Effect of Bowel Preparation Volume in Inpatient Colonoscopy. Results of a Prospective, Randomized, Comparative Pilot Study

Patricia V Hernandez
Mayo Clinic Arizona https://orcid.org/0000-0002-7340-3631
Jennifer L. Horsley-Silva
Mayo Clinic Arizona
Diana L. Snyder
Mayo Clinic Arizona
Noemi Baffy
Mayo Clinic Arizona
Mary Atia
Mayo Clinic Arizona
Laura Koepke
Mayo Clinic Arizona
Matthew R. Buras
Mayo Clinic Arizona
Elisabeth S. Lim
Mayo Clinic Arizona
Kevin Ruff
Mayo Clinic Arizona
Sarah B. Umar
Mayo Clinic Arizona
Sameer Islam
Mayo Clinic Arizona
Francisco C. Ramirez (Ramirez.Francisco@mayo.edu)
https://orcid.org/0000-0003-4731-4982

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Abstract

Background: Inpatient status has been shown to be a predictor of poor bowel preparation for colonoscopy; however, the optimal bowel preparation regimen for hospitalized patients is unknown. Our aim was to compare the efficacy of bowel preparation volume size in hospitalized patients undergoing inpatient colonoscopy. Methods: This prospective, single blinded (endoscopist), randomized controlled trial was conducted as a pilot study at a tertiary referral medical center. Hospitalized patients undergoing inpatient colonoscopy were assigned randomly to receive a high, medium, or low-volume preparation. Data collection included colon preparation quality, based on the Boston Bowel Preparation Scale, and a questionnaire given to all subjects evaluating the ability to completely finish bowel preparation and adverse effects (unpleasant taste, nausea, and vomiting). Results: Twenty-five colonoscopies were performed in 25 subjects. Patients who received low-volume preparation averaged a higher mean total BBPS (7.4, SD 1.62), in comparison to patients who received high-volume (7.0, SD 1.41) and medium-volume prep (6.9, SD 1.55), P = 0.77. When evaluating taste a higher score meant worse taste. The low-volume group scored unpleasant taste as 0.6 (0.74), while the high-volume group gave unpleasant taste a score of 2.2 (0.97) and the medium-volume group gave a score of 2.1 (1.36), P < 0.01. Conclusion: In this pilot study, the low-volume colon preparation Prepopik® may be preferred in the inpatient setting due its better rate of tolerability and comparable bowel cleanliness when compared to larger volume preparation, although we cannot overreach any definitive conclusion. Further more robust studies are required to confirm these findings.

Background

Colonoscopy examinations are the standard test to evaluate the colon and are frequently performed in hospitalized patients for a number of indications [1]. The quality of colon cleansing directly affects the ability to visualize mucosa which herein affects diagnostic yield and ability to perform therapeutics [1, 2]. When bowel preparation is poor, it leads to significant limitations and prevents an endoscopist from performing a high quality examination. This may result in delay of the procedure or earlier interval colonoscopy, which increases cost and decreases patient safety [3-5].

Inpatient status has been shown to be a predictor of poor bowel preparation. This is thought to be due to patient characteristics such as older age, decreased mobility, and more comorbidities, in addition to the need for more emergent evaluation than outpatient populations [6, 7]. The ideal colon preparation method should empty the entire colon from fecal material in a rapid fashion, be as comfortable as possible for patient use, be associated with minimal adverse risks, and be cost efficient. Unfortunately, many of these features are not currently available in bowel preparation solutions [1, 4]. All colonoscopy preparation regimens may cause adverse effects such as electrolyte and fluid shifts, nausea, vomiting, and abdominal discomfort [8].

Studies in outpatient populations have demonstrated that timing and choice of cathartic medication affects the cleanliness of the bowel preparations [9-11]. However, no standardized (or optimized) bowel

preparation regimen exists for inpatient populations undergoing colonoscopy. We hypothesized that a low-volume colon preparation regimen results in better quality of colon preparation in inpatient settings when compared to traditional high or medium-volume regimens. The purpose of this study is to compare the efficacy of a bowel preparation size in hospitalized patients undergoing colonoscopies in the inpatient setting. The primary outcome measured is the quality of bowel preparation scored through the Boston Bowel Preparation Scale (BBPS). Secondary outcomes include patient tolerance and cecal intubation.

