https://doi.org/10.29309/TPMJ/2023.30.09.7576

The Professional Medical Journal
www.theprofesional.com
2023, Volume, 30 Issue, 09

ORIGINAL ARTICLE

The efficacy and tolerability of polyethylglycol solution with and without bisacodyl in preparation of colon before colonoscopy.

Muhammad Bilal[1], Irfan Younus[2], Furqan Tahir[3], Omer Hassan Aftab Ahmad[4], Taimoor Hafeez[5], Adnan Qadir[6]

Article Citation: Bilal M, Younus I, Tahir F, Ahmad OHA, Hafeez T, Qadir A. The efficacy and tolerability of polyethylglycol solution with and without bisacodyl in preparation of colon before colonoscopy. Professional Med J 2023; 30(09):1091-1095. https://doi.org/10.29309/TPMJ/2023.30.09.7576

ABSTRACT… Objective: To compare the efficacy of four liter Polyethylin glycol alone with two liter polyethylin glycol plus bisacodyl in preparation of large bowel before colonoscopy. **Study Design:** Randomized Control Trial. **Setting:** Department of Gastroenterology, Hepatology and GI Endoscopy, SZABMU, Pakistan Institute of Medical Sciences, Islamabad. **Period:** 1st January 2021 to 31st December 2021. **Material & Methods:** One hundred seventy patients, both males and females, who had indications for colonoscopy were included. After informed consent two equal groups of 85 were made. In group A, bisacodyl was added with two liters polyethylin glycol while in group B four liter Polyethylin glycol alone was used to prepare the gut before colonoscopy. **Results:** Out of 170 patients, the calculated Ottawa score was almost same in both groups. Extraordinary cleaning was found more regularly within the combination group ($p < 0.05$). No intense adverse effects were found among the 2 regimens besides nausea, abdominal pain, and anal irritation which were seen a bit more in group B. The tolerability was better with bisacodyl and 2-L PEG preparation ($P<0.05$). **Conclusion:** 2 L PEG+ bisacodyl preparation is a good alternative to 4-L PEG preparation for bowel cleansing, with distinct advantages in terms of tolerability, acceptability and compliance.

Key words: Bisacodyl, Colonoscopy, Polyethylene Glycol.

INTRODUCTION

Colonoscopy has been used both for diagnostic as well as therapeutic purposes and it allows us to examine as well as treat the pathologies related to the rectum, colon and also the portion of the terminal ileum. A successful colonoscopy requires an adequate preparation of the large bowel that facilitates clear visualization of the mucosal surface.[1] The adequacy of the bowel preparation had a very significant influence on the quality of the colonoscopy, but the preparation is inadequate in up to 25 percent of examinations.[2] Inadequate bowel preparation may alleviate the risks of adverse events related to the procedure, lengthen the insertion time and overall procedure time, and therefore necessitates reducing the interval between procedures and lower pathology detection rates.[3] The ideal preparation should empty the colon of any material (solid, liquid, gaseous) completely and quickly without affecting the colon's gross or microscopic appearance, not causing significant fluid or electrolyte shifts and being well tolerated and accepted by the patient.[4]

Poly-ethylene glycolelectrolyte lavage solution (PEG-ELS) is a high-molecular weight, nonabsorbable polymer, formulated as mixture containing solution that passes through the colon without its very net absorption or secretion property and is a widely used agent for bowel preparation before colonoscopy. In order to attain a contented level of cleanser properties PEG is usually given as a four-liter solution. Although PEG-ELS is generally well tolerated, 5% to 15% of patients do not complete the preparation because of poor palatability and/or large volume.[5] In these cases, lower-volume preparations and split-dose preparations are better tolerated the

1. MBBS, MD (Gastroenterology), Medical Officer, Faisal Masood Teaching Hospital DHQ, Sargodha.
2. MBBS, MD (Gastroenterology), Assistant Professor Gastroenterology, Nawaz Sharif Medical College, Gujrat.
3. MBBS, MD (Gastroenterology), Medical Officer, Aziz Bhatti Shaheed Teaching Hospital, Gujrat.
4. MBBS, MD (Gastroenterology), Consultant Gastroenterologist, Advance Diagnostic International Hospital Islamabad.
5. MBBS, MD (Gastroenterology), Medical Officer Gastroenterology, PIMS Islamabad.
6. MBBS, FCPS (Gastroenterology), Assistant Professor Gastroenterology, Islamic International Medical College Rawalpindi.

