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Comparing the efficacy of oral mannitol and sodium phosphate for bowel preparation before colonoscopy: A randomized controlled trial.

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Abstract

Background

For a colonoscopy to be accurate, the colon must be clear. This is accomplished with dietary adjustments and the use of bowel-clearing drugs. Although sodium phosphate and mannitol taken orally are alternatives, more research is required to identify which is a better colon cleansing agent to achieve the best possible colonoscopy outcomes.

Objective

To compare the cleansing properties of oral mannitol to sodium phosphate as bowel preparatory agents for colonoscopy.

Patients and Methods

A study was conducted at the University of Abuja Teaching Hospital to compare oral mannitol and sodium phosphate for colonoscopy preparation. Participants were randomly assigned to one of the two groups and their bowel cleanliness was assessed using the Aronchick scale.

Result

In this study, sixty-six patients with comparable reasons for a colonoscopy were divided into groups and given either oral mannitol or sodium phosphate. Using the Aronchick grading method, sodium phosphate showed reduced stomach fullness, a greater completion rate (97.0 percent vs. 21.2 percent), and a better capacity for stool cleansing. The only notable difference between the two groups' side effects was that mannitol caused higher abdominal fullness.

Conclusion

Sodium phosphate provided superior bowel cleanliness compared to oral mannitol in this study, despite being less palatable and less affordable. However, due to limitations in study size and validation tools, further research with a larger sample and diverse centres is needed to definitively determine the optimal colonoscopy preparation agent.

Keywords: Mannitol, Sodium phosphate, Bowel preparation, Colonoscopy.

1. Introduction

Colonoscopy involves an examination of the colon using a flexible tube and camera, starting from the ano-rectum up to the caecum. It helps detect, localize, and characterize tumors, allowing biopsy and diagnosis. The procedure is done in various settings using advanced video colonoscopes with fragile components(1–3).

Common in patients over 50, colonoscopies serve diagnostic and therapeutic purposes, including cancer screening, surveillance, and treating bowel pathologies. Incomplete procedures often result from inadequate bowel preparation, with non-completion rates at 11 to 12 percent (1, 4, 5).

Bowel preparation is crucial, involving oral laxatives to swiftly clear the colon without causing imbalances. Despite being uncomfortable, it's vital for diagnostic accuracy, examination speed, and reducing incomplete procedures. The study compared oral mannitol to sodium phosphate for colonoscopy preparation, emphasizing the latter's effectiveness and cost (1, 2).

2. Theoretical Framework.

Bowel preparation is a vital requirement for successful colonoscopy, ensuring clear mucosal visualization for lesion detection. While patient discontent is not uncommon, it is important to keep in mind that optimal outcomes depend on excellent cleanliness. Inadequate preparation, occurring in up to 25% of cases, poses risks such as adverse events and prolonged procedure time, impacting caecal intubation and adenoma detection rates. Predictors of poor preparation include previous ineffectiveness, communication gaps, inpatient status, drug use, obesity, age, and comorbidities (6–9).

Patient involvement in the preparation process is crucial, requiring clear instructions and guidance. Adequate cleansing, allowing the detection of colonic polyps ≥5mm, is achievable with a liquid-only diet and low-fiber meals. Clear instructions, emphasizing the importance of colonoscopy, dietary requirements, and agent preparation, aid patient compliance. The common route for preparatory agents is oral, with contraindications including ileus, gastric retention, suspected obstruction, severe colitis, and impaired neurological or cognitive status (9–11).

Risk factors for inadequate preparation include patient-related factors like age, comorbidities, and gender, as well as procedure-related factors like adherence, purgative timing, and appointment waiting time. Reduced colonic bulk is achieved using dietary formulas that include clear fluids and low-residue meals. It is important to examine the osmotic qualities of bowel preparation agents in terms of patient tolerance and cleansing efficacy.(12–16).

