

Retrospective Study

Predictors of suboptimal bowel preparation in asymptomatic patients undergoing average-risk screening colonoscopy

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Veterans Affairs firewall in a secure research environment, the VA Informatics and Computing Infrastructure (VINCI). In order to comply with VA privacy and data security policies and regulatory constraints, only aggregate summary statistics and results of our analyses are permitted to be removed from the data warehouse for publication. The authors have provided detailed results of the analyses in the paper. These restrictions are in place in order to maintain patient privacy and confidentiality. Access to these data can be granted to persons who are not employees of the VA; however, there is an official protocol that must be followed for doing so. Those wishing to access the raw data that were used for this analysis may contact Shail Govani (shailg@umich.edu) to discuss the details of the VA data access approval process. The authors also confirm that an interested researcher would be able to obtain a de-identified, raw dataset upon request pending ethical approval.

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Abstract

AIM

To identify risk factors for a suboptimal preparation among a population undergoing screening or surveillance colonoscopy.

METHODS

Retrospective review of the University of Michigan and Veteran's Administration (VA) Hospital records from 2009 to identify patients age 50 and older who underwent screening or surveillance procedure and had resection of polyps less than 1 cm in size and no more than 2 polyps. Patients with inflammatory bowel disease or a family history of colorectal cancer were excluded. Suboptimal procedures were defined as procedure preparations categorized as fair, poor or inadequate by the endoscopist. Multivariable logistic regression was used to identify predictors of suboptimal preparation.

RESULTS

Of 4427 colonoscopies reviewed, 2401 met our inclusion criteria and were analyzed. Of our population, 16% had a suboptimal preparation. African Americans were 70% more likely to have a suboptimal preparation (95%CI: 1.2-2.4). Univariable analysis revealed that narcotic and tricyclic antidepressants (TCA) use, diabetes, prep type, site (VA vs non-VA), and presence of a gastroenterology (GI) fellow were associated with suboptimal prep quality. In a multivariable model controlling for gender, age, ethnicity, procedure site and presence of a GI fellow, diabetes [odds ratio (OR) = 2.3; 95%CI: 1.6-3.2], TCA use (OR = 2.5; 95%CI: 1.3-4.9), narcotic use (OR = 1.7; 95%CI: 1.2-2.5) and Miralax-Gatorade prep vs 4L polyethylene glycol 3350 (OR = 0.6; 95%CI: 0.4-0.9) were associated with a suboptimal prep quality.

CONCLUSION

Diabetes, narcotics use and TCA use were identified as predictors of poor preparation in screening colonoscopies while Miralax-Gatorade preps were associated with better bowel preparation.

Key words: Preparation; Quality; Narcotics; Diabetes; Colonoscopy

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Core tip: Suboptimal preparation quality affects the ability of endoscopists to identify polyps during colonoscopy, leading to repeated procedures or missed lesions. In this large retrospective review of screening and surveillance procedures, we found that suboptimal preparation affected 16% of the procedures. Diabetes, narcotics

use and tricyclic antidepressants use were identified as predictors of poor preparation in multivariable analysis. More aggressive preparations should be considered with patients with these risk factors.

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INTRODUCTION

Colorectal cancer (CRC) is the second leading cause of cancer mortality in the United States, with an estimated 50830 deaths in 2013 alone^[1]. Colonoscopy has been shown to be effective at detection and removal of pre-cancerous lesions^[2]. However, bowel wall mucosa that is obscured due to inadequate bowel preparation cleansing is a significant problem, affecting 17.5%-28.2% of colonoscopies^[3-5]. The importance of bowel cleanliness was highlighted in a study by Froehlich *et al*^[6]. While preparation quality did not affect cancer detection rates, the study demonstrated that patients with good and excellent bowel preparations were 1.7x and 1.5x, respectively, as likely to have a polyp detected and removed compared to poor bowel preparation quality.

Suboptimal bowel preparation inhibits the endoscopist's ability to visualize the mucosal lining for polyps and cancers; this lack of visualization influences recommended follow-up intervals for repeat screening or surveillance colonoscopy^[7,8]. Data presented by Karasek *et al*^[9] demonstrated that among all colonoscopies in a Veteran population, when the bowel preparation quality was inadequate the interval follow-up was 17.1 mo shorter than the average recommendation of 58.7 mo. Similarly in an Israeli study of seventy-eight gastroenterologists^[7], they found shorter follow-up intervals when bowel preparation became increasing worse.

