

## **PEG-3350, Senna and Solid Food Based Bowel Preparation for Colonoscopy Appears Safe, Effective and Well Tolerated**

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### **Abstract**

**Introduction:** Current options for bowel cleansing for colonoscopy have challenges including poor taste, clear liquid diet the day prior and many side effects. These challenges lead to poor preparations, cancelled procedures and some patients never attempting the procedure. PEG3350+FOOD is a new bowel preparation option that includes a standardized low-residue diet the day before the procedure with PEG3350 and senna to make a more tolerable and palatable preparation.

**Hypothesis:** PEG3350+FOOD will achieve adequate bowel preparation results (Boston Bowel Preparation Score  $\geq 6$  with no individual segment  $< 2$ ) in 90% of patients who took this preparation. PEG3350+FOOD will be safe and well tolerated.

**Methods:** We performed a retrospective case series of consecutive patients offered the PEG3350+FOOD at an outpatient gastroenterology practice in Oklahoma City, Oklahoma. Each patient was offered the bowel preparation and those who took it completed a survey regarding their experience and whether they would consider using it again. For each colonoscopy, the endoscopist rated the quality of the bowel preparation via the Boston Bowel Preparation Score and other important data points were recorded. Those with and without an adequate preparation were compared. A logistic regression was performed to identify factors associated with an adequate preparation.

**Results:** 546 patients were included in the analysis with mean age of  $60.2 \pm 11.4$  years. 73.4% were screening colonoscopies and 33.7% were having their first colonoscopy. 533 (97.6%) had adequate bowel preparations and 13 (2.4%) inadequate. 245 (44.8%) patients achieved a BPPS score of 9. The overall mean BBPS was  $8.0 \pm 1.3$  with  $2.5 \pm 0.5$ ,  $2.7 \pm 0.5$  and  $2.8 \pm 0.4$  in the right, transverse and left, respectively. The preparation was well tolerated with the majority of patients having “no” or “mild” episodes of cramps (89.2%), nausea (89.6%) or bloating (88.8%). 86.6% of patients would recommend this preparation to others and 83.9% would use the preparation again. When comparing those with and without adequate bowel preparation, patients who achieved an inadequate preparation were more likely to have a Body Mass Index (BMI) 35.0-39.9 ( $p = 0.065$ ) and  $\geq 40.0$  ( $p = 0.245$ ).

**Conclusion:** PEG3350+FOOD is a new option for bowel preparation that is very effective, safe and well tolerated. Further investigation with a randomized controlled trial is needed to further validate the findings in this case series.

**Keywords:** *Bowel Preparation; Colonoscopy; Solid; Food*

## Abbreviations

ADR: Adenoma Detection Rate; BBPS: Boston Bowel Preparation Scale; BMI: Body Mass Index; CRC: Colorectal Cancer; NaP: Sodium Phosphate; Oz: Ounces; OSS: Oral Sulfate Solution; PEG3350+FOOD: Split-Dose Bowel Preparation Including PEG3350, Senna and Solid Foods; PEG-ELS: Iso-osmotic Polyethylene Glycol Solution; PICO: Sodium Picosulfate

## Introduction

Colonoscopy is widely used for the detection of colonic mucosal disease and to prevent colorectal cancer. Cleansing of the colon is essential to achieving a high-quality colonoscopy, yet 20 - 25% of these procedures have inadequate bowel preparations [1,2]. The quality of the preparation in each segment of the bowel, has been directly correlated with higher detection rates of polyps and advanced polyps on subsequent colonoscopy [3]. In addition, concern regarding the preparation and its tolerability is the most common reason for people older than 50 to avoid this procedure [4]. Therefore, developing a more tolerable preparation might improve screening rates and compliance.

The ideal bowel preparation would be safe, effective, palatable and free from side effects [5]. The most common bowel preparations are either 2 liters or 4 liters in volume and usually taste poorly (e.g., Polyethylene Glycol – Electrolyte Lavage Solution (PEG-ELS), Oral Sulfate Solution (OSS), Sodium Picosulfate (PICO), and Sodium Phosphate (NaP)). They are safe and effective, but the side effects sometimes limit a patient's ability to complete the entire preparation. These preparations are frequently combined with a clear liquid diet the day prior to the procedure leaving patients unsatiated in terms of their food intake [6,7]. This presents three main challenges facing current bowel preparations: (1) Poor taste of the preparation, (2) No food intake during the preparation process and (3) Unintended side effects (e.g., nausea, vomiting, abdominal cramps, bloating).

