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Efficacy, Safety, And Patient Satisfaction Of Oral Sulfate Solution Versus Polyethylene Glycol With Ascorbic Acid For Colonoscopy Bowel Preparation: A Randomized Controlled Trial

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Abstract

Background

Adequate bowel preparation is essential for successful colonoscopy, as poor bowel cleansing may lead to missed lesions, prolonged procedure time, and incomplete examinations. Oral Sulfate Solution (OSS) and Polyethylene Glycol with Ascorbic Acid (PGA) are commonly used low-volume bowel preparation agents; however, evidence comparing their efficacy and tolerability in the Indian population is limited.

Aim

To compare the efficacy, safety, and patient acceptability of OSS and PGA for bowel preparation among Indian adults undergoing elective colonoscopy.

Methods

This single-centre randomized controlled trial included 90 adults aged ≥35 years undergoing elective colonoscopy. Participants were randomly assigned to receive either OSS (n=45) or PGA (n=45). Bowel preparation quality was assessed using the Boston Bowel Preparation Scale (BBPS). Patient satisfaction, adverse events, adenoma detection rate, and caecal intubation time were also evaluated.

Results

Baseline demographic characteristics were comparable between the two groups. Inadequate bowel preparation was significantly lower in the OSS group than in the PGA group (11.1% vs. 33.3%, p=0.011). The mean caecal intubation time was significantly shorter in the OSS group (3.80±0.99 min) compared with the PGA group (7.12±2.01 min; p<0.001). Overall bowel preparation success was higher with OSS (93.3%) than PGA (88.8%), although the difference was not statistically significant (p=0.456). Adequate bowel cleansing in the right, transverse, and left colon was comparable between groups. Patient satisfaction scores were significantly higher in the OSS group (7.9±0.1 vs. 5.8±0.4; p<0.001). The incidence of adverse events was similar between the groups.

Conclusion

OSS demonstrated comparable bowel cleansing efficacy and safety to PGA while providing higher patient satisfaction, lower rates of inadequate bowel preparation, and shorter caecal intubation times. OSS may be considered an effective and well-tolerated option for bowel preparation in adults undergoing colonoscopy.

Keywords: *Colonoscopy; Bowel preparation; Oral sulfate solution; Polyethylene glycol with ascorbic acid; Boston Bowel Preparation Scale; Adenoma detection rate; Patient satisfaction; Randomized controlled trial*

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I. Introduction

Colonoscopy is an endoscopic procedure that allows direct visualization of the entire colon and terminal ileum. It is widely regarded as the gold standard investigation for the diagnosis and screening of colorectal diseases, including colorectal cancer (CRC), colorectal polyps, inflammatory bowel disease, gastrointestinal bleeding, and other colonic pathologies. The increasing burden of colorectal diseases worldwide has further emphasized the importance of colonoscopy as an effective diagnostic and therapeutic tool.[1]

The diagnostic accuracy and effectiveness of colonoscopy largely depend on the quality of bowel preparation. Adequate bowel cleansing enables clear visualization of the colonic mucosa, facilitates identification of small lesions and polyps, improves adenoma detection rates, and reduces procedure-related complications. In contrast, inadequate bowel preparation may result in missed lesions, incomplete examination, prolonged procedure time, increased patient discomfort, greater use of sedatives and analgesics, and the need for repeat colonoscopy, thereby increasing healthcare costs and reducing overall procedural efficiency.[2]

The quality of bowel cleansing is influenced by several factors, including the type of bowel preparation agent used, the volume of preparation required, the timing of administration, the use of split-dose regimens, patient compliance, dietary restrictions, and associated medical conditions. Among these factors, the choice of bowel preparation agent plays a crucial role in determining both cleansing efficacy and patient acceptance.[2]

Polyethylene glycol (PEG)-based preparations have long been considered the standard bowel cleansing agents because of their proven efficacy and excellent safety profile. However, conventional PEG solutions require the consumption of large volumes of fluid, which many patients find difficult to tolerate. Common complaints include nausea, bloating, abdominal fullness, unpleasant taste, vomiting, and sleep disturbances, all of which may negatively affect patient compliance and the quality of bowel preparation.[4]

