

Original Article

The effect of MiraLAX/Gatorade bowel preparation versus Golytely on adenoma detection rate and interval to subsequent colonoscopy

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Abstract: Background and Aims: Colonoscopy is one of the main methods of colorectal cancer screening; there has been increasing emphasis on the quality of colonoscopy. Good bowel preparation is a quality indicator among others such as adenoma detection rate (ADR). Traditionally, Golytely has been the main bowel prep but it is not well tolerated by many. More recently, MiraLAX/Gatorade method was introduced to improve patient tolerance while maintaining bowel cleansing efficacy. Primary aim of this study was to examine ADR between MiraLAX/Gatorade and Golytely. Secondary aims were to examine rate of non-adherence to United States Multi-Society Task Force (USMSTF) recommendation for interval to subsequent colonoscopy and repeat colonoscopy within a year. Methods: Retrospective chart review was performed on patients who underwent screening colonoscopies during 4 consecutive months in 2012, when there was a department-wide change in bowel preparation to MiraLAX/Gatorade, and compared with same four calendar months in 2011, when Golytely was used. Results: Of 2,769 patients who met the inclusion criteria, 1,355 patients had MiraLAX/Gatorade and 1,414 had Golytely. MiraLAX/Gatorade group had higher ADR than Golytely group, 28% versus 24.5%, respectively, $P=0.041$. Golytely group had higher proportion of patients with repeat colonoscopies sooner than recommended by USMSTF (9.1% versus 6.9%, $P=0.030$) and repeat colonoscopy within one year (1.3% versus 0.5%, $P=0.046$) compared to MiraLAX/Gatorade group. Conclusions: MiraLAX/Gatorade group had a higher ADR, smaller percentage of patients with physician recommendation to repeat colonoscopies sooner than recommended by USMSTF, and fewer patients needing repeat colonoscopies within one year compared to the Golytely group.

Keywords: Miralax-gatorade, bowel preparation, golytely, adenoma detection rate, colonoscopy interval, quality indicators for colonoscopy

Introduction

Colorectal cancer (CRC) is the third most commonly diagnosed cancer in males and the second in females globally. In the United States, both the incidence and mortality have been slowly but steadily decreasing due to aggressive screening. Colonoscopy is one of the main methods of colon cancer screening. Quality is extremely important for colonoscopy in order to maximize its potential, and good bowel preparation has been selected as one of the quality indicators among others such as cecal intubation rate, withdrawal time, and ADR (adenoma detection rate) [1, 2].

Traditionally, Golytely or polyethylene glycol (PEG) has been the main bowel prep for colonoscopies. However, it is not well tolerated by many patients due to the large volume and taste. More recently, MiraLAX/Gatorade method has been introduced to obviate this problem and studies have been performed to prove its efficacy for bowel cleansing while improving patient tolerance [3, 4]. It was recently identified as an acceptable bowel regimen in adults by the multi-society task force [4].

There have been a few studies that demonstrated the non-inferiority of the MiraLAX/Gatorade prep compared to Golytely while maintain-

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ing safety and improved tolerability [5-7]. However, in a more recent meta-analysis, which included five studies, MiraLAX/Gatorade demonstrated significantly fewer satisfactory bowel preparations as compared with Golytely in addition to no statistically significant differences in polyp detection or side effects such as nausea, cramping, or bloating, concluding that Golytely appears superior to MiraLAX/Gatorade for bowel preparation before colonoscopy [8]. Enestvedt et al. found that ADR was higher for Golytely compared with MiraLAX [9].

Our study compared the ADR in the patients taking MiraLAX/Gatorade and Golytely in a large cohort within an integrated health system. We also investigated non-adherence to United States Multi-Society Task Force (USMSTF) recommendation for interval to subsequent colonoscopy (sooner than recommended) and repeat colonoscopy within a year, which may be surrogates for suboptimal bowel preparations with all other factors (initial screening exam, lack of family history of colon cancer, exclusion of patients diagnosed the colon cancer, etc.) being equal.

Methods

Retrospective chart review was performed on patients who underwent screening colonoscopies during 4 consecutive months in 2012, when there was a department-wide change in bowel preparation to MiraLAX/Gatorade (MiraLax 238 grams plus Gatorade 64 oz) and compared with same four calendar months in 2011, when Golytely was used. Split dosing was used for all patients, both MiraLAX/Gatorade and Golytely. Both groups were instructed to take Dulcolax (Bisacodyl) 10 mg at 3 pm on the day prior to the colonoscopy.