Regardless of indication for colonoscopy, numerous risk factors for inadequate preparation have been identified: Increasing age, male gender, diabetics, obesity, hypertension, cirrhosis, inpatient status, history of constipation, use of narcotics and tricyclic antidepressants (TCA), time of colonoscopy procedure, and patient comprehension of bowel preparation agent instructions^[4,10,11].

To the best of our knowledge no previous study has identified predictors of inadequate bowel preparation within a strictly asymptomatic outpatient screening population. Thus, the aim of this study was to estimate the impact of predictors on suboptimal bowel preparation among patients undergoing average-risk screening colonoscopy in the outpatient setting.

MATERIALS AND METHODS

Study design

This was a retrospective analysis of patient electronic medical records and colonoscopy reports from the Veterans Affairs Ann Arbor Medical Center (VA), and the University of Michigan in-hospital (Ann Arbor, MI, United States) medical procedures unit and two satellite ambulatory surgery medical procedures units (Ann Arbor, MI and Livonia, MI, United States). All colonoscopies were performed by board-certified gastroenterology staff or gastroenterology fellows under direct supervision of staff gastroenterologists.

Study population

All individuals 50 years or older undergoing average-risk screening colonoscopy in the outpatient setting between January 1st and December 31st, 2009 were reviewed for study eligibility. Subject exclusions included any listed concurrent gastrointestinal symptoms (*i.e.*, overt or occult GI bleeding, change in bowel habits, iron deficiency anemia or unexplained weight loss); family history of CRC; personal history of colon polyps, CRC, hereditary CRC syndromes (*i.e.*, hereditary non-polyposis colorectal cancer or familial adenomatous polyposis), and inflammatory bowel disease; any finding of large polyps (diameter ≥ 10 mm), or three or more polyps. Inpatient procedures or incomplete colonoscopies (determined by visualization of cecum and appendiceal orifice) resulted in study exclusion. Colonoscopy reports that lacked a preparation quality (adequate/inadequate or excellent/good/fair/poor) were also excluded.

Bowel preparation quality

The University of Michigan Healthcare System and VA Ann Arbor Medical Center use the Provation[®] Medical system (v5.0 and v4.2, respectively) to record endoscopic data. Physicians report bowel cleansing as "Quality" (excellent, good, fair, or poor), and/or "Adequacy" (Adequate or Inadequate/Unsatisfactory). For this analysis, bowel preparation quality was organized into a three-category variable: (1) Excellent and good and/or adequate; (2) Fair (defined as fair or fair-adequate); and (3) Poor (defined as poor and/or inadequate/unsatisfactory); and as a dichotomous variable: Optimal (excellent, good, adequate) and Suboptimal (fair, poor/inadequate).

Predictors of bowel preparation quality

Demographic and clinical factors were extracted from the patient's medical records. Demographic data included the patient's age at colonoscopy, gender, and race/ethnicity. Clinical factors included narcotic and TCA usage, diabetic status, body mass index (BMI): kg/m², endoscopy site, bowel preparation agent (GoLyte[®], Miralax[®]-Gatorade[®], *etc.*), number of polyps detected, and if a gastroenterology (GI) fellow was present during the procedure.

Statistical analysis

Descriptive statistics for continuous variables were cal-

culated as means and standard errors, and categorical variables were characterized as proportions. Continuous variables (patient age and BMI) were categorized for the analysis. Logistic regression was used to estimate relative risks as odds ratios (ORs) with 95% CIs.

The primary objective was to identify predictors of fair and poor bowel preparation quality. Age was categorized into 50-59 years, 60-69 year, and ≥ 70 year; BMI was categorized into < 30 kg/m² and ≥ 30 kg/m². Bowel preparation types were categorized as 8L polyethylene glycol (PEG)-3350, 4L PEG-3350, Miralax[®]-Gatorade[®], and other; bowel preparation effect estimates were referenced to 4L PEG-3350. All categorical variables were referenced to their lowest category, and effect estimates were adjusted for the site of colonoscopy and GI fellow presence. To measure the impact of risk factors on bowel preparation quality, a multivariable logistic regression model including all variables was fit.

