming, the majority of the patients in our study were able to complete the regimen in 120 to 219 minutes (25%–75% interquartile range). To ensure adequate preparation, we used a start time of 18:00 hours the day before the procedure to reduce the length of time between the bowel preparation and the colonoscopy. This start time may not be feasible with some patients, and thus we advise pediatric gastroenterologists to account for the start time of the colonoscopy when providing guidance on bowel preparations. Also, late start times may lead to procedure cancellation because of failure to meet fasting requirements for anesthesia as occurred in 1 of our patients.

The present study has several limitations. First, it did not compare the regimen to other available bowel preparations, such as lower volume, sulfur-free PEG-ELS solutions. Second, there was no blinding of study participants or the endoscopists to the regimen. This may have resulted in subject bias in those patients who had previous bowel preparations, who used PEG-3350 or who disliked Gatorade. Third, the adult bowel preparation efficacy scale (BBPS) we used has not been validated or previously used in other pediatric studies; however, there is no published, validated pediatric bowel preparation efficacy scale. We found the BBPS to be simple and more accommodating scale for our practice of ongoing lavage and suctioning during colonoscopy. It also provided minimized rater bias through its available training materials. Another limitation was that the study questionnaire that we devised was not validated. The adverse effect questions did not differentiate the symptoms very well (ie, nausea vs vomiting) and did not rate the severity of the symptoms. Finally, our study population was small and had limited power to find predictive parameters, which may have identified improved efficacy of the bowel preparation regimen.

In conclusion, PEG-3350 with Gatorade is an effective and safe regimen for bowel preparation in children when administered in a few hours; however, the large volume required for this regimen affects its overall tolerability and serves as a major limitation of this preparation, especially in young children. Further comparative research is needed on bowel preparations in children including determining an effective and safe regimen that is convenient, has minimal adverse effects, and has small volume requirements.

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