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A randomized, controlled trial of oral sulfate solution versus polyethylene glycol for bowel preparation for colonoscopy

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Abstract

Background The quality of colonoscopy is significantly influenced by the effectiveness of bowel preparation. In this study, we aimed to evaluate the efficacy, safety, and tolerability of bowel cleansing between a new oral sulfate solution (OSS) and standard polyethylene glycol electrolyte powder (PEG).

Methods This single center, randomized, superiority study recruited 679 outpatients who were assigned to either the new OSS group (Group A) or standard PEG group (Group B). The quality of bowel cleansing was evaluated using the Boston Bowel Preparation Scale (BBPS) and compared between the two groups. Furthermore, data pertaining to the duration of bowel preparation, patient tolerability, and the occurrence of adverse events were also analyzed.

Results According to BBPS scores, group A demonstrated significantly higher bowel preparation cleanliness than group B. Additionally, group A achieved superior bowel cleansing, as evidenced by a greater proportion of patients with BBPS scores ≥ 8 compared to group B (75.3% vs. 55.2%, $P < 0.05$). No severe adverse events were reported during examinations in either group.

Conclusions The magnesium sulfate, sodium sulfate, and potassium sulfate concentrated oral solution is a novel, safe, and effective bowel preparation for colonoscopy.

Trial registration This study was registered in the Chinese Clinical Trial Registry on 20/02/2024 (clinical trial registration number: ChiCTR2400081004).

Keywords Bowel Preparation, Colonoscopy, Oral sulfate solution, Polyethylene glycol, Side effects

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Background

Colonoscopy is an essential tool for the screening, diagnosis, and treatment of colorectal lesions [1]. The accuracy of diagnosis and safety of treatment is inextricably linked to the quality of bowel preparation [2]. Nevertheless, 18–35% of colonoscopies are impeded by insufficient bowel preparation [3]. Inadequate bowel preparation not only diminishes the effectiveness and safety of colonoscopy but also adversely affects the adenoma detection rate and increases the costs due to repeat examinations. Tamai et al. [4] demonstrated that low-quality bowel preparations were associated with reduced adenoma detection rates.

The optimal bowel cleansing agents should include the rapid evacuation of fecal matter from the bowels, the absence of induction of changes in the colonic mucosa, the absence of discomfort, the absence of electrolyte imbalances, a palatable taste, and a reasonable cost [5]. In clinical practice, the most commonly used bowel cleansing agents include polyethylene glycol (PEG), sodium picosulfate compound, sodium phosphate, magnesium sulfate, and mannitol [6]. It is evident that none of the agents currently in use fully meet al.l the ideal criteria.

The oral sulfate solution (OSS) is a novel osmotic bowel cleansing agent comprising sodium sulfate, magnesium sulfate, and potassium sulfate [7]. Following oral administration, the solution is minimally absorbed, thereby increasing the osmotic pressure within the bowel. This osmotic shift causes water to move into the bowel lumen, increasing the volume and stretching the bowel walls, which stimulates the nerve endings in the bowel wall [8]. This reflexively enhances bowel peristalsis and facilitates bowel cleansing through defecation. OSS has shown promise for populations requiring repeated bowel preparations, such as inflammatory bowel disease (IBD) patients, with studies reporting over 90% willingness to reuse it due to its improved tolerance [9]. Nevertheless, the current literature on the efficacy and adverse reactions of OSS and PEG regimens is limited [10]. In this study, we compared the efficacy, tolerability and safety of OSS and PEG on bowel preparation, with the aim of identifying a more effective regimen for clinical bowel preparation.

Methods

Study subjects

This study was a prospective, single center, randomized, single-blind superiority trial, and was conducted in accordance with the Declaration of Helsinki and the guidelines of the Consolidated Standards of Reporting Trials (CONSORT). The study protocol was approved by the Institutional Ethics Board of the Civil Aviation General Hospital, Beijing, China (No. 2023-L-K-39) and registered in the Chinese Clinical Trial Registry (No: ChiCTR2400081004). Enrollment between October 2023 and January 2024.

