Original Article

Split dose bowel preparation before colonoscopy of PEG (Nulytely) in comparison to routine single dose bowel preparation

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Abstract

Background: The aim of this study was to compare the efficacy and tolerability of polyethylene glycol (PEG) in single- or split-dose regimens for colonoscopy bowel preparation.

Methods: This is a prospective, randomized, endoscopist blinded, single-center study, that included adult patients who underwent colonoscopy during the period from December 2017 to October 2018. Two groups were enrolled in the same period: One group used 4 L of PEG (Nulytely) in a single-dose preparation, administered a day before the procedure, and the other group received a split-dose regimen of 2 L PEG (Nulytely), given a day before the procedure and 2 L on the day of the procedure in the early morning. The Boston Bowel Preparation Scale (BBPS) was used for bowel preparation adequacy; scales 0 and 1 were considered inadequate, and scales 2 and 3 were considered adequate preparation.

Results: Two hundred and forty patients were enrolled, 120 (50%) using the split-dose regimen and 120 (50%) using the single-dose regimen, for bowel preparation. Males constituted 51.6% of the study cohort. In the single-dose group, 62.5% achieved adequate bowel preparation compared to 89.2% in the split-dose group ($p < 0.001$). In addition, polyp detection in the split-dose group was 23.3% in comparison to 10.8% in the single-dose group ($P = 0.016$). We also found hypertension and diabetes as significant predictors of bowel preparation inadequacy, while sex and age were not related to bowel preparation adequacy.

Conclusions: Split-dose bowel preparation for colonoscopy with PEG (Nulytely) is better than routine single-dose, in terms of adequate bowel preparation and polyp detection.

Keywords: Bowel-preparation, colonoscopy, diabetes, polyethylene-glycol (PEG), polyps

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INTRODUCTION

Colonoscopy is the current standard method for evaluation of colonic disorders such as colorectal cancer, IBD, polyps, and other conditions.[1] Diagnostic accuracy and the therapeutic safety of colonoscopy depend on the quality of the colonic cleaning or preparation. The ideal preparation for colonoscopy reliably empties the colon of all fecal material in a rapid fashion, with no gross or histologic

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alteration. The preparation should not discomfort or shifts in fluids in patients or electrolytes and should be inexpensive. Unfortunately, none of the preparations currently available meet all these requirements. Different modalities are used for bowel preparation, but the most common is polyethylene glycol (PEG) solution because it is safer and does not cause major electrolyte abnormalities. A major disadvantage is the large volume required to be taken over a short time,which may result in patient intolerance and poor compliance, leading to poor preparation. From 2005 till 2010 an audit conducted at the Royal Liverpool University revealed that out of 8910 colonoscopies, 693 were incomplete (7.8%), and for 25% of failure was because of inadequate bowel preparation.[2]

Recent trials have explored new approaches in administering PEG solution to improve patient tolerability. A large meta-analysis comparing split-dose preparation in the usual day-before procedure was published in 2015; in all, 47 trials fulfilled the criteria between January 1980 and March 2014. Results demonstrated that split-dose preparations provided significantly better colon cleansing than day-before as well as on-?? day preparations, with PEG and sodium phosphate. PEG split-dose preparations of 3 L or more yielded greater bowel cleanliness than low-volume split-dose preparations. A higher proportion of patients were willing to repeat split-dose versus day-before cleansing.[3,4]A head-to-head comparison of 4L polyethylene glycols and low-volume solutions before colonoscopy was conducted to determine which one had the best results. Comparing polyethylene glycol (PEG), sodium magnesium citrate (SPMC), and low-volume polyethylene glycol/ascorbic acid (PEGA) in a single- or split-dose revealed, that the split-dose preparation was more effective in all agents.[5,6]A large survey was also done in the USA in 2018 and demonstrated that split-dose treatment was more tolerable than single-dose treatment for bowel preparation.[7]

Colonic cancers are a major concern in the Middle East and the world in general, and every institute has attempted to initiate various clinical and investigatory procedures to detect the disease early in its development.[8,9] Hence, we conducted a randomized control study to assess the preparation of split-dose versus single-dose treatment used in bowel preparation, to determine the best procedure for patients in the region.

