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Original Research Article

Efficacy of single-dose compared with split-dose low-volume polyethylene glycol for colonoscopy preparation: a randomized controlled trial

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ABSTRACT

Background: A successful colonoscopy requires adequate bowel preparation. Polyethylene glycol (PEG) is an appropriate bowel preparation agent for colonoscopy. The timing of ingestion of PEG solution is a major determinant of the quality of bowel preparation which has evolved from the previous day evening to the currently recommended split-dose regimen in the West. It was observed that consuming an entire or a portion of PEG on the previous day can interfere with routine activities, work and sleep. Objectives were to compare the efficacy of single-dose morning low-volume PEG with split-dose low-volume PEG as bowel cleansing preparation for colonoscopy in a tertiary care hospital.
Methods: Based on the bowel preparation agent they received-a single-dose (Group-A) or a split-dose (Group-B) of a 2 L PEG solution-128 participants were randomly assigned to one of two groups. All colonoscopy was performed between 10 AM and 12 PM without sedation. The Boston bowel preparation scale (BBPS) was used to evaluate the quality of bowel preparation.
Results: The single-dose group had a better quality of bowel preparation than the split-dose group with a total BBPS score of 7.09±1.18 versus 6.61±1.20 (p=0.023). Similarly, higher proportion of patients in single-dose group (87.5%) achieved adequate bowel preparation (BBPS score ≥6) when compared to those in split-dose group (78.1%) (p=0.160).
Conclusions: Single-dose morning low-volume PEG provided an improved bowel preparation than the split-dose regimen for morning colonoscopy in the Bangladeshi population.

Keywords: Colonoscopy preparation, Polyethylene glycol, Single-dose regimen, Split-dose regimen, Boston bowel preparation scale

INTRODUCTION

Colonoscopy has been the accepted diagnostic procedure for viewing the mucosa and vascular pattern of the whole colon.[1] The standard approach for evaluating colon disease and screening for colorectal cancer by detecting colonic polyps is a colonoscopy. The ability to see mucosa clearly is crucial for identifying lesions and may help in the early

diagnosis of colorectal cancer.[2] The quality of colonic cleaning has a major impact on the safety of therapeutic interventions during colonoscopy and the accuracy of diagnosis.[3] When the mucosal lining cannot be seen well or cecal intubation is not possible, the procedure is called an incomplete colonoscopy.[4] There is a rate of incomplete colonoscopies that varies from 4% to 25%. These reasons include poor bowel preparation, pain and intolerance, low body mass, female sex, young age, adhesions from prior surgeries, angulation or fixation of bowel loops, and insufficient experience on the part of the colonoscopist.[5] Inadequate bowel preparation is one of the leading causes of incomplete colonoscopies, accounting for roughly 25% of failed colonoscopies.[6] In approximately one-third of instances, inadequate bowel preparation results in a failure to detect lesions. Furthermore, poor bowel preparation causes patient discomfort, increased technical difficulty, failure of cecal intubation, and increased expenditures for the procedure, ranging from 12% to 22% due to prolonged procedure times and the need for repeated procedures or earlier surveillance.[7] An ideal preparation regimen should be small in volume, well accepted by patients, and cause minimum adverse gastrointestinal symptoms in addition to clearing the colon of all fecal material on time and without causing any gross or histologic alterations to the colonic mucosa.[8] All these expectations have not yet been fulfilled by the bowel preparation agents that are currently available on the market.[9,10] The most popular bowel cleansing agents include PEG; sodium phosphate (NaP); magnesium citrate (MgC); and sodium picosulfate, citric acid, and magnesium oxide (SPS)-containing preparations.[11,12] Since its introduction as a bowel cleansing agent in 1980, PEG has shown to be the optimal choice for guaranteeing adequate bowel preparation because of its safety, efficacy, and tolerability.[13] However, the underlying 'salty' taste and the requirement of significant volume consumption of 4 L PEG remains a concern for many patients, with 5% to 15% of patients not completing the preparation.[14] The large volume of 4 L PEG is not well tolerated and may cause nausea, cramping, and vomiting. The low-volume 2 L PEG is recommended in Asian countries without compromising the quality of bowel preparation as compared to conventional 4 L PEG due to the smaller body size and lower body weight. The effectiveness of bowel preparation is also impacted by the time of PEG administration. Split-dose bowel preparation produces a better-quality colonoscopy examination for a morning colonoscopy than ingesting the entire preparation on the day or evening before the procedure. The final dose of PEG should be administered within 5 hours of the start of the colonoscopy procedure, and the preparation should be completed at least 2 hours beforehand.[15] The 2 L PEG solution consumed the day before did not offer adequate colon preparation due to the prolonged interval between PEG administration and colonoscopy when the colon gets increasingly loaded with bile, fluid, or debris. Hence, it is given in a split-dosage regimen, with one dose taken the day before the colonoscopy and another the morning of the procedure. However, taking drugs at night might disturb sleep and interfere with daily routines. This prompted the consideration of a single-dose morning preparation as an alternative to a split-dose regimen.[16] Furthermore, studies examining the effectiveness of split-dose and single-dose preparations have concentrated on Western people, which may differ from Asian communities regarding food habits and colon transit times.[17] Research has demonstrated that single-dose preparation is equally beneficial as split-dose preparation in India, where the lifestyle and dietary habits are comparable to those of Bangladesh.[18] In the Bangladeshi population, it has not been precisely investigated which preparation of PEG is more effective-a single-dose morning or a split-dose.

