



ORIGINAL RESEARCH PAPER

General Surgery

A STUDY OF WHOLE VERSUS SPLIT DOSE PREPARATION WITH EXELYTE SOLUTION PRIOR TO COLONOSCOPY.

KEY WORDS: Exelyte solution, Split-dose bowel preparation, Whole bowel preparation, Colonoscopy.

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ABSTRACT

Introduction: Colonoscopy is the current standard method for evaluation of the colon. Diagnostic accuracy and therapeutic safety of colonoscopy depends on the quality of the colonic cleansing or preparation. To assess the Cleanliness quality score of split-dose preparation and one-time preparation, assess the clarity of mucosa and compare cleanliness quality scores in split-dose vs one-time preparation.

Material and Method: It is a prospective study on patients coming for Colonoscopic evaluation at department of general Surgery of MIMER Medical College & Hospital Talegaon. All the details of the patients were collected according to pre-designed proforma. Total of 50 patients aged between 18-70years were included in study after obtaining informed consent. 50 patients were divided into 2 groups as; Group A: 25 patients with whole dose one-time preparation; Group B: 25 patients with split-dose preparation.

Result: There were total 14 females and 36 males in study. The Mean cleanliness quality score was found to be significantly lower in the Group B (3.20 ± 1.11) patients compared to patients in Group A (1.44 ± 0.58). Split preparation had a better efficacy compared to the one-time bowel preparation. There is a significant strength of association of cleanliness of bowel and the type of preparation done in patients, Group B showed to be better.

Discussion and Conclusion: There is significant association of bowel cleanliness grade and type of bowel preparation performed in patients. Split-dose bowel preparation is significantly correlated strongly with cleanliness and visibility during the colonoscopy compared with the one-time-bowel preparation. The grade scores are significantly better in the split-dose preparation than the conventional one-time bowel preparation. Split evening-morning dose for colonoscopy preparation is found to be superior to the single conventional one-time bowel preparation with a better colon cleansing and visibility on colonoscopy. The Exelyte solution for the colon preparation is found to be effective, better tolerability, and acceptable with low cost of price benefit.

INTRODUCTION

Colonoscopy is the current standard method for evaluation of the colon. Diagnostic accuracy and therapeutic safety of colonoscopy depends on the quality of the colonic cleansing or preparation. The ideal preparation for colonoscopy would reliably empty the colon of all faecal material in a rapid fashion with no gross or histological alteration of the colonic mucosa.(1) The preparation also would not cause any patient discomfort or shifts in fluids or electrolytes. The preparation should be safe, convenient, tolerable, and inexpensive. Unfortunately, none of the preparations currently available meet all of these requirements.(1,2) Adequate bowel preparation is essential for proper visualization of mucosa. Proper cleansing minimizes the risk of missed lesions, repeated procedures and even decreases the cost of colonoscopy.

According to previous study, colonoscopy quality is closely related to the degree of bowel cleansing achieved. Better colon preparation results in shorter procedures, an improved cecal intubation rate, increased detection of small, large, and flat polyps, decreased patient discomfort, and reduced costs.(3) Successful completion of colonoscopy depends to a large extent on the quality of bowel preparation.(4,5) Poorly visualized mucosa leads to missed diagnoses and increases Colonoscopic risk.(6,7) Even a small amount of residual stool can obscure small lesions such as angiodysplasia.(6) So most commonly used in recent years as cleansing agent for bowel preparation were polyethylene glycol (PEG) and Exelyte solution. Polyethylene glycol (PEG) solution is non-digestible, non-absorbable osmotically balanced laxative lavage solution does not alter fluid and electrolyte balance.(8,9) Despite the improved tolerance to the two-day standard preparation of clear liquids, laxatives, and enemas, the large fluid intake may lead to nausea and abdominal discomfort. Whereas Exelyte solution which is composed of (Monobasic Sodium Phosphate Dihydrate USP 24.417g, Disodium Hydrogen Phosphate Dihydrate BP 5.439g, Sodium Benzoate

