ORIGINAL ARTICLE

A prospective randomized trial to compare the effectiveness of zero calorie carbonated drink and water as a solvent in sodium phosphate for colonoscopy

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Abstract

Objective: To compare the effectiveness of zero-calorie soft drink and plain water as a solvent for sodium phosphate in terms of good palatability and better patient tolerance.

Methods: The randomised controlled trial was conducted from May to December 2019 at the Dowites Operation Theatre Endoscopy Suite, Surgical Unit 3, Civil Hospital Karachi, and comprised patients aged >18 years of either gender undergoing colonoscopy for screening and non-emergency/non-urgent colorectal diseases. The patients were randomised into group A, which was assigned to take sodium phosphate in water, and group B, which was assigned to take sodium phosphate in zero-calorie soft drink. Bowel preparation was assessed by the consultant during endoscopy. Outcome variables, such as bowel cleanliness, palatability, tolerance of solution, adverse effects, and willingness to repeat the preparation, were evaluated in both groups. Data was analysed using SPSS 21.

Results: Of the 162 patients, there were 81(50%) in each of the two groups. There were 124(76.5%) males and the overall mean age was 43±8.66 years. The palatability score was significant (p=0.01) for group B compared to group A. Due to better palatability and tolerance, 64(79%) patients in group B took the preparation in <6 hours.

Conclusion: Use of zero-calorie soft drink was found to be a better option for colonoscopic preparation compared to plain water.

RCT Registration: Clinical trial unit (www.clinicaltrials.gov)

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Introduction

Colonoscopy is a gold standard procedure[1] for colorectal diseases, and proper cleansing of the bowel is a cornerstone for evaluation. Inappropriate bowel preparation can cause missing the pathology, repeated colonoscopies, and an increased financial burden of colonoscopy procedures.[2] There are numerous regimens for bowel cleansing. Polyethyleneglycol (PEG) is the commonly available non-digestible, non-absorbable hyperosmotic laxative for bowel preparation, but, as it is taken in large quantity and has an unpleasant taste, patients are often reluctant to take it. PEG also induces nausea in ≤50% patients.[3-5] Sodium phosphate (NaP) is a small-volume hyperosmotic laxative with better tolerance.[3] Oral NaP is well-tolerated and is more effective in colon cleansing compared to PEG and is being widely used nowadays.[6]

A number of solutions have been tried as a solvent to improve the palatability of the solution, such as orange juice, pineapple juice, Gatorade, and zero-calorie Coca Cola.[1,6,7] Coke Zero contains carbonated water, caramel colour, phosphoric acid, aspartame, potassium benzoate, natural flavours, potassium citrate, acesulfame potassium and caffeine. Zero-calorie carbonated drink does not have carbohydrates that alters the blood glucose levels, therefore the American Diabetes Association (ADA) has listed it safe for diabetes patients.[8,9] Interestingly, carbonated drinks have a therapeutic role in the gastrointestinal tract (GIT). In a systemic review, Coke was effective first-line dissolution therapy for gastric phytobezoars, and was also effective for impacted food in the oesophagus where endoscopic removal was difficult.[7,10] Sodium bicarbonate is a substance in Coke which acts as a mucolytic agent with the effervescent carbon dioxide gas penetrating food boluses and creating an acidic environment for the dissolution of fibres.[11] It is still unknown if other properties of Coke Zero may assist in bowel cleansing or aid in the removal of the thick bile stained mucous which commonly coats the right colon.

No study has been done in this regard in Pakistan thus far. The current study wsa planned to fill the gap to compare the effectiveness of Coke Zero with plain water as a solvent for NaP.

Materials and Methods

The randomised controlled trial (RCT) was conducted at the Dowites Operation Theater, Endoscopy Suite, Surgical Unit III, Dr Ruth Pfau Civil Hospital, Karachi (CHK), from May to

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December 2019. After approval from the ethics review board of Dow University of Health Science (DUHS), Karachi, the trial was registered with the Clinical trial unit (www.clinicaltrials.gov) with reference number NCT04316858 number. The sample size was estimated using OpenEpi calculator[12] by taking statistics of willingness to repeat the same process as 90.4% in orange juice group and 66.7% in the control group[1], confidence level 99% and power of test 90%. The sample was inflated by 5% to cover up for dropouts.

The sample was raised using non-probability consecutive sampling technique. Those included were patients of either gender aged >18 years undergoing colonoscopy for screening and non-emergency/non-urgent colorectal diseases, like inflammatory bowel disease (IBD), suspected colonic polyps, and colorectal cancer. Patients who were pregnant, having intestinal obstruction, acute or serious illness and coagulopathy were excluded.

After taking informed consent from the subjects, they were randomised into two equal groups using computer-generated random numbers. Group A was assigned to take NaP in water and group B was assigned to take NaP in Coke Zero. All patients in both the groups received 2 bottles of NaP, each containing 45ml, and were instructed to mix the content of each bottle in 400ml of plain water or Coke Zero, depending on the group allocation, and finish it 6 hours before colonoscopy. The patients were kept nil per oral (NOP) from midnight other than clear liquids. Serum electrolytes, urea, creatinine were measured after and before bowel preparation for any change. Bowel preparation was assessed by the consultant with >5 years of experience during endoscopy who was blinded to the patients' group. The time was calculated to see how early had the patients taken bowel preparation i.e. within 6 hours or >6 hours. All endoscopies were performed under sedation.