Therefore, the study aimed to determine whether single-dose morning preparation is superior to split-dose preparation in our population. By investigating this contrast, we intended to address the issue of sleep interruption and work interference caused by taking medications at night while still ensuring proper bowel cleansing for colonoscopy procedures.

METHODS

Single-blind, randomized controlled trial. This study was conducted in the Department of Gastroenterology, Bangladesh Medical University, Dhaka, Bangladesh from July 2023 to June 2024. The total sample size was 128. Patients aged ≥18 years undergoing colonoscopy as a procedure for appropriate indications attending the inpatient and outpatient in the Department of Gastroenterology, BMU, Dhaka.

Inclusion criteria

Patients with age 18 years or above, patients undergoing colonoscopy as a procedure for appropriate indications attending the inpatient and outpatient departments of the Department of Gastroenterology at BMU were included in the study.

Exclusion criteria

Patients with suspected bowel perforation or obstruction, previous surgical bowel resection, severe renal impairment (creatinine clearance <30 mL/min) and on hemodialysis. Acute coronary syndrome, unstable angina. Severe congestive heart failure (New York heart association [NYHA] 3 or 4). Pregnant or lactating women, known allergies to PEG and major psychiatric illness were excluded.

Study procedure

Patients who underwent a colonoscopy procedure for appropriate indications and visited the inpatient and outpatient departments of the Department of Gastroenterology at BMU during the study period were initially recruited in the study after giving consent while adhering to the inclusion and exclusion criteria, following IRB approval. This study comprised 128 participants in

total. Eligible individuals were randomly allocated in a 1:1 manner by lottery into two bowel preparation groups: the single-dose (SD)/group-A or the split-dose (SPL)/ group-B, with 64 participants in each group. Participants and the colonoscopist were blinded to the group's allocation.

Data collection

Data was collected in a preformed questionnaire by taking history, examining the subjects clinically, and performing colonoscopy and laboratory investigations. The researcher himself collected the data.

Statistical analysis

Computer-based statistical analysis was carried out with appropriate techniques and systems. All data was recorded systematically in the preformed data collection form. Statistical analyses were performed using Windows-based computer software devised with SPSS-26. Numerical variables were expressed as mean and standard deviation. Categorical variables were expressed as percentages. Quantitative variables were compared using Student's 't' test. Qualitative variables were analyzed by Chi-square test/ Fisher's exact test. Multivariate logistic regression model assessed the risk factors predicting inadequate bowel preparation A $p<0.05$ was considered as statistically significant.

Ethical implications

The institutional review board (IRB) of BMU, Dhaka, registration no. -4674, authorized the research protocol before the study's initiation. The aims and objectives of the study, along with its procedure, risk, and benefits, were explained to the patients/guardians in an easily understandable local language, and then informed consent was taken from each patient or guardian (if the patient was incapacitated/incompetent). There was a guarantee that all the information and records would remain protected. Participants reserve the right to withdraw during any time of thesis work.

RESULTS

In this study, 134 patients were attended for eligibility. Six patients did not meet the criteria because of incomplete colonoscopy (n=2) and failure to finish colonoscopy due to obstructive bowel lesions (n=4). Finally, there were 64 patients in the single-dose group and 64 patients in the split-dose group.