METHODS

This was a randomized, controlled clinical trial of bowel preparation, for split-dose versus single-dose treatment. The study included adult patients who underwent colonoscopy at the Gastroenterology Department, Royal Hospital, Muscat. It was conducted from January to December 2018. Exclusion criteria included age >90 years, prior colonic or rectal surgery, severe heart failure, end-stage renal disease,and pregnancy.

Ethical approval for this research study was obtained from the research committee at the Royal Hospital. The details of the research study and its purpose were written and explained in the consent form. Informed consent was obtained from all participants who were involved in this study. Additionally, there was a brief explanation about the purpose and aim of the study. The participants were informed that the outcome of this study would be published, but their identities would be kept confidential and anonymous. They were also informed that there would be no risk for them in refusing to participate in the study, that there might be no direct benefits and that withdrawal from the study was permitted at any time.

None of the clinicians were involved in the enrollment process. The enrollment of participants was performed by a senior research nurse study coordinator. A computer was used to generate a randomization table with blocks of eight. Allocation concealment was maintained with consecutively numbered sealed envelopes. The clinicians and investigators were blinded to the allocation groups. The study assistant assigned patients to their group and instructed them on the proper use of their assigned bowel preparation method, and the patients were assigned to two groups in the same period, in a 1:1 manner.

Upon enrollment, participants were referred to a dietician for dietary advice. Participants were taught to begin a low residue diet 4 days preceding the colonoscopy. The general preparation for both groups was the same,which included taking a soft diet that lasted 2 days and drinking only clear fluids the day before the procedure. One group used 4 L of PEG (Nulytely) single-dose preparation given a day before the procedure, to be started at 4:00 pm and finished before midnight. The other group used split-dose regimens of 2 L PEG (Nulytely) given a day before the procedure at 6:00 pm, and 2 L on the day of the at 5:00 am. The solution had to be finished at least 4 hours before the scheduled procedure.

We used the Boston Bowel Preparation Scale (BBPS) for bowel preparation adequacy; scales 0 and 1 were considered inadequate, and scales 2 and 3 were considered adequate preparation.[10]

The primary outcome was the quality of bowel preparation. Secondary outcomes included polyp detection, tolerability,

and the impact of additional factors (age, sex, hypertension, and diabetes).

We conducted a pilot study to determine the sample size; hence, it was calculated based on an observed effect size of 1.0 and a two-tailed α of 0.05 and 80% power. The two-group ANOVA test suggested approximately 200 as a sample size. A 20% additional sample was added for withdrawals and incomplete colonoscopies. Hence, we required approximately 240 participants to be enrolled in our study. All relevant information about patients was collected and entered into Epi-data entry software and then transferred to SPSS software for analysis. Data were presented as numbers and percentages. Student's *t* test was used for continuous variables, and the Chi-square test was used for dichotomous variables.

RESULTS

During the study period, 240 patients were recruited, 120 (50%) patients in the split-dose group and 120 (50%) patients in the single-dose group, for bowel preparation before colonoscopy. Males constituted 51.6% of the studied sample and females 48.4%. There was no significant difference in the baseline characteristics between the two groups, as shown in Table 1.

Primary outcome

In the single-dose group, 62.5% achieved adequate bowel preparation compared to 89.2% in the split-dose group ($p < 0.001$), as shown in Figure 1 and Table 2. Further multivariable analyses also showed that the split dose was an independent factor for adequate bowel preparation (OR = 5.397, 95% CI= 2.657-10.961, $P = 0.0001$), as shown in Table 3.

Secondary outcomes

Polyp detection in the split-dose group was 23.3% in comparison to 10.8% in the single-dose group, with a significant difference ($P = 0.016$).

