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Comparison between Split Dose and Single Dose Bowel Laxatives for Preparation of Colonoscopy in Patients with Bangladeshi Diets: A Randomized Clinical Trial

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Abstract

Introduction: ***Colonoscopy is an important diagnostic tool for colonic disease and its efficacy and safety have been correlated with adequate bowel preparation. This study compared the efficacy and tolerability of single-dose and split-dose sodium picosulfate lavage as a colon cleansing agent for colonoscopy preparation.***

Methods: ***This randomized clinical trial was conducted at the Department of Gastroenterology in Sylhet MAG Osmani Medical College Hospital, Sylhet, Bangladesh from June 2021 to May 2022.A total of 110 patients were selected by randomized sampling technique who underwent elective colonoscopy and were divided into split-dose (n=57) and single-dose (n=53) laxative groups. Bowel preparation was assessed by the Ottawa Bowel Preparation Scale (OBPS) and data were analyzed by SPSS 24.0.***

Result: ***The mean age of the patients was 47.4±17.7(SD) years in split-dose and 47.6±15.9 (SD) years in single-dose group. Both groups were statistically similar in terms of socio-demographic profile, medical history, clinical manifestation, and indication of colonoscopy (p>0.05). The mean of total OBPS score (4.39±2.0 vs 5.56±2.2, p=0.004) and caecal intubation time (6.60±3 vs 7.74±2.5, p=0.035) was lower significantly in split-dose than the single-dose group. However, colonoscopy findings, adverse events, and patient compliance were similar between groups (p>0.05).***

Conclusion: ***Split-dose is superior to single-dose bowel laxatives for colonoscopy preparation in terms of better mucosal cleanliness and lower caecal intubation time. However, further randomized controlled trial is recommended.***

Keywords: ***Colonoscopy, Laxative, Bowel preparation, Split-dose, Single-dose***

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Introduction

Colonoscopy is the most utilized and cost-effective tool for screening a variety of diseases, including colorectal cancer. Its accuracy and sensitivity are highly dependent on the quality of bowel preparation [1-3]. Adequate bowel preparation effectively removes all fecal material from the gut before colonoscopy [4, 5]. Even a small amount of residual stool in the colon can obscure visualization of the target tissue, potentially leading to missed small lesions such as angiodysplasia [6]. Poor bowel preparation has also been identified as a factor associated with incomplete colonoscopy [7]. The ideal laxative should be well tolerated, easily administered, inexpensive, and produce adequate clearance without allowing the formation of explosive gases [8]. Bowel laxatives, such as sodium picosulfate, polyethylene glycol, lactulose, sorbitol, and magnesium citrate, produce an osmotic or purgative effect in the colon, resulting in distention and promoting peristalsis. However, the need to ingest a large volume of fluid can reduce patient compliance and result in suboptimal preparation [9]. Considering the smaller body size and lower BMI of individuals in Asian countries, a low-volume (2L) laxative is sufficiently effective for preparing the bowel before evening colonoscopy [10, 11]. However, laxative intake the day before the procedure

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may interfere with sleep and cause delayed bowel content appearance during the procedure. For morning colonoscopy, a single dose may be inadequate if there is a prolonged time lapse of more than 6 hours between laxative intake and the procedure[12]. Consequently, patients need to wake up early to finish the laxative at least 2 hours before the colonoscopy, potentially leading to poor compliance and dissatisfaction[13]. To ensure adequate bowel preparation that minimizes discomfort and increases tolerability and patient adherence, split dosing of bowel laxatives/purgatives has proven useful. Patients take half the solution the evening before colonoscopy and the other half in the morning, usually about 4 to 5 hours before the scheduled procedure[14]. Prior studies have demonstrated that split dosing improves both patient compliance and bowel cleansing quality when part or all of the bowel preparation is administered on the morning of the scheduled colonoscopy [13, 15-19]. The quality of colonic lavage is gauged by the volume of liquid consistency of stool in the lumen. An adequate colonic examination can be performed confidently when the preparation allows mass lesions, other than small (<5 mm) polyps, to be unobscured [20]. In Bangladesh, the number of incidental cases of colorectal carcinoma per year increased twofold from 1990 (4,935 cases/year) to 2017 (10,188 cases/year) [21]. One reason for this rapid increase in malignant case detection is the higher number of screenings through colonoscopic procedures. Since its inception, the field of colorectal surgery has been revolutionized with innovations such as painless colonoscopy, capsule-based optical colonoscopy, and machine-guided virtual colonoscopy. However, a developing country like Bangladesh has been slowly but steadily adapting to these rapid technological advancements[22]. To improve the diagnostic accuracy of colonoscopy and minimize patient dissatisfaction before the procedure, a randomized clinical trial was designed for patients awaiting colonoscopy.

