

Comparison of Mean Bowel Cleanliness Score in Patients Undergoing Colonoscopy Prepared by Sodium Phosphate versus Polyethylene

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ABSTRACT

Background: Adequate bowel preparation is essential for accurate colonoscopy. Both oral sodium phosphate (NaP) and polyethylene glycol-based lavage (PEG-ELS) are used predominantly as bowel cleansing modalities. However, NaP has gained popularity due to low drinking volume and lower costs.

Objective: To compare the mean bowel cleanliness score in patients undergoing colonoscopy prepared by sodium phosphate vs. polyethylene glycol.

Study Design: It's a randomized controlled trial

Settings and Duration: Department of Gastroenterology Shaikh Zayed Hospital, Lahore, 6 months after the approval of synopsis, from Nov 2019 to April 2020.

Methodology: After approval from ethical review committee of the hospital, 100 cases (50 in each group) patients who presented in Department of Gastroenterology Shaikh Zayed Hospital, Lahore and who fulfilled the criteria were counselled and explained the details of the study. Written informed consent and detailed history was taken from each patient. These patients were then randomly divided into following two groups using lottery method, Group-S: Sodium phosphate and Group-P: polyethylene glycol. Cleanliness of the colon was noted as per operational definition. All the data was noted and recorded into the attached proforma along with demographic details of the patient. All the colonoscopies were done by the endoscopists with a same single observer recording the findings to eliminate bias, and confounding variables were controlled by exclusion.

Results: In our study, of 100 cases (50 in each group) 48%(n=24) in Group-S and 52%(n=26) in Group-P were between 18-50 years of age whereas 52%(n=26) in Group-S and 48%(n=24) in Group-P were between 51-70 years of age, mean+sd was calculated as 51.64+8.82 years in S and 51.24+8.67 in P groups, 50%(n=25) in Group-S and 60%(n=30) in Group-P were male whereas 50%(n=25) in Group-S and 40%(n=20) in Group-P were females. Comparison of mean bowel cleanliness score in patients undergoing colonoscopy prepared by sodium phosphate vs. polyethylene glycol shows that Group-S had 3.82+0.92 and Group-P had 2.68+0.68 cleanliness score, p value was 0.0001. The results of our study are comparable with the above study.

Conclusion: We concluded that the mean bowel cleanliness score was significantly better in patients undergoing colonoscopy prepared with sodium phosphate when compared with polyethylene glycol.

Keywords: Colonoscopy, Sodium phosphate, Polyethylene glycol, Bowel cleanliness

INTRODUCTION

Colonoscopy is the principal diagnostic tool to inspect mucosa of the colon for any pathology such as inflammation, polyp, adenoma or cancer. It is preferred over other imaging modalities like barium enema or computed tomography (CT) colonography in many situations because of its capacity to intervene and sample or remove pathology encountered.^{1,2,3}

The pre-requisite for the optimal endoscopic visualization is adequate bowel cleansing as it affects safety, quality, efficacy and diagnostic accuracy of the procedure. The colonoscopic detection rate of lesions is affected by bowel preparation quality.¹ Previous studies showed that at the time of colonoscopy about 20% patients had inadequate bowel preparation.⁴ Inadequate bowel preparation may result in increased risk of missing lesions, decreased cecal intubation rate, increased patient discomfort due to repeated washings and suctioning, prolonged procedure time, higher risk of complications, increased rate of cancelled procedure with increasing costs and need to repeat the procedure.⁵

There are various quality assessment indicators proposed by GI societies include the rate of cecal intubation and adenoma detection rate.⁶ So ideally the colon cleansing method should be fast, safe and able to do proper cleaning with minimal side effects and discomfort for the patient.⁷ There are different agents used for colonoscopy preparation including Polyethylene glycol, Sodium phosphate, Picosulfate solution, Oral sulphate solution. There are two regimens used for colonoscopy preparation including split dose and day before cleansing method.⁸ The agents which are used commonly include sodium phosphate and polyethylene glycol electrolyte solution. PEG and Sodium phosphate, both are osmotic laxatives which cause water retention in stools and increase stool

frequency. The preference of one preparation over the other is guided by consensus regarding two preparations, relative safety, tolerability and effectiveness.⁹ Preferentially PEG based preparations are given in patients who have renal insufficiency. It is also preferred in patients who have diabetes mellitus or congestive cardiac failure.¹⁰