Some of these limitations have been addressed individually. A more palatable bowel preparation has been devised by combining 238 grams (sometimes 306 grams) of over the counter PEG3350 (Miralax, Bayer Pharmaceuticals) with 65 ounces of Gatorade (Pepsico, Chicago, IL), a flavored sports drink. There have been several studies comparing PEG3350 and Gatorade preparations with "standard" 4-L PEG-ELS bowel preparations showing mostly comparable rates of adequate bowel cleansing, rare adverse events and the taste of PEG3350 with Gatorade being better tolerated [8-12]. In addition, Walter, *et al.* compared a PEG-ELS preparation in patients who ate a low residue diet for breakfast and lunch the day prior to colonoscopy with those on a strict clear liquid diet finding that the low residue diet was non-inferior to the "standard" clear liquid diet [13]. Therefore, individually, a more palatable preparation and solid foods the day prior to the colonoscopy may not hinder the bowel preparation quality.

To date, there has never been data presented considering a preparation that combined a more palatable preparation with solid food intake the day prior to the procedure. PEG3350+FOOD is a bowel preparation that was specially designed to include a standardized low-residue diet throughout the day and night prior to the colonoscopy combined with PEG3350 plus senna and dosed in a new interval schedule. We hypothesize that patients receiving this preparation will frequently have adequate bowel preparations. Secondly, we hypothesize that this preparation will be well tolerated with respect to palatability and side effect profile with participants frequently wanting to use this preparation again and recommend this to others. Safety and side-effect profiles will be reported.

## Methods

### Patient Selection, Screening and Data Collection

We performed a retrospective case series analysis of consecutive patients referred to Digestive Disease Specialists, Inc., Oklahoma City, Oklahoma from April 1, 2016 through March 30, 2017 for various diagnoses including screening (Colorectal Cancer (CRC) screening, Family history of CRC, personal history of adenomatous polyps and Lynch syndrome) and diagnostic (change in bowel habits, blood in stool, iron deficiency anemia, Inflammatory Bowel Disease, abnormal imaging of colon, and positive Cologuard®). Any patient indicated for a colonoscopy was eligible to receive PEG3350+FOOD. All patients were offered the preparation independent of co-morbid medical

conditions and risk factors for poor preparation. At the time of scheduling the colonoscopy, PEG3350+FOOD was introduced to the patient and if the patient accepted, they were provided the kit with comprehensive instructions. These instructions were reviewed verbally and also given to the patient in paper format.

With a PEG3350+FOOD kit, each participant received a questionnaire (Figure 1) inquiring about their experience with the PEG3350+FOOD and were asked to submit this following the completion of the preparation. A total of three providers from Digestive Disease Specialists, Inc. participated. Following the procedure, each provider rated the quality of the bowel preparation according to the Boston Bowel Preparation Scale. Each provider received standardized training about the Boston Bowel Preparation Scale by reviewing the website: [cori.org/bbps](http://cori.org/bbps). Procedures were performed at three sites in Oklahoma City: Digestive Disease Specialist (DDS) North Ambulatory Endoscopy Center; DDS South Ambulatory Endoscopy Center and Lakeside Women’s Hospital. All procedures were performed with board certified anesthesiologists and certified registered nurse anesthetists with patients receiving monitored anesthesia care.

Name: \_\_\_\_\_ Date of Procedure: \_\_\_\_\_  
 Age: \_\_\_\_\_ Weight: \_\_\_\_\_ Height: \_\_\_\_\_ Dr. \_\_\_\_\_  
 Medications: \_\_\_\_\_  
 \_\_\_\_\_

Your average bowel habits:  
 Number of stools per day? \_\_\_\_\_ Consistency (hard, firm, soft, loose, watery)? \_\_\_\_\_

