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MiraLAX-Gatorade Bowel Prep vs. GoLytely Prior to Screening Colonoscopy: An Endoscopic Database Study in a Community Hospital

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Abstract

Background—Polyethylene Glycol-3350 without electrolytes (MiraLAX®; Schering-Plough Healthcare Products Inc.) + a carbohydrate-electrolyte solution (Gatorade; PepsiCo Inc.) + bisacodyl is frequently used for bowel cleansing, although limited data quantifies its efficacy and safety. No prior studies have assessed this in a community setting or with PM-only dosing, which is still used frequently.

Aim—To compare the frequency of excellent/good/fair/poor bowel cleansing with PM-only dosing of MiraLAX®-Gatorade-bisacodyl vs. 4L GoLytely®.

Methods—This is a retrospective endoscopic database analysis of ≥ 50 year old average-risk individuals with a normal screening colonoscopy at a community hospital and ambulatory endoscopy center. Data was extracted for the last four months when 4L GoLytely® was the preferred bowel purgative and the first 4 months when 238g MiraLAX® in 64 ounces Gatorade and four 5-mg bisacodyl tablets became the preferred purgative. All patients used PM-only dosing of bowel purgative.

Results—778 subjects [GoLytely® (n=395) vs. MiraLAX® + Gatorade + bisacodyl (n=383)] were identified. Patients who took the MiraLAX® bowel preparation were more likely to achieve an excellent/good bowel cleansing compared to patients taking the GoLytely® preparation (93.3% vs. 89.3%, respectively; p = 0.048). However, when only ASA Class I patients are studied, there was no difference in frequency of excellent/good bowel cleansing (91.1% vs 93.6%, respectively; p = 0.498). No serious adverse events were identified. An excellent/good bowel cleansing was strongly associated with a recommendation for repeat colonoscopy in 10 years compared to patients with a fair cleansing [OR = 28.01; 95% CI: 13.96-56.19].

Conclusions—The MiraLAX® + Gatorade + bisacodyl combination produces similar rates of excellent/good bowel cleansing as compared to GoLytely® in most average-risk individuals undergoing colonoscopy for CRC screening in a community setting.

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Abbreviations: None

The authors note no conflicts of interest.

Introduction

Colonoscopy is considered the optimal method for colorectal (CRC) screening in patients ≥ 50 years old(1, 2). However, in order to be effective, the entire colonic mucosa must be visualized. Inadequate preparations can result in incomplete procedures, hampers the ability of the endoscopist to reliably detect polyps of any size, and increases screening costs as much as 12-22%(5, 6). In patients who achieve suboptimal bowel preparations, some endoscopists recommend repeat colonoscopy earlier than recommended based on current published guidelines(7). This incurs increased costs, increased risks from repeated procedures and increased strain on endoscopy units.

Based on anecdotal reports, the MiraLAX® + Gatorade + bisacodyl combination (i.e., 238 grams of PEG-3350 without electrolytes mixed in 64 ounces of Gatorade plus four 5-mg tablets of bisacodyl) is used frequently as a bowel purgative since patient tolerability may be improved compared to standard bowel purgatives, such as 4 liters GoLytely® (Polyethylene Glycol-Electrolyte Lavage Solution or PEG-ELS), and patients reported that they are more willing to take it again(8, 9). As many as 5-15% of patients who are prescribed 4 liters GoLytely® do not take the entire amount due to the large volume of liquid and unpalatable taste of the solution(10, 11). Two recent randomized controlled trials (RCTs) at academic hospitals indicated that the MiraLAX® + Gatorade + bisacodyl combination preparation was less effective than 4 liters GoLytely® for bowel cleansing prior to screening colonoscopies(8, 9). However, these studies, which evaluated approximately 500 patients, may not provide a comprehensive picture about these bowel purgatives. No prior studies have compared these bowel purgatives in a community setting nor in PM-only dosing where all of the solution is consumed on the evening before the colonoscopy. Although split-prep dosing, where half of the purgative is consumed on the day of the colonoscopy, is the preferred and recommended protocol, many endoscopists have not adopted this practice because of concerns about patient non-compliance, consumption of liquid within 2-4 hours of moderate sedation with IV propofol, or patient unwillingness to rise early to consume the second half of the purgative. Since the MiraLAX® + Gatorade + bisacodyl combination is used frequently, has not been studied comprehensively, and is not FDA-approved, more information is needed because over 14 million colonoscopies are performed each year and bowel purgatives are one of the most commonly prescribed medications by gastroenterologists.