A questionnaire was used to assess the bowel cleanliness, palatability, tolerance of solution, adverse effects, and willingness to repeat the preparation. Bowel cleanliness was assessed using Aronchick scale (Table 1).13 Score 0-1 was graded excellent, score 2 satisfactory and score 3 bad. The palatability score was graded as 1 = excellent, 2 = good, 3 = satisfactory, and 4 = bad. Adverse effects, like nausea, vomiting, bloating and cramps, after ingestion of bowel preparation were reported by the patients. Data regarding patient's demographics, as well as pre- and post-procedure data was also noted.

Table-1: Aronchick scale.

Score	Grades	Description
0	Excellent	Small volume of clear liquid >95% of the surface seen
1	Good	Large volume of clear liquid covering 5% to 25% of the surface but >90% of the surface seen
2	Fair	Some semisolid stool that could be suctioned or washed away but >90% of the surface seen
3	Poor	Semisolid stool that could not be suctioned or washed away and <90% of the surface seen
4	Inadequate	Re-preparation

Data was analysed using SPSS 21. Mean and standard deviation were calculated for numeric variable, like age. Frequencies and percentages were calculated for categorical variables, like gender, presenting type and outcome variables. Chi-square test was used to assess the significance of inter-group differences for bowel cleanliness, palatability, tolerance of solution, adverse effects and willingness to repeat the preparation. P≤0.05 was considered statistically significant.

Results

Of the 162 patients, there were 81(50%) in each of the two groups. There were 124(76.5%) males and the overall mean

Table-2: Baseline characteristics.

	Coke Zero (n=81) n (%)	**Water** (n=81) n (%)	***p*-value**
Gender			
Male	58 (46.8)	66 (53.2)	
Female	23 (60.5)	15 (39.5)	0.138
Lesions			
Benign	45 (53.6)	39(46.4)	
Malignant	36(46.2)	42(53.8)	0.345
Electrolytes			
Normal	79 (52.7)	71 (47.3)	
Abnormal	2 (16.7)	10 (83.3)	0.16
Time to take preparation			
<6 hours	64 (79.0)	38 (46.9)	0.000
>6 hours	17 (21.0)	43 (53.1)	

Table-3: Bowel cleanliness, palatability and complications.

	Coke Zero (n=81) n (%)	**Water** (n=81) n (%)	***p*-value**
1. Bowel Cleanliness			
Excellent	21 (25.9)	18 (22.2)	0.01
Satisfactory	43 (53.1)	58 (71.6)	
Bad	17 (21)	5 (6.2)	
2. Palatability			
Excellent	5 (6.2)	1 (1.2)	0.001
Good	32 (39.5)	5 (6.2)	
Satisfactory	42 (51.9)	65 (80.2)	
Bad	2 (2.5)	10 (12.3)	
3. Complications			
Nausea/ vomiting	6 (7.4)	9 (11.1)	0.201
Bloating	0	2 (2.5)	
Cramps	8 (9.8)	9 (11.2)	
None	67 (82.7)	61 (75.3)	
4. Willingness to take preparation			
Yes	53 (65.4)	37(45.7)	0.01
No	28(34.6)	44(54.3)	

age was 43±8.66 years (range: 18-70 years). Due to better palatability and tolerance, 64(79%) patients in group B took the preparation in <6 hours (p=0.001) (Table 2).The bowel cleanliness was superior in group A (p = 0.01)There was no significant difference (p=0.2) in complications between the groups and more patients in group B were willing to take the Coke Zero preparation in future compared to group A (p= 0.01) (Table 3).

Discussion

There are many solutions available for mixing NaP, like orange juice, pineapple juice and Gatorade, as alternatives to water to improve the palatability and tolerance to the solution.[1,7,8,14,15] The current study used Coke Zero as a solvent for NaP as it improves taste, tolerance and palatability, while it is safely indicated in diabetes patients.[9] The current is the first such study in Pakistan.

The quality of diagnostic colonoscopy, proper findings and therapeutic measures are related to adequate intake of bowel preparations and hydration. Inadequate bowel preparation results in missed lesions, prolonged colonoscopy time, and increased risks of complications.[16,17] An additional cost is also a problem because the colonoscopy has to be re-planned.[18] The ideal solution should be compliable and good in taste with small quantity and patient satisfaction, but, unfortunately, no single preparation is reliable to date.[19,20] In the current study, surprisingly the bowel cleanliness was superior in water-based group, and it was also statistically significant compared to Coke Zero, while an earlier study found better bowel cleanliness in the Coke Zero group than the control group (p=0.0297).[7] Another study[1] did not find any difference in bowel cleansing when using orange juice.

The current study observed better palatability and acceptance when using Coke Zero with NaP, which is comparable with other trials.[1,7,21,22] Improved palatability is a contributing factor for willingness to repeat the procedure, if required. In the current study, only 2 patients had deranged electrolytes compared to water preparation. Although few adverse effects were observed in both the groups, like nausea, vomiting, cramps and bloating, none was severe or statistically significant.

The current study has limitations as it was a single-centre research based on a small sample size. Further, multi-centre studies with larger sample size are needed to validate the findings.

Conclusion

Addition of Coke Zero to the bowel preparation as a solvent was found to be a better option compared to water as it increased the palatability, acceptance and satisfaction. It can easily be used in diabetic patients as well.

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Conflict of interest: None.

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