1. Was this your first colonoscopy? Y N  
 if no, when was your last colonoscopy? \_\_\_\_\_

2. How would you rate the cost of Gourmet Prep?  
 Too High  Too Low  Just Right

On a scale of 1 – 10 with 1 = terrible and 10 = excellent

3. Using the above scale, how would you rate the Prep instructions? \_\_\_\_\_  
 4. Using the above scale, how would you rate the quality of the food? \_\_\_\_\_

5. Did you feel like there was:  
 A perfect amount of food  Not enough food  Too much food

6. Once you started this prep, when did you experience your 1<sup>st</sup> loose or diarrhea like stool?  
 \_\_\_\_\_

7. Did you experience any of the following? (Circle one for each symptom)  
 Cramps none mild moderate severe  
 Bloating none mild moderate severe  
 Nausea none mild moderate severe

8. After going to bed, how many night time stools did you have? \_\_\_\_\_

9. Would you recommend this prep to a friend or family member? Y N  
 10. Would you choose this prep again if you needed a future colonoscopy? Y N  
 Comments: \_\_\_\_\_  
 \_\_\_\_\_

11. How much of the meals did you finish? Give a percentage 0% = ate none to 100% = ate all  
 Breakfast \_\_\_\_\_ Lunch \_\_\_\_\_ Dinner \_\_\_\_\_

Check box if you are willing to be included in testimonials for this new prep.

Signature \_\_\_\_\_ Date \_\_\_\_\_

Office Use Only:  
 Dx: \_\_\_\_\_  
 Start time: \_\_\_\_\_  
 Last dose time: \_\_\_\_\_  
 BBPS: \_\_\_\_\_  
 Notes:

Figure 1: Patient Questionnaire.

### PEG3350+SOLID Description

PEG+FOOD is a kit containing a 238 gram bottle of PEG3350, 8 senna tablets with 3 meals, 3 snacks and various flavored individual drink mixes. This kit uses solid foods as a promoter of gut motility with osmotic and stimulant laxatives. The laxatives are given together in small frequent doses throughout the day prior to the colonoscopy, with the food, allowing them to work synergistically. The drink mixes are single serving flavored powder mixes individually packaged to be used with each 20 ounces (oz) drink.

The instructions advise a low-fiber diet one-day prior to the preparation and provides examples of low fiber foods that would be beneficial for the preparation. For the day prior to the procedure, patients are given a timeline and instructed to prepare each meal as directed on the packaging. With each meal, the patients are advised to mix two capfuls (34 grams) of PEG 3350 in 20 oz of water flavored with drink mixes, as desired, and ingest. They are also instructed to take one 25 mg Senna tablet. The snacks are also ingested on a timeline along with two capfuls of PEG 3350 in 20 oz of water with drink mixes, as desired, and one 25 mg Senna tablet. All of the food and snacks are consumed on the day prior to the procedure following the protocol provided. The sixth dose of senna is increased to two 25 mg Senna tablets to aid with motility during the nighttime fast. As part of the split dose preparation, one more dose of PEG 3350 with water and one 25 mg Senna, but no food products are given six hours prior to the procedure.

### Boston Bowel Preparation Scale (BBPS)

The BBPS is a validated scoring scale for rating the quality of bowel preparation in patients undergoing colonoscopy [14,15]. It divides the colon into three segments, the right colon (cecum and ascending colon), the transverse colon and the left colon (descending colon, sigmoid colon and rectum). For each segment, the endoscopist rates the quality of the preparation on a 4 point scale including 0 (Unprepared colon segment with mucosa not seen due to solid stool or thick liquid stool that cannot be cleared), 1 (Portion of mucosa of the colon segment seen, but other areas of the colon segment not well seen due to staining, residual stool and/or opaque liquid), 2 (Minor amount of residual staining, small fragments of stool and/or opaque liquid but mucosa of colon segment seen well) or 3 (Entire mucosa of the colon segment seen well with no residual staining, small fragments of stool or opaque liquid). Patients who had an adequate bowel preparation had a total BBPS score of at least 6 with no single segment having a score less than 2. BBPS is scored after each segment is irrigated and suctioned.