3. Mannitol:

Mannitol is a hyper-osmotic diuretic, and renal vasodilator that acts as a bowel preparation drug by causing osmotic diarrhea especially when taken in a large dose. As a polyol (sugar-alcohol), it is digested by colonic flora, specifically Escherichia coli. Its attributes include being cost-effective, readily available, palatable, rapidly effective, and widely accepted, making it prevalent in low-resource areas. Orange or lemon juice can be added to mannitol preparations, which are typically 10 to 20 percent concentrated, to enhance their flavor. Adverse effects include dehydration, nausea, abdominal cramps, dyselectrolytaemia, and potential explosive effects during electro-cautery, mitigated by proper bowel preparation techniques and the use of specific antibiotics and insufflation gases (17–19).

4. Sodium Phosphate:

Sodium phosphate, available in aqueous or tablet form, is a hyperosmotic lavage solution with higher tolerability than high-volume polyethylene glycol solutions. However, it causes significant fluid shifts with electrolyte abnormalities, limiting its use in certain patient populations, including those with renal, cardiac, and hepatic dysfunction. Fleet phospho-soda, a sodium phosphate preparation, enhances palatability when taken with clear sugar soft drinks or juice. Despite its benefits, such as improved tolerance, enhanced bowel preparation, better mucosal visualization, and decreased aspiration risk due to its lower volume, sodium phosphate may alter colonic mucosa characteristics, potentially leading to complications like aphthous ulcers and elevated blood urea nitrogen levels with associated risks of seizures, acute renal failure, and nephrocalcinosis (17, 20–22).

5. Aronchick Scale

The Aronchick scale, the first evaluated bowel preparation quality scale for reliability, rates preparation based on the percentage of residual stool during initial inspection before mucosal irrigation. With a scale ranging from 1 to 5, it categorizes preparations as Excellent (small volume of clear fluid, >95% mucosa seen), Good (large volume of clear fluid, 5%-25% on the surface but >90% mucosa seen), Fair (semisolid stool washable, >90% mucosa seen), Poor (unwashable semisolid stool, <90% mucosa seen), and Inadequate (requires repeat preparation). This scale

primarily assesses preparation quality upon the initial inspection of the bowel (23).

The Aronchick Grading Scores:

1. **Excellent**: small volume of clear fluid i.e. >95% mucosa seen.
2. **Good**: large volume of clear fluid 5%-25% on the surface but greater than 90% of mucosa seen.
3. **Fair**: semisolid stool that can be washed away, but greater than 90% mucosa seen.
4. **Poor**: semisolid stool that could not be washed. Less than 90% mucosa seen.
5. **Inadequate**: repeat preparation needed.

6. Research Questions

Does oral mannitol offer comparable efficacy to sodium phosphate for bowel preparation before colonoscopy?

7. Research Hypothesis

Null Hypothesis:

For patients undergoing colonoscopy, there is no difference in the efficacy of oral mannitol compared to sodium phosphate for achieving adequate bowel preparation.

Alternative Hypothesis:

For patients undergoing colonoscopy, oral mannitol is either more or less effective than sodium phosphate for achieving adequate bowel preparation.

8. Justification

To the best of our knowledge, there is no ideal bowel preparatory agent worldwide, and those available in developed nations are relatively expensive to procure. The nature of this study in Nigeria with respect to patient's outcome following the use of both preparatory agents in comparison with a standard validation tool had not been carried out, hence justifying the need for this study. This is important to assess the cost-effectiveness of the bowel preparation agents, and to allow for cleanliness of the large gut, to allow for seamless colonoscopy procedure to pick up colorectal lesions and reduce the burden of repetition or postponement of procedure on both the patient and the endoscopist.

9. Aims and Objectives

Aim:

The aim of this study is to compare the efficacy of oral mannitol with that of sodium phosphate for bowel preparation for colonoscopy in University of Abuja Teaching Hospital (UATH), Nigeria.

Objectives:

To compare the efficacy of oral mannitol versus sodium phosphate for bowel preparation for colonoscopy using the Aronchick scoring system.