This is intended to be a clinical effectiveness study as opposed to an efficacy study. The two recently published RCTs are excellent efficacy studies which utilized split-dosing and validated bowel cleansing scales (e.g., Boston Bowel Preparation Scale) in the highly structured setting of an RCT(8, 9). However, there are limitations when applying these study results to the community setting, and a comprehensive assessment of a treatment should include clinical effectiveness studies which may replicate the experience in a “real world” or community setting. Since many endoscopists continue to use PM-only dosing and utilize a non-validated scale to grade quality of bowel cleansing (i.e., excellent, good, fair, and poor), a clinical effectiveness study is needed.

We hypothesized that PM-only MiraLAX® + Gatorade + bisacodyl combination would produce excellent/good bowel cleansing as frequently as PM-only 4L GoLytely® among individuals undergoing screening colonoscopy in a community setting. Furthermore, we hypothesized that most patients in both groups would achieve excellent/good bowel cleansing and that serious adverse events would be infrequent with the MiraLAX® + Gatorade + bisacodyl combination. We also hypothesized that excellent/good bowel cleansing would be associated with recommendations to repeat screening colonoscopy in 10 years compared to patients with fair bowel cleansing.

Methods

Inclusion and Exclusion Criteria

All average risk, outpatient, asymptomatic patients ≥ 50 years old getting screening colonoscopy during an 8-month period at a single large community medical center/ ambulatory surgery center were eligible for this study. Only patients receiving 4L GoLytely® or the 238 grams MiraLAX® + 64 ounces Gatorade + four 5-mg tablets bisacodyl combination were included, and only patients with a normal colonoscopy were included. All patients did PM-only dosing of bowel purgative and all patients remained on clear liquids for the entire day before the colonoscopy. All colonoscopies were performed by 15 board-certified gastroenterologists from a large group private practice. In the middle of this 8-month period (i.e., at the end of month 4), the preferred bowel purgative for average-risk individuals undergoing screening colonoscopy changed from PM-only 4L GoLytely® to the MiraLAX® + Gatorade + bisacodyl combination.

Patients were excluded if they had any personal history of polyps, any personal or family history of colon cancer, or other symptoms for which diagnostic colonoscopy might be indicated, including diarrhea, constipation, abdominal pain, or weight loss. Patients with adenomas found on their index screening colonoscopy were excluded in order to insure that all study patients should have been instructed to return for repeat colonoscopy in 10 years. Patients were also excluded if they had any established diseases which might affect recommendations regarding follow-up endoscopy, including anemia, cancers, inflammatory bowel diseases, or diverticulitis. Incomplete procedures due to technical inability to reach the cecum, not due to poor preparation, were excluded as well. Patients with renal insufficiency were also excluded since these patients were not considered average-risk and because of the possibility of hyponatremia with the MiraLAX + Gatorade + bisacodyl preparation. All patients underwent sedation with IV propofol.

Data Extraction and Data Analysis

Data was collected retrospectively through the ProVation database (ProVation Medical, Inc., Minneapolis, MN) at a single, large community hospital and ambulatory endoscopy center. Preparation quality was graded as “excellent” (0-5% of mucosa obscured by residual fluid/ stool), “good” (5-10% obscured), “fair” (10-20% obscured) and “poor” (>20% obscured). Age, gender, history of diabetes, BMI, American Society of Anesthesiology risk class, and time of day procedure was done (a.m. vs. p.m.) and length of the recommended follow-up interval were also recorded. Frequency of serious adverse events was reviewed based upon endoscopic reports which only report peri-procedure adverse events. Serious adverse events occurring after the procedure were not obtained. Serum chemistries were not routinely obtained before colonoscopy.

Our primary endpoint was the frequency of excellent/good bowel cleansing for MiraLAX® + Gatorade + bisacodyl-treated patients compared to patients treated with 4L GoLytely®. When excellent/good bowel cleansing is compared to fair bowel cleansing, excellent/good bowel cleansing is associated with higher polyp detection rates and greater likelihood of being appropriately instructed to repeat colonoscopy at 10-year intervals after a normal screening colonoscopy(5, 12). Secondary endpoints compared MiraLAX® + Gatorade + bisacodyl-treated patients to patients treated with 4L GoLytely® for: (a) comparison of frequency of excellent, good, fair, and poor bowel cleansing; (b) frequency of receiving a recommendation to repeat colonoscopy at 10-year intervals after a normal screening colonoscopy; and (c) frequency of serious adverse events. We also assessed multiple factors associated with getting an excellent/good bowel cleansing and receiving a 10-year recommendation for repeat screening colonoscopy using logistic regression analysis.