### Statistics

Data initially were collated in a Microsoft Excel database (Microsoft, Seattle, WA). Following completion of data collection, the database was imported into SAS 9.4 (Cary, NC) for statistical analysis. Continuous baseline descriptive variables were expressed as means with standard deviation and were compared using the Student's t-test. Categorical variables were expressed as absolute numbers and proportions. The  $\chi^2$  statistic was used to compare most categorical variables, whereas the Fisher's exact test was used for small numbers. A logistic regression analysis was performed considering binary outcomes such as adequate bowel preparation. A broad range of risk factors were adjusted in the logistic regression model, including age, gender, BMI category, indication, first colonoscopy, baseline bowel habits, and prescription drug use. A two-sided p-value of  $< 0.05$  was considered statistically significant.

## Results

### Overall Cohort (Table 1)

Of the 549 patients who completed the survey, 546 patients were included in the analysis after excluding 3 patients who did not have complete BBPS scores. 57 (10.4%), 292 (53.5%) and 197 (36.1%) of patients were aged 18 - 49, 50 - 64 and 65 and above, respectively. The mean age was  $60.2 \pm 11.4$  years. 73.4% of the cases were screening colonoscopies and 33.7% of patients used PEG3350+FOOD as their bowel preparation for their first colonoscopy. 425 (77.8%) of patients classified their baseline bowel habits as having 1 to 3 spontaneous formed bowel movement's daily; 54 (9.9%) had a bowel movement fewer than once a day and 53 (9.7%) had more than 3 stools daily. A small portion of patients were on greater than 8 medications prior to the colonoscopy (13.6%) with many on anti-hypertensive

treatments (46.5%) and less on anti-psychotics (25.5%), anti-diabetics (17.4%), narcotics (12.1%) and chronic treatments for constipation (2.7%). 401 (73.4%) patients had the colonoscopy for screening purposes whereas 145 (26.6%) had a diagnostic procedure. 533 (97.6%) had adequate bowel preparations and 13 (2.4%) inadequate. 245 (44.8%) patients achieved a BBPS score of 9. The mean BBPS was 8.0 ± 1.3. The mean BBPS in the right was 2.5 ± 0.5, transverse 2.7 ± 0.5 and left 2.8 ± 0.4. 33.3% of patients reported their first loose bowel movement less than 3 hours after starting the preparation, whereas 34.7% reported their first loose stool 3-6 hours after starting, 23.8%, 6 - 9 hours after initiation and 8.2% greater than 9 hours after starting the cleanse. 9.3% of patients reported no bowel movements overnight, with 11.8%, 23.3%, 23.3%, 14.0%, and 6.8% reporting 1, 2, 3, 4 or 5 bowel movements overnight, respectively. The preparation was well tolerated with the majority of patients having “no” or “mild” episodes of cramps (89.2%), nausea (89.6%) and bloating (88.8%) (Figure 2). 86.6% of patients would recommend this preparation to others and 83.9% would use the preparation again.