Correspondence Address:
Dr. Irfan Younus
Department of Gastroenterology,
Nawaz Sharif Medical College, Gujrat
Aziz Bhatti Shaheed Teaching Hospital,
Irfanyounis7887@gmail.com

Article received on: 05/04/2023
Accepted for publication: 19/06/2023

timing and dosing schedule affect the efficacy, patient acceptance, and patient tolerance of the preparation.[6-7]

Bisacodyl is a diphenylmethane derivative that is poorly absorbed in the small intestine and is hydrolyzed by endogenous esterases. Its active metabolites stimulate colonic peristalsis.[8] Present study is designed to compare low volume preparation with bisacodyl tablets with high volume preparation. The gathered data will help in offering better of the two preparations in terms of efficacy and tolerability.

MATERIAL & METHODS

It was a randomized controlled trial of one year (2021) which was conducted in department of Gastroenterology, Hepatology and GI Endoscopy, SZABMU, Pakistan Institute of Medical Sciences, Islamabad. 170 patients of both genders, who were planned for colonoscopy, were included in study. There ages were between 21 to 78 years. Patients were randomly divided into 2 groups by lottery method. Group A (intervention group) received 2 L P.E.G combined with two bisacodyl 5 mg tablets a day prior to colonoscopy. Group B (Standard treatment group) received the standard 4 liter P.E.G. (poly-ethylene glycol 3350 with electrolyte lavage solution) a day prior to colonoscopy. Primary outcome was the status of cleansing of bowel as per Ottawa scale assessed during colonoscopy while secondary outcome was the tolerability of the two preparations.

Before initiating study enrollment, an ethical approval for the study was gained from hospital ethical board having reference no. F1-1/2015/ERB/SZABMU/253. All patients fulfilling the inclusion criteria were included in the study through gastroenterology unit, PIMS, Islamabad. The purpose and benefits of the study were explained to the patients and an informed consent was obtained.

The examinations performed by experienced endoscopists. A standard colonoscope was used for the examinations. Same sedation was given to both groups in the form of IV dormicum (midazolam) was administered. Information about bowel cleansing was recorded during colonoscopy and tolerability of both preparations was recorded by interviewing the patients. All the information was recorded in the pre-designed proforma.

All the data collected was entered in SPSS version 17 and results was analyzed accordingly. Frequencies and percentage were calculated for gender, bowel cleansing levels, symptoms and their severity. Mean standard deviation was calculated for age and Ottawa score. Chi square was applied to compare the bowel cleansing levels in both groups. Effect modifiers like age, gender. P was controlled by stratification. Post stratification chi square test was applied. P value ≤ 0.05 will be considered significant.

RESULTS

The study included 170 patients with 85 patients given to each group. The patients mean age was 46.612 years with standard deviation of 14.89 years. 21 years was the minimum age of the patients; maximum age of patients was 78 years. Out of 170 patients, 77(45.3%) patients were male and 93 (54.7%) patients were female, Mean Ottawa Score was 2.78 + 1.95 in Group A while 3.41 +/- 1.90 in Group B (Table-I).

Total Patients (n) Male Female	**170** 77 (45.29%) 93(54.71%)
Mean Age(years)	46.612
Minimum Age(years)	21.0
Maximum Age(years)	78.0
Standard Deviation	14.89
Mean Ottawa Score in Group A	2.78 + 1.95

Table-I. Demographic profile of the study population (Age distribution)

Out of 170 patients, level of cleansing was excellent in 109 patients(64.1%)[63 in group A and 46 in group B], good in 64(28.2%) patients [16 in group A and 32 in group B]and fair in 13 (7.6%) patients [6 in group A and 7 in group B] significant p value (p=0.018) Table-II. While insignificant p value (p=0.091) was found between stratification of level of cleansing and genders. (Table-II)

Groups				P-Value
	Excellent	Good	Fair	
Group A	63 (74.12%)	16 (18.82%)	06 (7.06%)	0.018
Group B	46 (54.18%)	32 (37.65%)	07 (8.23%)	
Gender				
Male	43(50.59 %)	28(32.94%)	06(7.06%)	0.091
Female	66 (77.65%)	20(23.53%)	07(8.23%)	

Table-II. Level of cleansing among groups and gender.