Objective

To compare the efficacy and tolerability between split-dose and single-dose bowel laxatives for colonoscopy preparation.

Methods

This randomized clinical trial was conducted over a 12-month period at the Department of Gastroenterology, Sylhet MAG Osmani Medical College Hospital. The study population consisted of all patients aged over 18 years who were scheduled to undergo colonoscopy. Participants were randomly assigned to one of two groups using a computer-generated randomization list: Group 1 received a split-dose laxative regimen (sodium picosulfate), while Group 2 received a single-dose regimen. The ethical clearance number for this study is obtained under BCPS registration no: 2019090809. The sample size was calculated using a standard formula, resulting in a required sample of 210 patients; however, due to time limitations and the COVID-19 pandemic, the final sample size included 110 patients, with 57 in the split-dose group and 53 in the single-dose group. Inclusion criteria included patients over 18 years of age, of either gender, seen in the outpatient department or hospitalized patients requiring elective colonoscopy, and those willing to participate with a good understanding of the study's aim and benefits. Exclusion criteria included patients under 18 years, those with severe renal impairment or on hemodialysis, pregnant or lactating women, patients with severe congestive heart failure, history of bowel obstruction or resection, known allergies to sodium picosulfate, refusal of consent, known or suspected bowel obstruction or partially completed colonoscopy, and those with a known malignant condition. The Ottawa Bowel Preparation Scale (OBPS) was used to assess the quality of bowel preparation, rating each colon segment from 0 (excellent) to 4 (inadequate) and the amount of fluid in the whole colon from 0 (small) to 2 (large). The total OBPS score ranges from 0 (excellent) to 14 (very poor). The OBPS is calculated by adding the scores of the right, transverse/descending, and sigmoid/rectum colon segments and the score for the fluid in the whole colon. Reference for OBPS: (include proper citation). Sodium picosulfate (Ezycolon) was used as the laxative, with its formula being C18H13NNa2O8S2. The split-dose regimen involved administering the first dose the evening before the colonoscopy and the second dose on the morning of the procedure, 3 to 8 hours before the start. The single-dose regimen involved consuming the entire preparation the night before the morning colonoscopy. Patients were given a standardized explanation of the bowel preparation procedure and were asked to rate their satisfaction levels on a Likert scale ranging from 1 (very dissatisfied) to 5 (very satisfied). Caecal intubation and examination times were recorded by the endoscopists performing the colonoscopy. To

minimize bias, the endoscopist performing the colonoscopy was blinded to the patient's group allocation, and OBPS scores were calculated by an independent observer who was also blinded to the group allocation. Data collection followed a standardized procedure: ethical clearance was obtained from the Ethical Review Committee (ERC) of Sylhet MAG Osmani Medical College Hospital, patients were approached for inclusion, and informed written consent was obtained. Patients were randomized into the split-dose or single-dose groups using a computer-generated list. Each patient followed a specific diet chart and prepared the bowel cleanser as instructed. The split-dose group took the first sachet the evening before the procedure with 1,250mL of clear liquids, and the second sachet on the morning of the procedure with 750mL of clear liquids. The single-dose group consumed two sachets the night before with 2L of water. All patients underwent full history taking, clinical examination, and bowel preparation with either regimen. They completed a questionnaire after bowel preparation and before the colonoscopy. Colonoscopies were performed by professors and associate professors of the gastroenterology department without sedation. Findings were documented, and data were managed, edited, entered, and analyzed using SPSS version 24. Statistical comparisons were made using the Student t-test and chi-square test, with significance set at a p-value of <0.05.