Methods

Trial design and setting

This prospective, single-blinded, randomized control trial (clinicaltrials.gov NCT01978509) was approved by the Institutional Review Board (IRB) and adheres to Consolidated Standards for Reporting Trial (CONSORT) guidelines for reporting clinical trials. It was conducted as a pilot study at Mayo Clinic Arizona between September 2013 and March 2019.

Study population

Eligible subjects included hospitalized patients 18 years or older who were able to provide consent and in whom colonoscopy was deemed medically necessary while hospitalized. Patients who were unable to give consent, were pregnant or breastfeeding, had renal impairment, ileus, ascites, toxic megacolon, evidence of gastrointestinal obstruction, or presence of an allergy to study drug were excluded. Risks and benefits were explained to all subjects and written informed consents were obtained.

Bowel preparation

After informed consent was obtained, patients were randomly assigned to the high-volume solution polyethylene glycol – PEG (GoLYTELY®), PEG+ascorbic acid medium-volume solution (MoviPrep®) or sodium picosulfate low-volume solution (Prepopik®), see table 1 for full list of ingredients. All doses were prescribed and administered as split dose, with half of the required preparation being administered the night before the procedure starting at six in the evening and the other half being administered the morning of the procedure starting at three in the morning. All patients were required to complete the liquid purgative two hours prior to their procedure. These are further described in Table 1. All subjects received a clear liquid diet the day before the procedure.

Randomization

Physicians performing the endoscopy were blinded to what type of bowel preparation each patient received. Fellow physicians within the gastroenterology department on service at the hospital enrolled participants. The allocation ratio was 1:1:1 for the intervention. Randomization was carried out using a computer-generated random numbers model and performed by a nurse practitioner who then placed bowel preparation orders without informing the inpatient gastroenterology service or endoscopist(s) performing the colonoscopy. Additionally, the patients were told not to speculate or inform their nursing staff, physicians, or performing endoscopist(s) if they were aware which bowel preparation regimen they consumed. Both fellow physicians and faculty physicians completing the procedures were involved in the creation of the BBPS for formal reports and blinded to the preparation the patient received.

Procedures

Colonoscopy procedures were performed by the inpatient gastroenterology hospital service, which included attending faculty and fellows (under direct supervision of an attending), using Olympus Exera II 180 series colonoscopes in 4 subjects and Olympus 190-series (CF-HQ190AL and PCF-H190L) colonoscopes in the remaining cases (Olympus Corp., Tokyo, Japan). The success of cecal intubation was established by visualization of anatomic landmarks (appendiceal orifice and ileocecal valve). Procedures were performed under conscious sedation (IV fentanyl, IV midazolam) in 21 subjects while 4 patients underwent deep sedation (IV fentanyl, IV midazolam, and IV propofol) with assistance of anesthesia providers.

Therapeutic interventions, such as biopsies, polypectomies, clip placement, argon plasma coagulation, or other electrocoagulation modality were performed as indicated. During the colonoscopy, quality metrics (BPSS, and cecal intubation) were obtained. No procedures were required to be repeated due to inadequate preparation. Withdrawal time was not a quality metric tracked in this study due to inpatient procedures being performed for diagnostic purposes, not screening or surveillance.

Primary Outcome

To determine quality of bowel preparation among three different volume solutions, we used the Boston Bowel Preparation Scale (BBPS) in the three colon segments (right, transverse and left colon) along with total score.

Secondary outcomes

After colonoscopy, all subjects received a questionnaire about their experiences with the colonoscopy preparation (Table 2), and cecal intubation rate was obtained. The questionnaire given to patients

included questions on percentage of bowel preparation completion, perceived unpleasant taste, nausea and vomiting.

Statistical Analysis

This was a pilot study, in which a modest sample size was achieved. Number of patients enrolled in this study was determined by willingness for participation. The trial ended due to a difficulty of recruiting participants, partly due to faculty and fellow bias that low volume colon preparation would lead to poor bowel preparation and need for repeat procedures.

Continuous variables are described with their mean and standard deviation while categorical variables are described by count and percentage. The Chi-Square test was used for demographics, indication for colonoscopy, diabetic status, history of constipation, purgative type, and if patient completed bowel preparation. The three groups were compared in terms of BMI, quality of bowel preparation (using Boston Bowel Preparation Scale), and side effects (unpleasant taste, nausea, vomiting, abdominal pain scored in a five-point scale) by the one-way analysis of variance (one-way ANOVA) test. All hypothesis tests were two-sided with $P < 0.05$ considered statistically significant. Analyses were performed using SAS 9.4 (SAS Institute, Inc.; Cary, NC).