But the large fluid intake leads to nausea and abdominal discomfort. Sodium phosphate has become one of the preferred agent because it is well tolerated due to low volume preparation providing rapid and satisfactory bowel cleansing which could be a result of better compliance, acceptable due to easier intake and few adverse events.¹¹ So it is proposed that detection of neoplastic lesions requires excellent quality of colonoscopic preparation. Despite various meta-analyses trials, there is confusion regarding better cleansing property of either of these two agents.^{4,12,13}

Kössi et al. in 2003 conducted a study on the comparison of bowel cleanliness score in patients undergoing colonoscopy prepared by sodium phosphate vs. polyethylene glycol and found that to be 3.64 ± 0.16 vs. 2.69 ± 0.9 respectively; p=0.005.¹⁴

There is no local publish data present on this topic to the best of the candidate's knowledge. Due to immense importance of colonoscopic preparation affecting the quality of the colonoscopy and the agents used commonly for this are sodium phosphate and polyethylene glycol electrolyte solution. There is therefore a need to conduct this study in local population so that the superiority of one over the other as given in the study (3.64 ± 0.16 sodium phosphate vs. 2.69 ± 0.9 polyethylene glycol) could be determined which could help in getting better results of the colonoscopy and reduce the frequency of bowel re preparation for

colonoscopy, thus helping to reduce the misery of the patient and getting more accurate results of colonoscopy.

MATERIALS AND METHODS

This randomised controlled trial was conducted at Department of Gastroenterology Shaikh Zayed Hospital, Lahore. During from the period Nov 2019 to April 2020. Total 100 patients with ages in the range of 18-70 years undergoing elective colonoscopy for bleeding from the large gut were enrolled in this study. Patients who have undergone colonic resection as per clinical record, patients with renal impairment (serum creatinine >1.2mg/dl), cardiac failure (ejection fraction < 45%), shrunken liver with ascites on ultrasound (as per investigations), and patients with serum sodium beyond 135-145 mEq/L or serum potassium beyond 3.5-5.0 mEq/L were excluded. Written informed consent and detailed history was taken from each patient. These patients were then randomly divided into following two groups using lottery method

- Group-S: Sodium phosphate
- Group-P: polyethylene glycol

All patients were asked to avoid eating seeds containing vegetables, berries, fruits and bread in the week before colonoscopy. Patients in the group-S received first dose of 45 mL oral sodium phosphate in the evening before the examination (07:00 p.m) and second dose in the morning on the day before examination(07:00 a.m). In addition, they were told to drink 2–3 litres of clear liquids. Patients in group-P was told to drink 3–4 litres of PEG-EL solution (1.2–1.8 L/h) starting in the afternoon (02:00pm) on the day before colonoscopy. Analgesia was given with IV tramadol and phloroglucinol and sedated with midazolam prior to the procedure.

The procedure was done by the endoscopist by keeping the patient at lateral or supine position. Cleanliness of the colon was noted as per operational definition. All the data was noted and recorded into the attached proforma along with demographic details of the patient. All the colonoscopies were done by the endoscopists with a same single observer recording the findings to eliminate bias and confounding variables were controlled by exclusion.

All the collected data was entered and analysed into SPSS version 24. Numerical variables i-e age and mean bowel cleanliness score was presented by mean ±SD and range. T-test was applied for comparison of mean bowel cleanliness score between the two groups. Categorical Variable i.e gender was presented as frequency and percentage. Data was stratified for age and gender, indication of colonoscopy. Post stratification T-test was applied taking p value of ≤0.05 as statistically significant.