Nausea				P-Value
	Group A	Group B	Total	
Absent	70 (82.35%)	62 (72.94%)	132 (77.64%)	0.099
Present	15 (17.65%)	23 (27.06%)	38 (22.36%)	
Bloating				
Absent	69 (81.18%)	62 (72.94%)	131(77.06%)	0.137
Present	19 (18.82%)	23 (27.06%)	39(22.94%)	
Abdominal pain				
Absent	72(84.71%)	44 (51.76%)	116(68.24%)	0.001
Present	13 (15.29%)	41(48.24%)	54(31.76%)	

Table-III. Stratification of Tolerability (Nausea, bloating and abdominal pain) in Groups (A and B)

Out of 170 patients, we have found insignificant p value in tolerability i.e Nausea and bloating between both groups while significant p value (<0.005) was found of abdominal pain. (Table-III)

DISCUSSION

Researchers who tried a low volume preparation that combines two liters PEG. with bisacodyl have proposed equivalent efficacy and better tolerability.[9-10] Our study also showed that the same day low-volume (2 liter PEG+ bisacodyl) actually provides similar or perhaps even better bowel cleansing properties than split-dosing 4 liters PEG in terms of better tolerability, acceptability and better compliance. These results are similar to a trial conducted by Cesaro P, et al in which they compared the efficacy of bisacodyl and 2-L poly-ethylene glycol (PEG) with citrates and simethicone the day prior to the starting of procedure with a control groups that received the standard 4 liters PEG. (polyethylene glycol 4000 with electrolyte lavage solution). Ottawa scale was used to measure and evaluate the level of bowel cleansing. Their results showed that excellent bowel cleansing was achieved in 70% of patients who received bisacodyl and 2-L PEG. compared to 49% of patients who received standard four 4 L PEG. (P<0.05). The tolerability was better with bisacodyl and 2-L PEG (P<0.05).[7]

Multiple studies show that the routine addition of prokinetic agents or bisacodyl to 4-L PEG-ELS administration does not improve patient tolerance or colonic cleansing.[11-13]

One study of bisacodyl as a preparation adjunct found that the laxative shortened the duration of whole-gut irrigation, although no significant difference in colonic cleansing was identified.[14] When used as an adjunct to PEG-ELS, bisacodyl did allow for less volume of PEG-ELS required for adequate colonic cleansing.[15,16] Bisacodyl can cause abdominal cramping and has been associated with ischemic colitis.[17] Accordingly, when used as an adjunctive agent for bowel preparations, 5-and 10-mg doses are recommended.

The second main finding of our study is apparently similar results of colon cleansing between the day before 2-L PEG + bisacodyl and split-dose 4-L PEG. As ACG guidelines recommend split-dose bowel preparation to improve the quality of bowel preparation, there is need to evaluate the performance of this new formulation in further studies.[18]

In terms of colonoscopy timings, the new formulation offers more flexibility than normally

used PEG. formulations. The lower volume of PEG. solution that patients need to drink will probably be associated with improved patient acceptance and better taste with minimal adverse effects.

In our study, there were some limitations. The study is relatively very small, single-centered and has therefore reduced external validation of findings in a university hospital. The understanding of the bowel preparation scale is somewhat subjective, although the determination distortion could affect both groups equally. Prior and after preparation, we did not evaluate the electrolyte level. However, safety of the preparations and mixtures based on the iso-osmotics PEG. has been extensively reported. However, it has already been clarified that the precise colonoscopy was linked to an adequate level of preparation regardless of the type of bowel preparation being used.

CONCLUSION

2 L PEG+ bisacodyl preparation is a good alternative to 4-L PEG preparation for bowel cleansing, with distinct advantages in terms of tolerability, acceptability and compliance.

REFERENCES

1. Kurlander JE, Sondhi AR, Waljee AK, Menees SB, Connell CM, Schoenfeld PS, Saini SD. **How efficacious are patient education interventions to improve bowel preparation for colonoscopy?** A systematic review. PloS one. 2016 Oct 14; 11(10):e0164442.

2. Lewin S, Bohren M, Rashidian A, et al. **Applying GRADE-CERQual to qualitative evidence synthesis findings—paper 2: how to make an overall CERQual assessment of confidence and create a Summary of Qualitative Findings table.** Implementation Science. 2018 Jan; 13(1):11-23.

3. Franco DL, Leighton JA, Gurudu SR. **Approach to incomplete colonoscopy: New techniques and technologies.** Gastroenterology & hepatology. 2017 Aug; 13(8):476.

4. Stoffel EM, Erichsen R, Frøslev T, et al. **Clinical and molecular characteristics of post-colonoscopy colorectal cancer: A population-based study.** Gastroenterology. 2016 Nov 1; 151(5):870-8.

