

## Original Article

## Bowel Cleansing Agents in Clinical Practice: A Cross-Sectional Study on Safety, Efficacy, and Predictor of Good Bowel Preparation

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## ABSTRACT

**Background:** A good bowel preparation for colonoscopy is the most important factor that has an impact on visualization and outcome of the procedure. **Aim:** The primary aim of the study was to assess the quality of bowel preparation as reported by the Boston Bowel Preparation Score (BBPS). The secondary aim of the study was to analyze the patient feedback on ease of administration, palatability, and side effects with the bowel preparation. **Materials and Methods:** Patients undergoing colonoscopy between March 2018 and September 2018 were enrolled in the study. Patients <18 years of age, those with the previous history of colorectal surgery, emergency procedures in an unprepared colon, and those not willing to participate were excluded from the study. Colon preparation of the patient was decided by senior consultants. A predesigned pro forma that included demography, indication for the procedure, preparation details, dietary recommendations the previous day if any, side effects, and patient's comfort to preparation was completed by two-independent observers. The BBPS was used to assess the bowel preparation. A score of <5 was deemed inadequate.  $P < 0.05$  was considered statistically significant. **Results:** The study cohort consisted of 141 patients, of which 78 were male (55.3%). Eighty (56.7%) patients received oral sulfate-based preparation and 61 (43.4%) polyethylene glycol-based preparation. Nearly one third of cases reported the solution to be non palatable. 15.4% respondents reported nausea, vomiting and bloating as the major side effects of the preparation. The median duration of colonoscopy was 25 min (8–45 min). One hundred and eighteen patients (83.6%) had a BBPS score of  $\geq 5$ . Sulfate preparation resulted in better bowel cleansing ( $P = 0.01$ ). Age, gender, and dosing schedule of preparation, including bedtime dosing of stimulant laxative, did not alter the BBPS score. **Conclusion:** Sulfate- and polyethylene glycol-based preparations are commonly used for cleansing the colon. Bowel cleansing was adequate in most patients and sulfate-based yielded better bowel cleansing. Nearly 15.4% of patients reported side effects to these preparations.

**KEYWORDS:** Bowel, cleansing, colonoscopy, polyethylene glycol

## INTRODUCTION

Good bowel preparation for colonoscopy is the most important factor that has an impact on the outcome of the procedure. Benefits of a good preparation include early completion of the procedure and identifying small mucosal lesions that are likely to be missed with poor preparation. Further, addition of advanced mucosal

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**How to cite this article:** Joshi V, Jain M, Srinivas M, Mahadevan B, Kumar GS, Ganesh P, et al. Bowel cleansing agents in clinical practice: A cross-sectional study on safety, efficacy, and predictor of good bowel preparation. J Dig Endosc 2019;10:XX-XX.

## Access this article online

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Website: www.jdeonline.in

DOI: 10.4103/jde.JDE\_71\_18

imaging such as narrow-band imaging requires a clean colon.<sup>[1]</sup> It has been reported that ileal intubation and adenoma detection rates are directly related to the quality of colon preparation.<sup>[2-5]</sup> Inadequate preparation is associated with incomplete or prolonged procedure time resulting anesthetic and procedure-related complications.<sup>[6]</sup> The ideal colon preparation should enable one to detect colonic polyps of even 5 mm in size.<sup>[7]</sup>

### Aim

The primary aim of the study was to assess the quality of bowel preparation as reported by the Boston Bowel Preparation Score (BBPS). The secondary aim of the study was to analyze patient feedback on ease of administration, palatability, and side effects with the bowel preparation. We also evaluated the factors affecting bowel cleansing.

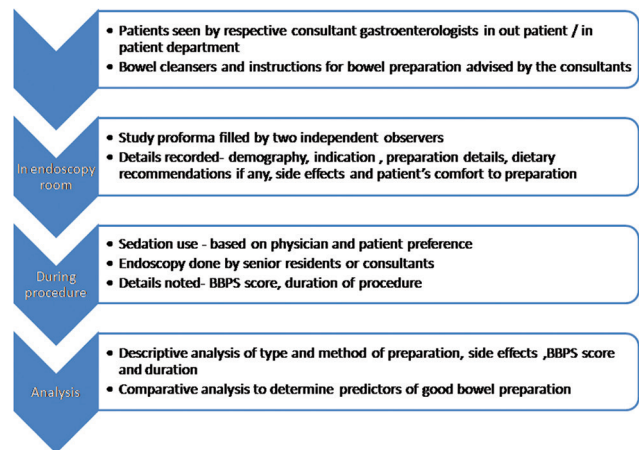
### MATERIALS AND METHODS

Common bowel preparations preferred by consultants in our day-to-day practice have been the use of sulfate-based preparation containing sodium sulfate, potassium sulfate, and magnesium sulfate (1000 mL) or polyethylene glycol-based preparations with electrolyte (2000 mL), in diverse schedules some as split, others as one time with variable diet instructions. A bedtime oral stimulant laxative is given arbitrarily.