RESULTS

Age distribution shows that 48%(n=24) in Group-S and 52%(n=26) in Group-P were between 18-50 years of age whereas 52%(n=26) in Group-S and 48%(n=24) in Group-P were between 51-70 years of age, mean+sd was calculated as 51.64+8.82 years in S and 51.24+8.67 in P groups. (Table No.1)

Gender distribution shows that 50%(n=25) in Group-S and 60%(n=30) in Group-P were male whereas 50%(n=25) in Group-S and 40%(n=20) in Group-P were females. (Table No. 2)

Table 1: Age Distribution (n=100)

| Age (in years) | Group-S (n=50) | | Group-P (n=50) | |
|----------------|-----------------|-----|-----------------|-----|
| | No. of patients | % | No. of patients | % |
| 18-50 | 24 | 48 | 26 | 52 |
| 51-70 | 26 | 52 | 24 | 48 |
| Total | 50 | 100 | 50 | 100 |
| Mean±SD | 51.64+8.82 | | 51.24+8.67 | |

Comparison of mean bowel cleanliness score in patients undergoing colonoscopy prepared by sodium phosphate vs. polyethylene glycol shows that Group-S had 3.82+0.92 and Group-

P had 2.68+0.68 cleanliness score, p value was 0.0001. (Table No. 3)

The data was stratified for age and gender, indication of colonoscopy. Post stratification T-test was applied taking p value of ≤0.05 as statistically significant. (Table No. 4-6)

Table 2: Gender Distribution (n=100)

| Gender | Group-S (n=50) | | Group-P (n=50) | |
|--------|-----------------|-----|-----------------|-----|
| | No. of patients | % | No. of patients | % |
| Male | 25 | 50 | 30 | 60 |
| Female | 25 | 50 | 20 | 40 |
| Total | 50 | 100 | 50 | 100 |

Table 3: comparison of mean bowel cleanliness score in patients undergoing colonoscopy prepared by sodium phosphate vs. Polyethylene glycol (n=100)

| Cleanliness score | Group-S (n=50) | | Group-P (n=50) | |
|-------------------|----------------|------|----------------|------|
| | Mean | SD | Mean | SD |
| | 3.82 | 0.92 | 2.68 | 0.68 |

P value=0.0001

Table 4: Stratification For Age (n=100) 18-50 years

| Cleanliness score | Group-S | | Group-P | |
|-------------------|---------|------|---------|------|
| | Mean | SD | Mean | SD |
| | 3.71 | 0.95 | 2.77 | 0.71 |

P value=0.0002

Table 5: 51-70 years

| Cleanliness score | Group-S | | Group-P | |
|-------------------|---------|------|---------|------|
| | Mean | SD | Mean | SD |
| | 3.92 | 0.89 | 2.58 | 0.65 |

P value=0.0001

Table 6: Stratification For Gender (n=100) Male

| Cleanliness score | Group-S | | Group-P | |
|-------------------|---------|------|---------|------|
| | Mean | SD | Mean | SD |
| | 3.68 | 0.99 | 2.83 | 0.75 |

P value=0.0007

Table 7: Female

| Cleanliness score | Group-S | | Group-P | |
|-------------------|---------|------|---------|------|
| | Mean | SD | Mean | SD |
| | 3.96 | 0.84 | 2.45 | 0.51 |

P value=0.0001

Table 8: Stratification For Indications Of Colonoscopy (n=100)

| Indications | Group-S | | Group-P | | P value |
|---|---------|------|---------|------|---------|
| | Mean | SD | Mean | SD | |
| Abdominal symptoms | 3.75 | 0.96 | 2.83 | 0.41 | 0.06 |
| Chronic diarrhoea/constipation | 4.00 | 1.00 | 2.50 | 1.00 | 0.10 |
| Anaemia | 3.43 | 1.27 | 2.60 | 0.84 | 0.12 |
| Hematochezia | 3.78 | 0.83 | 2.63 | 0.52 | 0.004 |
| Chronic abdominal pain | 3.50 | 0.93 | 3.00 | 0.76 | 0.26 |
| Screening for colorectal carcinoma | 3.92 | 0.86 | 2.56 | 0.73 | 0.0009 |
| Aggravation of pre-existing colonic disease | 4.50 | 0.55 | 2.60 | 0.55 | 0.0003 |

DISCUSSION

Adequate bowel preparation is essential for accurate colonoscopy. Both polyethylene glycol-based lavage (PEG-ELS) and oral sodium phosphate (NaP) are used predominantly as bowel cleansing modalities. However, due to low drinking volume and lower costs, NaP has gained popularity.