Inclusion and exclusion criteria

Eligible participants were men and women aged 18 – 70 years undergoing screening, surveillance, or diagnostic colonoscopy. Patients were enrolled in the trial by clinicians during their initial assessment, prior to the procedure. All patients provided with written informed consent. The exclusion criteria were as follows: pregnant or lactating women; known or suspected gastrointestinal (GI) obstruction or perforation, severe acute IBD or diverticulitis, or active intestinal bleeding; severe renal insufficiency (glomerular filtration rate < 30 mL/min/1.73 m^2) or kidney failure (serum creatinine > 3 mg/dL for > 6 months); severe liver damage (Child-Pugh class C) [11]; heart failure (class III or IV); severe hypertension [12]; history of intestinal surgery, ascites, or heart disease; severe constipation requiring repeated use of laxatives, enemas, or physical intervention; electrolyte abnormalities identified prior to bowel preparation; prior colonoscopy within the last 6 months or participation in another clinical trial during the past 6 months; psychiatric disorders; and those who refused informed consent.

Study medications

Magnesium sulfate, sodium sulfate and potassium sulfate concentrate oral solution (OSS, SFDA Approval No. H20223027, Jumpcan Pharmaceutical Group Co. Ltd., Jiangsu, China) consists of sodium sulfate 17.5 g, magnesium sulfate 1.6 g, and potassium sulfate 3.13 g in aqueous liquid form supplied in a 177 mL plastic bottle. Polyethylene glycol electrolyte powder (PEG, SFDA Approval No. H20040034, Staldson Biopharmaceuticals Co. Ltd., Beijing, China) consists of two components, component A (polyethylene glycol 4000, 13.125 g) and component B (sodium bicarbonate 0.1785 g, potassium chloride 0.0466 g, and sodium chloride 0.3507 g). Before administration, components A and B from each box of PEG were dissolved in 750 mL of warm water.

Study colon-cleansing methods

On the day prior to the colonoscopy, patients were instructed to eat low-fiber, low-residue, and easily digestible foods [13]. Foods such as fruits, vegetables, cereals, fried or spicy items, chocolate, coffee, and tea were not allowed [14]. Patients were assigned to either the new OSS group (Group A) or the standard PEG group (Group B), each administered as an evening/morning split-dosing regimen. The first dose was administered to patients in group A between 18:00 and 20:00 one day before the examination. This involved pouring one bottle of OSS into a prepared mixing container, adding 500 mL warm water, and then drinking the entire mixture.

Subsequently, they consumed a total of approximately 1000 mL of warm water in two separate 500 mL doses within the subsequent hour, concluding this within two hours. On the morning of the colonoscopy, a second dose was administered between 7:00 and 9:00 a.m. The second OSS was diluted with water to 500 mL and consumed entirety. Over the following hour, an additional 1000 mL of warm water was consumed in two separate 500 mL doses, with each dose completed within half an hour. Patients in Group B were given two boxes of PEG two hours after the evening meal one day before the examination, with each box dissolved in 750 mL warm water and consumed within one hour. On examination day, patients consumed three boxes of PEG, dissolving each box in 750 mL warm water and consuming the entire solution within 2 h; administration began at 4:00 for morning examinations and at 8:00 for afternoon examinations.

Adequacy of bowel cleansing

The BBPS was developed by Boston Medical Centre section of gastroenterology to provide a standardized score to rate the quality of bowel preparation during colonoscopy [15]. The following criteria had to meet for a satisfactory result: score of zero indicated the presence of faces that cannot be cleared within the colon, with the mucosa not visible. Score of one was awarded in the mucosa was partially visible, with other areas obscured by faces and opaque liquid. Score of two was the presence of small amounts of faces and opaque liquid residue within the colon, with the mucosa largely visible. A score of three was the mucosa was clearly visible, with no evidence of faces or opaque liquid residue. Each segment of the colon was scored on a scale of 0 to 3, with a total score ranging from 0 to 9. Total score of at least six and a score of at least two in each segment indicated that bowel preparation was sufficient. Furthermore, the colonoscopy evaluation of intraluminal bubbles was also assessed according to the following criteria: a score of zero was indicative of the presence of numerous bubbles, which necessitated a thorough cleansing with water for observation; score of one was indicative of a lower number of bubbles, which could be observed with minimal water; score of two was indicative of the specimen exhibiting minimal to no bubbles, thus requiring no washing for clear observation. Score of 1 or 2 was considered to be satisfactory. Furthermore, the frequency of bowel movements, the rates of cecal intubation and colonoscopy, the time taken for colonoscopy, adenoma detection rate (ADR), polyp detection rate (PDR), and the quality of sleep of the two groups of patients were observed. After the colonoscopy, patients were transferred to a recovery room and monitored until they had fully recovered from sedation. They were instructed to consume a clear, cool liquid diet two hours post-procedure.

