

# Use of Powder PEG-3350 as a Sole Bowel Preparation: Clinical Case Series of 245 Patients

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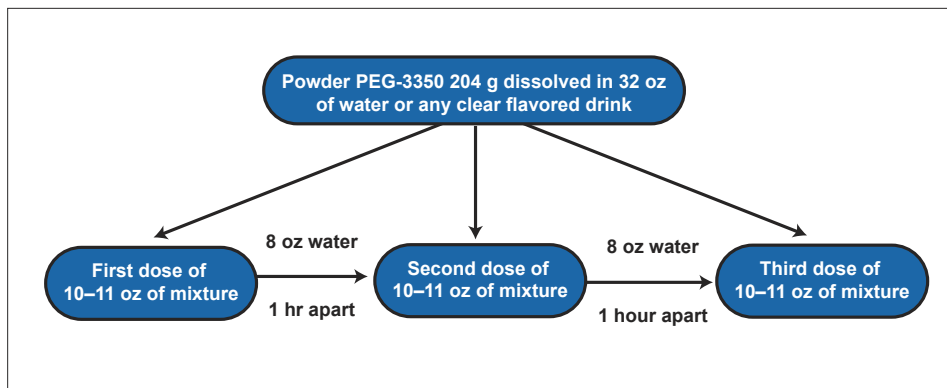
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**Abstract: Objective:** To assess the efficacy of low-volume powder polyethylene glycol (PEG)-3350 as a sole bowel preparation for colonoscopy. **Methods:** This case series examined 245 consecutive patients (a mixture of inpatients and outpatients undergoing screening colonoscopy) at a hospital endoscopy center over a 2-year period. The patients received powder PEG-3350 in the amount of 204 g dissolved in 32 oz of water and taken in 3 divided doses 1 hour apart with 8 oz of water in between each dose. Colon preparation scores (CPS) were used to assess the quality of colon cleansing. The results obtained from the 245 patients were collated and compared to those of patients receiving sodium phosphate, the historical control. **Results:** The mean CPS was calculated to be 3.43, with a standard deviation of 1.12. Of the 245 patients, 92 were scored with a grade of 4, and 5 patients had incomplete colonoscopies secondary to failure of bowel preparation (CPS=0). Among the remaining patients, 22 and 26 were graded as poor (CPS=1) or fair (CPS=2) bowel preparations, respectively. **Conclusion:** The low-volume powder PEG-3350 formula used in our case series showed effective colon cleansing and may be considered for use as a sole bowel preparation.

Colonoscopy has become the procedure of choice for examination of the colon for neoplastic and inflammatory bowel disease. The diagnostic accuracy of colonoscopy depends upon the quality of the preparation, and a successful colonoscopy requires optimal visualization of the entire mucosal surface. Cleansing quality is a critical factor in determining the quality, difficulty, speed, and completeness of colonoscopy.<sup>1</sup> The ideal preparation for colonoscopy would reliably empty the colon of all fecal material; have no effect on the gross or histologic appearance of the mucosa; require a relatively short period for ingestion and evacuation; cause no patient discomfort; and produce no significant shifts in fluids or electrolytes.<sup>2</sup> Ineffective cleansing increases the possibility of missing important lesions, prolongs the insertion time,<sup>3</sup> increases patient discomfort,<sup>3,4</sup> and increases the cost of colonoscopy because of the need for repeating the procedure.<sup>5</sup>

## Keywords

Bowel preparation, colonoscopy, powder polyethylene glycol (PEG)-3350



**Figure 1.** Schematic of the powder polyethylene glycol (PEG)-3350 bowel preparation used in the case series.

Given that over 14 million colonoscopies are performed annually in the United States alone,<sup>6</sup> the potential cost of inadequate colon preparation both in terms of cost to the healthcare system and patient satisfaction are substantial.<sup>7</sup> Some of the most important predictors of poor colon preparations include the inability of patients to follow their instructions and the inability to complete them because of their large volume (large-volume polyethylene glycol electrolyte lavage solution [PEG-ELS; Golytely, Braintree]).<sup>7,8</sup>