Among hypertensive patients, 66.2% achieved adequate bowel preparation in comparison to 79.4% who were non-hypertensive ($P = 0.042$). In patients with diabetes, 62.5% achieved adequate bowel preparation in comparison to 79.9% who were nondiabetic ($P = 0.012$), as shown in Table 2.

Univariable analysis showed that there was no significant difference in bowel preparation in terms of gender, as 74.2% of men and 77.6% of women achieved adequate bowel preparation($P = 0.55$). No significant difference in terms of age was detected, as 78.9% of patients aged <50 years achieved adequate preparation in comparison to 72.6% patients aged ≥50 years ($P = 0.293$), as shown in Table 2. Further multivariable analysis did not show diabetic and hypertensive as independent factors for inadequate bowel preparation [Table 3].

Table 1: Shows the baseline characteristics of the participants

	Single-dose (*n*=120)	Split-dose (*n*=120)
Male gender	65 (54.2)	59 (49.2)
Age	48.14±14.60	48.41±16.10
Comorbidities		
Diabetes	28 (23.3)	28 (23.3)
Hypertension	30 (25.0)	35 (29.2)
Indication		
History of polyps	4.0 (3.3)	13.0 (10.8)
Screening (no personal history of polyps or cancer)	17.0 (14.2)	16.0 (13.3)
Change in bowel habits	43.0 (35.8)	43.0 (35.8)
Inflammatory Bowel Disease	23.0 (19.2)	18.0 (15.0)
Rectal bleeding	19.0 (15.8)	20.0 (16.7)
Cancer surveillance	4.0 (3.3)	5.0 (4.2)
Anemia	9.0 (7.5)	8.0 (6.7)
Others	16.0 (13.3)	22.0 (18.3)

Data represented as *n* (%), and mean±SD as appropriate

The most common reasons for colonoscopy included changes in bowel habits, inflammatory bowel diseases, history of polyps, rectal bleeding, screening, and radiological findings of colon thickening, as shown in Table 1. We found no relation between adequate bowel preparation and the reason for doing colonoscopy, as shown in Table 4.

DISCUSSION

This is the first randomized controlled study from the region (which has a high burden of diabetes and hypertension) to assess the bowel preparation of split-dose

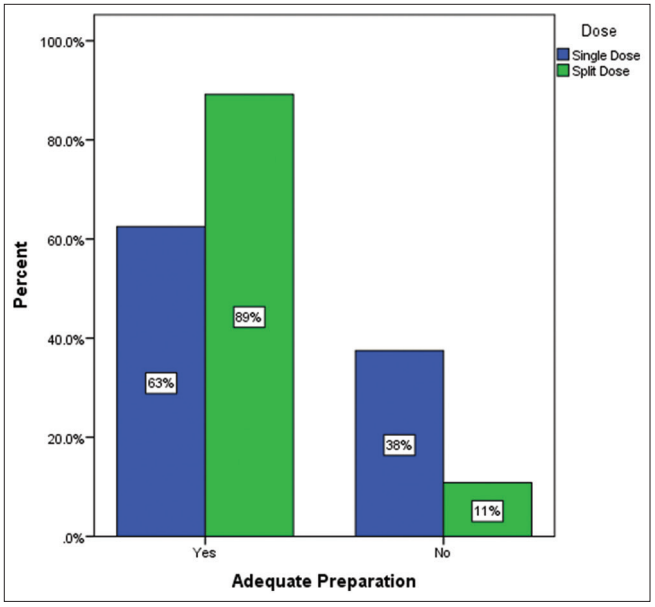

Figure 1: The primary outcomes of adequate bowel preparation

Table 2: Predictors for adequate bowel preparation*

Variable	Adequate Bowel Preparation		*P*
	Yes *n* (%)	No *n* (%)	
Sex			
Male	92 (74.2)	32 (25.8)	0.550
Female	90 (77.6)	26 (22.4)	
Age			
<50 years	97 (78.9)	26 (21.1)	0.293
≥50 years	85 (72.6)	32 (27.4)	
HTN			
Present	43 (66.2)	22 (33.8)	0.042
Absent	139 (79.4)	36 (20.6)	
DM			
Present	35 (62.5)	21 (37.5)	0.012
Absent	147 (79.9)	37 (20.1)	
Dose			
Single Dose	75 (62.5)	45 (37.5)	0.0001
Split Dose	107 (89.2)	13 (10.8)	