Colonoscopies were performed by six endoscopists with a mean of 10 years of endoscopic experience. To maintain blinding, patient questions about the preparation were addressed by the study coordinator. Colonoscopies were recorded and reviewed by other endoscopists for re-evaluation of bowel preparation. Endoscopic images were evaluated by two endoscopists who were blinded to the type of bowel preparation, and bowel cleansing efficacy was assessed accordingly. Any discrepancies in the BBPS scores between the two endoscopists were resolved through consensus.

Study outcomes

The primary endpoint was the comparison of the colon-cleansing efficacy, measured by the proportion of patients achieving BBPS scores ≥ 8, between the two groups. The secondary endpoints included the assessment of bowel preparation times, compliance and tolerability, procedure-related outcomes, and the incidence of adverse events in both groups. Patient tolerability and adverse events related to the bowel preparation were assessed using pre-colonoscopy questionnaires, which recorded tolerance, preparation completed, and the presence or absence of nausea, vomiting, abdominal pain or fullness, dizziness, palpitations, or other adverse events. Adverse events were assessed according to the World Health Organization (WHO) criteria [16]. Cecal intubation was defined as successful visualization and intubation of the cecum, confirmed by identifying the ileocecal valve and the triradiate cecal fold as visual landmarks [17].

Sample size and randomization

Based on the published literature, the bowel preparation compliance rate in the control group was 70%, while the experimental group demonstrated a superior compliance rate of 80% [18]. To compare these rates, a superiority assumption was employed with a superiority cut-off value of 10% [19–21] and a unilateral test conducted with a type I error rate (α) of 0.025. Assuming a 1:1 ratio for the two groups and a β of 0.20, calculations using PASS software indicated that a total of 330 patients were needed in each group. Accounting for a 10% dropout rate, a total of 363 patients were needed in each group. Participants were randomly assigned to groups using a random-number table generated by SAS statistical software, with an allocation ratio of 1:1 between group A and group B. Randomization concealment was maintained by personnel who were not involved in the colonoscopy procedure, outpatient clinic, data collection, or analysis. An unblinded study coordinator enrolled participants electronically, distributed the assigned bowel preparation, and provided instructions to participants and caregivers on its proper use. Endoscopists were prohibited from participating in any activities related to randomization or

bowel preparation before or after the colonoscopy. They were also required to avoid any discussions with patients or staff that could inadvertently disclose the type of bowel preparation used.

Data analysis

The statistical analysis was conducted using the SPSS 26.0 software for the processing and analysis of the data. We conducted both intention-to-treat (ITT) and per-protocol (PP) analyses. Quantitative data that adheres to a normal distribution was presented as the mean ± standard deviation (SD). The statistical significance of differences between two groups was evaluated using the *t*-test. The presentation of count data was in terms of the number of cases and percentages. The chi-squared test was employed for comparisons between two or more groups. A *P*-value of less than 0.05 was considered statistically significant. Efficacy tests were conducted using the SAS 9.2 software.

Results

Baseline characteristics of patients

The study flow chart is shown in Fig. 1. Thirty-nine patients in group A and eight in group B were excluded due to inadequate bowel preparation. A total of 679 participants successfully completed the study protocol and were included in the final PP analysis.

Group A included 145 males and 179 females, with an age range of 21 to 70 years and a mean age of 49.2 years. Group B consisted of 177 males and 178 females, with an age range of 20 to 70 years and a mean age of 46.0 years. No significant differences were observed between the groups regarding marital status, smoking history, sleep habits, and medical and allergy histories. However, a significantly higher proportion of patients in group B had a history of alcohol consumption compared to group A (25.6% vs. 19.1%, $P<0.05$). Additionally, group B had a higher incidence of irregular eating habits (out-eating, overeating, skipping meals and high salt diet), with 47 patients compared to 23 patients in group A (13.3% vs. 7.1%, $P<0.05$). The prevalence of hypertension was also