Historically, peroral gut lavage with saline solution or balanced electrolyte solution has been found to provide rapid and effective cleansing of the colon for various diagnostic and therapeutic procedures.<sup>2</sup> However, the resulting fluid and electrolyte imbalances have prompted formulation of osmotically balanced solutions to provide minimal water loss into the bowel lumen. Several early preparations contained mannitol, which, when fermented by colonic bacteria, led to combustible amounts of luminal hydrogen and methane with reports of explosions during surgical electrocautery and colonoscopic polypectomy.<sup>2,9</sup> Large-volume PEG-ELS and oral sodium phosphate solution (Phospho-soda, Fleet) have become widely used laxatives for colonic cleansing before colonoscopy.<sup>10</sup> More recently, powder PEG-3350 (Miralax, Schering-Plough) has been used as an effective laxative in children<sup>11-13</sup> and adults.<sup>14</sup> Pashankar and associates have described powder PEG-3350 as a safe, effective, and palatable bowel preparation for colonoscopy in children at the dose of 1.5 mg/kg for 4 consecutive days.<sup>15</sup> However, there has not been a published trial of powder PEG-3350 as a sole agent for bowel preparation prior to colonoscopy in the adult population.

## Methods

This case series was part of a periodic quality assurance (QA) audit and included 245 consecutive patients who

underwent colonoscopy at a hospital endoscopy center over a 2-year period.

The patients included in this case series were:

- A mixture of inpatients and outpatients who completed their bowel preparation according to the physician's instructions.

The patients excluded were:

- Patients with a reported allergy to PEG-3350
- Patients who required emergency colonoscopy without bowel preparation
- Noncompliant patients.

All the patients received powder PEG-3350 in the amount of 204 g dissolved in 32 oz of water taken in three divided doses 1 hour apart with 8 oz of water in between each dose (Figure 1). The patients were instructed to finish the bowel preparation by 8 PM of the night prior to colonoscopy, irrespective of its timing (morning vs afternoon). Those patients undergoing colonoscopy in the afternoon were allowed clear liquids until 7 AM on the morning of the procedure. Oral medications were allowed ad libitum with one or more sips of water. A previously designed, internally validated colon preparation score (CPS) was used to assess the quality of the colon preparation in the study group (Table 1). The assessment was made by the gastroenterology registered nurse or the technician involved in the procedure. The results were collated and compared to a historical control of 245 patients who underwent colonoscopy using sodium phosphate solution at our institution in a similar prior QA audit.

## Results

The mean CPS was calculated to be 3.43, with a standard deviation of 1.12 (Figure 2). Of the 245 patients, 192 had excellent colon cleansing and were graded as 4 on CPS whereas 5 patients had incomplete colonoscopies

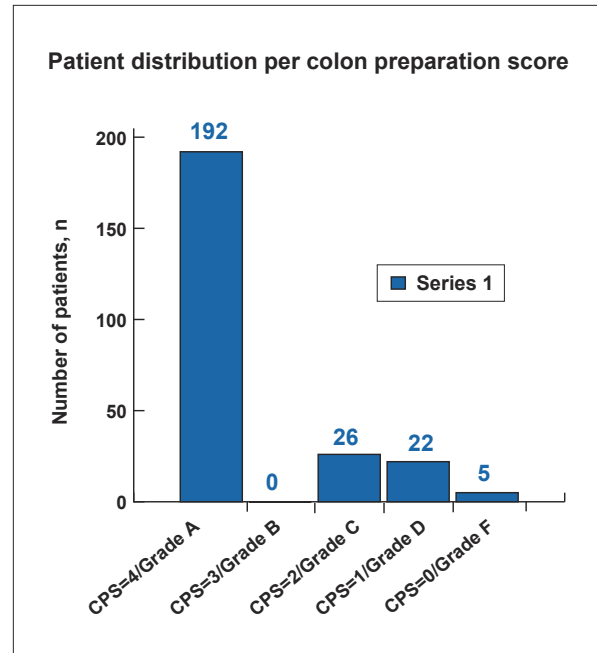
**Table 1.** Colon Preparation Scores

Grade	Score	Description
A	4	A completely clean colon with no stool and little or no liquid residue
B	3	A moderately clean colon with small pools of liquid residue but no solid stool
C	2	A fair preparation with large pools of liquid residue or solid stool sticking to the colon wall but no solid stool in the lumen
D	1	A poor preparation with large amounts of liquid residue and some solid stool but study completed
F	0	A failed preparation due to large amounts of solid or liquid stool preventing complete examination of the colon