We prospectively studied the effectiveness, tolerability, and side effects of these bowel cleansing preparations at two tertiary gastrointestinal centers, Gleneagles Global Health City (center 1) and Sri Ramachandra Institute of Higher Education and Research (center 2), Chennai, India, in patients undergoing colonoscopy between March 2018 and September 2018. Informed consent was obtained before the procedure. Patients <18 years of age, those with the previous history of colorectal surgery, those not willing to participate and emergency colonoscopy in an unprepared colon as in hematochezia, acute ulcerative colitis, or colonic obstruction were excluded from the study. The study was approved by the Institutional Ethics Committee.

Type of preparation regimen for colonoscopy of the patient was decided by senior consultants. A predesigned pro forma that included demography, indication for procedure, preparation details, dietary recommendations the previous day if any, side effects, and patient's comfort to preparation were completed by two observers (VJ and ALR) at the respective centers [Figure 1].

Colonoscopy was performed by consultants or senior trainees under supervision. Intravenous sedation was used as per the patient's preference. Vitals were



**Figure 1:** Study methodology

monitored for an hour after the procedure. The BBPS was used to assess the bowel preparation. The scores were noted by VJ, SKGS, and ALR, during the colonoscopy. A score of <5 was a measure of inadequacy and >5 as adequate.<sup>[8]</sup>

### Statistical analysis

All parameters were expressed as absolute numbers and percentages. Age and BBPS were expressed as median and range. Comparison of two medians was performed using Mann-Whitney U-test. Comparison of proportions was performed using the Chi-square test.  $P < 0.05$  was considered statistically significant.

### RESULTS

The study cohort consisted of 141 patients who had colonoscopy [Table 1]. Eighty-two patients were recruited from center 1 and 59 patients from center 2. There were 78 (55.3%) men. Hypertension and diabetes were the two major comorbid states. Dietary modifications in the form of liquid or low-fiber diet, 1 day before endoscopy, were advised to 38 (27%) patients. The most common indication for endoscopy was chronic constipation followed by iron-deficiency anemia. Eighty (56.7%) patients received sulfate-based preparation and 61 (43.4%) polyethylene glycol-based preparation; 80 patients (56.7%) received the preparation between 4 am and 6 am and the remaining as 50:50 split preparation (previous night and same-day morning preparation). Overall, 80 (56.7%) patients received two tablets of sodium picosulfate tablets at bedtime. The patients at both centers were comparable in age, sex, indication of procedures, and comorbidity profile. However, same-day preparation (79.5% vs. 7.2%;  $P < 0.0001$ ) and use of sulfate preparations (64.3% vs. 24.6%;  $P < 0.0001$ ) were significantly more common in center 1 as compared to center 2.

Irrespective of the type of preparation, 63.8% reported the first bowel movement within 30 min of taking the prepared fluid. Seventy-two percent reported that the last stool passed was clear with no yellow color or food residue [Table 2]. Nearly one third of cases reported

the solution to be non palatable. 15.4% respondents reported nausea, vomiting and bloating as the major side effects of the preparation. There was no difference in the side effect profile in the two types of preparations used ( $P = 0.87$ ). The median duration of colonoscopy was 25 min (8–45 min). One hundred and eighteen (83.6%) patients had a BBPS score of  $\geq 5$ .

**Table 1: Baseline characteristics of the study population (n=141)**

Baseline characteristics	Parameters	n (%)
Age (years), median (range)	48 (21-78)	
Sex	Males	78 (55.3)
Indications for colonoscopy	Chronic constipation	59 (42.1)
	Diarrhea	8 (5.7)
	IBD	8 (5.7)
	Screening for CRC	14 (9.9)
	Iron-deficiency anemia	52 (36.9)
Comorbid states	Diabetes mellitus	15 (9)
	Hypertension	20 (12)
	Diabetes + hypertension	3 (1.8)
	Coronary artery disease	3 (1.8)
	Chronic kidney disease	1 (0.6)
	Miscellaneous	2 (1.2)
Colon preparations	Polyethylene glycol based	61 (43.3)
	Oral sulfate based	80 (56.7)
	Sodium picosulfate (premed)	80 (56.7)
Previous day diet recommendation	Liquid diet, early dinner, and low-fiber diet	38 (27)
Split-dose (previous night and next morning) or same-day preparation (n=144)	Same day	80 (56.7)
	Split-dose	61 (43.3)