To overcome these limitations, low-volume bowel preparation regimens have been developed. Polyethylene Glycol with Ascorbic Acid (PGA/PEG-AA) and Oral Sulfate Solution (OSS) are among the most commonly used low-volume preparations. These agents require a smaller volume of intake while maintaining effective bowel cleansing, thereby improving patient comfort and adherence to preparation instructions.[3]

Oral Sulfate Solution is a sulfate-based preparation containing sodium sulfate, potassium sulfate, and magnesium sulfate. It works by retaining water within the intestinal lumen, resulting in effective bowel cleansing. Several studies have reported that OSS provides comparable or superior bowel cleansing quality when compared with PEG-based preparations. In addition, OSS has been associated with improved patient satisfaction, better tolerability, and a higher willingness to repeat the same preparation for future colonoscopies.[5]

Recent evidence further supports the effectiveness of OSS. A systematic review and meta-analysis published in 2025, which included 21 randomized controlled trials involving more than 6,000 participants, reported significantly higher Boston Bowel Preparation Scale (BBPS) scores, better adenoma detection rates, and improved polyp detection rates with OSS compared to PEG-based bowel preparations.[6] These findings suggest that OSS may offer clinical advantages in achieving optimal bowel cleansing and enhancing the diagnostic yield of colonoscopy.

Although several international studies have compared OSS and PEG-based preparations, data from the Indian population remain limited. Differences in dietary habits, bowel transit patterns, body composition, and patient preferences may influence the effectiveness and tolerability of bowel preparation regimens in Indian patients. Furthermore, there is a lack of evidence specifically evaluating these preparations among Indian adults aged 35 years and above, an age group increasingly undergoing colonoscopy for both screening and diagnostic purposes.

Therefore, the present study was undertaken to compare the efficacy, safety, and patient acceptability of Oral Sulfate Solution (OSS) and Polyethylene Glycol with Ascorbic Acid (PGA) for bowel preparation among Indian adults aged 35 years and above undergoing elective colonoscopy. The study hypothesized that there would be no significant difference in bowel cleansing efficacy between OSS and PGA as assessed during colonoscopy.

II. Methodology

Study design and population

This single-centre, randomized controlled trial was conducted in accordance with the Consolidated Standards of Reporting Trials (CONSORT) guidelines. The study included adults aged ≥35 years undergoing elective colonoscopy in the Department of General Surgery, SS Institute of Medical Sciences, Karnataka, India. Patients with known colorectal malignancy, intestinal obstruction or perforation, severe renal failure, congestive heart failure, severe liver disease, pregnancy or lactation, known hypersensitivity to the study medications, and those unwilling to participate were excluded from the study.

Sample size

The sample size was calculated using G*Power software version 3.1.9.4. Based on a previously reported difference in Boston Bowel Preparation Scale (BBPS) scores between study groups, an effect size of 0.6 was

considered.[4] With a two-sided alpha error of 5% and a study power of 80%, the minimum required sample size was estimated to be 90 participants, comprising 45 participants in each study group.

Colonoscopy Procedure

All enrolled participants underwent colonoscopy using a video colonoscope performed by experienced endoscopists. Intravenous midazolam was administered to patients who opted for sedation, with the dosage determined according to institutional protocols. Meperidine was routinely used as an analgesic during the procedure.

Randomization

Participants were randomly assigned in a 1:1 ratio to either the Oral Sulfate Solution (OSS) group or the Polyethylene Glycol with Ascorbic Acid (PEG-AA) group using a computer-generated randomization sequence.

Bowel Preparation

Participants in the OSS group received a sulfate-based bowel preparation containing sodium sulfate, potassium sulfate, and magnesium sulfate supplied in a 177 mL bottle. The solution was diluted with water up to the marked 473 mL level and consumed along with an additional 1 L of water. The same regimen was repeated for the second dose. OSS was administered as a split-dose preparation at a 12-hour interval. For morning colonoscopies, doses were administered at 5:00 PM on the day before the procedure and at 5:00 AM on the day of colonoscopy. For afternoon colonoscopies, the doses were administered at 7:00 PM on the preceding day and at 7:00 AM on the day of the procedure.

Participants in the PEG-AA group received a preparation containing polyethylene glycol, potassium chloride, sodium chloride, sodium sulfate, ascorbic acid, and sodium ascorbate. Patients consumed 1 L of PEG-AA solution followed by 500 mL of water, and the regimen was repeated for the second dose. For morning colonoscopies, a split-dose regimen was followed, with 1 L administered at 8:00 PM on the day before the procedure and the second litre at 5:00 AM on the day of colonoscopy. For afternoon colonoscopies, a same-day regimen was used, with 1 L administered at 5:00 AM and the second litre at 8:00 AM on the day of the procedure.