secondary to failure of bowel preparation (CPS=0). Among the remaining patients, 22 and 26 were graded as poor (CPS=1) or fair (CPS=2) bowel preparations, respectively. The data were compared to a historical control of patients using sodium phosphate solution, in which the average CPS was 3.23, with a standard deviation of 1.01 ( $P>.05$ , not significant). We did not routinely measure electrolytes prior to and following bowel preparation; however, in 12 patients, we were able to identify laboratory examinations within a 24-hour period following bowel cleansing that revealed a lack of significant perturbations of electrolytes. The electrolytes measured prior to and following bowel preparation showed no significant changes. None of the patients in this case series experienced any clinically significant events, dehydration, or other significant symptoms attributable to the colon preparation. Anecdotally, patients who took colon preparations in the past appeared to favor low-volume solutions; however, this was not assessed in an iterative manner.

## Discussion

The powder formulation of PEG-3350 has been recently shown to be an effective laxative among pediatric<sup>11-13</sup> and adult populations,<sup>14,16,17</sup> but there have been no reports of its usage in higher doses (136–204 g) as a sole bowel preparation or in combination. Use of the powder formulation of PEG-3350 as a sole bowel preparation is mentioned in the proceedings of the 2004 American College of Gastroenterology annual meeting, but no studies have been published thus far in this regard and there has

**Figure 2.** Bar graph showing patient population distribution (n) per colon preparation score (CPS).

been no mention of any formula for preparation of this compound for bowel preparation. Our study examined the efficacy of powder PEG-3350 as a sole bowel preparation for providing superior colon cleansing, according to CPS, prior to colonoscopy. Our observations suggest that powder PEG-3350 achieved impressive colon cleansing and can be utilized as a sole bowel preparation agent.

In studies, the most important predictors of poor colon preparation include the inability of patients to follow instructions for bowel preparations and the inability to complete large-volume bowel preparations such as large-volume PEG-ELS.<sup>7,8</sup> Thus, it follows that patient compliance can be improved by simplifying the instructions and reducing the volume of bowel preparation agents. In our case series, the powder PEG-3350 preparation required the consumption of comparatively small volumes of liquid (32 oz, approximately equal to 1 L) as opposed to 4 L of large-volume PEG-ELS and 2 L of PEG-3350 with sodium chloride, sodium bicarbonate, potassium chloride, and bisacodyl tablets (Halflytely, Braintree). Thus, using a reduced volume of 32 oz (approximately 1 L) in lieu of 140 oz (approximately 4 L) can help overcome one hurdle in patient noncompliance. In addition, the ease of mixing powder PEG-3350 with clear flavored drinks makes the low-volume bowel preparation more patient-friendly and improves the palatability of otherwise bland chemicals.

Most patients in this case series were able to complete the preparation, suggesting that the powder PEG-3350

preparation is very well tolerated, at a rate higher than that of our prior experience at our center. The low volume of the preparation is easier for patients to complete and tolerate; thus, this low-volume powder PEG-3350 bowel preparation may have a role in the rapid purge approach for urgent colonoscopy, though this was not formally evaluated in our study. There have been no previously published reports of clinically significant events following the use of powder PEG-3350 in appropriate patients in the literature.

Our study was limited by the use of CPS, which has yet to be externally validated; however, this score is clinically intuitive, internally reproducible, and relevant. We recognize the many limitations of a case series; however, this experience prompts consideration of these data as indicators that the powder PEG-3350 formula can be utilized for colonoscopy preparation in the adult population. Further randomized controlled studies must be performed on a larger scale and in diverse populations to compare powder PEG-3350 to other standard precolonoscopy bowel cleansing preparations. Its potential role as a rapid purge cleansing agent for urgent colonoscopy should also be evaluated. An easy, safe, and effective bowel-cleansing regimen would have a potentially significant economic and practical impact on gastrointestinal endoscopy. Powder PEG-3350 has all of these potential characteristics and may yet be such an agent, though further comparative evaluations of efficacy, safety, and patient satisfaction will be necessary.

*Drs. Arora and Okolo III declare that they do not have any conflicts of interest. This article is a report on a clinical quality assurance audit and thus exempt from the Institutional Review Board.*

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