However, there is no local published data present on this topic. Due to immense importance of colonoscopic preparation affecting the quality of the colonoscopy and the agents used commonly for this are sodium phosphate and polyethylene glycol electrolyte solution. There was therefore a need to conduct this study to help in getting better results of the colonoscopy and reduce the frequency of bowel re preparation for colonoscopy, thus

helping to reduce the misery of the patient and getting more accurate results of colonoscopy.

In our study, of 100 cases (50 in each group) 48%(n=24) in Group-S and 52%(n=26) in Group-P were between 18-50 years of age whereas 52%(n=26) in Group-S and 48%(n=24) in Group-P were between 51-70 years of age, mean+sd was calculated as 51.64+8.82 years in S and 51.24+8.67 in P groups, 50%(n=25) in Group-S and 60%(n=30) in Group-P were male whereas 50%(n=25) in Group-S and 40%(n=20) in Group-P were females. Comparison of mean bowel cleanliness score in patients undergoing colonoscopy prepared by sodium phosphate vs. polyethylene glycol shows that Group-S had 3.82+0.92 and Group-P had 2.68+0.68 cleanliness score, p value was 0.0001. The results of our study are comparable with the above study.

Another study¹⁵ compared Sodium Phosphate with Polyethylene Glycol for colonoscopy bowel preparation and revealed that sodium phosphate as a cleansing agent in patients displayed better compliance, preparation taste, acceptability, polyp detection rate, cleansing scores and less adverse effects including nausea, vomiting, abdominal pain ($P < 0.05$). Regarding procedure time, adequate preparation rate and electrolyte concentration, there was no significant difference between both regimens ($P > 0.05$). So the conclusions offered by pooling analysis verified by our sensitivity analysis. The demonstration of symmetric funnel plot showed no publication bias across the studies and the result of Egger's test was $P = 0.56$. They concluded sodium phosphate to be a better agent than polyethylene glycol for colonoscopy bowel preparation considering its advantages of higher efficacy, better tolerability and acceptability as well as comparable safety.

Another study¹⁶ assessed the comparison of colonic preparation between oral sodium phosphate solution (Exelyte) and a polyethylene glycol solution (Peglec) regarding safety, acceptability and effectiveness. It was a colonoscopist-blinded, prospective, randomized, observational clinical study. One hundred patients undergoing colonoscopy for various indications were randomized (n = 50 each) to receive either 90 mL of oral sodium phosphate mixed with 300 mL clear liquid and then consume about 4-5 glasses of water, or 2 liters of polyethylene glycol solution. Sodium phosphate showed a safety profile similar to that of polyethylene glycol. However, patients tolerated it better. The colonoscopist reported similar cleansing of bowel in both groups. Oral sodium phosphate was well tolerated, safe and provided bowel cleansing similar to that with a polyethylene glycol solution.

Naoki Hosoe and others¹⁷ evaluated the patient acceptance of sodium phosphate (NaP) tablets and polyethylene glycol solution (PEG) with sodium picosulfate and concluded that preference for and acceptance of NaP tablets was significantly higher than that for PEG with sodium picosulfate solution.

It is evident that Sodium phosphate (NaP), a buffered saline laxative, containing monobasic sodium phosphate and dibasic sodium phosphate, gained popularity for colonic preparation as an alternative method due to its smaller volume. NaP is an osmotic laxative acts by drawing fluids into the gastrointestinal tract and cleansing the colon.

Several meta-analyses and randomized controlled trials comparing NaP and PEG-ELS have suggested that regarding safety, tolerability, cost effectiveness, NaP is better and is equally or more effective.¹⁸⁻²¹ In order to improve the taste and reduce the volume required for bowel preparation, NaP tablets (Visicol®) were designed. NaP tablets contain microcrystalline cellulose which can be deposited in the colon requiring additional irrigation. A newer residue-free formulation of sodium phosphate tablets (OsmoPrep™) was introduced²² to overcome this limitation.

Considering the above discussion and results of our study, the hypothesis **“there is a difference in mean bowel cleanliness score for bowel preparation in patients undergoing colonoscopy with sodium phosphate as compared to polyethylene glycol”** is justified. However, further trials are required to validate our results.

CONCLUSION

We concluded that the mean bowel cleanliness score was significantly better in patients undergoing colonoscopy prepared with sodium phosphate than with polyethylene glycol.

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