IP (As Preservative) 0.2 % w/v) is a highly osmotically laxative, has also proven to be an effective and well-tolerated agent.(10) Because of the small quantity needed, it has become one of the preferred agents. Over the past decade, numerous studies have demonstrated that oral Exelyte solution is even better tolerated and results in more effective colon cleansing compared with PEG.(11,12) Bowel preparation has evolved from previous evening whole dose regimen to split dose regimen. Traditional colon preparation involves the unpleasant task of drinking a large volume of a cleansing solution the evening before the procedure. One way to increase tolerability and patient adherence is to split the dose so that the patient takes half the solution the evening before colonoscopy and the other half in the morning, usually about 4 to 5 h before the scheduled time of the procedure.(13,14) Split regimens of bowel preparation have been associated with a higher level of colon cleansing. Prior studies have demonstrated that split dosing not only improves patient acceptability, but also cleans the colon better.(15) Despite the strong evidence indicating that split-dose bowel preparations are more effective than single-dose regimens, promotion of the split-dose preparation for colonoscopy has encountered resistance.(15) So the present study was undertaken to compare not only tolerability as the primary aim but also the efficacy and safety profile of the bowel preparation solely using Exelyte solution as a whole and part preparation of the patient.

AIM AND OBJECTIVE

To assess the Cleanliness quality score of split-dose preparation and one-time preparation, assess the clarity of mucosa and compare cleanliness quality scores in split-dose vs one-time preparation.

MATERIAL AND METHOD

It is a prospective study on patients coming for Colonoscopic evaluation at department of general Surgery of MIMER

Medical College & Hospital Talegaon. All the details of the patients were collected according to pre-designed proforma. Total of 50 patients aged between 18-70years were included in study after obtaining informed consent. 50 patients were divided into 2 groups as

Group A: 25 patients with whole dose one-time preparation.
Group B: 25 patients with split-dose preparation.

Bowel preparation: Both the groups are instructed to remain on clear liquid diet for 24 hrs prior to procedure.

Exelyte solution contents;

Monobasic Sodium Phosphate Dihydrate USP 24.417 g,
Disodium Hydrogen Phosphate Dihydrate BP 5.439 g
Sodium Benzoate IP (As Preservative) 0.2 % w/v

Sodium phosphate is a saline laxative that is thought to work by increasing fluid in the small intestine. It usually results in increase bowel movement after 30 mins to 6 hrs. After taking medication drink plenty of clear liquids.

Whole bowel preparation: given 90 ml of Exelyte solution with 300 ml of soda lime in the evening around 6 pm prior to procedure

Split-dose preparation: given 45 ml of Exelyte solution with 300 ml of soda lime in the evening around 6 pm prior to the procedure and next morning at about 7 am, 45 ml of Exelyte solution with 300 ml of soda lime will be given. Patients are allowed to drink plenty clear liquids until the procedure; Colonoscopy was performed at about 11 am in the morning.

Cleanliness quality score of the blinded endoscopist

- 1 Dry colon, no solid feces
- 2 Only transparent fluid
- 3 Fluid feces
- 4 Small amount of solid feces, >90% mucosa visible
- 5 Solid feces, <90% of the mucosa visible

STATISTICS:

patient demographic details was represented as frequency and mean score of grade in different groups as mean ± SD. Difference between the mean grade score was assessed using students t-test and the distribution of the grade in the groups using chi-square test and strength of association between type of colon preparation and grade of cleanliness using phi and Cramer's test. All the statistical analysis was done using sophisticated statistical SPSS v23.

RESULTS

In this prospective study, we enrolled 50 patients for duration of three months. 25 patients were given conventional whole one-time bowel preparation (Group A) and other 25 with split bowel preparation (Group B). There were total 14 females and 36 males in study, distributed in groups as in Table 1.

Table 1 . Distribution of the gender in different Group.

		Groups		Total
		Group A	Group B	
Gender	Female	8	6	14
	Male	17	19	36

Table 2. Mean difference between the mean score in both the Group using student t-test.

	Group	N	Mean ± SD	Sig
Grade	Group A	25	3.20 ± 1.11	<.001
	Group B	25	1.44 ± 0.58	

p<.05 is statistically significant and p<.001 considered statistically highly significant (HS)

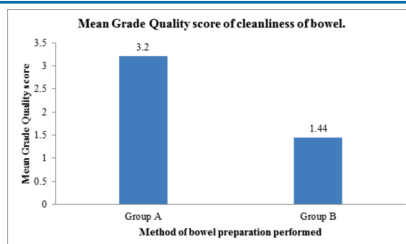


Figure 1. Showing mean Grade Quality score in both Groups.

