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Oral sulfate solution versus Polyethylene glycol solution for bowel preparation for colonoscopy: A randomised controlled trial in a tertiary care centre

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Abstract

Background: Colonoscopy is an indispensable procedure in the armamentarium of an endoscopist to diagnose the pathologies of the distal gastrointestinal tract. A well-prepared bowel is mandatory for an ideal colonoscopy aiding the diagnosis. The aim of the study was to compare the palatability, tolerance, volume and side effects of Polyethylene Glycol (PEG) solution as well as Oral Sulfate Solution (OSS) for bowel preparation and to assess the quality of bowel preparation using Boston Bowel Preparation Scale (BBPS) in a controlled, randomised, and double-blinded manner.

Methods: 200 patients were randomly assigned in both the groups (OSS vs PEG) where they completed a questionnaire regarding their experience with the ease of consuming the solution, the taste of the solution used, any side effects, number of stools passed and the consistency of the stools passed. The BBPS was used to grade the bowel cleansing quality of each solution and cecal intubation time.

Results: There was significant statistical difference on comparison of the taste with better tolerability in OSS group. All the adverse events were mild to moderate in intensity and their frequencies were comparable in both the groups. The OSS group had better bowel preparation as per the BBPS (p= 0.001) and lesser cecal intubation time (p= 0.001).

Conclusion: The present study demonstrated that 1 litre of OSS is better than the 2 litre PEG solution, in terms of palatability, bowel preparation and shorter cecal intubation time.

Keywords: Colonoscopy, Bowel preparation, Polyethylene glycol, Oral sulfate solution, Boston Bowel Preparation Scale.

Introduction:

Colonoscopy is an indispensable procedure in the armamentarium of an endoscopist to diagnose the pathologies of the distal gastrointestinal tract i.e., distal small bowel, large bowel, rectum and anal canal.[1] The diagnostic abilities

are unrivalled as compared to the other radiological imaging procedures as it enables direct visualization of the lumen and also facilitates biopsy and endoscopic procedures. An inadequate bowel preparation may lead to an incomplete, sub-standard colonoscopy which will require either repeating the procedure or alternative investigations which is cumbersome, time consuming and also adds to the financial burden of the patient. A well-prepared bowel is mandatory for an ideal colonoscopy which will facilitate in clinching the diagnosis for e.g., better adenoma and polyp detection rates.[2]

Several commercially available preparations like Polyethylene Glycol (PEG) solution and a formulation of sodium sulfate, potassium sulfate and magnesium sulfate also called Oral Sulfate Solution (OSS) have been used for bowel preparation prior to colonoscopy.[3] Currently, PEG is considered the safest and hence is the most commonly used bowel cleansing agent.[4] This osmotically balanced oral laxative solution is poorly absorbed in the intestine and causes water to be retained within the lumen of the intestine inducing copious diarrhea. The downsides of PEG are that the patient has to consume large volume of the solution along with water and the unpleasant taste reduces patient compliance. A new low-volume bowel preparation agent, OSS, has recently been approved for pre-colonoscopy bowel cleansing in 2009 with proven efficacy and safety in various studies.[5,6] The purpose of this study was to compare the tolerability and efficacy of 1 litre (L) OSS vs 2 L PEG solution in a single day bowel preparation.[7]

Aims and Objectives:

This study was performed at a single tertiary care centre in the department of Medical Gastroenterology with the aim of comparing the quality of the bowel preparation as determined by a pre-existing widely accepted metric which is the Boston Bowel Preparation Scale (BBPS)[8,9] between PEG and OSS along with the other important variables such as palatability, tolerance, volume and associated side effects.[10] The study was designed as a controlled, randomised, and double-blinded investigation with a demographically matched sample size of 200 participants, 100 participants in each group. The patients in each of these groups were carefully matched with respect to the indications warranting the colonoscopy in order to minimize any bias in the outcomes.

Materials and Methods:

In the proposed study, keeping in mind the Helsinki protocol, we enrolled 200 participants in a tertiary care centre in a randomised, double-blinded manner focusing on the efficacy of bowel preparation by OSS and PEG. The study was conducted from March 2023 to August 2023. Data was meticulously gathered through observational techniques. Participants from both genders aged 12 years and above were selected randomly from the outpatient (OPD) and inpatient (IPD) departments for screening, surveillance and diagnostic colonoscopy. However, strict exclusion criteria had been established barring individuals below the age of 12 years, those with congestive cardiac failure (CCF), severe renal insufficiency (GFR <30 ml/min/1.73m^2), ascites, patients with a surgical history of extensive colonic resection, individuals diagnosed with inflammatory bowel disease (IBD), and pregnant or lactating women.

The patients in the PEG group were orally administered 137.15 g of a PEG solution mixed in 2 L of water, while the OSS group ingested 117 ml of OSS mixed with water to create a 500 ml solution in total, wherein two such bottles were prepared and given within one hour with the preparation being initiated 6 to 8 hours prior to the planned colonoscopy.