Bivariate statistics (chi-square, fisher's exact, and two sample t-tests) were used to assess the differences between MiraLAX® + Gatorade + bisacodyl combination and GoLytely® preparations in the study population for the distributions of patient age, gender, diabetes status, BMI, ASA risk class, time of day procedure and for frequency of excellent/good bowel cleansing. In order to assess the frequency of excellent, good, fair, poor preps between both groups, Pearson's chi-square was utilized. All p-values are two-sided.

In order to determine the predictors of receiving a 10-year follow up recommendation and of receiving an excellent/good preparation, multivariable logistic regression analyses were performed. Both multivariate models controlled for the following variables: patient age, gender, diabetes status, BMI, ASA risk class and time of day procedure was done. All analyses were performed using Stata 9 (StataCorp LP; College Station, TX). The study was approved by the Institutional Review Boards at the University of Michigan School of Medicine and the St. Joseph's Mercy Ann Arbor Medical Center.

Results

Demographic Data

A total of 778 subjects were included in the study. Of these patients, 395 patients received the GoLytely® solution and 383 patients received the MiraLAX® + Gatorade + bisacodyl combination. The demographic characteristics were similar in both patient groups (Table 1). There were no significant differences between the two groups in terms of age, gender, BMI, time of colonoscopy (AM vs. PM), or presence of diabetes, but patients with ASA risk class 1 were more common in the MiraLAX® + Gatorade + bisacodyl group compared to the GoLytely® group (32.5% vs. 23.8%, p = 0.01).

Quality of Bowel Cleansing

Patients who took the MiraLAX® + Gatorade + bisacodyl combination bowel preparation were more likely to achieve an excellent/good cleansing compared to patients using GoLytely® (93.3% vs. 89.3%, p = 0.048). Most of this difference was due to more frequent good cleansing (57.2% vs. 47.0%, respectively) and less frequent fair cleansing (5.6% vs. 10.2%, respectively) in the patients treated with MiraLAX® + Gatorade + bisacodyl combination vs. patients treated with GoLytely® (Table 2). Excellent colon cleansing was numerically lower in the MiraLAX® + Gatorade + bisacodyl group: 36.1% vs. 42.4%, respectively. In multivariate analysis, both ASA risk class of 1 [OR = 2.38; 95% CI: 1.14-4.98)] and lack of diabetes [OR = 2.34; 95% CI: 1.01-5.43)] were associated with an excellent/good bowel preparation. When only ASA Class I patients are studied, there was no difference in frequency of excellent/good bowel cleansing (91.1% vs 93.6%, respectively; p = 0.498). No hospitalizations or serious adverse events were identified in either group.

Factors Associated with Excellent/Good Bowel Cleansing and Recommendation for Repeat Colonoscopy in 10 Years

Multivariate logistic regression analysis revealed that an excellent/good bowel cleansing was associated with a 30-fold increase in the likelihood of receiving a recommendation for repeat colonoscopy in 10 years compared to patients with a fair/poor preparation [OR = 32.97; 95% CI: 16.63-65.35)]. When patients with poor preparation are excluded, excellent/good cleansing is also associated with a much higher likelihood of receiving a recommendation for repeat colonoscopy in 10 years [OR = 28.01; 95% CI: 13.96-56.19]. However, an ASA risk class of 1 was associated with a lower likelihood of receiving the 10-year repeat screening colonoscopy recommendation compared to patients with ASA class 2/3 [OR=0.48, CI(0.24-0.96)] (Table 3).

Absence of diabetes [OR = 2.34; 95% CI: 1.01-5.43] and ASA Class 1 [OR= 2.38; 95% CI: 1.14-4.98] were associated with achieving excellent/good bowel cleansing (Table 4). In multivariate logistic regression analysis, patients treated with the MiraLAX® + Gatorade + bisacodyl combination trended toward more excellent/good bowel cleansing compared to GoLytely® treated patients, but this difference did not achieve statistical significance [OR=1.47; 95% CI: 0.86-2.49; p = 0.16].

Discussion

This clinical effectiveness study investigates the efficacy of MiraLAX® + Gatorade + bisacodyl combination to 4 liters of GoLytely® for bowel cleansing prior to screening colonoscopy in a community hospital setting. Our retrospective endoscopic database study is the largest study to compare these two bowel purgatives, and the first study to compare these bowel purgatives using PM-only dosing. Although split-dosing is recommended by CRC screening guidelines(4), anecdotal evidence suggests that many endoscopists have not instituted split-dosing, so these data are applicable to these endoscopists.