Results

The age of the patients in group A, varied from 18 to 75 years with a mean of 47. 4±17. 7 while the age of the patients in group B varied from 18 to 94 years with a mean of 47. 6±15. 9. No significant difference was found between both groups. In Group 1, 50. 9% were male and 49. 1% were female and in Group 2, 52. 8% were female and 47. 2% were male. No significant difference was found between both groups regarding socio-demographic profile. The majority of the patients had normal weight in both Group 1 (65%) and Group 2 (62. 3%). Mean BMI was 21. 5±3. 1 kg/m^2 and 22. 1±3. 7 kg/m^2 in Group 1 and Group 2 accordingly. No significant difference was found between both groups regarding HTN, DM, and previous H/O abdominal surgery. No significant difference was found between both groups regarding clinical presentation. No significant difference was found between both groups regarding clinical signs. Indications of colonoscopy in both groups were statistically similar. No significant difference was found between both groups regarding Bowel preparation-related adverse symptoms or signs. The mean OBPS score in Group 1 and Group 2 was 4. 39±2. 0 and 5. 56±2. 2 accordingly. Mean OBPS score along with OBPS score in the right and mid colon area were significantly lower in Group 1 than in Group 2. No significant difference was found between both groups regarding Caecal intubation access, and total examination time but caecal intubation time was significantly lower in Group 1 than Group 2. No significant difference was found between both groups regarding colonoscopy findings. The adverse effect was higher in Group 2 than in Group 1 but no significant difference was found. Positive opinion and satisfaction level was higher in Group 1 than in Group 2 but no significant difference was found.

Table-I

Distribution of the patients by previous history (N=110)

Characteristics	Group 1 n (%)	Group 2 n (%)	P value
Age group (years)			
18 to 38	20 (35.1%)	14 (26.4%)	0.255*
39 to 59	19 (33.3%)	26 (49.1%)	
≥60	18 (31.6%)	13 (24.5%)	
Mean ± SD	47.4 ± 17.7	47.6 ± 15.9	0.964**
Gender			
Male	29 (50.9%)	25 (47.2%)	0.708*
Female	28 (49.1%)	28 (52.8%)	
Residence			
Rural	40 (70.2%)	37 (69.8%)	0.566*
Urban	17 (29.8%)	16 (30.2%)	
Occupation			
Businessman	10 (17.5%)	12 (22.6%)	0.676**
Farmer	10 (17.5%)	7 (13.2%)	
Service Holder	4 (7%)	3 (5.7%)	
Housewife	22 (38.6%)	25 (47.2%)	
Student	7 (12.3%)	3 (5.7%)	
Teacher	0 (0%)	1 (1.9%)	
Day Laborer	2 (3.5%)	2 (3.8%)	
Shopkeeper	2 (3.5%)	0 (0%)	
Monthly expense			
<5000	28 (49.1%)	20 (37.7%)	0.475*
5000 > 10000	17 (29.8%)	19 (35.8%)	
≥10000	12 (21.1%)	14 (26.4%)	
BMI (kg/m^2)			
Underweight	10 (17.5%)	9 (17%)	0.961*
Normal weight	37 (65%)	33 (62.3%)	
Overweight	10 (17.5%)	11 (20.8%)	

p-value was determined by *Chi-square test and **Independent sample t-test.

Table-II

Distribution of the patients by previous history (N=110)

History	Group 1 n (%)	Group 2 n (%)	P value
Medical history			
DM	6 (10.5)	11 (20.8)	0.188*
HTN	9 (15.8)	11 (20.8)	0.622*
H/O abdominal surgery	2 (3.5)	1 (1.9)	0.528**

p-value was determined by the *Chi-square test and **Fisher Exact test.

Table-III

Distribution of the patients by clinical presentation (N=110)

Clinical Presentation	Group 1 n (%)	Group 2 n (%)	P value
Pain	18 (31.6)	20 (37.7)	0.550*
Persistent abdominal discomfort	8 (14)	6 (11.3)	0.778*
Nausea	1 (1.8)	1 (1.9)	0.734**
Vomiting	4 (7)	2 (3.8)	0.375**
Generalized weakness	13 (22.8)	8 (15.1)	0.340*

p-value was determined by the *Chi-square test and **Fisher Exact test.