To compare patients' tolerance and side effects following the use of oral mannitol versus sodium phosphate for bowel preparation for colonoscopy.

10. Research design.

This was a prospective Cohort Study.

11. Description of the Study Area:

The survey was carried out in the Endoscopic Suite, University of Abuja Teaching Hospital, Gwagwalada Federal Capital Territory (FCT) Abuja, Nigeria. The hospital attends to patients within the Federal Capital Territory, Kogi, Niger, Nasarawa and Kaduna states. Gwagwalada town is located on latitude 8.94°N and Longitude 7.09°E. It is an urban town located in the North-central geopolitical zone of Nigeria. It is one of the six area councils including Abuja Municipal Area Council that makes up FCT.

12. Population of the study

Patients with indications for colonoscopy for diagnostic, therapeutic and screening purposes were recruited for the study. Recruited patients were randomized using simple randomization by the endoscopic Nurse based on lottery into two groups with one group receiving oral mannitol (group A) for bowel preparation while the other group will have sodium phosphate (group B) as bowel preparatory agent.

13. Sample and Sampling Procedure

All adult patients (18 years and above) who presented with third and fourth-degree haemorrhoids through the surgical outpatient clinics and emergency departments of the Department of Surgery, University of Abuja Teaching Hospital, Gwagwalada, Abuja, Nigeria, over a period of one year (August 2022 to July 2023) and who consented to participate in the study. Patients less than 18

years, or patients with anal cancers, colorectal tumors, chronic liver disease, coagulopathies, coexisting anal fissures and fistulae, recurrent disease following previous haemorrhoidectomy, and patients with other serious comorbidities that may contraindicate surgery were excluded from the study. Eligible patients were by simple random sampling assigned to either open (Group A) or closed (Group B).

14. Period of Study

This study was carried out over one year from January 2020 to December 2020

15. Study Eligibility

Inclusion Criteria

All consenting patients between 18 to 70 years of age for colonoscopy.

Patients with normal levels of serum electrolytes, blood urea and creatinine.

Exclusion Criteria

Patients who were in this research protocol were informed about the study, provided written consent, and had the option to withdraw at any stage. Approval was obtained from the Health Research Ethics Committee of the University of Abuja Teaching Hospital. The endoscopist, experienced with a success rate of 90%, was blinded to the bowel preparatory agent to reduce bias. Patient proforma record included biodata, indications, and complications, while the study proforma included the Aronchick bowel preparation scale.

16. Protocol

The bowel preparation procedure involved simple randomization into two groups (mannitol and sodium phosphate). Both groups adhered to a low-residue diet three days before colonoscopy. Mannitol group received 500mls of 10% mannitol thrice daily, while the sodium phosphate group had 45ml solution morning and evening. A strict clear liquid diet and 5 liters of water were prescribed. Outcome measures included the Aronchick scale for bowel cleansing and patient tolerability.

During colonoscopy, patients received sedation or analgesia based on tolerance. The procedure, conducted by the endoscopist and researchers, used an Olympus CV-170 video endoscopy system. The colonoscope was introduced, reaching the caecum, and visualizing the entire colonic mucosa. Lesions were identified, photographed, and biopsied when necessary. The endoscopist filled the proforma on the procedure's outcome. Patients who declined giving consent as well as those who

were unstable for the procedure were excluded from the study. Excluded also were all patients with risk of ongoing massive lower gastrointestinal bleeding, patients with haemodynamic instability, patients with history suggestive of renal insufficiency, poorly controlled diabetic, and hypertensive patients.

17. Sample size:

Based on sample size calculation, total participants recruited for this study was 66 patients, which were split to 33 participants for each group.

18. Result

A total of sixty-six (66) patients participated in the study with thirty-three patients per group. Thirty-three patients were assigned to oral mannitol use while the other thirty-three were assigned to sodium phosphate. The oral mannitol group was designated as group A (study group), while the sodium phosphate group was designated as group B (control group). Presented in the Table 18:1 is the comparison of the demographic characteristics of the study and control groups.