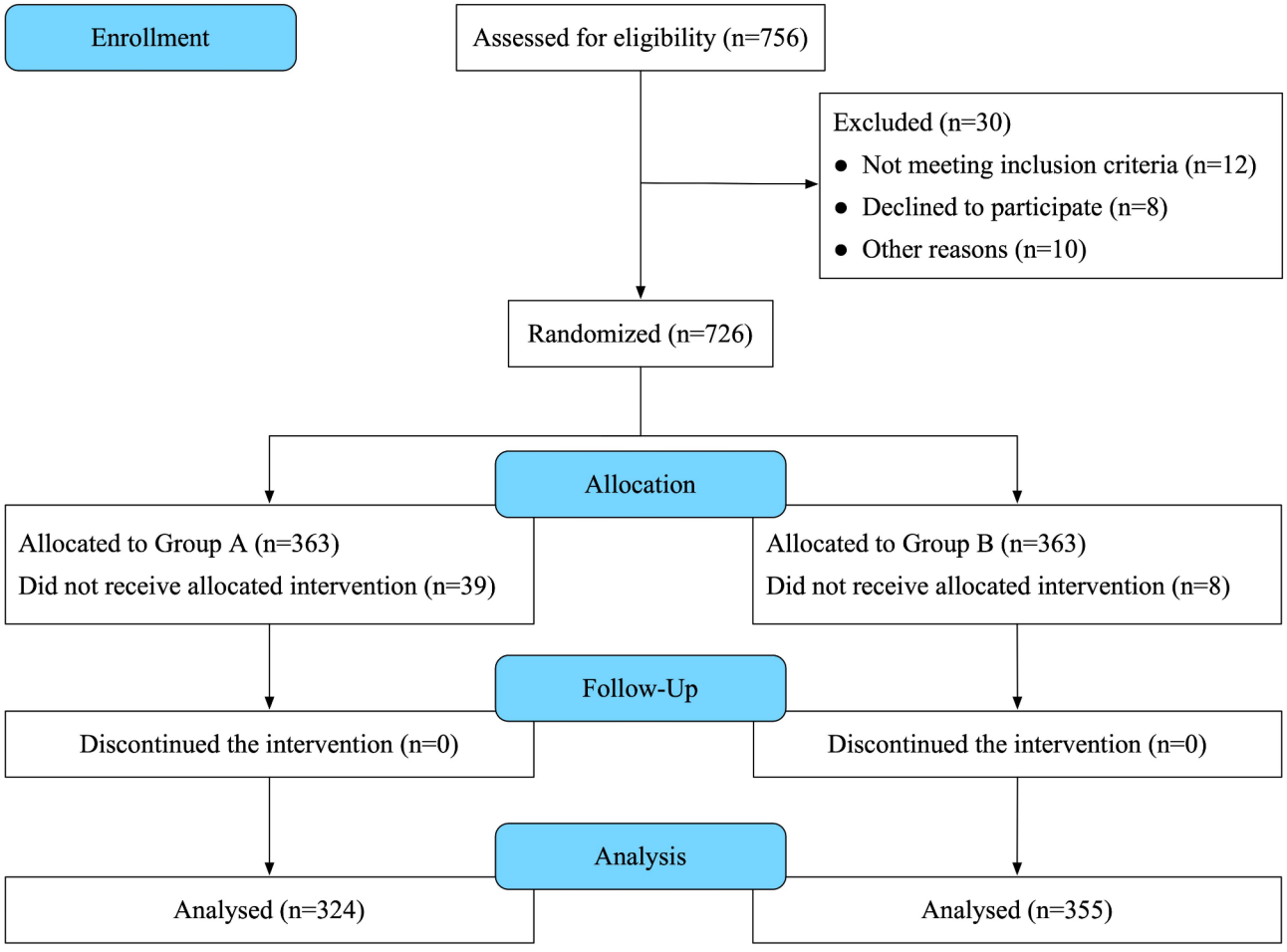

Fig. 1 Consort flow diagram of the study. Group A, magnesium sulfate, sodium sulfate and potassium sulfate concentrate oral solution; Group B, polyethylene glycol electrolyte powder

significantly higher in group B than in group A (21.4% vs. 12%, $P<0.05$). Comparisons of the baseline clinical and demographic characteristics of the two groups are presented in Table 1.

Bowel Preparation quality and adenomas detection rate

Table 2 shows the quality of bowel preparation. Compared with the group B, the group A obtained significantly higher total BBPS scores (7.2 ± 1.1 vs. 6.5 ± 1.4, $P<0.05$). Specifically, 92.3% of patients in group A achieved a BBPS score of ≥ 6, compared to 87.3% in group B. Furthermore, 84.3% of patients in group A achieved a BBPS score of 7 or higher, significantly higher than the 71.5% observed in group B ($P<0.05$). The primary analysis indicated that 75.3% of patients in group A reached a BBPS score ≥ 8, compared to 55.2% in group B ($P<0.05$). This significant difference in BBPS completion rates for scores ≥ 8 highlights the superiority of OSS treatment (Table 3). No significant differences were found between the groups regarding colonoscopy procedure duration, blind insertion time, frequency of bowel movements and ADRs (Table 4).