Assessment of Bowel Cleansing

The quality of bowel preparation was evaluated by endoscopists who were blinded to the assigned preparation regimen using the Boston Bowel Preparation Scale (BBPS).[7] The BBPS assesses bowel cleanliness in three colonic segments: the right colon (cecum and ascending colon), transverse colon (including hepatic and splenic flexures), and left colon (descending colon, sigmoid colon, and rectum). Each segment is scored from 0 to 3, resulting in a total score ranging from 0 to 9, with higher scores indicating better bowel cleansing.

Adequate bowel preparation was defined as a BBPS score of ≥2 in each colonic segment, whereas preparation was considered inadequate if any segment received a score of <2.

Statistical analyses

The primary outcome was the quality of bowel preparation, categorized as adequate or inadequate based on the Boston Bowel Preparation Scale (BBPS). Continuous variables were expressed as mean ± standard deviation (SD), while categorical variables were presented as frequencies and percentages. Baseline characteristics and study outcomes were compared between the OSS and PEG-AA groups using the independent-samples t-test for continuous variables and the Chi-square test or Fisher's exact test for categorical variables, as appropriate. All statistical tests were two-tailed, and a p-value <0.05 was considered statistically significant. Statistical analyses were performed using IBM SPSS Statistics for Windows, Version 25.0 (IBM Corp., Armonk, NY, USA).

III. Results

A total of 90 participants were enrolled in the study, with 45 participants each in the OSS and PGA groups. The baseline demographic and clinical characteristics of the study population are presented in Table 1.

The mean age of participants was comparable between the OSS and PGA groups (46.78 ± 10.11 years vs. 49.31 ± 12.92 years, $p = 0.304$). There were no significant differences between the groups with respect to sex distribution, body mass index, hospitalization status, or timing of colonoscopy (all $p > 0.05$).

A significantly higher proportion of participants in the OSS group received split-dose bowel preparation compared with the PGA group (91.1% vs. 44.4%, $p < 0.001$).

The bowel-cleansing efficacy for individual colonic segments is shown in Table 2. Adequate bowel preparation (BBPS score ≥2) in the transverse colon was achieved in 95.5% of participants in the OSS group and 93.3% in the PGA group ($p = 0.645$). Similarly, adequate bowel cleansing of the right colon was observed in 95.5% and 91.1% of participants in the OSS and PGA groups, respectively ($p = 0.396$). In the left colon, adequate

bowel preparation was achieved in 97.7% of participants receiving OSS and 95.5% of those receiving PGA (p = 0.558).

Overall bowel preparation success was achieved in 93.3% of participants in the OSS group and 88.8% of participants in the PGA group. Although bowel preparation success was numerically higher in the OSS group, the difference did not reach statistical significance (p = 0.456).

Clinical Outcomes Following Bowel Preparation are depicted in Table 3. Inadequate bowel preparation was observed less frequently among participants receiving OSS than those receiving PGA (11.1% vs. 33.3%, p = 0.011). The mean caecal intubation time was significantly shorter in the OSS group compared with the PGA group (3.80 ± 0.99 minutes vs. 7.12 ± 2.01 minutes, p < 0.001). However, the adenoma detection rate was similar between the two groups (26.6% vs. 35.5%, p = 0.362).

Patient satisfaction and safety outcomes are presented in Table 4. Participants receiving OSS reported significantly higher overall satisfaction scores compared with those receiving PGA (7.9 ± 0.1 vs. 5.8 ± 0.4, p < 0.001).

Overall, adverse events were reported in 22.2% of participants in the OSS group and 26.6% of participants in the PGA group, with no significant difference between the groups (p = 0.624). Abdominal distention was reported by 11.1% of participants receiving OSS and 2.2% receiving PGA (p = 0.090). Nausea occurred in 15.5% and 31.1% of participants in the OSS and PGA groups, respectively (p = 0.081).

Pain, vomiting, headache, and dizziness were infrequent in both groups, and no statistically significant differences were observed between the treatment groups (all p > 0.05).