Distribution of the baseline characteristics of the 128 study participants divided into two groups: single-dose/ experimental group (n=64) and split-dose/control group (n=64) bowel preparation regimens for colonoscopy. The mean age in the experimental group was 40.52±13.86 years, while in the control group it was 39.56±13.55 years, showing no statistically significant difference (p=0.695). The majority of participants were male, though the difference between groups was not significant (p=0.147). Regarding BMI, most participants in both groups fell within the normal weight category (84.4% in the experimental group and 76.6% in the control group). The prevalence of underweight participants was slightly higher in the control group (9.4%) compared to the experimental group (6.3%), while overweight individuals were more common in the control group (14.1% vs. 9.4% in the experimental group), but these differences were not statistically significant. The mean BMI was 21.59±2.08 in the experimental group and 21.99±2.60 in the control group (p=0.346), indicating no significant difference in BMI between the groups. Marital status, level of education and occupation also showed no significant differences between the two groups. Smoking status was higher in the control group (18.8%) compared to the experimental group (10.9%), but the difference was not statistically significant (p=0.301).

The most common indications in both groups were per rectal bleeding (32.8%) and chronic diarrhea, with similar proportions in both groups (p=1.000). Overall, there were no statistically significant differences in colonoscopy indications between the experimental/single-dose group and control/split-dose groups. Regarding comorbidities, hypertension (HTN) was more common in the control group (17.2%) compared to the experimental group (9.4%), though the difference was not statistically significant (p=0.193). Chronic kidney disease (CKD) was reported in 4.7% of the control group and 1.6% of the experimental group (p=0.310), while prior history of myocardial infarction (MI) was noted in 3.1% of control participants and none in the experimental group (p=0.154). Diabetes mellitus (DM) and hypothyroidism were identical between the groups. The comorbidities of the experimental and control groups were not significantly different overall.

The right and transverse colon BBPS score show no significant difference between the two groups. However, a statistically significant difference was observed in the left colon, where the experimental/single-dose group had a higher score of 2.73±0.45 compared to 2.53±0.53 in the control/split-dose group (p=0.021). The total BBPS score was also significantly higher in the experimental group (7.09±1.18) compared to the control group (6.61±1.20) (p=0.023), indicating overall better bowel preparation with the single-dose morning low-volume regimen.

Figure 1 shows the bowel preparation quality among study participants receiving single-dose versus split-dose low-volume polyethylene glycol. In the single-dose/experimental group, 12.5% had inadequate bowel preparation, compared to 21.9% in the split-dose/control group, though this difference was not statistically significant (p=0.160). Conversely, 87.5% of participants in the experimental group achieved adequate bowel preparation, while 78.1% of those in the control group had adequate results.

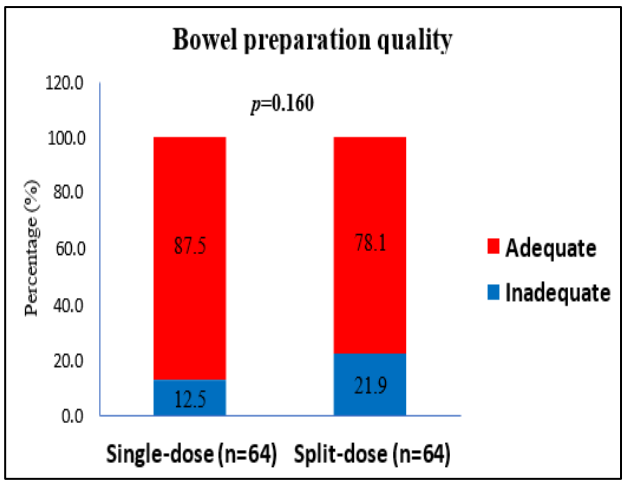

Figure 1: Bowel preparation quality between the two groups.