Adverse events

Adverse reactions observed included nausea, sleep disturbance, vomiting, abdominal pain, bloating, mucopurulent bloody stool, and rash (Table 5). In the group B, the incidence of nausea and vomiting during bowel preparation was 12.7%, which was higher than the 8.8% observed in the group A ($P>0.05$). The incidence of

Table 1 Patient demographics and baseline characteristics

Characteristic	Group A ($n=324$)	Group B ($n=355$)	Z/χ^2	P value
Gender			1.771	0.183
Male	145 (44.8%)	177 (49.9%)		
Female	179 (55.2%)	178 (50.1%)		
Age, y			3.515	0.061
≤ 60	263 (81.2%)	267 (75.2%)		
> 60	61 (18.8%)	88 (24.8%)		
BMI (kg/m^2)	24.20 ± 3.59	24.67 ± 3.98	0.334	0.112
Marital status			1.623	0.203
Unmarried	42 (13.0%)	35 (9.9%)		
Married	282 (87.0%)	320 (90.1%)		
Smoking			0.019	0.892
No	256 (79.0%)	282 (79.4%)		
Yes	68 (21.0%)	73 (20.6%)		
Drinking			4.098	0.043
No	262 (80.9%)	264 (74.4%)		
Yes	62 (19.1%)	91 (25.6%)		
Eating habits			6.908	0.009
Irregular	23 (7.1%)	47 (13.2%)		
Regular	301 (92.9%)	308 (86.8%)		
Sleep habits			0.361	0.548
Irregular	50 (15.4%)	49 (13.8%)		
Regular	274 (84.6%)	306 (86.2%)		
Medical history			0.244	0.622
No	240 (74.1%)	257 (72.4%)		
Yes	84 (25.9%)	98 (27.6%)		
Allergy history			0.832	0.362
No	313 (96.6%)	338 (95.2%)		
Yes	11 (3.4%)	17 (4.8%)		
Comorbidities				
Diabetes	24 (7.4%)	22 (6.2%)	0.393	0.531
Hypertension	39 (12.0%)	76 (21.4%)	10.575	0.001
Severe organ dysfunction	5 (1.5%)	11 (3.1%)	1.781	0.182
Cancer	0 (0%)	6 (1.7%)	N/A	N/A
Autoimmune disease	0 (0%)	2 (0.6%)	N/A	N/A
Anemia	0 (0%)	2 (0.6%)	N/A	N/A
Constipation	1 (0.3%)	1 (0.3%)	N/A	N/A

BMI, body mass index. Data are presented as mean ± standard deviation or number (percentage) as appropriate

Table 2 Comparison of bowel Preparation between two groups (BBPS)

Characteristic	Group A (*n* = 324)	Group B (*n* = 355)	Z/χ^2	*P* value
BBPS	7.2 ± 1.1	6.5 ± 1.4	6.120	< 0.001
BBPS			4.507	0.034
< 6	25 (7.7%)	45 (12.7%)		
≥ 6	299 (92.3%)	310 (87.3%)		
BBPS			15.750	< 0.001
< 7	51 (15.7%)	101 (28.5%)		
≥ 7	273 (84.3%)	254 (71.5%)		
BBPS			29.997	< 0.001
< 8	80 (24.8%)	159 (44.8%)		
≥ 8	244 (75.3%)	196 (55.2%)		

Data are presented as mean ± SD or number (percentage) as appropriate. BBPS: Boston bowel preparation scale

Table 3 Superiority testing results for BBPS

Indicator	Point estimate	95% CI	Z	*P* value
BBPS ≥ 6	0.0496	0.0044 – 0.0948	-2.1860	0.9856
BBPS ≥ 7	0.1271	0.0657 – 0.1885	2.8644	0.1937
BBPS ≥ 8	0.2010	0.1311 – 0.2708	2.8328	0.0023

BBPS: Boston bowel preparation scale

abdominal pain and bloating was low in both groups, with no serious adverse reactions reported. No patients withdrew from the examination due to adverse reactions in either group.