The potential benefits of exploring an alternative agent for bowel preparation is essential not only to cleanse the bowel better leading to a more effective colonoscopy but also to mitigate the potential risks, including abdominal discomfort, nausea, vomiting, bloating, and electrolyte disturbances posed by the current PEG based regimes. Patient compliance also improves when the solution required to be consumed is less in volume and more palatable. By comparing OSS against PEG, OSS has shown not to alter the serum electrolyte balance.[10] We have not merely paved the way for prospective advancements aimed at enhancing the diagnostic process of colonoscopic procedures, but concurrently, we have accorded significant innovations directed towards bettering the diagnostic capabilities of colonoscopy and given due attention towards refining the pre-colonoscopy preparation experience making it more

patient centric. OSS has shown to be more efficacious with similar safety profile[11] and has also proven to be better accepted by the patients undergoing pre-colonoscopy bowel preparation.

Statistical Analysis:

The data was coded and entered into Microsoft Excel spreadsheet. Analysis was done using IBM SPSS (SPSS Inc., IBM Corporation, NY, and USA) Statistics Version 25 for Windows software program. Descriptive statistics included computation of percentages, means and standard deviations. The data were checked for normality before statistical analysis using Kolmogorov Smirnov test. The student's t-test (for quantitative data to compare two independent observations) was applied. The chi square test was used for qualitative data comparison of all clinical indicators. Level of significance was set at $p \leq 0.05$.

Results:

We included 200 patients in our study from both the outpatient and inpatient departments at Mahatma Gandhi Medical College and Hospital, Sitapura, Jaipur. 100 patients received PEG and 100 patients were prepared using OSS. The PEG group comprised of 67 males (67%) and 33 females (33%) in comparison to the OSS group which included 65 males (65%) and 35 females (35%). It was also noted that there was no gender bias (p= 0.76) and the mean age of the study population was 46.01 years in the OSS group and 48.8 years in the PEG group which were similar in both the comparison groups.

In our study we also ensured that the patients in both the groups were distributed evenly with respect to the indications for colonoscopy. The most common indication was haematochezia in both the study groups. Table 1 shows the indications for colonoscopy in our study.

Table 1. Indications for colonoscopy

			Groups		Total
			OSS	PEG	
Indication	Abdominal Koch's	n	1	1	2
		%	1.0%	1.0%	1.0%
	Altered bowel habits	n	1	6	7
		%	1.0%	6.1%	3.5%
	Anemia	n	14	19	33
		%	14.1%	19.2%	16.7%
	Chronic diarrhea	n	6	10	16
		%	6.1%	10.1%	8.1%
	Colorectal cancer screening	n	4	0	4
		%	4.0%	0.0%	2.0%
	Constipation	n	5	8	13
		%	5.1%	8.1%	6.6%
	Fissure in ano	n	0	1	1
		%	0.0%	1.0%	0.5%
	Hematochezia	n	29	21	50
		%	29.3%	21.2%	25.3%
	Inflammatory bowel disease	n	2	1	3
		%	2.0%	1.0%	1.5%
	Irritable bowel syndrome	n	1	1	2
		%	1.0%	1.0%	1.0%

Melena	n	5	9	14
	%	5.1%	9.1%	7.1%
Pain abdomen	n	22	16	38
	%	22.2%	16.2%	19.2%
Rectal pain	n	1	0	1
	%	1.0%	0.0%	0.5%
Significant weight loss	n	6	2	8
	%	6.1%	2.0%	4.0%
Suspected partial intestinal obstruction	n	3	5	8
	%	3.0%	5.0%	4.0%
Total	n	100	100	200
	%	100.0%	100.0%	100.0%

Following the administration of the preparatory agents, the stool frequency was noted and it was concluded that patients being given OSS had statistically significant increase in the number of passage of stools compared to the PEG group (OSS- 8.91 vs PEG- 8.05, p= 0.001) which was indicative of a better bowel cleanse which meant better preparation (Table 2). This was confirmed when we compared the bowel preparation of these agents with the widely accepted standard of bowel preparation called the BBPS (OSS- 100% adequate vs PEG-78% adequate, p= 0.001) (Table 3).

Table 2. Stool frequency

	Mean	Std. Deviation	Minimum	Maximum	*p* value
OSS	8.91	1.464	5	12	0.001
PEG	8.05	1.702	5	12	

Table 3. Boston Bowel Preparation Scale

			Groups		*p* value
			OSS	PEG	
BBPS	Adequate	n	100	78	0.001
		%	100.0 %	78.0%	
	Inadequate	n	0	22	
		%	0.0%	22.0%	
Total		n	100	100	
		%	100.0 %	100.0%	

The mean cecal intubation time taken in the OSS group was 12.84 minutes vs 16.33 minutes in the PEG group which

was statistically significant (p= 0.001) (Table 4). This also meant faster and more efficient colonoscopy in the OSS group.