Quality of Bowel preparation: The Mean cleanliness quality score was found to be significantly lower in the Group B (3.20 ± 1.11) patients compared to patients in Group A (1.44 ± 0.58). Split preparation had a better efficacy compared to the one-time bowel preparation.

Table 3. Grade of quality of preparation for colonoscopy, analysed by chi-square test and Phi and Cramer's for strength of association.

Cleanliness Quality Score	Groups		Chi-square (χ^2)		Correlation	
	Group A (n)	Group B (n)	value	Sig	Value	Sig
Grade 1	0	15	29.45	<.001	.768	<.001
Grade 2	8	9				
Grade 3	9	1				
Grade 4	3	0				
Grade 5	5	0				

p<.05 is statistically significant and p<.001 considered statistically highly significant (HS); correlation for strength of association was performed using Phi and Cramer's V test. Likelihood ratio was 39.30 (p<.001).

Over all, the bowel preparation quality score in Grade was less than 3 in the group B, who underwent split-dose bowel preparation compare to many of the patients in group A belonged to the Grade 2-5. There is a significant strength of association of cleanliness of bowel and the type of preparation done in patients, Group B showed to be better.

DISCUSSION

Colonoscopy is an important tool for diagnosis and follow-up of the patients with colonic disease/disorders and also in prevention of neoplasms. There is search of an better and ideal cleansing preparation for colonoscopy, with shorter colonic preparation time, better cleansing results and better acceptability with less adverse effects. Traditionally, the one-time bowel cleansing procedure involve the solution given in the evening prior to the colonoscopy. Whereas in split bowel preparation, solution is give in split dose 8-12hr apart.

In this study, split dosing showed a better result of bowel preparation for Colonoscopic examination. The Mean cleanliness quality score of split preparation was significantly low compared to the conventional one-time bowel preparation and maximum cleansing result was obtained, similar to another study conducted by Marmo R et.al.(16) There is significant association of bowel cleanliness grade and type of bowel preparation performed in patients. Split-dose bowel preparation is significantly strongly correlated with cleanliness and visibility during the colonoscopy compared with the one-time-bowel preparation.

The grade scores are significantly better in the split-dose preparation than the conventional one-time bowel preparation, which was similar to study conducted by Shah H et.al.(17) In a non-randomized study conducted by Huffman MBS et.al, on split dose bowel preparation, suggested on the safety, effectiveness and better tolerated than the conventional preparation.(18) Kilgore TW et.al, in meta-analysis of randomized control trials have found that split-

dose bowel preparation has increased the number of satisfactory bowel preparation in 1232 patients outcome and willingness to repeat the same preparation by patients was better than the full dose conventional procedure. Also reduced discontinuation in split dose was documented. They concluded with use of split-dose bowel preparation before colonoscopy significantly improved the visibility during the procedure and quality.(19) Despite high level of apprehension among the patients, the majority of colonoscopy patient willing to compile with split-dose preparation, and also showed a better cleanliness of the bowel compared to the conventional preparation of bowel for colonoscopy in study conducted by Altawil J.(20) Seo EH et.al, in a nonrandomized control single-center trial with 366 consecutive outpatients undergoing colonoscopy with split-dose preparation with PC interval of 3-5hr had the best bowel preparation quality.(21) In present study, there was no difference in tolerability between the conventional and split-dose preparation and equally well tolerated.

Study conducted by Schanz S et.al, (2008) on 360 patients a randomized trial to assess the cleanliness with various preparation of Sodium Phosphate (NaP) and Polyethylene glycol (PEG). They concluded with a better tolerability, acceptance and effectiveness of bowel cleansing regimen for elective colonoscopy for both the type of preparation solution and no significant difference was observed.(22) In our present study we got better results with the Exelyte solution which contains the NaP and better Cleanliness Quality Score.

Conclusion

Split evening-morning dose for colonoscopy preparation is found to be superior to the single conventional one-time bowel preparation with a better colon cleansing and visibility on colonoscopy. The Exelyte solution for the colon preparation is found to be effective, better tolerability, and acceptable with low cost of price benefit.

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