Included were average risk adult patients between ages 50 and 65 years going through initial screening (not surveillance) colonoscopies. Exclusion criteria were as follows: 1) Surveillance colonoscopy, 2) Any colonoscopy that was not the first-time colonoscopy including repeat exams due to a recent poor prep, 3) Family history of colon cancer, 4) History of inflammatory bowel disease (IBD) or diagnosis of IBD at index colonoscopy, 5) History of colon cancer or diagnosis of colon cancer at index colonoscopy, 6) History of hereditary conditions such as FAP (Familial Adenomatous Polyposis), 7) En-

doscopic mucosal resection (EMR) cases, 8) History of colon resection.

Colonoscopies were performed by eleven attending physicians using either Olympus CF-Q180A or PCF-Q180A. There was no change in the equipment during the study period. No distal attachments were used.

Information regarding the patients' basic demographics were recorded, including gender, race, and age. Clinical parameters (body mass index (BMI), narcotic pain medication usage, and diabetes) were collected.

This study was approved by the Southern California Kaiser Permanente Institutional Review Board. None of the authors have any conflict of interest to declare.

Statistics

The distributions of demographic and clinical characteristics of the study cohort were calculated by bowel preparation; differences were assessed using the t-test or chi-squared test. The percentages of outcomes of interest (colonoscopies repeated sooner than recommended by USMSTF; reoperation done within one year; adenoma) by bowel preparation were also tabulated, and *P*-values were generated from penalized maximum likelihood estimation of logistic regression. Penalized logistic regression was conducted to reduce the bias caused by the rare events of reoperation done within one year. Multivariable penalized logistic models adjusting for gender, age at colonoscopy, baseline BMI, narcotic use, diabetes mellitus, and physicians/operators were performed to examine the associations between outcomes of interest and exposure. Crude odds ratio from univariate penalized logistic regressions were also calculated for comparison. All analyses were conducted using SAS version 9.3, Cary, North Carolina, USA.

Results

There were total of 6509 patients who underwent colonoscopies during the study period. Of these, 2,769 patients met the inclusion criteria. 1,355 patients had MiraLAX/Gatorade for bowel preparation, and 1,414 had Golytely. There was no statistical difference between the two groups in age, gender, ethnicity, narcotic

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Table 1. Baseline characteristics by bowel preparation

	MiraLAX (N=1,355)	Golytely (N=1,414)	Total (N=2,769)	P-value‡
Age, Mean (SD)	56.3 (4.80)	56.1 (4.70)	56.2 (4.75)	0.150
Male, n (%)	630 (46.5%)	653 (46.2%)	1283 (46.3%)	0.869
Race/ethnicity, n (%)				0.833
White	685 (50.6%)	722 (51.1%)	1407 (50.8%)	
Black	164 (12.1%)	167 (11.8%)	331 (12.0%)	
Hispanic	359 (26.5%)	358 (25.3%)	717 (25.9%)	
Asian/Pacific Islander	96 (7.1%)	115 (8.1%)	211 (7.6%)	
Unknown/other	51 (3.8%)	52 (3.7%)	103 (3.7%)	
Narcotic, n (%)	171 (12.6%)	145 (10.3%)	316 (11.4%)	0.050
BMI, n (%)				0.253
No obesity (BMI<30)	839 (61.9%)	851 (60.2%)	1690 (61%)	
Obesity (BMI: 30-40)	439 (32.4%)	495 (35%)	934 (33.7%)	
Severe obesity (BMI≥40)	77 (5.7%)	68 (4.8%)	145 (5.2%)	
Diabetes, n (%)	230 (17%)	207 (14.6%)	437 (15.8%)	0.092

‡P-values are generated from Chi-squared test or t-test for categorical and continuous variables, respectively.

Table 2. Post-procedural outcomes by bowel preparation

	MiraLAX (N=1,355)	Golytely (N=1,414)	Total (N=2,769)	P-value§
Adenoma, n (%)	379 (28%)	347 (24.5%)	726 (26.2%)	0.041
Colonoscopy repeated sooner than recommended by USMSTF, n (%)	93 (6.9%)	129 (9.1%)	222 (8%)	0.030
Repeat colonoscopy in 1 year, n (%)	7 (0.5%)	18 (1.3%)	25 (0.9%)	0.046

§P-values are from univariable penalized likelihood logistic regression.

medication usage, BMI, or diabetes status (**Table 1**).

MiraLAX/Gatorade group had higher ADR than Golytely group, 28% versus 24.5%, respectively, $P=0.041$ (**Table 2**). Higher proportion of patients in the Golytely group (9.1%) were instructed to repeat colonoscopies sooner than recommended by USMSTF compared to the MiraLAX/Gatorade group (6.9%, $P=0.030$). More colonoscopies in the Golytely group were repeated within one year compared to MiraLAX/Gatorade group (1.3% versus 0.5%, $P=0.046$).