Table-IV

Distribution of the patients by clinical sign (N=110)

Clinical Sign	Group 1 n (%)	Group 2 n (%)	P value
Dehydration	1 (1.8)	0 (0)	1.00**
Weight loss	13 (22.8)	14 (26.4)	0.413*
Abdominal lump	2 (3.5)	1 (1.9)	1.00**
Oedema	1 (1.8)	1 (1.9)	0.734**
Ascites	2 (3.5)	0 (0)	0.496**
Anemia	20 (35.1)	21 (39.6)	0.384*
Constipation	2 (3.5)	2 (3.8)	1.00**
Diarrhea >14 days	17 (29.8)	8 (15.1)	0.073*

p-value was determined by *Chi-square test and **Fisher Exact test

Table-V

Indication of colonoscopy among the patients (N=110)

Indication	Group 1 n (%)	Group 2 n (%)	P value
Per rectal bleeding	11 (19.3)	14 (26.4)	0.495*
Diarrhea >14 days	17 (29.8)	8 (15.1)	0.073*
Altered Bowel habit	7 (12.3)	3 (5.7)	0.324**
Constipation	2 (3.5)	2 (3.8)	1.00**
Evaluation of Anemia	20 (35.1)	21 (39.6)	0.384*

p-value was determined by the *Chi-square test and **Fisher Exact test.

Table-VI

Bowel preparation-related adverse symptoms or signs among the patients (N=110)

Adverse Symptoms	Group 1 n (%)	Group 2 n (%)	P value
Due to 1st dose symptoms present	15 (26.3)	13 (24.5)	0.502*
Nausea	5 (8.8)	7 (13.2)	0.330**
Vomiting	1 (1.7)	0 (0)	0.518**
Abdominal pain	5 (8.8)	4 (7.5)	0.546**
Bloating	8 (14)	6 (11.3)	0.445*
Due to 2nd dose symptoms present			
Nausea	3 (5.3)	-	
Bloating	2 (3.5)	-	

p-value was determined by the *Chi-square test and **Fisher Exact test.

Table-VII

Distribution of the patients by Ottawa Bowel Preparation Scale (N=110)

OBPS score	Group 1 mean± SD	Group 2 mean± SD	P value*
Recto-sigmoid segments of the colon	.1.03±0.8	1.23±0.7	0.193
Mid Colon (Transverse & Descending)	1.23±0.6	1.60±0.8	0.010
Colon (Ascending segments/right colon)	1.42±0.8	2.0±0.9	0.001
Fluid score	0.68±0.7	0.79±0.6	0.344
Total score	4.39±2.0	5.56±2.2	0.004

p-value was determined by *Independent sample t-test.

Table-VIII

Caecal intubation and examination time among the patients (N=110)

Caecal intubation access at first attempts (n%)	Group 1	Group 2	P value
Yes	54 (94.7%)	46 (86.8%)	0.264*
No	3 (5.3%)	7 (13.2%)	
Mean± SD caecal intubation time (min)	6.60±3	7.74±2.5	0.035**
Mean± SD total examination time (min)	11.49±6.0	11.96±3.6	0.628**

p-value was determined by the * Fisher Exact test and **Independent sample test.

Table-IX

Colonoscopy findings among the patients (N=110)

Findings	Group 1 n (%)	Group 2 n (%)	P value
Normal	30 (52.6)	25(47.2)	0.351*
Polyp	12 (21.1)	15 (28.3)	0.254*
Hemorrhoids	15 (26.3)	12 (22.6)	0.411*
Ulcer	6 (10.5)	2 (3.8)	0.160**

p-value was determined by the *Chi-square test and **Fisher Exact test.

Table-X

Common Terminology Criteria for Adverse Events (CTCAE) of the patients (N=110)

CTCAE	Group 1 n (%)	Group 2 n (%)	P value
Abdominal pain	22	23	0.375*
Grade 1	4	6	0.124**
Grade 2	6	7	
Grade 3	4	2	
Grade 4	7	2	
Grade 5	1	6	
Dyspnea Grade 1	0	1	0.482**
Palpitation Grade 3	0	1	0.482**

p-value was determined by the *Chi-square test and **Fisher Exact test.