A small increase in the frequency of excellent/good bowel cleansing was observed in patients receiving the MiraLAX® + Gatorade + bisacodyl combination compared to patients receiving 4L GoLytely® (93.3% vs. 89.3%, p = 0.048), although this difference was not significant [OR=1.47; 95% CI 0.86-2.49; p = 0.16] in multivariate analysis which accounted for multiple other factors, including proportion of patients with ASA Class I designation in both groups. Multivariate analysis revealed that an excellent/good bowel cleansing was associated with greater likelihood of receiving a recommendation for repeat colonoscopy in 10 years compared to patients with a fair bowel cleansing [OR = 28.01; 95% CI: 13.96-56.19].

Although prior RCTs demonstrated the superiority of 4L GoLytely® compared to the MiraLAX® + Gatorade + bisacodyl combination, our study demonstrated a small, but significant, improvement in bowel cleansing with the MiraLAX® + Gatorade + bisacodyl combination. We hypothesize that improved palatability of this combination could have improved compliance compared to 4L GoLytely® and led to the observed difference. In the setting of a RCT, compliance with 4L GoLytely® could have been improved for multiple reasons, including additional education about proper use of bowel purgative, interaction with study personnel who encourage patients to be compliant, and the possibility that patients who agree to participate in RCTs could also be patients who are more likely to be compliant with use of study medication. In the community setting, this would not be applicable. However, compliance with each bowel purgative was not recorded in the endoscopic database for our study, so we acknowledge that this is a hypothesis for the difference in bowel cleansing that we observed.

Current guidelines suggest that screening colonoscopy should be performed every 10 years in average-risk patients who are ≥ 50 years old(3, 4). However, patients are often told to return in fewer than 10 years which translates into wasted resources(13). In a study where endoscopists were shown photos of excellent/good/fair/poor colon cleansing during a colonoscopy, endoscopists recommended briefer intervals between screening colonoscopies when the colon cleansing was suboptimal. Our study quantifies the impact of colon cleansing on this issue and determined that patients with excellent/good cleansing were much more likely to receive a recommendation for repeat colonoscopy at 10 years compared to individuals with fair bowel cleansing [OR = 28.01; 95% CI: 13.96-56.19]. This finding is likely due to the concern of missing polyps if the cleansing is suboptimal. This is understandable because suboptimal colon cleansing is associated with lower polyp detection rates(5, 7). Notably, current guidelines do not make allowances for repeating colonoscopies

at intervals shorter than 10 years if the colon cleansing is sub-optimal(4, 14-16). Ultimately, efficient utilization of endoscopic resources and optimal polyp detection rates are associated with excellent/good colon cleansing, and we should identify interventions to achieve this level of colon cleansing. These interventions may include educational interventions with patients and the development of more palatable bowel purgatives that enhance compliance among patients. However, these bowel purgatives must be proven to be effective and safe.

Based on our effectiveness study, the MiraLAX® + Gatorade + bisacodyl combination appears to produce excellent/good bowel cleansing as least as frequently as 4L GoLytely® for colon cleansing when PM-only dosing is used. However, adequate safety data about the MiraLAX® + Gatorade + bisacodyl combination has not been published and this regimen is not FDA-approved. Our study and the two prior RCTs did not report any serious adverse events or clinically important electrolyte abnormalities among patients treated with MiraLAX® + Gatorade + bisacodyl combination (8, 9). However, these studies assessed < 1500 patients and serious adverse events with bowel purgatives are uncommon. The MiraLAX® + Gatorade + bisacodyl combination is not an osmotically balanced preparation like GoLytely®. Case series have reported multiple cases of severe hyponatremia with this regimen and database studies suggest that the risk of severe hyponatremia could be as much as 4× greater with this combination compared to osmotically balanced purgatives, such as GoLytely®(17-19). Also, the use of four 5-mg tablets of bisacodyl for bowel cleansing has been associated with a 7-fold increase in the risk of ischemic colitis(20). Since the MiraLAX® + Gatorade + bisacodyl combination is not FDA-approved for colon cleansing and since very limited safety data is available, endoscopists should exercise caution about the use of this bowel cleansing regimen until further safety data is available.

Our study has several limitations that should be noted. As previously discussed, this is a clinical effectiveness study that did not utilize split-dosing of the bowel purgative or validated bowel cleansing scales, but we feel that these are potential strengths that enhance the applicability of our results to endoscopists' practice. As a retrospective database study, there are multiple inherent limitations, including lack of blinding of endoscopists about type of bowel preparation utilized and data extraction was limited to data recorded in the database. For example, it would have been very helpful if tolerability and compliance of each bowel purgative was recorded. In fact, patients in this private practice setting underwent extensive education by allied medical personnel about the bowel preparation process, and we believe that this probably led to high compliance with bowel preparation instructions. This may account for high rates of “good” or “excellent” preps that are higher than reported in previous studies and may diminish the generalizability of our findings(5, 21).