Results

Out of 32 initially randomized subjects, 7 patients did not complete the questionnaire after colonoscopy and therefore had incomplete data. A total of 25 inpatient colonoscopies were performed in 25 subjects whom all had complete data. Nine patients were assigned to receive GoLYTELY®, eight to receive MoviPrep®, and eight to receive Prepopik®. Demographic data and underlying conditions such as diabetes and chronic constipation are reported in Table 3.

Patients who received Prepopik® achieved a higher total BBPS score (mean 7.4, SD±1.62) than patients who received GoLYTELY® (mean total BBPS score 7.0, SD±1.41) and MoviPrep® (mean total BBPS score 6.9, SD±1.55), although the differences were not statistically significant ($P = 0.77$) (Figure 1). Seven patients in the Prepopik® group, eight in the GoLYTELY®, and six in the MoviPrep® group had BBPS score ≥ 6 ($P = 0.70$), which is considered adequate colon preparation [12].

In the GoLYTELY® group, mean BBPS score for right colon was 2.4 (0.52), for transverse colon was 2.5 (0.53) and for left colon was 2.3 (0.46). In the MoviPrep® group, mean BBPS for right colon was 2.4 (0.74), for transverse colon was 2.5 (0.53) and for left colon was 2.0 (0.53). Finally, in the Prepopik group, BBPS score for right colon, transverse colon and left colon was 2.6 (0.53), 2.7 (0.76), and 2.1 (0.69), respectively. In all cases, cecal intubation was achieved.

With regard to tolerance to colon cleansing, 100% of patients who received Prepopik® reported finishing bowel preparation completely, whereas 77.8% of the GoLYTELY® group and 75% of the MoviPrep® group

reported accomplishment all purgative intake (P = 0.32), shown in the Figure 2. Among patients who did not finish the preparation, two individuals receiving GoLYTELY® took 3920 and 1500 mL, and two patients receiving MoviPrep® took 1860 and 1800 mL.

The perception of unpleasant taste demonstrated a significant difference between the Prepopik® group and GoLYTELY®/ MoviPrep® groups ($P \leq 0.01$). Mean (SD) score for this adverse event reported by patients who had Prepopik® was 0.6 (0.74), while patients who had GoLYTELY® reported 2.2 (0.97) and MoviPrep® mean score was 2.1 (1.36). Other parameters analyzed were nausea and vomiting. Mean (SD) score for patient reported nausea was 0.9 (1.27), 0.5 (1.07), and 0 in the GoLYTELY®, MoviPrep®, and Prepopik® groups respectively, and mean (SD) score for vomiting was 0.1 (0.33), 0 and 0 in the GoLYTELY®, MoviPrep®, and Prepopik® respectively (Table 4).

Discussion

Our pilot study is the first to compare the quality of bowel preparation based on volume in a prospective and randomized manner in hospitalized patients. Our results show that patients who received the low-volume preparation showed a trend towards better BBPS score, compared to those receiving larger-volume preparations, but that was not stastically significant.. Importantly, low-volume preparation was perceived to taste better to patients, which likely plays a factor in patient compliance. Additionally, the low-volume preparation had lower rates of patient reported nausea and vomiting which also likely contributes to a higher rate of bowel preparation completion in this group.

A poor bowel preparation for colonoscopy has detrimental consequences, such as decreased identification of pathology, increased procedure time, and decreased rates of cecal and terminal ileum intubation. Inadequate bowel preparation also leads to shortened interval colonoscopy duration and increased health care costs, not to mention additional risks to the patient and increased time off of work than would be required otherwise [13, 14]. Furthermore, risk of adverse events such as colon perforation may be increased with inadequate colon cleansing [14].These factors emphasize the importance of prospective studies reviewing the efficacy and quality of bowel cleansing, especially in hospitalized patient cohorts.

Predictors of inadequate bowel preparation for ambulatory colonoscopies cannot be extrapolated to the inpatient setting given the differences between inpatient and outpatient populations. These differences include distribution of age, level of physical activity, prevalence of comorbidities and indication for colonoscopy which are vastly different between the two populations [7].