Table-XI

Patients' opinions and satisfaction level regarding assigned bowel preparation between both groups (N=110)

Patients Opinion	Group 1 n (%)	Group 2 n (%)	P value*
Excellent	3	1	0.434**
Good	41	39	
Fair	7	4	
Poor	5	9	
Inadequate	1	0	
Satisfaction level			
Satisfied	46	40	0.833
Neutral	4	4	
Dissatisfied	7	9	

p-value was determined by *the Fisher Exact test.

Discussion:

Colorectal cancer (CRC) is the third most prevalent cancer in the world, and colon endoscopy is the gold standard for examining colon abnormalities and is an integral part of all colorectal cancer screening programs[23]. Poor bowel preparation for colonoscopy can cause significant clinical and financial harm. The quality of this procedure depends largely on the quality of the colon cleanser. The current study observed that the mean OBPS score in the split-dose group was 4.39±2.0, significantly lower than the 5.56±2.2 in the single-dose group. Lower OBPS scores indicate better bowel preparation, particularly in the right and mid-colon areas. Emami et al. also showed that the Ottawa score was significantly lower in the split-dose group, indicating better preparation in the right and mid-colon areas[24]. Marmo et al. revealed better performance of a split-dose regimen compared to a single-dose regimen[25], and Martel et al. observed that split-dose regimens increase the quality of colon cleansing[26]. In this study, caecal intubation access at first attempt was 94.7% in the split-dose group and 86.8% in the single-dose group, with caecal intubation time significantly shorter in the split-dose group. This is consistent with previous findings by Emami et al., who revealed that optimal colon cleansing requires purgative administration close to the time of colonoscopy[24]. The relationship between caecal intubation and the split-dose regimen can be explained by better bowel preparation quality, which facilitates

easier and quicker intubation. The lower OBPS score in the split-dose group can be attributed to the reduced time between laxative administration and the colonoscopy, leading to more effective bowel cleansing. This results in better visibility during the procedure and shorter caecal intubation times. Additionally, the adverse effects were comparatively lower in the split-dose group, and patient satisfaction levels were higher. Emami et al. also showed that split-dose preparation is better than conventional single-dose preparation in terms of patient compliance[24]. Martel et al. found that a split-dose regimen was preferable to a single dose[26], and Kotwal et al. observed a trend toward more side effects among patients in the single-dose group compared to the split-dose group[29]. Mohamed et al. also revealed that the split-dose lavage was well-tolerated and associated with fewer side effects than the single-dose lavage[30]. In terms of demographic factors, this study found no significant difference in OBPS scores between younger and older patients or between males and females in both groups. However, a previous study by Wang et al. revealed that increased age and male sex were associated with increased OBPS scores[27]. Older age is often associated with reduced gastrointestinal motility, which can impair bowel preparation quality[28]. In conclusion, this study demonstrates that split-dose sodium picosulfate is superior to a single-dose regimen for colonoscopy preparation, resulting in better mucosal cleanliness and shorter caecal intubation times. These findings suggest that split-dose regimens should be considered the preferred method for bowel preparation in clinical practice.

Limitations of the study

This single-center study with a small sample size and short duration may not be broadly applicable. The study also lacked detailed information on dietary habits, bowel habits, and drug history, which could have offered valuable insights. To gain a more comprehensive understanding of colonoscopy preparation methods and outcomes, future research should involve larger, more diverse populations, and a more detailed assessment of patient characteristics.

Conclusion

The success of a colonoscopy is determined by high-quality bowel preparation, which makes the intestinal mucosa visible and facilitates smooth diagnosis and treatment. This study revealed that split-dose laxatives are superior to single-dose laxatives, as evidenced by lower OBPS scores and shorter caecal intubation times. Additionally, split-dose regimens result in fewer complications and higher patient compliance and satisfaction levels compared to single-dose regimens. These findings support the use of split-dose laxatives as the preferred method for bowel preparation in clinical practice, providing better overall outcomes for patients undergoing colonoscopy.

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Ethical approval: The study was approved by the institutional ethics committee.

Recommendation

Further studies are required considering detailed dietary history and drug history. Moreover, further studies should be conducted involving a large sample size and multiple centers to validate the findings in this regard.

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