Table 18:1 The comparison of the demographic characteristics of the study and control groups

Variables	Mannitol (n=33)	Sodium Phosphate (n=33)	χ^2/FET	p-value
Age (Mean±SD)	54.27±10.18	51.88±9.71	0.977(t-test)	0.332
Gender Male				
	20(57.6)	18(54.5)	0.062	0.804
Female	14(42.4)	15(45.5)		
Total	33(100.0)	33(100.0)		
Marital status Single				
	2(6.1)	4(12.2)	1.088**	0.750
Married	29(87.8)	28(84.8)		
Widowed	2(6.1)	1(3.0)		
Total	33(100.0)	33(100.0)		
Occupation				
Skilled	17(51.5)	14(42.4)	1.891**	0.645
Unskilled	9(27.3)	12(36.4)		
Professional	3(9.1)	5(15.2)		

Retired	4(12.1)	2(6.1)		
Total	33(100.0)	33(100.0)		
Level of education Primary				
	8(24.2)	4(12.1)	3.394	0.509
Secondary	5(15.2)	6(18.2)		
Tertiary	7(21.2)	4(12.1)		
Graduate	11(33.3)	16(48.5)		
Postgraduate	2(6.1)	3(9.1)		
Total	33(100.0)	33(100.0)		

*p-value significant at <0.05

The mean age of the patients in the oral mannitol group was 54.27±10.18 while that of the sodium phosphate was 51.88±9.71. A total of 37 males and 29 females were recruited. There was no statistically significant difference between the two groups with regards to age, gender, marital status, occupation, and level of education (p-values of 0.332, 0.804, 0.750, 0.645 and 0.509 respectively).

Table 18:2Table 18:2 below shows there was a statistically significant difference between both groups with regards to cleanliness of the bowel as p value is <0.001. Ninety-seven percent (97%) of the sodium phosphate group had an excellent outcome while 21.2% gave an excellent outcome for the mannitol group.

Table 18:2 Aronchick bowel preparatory scale of both groups

Variables	Mannitol (n=33)	Sodium Phosphate (n=33)	χ^2/FET	p-value
ABPS				
Excellent	7(21.2)	32(97.0)	48.806**	<0.001*
Good	18(54.5)	0(0)		
Fair	4(12.1)	0(0)		
Poor	0(0)	1(3.0)		

Inadequate	4(12.1)	0(0)
Total	33(100.0)	33(100.0)

*p-value significant at <0.05

** FET = Fisher's exact test

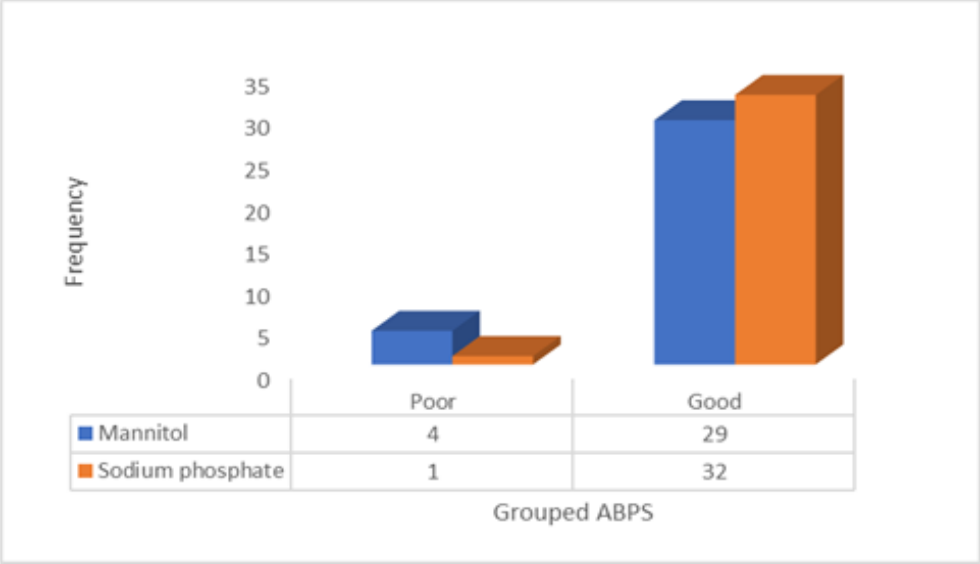

Figure 18-1 The Quality of Bowel Preparation among the Patients using the Aronchick Bowel Preparation Scale (ABPS)