The results show that for nausea, 81.3% of participants in the single-dose/experimental group and 75.0% in the split-dose/control group had no symptoms, with no significant difference between the groups (p=0.392). Mild nausea was reported by 18.8% in the experimental group and 25.0% in the control group, with no reports of moderate, severe, or very severe symptoms. Mild vomiting occurred in 6.3% and 7.8% of participants in the experimental and control groups, respectively (p=0.730). Regarding bloating, 90.6% of participants in both groups experienced no symptoms, and 9.4% reported mild bloating (p=1.000). For abdominal pain, 1.6% of the experimental group and 3.1% of the control group had mild symptoms, with no significant difference (p=0.559). Moreover, 3.1% of the control group and 1.6% of the experimental group had mild dizziness (p=0.559). Anal irritation, headache, or other significant adverse symptoms were not reported, with all participants being asymptomatic for those variables.

Figure 2 shows the diagnosis of study participants receiving either single-dose or split- dose polyethylene glycol bowel preparation. In the single-dose/experimental group, 35.9% were diagnosed with normal findings, compared to 40.6% in the split-dose/control group. The incidence of colonic polyps was slightly higher in the experimental group (10.9%) compared to the control group (7.8%), though the difference is not statistically significant. Colorectal cancer was identified in 1.6% of the experimental group and 3.1% of the control group. Ulcerative colitis was diagnosed in 7.8% of the experimental group versus 12.5% in the control group, while Crohn's disease was present in 4.7% of both groups. Diverticular disease and hemorrhoids were seen in 1.6% and 25.0% of the experimental group, respectively, versus 1.6% and 15.6% in the control group. Intestinal tuberculosis was diagnosed in 6.3% of the experimental group and 9.4% of the control group. Other diagnosis was reported in 6.3% of the experimental group and 4.7% of the control group. Overall, the distribution of diagnosis shows no significant difference between the two bowel preparation regimens (p=0.901).

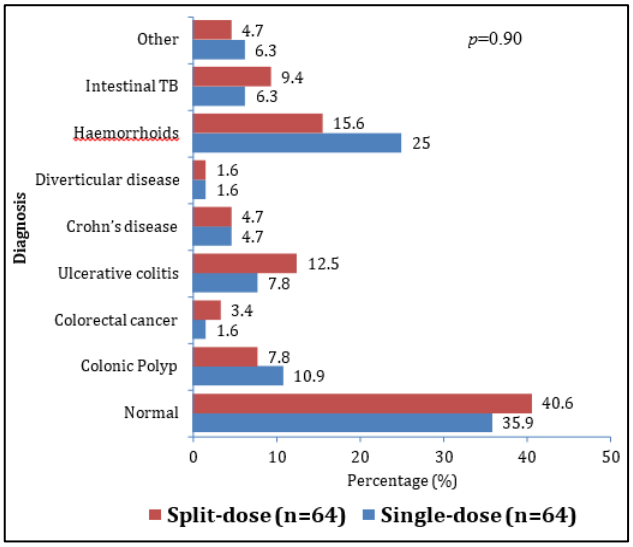

Figure 2: Diagnosis of study participants receiving single-dose vs. split-dose PEG.

In the multivariate logistic regression analysis for predicting inadequate bowel preparation, the variable "overweight" emerged as a significant predictor, with an odds ratio (OR) of 14.798 and a p=0.036, indicating a substantial increased risk. Chronic constipation also showed a trend towards significance with an OR of 1.189 and a p=0.030. Other variables, including age (>50 years), sex (male), DM, and HTN did not demonstrate statistical significance, as their p values exceeded 0.05.

Table 1: Baseline characteristics of the study participants in two groups, (n=128).

Variables	Experimental group, (n=64)		Control group, (n=64)		P value
	N	%	N	%	
Age group (in years)					
≤30	20	31.3	22	34.4	0.695
31-50	27	42.2	29	45.3	
>50	17	26.6	13	20.3	
Mean±SD	40.52±13.86		39.56±13.55		
Sex					
Male	35	54.7	43	67.2	0.147
Female	29	45.3	21	32.8	

Continued.