Overall, OSS was associated with higher patient satisfaction, while the frequency of adverse events was comparable between the two bowel preparation regimens.

Table 1 Baseline characteristics of study population

Variables	OSS N=45	PGA N=45	p-value
Age in yrs (Mean ± SD)	46.78±10.11	49.31±12.92	0.304
Male, n (%)	26 (57.7)	27 (60)	0.830
BMI kg/m^2	24.40±1.0	24.63±0.90	0.250
Hospitalization, n (%)	8 (17.7)	11 (24.4)	0.438
Morning colonoscopy, n (%)	6 (13.3)	9 (20)	0.396
Split-dose, n (%)	41 (91.1)	20 (44.4)	<0.001

Table 2 Bowel cleansing efficacy according to individual colonic segments

BBPS scores	OSS N=45	PGA N=45	p-value
BBPS score ≥ 2 in the transverse colon, n (%)	43 (95.5)	42 (93.3)	0.645
BBPS score ≥ 2 in the right colon, n (%)	43 (95.5)	41 (91.1)	0.396
BBPS score ≥ 2 in the left colon, n (%)	44 (97.7)	43 (95.5)	0.558
Bowel preparation success	42 (93.3)	40 (88.8)	0.456

Table 3 Clinical Outcomes Following Bowel Preparation in the Study Groups

Variables	OSS N=45	PGA N=45	p-value
Inadequate bowel preparation, n (%)	5 (11.1)	15 (33.3)	0.011
Caecal intubation time (min), mean ± SD	3.80±0.99	7.12±2.01	<0.001
Adenoma detection rate, n (%)	12 (26.6)	16 (35.5)	0.362

Table 4 Patient satisfaction, acceptability, and safety

Variables	OSS N=45	PGA N=45	p-value
Overall satisfaction (Mean ± SD)	7.9±0.1	5.8±0.4	<0.001
Overall adverse events, n (%)	10 (22.2)	12 (26.6)	0.624
Abdominal distention, n (%)	5 (11.1)	1 (2.2)	0.090
Pain, n (%)	2 (4.4)	0	0.154
Nausea, n (%)	7 (15.5)	14 (31.1)	0.081
Vomiting, n (%)	3 (6.6)	1 (2.2)	0.307
Headache, n (%)	1 (2.2)	1 (2.2)	1.000
Dizziness, n (%)	2 (4.4)	1 (2.2)	0.558

IV. Discussion

Adequate bowel preparation is essential for high-quality colonoscopy, as poor bowel cleansing can reduce lesion detection, prolong procedure time, increase patient discomfort, and lead to incomplete examinations. Previous studies have identified bowel preparation quality as one of the most important indicators of colonoscopy performance. [8,2,9]

In the present study, the rate of inadequate bowel preparation was significantly lower in the OSS group than in the PGA group (11.1% vs. 33.3%, p=0.011). Similar findings were reported by Nam et al., who observed inadequate bowel preparation in 12.3% of patients receiving OSS compared with 32.8% of those receiving PEG-AA. The authors concluded that OSS was independently associated with better bowel cleansing and was particularly effective among patients aged 50 years and above.[5] The close similarity between their findings and ours further supports the effectiveness of OSS in achieving adequate bowel preparation.

Overall bowel preparation success was achieved in 93.3% of participants in the OSS group and 88.8% in the PGA group. Although the difference was not statistically significant, the findings are comparable with those reported by Di Palma et al., who demonstrated cleansing success rates of 92% with sulfate-based preparations and 89% with PEG and ascorbate preparations.[10] Similarly, Park et al. reported bowel preparation success rates of 95.1% with oral sodium sulfate tablets and 91.3% with 1 L PEG plus ascorbic acid, with no significant difference between groups.[4] These findings suggest that both sulfate-based and PEG-based regimens can provide adequate bowel cleansing when appropriately administered.

In our study, adequate bowel cleansing of the right, transverse, and left colon was achieved in more than 90% of patients in both groups. Although no statistically significant differences were observed, OSS consistently showed numerically higher cleansing rates across all colonic segments. This observation is in agreement with the study by Di Palma et al., who reported significantly higher rates of excellent bowel preparation in the proximal colon among patients receiving sulfate-based preparations.[10] Better cleansing of the proximal colon is clinically important because missed lesions are more likely to occur in this region.