Discussion

We conducted a prospective, single center, randomized, single blind superiority trial comparing the efficacy, safety, and tolerability of OSS and PEG bowel preparations. This study is the first to analyze the efficacy and acceptability of OSS, the first newly approved agent for bowel cleansing available in China since 2022, among patients in Beijing. Our findings demonstrated that OSS was superior to PEG in bowel cleansing, as indicated by a higher proportion of patients achieving BBPS scores ≥ 8. Tolerability and adverse events associated with both preparations were comparable and generally acceptable.

PEG is a commonly used bowel cleanser both nationally and internationally. However, its disadvantages include the need for large amounts of liquid and poor taste. Statistical data suggest that between 5% and 15% of patients are unable to complete bowel preparation due to the large volume of PEG solution or its unpleasant taste, significantly reducing medication compliance [22]. After oral administration, mannitol creates a hyperosmotic

Table 4 Procedure-related outcome

Characteristic	Group A (*n* = 324)	Group B (*n* = 355)	Z/χ^2	*P* value
Completion time (min)	12 (10, 15)	12 (10, 15.)	1.046	0.296
Cecal intubation time (min)	3 (2, 4)	3 (2, 5)	-1.848	0.065
Bowel movements frequency	10 (8, 10)	10 (8, 10)	-0.218	0.828
Adenoma	107 (33.0%)	120 (33.8%)	0.046	0.830
Polyps	81 (25.0%)	79 (22.3%)	0.076	0.732
≤ 5 mm Polyps	61 (18.8%)	65 (18.3%)	0.273	0.594
Transverse colon polyp	31 (9.6%)	28 (7.9%)	0.103	0.712
Left colonic polyp	30 (9.3%)	29 (8.2%)	0.029	0.891
Right colonic polyp	57 (17.6%)	56 (15.8%)	0.071	0.803

Data are presented as median (interquartile range) or number (percentage) as appropriate. Bowel movement frequency: The frequency of bowel movements in patients following the administration of the medications was assessed through self-reported data

Table 5 Comparison of adverse events

Characteristic	Group A (*n* = 324)	Group B (*n* = 355)	Z/χ^2	*P* value
Nausea and Vomiting	28 (8.6%)	45 (12.7%)	2.873	0.090
Sleep disturbance	56 (17.3%)	61 (17.2%)	0.001	0.972
Rash	1 (0.3%)	0	N/A	N/A
Abdominal Pain	2 (0.6%)	1 (0.3%)	0.439	0.608
Mucopurulent Bloody Stool	1 (0.3%)	0	N/A	N/A
Bloating	4 (1.2%)	5 (1.4%)	0.039	1.000

Data are presented as number (percentage). N/A, not applicable. Sleep disturbance was assessed using the validated Chinese version of the Athens Insomnia Scale (AIS), with a cut-off score of ≥ 6 indicating the presence of insomnia

state in the intestinal lumen, reducing water absorption in the intestine and promoting the entry of fluid into the intestinal lumen, thereby achieving bowel cleansing [23]. However, as a hyperosmotic solution, its use can easily disrupt water and electrolyte balance, causing significant gastrointestinal irritation and leading to nausea, vomiting, bloating and abdominal pain [24]. There have been reports of explosive complications during bowel cleansing with mannitol, attributed to the production of hydrogen and methane gases during the fermentation process of mannitol [25]. Other bowel prep agents, including sodium picosulfate, sodium phosphate and magnesium sulfate, have been associated with risks of electrolyte imbalance, intestinal mucosal inflammation, arrhythmias and other adverse events [26].

Unlike phosphate-based detergents, OSS does not cause acute phosphate nephropathy, reducing the incidence of bowel preparation failures due to side effects and improving bowel preparation success [27]. Multicenter randomized controlled trials show that OSS has a higher bowel preparation success rate compared to 4 L PEG and sodium picosulphate mixtures, with significantly higher adenoma detection rates [28]. Phase III clinical trials registered in China have shown that split-dose OSS significantly improves whole and segmental colon BBPS scores compared to 3–4 L PEG regimens, particularly in the more difficult-to-clean right colon [29]. In addition, OSS facilitates faster defecation (64.5 vs. 90.0 min, $P<0.01$) and produces clearer watery stools (174.0 vs. 230.0 min, $P=0.012$) without disrupting sleep and with a lower proportion of patients requiring nocturnal defecation (32.0% vs. 44.3%) [30]. However, in a meta-analysis involving 2049 participants, the adequate bowel preparation rate in OSS was not significantly different from that of the low-volume PEG (93.3% vs. 90.6%, $P=0.16$) [8]. Furthermore, OSS did not significantly improve patient compliance compared to PEG [31]. This may be attributed to the comparable total volume of OSS intake and low-volume PEG, as well as the higher frequency of nausea and vomiting associated with OSS. Additionally, abdominal pain was reported more frequently with OSS than with 4 L PEG [32].