Some authors have reported better results of inpatient colonoscopy preparation with split-dose administration of 4-liter polyethylene glycol (PEG) [15], based on the outpatient data that shows that split-dose PEG solution is superior to single-dosing [8, 16, 17]. In the outpatient setting, it is known that timing between completion of purgative intake and the colonoscopy is an important factor for bowel-preparation quality, regardless if the procedure is performed in the morning or afternoon [9-11]. In our study, we used split dosing of bowel preparation in all subjects received colon cleansing preparations giving half of the

solution starting the evening prior to day of procedure and the remaining half in the morning of the planned procedure.

Physician, nursing, and patient education has also shown to be an efficient tool for colonoscopy cleansing in the inpatient setting [18]. However, Chorev *et al* did not find significant improvement in preparation quality or in colonoscopy success in hospitalized patients after departmental institution of an educational program for healthcare providers [15, 18].

The standard preparation for patient with medical comorbidities of renal failure, congestive heart failure, or liver disease is 4-liter PEG-electrolyte solutions [1, 2, 5]. Nonetheless, it is reported that 1 in 7 patients may not be compliant to bowel preparation regimen mainly due to the volume [19]. Improved results of preparation are achieved with better compliance, which has been shown to be related to decreased bowel cleansing volume, palatability and regimen simplicity [2, 17, 19-21]. We found that 100% of subjects who received Prepopik® finished their bowel preparation completely, in opposition to MoviPrep® (75%) and GoLYTELY® (77.8%). Reasons for this difference may be explained by the lower volume of Prepopik® and perceived better taste ($P \leq 0.01$), both of which can enhance adherence of a colon cleansing regimen.

Our findings are consistent with a prospective study performed by Gu et al. with more than 4,300 outpatient colonoscopies that reports better tolerability and cleansing with SuPrep® (low-volume regimen bowel preparation) than GoLYTELY® [17].

A retrospective study by Corliss et al. described a rate of 44.1% of inadequate bowel preparation (total BBPS <7) among hospitalized patients receiving standard solution (4-liter of GoLYTELY ®), in comparison to a rate of 22.6% among inpatients receiving SuPrep® (low-volume regimen) in split-dose fashion [22].

Our study has some limitations. While novel and prospective, one of the largest limitations to our study is our sample size is small, which may affect the statistical significance and impairs any definitive conclusions. There is no FDA approved purgative for patients with some medical conditions as such as congestive heart failure, advanced renal disease, and decompensated liver disease; therefore the standard 4-liter Polyethylene Glycol has been the default choice for such patients. Since the hospitalized population has more patients with these conditions, our findings may not be generalized to all inpatients and the potential for prescribing error in such patients should be considered. Additionally, these results are not generalizable to all other low-volume preparations. Given the prospective nature of our study, all our patients were on a clear liquid diet the day prior to procedures, and this may not be the case for all hospitalized patient colonoscopies. This study can not be generalized to very urgent colonoscopies that could require rapid preparation as split dose preparation would not be appropriate in this setting. Some patients in our study were currently using opioids, one patient was on nortriptyline and one patient was on Carbidopa; medications which may decrease intestinal motility. When evaluated these medication usages were not different among the preparation groups. Finally, the lack of information about prior inadequate bowel preparation along with subjective patient report about completion of preparation solutions in each group may have affected our results.

Conclusions

In summary, in this pilot study, , the low-volume colon preparation Prepopik ® may be preferred in the inpatient setting due to its better rate of tolerability and comparable bowel cleanliness when compared to larger volume preparations, although we cannot overreach any definitive conclusion. . This low-volume preparation also demonstrated a lower rate of reported unpleasant taste and nausea than other medium and large volume preparations. This study highlights the fact that larger volume preparation may not be superior to low volume preparation in the inpatient setting and further more robust studies are required to confirm these findings.

List Of Abbreviations

BBPS: Boston Bowel Preparation Scale

Declarations

Ethics approval and consent to participate: this study was approved by Institutional Review Board of Mayo Clinic Arizona (13-003983). It was registered at www.clinicaltrial.gov (NCT01978509) in September 2013, and adheres to CONSORT guidelines for reporting clinical trials. Risks and benefits were explained to all patients and written informed consents were obtained. All patients enrolled were older than 18 able to give consent for the procedure and research

Consent to publish: consent for publication of the research results in professional journals without identities revealed was obtained from all patients.