Figure 18-1 illustrates the quality of bowel preparation among the patients using the Aronchick Bowel Preparation Scale (ABPS). Twenty-nine (29) patients of the mannitol group had a good preparation overall while thirty-two (32) patients of the sodium phosphate group had a good cleansing outcome. Four patients (4) from group A had a poor outcome while one (1) patient from group B had the same poor outcome.

19. Hypothesis testing

To test the Null hypothesis, we collected data to compare the Aronchick scores for mannitol and sodium phosphate groups separately as shown in Table 18:2. The P value (<0.001) shows a statistically significant difference between the mannitol and sodium phosphate group in terms of bowel cleansing power. Therefore, the Null hypothesis that says, "For patients undergoing colonoscopy, there is no difference in the efficacy of oral mannitol compared to sodium phosphate for achieving adequate bowel preparation" is rejected and the alternate hypothesis that says, "For patients undergoing colonoscopy, oral mannitol is either more or less effective than sodium

phosphate for achieving adequate bowel preparation upheld. The sodium phosphate group is more effective for bowel cleansing before colonoscopy.

20. Discussion

The mean age of patients (54 years in group A and 51 years in group B) aligns with similar studies, linked to colorectal cancer risk (19, 20). Indications for colonoscopy primarily include lower gastrointestinal bleeding, bowel habit changes, and abdominal pain. In terms of preparation consumption, group A (study group) demonstrated higher completion rates than group B, resembling patterns observed in prior studies, potentially influenced by the taste attributes of the agents. In this study abdominal fullness symptoms varied between the groups, with nausea and vomiting following bowel agent consumption showing similarities to previous studies, possibly attributed to the sweet nature of mannitol (20, 21).

Assessment of bowel preparation quality using the Aronchick scale(23) revealed excellent scores in 21.2% of the mannitol group and 97.0% in the sodium phosphate group. Colonoscopy completion rates were affected in a few patients due to poor bowel cleansing, emphasizing the importance of clear preparation instructions. Similar outcome scores were observed in previous studies, with caecum intubation rates slightly higher in the mannitol group (18, 23, 24). Common endoscopic findings included hemorrhoids, colonic tumors, and polyps, consistent with prior research. Cost analysis favored oral mannitol's affordability over sodium phosphate, despite the latter's slightly higher efficiency. Sodium phosphate's smaller volume compared to mannitol is noteworthy, with the overall cost of a colonoscopy procedure being $105.26.

21. Limitations

The sample size was small due to the duration and the Covid period of the study. At the time of Covid pandemic, patient turnover was limited hence the few numbers of participants.

22. Conclusion

This study sought to compare the efficacy of oral mannitol against sodium phosphate for bowel preparation for colonoscopy. There is statistically significant difference between oral mannitol and sodium phosphate in relation to the cleanliness of the bowel for colonoscopy between both preparations as sodium phosphate is more effective in bowel cleansing than oral mannitol. There is a significant difference in relation to taste and abdominal fullness between both preparations. Oral mannitol is more affordable than sodium phosphate.

23. Recommendations

From the result of the study, sodium phosphate had slightly better efficacy than mannitol though more expensive, we recommend that both bowel preparation agents may be beneficial for bowel preparation for diagnostic colonoscopy. However, larger sample sizes with other validation tools for assessing bowel cleanliness with different agents may be studied to the best of our knowledge; ideal preparatory agent does not seem to exist yet.

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