*Univariable Analysis

versus single-dose treatments. The studied population was young and displayed almost equal gender distribution. Results showed that the split-dose group had better adequate bowel preparation compared to the single-dose group (OR = 5.397, 95% CI = 2.657-10.961, $P = 0.0001$), and almost two-thirds of diabetic and hypertension patients had adequate bowel preparation. Furthermore, split-dose treatment was better at detecting polys.

The consensus of the American Society for Gastrointestinal Endoscopy (ASGE) and the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) is that PEG represents the gold standard for colonoscopic bowel preparation, and sodium phosphate may serve as an alternative to PEG solutions.[11] Multiple studies have assessed the effect of various types of bowel preparation and their procedures. PEG, SPMC, and low-volume PEGA in a split-dose regimen are more effective than in single-dose ones, as demonstrated in a large meta-analysis published in 2015.[5] Other studies have compared sodium picosulphate/magnesium citrate (PMC) and PEG and yielded similar results in bowel preparation efficacy, regardless of whether they were administered in single or separate doses.[4,12]

Table 3: A multivariate binary logistic regression analysis to determine the independent predictors of an adequate bowel preparation for colonoscopy

Variable	*P*	Odds ratio (OR)	95% CI for OR	
			Lower	Upper
Sex				
Male (Reference)	0.616	1.178		
Female				
Age				
< 50 years (Reference)	0.799	0.908	0.433	1.905
≥50 years				
DM				
Absent (Reference)	0.137	0.503	0.204	1.243
Present				
HTN				
Absent (Reference)	0.396	0.666	0.260	1.703
Present				
Dose				
Single Dose (Reference)	0.0001*	5.397	2.657	10.961
Split Dose				

The variable 'Dose' was the only significant predictor of an adequate bowel preparation for colonoscopy. The split dose is five times more likely to provide an adequate bowel preparation for colonoscopy compared to the single dose (OR=5.397, 95% CI=2.657-10.961, P=0.0001)

Furthermore, one study done on an Asian population comparing single- versus split-dose bowel preparation in India, published in 2014, included 200 patients and demonstrated that a split-dose bowel preparation regimen resulted in better bowel cleansing for colonoscopy compared to single-dose treatment.[13]

This study also revealed a significant difference in outcomes in polyp detection in split-dose bowel preparation compared to single-dose treatment, the day prior to colonoscopy. This was also shown in a large meta-analysis done in 2019 for adenoma detection in split-dose treatment, which revealed that compared with day-before bowel preparation regimens, split-dose bowel preparations regimens increased the detection of adenomas and advanced adenomas and had the greatest benefit in SSP detection.[14]

Adequate bowel preparation is a necessary condition for a successful colonoscopy. The ability to visualize the entire mucosal surface not only improves the rates of cecal intubation and polyp detection but also shortens the procedure time, thus optimizing procedural efficiency. Therefore, it is important to identify the predictors for inadequate bowel preparation.[15] Predictors of inadequate bowel preparations include male gender, inpatient status, diabetes mellitus, hypertension, cirrhosis, narcotic use, constipation, stroke, and low socioeconomic status.[16–26]

Our study demonstrated that 62.5% of diabetic patients achieved adequate bowel preparation in comparison to 79.9% who were nondiabetic. This was similar to other studies done worldwide. Taylor and Schubert used a standard polyethylene glycol (PEG) bowel preparation and showed that the optimal bowel cleaning rate was 97% in nondiabetic patients compared to 62% in diabetic patients.[27] HTN also showed significant results in terms of predictors; this was also suggested in different studies showing that comorbidity led to poor preparation.