Variables	Experimental group, (n=64)		Control group, (n=64)		P value
	N	%	N	%	
Marital status					
Married	55	85.9	52	81.3	0.474
Unmarried	9	14.1	12	18.8	
BMI (kg/m^2)					
Underweight (<18.5)	4	6.3	6	9.4	0.346
Normal weight (18.5-24.9)	54	84.4	49	76.6	
Overweight (25.0-29.9)	6	9.4	9	14.1	
Mean±SD	21.59±2.08		21.99±2.60		
Level of education					
Illiterate	9	14.1	5	7.8	0.633
Primary	17	26.6	24	37.5	
SSC	11	17.2	10	15.6	
HSC	12	18.8	10	15.6	
Graduate	15	23.4	15	23.4	
Occupation					
Housewife	25	39.1	19	29.7	0.797
Student	6	9.4	7	10.9	
Govt. officer	4	6.3	4	6.3	
Teacher	1	1.6	3	4.7	
Businessman	5	7.8	2	3.1	
Worker	7	10.9	7	10.9	
Cultivator	5	7.8	5	7.8	
Service	9	14.1	12	18.8	
Other	1	1.6	1	1.6	
Unemployed	1	1.6	4	6.3	
Smoking status					
Smoker	7	10.9	12	18.8	0.301
Non-smoker	54	84.4	51	79.7	
Ex-smoker	3	4.7	1	1.6	

Table 2: Indications of colonoscopy and comorbidities between the study groups, (n=128).

Variables	Experimental group, (n=64)		Control group, (n=64)		P value
	N	%	N	%	
Indications of colonoscopy					
Colorectal cancer screening	1	1.6	0	0.0	0.315
Surveillance	1	1.6	1	1.6	1.000
Per rectal bleeding	21	32.8	21	32.8	1.000
Chronic diarrhea	16	25.0	15	23.4	0.837
Altered bowel habit	9	14.1	11	17.2	0.309
Anemia	8	12.5	9	14.1	0.795
Chronic constipation	8	12.5	7	10.9	0.783
Comorbidities					
DM	10	15.6	9	14.1	0.804
HTN	6	9.4	11	17.2	0.193
CKD	1	1.6	3	4.7	0.310
Prior history of MI	0	0.0	2	3.1	0.154
Hypothyroidism	1	1.6	1	1.6	1.000

Table 3: BBPS scores of the two study groups, (n=128).

Variables	Experimental group, (n=64)	Control group, (n=64)	P value
Right colon	2.05±0.52	1.91±0.53	0.130
Transverse colon	2.31±0.53	2.17±0.49	0.122
Left colon	2.73±0.45	2.53±0.53	0.021
Total score	7.09±1.18	6.61±1.20	0.023

Table 4: Tolerability of bowel preparation between the two groups, (n=128).

Variables	Experimental group, (n=64)		Control group, (n=64)		P value
	N	%	N	%	
Nausea					
Well-tolerated	52	81.3	48	75.0	0.392
Not well-tolerated	12	18.8	16	25.0	
Vomiting					
Well-tolerated	60	93.8	59	92.2	0.730
Not well-tolerated	4	6.3	5	7.8	
Bloating					
Well-tolerated	58	90.6	58	90.6	1.000
Not well-tolerated	6	9.4	6	9.4	
Abdominal pain					
Well-tolerated	63	98.4	62	96.9	0.559
Not well-tolerated	1	1.6	2	3.1	
Anal irritation					
Well-tolerated	64	100.0	64	100.0	-
Not well-tolerated	0	0.0	0	0.0	
Dizziness					
Well-tolerated	63	98.4	62	96.9	0.559
Not well-tolerated	1	1.6	2	3.1	
Headache					
Well-tolerated	64	100	64	100.0	-
Not well-tolerated	0	0.0	0	0.0	

Table 5: Multivariate logistic regression to predict the risk factors of inadequate bowel preparation, (n=128).

Variables	OR	95%CI	P value
Age (>50 years)	0.213	0.038-1.202	0.080
Sex (male)	1.520	0.407-5.676	0.534
Chronic constipation	1.189	0.142-2.852	0.030
Overweight (BMI=25-29.9)	14.798	1.194-183.433	0.036
DM	3.244	0.445-23.645	0.246
HTN	0.142	0.016-1.229	0.076