Availability of data and materials: the datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Competing interests: S. Islam is speaker for Salix Medical.

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Author contributions: JLHS, KR, FCR conceptualized and designed the study. KR, JLHS, NB, MA, SI and DLS collected data. PVH, MRB, ESL, SBU and FCR analyzed data and results. PVH drafted the manuscript. JLHS, DLS, SBU and FCR reviewed the manuscript. All authors read and approved the final manuscript.

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Tables

Table 1 – Bowel preparations regimens

Prep Types	Volumes of Prep	Ingredients	Administration (full dose regimen)
GoLYTELY®	4,000 mL	Polyethylene glycol, sodium sulfate, sodium bicarbonate, sodium chloride, potassium chloride	2 L-solution of water mixed to GoLYTELY® given in the evening before the colonoscopy. This regimen was repeated again the next morning
MoviPrep®	2,000 mL	Polyethylene glycol, sodium sulfate, sodium bicarbonate, sodium chloride, potassium chloride, sedum ascorbate and ascorbic acid	1 L-solution of water mixed to MoviPrep® given in the evening before the colonoscopy. This regimen was repeated again the next morning
Prepopik®	300 mL	Sodium sulfate, potassium sulfate and magnesium sulfate	150 mL-solution of water mixed with Prepopik® given in the evening before colonoscopy. This regimen was repeated again the next morning

Table 2 – Data collection

Variables	Data
Patient demographics	• Sex • Age • BMI • Diabetes status • History of constipation • Indication for colonoscopy • Purgative type
Colonoscopy features	• Colon cleanliness quality, based on the Boston Bowel Preparation Scale • Cecal intubation
Patient questionnaire	• Ability to completely finish bowel preparation • Evaluation of adverse effects (unpleasant taste, nausea, and vomiting) using a five-point scale ranging from 0 (no symptoms) to 4 (severe symptoms)

Table 3 – Patient demographics and indication for colonoscopy

	GoLYTELY® (n=9)	MoviPrep® (n=8)	Prepopik® (n=8)	Total (n=25)	P-value
Female gender, n (%)	3 (33.3%)	3 (37.5%)	2 (25.0%)	8 (32.0%)	0.86
Age (y) Mean (± SD) Range	70.8 (±12.33) 51-86	62.1 (±17.46) 32-85	66.5(±19.79) 35-84	66.6 (±16.34) 32-86	0.57
BMI (kg/m□) Mean (±SD) Range	29.1 (±4.21) 22.9-35.7	25.3 (±3.67) 18.2-29.8	29.8 (±7.59) 23.2-45.6	28.2 (±5.57) 18.2-45.6	0.25
Diabetes, n (%)	2 (22.2)	2 (28.6)	2 (25.0)	6 (25.0)	0.96
Chronic constipation, n (%)	1 (11.1)	1 (14.3)	2 (25.0)	4 (16.7)	0.73
Neurologic disease, n (%)	0	Lewy body dementia: 1(12.5)	Paraplegia: 1(12.5)	2 (8)	0.36
Use of medication that may cause constipation	Opioid: 2 (22.2)	Opioid: 1 (12.5) Opioid + Carbidopa: 1 (12.5)	Opioid: 2 (25) Nortryptiline: 1 (12.5)	Opioid: 5 (20) Opioid + carbidopa: 1 (4) Nortryptiline: 1 (4)	0.58
Indication for colonoscopy					0.71
Abnormal imaging	0 (0.0%)	1 (12.5%)	0 (0.0%)	1 (4.0%)	
Diarrhea	1 (11.1%)	2 (25.0%)	2 (25.0%)	5 (20.0%)	
Hematochezia	6 (66.7%)	3 (37.5%)	3 (37.5%)	12 (48.0%)	
IBD	0 (0.0%)	0 (0.0%)	1 (12.5%)	1 (4.0%)	
Melena	1 (11.1%)	0 (0.0)%	1 (12.5%)	2 (8.0%)	
Abdominal pain	0 (0.0%)	1 (12.5%)	0 (0.0%)	1 (4.0%)	
Anemia	1 (11.1%)	1 (12.5%)	1 (12.5%)	3 (12.0%)	