This study showed no difference in bowel preparation in terms of age and gender. Many studies have revealed that being elderly[19] and male were associated with poor preparation, including for populations from the Middle East and Asia.[15] However, studies are conducted on either

Table 4: Subgroup analysis for screening colonoscopy indication

Reasons for colonoscopy	Single Dose (*n*=120)			Split Dose (*n*=120)		
	Adequate Bowel Preparation		*P*	Adequate Bowel Preparation		*P*
	Yes *n* (%)	No *n* (%)		Yes *n* (%)	No *n* (%)	
History of polyps	1 (25.0)	3 (75.0)	0.148	11 (84.6)	2 (15.4)	0.632
Screening (no personal history of polyps or cancer)	12 (70.6)	5 (29.4)	0.592	15 (93.8)	1 (6.3)	1.000
Change in bowel habits	26 (60.5)	17 (39.5)	0.844	34 (79.1)	9 (20.9)	0.013
Inflammatory bowel disease	19 (82.6)	4 (17.4)	0.032	17 (94.4)	1 (5.6)	0.689
Rectal bleeding	10 (52.6)	9 (47.4)	0.439	18 (90.0)	2 (10.0)	1.000
Cancer surveillance (follow-up evaluation)	2 (50.0)	2 (50.0)	0.630	5 (100)	0 (0)	1.000
Anemia	4 (44.4)	5 (55.6)	0.293	8 (100)	0 (0)	0.597
Others	10 (62.5)	6 (37.5)	1.000	19 (86.4)	3 (13.6)	0.704

inpatient or outpatient bases, and it is well known that inpatient bowel preparation is associated with poor bowel preparation compared to outpatient appointments.

As previously demonstrated, this study confirms two critical elements. First, cleaning efficacy is driven by time, and thus a short time interval before the beginning of colonoscopy would be ideal. In other words, the second dose of laxative should be considered as the critical factor for optimal bowel preparation, irrespective of the timing of the first dose, which consequently can be taken the evening before the examination or the same morning, depending on the subject's need and endoscopy service organization; secondly, more efforts should be made to optimize the patients' compliance, which should be regarded as a surrogate marker of quality in endoscopy.[15]

The strength of the study includes the fact that a relatively high number of patients were in both groups, and the initial characteristics of both groups were similar. Populations in Gulf countries have multiple comorbidities(e.g., diabetes and HTN), which allows us to better study the predictors for bowel preparation. The endoscopists in both groups were the same.

The limitations of this study included the fact that it was a single-center study. However, considering that this center is the biggest in the country and that most centers refer to this institute, it represents a large and varied population. We also encountered some patients for whom split-dose treatment was inconvenient as they lived far away from the hospital and bowel opening could interrupt their travel, so most of them had to stay overnight near the hospital, for the sake of convenience. Patients in general, when questioned by the nursing staff regarding tolerability and preferred choice, preferred the split-dose treatment, but no assessment tool was used to determine this. We did not use a specific questionnaire to assess patient tolerability and compliance with both regimens, as the study was done as outpatient basis and the endoscopy department had a busy schedule. Further studies are required in this field to compare different regimens in our population and to investigate the predictors of adequate bowel preparation, to avoid incomplete colonoscopies.

CONCLUSIONS

Split-dose bowel preparation for colonoscopy with PEG (Nulytely) is better than routine single-dose treatment in terms of adequate bowel preparation and polyp detection.

Disclosure of potential conflicts of interest

The study was approved by the Scientific Research Committee at the Royal Hospital, Muscat, Oman, which certified that the study was performed in accordance with the ethical standards in the 1964 Declaration of Helsinki and its later amendments.

Author contribution statement

All authors have contributed equally.

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Conflicts of interest

There are no conflicts of interest.

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