	All eligible patients (N = 546)	Patients with Adequate BBPS (N = 533)	Patients with Inadequate BBPS (N = 13)	p-value
<b>Demographics</b>				
Age (Mean (SD))	60.2 (11.4)	60.1 (11.4)	64.2 (8.3)	0.2030
Gender (Female)	327 (59.9%)	322 (60.4%)	5 (38.5%)	0.0862
BMI: Underweight (< 18.5)	7 (1.3%)	7 (1.3%)	0	N/A
BMI: Normal (18.5 - 24.9)	108 (19.8%)	106 (19.9%)	2 (15.4%)	> 0.999
BMI: Overweight (25.0 - 29.9)	200 (36.6%)	195 (36.6%)	5 (38.5%)	0.890
BMI: Obesity Class I (30.0 - 34.9)	133 (24.4%)	132 (24.8%)	1 (7.7%)	0.204
BMI: Obesity Class II (35.0 - 39.9)	58 (10.6%)	55 (10.3%)	3 (23.1%)	0.065
BMI: Obesity Class III (> = 40.0)	40 (7.3%)	38 (7.1%)	2 (15.4%)	0.245
<b>Medication History</b>				
Anti-diabetic	95 (17.4%)	90 (16.9%)	5 (38.5%)	0.043
Anti-hypertensive	254 (46.5%)	249 (46.7%)	5 (38.5%)	0.556
Narcotics	66 (12.1%)	61 (11.4%)	5 (38.5%)	0.003
Antipsychotics	139 (25.5%)	133 (25.0%)	6 (46.2%)	0.083
Constipation treatments	15 (2.7%)	15 (2.8%)	0	N/A
More than 8 medications	74 (13.6%)	68 (12.8%)	6 (46.2%)	0.001
<b>Bowel Habits</b>				
Less than once per day	54 (9.9%)	53 (9.9%)	1 (7.7%)	> 0.999
1 per day	1 (0.2%)	1 (0.2%)	0	N/A
1 to 3 times per day	425 (77.8%)	414 (77.7%)	11 (84.6%)	0.743
More than 3 times per day	53 (9.7%)	52 (9.8%)	1 (7.7%)	> 0.999
Ostomy or Unknown	13 (2.4%)	13 (2.4%)	0	N/A
Bowel consistency (hard and firm)	246 (45.1%)	240 (45.0%)	6 (46.2%)	0.936
<b>Indications for Colonoscopy</b>				
Diagnostic	145 (26.6%)	140 (25.6%)	5 (38.5%)	0.345
Screening	401 (73.4%)	393 (72.0%)	8 (61.5%)	
Initial Colonoscopy	184 (33.7%)	180 (33.8%)	4 (30.8%)	> 0.999
<b>Outcomes</b>				
Boston Bowel Preparation Score (Mean (SD))	8.0 (1.3)			
Adequate BBPS score (left > = 2, transverse > = 2, right > = 2), n (%)	533 (97.6%)			
Excellent BBPS score (left = 3, transverse = 3, right = 3), n (%)	245 (44.8%)			
Cecal Intubation	540 (98.9%)	532 (99.8%)	8 (61.5%)	< 0.001
Adenoma Detection Rate	154 (28.2%)	149 (28.0%)	5 (38.5%)	0.532
Adenoma Detection Rate in Men	72 (34.1%)	68 (33.5%)	4 (50.0%)	
Adenoma Detection Rate in Women	82 (24.5%)	81 (24.6%)	1 (20.0%)	
Withdrawal time in minutes, mean (SD)*	8.8 (3.1)	8.7 (3.1)	10.0 (5.2)	0.166
Withdrawal time of 6 minutes or more*	500 (99.8%)	489 (100.0%)	11 (91.7%)	N/A
Recommend to others	473 (86.6%)	461 (86.5%)	12 (92.3%)	0.616
Would use preparation again	458 (83.9%)	445 (83.5%)	13 (100.0%)	N/A

Table 1: Demographics and Outcomes.

\*: There were 45 patients at one site where the withdrawal time was not reported

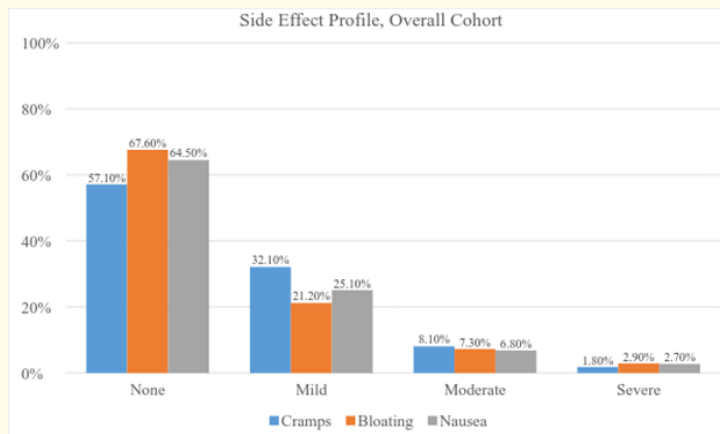


Figure 2: Side effect profile, overall cohort.

Logistic regression considering the end-point of an “adequate” bowel preparation (BPPS > 6 with no single segment having a BPPS < 2) showed that patients on anti-hypertensive medications had a strong association with adequate bowel preparation (OR: 6.25, CI: 1.36 - 28.78, p = 0.02). When considering the end-point of excellent bowel preparation (BBPS = 9), patients who were overweight (BMI 25.0 - 29.99, OR: 0.49, CI 0.29 - 0.82, p = 0.01) or obese (BMI: 30.0 - 34.9, OR: 0.47, CI: 0.27 - 0.82, p = 0.01; BMI 35.0 - 39.9, OR: 0.34, CI: 0.17 - 0.70 (p < 0.01); BMI > 40, OR: 0.24, CI: 0.10 - 0.58, p < 0.01) were less likely to achieve a BBPS of 9 compared with those with a normal BMI. Patients with a baseline stool consistency as “hard” were also less likely to achieve a BPPS of 9 (OR: 0.64, CI: 0.43 - 0.94, p = 0.02) as were patients chronically on narcotics (OR: 0.45, CI: 0.24 - 0.87, p = 0.02).