Table 4. Cecal intubation time

	Mean	Std. Deviation	Minimum	Maximum	*p* value
OSS	12.84	3.107	8	20	0.001
PEG	16.33	2.775	7	19	

Volume and taste of the bowel preparatory agent have been limiting factors in the preparation of patients undergoing colonoscopy. With the help of a questionnaire filled by the patients who were blinded about the solution being given, showed that both the taste (OSS- 100% vs PEG- 93%, p= 0.01) and lesser volume (OSS- 1L vs PEG- 2L, p= 0.01) in the OSS group were a welcome advantage.[10]

Table 5. Palatability/ Taste

			Groups		*p* value
			OSS	PEG	
Palatability/taste	Nausea	n	0	1	0.01
		%	0.0%	1.0%	
	Non-Palatable	n	0	7	
		%	0.0%	7.0%	
	Palatable	n	100	92	
		%	100.0%	92.0%	

The side effect profile was better in the OSS group. 82% patients experienced no side effects in the OSS group vs 78% in the PEG group. However, this was not significant. The most common side effect in both the groups was nausea which was 14% in OSS group and 10% in PEG group; however, bloating was 7% in PEG group vs 4% in OSS group. None of the groups showed any major side effects warranting prolonged admission, observation or biochemical analysis.

We were able to diagnose and complete the investigation in all the patients in our study using both the agents as indicated by the following table (Table 6).

Table 6. Colonoscopic findings

			Groups		Total
			OSS	PEG	
Colonoscopic finding	Abdominal Koch's	n	4	3	7
		%	4.0%	3.0%	3.5%
	Ascending colon growth	n	2	3	5
		%	2.0%	3.0%	2.5%
	Cecal growth	n	1	2	3

	%	1.0%	2.0%	1.5%
Cecal ulcers	n	3	1	4
	%	3.0%	1.0%	2.0%
Colonic polyposis	n	0	1	1
	%	0.0%	1.0%	0.5%
Colonic telangiectasia	n	1	0	1
	%	1.0%	0.0%	0.5%
Colonic ulcers	n	11	8	19
	%	11.1%	8.1%	9.6%
Descending colon growth	n	1	1	2
	%	1.0%	1.0%	1.0%
Descending colon polyp	n	1	1	2
	%	1.0%	1.0%	1.0%
Descending colon ulcer	n	1	0	1
	%	1.0%	0.0%	0.5%
Diverticulosis	n	1	1	2
	%	1.0%	1.0%	1.0%
External compression seen in right colon	n	0	1	1
	%	0.0%	1.0%	0.5%
Extrinsic rectal compression	n	2	0	2
	%	2.0%	0.0%	1.0%
Hepatic flexure growth	n	1	1	2
	%	1.0%	1.0%	1.0%
Hepatic flexure ulcers	n	0	1	1
	%	0.0%	1.0%	0.5%
Ileal ulcers	n	1	1	2
	%	1.0%	1.0%	1.0%
Inflammatory bowel disease	n	5	5	10
	%	5.1%	5.1%	5.1%
Internal hemorrhoids	n	27	33	60
	%	27.3%	33.3%	30.3%
Mid transverse colon narrowing	n	2	0	2
	%	2.0%	0.0%	1.0%
Multiple sigmoid colon polyps	n	1	1	2
	%	1.0%	1.0%	1.0%
Normal study	n	19	23	42
	%	19.2%	23.2%	21.2%
Rectal growth	n	7	5	12
	%	7.1%	5.1%	6.1%
Rectal polyps	n	4	3	7
	%	4.0%	3.0%	3.5%
Rectal stricture	n	2	2	4
	%	2.0%	2.0%	2.0%

	Rectal ulcer	n	0	1	1
		%	0.0%	1.0%	0.5%
	Rectosigmoid growth	n	1	1	2
		%	1.0%	1.0%	1.0%
	Sigmoid colon narrowing	n	0	1	1
		%	0.0%	1.0%	0.5%
	Transverse colon growth	n	2	0	2
		%	2.0%	0.0%	1.0%
Total		n	100	100	200
		%	100.0%	100.0%	100.0%

None of these patients required a repeat colonoscopy. However, it was determined that the OSS group showed better preparation, faster caecal intubation, palatability, tolerability as compared to PEG group.

DISCUSSION:

In a carefully matched patient demographic with similar indications for undergoing colonoscopy, the OSS group exhibited several integral advantages over the PEG group. The participants in the OSS group reported a heightened frequency of stool passage, culminating in a more thorough bowel cleansing as determined by the BBPS and better adenoma and polyp detection rate. The OSS regimen necessitated the intake of lesser volume, coupled with enhanced palatability, thereby increasing patient compliance. Lastly, the OSS group was associated with shorter cecal intubation time, further underscoring its efficacy by making colonoscopy less time consuming and more efficient.

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