Table 4 – Adverse effects of bowel preparation regimens

	GoLYTELY®	MoviPrep®	Prepopik®	P-value
Unpleasant taste				≤ 0.01
Mean (SD)	2.2 (±0.97)	2.1 (±1.36)	0.6 (±0.74)	
Range	1-3	0-4	0-2	
Nausea				0.19
Mean (SD)	0.9 (±1.27)	0.5 (±1.07)	0 (0.0)	
Range	0-3	0-3	0	
Vomiting				0.43
Mean (SD)	0.1 (±0.33)	0 (0.0)	0 (0.0)	
Range	0-1	0	0	

Figures

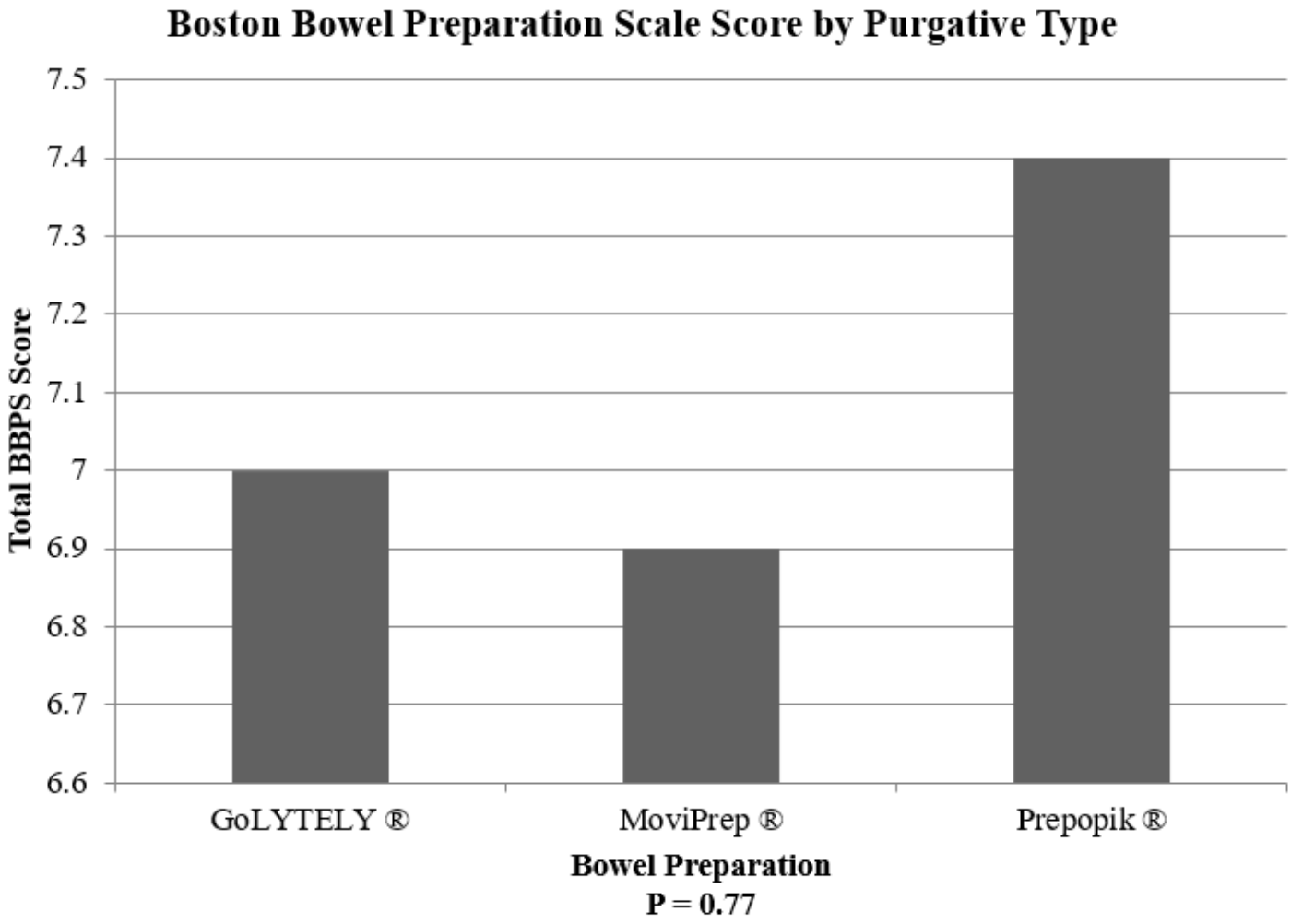

Figure 1

Relation between mean total Boston Bowel Preparation Scale Score (BBPS) and type of purgative