All study database management and all statistical analyzes were performed using SAS 9.2 (SAS Institute Inc., Cary, NC, United States) and $P < 0.05$ was considered statistically significant. IRB approval was obtained from the University of Michigan and Veterans Affairs Ann Arbor Medical Complex prior to commencement of the data collection.

RESULTS

We reviewed 4427 average-risk screening colonoscopies performed between 1/1/2009 and 12/31/2009; 2026 (45.8%) subjects were excluded. The most frequent exclusionary criteria was polyp diameter ≥ 10 mm and/or three or more polyps, $n = 709$ (15.9%). Ninety-two (2.1%) subjects were excluded due missing bowel preparation quality data. The analysis included 2401 subjects: 1507 (62.8%) from the University of Michigan satellite outpatient ambulatory surgery centers, 407 (16.9%) from the University of Michigan in-hospital endoscopy unit, and 487 (20.3%) from the Ann Arbor VA endoscopy unit.

The study population had a mean age of 56.9 (± 7.1) and mean BMI of 28.6 (± 5.9). Males made up 55.3% of the population, and a majority (78.3%) of the population was Caucasian (Table 1). Fair bowel preparation was significantly greater amongst male subjects (12.9% vs 9.9%, $P = 0.02$), procedures performed in the presence of a GI fellow (16.0% vs 10.6%, $P < 0.01$), and procedures completed at the University of Michigan in-hospital and VA endoscopy units (11.8% and 17.1% vs 9.7%, respectively, $P < 0.01$). African-American individuals more frequently received fair and poor preparations ratings. Narcotics and tri-cyclic antidepressant users, and diabetics more frequently received fair and poor bowel preparations. Miralax/Gatorade bowel preparation users had the lowest occurrence of fair or poor bowel quality. No trends existed in the distribution of bowel cleansing quality by increasing age or number of polyps detected.

Table 2 provides adjusted effect magnitudes of predictors of suboptimal bowel cleansing after adjust-

Table 1 Frequency distribution of subject characteristics across level of bowel preparation quality

Characteristics	Bowel preparation quality ¹			Poor or inadequate	
	Excellent or good <i>n</i> (%)	Fair <i>n</i> (%)	<i>P</i> value ²	<i>n</i> (%)	<i>P</i> value ²
Demographics					
Age (yr)					
50-59	1385 (84.8)	177 (10.8)	0.21	71 (4.4)	0.20
60-69	502 (82.0)	78 (12.8)		32 (5.2)	
≥ 70	130 (83.3)	23 (14.7)		3 (1.9)	
Gender					
Female	916 (85.3)	106 (9.9)	0.02	52 (4.8)	0.46
Male	1101 (83.0)	172 (13.0)		54 (4.1)	
Race/ethnicity					
White	1596 (84.9)	210 (11.2)	0.16	73 (3.9)	< 0.01
Black	134 (75.3)	27 (15.2)		17 (9.6)	
Other ³	150 (82.8)	21 (11.6)		10 (5.5)	
Body mass index, (kg/m ²)					
< 25	523 (85.9)	59 (9.7)	0.05	27 (4.4)	0.79
≤ 25 to < 30	744 (85.1)	96 (11.0)		34 (3.9)	
≤ 30 to < 35	403 (81.3)	73 (14.7)		20 (4.0)	
≥ 35	238 (81.5)	39 (13.4)		15 (5.1)	
Clinical					
Narcotics use ⁴					
Yes	159 (74.0)	37 (17.2)	< 0.01	19 (8.8)	< 0.01
No	1842 (85.0)	239 (11.0)		86 (4.0)	
TCA use ⁴					
Yes	36 (69.2)	10 (19.2)	0.04	6 (11.5)	0.01
No	1965 (84.3)	266 (11.4)		99 (4.3)	
Prior diagnosis of diabetes					
Yes	204 (70.3)	61 (21.0)	< 0.01	25 (8.6)	< 0.01
No	1798 (85.9)	215 (10.3)		80 (3.8)	
GI fellow present					
Yes	344 (78.7)	70 (16.0)	< 0.01	23 (5.3)	0.22
No	1673 (85.2)	208 (10.6)		83 (4.2)	
No. of polyps ⁵ detected					
None	1232 (83.2)	179 (12.1)	0.57	69 (4.7)	0.65
1	537 (85.4)	68 (10.8)		24 (3.8)	
2	248 (84.9)	31 (10.6)		13 (4.5)	
Bowel prep type					
8L PEG-3350	334 (79.9)	70 (16.8)	< 0.01	14 (3.4)	0.01
4L PEG-3350	843 (81.8)	125 (12.1)		62 (6.0)	
MiraLAX®/Gatorade®	466 (90.0)	39 (7.5)		13 (2.5)	
Other ⁶	306 (85.7)	35 (9.8)		16 (4.5)	
Endoscopy site					
UMich Satellite Outpatient Units ⁷	1302 (86.4)	146 (9.7)	< 0.01	59 (3.9)	0.11
UMich in-Hospital Outpatient Unit	334 (82.1)	48 (11.8)		25 (6.1)	
Veterans Affairs Unit	381 (78.2)	84 (17.3)		22 (4.5)	
Total	2017 (84.0)	278 (11.6)		106 (4.4)	