IBD=Inflammatory bowel disease, CRC=Colorectal cancer

**Table 2: Preparation details, side effect profile, and procedure details in those undergoing colonoscopy (n=141)**

Parameters	Outcome	n=141, n (%)
Onset of first motion after starting oral preparation (min)	<30	90 (63.8)
	30-90	33 (23.4)
	>90	18 (12.8)
Details of last motion passed	Clear	101 (72)
	Yellow	30 (28)
Patient's assessment of preparation	Satisfied	101 (72)
	Not satisfied	30 (28)
Side effects	Bloating	7 (5.0)
	Vomiting	13 (9.2)
	Nausea	2 (1.2)
Palatability	Good	70 (49.6)
	Bad	45 (32.1)
	Tolerable	26 (18.5)
Duration of procedure (min), median (range)	25 (8-45)	
BBPS	<5	23 (16.4)
	$\geq 5$	118 (83.6)

BBPS=Boston Bowel Preparation Score

**Factors affecting preparation**

Sulfate-based preparation was associated with higher BBPS score ( $P < 0.01$ ) compared to polyethylene glycol. Age, gender, dietary changes a day before the procedure, and dosing schedule of preparation, including bedtime dosing of stimulant laxative ( $P = 0.68$ ) did not alter the BBPS score. Furthermore, the time required for completion of the procedures was similar ( $P = 0.23$ ) [Table 3].

**DISCUSSION**

The present study highlights that sulfate-based preparations are the most commonly used agents for bowel cleansing before colonoscopy, followed by polyethylene glycol-based preparations in the two centers. The use of same-day early morning preparation and split dose differed between the two study centers but did not lead to significant difference in bowel cleansing. Sulfate preparations resulted in better bowel preparation. Nearly, one-sixth (15.4%) of patients encountered side effects to these agents.

Polyethylene glycol was introduced by Davis *et al.*<sup>[9]</sup> The high volume and the unpleasant taste are among the major disadvantages of this solution.<sup>[10]</sup> To overcome the problems with polyethylene glycol, sodium phosphate was introduced. However, there was a concern in patients with a history of or risk of developing renal dysfunction.<sup>[11]</sup> An alternative to sodium phosphate is sulfate-based preparation. A recent study has shown a better preparation with no difference in adverse effects.<sup>[12]</sup> A Japanese study reported that sodium sulfate was effective in cleansing the colon in 98% of the cases.<sup>[13]</sup> We also noted better bowel preparation scores with sulfate-based preparations.

In this study, 15.4% of patients reported side effects to these preparations. This is similar to earlier studies.<sup>[14]</sup>

The role of adjuncts such as enemas, bisacodyl, or metoclopramide in addition to the standard dose of polyethylene glycol is controversial.<sup>[15-19]</sup> Some studies did not show improvement in the quality of the preparation or the patient's tolerance.<sup>[15,16]</sup> However, bisacodyl did improve the effectiveness of the preparations of low-volume polyethylene glycol (2 L), 56.7% of cases in our study received sodium picosulfate the night before the

**Table 3: Factors affecting preparation**

	BBPS <5 (n=23)	BBPS ≥5 (n=118)	P
Males, n (%)	12 (52.2)	53 (44.9)	0.52
Age, median (range)	52 (25-72)	48 (21-78)	0.41
Polyethylene glycol based, n (%)	16 (70)	45 (38.2)	0.01
Sulfate based, n (%)	7 (30)	73 (61.8)	
Modified diet, n (%)	8 (34.8)	30 (25.2)	0.34
Previous night laxative, n (%)	14 (60.8)	77 (65.2)	0.68
Split preparation, n (%)	13 (56)	48 (40.6)	0.17
Procedural time	25 (15-40)	25 (15-45)	0.23

BBPS=Boston Bowel Preparation Score

procedure. Earlier studies have demonstrated that sodium picosulfate is safe and effective for bowel preparation with good tolerability and few side effects.<sup>[17-19]</sup>

The timing of bowel preparation is an important factor affecting the quality of cleansing. “Same-day” preparation appears to be ideal.<sup>[20]</sup> These patients have no disturbed sleep, no interference with their work schedule, and less abdominal pain during preparation.<sup>[20,21]</sup> We noted that though preference for same-day versus split preparation differed in the two study centers, there was no difference in bowel cleansing and preparation scores.

Although the type of diet before colonoscopy may affect the quality of cleansing, there are surprisingly few studies on this question. A well-defined low-fiber diet is generally adequate for outpatient colonoscopy. In certain situations with a high risk of inadequate cleansing, a liquid diet seems appropriate.<sup>[22-24]</sup> In the present study, 27% of cases received dietary modification on the day before the procedure. These were primarily patients with long-standing constipation.

Limitations of the study – Small sample size; no standardized protocol regarding diet, use of stimulant laxatives, method of administering the preparation, and type of preparation was not followed. Prospective studies, including randomized control trials, in Indian patients, are required to assess the influence of these factors on bowel cleansing.

## CONCLUSION

Our study suggests that dosing schedule, premedication, or dietary modifications do not influence the quality of bowel cleansing. Low-volume sulfate preparation appears to be better than high-volume polyethylene glycol preparation for bowel cleansing for colonoscopy.

## Financial support and sponsorship

Nil.

## Conflicts of interest

There are no conflicts of interest.

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