The most important limitation of this study may be the significant increase in the proportion of ASA Class I patients in the MiraLAX® + Gatorade + bisacodyl group compared to the GoLytely®-treated patients (32.5% vs. 23.8%, p = 0.01). This difference most likely occurred because healthier, ASA Class I, patients were preferentially prescribed the newer Miralax-Gatorade prep, and these healthier, ASA Class I, patients were also more capable of completing the bowel prep and complying with all bowel preparation instructions. Based on our analysis, ASA Class I was associated with excellent/good cleansing in multivariate logistic regression analysis [OR= 2.38; 95% CI: 1.14-4.98], and, when only ASA Class I patients are studied, there was no difference in frequency of excellent/good bowel cleansing between Miralax® + Gatorade + bisacodyl vs Golytely® (91.1% vs 93.6%, respectively; p = 0.498). In conclusion, our community-based study demonstrated that PM-only dosing of MiraLAX® + Gatorade + bisacodyl combination produces excellent/good bowel cleansing in most average-risk individuals and with similar frequency to PM-only dosing of 4L GoLytely®. Also, no serious adverse events were observed. Since the MiraLAX® +

Gatorade + bisacodyl combination is lower volume than 4L GoLytely® and since it may be more palatable, this may be an appropriate alternative to GoLytely®. However, endoscopists should remember that this regimen is not FDA-approved, is not osmotically balanced like GoLytely®, and limited safety data is available. Large prospective studies should be conducted to fully assess tolerability, compliance, and electrolyte abnormalities with GoLytely®, Miralax® + Gatorade + bisacodyl, and other bowel purgatives.

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Table 1

Demographic Data

	MiraLAX® N=383	GoLytely® N=395	p-value
Age group, %			0.39 *
65yrs or less	84.1	81.8	
>65	15.9	18.2	
Gender, %			0.32 #
Male	43.3	46.8	
Female	56.7	53.2	
BMI group, %			0.92 *
Less than or equal to 30	72.8	73.2	
Greater than 30	27.2	26.8	
ASA risk class, %			0.01 #
ASA1	32.5	23.8	
ASA2/3	67.5	76.2	
Time of colonoscopy, %			0.97 #
AM	54.3	54.4	
PM	45.7	45.6	
Diabetes, %			0.23 #
Yes	5.5	7.6	
No	94.5	92.4	

* Two sample t-test analysis

Pearson's chi-squared or Fisher's exact

Table 2
Comparison Between Preparation Quality and Preparation Type

	MiraLAX® N=383	GoLytely® N=395	p-value
Prep quality, %			0.01#
Excellent	36.1	42.4	
Good	57.2	47.0	
Fair	5.6	10.2	
Poor	1.1	<1	
Good/Excellent prep, %			0.048#
Yes	93.3	89.3	
No	6.7	10.7	
Follow up recommendation, %			0.17#
Ten years	91.0	87.7	
Less than ten years	9.0	12.3	

#Pearson's chi-squared

Table 3
Logistic Regression for Having 10 Year Follow Up

Factor	Odds Ratio (95% CI), p value
Age greater than 65 vs. <=65	0.87 (0.37-2.04), 0.75
Female gender	1.08 (0.59-2.00), 0.80
MiraLAX® vs. GoLytely®	1.13 (0.61-2.11), 0.68
BMI greater than 30 vs. <=30	0.73 (0.37-1.44), 0.37
ASA risk class 1 vs. ASA risk class 2/3	0.48 (0.24-0.96), 0.04*
Time of appointment (PM vs. AM)	0.59 (0.31-1.11), 0.10
No diagnosis of diabetes	1.08 (0.31-3.69), 0.91
Good/Excellent prep vs. Fair/Poor	32.97 (16.63-65.35), <0.001*

Table 4
Logistic Regression for Having Good or Excellent Preparation

Factor	Odds Ratio (95% CI), p-value
Age greater than 65 vs. <=65	1.13 (0.57-2.25), 0.71
Female gender	0.90 (0.53-1.52), 0.70
MiraLAX® vs. GoLytely®	1.47 (0.86-2.49), 0.16
BMI greater than 30 vs. <=30	1.13 (0.63-2.02), 0.68
ASA risk class 1 vs. ASA risk class 2/3	2.38 (1.14-4.98), 0.02
Time of appointment (PM vs. AM)	0.85 (0.50-1.44), 0.55
No diagnosis of diabetes	2.34 (1.01-5.43), 0.047