This study showed that patients in group A taking OSS consumed a total of 3 L of the solution, while the group B needed 3.75 L PEG in divided doses to complete the preparation. OSS demonstrated excellent tolerability, with participants expressing willingness to repeat if necessary. Several properties of OSS likely contribute to favorable tolerability, including palatable taste, reduced volume for ingestion, and the flexibility to supplement with clear liquids of the patient's choice. These characteristics improve patient compliance and enhance the overall bowel preparation experience, making OSS a preferred option in clinical practice. During the preparation process, bowel frequency and sleep disturbance were similar in both groups. In terms of bowel cleanliness, the group A achieved a higher BBPS, confirming the superiority of OSS. High-quality bowel preparation significantly enhances the adenoma ADR, including diminutive lesions and sessile serrated polyps [33, 34]. Elevated ADRs have been directly correlated with a reduction in both the incidence and mortality of colorectal cancer (CRC), underscoring the critical role of optimal bowel preparation in colorectal cancer screening programs [35]. Excellent bowel preparation enhances the detection of polyps and adenomas, which can subsequently reduce medical expenditures. From a cost-savings perspective, the use of OSS as a cleansing agent is considered to have the potential to increase polyp and adenoma detection during colonoscopy [7]. Although there was no significant statistical difference in cecal intubation times, colonoscopy duration or adenoma detection rates between the two groups, cecal intubation time was slightly shorter in the group A. This may be due to the higher level of bowel cleanliness, which shortened the cecal intubation time. Study has found that the cleanliness of bowel preparation with OSS was superior to that with PEG, significantly reducing cecal intubation time [36]. Recent studies have also confirmed the low incidence of adverse events with OSS, demonstrating its safety [37]. The majority of CRC are sporadic and typically arise from precancerous lesions, such as adenomas or polyps [38]. Lifestyle factors have been shown to influence the risk of CRC, with alcohol consumption being a significant contributor to an increased risk of adenomatous colorectal polyps [39, 40]. Conversely, adopting healthy dietary patterns has been associated with a 70% reduction in the risk of developing CRC [41]. The absence of a statistically significant in adenoma and polyp detection rates between the two groups may be attributed to the relatively small sample size, which may have limited the statistical power to detect meaningful differences.

The current study acknowledges several limitations. Specifically, blood electrolyte tests were not conducted before or after bowel preparation. Future research could benefit from incorporating relevant electrolyte assessments. Furthermore, as a single-center study, this investigation has methodological limitations, including the use of a 10% superiority threshold, which may not fully account for clinical heterogeneity across diverse populations or healthcare systems. These limitations underscore the necessity of multicenter validation to confirm external validity and guide broader implementation.

Conclusion

In summary, the low-volume OSS regimen is effective, convenient to administer, well tolerated by patients and highly safe. It is therefore highly recommended for widespread clinical use.

Abbreviations

OSS	Oral sulfate solution
PEG	Polyethylene glycol electrolyte powder
BBPS	Boston Bowel Preparation Scale
CONSORT	Consolidated Standards of Reporting Trials
ITT	Intention-to-treat
PP	Per-protocol
BMI	Body mass index

Author contributions

CJP: study design, data analysis, data interpretation, and manuscript writing. GYH: study design and critical revision of the manuscript. XDL, FJH and FCJ: patient recruitment, material preparation, and data collection. All authors have read and approved the submitted manuscript.

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None.

Data availability

The datasets used during the current study are available from the corresponding author on reasonable request.

Declarations

Ethics approval and consent to participate

Approved by the Institutional Ethics Board of the Civil Aviation General Hospital, Beijing, China (No. 2023-L-K-39) and registered in the Chinese Clinical Trial Registry (No: ChiCTR2400081004). All patients provided with written informed consent. The study was conducted in accordance with the principles of the Declaration of Helsinki.

Consent for publication

Not applicable.

Competing interests

The authors declare no competing interests.

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