The mean caecal intubation time was significantly shorter in the OSS group than in the PGA group (3.80 ± 0.99 vs. 7.12 ± 2.01 minutes, p<0.001). This finding may be explained by better bowel cleanliness, which facilitates easier advancement of the colonoscope and improves mucosal visualization. Wong et al. demonstrated that poor bowel preparation was associated with longer caecal intubation times and reduced procedural efficiency.[8] Similarly, clinical practice recommendations from the American Gastroenterological Association emphasize that adequate bowel preparation improves procedural quality and efficiency.[9]

The adenoma detection rate was 26.6% in the OSS group and 35.5% in the PGA group, with no significant difference between groups. Although adenoma detection was numerically higher in the PGA group, the difference was not statistically significant. The relatively small sample size and low number of adenoma events may explain this finding. In contrast, Akram et al., in a recent meta-analysis of 21 randomized controlled trials involving 6,346 participants, reported significantly higher adenoma and polyp detection rates among patients receiving OSS. [6] The difference between our findings and those of the meta-analysis may be attributed to our relatively small sample size, which may have limited the statistical power to detect differences in adenoma detection.

Patient satisfaction was significantly higher in the OSS group than in the PGA group (7.9 ± 0.1 vs. 5.8 ± 0.4, p<0.001). This finding is consistent with previous studies evaluating low-volume bowel preparation regimens. Park et al. reported significantly greater overall satisfaction among patients receiving sulfate-based preparations than among those receiving PEG plus ascorbic acid.[4] Likewise, Jha highlighted that low-volume bowel preparation regimens are generally associated with improved patient acceptance and compliance compared with conventional PEG-based preparations because of reduced fluid intake requirements.[2] Improved patient satisfaction is clinically relevant, as it may enhance adherence to bowel preparation instructions and improve the quality of future colonoscopy examinations.

Regarding safety, the incidence of adverse events was comparable between the two groups. Although gastrointestinal symptoms such as nausea, abdominal distension, and vomiting were reported, no serious adverse events were observed. Similar safety findings have been reported by Di Palma et al., who found comparable adverse event rates between sulfate-based preparations and PEG with ascorbate.[10] Park et al. also demonstrated similar overall adverse event rates between oral sodium sulfate tablets and PEG-AA preparations despite minor differences in individual symptoms.[4] Furthermore, the meta-analysis by Akram et al. reported no significant differences in most adverse events between OSS and PEG preparations, supporting the overall safety of OSS.[6]

An additional observation in our study was the significantly higher use of split-dose preparation in the OSS group. Split-dose regimens are known to improve bowel cleansing quality and are currently recommended by international guidelines.[9] Jha also emphasized that split-dose bowel preparation consistently produces better cleansing outcomes than single-dose regimens.[2] Therefore, the higher proportion of split-dose administration in the OSS group may have contributed, at least in part, to the superior bowel preparation outcomes observed in our study.

Overall, the findings of the present study are consistent with previous randomized trials, observational studies, and recent meta-analyses showing that OSS provides effective bowel cleansing with good patient acceptance and a favorable safety profile. While both OSS and PGA achieved high rates of successful bowel preparation, OSS was associated with lower rates of inadequate bowel preparation, higher patient satisfaction, and shorter caecal intubation times.

The strengths of this study include its randomized design, blinded assessment of bowel preparation quality, and evaluation of both efficacy and patient-reported outcomes. However, certain limitations should be acknowledged. The study was conducted at a single centre with a relatively small sample size, which may have limited the ability to detect differences in some outcomes such as adenoma detection rate. In addition, the higher proportion of split-dose preparation in the OSS group may have influenced bowel cleansing quality. The proportion of participants receiving split-dose preparation was significantly higher in the OSS group. As split-dose regimens are known to improve bowel cleansing quality, this imbalance may have influenced the observed efficacy outcomes

V. Conclusion

In conclusion, both OSS and PGA provided effective bowel cleansing for colonoscopy with acceptable safety profiles. OSS was associated with a lower rate of inadequate bowel preparation, significantly higher patient satisfaction, and shorter caecal intubation time. Although overall bowel preparation success and adenoma detection rates were comparable between the groups, the findings suggest that OSS is a well-tolerated and effective alternative to PGA for bowel preparation among Indian adults undergoing colonoscopy. Larger multicentre studies are warranted to further confirm these findings and evaluate long-term clinical outcomes.

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