**Safety**

There were no reported complications associated with the bowel preparation itself. In one patient undergoing a screening colonoscopy, a large polyp that was not endoscopically resectable but was identified and biopsied. The patient presented to the hospital with rectal bleeding several hours after the procedure. This was self-limited with no significant decrease in hemoglobin and the patient was discharged the following day with no further intervention required.

**Comparison of Adequate versus Inadequate Preparation Cohorts (Table 1)**

97.6% of patients that received PEG3350+FOOD achieved an adequate bowel preparation defined by BBPS > 6 with no individual segment rating less than 2. When comparing those with and without adequate bowel preparation, patients who achieved an adequate preparation were less likely to have a Body Mass Index (BMI) 35.0 - 39.9 (p = 0.065) and ≥ 40.0 (p = 0.245). There was a trend for the indication for the procedure to be screening more frequently in those who had an adequate preparation compared with those with an inadequate preparation (72.0% vs. 61.5%, p = 0.345). Also, those with an adequate bowel preparation were less frequently on anti-diabetic medications (p = 0.043) and narcotics (p = 0.003).



Sub-Groups (Table 2)

	Male	Female	Age > 65 years	Age < 65 years	First Colonoscopy	Repeat Colonoscopy	Screening Colonoscopy	Diagnostic Colonoscopy
Total patients (n)	221	335	197	349	184	362	401	145
Age (Mean ± SD)	61.0 ± 12.4	59.7 ± 10.7	72.5 ± 5.3	53.8 ± 8.6	60.2 ± 11.4	62.9 ± 11.2	61.0 ± 8.7	58.0 ± 16.5
Gender (N Female (% Female))	-	-	106 (53.8%)	221 (63.3%)	327 (59.9%)	215 (59.4%)	242 (60.3%)	85 (58.6%)
Boston Bowel Preparation Score Total (Mean ± SD)	7.8 ± 1.5	8.1 ± 1.2	7.9 ± 1.3	8.0 ± 1.3	8.1 ± 1.3	7.9 ± 1.3	8.0 ± 1.6	8.0 ± 1.6
Successful BBPS score (left ≥ 2, transverse ≥ 2, right ≥ 2), n (%)	203 (96.2%)	330 (98.5%)	191 (97.0%)	342 (98.0%)	180 (97.8%)	353 (97.5%)	393 (98.0%)	140 (98.6%)
Excellent BBPS score (left = 3, transverse = 3, right = 3), n (%)	84 (39.8%)	161 (48.1%)	86 (43.7%)	159 (45.6%)	90 (48.9%)	155 (42.8%)	174 (43.4%)	71 (49.0%)
Cecal Intubation, n (%)	208 (98.6%)	332 (99.1%)	196 (99.5%)	344 (98.6%)	182 (98.9%)	358 (98.9%)	397 (99.0%)	143 (98.6%)
Adenoma Detection Rate, n (%)	72 (34.1%)	82 (24.5%)	74 (37.6%)	80 (22.9%)	48 (26.1%)	106 (29.3%)	124 (30.9%)	30 (20.7%)
Recommend This Preparation to Others (N Yes (% Yes))	184 (87.2%)	289 (86.3%)	155 (78.7%)	318 (91.1%)	473 (86.6%)	304 (84.0%)	344 (85.8%)	129 (89.0%)
Choose this Preparation Again (N Yes (% Yes))	183 (86.7%)	275 (82.1%)	152 (77.2%)	306 (87.7%)	458 (83.9%)	293 (80.9%)	335 (83.5%)	123 (84.8%)

Table 2

When considering the overall cohort sub-divided based upon age, gender, initial colonoscopy, previous history of colonoscopy, screening indication or diagnostic indication, the preparation was universally well tolerated with > 95% of patients in each cohort achieving an adequate preparation and > 40% of patients having an excellent BBPS of 9.