¹Values may not sum to "All Subjects" due to missing data; ²Association relative to "Excellent or Good"; ³Other includes Asian, Hispanic, Native American, and those self-reported bi- or multi-racial; ⁴Defined as usage at time of colonoscopy procedure; ⁵Defined as polyps < 10 mm in diameter, and without villous histology; ⁶Includes Osmoprep®, Half-Lytely®, and MoviPrep®; ⁷Includes data from two satellite endoscopy units from the academic hospital. TCA: Tricyclic antidepressants; GI: Gastroenterology; PEG: Polyethylene glycol.

ment for site of endoscopy and GI fellow presence during the procedure. Diabetic status (OR = 2.3, 95%CI: 1.7-3.1), TCA use (OR = 2.5, 95%CI: 1.4-4.6), and narcotics use (OR = 1.8, 95%CI: 1.3-2.5) were associated with suboptimal bowel preparation. Compared to Caucasians, African-Americans were 70% (95%CI: 1.2-2.4) more likely to have suboptimal bowel cleansing. Relative to the 4L PEG-3350 preparations, 8L PEG-3350 and MiraLAX®/Gatorade® bowel preparation agents were associated with decreased odds of suboptimal bowel cleansing (OR = 0.52, 95%CI: 0.30-0.91 and OR = 0.55, 95%CI: 0.39-0.76), respectively. Patients with BMI ≥

30 trended towards increased frequency of suboptimal bowel cleansing (relative to those with a BMI < 30).

After adjustment for all variables (Table 3), the University of Michigan in-hospital endoscopy unit patients were 10% more likely to have suboptimal bowel preparations, relative to those at the satellite ambulatory surgery centers. However, the Veteran population was at a 2.2-fold increased risk of suboptimal bowel preparation relative to the same population. All other previously noted associations remained statistically significant after fitting the saturated multivariable logistic regression model.

Table 2 Adjusted estimates [odds ratio (95%CI)] of predictors of suboptimal bowel preparation

Suboptimal bowel prep Predictors	OR (95%CI) ¹
Age (yr)	
50-59	1.0
60-69	1.1 (0.84-1.4)
≥ 70	1.0 (0.67-1.6)
Male gender	0.99 (0.77-1.3)
Race	
White	1.0
Black	1.7 (1.2-2.4)
Other	1.2 (0.80-1.8)
Body mass index (kg/m ²)	
< 30	1.0
≥ 30	1.3 (0.99-1.6)
Clinical	
Narcotics use	1.8 (1.3-2.5)
TCA use	2.5 (1.4-4.6)
Diagnosis of diabetes	2.3 (1.7-3.1)
GI fellow present	1.1 (0.82-1.6)
Polyps detected	0.85 (0.68-1.1)
Bowel prep type	
4L PEG 3350	1.0
8L PEG 3350	0.52 (0.30-0.91)
MiraLAX®/Gatorade®	0.55 (0.39-0.76)
Other	0.76 (0.54-1.1)
Endoscopy site	
UMich Satellite Outpatient Units	1.0
UMich in-Hospital Outpatient Unit	1.3 (0.94-1.8)
Veterans Affairs in-Hospital Unit	1.6 (1.2-2.3)

¹Effect adjusted for endoscopy site and GI fellow presence. TCA: Tricyclic antidepressants; GI: Gastroenterology; PEG: Polyethylene glycol; OR: Odds ratio.