5. de Wijkerslooth TR, de Haan MC, Stoop EM, et al. **Burden of colonoscopy compared to non-cathartic CT-colonography in a colorectal cancer screening programme: Randomised controlled trial.** Gut. 2012 Nov 1; 61(11):1552-9.

6. Rex DK, Boland CR, Dominitz JA, et al. **Colorectal cancer screening: Recommendations for physicians and patients from the US Multi-Society Task Force on Colorectal Cancer.** Am J Gastroenterol. 2017 Jul; 112(7):1016-1030.

7. Cesaro P, Hassan C, Spada C, et al. **A new low-volume isosmotic polyethylene glycol solution plus bisacodyl versus split-dose 4 L polyethylene glycol for bowel cleansing prior to colonoscopy: A randomised controlled trial.** Digestive and Liver Disease. 2013 Jan 1; 45(1):23-7.

8. Zorzi M, Valiante F, Germanà B, et al. **Comparison between different colon cleansing products for screening colonoscopy. A noninferiority trial in population-based screening programs in Italy.** Endoscopy. 2016 Mar; 48(03):223-31.

9. Kluge MA, Williams JL, Wu CK, et al. **Inadequate Boston Bowel Preparation Scale scores predict the risk of missed neoplasia on the next colonoscopy.** Gastrointestinal endoscopy. 2018 Mar 1; 87(3):744-51.

10. Sidhu S, Geraghty J, Karpha I, et al. **Outcomes following an initial unsuccessful colonoscopy: A 5-year complete audit of teaching hospital colonoscopy practice.** Presented at 2011 British Society of Gastroenterology Annual General Meeting; March 14-17, 2011; Birmingham, United Kingdom.

11. Saltzman JR, Cash BD, Pasha SF, et al. **Bowel preparation before colonoscopy.** Gastrointestinal endoscopy. 2015 Apr 1; 81(4):781-94.

12. Bhat AH, Parray FQ, Chowdri NA, et al. **Mechanical bowel preparation versus no preparation in elective colorectal surgery: A prospective randomized study.** International Journal of Surgery Open. 2016 Jan 1; 2:26-30.

13. Metheny NA, Meert KL. **Administering polyethylene glycol electrolyte solution via a nasogastric tube: Pulmonary complications.** American Journal of Critical Care. 2017 Mar; 26(2):e11-7.

14. Bharucha AE, Wald A. Chronic constipation. InMayo Clinic Proceedings 2019 Nov 1 (Vol. 94, No. 11, pp. 2340-2357). Elsevier.Jeon SR, Kim HG, Lee JS, Kim JO, Lee TH, Cho JH, Kim YH, Cho JY, Lee JS. **Randomized controlled trial of low-volume bowel preparation agents for colonic bowel preparation: 2-L polyethylene glycol with ascorbic acid versus sodium picosulfate with magnesium citrate.** International journal of colorectal disease. 2015 Feb; 30:251-8.

15. Weir MA, Fleet JL, Vinden C, et al. **Hyponatremia and sodium picosulfate bowel preparations in older adults.** Am J Gastroenterol 2014; 109:686-94.

16. Kwon KH, Lee JA, Lim YJ, et al. **A prospective randomized clinical study evaluating the efficacy and compliance of oral sulfate solution and 2-L ascorbic acid plus polyethylene glycol.** The Korean Journal of Internal Medicine. 2020 Jul; 35(4):873.

17. Kim SH, Kim JH, Keum B, et al. **A randomized, endoscopist-blinded, prospective trial to compare the efficacy and patient tolerability between bowel preparation protocols using sodium picosulfate magnesium citrate and polyethylene-glycol (1 L and 2 L) for Colonoscopy.** Gastroenterology Research and Practice. 2020 Mar 3; 2020.

18. Altinbaş A, YILMAZ B, Aktaş B, et al. **What is the main target: A clearer colon with a sennoside-based regime, or adequate bowel cleansing before colonoscopy with a PEG-EL-based regime?.** Turkish Journal of Medical Sciences. 2015; 45(2):404-8.

AUTHORSHIP AND CONTRIBUTION DECLARATION

No.	Author(s) Full Name	Contribution to the paper	Author(s) Signature
1	Muhammad Bilal	Conception or design of the work.	
2	Irfan Younus	Acquisition, analysis and interpretation of data.	
3	Furqan Tahir	Drafting the work.	
4	Omer Hassan Aftab Ahmad	Drafting.	
5	Taimoor Hafeez	Final approval of the version.	
6	Adnan Qadir	Revising it critically intellectual content.