#### Cecal intubation rates, Withdrawal times and Adenoma Detection Rate (ADR)

Out of 546 patients, cecal intubation was achieved in 540 with a 98.9% cecal intubation rate. The average withdrawal time was 8.8 minutes for the majority of the cohort (n = 501). Withdrawal times were not available for 45 patients, all emanating from one site that did not record this data. Adenomas or CRC were detected in 124 of the 401 CRC screening patients for an overall ADR of 30.9%.

#### Discussion

We present a case series of patients who received a novel bowel preparation that includes solid foods throughout the day prior to the colonoscopy and a more palatable PEG3350 based solution that was well tolerated showing an adequate response in 97.6% of patients with 44.8% having a BBPS of 9. Patients frequently would use this preparation again themselves and recommend this to others. PEG3350+FOOD appeared very safe with no serious adverse events reported in this large case series.

One major complaint that patients have the day prior to their colonoscopy is the requirement of a clear liquid diet. Liberalizing this diet is one option to alleviate this hindrance and one recent randomized controlled trial assigned patients taking split dose iso-osmotic polyethylene glycol solution (PEG-ELS) to either a low residue diet for breakfast and lunch followed by clear liquid dinner or clear liquids the entire day prior to the procedure. Preparation adequacy

(BPPS > 5) was 88.2% for the low residue, 94.4% for the clear liquids and the group receiving the low-residue diet were overall more satisfied with their preparation experience [13]. The non-inferiority shown in this study indicates that patients might be able to eat solid foods the day prior to colonoscopy with no significant loss of bowel preparation quality. The preparation in the case series presented, PEG3350+SOLID, showed adequate results, defined as BPPS  $\geq$  6 with no single segment < 2, 97.6% of the time. Walter, *et al.* allowed the low-residue cohort to eat from a list of “low residue” options prior to 1 PM the day prior to colonoscopy whereas PEG3350+SOLID has a structured eating regimen of foods provided to the patient as part of a kit timed according to the dosing of the PEG3350. Also, PEG3350+SOLID continues the solid food intake through the day including solid food snacks between 3 - 4 PM and just prior to sleep, in addition to the clear liquid dinner that is provided. Therefore, the PEG3350+SOLID offers solid foods throughout the day prior but seems to have excellent response rates.

More palatable bowel preparations are believed to help improve patient compliance and might help increase overall screening rates. One option that has been used in practice and studied are PEG-Gatorade-based solutions. In these preparations, 238 grams (sometimes 306 grams) of PEG (MiraLAX<sup>®</sup>, Merck and Co. Whitehouse Station, NJ) is mixed with 64 ounces of Gatorade Sports Drink (Pepsico, Chicago, IL) to create a 2-liter bowel preparation. Sometimes adjuncts such as Bisacodyl or magnesium citrate are also added to enhance the purge [5]. The Gatorade sports drink provides an improved flavor profile over the standard 2-Liter and 4-Liter PEG-ELS preparations, minimizing the “salty” flavor [9]. Several randomized controlled trials have considered this type of bowel preparation and have shown non-inferiority to standard large-volume PEG based preparations [9-12,16,17]. Only one study has shown this type of preparation to be inferior to the standard PEG-ELS in patients undergoing screening colonoscopy [8]. The solution used in PEG3350+FOOD included 238 grams of PEG3350 with various flavored drink mixes used per patient preference with the various meals and snacks. The individual drink mixes had sodium (Na) and potassium (K) ranging from 0 - 35 mg of Na per package to 5 - 25 mg of K per package. The enhanced flavor and solid food access in the PEG3350+FOOD resulted in the overall cohort stating that 86.6% would recommend this preparation to others and 83.9% would use this preparation again with similar numbers seen in all the sub-groups including those patients who had a previous colonoscopy who were likely to previously have taken standard preparations.