The distribution of bowel cleansing ratings between the University of Michigan in-hospital and VA endoscopy units varied depending on whether a GI fellow was present during the colonoscopy (Table 4). In the absence of GI fellows, endoscopists at the University of Michigan were more likely to issue bowel quality rates of poor, compared to those at the VA endoscopy unit (7.4% vs 3.1%, *P* = 0.05). However, when GI fellows were present during the procedure, VA endoscopists were more likely (18.9% vs 11.7%, *P* = 0.04) to rate bowel preparations as fair.

DISCUSSION

This retrospective study is the first to focus on identifying predictors of bowel preparation quality among patients undergoing average-risk screening colonoscopy. In addition to reduced adenoma detection rates and increased risk of procedural complications, suboptimal preparation leads to increased healthcare costs by increasing the likelihood that a patient receives a shorter interval recommendation for repeat endoscopy^[7,9]. Repeat colonoscopy procedures due to suboptimal bowel preparation have significant implications on the increasing cost of medical care in the United States, especially within the average-risk screening population that accounts for approximately two million colonoscopies

Table 3 Multivariable estimates [odds ratio (95%CI)] of predictors of suboptimal bowel preparation

Factor	Suboptimal prep, OR (95%CI)
Endoscopy site	
Academic in-Hospital Unit	1.1 (0.76-1.6)
Veterans Affairs Hospital	2.2 (1.1-4.3)
African-American	1.5 (1.0-2.2)
Diabetic	2.3 (1.6-3.2)
TCA use	2.5 (1.3-4.9)
Narcotics use	1.7 (1.2-2.5)
Bowel prep type	
8L PEG-3350	0.46 (0.24-0.87)
MiraLAX®/Gatorade®	0.61 (0.43-0.86)

TCA: Tricyclic antidepressants; OR: Odds ratio; PEG: Polyethylene glycol.

performed annually^[12,13]. With an aging population the increased need for screening colonoscopy is greater than ever. However, predictions show no significant increase in the number of practicing gastroenterologists, thus reducing the percentage of endoscopies with suboptimal preparations is critical to utilization sustainability.

The findings of our study within an asymptomatic average-risk population are similar to those which included other indications for CRC screening. Amongst average-risk screening individuals, we identified that diabetes along with narcotics and TCA use was associated with approximately a two-fold increase in the risk of suboptimal bowel preparation. Though not statistically significant, our study showed that individuals with a BMI ≥ 30 trended towards suboptimal bowel preparations compared those with a BMI < 30. Our study also identified that African-American patients were less likely to have optimal bowel cleansing relative to Caucasians. African-Americans have been found to have both more advanced disease at diagnosis and poorer outcomes than other groups^[14]. However, unlike previous studies, we did not find that patient age or gender were predictors of suboptimal preparation quality.

Our study is novel in that it compared average-risk screening patients amongst an academic in-hospital and satellite ambulatory endoscopy centers, and a Veterans Affairs endoscopy suite. Relative to the study population at the outpatient ambulatory academic satellite surgery centers, the Veteran population was twice as likely to produce a suboptimal bowel preparation. The 2010 Veterans Health Administration Health Report^[15] indicated that in the fiscal year 2009, 214955 colonoscopies were performed for all indications; our study found that 22.2% of the screening colonoscopies amongst Veterans had suboptimal bowel preparations. This has significant implications on the already scarce availability of colonoscopy for repeat procedures especially as the VHA continues to increase the rate of colorectal screening amongst Veterans.

A number of studies have compared the results of different bowel preparation types on colonoscopy preparation quality^[16,17]. The finding of the MiraLAX®-Gatorade® bowel preparation producing superior bowel preparation quality is in contrast to published literature.

Table 4 Distribution of bowel preparation quality and endoscopy site, across level of gastroenterology fellow presence during colonoscopy

GI fellow presence	Bowel preparation quality				
	Excellent/good <i>n</i> (%)	Fair <i>n</i> (%)	<i>P</i> value ¹	Poor <i>n</i> (%)	<i>P</i> value ¹
Not present					
UMich in-Hospital Endoscopy Unit	186 (80.9)	27 (11.7)	0.34	17 (7.4)	0.05
Veterans Affairs Endoscopy Unit	185 (81.5)	35 (15.4)		7 (3.1)	
Present					
UMich in-Hospital Endoscopy Unit	148 (83.6)	21 (11.9)	0.04	8 (4.5)	0.44
Veterans Affairs Endoscopy Unit	196 (75.4)	49 (18.9)		15 (5.8)	
Total	715 (80.0)	132 (14.8)		47 (5.2)	

¹Relative to excellent/good. GI: Gastroenterology.