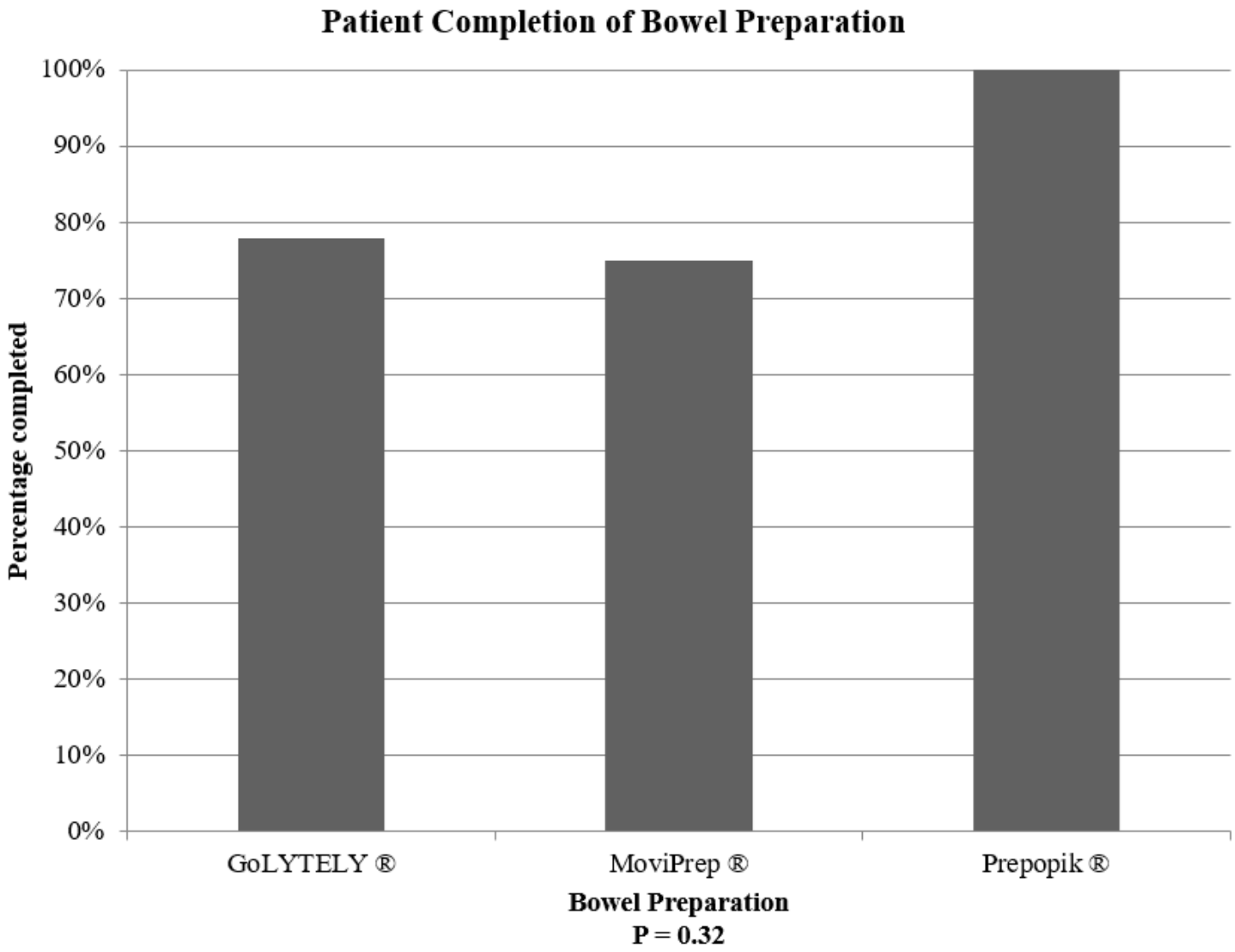

Figure 2

Tolerance and ability to completely finish colon preparation among different colon preparation solutions

Supplementary Files

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- CONSORT2010Checklist.BMC22020.doc