A multivariate analysis corroborated the findings for the three outcomes mentioned above albeit the odds ratio for ADR decreased slightly after adjusting for all the covariates listed (**Table 3**). There was an association between the male gender and higher ADR as well as older age and higher ADR, which were expected. There was a trend toward more colonoscopies repeated sooner than recommended by USMSTF among males and repeat colonoscopies in one year among patients with obesity in the BMI 30-40 category, but the clinical signifi-

cance of these findings is unclear. In addition, there was a trend toward more repeat colonoscopies within one year among patients taking narcotic pain medications at the time of procedures. When this was further analyzed between the MiraLAX/Gatorade and the Golytely group, there was no statistical significance (**Table 4**). Physicians/colonoscopists were used as covariates in univariate and multivariate analyses (**Table 3**); the 'reference' physician used in the analysis is the one that performed the most colonoscopies during the study period.

None of the patients had bowel preparation related complications such as severe hyponatremia. A total of 8 patients had documented hyponatremia (range 128-134 mmol/L) with most patients in the mild hyponatremia category and only one patient in moderate (128 mmol/L) category; none of the cases led to clinically significant sequelae.

Discussion

Colonoscopy is one of the main methods of colon cancer screening and the importance of

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Table 3. Crude and multivariable adjusted odds ratios with 95% confidence interval limits for interested outcomes

	Colonoscopy repeated sooner than recommended by USMSTF		Adenoma		Repeat colonoscopy within one year	
	Crude	Adjusted	Crude	Adjusted	Crude	Adjusted
Bowel prep (MiraLAX vs. Golytely)	0.74 (0.56, 0.97)	0.70 (0.52, 0.94)	1.19 (1.01, 1.41)	1.15 (0.96, 1.38)	0.42 (0.18, 0.98)	0.39 (0.17, 0.86)
Gender (male vs. female)	1.64 (1.24, 2.16)	1.54 (1.16, 2.04)	1.74 (1.47, 2.06)	1.69 (1.42, 2.01)	1.72 (0.78, 3.78)	1.75 (0.86, 3.58)
Age at colonoscopy (5-year increment)	1.09 (0.94, 1.25)	1.05 (0.90, 1.21)	1.19 (1.09, 1.30)	1.18 (1.08, 1.29)	1.01 (0.68, 1.52)	0.95 (0.66, 1.38)
BMI						
No obesity (BMI<30)	Reference		Reference		Reference	
Obesity (BMI: 30-40)	1.19 (0.89, 1.59)	1.19 (0.88, 1.60)	1.20 (1.00, 1.43)	1.20 (0.99, 1.44)	2.52 (1.13, 5.60)	2.37 (1.14, 4.90)
Severe obesity (BMI≥40)	1.04 (0.55, 1.95)	1.06 (0.55, 2.05)	1.29 (0.89, 1.87)	1.36 (0.92, 2.00)	1.66 (0.30, 9.32)	1.67 (0.34, 8.07)
Narcotic (yes vs. no)	1.20 (0.80, 1.80)	1.32 (0.87, 2.02)	1.03 (0.79, 1.34)	1.08 (0.82, 1.42)	3.19 (1.35, 7.52)	3.38 (1.53, 7.46)
Diabetes (yes vs. no)	1.28 (0.90, 1.82)	1.27 (0.88, 1.84)	1.13 (0.90, 1.41)	0.996 (0.78, 1.27)	1.44 (0.56, 3.70)	1.20 (0.50, 2.88)
Physician						
Physician 1	Reference		Reference		Reference	
Physician 2	0.08 (0.03, 0.21)	0.08 (0.03, 0.22)	0.54 (0.39, 0.75)	0.57 (0.41, 0.78)	0.38 (0.07, 2.29)	0.42 (0.08, 2.26)
Physician 3	0.27 (0.14, 0.55)	0.26 (0.13, 0.53)	0.57 (0.39, 0.83)	0.63 (0.43, 0.91)	0.20 (0.01, 3.57)	0.18 (0.01, 2.79)
Physician 4	0.12 (0.06, 0.24)	0.12 (0.06, 0.24)	0.46 (0.34, 0.62)	0.48 (0.35, 0.64)	0.27 (0.05, 1.61)	0.27 (0.05, 2.88)
Physician 5	0.29 (0.14, 0.58)	0.34 (0.17, 0.68)	0.54 (0.37, 0.80)	0.57 (0.38, 0.84)	1.06 (0.24, 4.61)	1.45 (0.35, 6.03)
Physician 6	0.37 (0.19, 0.70)	0.36 (0.19, 0.69)	0.53 (0.36, 0.80)	0.55 (0.37, 0.82)	1.54 (0.41, 5.72)	1.40 (0.39, 4.98)
Physician 7	0.44 (0.21, 0.92)	0.53 (0.25, 1.13)	0.99 (0.64, 1.51)	0.95 (0.62, 1.48)	1.05 (0.18, 6.32)	1.87 (0.32, 11.07)
Physician 8	0.78 (0.44, 1.40)	0.77 (0.43, 1.38)	0.35 (0.21, 0.59)	0.35 (0.21, 0.59)	1.62 (0.37, 7.11)	1.58 (0.38, 6.53)
Physician 9	0.36 (0.23, 0.58)	0.35 (0.22, 0.57)	0.79 (0.59, 1.04)	0.80 (0.60, 1.06)	0.71 (0.19, 2.62)	0.66 (0.19, 2.28)
Physician 10	1.06 (0.46, 2.41)	0.93 (0.40, 2.13)	0.69 (0.35, 1.36)	0.72 (0.36, 1.43)	4.51 (1.00, 20.25)	3.07 (0.69, 13.69)
Physician 11	1.47 (0.99, 2.20)	1.55 (1.03, 2.32)	1.00 (0.72, 1.40)	1.04 (0.74, 1.45)	1.67 (0.49, 5.59)	1.88 (0.58, 6.05)