Two recently published randomized controlled trials comparing MiraLAX[®] to Golytely[®] have shown Golytely[®] to produce superior preparation quality^[18,19]. The study by Enestvedt *et al.*^[18] focused on screening colonoscopies, but excluded patients with a history of constipation; whereas, Hjelkrem *et al.*^[19] did not exclude patients with risk factors of suboptimal preparation (except prior surgery). Though our study did not directly compare GoLytely[®] to MiraLAX[®], it did demonstrate that compared to all 4L PEG-3350 solutions, MiraLAX[®]-Gatorade[®] produced superior bowel preparation qualities. Noting the retrospective nature of the study design, our study consisted of a large population and allowed for statistical adjustment of known risk factors such as narcotics and TCA use, and diabetic status. Given these conflicting findings, further research on the efficacy of MiraLAX[®] as a colonoscopy preparation agent is warranted.

We are aware that our study has several limitations due to its design. The first limitation is the retrospective nature of medical records relies on patient self-report and documentation by nursing and physician personnel. Between January 1 and December 31, 2009, there were forty-eight practicing gastroenterologists. Some physicians only performed colonoscopy at a single endoscopy center, while others at performed at multiple sites; similarly not all physicians performed colonoscopy in the presence of a GI fellow. We attempted to control for this through our statistical modeling with adjustments for endoscopy site and GI fellow presence. Secondly, our measured outcome was not a standardized scale system such as the Boston Bowel Preparation Scale or the Ottawa scale, but rather subjective determination by our endoscopists using the Aronchick scale (*i.e.*, excellent, good, fair, and poor). Third, data were not collected on previously identified predictors of suboptimal prep such as patient comprehension of bowel preparation instructions, concurrent comorbidities (*i.e.*, dementia, cirrhosis, and stroke), or previous gastrointestinal and/or genitourinary surgeries. The analysis of preparation types is limited by the lack of data on the amount of prep consumed. It is possible that patients may have found the MiraLAX[®]/Gatorade preparation more tolerable and consumed more of this than the PEG-3350 preparations. Lastly, due the tertiary nature of our hospital system,

our results may not be generalizable to the community setting.

In conclusion, our study identified that average-risk patients using narcotics or TCAs prior to colonoscopy, as well as, diabetics are at increased risk for suboptimal bowel preparation quality when undergoing screening colonoscopy. Similarly, our study noted a strong disparity between bowel preparation outcomes amongst Veterans and African-Americans. Further studies aimed at improving bowel preparation outcomes of colonoscopic preparations within these populations are warranted.

COMMENTS

Background

Suboptimal bowel preparation affects approximately 20% of colonoscopies. Suboptimal preparation leads to reduced polyp detection and leads endoscopist to recommend shorter interval follow-up.

Research frontiers

Identifying predictors of suboptimal preparation may allow endoscopists to risk-stratify patients into high and low risk groups and prescribe a more aggressive preparation type for those in the high risk group.

Innovations and breakthroughs

Diabetes, narcotics and tricyclic antidepressant use predict suboptimal preparation.

Applications

Suboptimal preparation affected 1 out of every 6 colonoscopies in this population. Prescription of more aggressive preparation types for patients with diabetes or those who use narcotics or tricyclic antidepressants may reduce the incidence of suboptimal preparations.

Terminology

Suboptimal preparation occurs when the endoscopist characterizes the preparation as fair, poor or inadequate. Screening or surveillance colonoscopies are done to identify polyps and with the aim of preventing subsequent colorectal cancer.

Peer-review

The manuscript by Govani *et al* deals with clinically important question how to improve bowel cleansing before colonoscopy. Given the incidence of colon cancer, the implications of missed lesions due to suboptimal preparation and the costs of performing repeated procedures due to suboptimal preparation, this topic is of immense clinical importance.

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