Previous randomized controlled trials comparing PEG+Gatorade with and without adjunctive therapy (e.g., Bisacodyl) with standard bowel-preparations have shown adequacy rates (BPPS  $\geq$  6) of 86.1% - 97.7% and 84.8% - 97.5% for PEG+Gatorade with and without adjunctive therapy, respectively [8,9,11,12,16,17]. In those studies, rates of adequacy for the standard 4L-PEG or 2L-PEG+Ascorbic acid ranged from 86.0% - 99.0% [8,9,11,12,16,17]. Our cohort experienced similar rates of adequate preparations with 97.6% of patients achieving adequate preparation score and 44.8% an excellent score of 9. PEG3350+FOOD effectively cleansed this cohort’s colons for their colonoscopy.

Split dose bowel preparations are superior to single-dosing the day prior and this trend is also seen with PEG-Gatorade preparations [5,10]. PEG3350+FOOD was designed with split dosing and a stimulant laxative (e.g. senna) to enhance the purge. There might be concern for the stimulant laxatives, such as senna, to cause cramping abdominal pains, however, frequencies of this side effect were similar to other studies. PEG3350+FOOD was associated with mild, moderate and severe cramps in 32.1%, 8.1% and 1.8% of patients, respectively. Gerard, *et al.* similarly found that 46.2%, 4.5% and 0.7% of patients who received split-dose PEG+Gatorade without adjunctive therapy had mild, moderate and severe cramps, respectively. Matro, *et al.* used PEG+Gatorade with bisacodyl, finding that 27% of their patients had abdominal pains during the preparation [17]. PEG3350+FOOD has similar rates of abdominal cramping with other preparations and the addition of senna does not seem to increase these rates.

Nausea and bloating are also commonly seen in patients undergoing bowel preparation. 34.6% and 31.4% of the patients receiving PEG3350+FOOD experienced some nausea or bloating, respectively, which is less than the 49.3% and 72.4% of patients who received split dose PEG+Gatorade in the study by Gerard, *et al.* but more than the 10.2% and 20.3% in those receiving PEG+Gatorade in McKenna’s study [9,12]. PEG3350+FOOD overall was well tolerated.



Since approximately 20 - 25% of all colonoscopies have inadequate bowel preparations, it remains essential for patients undergoing colonoscopy to achieve an adequate bowel preparation [1-3]. Govani, *et al.* found that risk factors for poor bowel preparation include presence of a GI fellow, tricyclic anti-depressant use and narcotic use whereas Miralax-Gatorade based preparations are associated with better bowel preparations [18]. In our study, being overweight or obese was associated with worsened preparation. This finding is not unique to PEG3350+FOOD as Borg, *et al.* found that BMI  $\geq 25$  was associated with inadequate bowel preparation and that for each 1 unit increase in BMI, the risk of inadequate preparation increased 2.1% [19]. In these cohorts, a more enhanced purge might be required to achieve adequacy of the bowel preparation.

Our study has several weaknesses. Firstly, this is a case series without a control group to compare PEG3350+FOOD against a standard of care. Secondly, it is retrospective with the inherent bias associated with this. Thirdly, our study included the experience of gastroenterologists from one practice. Despite these limitations, we feel that this study presents a novel bowel preparation that initially appears very effective and safe.

Our study presents a new type of bowel preparation kit that includes a standardized solid food eating regimen the day prior to colonoscopy combined with a PEG3350/senna based cathartic with enhanced flavor of the laxative solution. This preparation was frequently associated with adequate bowel preparations, was well tolerated and safe. Further randomized controlled trials are needed to compare PEG3350+FOOD with standard PEG-ELS based solutions to further validate the efficacy and safety of this new option.

### **Relevant Financial Disclosures:**

Jeff Scott and Marisa Scott are the owners and founders of Happy Colon Foods, the parent company of Happy Colon Food based bowel preparation.

Paul Feuerstadt is a minority investor in Happy Colon Foods.

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None.

### **Author Contributions**

- Jeff Scott: Assisted in study concept and design, data collection along with drafting and critical revision of the manuscript for intellectual content.
- David Wei: Assisted in study concept and design, statistical analysis along with critical revision of the manuscript for intellectual content.
- Marisa Scott: Assisted in study concept and design, data collection, along with critical revision of the manuscript for intellectual content.
- Paul Feuerstadt: Assisted in study concept and design, statistical analysis along with drafting and critical revision of the manuscript for intellectual content.

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