Note: Results from penalized logistic regression. Crude results are based on univariable analysis and adjusted results from multivariable analysis.

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Table 4. Adjusted odds ratios with 95% confidence interval limits from stratified analysis

Bowel prep (MiraLAX vs. Golytely)	Repeat colonoscopy within one year
Among those with no narcotic use	0.40 (0.16, 1.02)
Among those with narcotic use	0.39 (0.10, 1.56)

Note: Adjusted for gender, age, BMI, diabetes mellitus, and physician.

quality has been emphasized in the recent years. Good bowel preparation is among few items that define quality, in addition to others such as ADR [1].

While Golytely has traditionally been the main bowel preparation for colonoscopies, MiraLAX/Gatorade method has been identified as an acceptable bowel regimen in adults by the multi-society task force due to its efficacy for bowel cleansing while improving patient tolerance [3, 4]. Although there have been a few studies that demonstrated the non-inferiority of the MiraLAX/Gatorade prep compared to Golytely while maintaining safety and improved tolerability [5-7], a recent meta-analysis showed that the MiraLAX/Gatorade method demonstrated significantly fewer satisfactory bowel preparations compared with Golytely in addition to not having statistically significant differences in polyp detection or side effects between the two preparations [8]. Enestvedt et al. found that ADR was higher for Golytely compared with MiraLAX, although this was a post hoc analysis of an RCT with small number of patients and the difference reaching statistical significance only after multivariate analysis [9].

Our study examined ADR between MiraLAX/Gatorade and Golytely retrospectively in a large number of patients within an integrated health system. We also looked at non-adherence to United States Multi-Society Task Force (USMSTF) recommendation for interval to subsequent colonoscopy (sooner than recommended) and repeat colonoscopy within a year. Our results showed that the MiraLAX/Gatorade group had higher ADR, smaller percentage of patients with physician recommendation to repeat colonoscopies sooner than recommended by USMSTF, and fewer patients needing repeat colonoscopies within one year compared to the Golytely group.

Limitations of our study includes the fact that it is a retrospective study. In addition, we did not

capture bowel preparation quality data. In the preparatory phase of the study, we considered capturing this information and reviewed a number of sample procedure reports. We noted that the written description of the bowel preparation quality did not always match up with actual endoscopic pictures taken by the physicians. We think that this might be due to physicians choosing default colonoscopy prep quality in the note-writing program which is set as 'fair' rather than actively changing this to a description that accurately depicts the prep quality. However, non-adherence to United States Multi-Society Task Force (USMSTF) recommendation for interval to subsequent colonoscopy (sooner than recommended) and repeat colonoscopy within a year may be surrogates for suboptimal bowel preparations with all other factors (initial screening exam, lack of family history of colon cancer, exclusion of patients diagnosed the colon cancer, etc.) being equal. Studies indicate that endoscopists repeat colonoscopy earlier than recommended based on current published guidelines for patients who achieve suboptimal bowel preparations, in particular 'fair preps' [10, 11].

While this study revealed potential merits of the MiraLAX/Gatorade bowel preparation, higher ADR being especially noteworthy, further studies should be performed to confirm this association.

Disclosure of conflict of interest

None.

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