DISCUSSION

An accurate and successful colonoscopy depends on several factors, such as the type and dosage of the bowel cleansing agent, the use of adjunctive medications when they are administered, adherence to the diet, and providing patients with the necessary procedural information. A number of national and international societies have approved the use of PEG-based regimens in split doses, meaning that some of the medication is given the day before the colonoscopy and the remaining portion is given that day.[19] The full intestinal cleansing procedure is typically administered in the evening before a morning colonoscopy. Furthermore, it must be administered early in the evening to prevent sleep disturbance. This leads to poor bowel cleansing, which is reported to be about 70% adequate cleaning rate.[20] This rate was considerably lower at 50% when bowel preparation was done with low-volume 2 L PEG.[21] We found the most common indications in both groups were per rectal (P/R) bleeding (32.8%) and chronic diarrhea, with identical proportions in both groups. Other common indications included altered bowel habits and chronic constipation, which were also similar between the two groups. Overall, there were no statistically significant differences in colonoscopy indications between the single-dose and split-dose groups. This is consistent with previous studies.[18,21-23] BBPS scores of study participants of two groups receiving single-dose versus split-dose polyethylene glycol for bowel preparation showed the right colon scored an average of 2.05±0.52 in the single-dose group and 1.91±0.53 in the split-dose group, with no significant difference between the two groups (p=0.130). Similarly, the transverse colon had scores of 2.31±0.53 in the single-dose group and 2.17±0.49 in the split-dose group (p=0.122). However, a statistically significant difference was observed in the left colon, where the single-dose group had a higher score of 2.73±0.45 compared to 2.53±0.53 in the split-dose group (p=0.021). The total BBPS score was also significantly higher in the single-dose group (7.09±1.18) compared to the split-dose group (6.61±1.20) (p=0.023), indicating overall better bowel preparation with the single-dose regimen as observed by other studies.[18] This study concluded as SD morning PEG regimen as an effective

bowel preparation for colonoscopy. In the single-dose group, 87.5% of participants achieved adequate bowel preparation, while 78.1% of those in the split-dose group. Tolerability of bowel preparation by symptom severity for study participants receiving single-dose vs. split-dose polyethylene glycol showed, 81.3% of participants in the single-dose group and 75.0% in the split-dose group had no nausea, with no significant difference between the groups. Mild nausea was reported by 18.8% in the single-dose group and 25.0% in the split-dose group, with no reports of moderate, severe, or very severe symptoms. For vomiting, the majority in both groups reported no vomiting (93.8% in the single-dose group vs. 92.2% in the split-dose group). Mild vomiting occurred in 6.3% and 7.8% of participants in the single-dose and split-dose groups, respectively. Regarding bloating, 90.6% of participants in both groups experienced no symptoms. No moderate, severe, or very severe cases of bloating were noted. For abdominal pain, 98.4% of the single-dose group and 96.9% of the split-dose group had no symptoms, with no significant difference. Mild abdominal pain was reported in 1.6% and 3.1% of the participants, respectively. Moreover, 3.1% of the SPL group and 1.6% of the SD group had mild dizziness. Anal irritation, headache, or other significant adverse symptoms were not reported, with all participants being asymptomatic for those variables. We found all are statistically insignificant. A study from India concluded that, same-day morning PEG regimen can be considered a well-tolerated, and acceptable bowel preparation for colonoscopy.[18] Another study from China concluded, for morning colonoscopy, split-dose 2 L PEG is superior to single-dose 2 L PEG by better tolerability, and patient satisfaction.[21] The distribution of diagnosis between the two groups shows no significant difference overall. In the single-dose group, 35.9% were diagnosed with normal findings, compared to 40.6% in the split-dose group. The incidence of colonic polyps was slightly higher in the single-dose group (10.9%) compared to the split-dose group (7.8%), though the difference is not statistically significant. Overall, distribution of diagnosis is similar between the two bowel preparation regimens as other studies.[18,21] BMI≥25 kg/m^2 was an independent risk factor for bowel preparation failure in patients undergoing colonoscopy. Similarly to the results of this study, Borg et al showed that patients with a BMI >25 kg/m^2 had a greater risk of bowel preparation failure.[24] Constipation was found to be an independent risk factor for the failure of bowel preparation before colonoscopy. This is consistent with the findings.[25] In the multivariate logistic regression analysis of risk factors for inadequate bowel preparation, none of the variables such as age, sex, DM, HTN and split-dose-were found to be statistically significant predictors.

Limitations

The study was single-centered. The outcome of the study cannot be applicable to certain populations because of the exclusion of patients who had undergone bowel resection and the assessment of bowel preparation adequacy only for patients undergoing late morning colonoscopy.

CONCLUSION

In conclusion, single-dose administration of low-volume polyethylene glycol was more effective than the split-dose regimen in terms of appropriate bowel preparation in patients undergoing late morning colonoscopy. So, single-dose morning low-volume polyethylene glycol should be the regimen of choice for bowel cleansing in the Bangladeshi population.

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