# Assessment of efficacy and Patient Tolerance of two Bowel Preparations for Colonoscopy, A Prospective Study

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#### **Abstract**

Bowel cleansing is a critical step obtains to diagnostic efficacy during colonoscopy procedures. Polyethylene glycol (PEG) lavage solution is one of the standard regimens used to prepare patients for colonoscopy. Apparently, oral laxative tablets are better tolerated by patients than PEG. The purpose of this study was to compare the effectiveness and patient tolerability of the two Bowel Preparations for Colonoscopy including PEG and bisacodyL tablets. Methods This study was a prospective, single-blinded, randomized evaluation of outpatients scheduled for screening colonoscopies. Patients assigned to one of the two bowel preparation groups: group 1 received instructions for a clear liquid diet and a PEG; group 2 received clear liquid diet and bisacodyL tablet. Colonic cleansing was assessed on a three-point scale by the endoscopist during the procedure. Results A total of 100 patients (59male, 41female; 19to 84 years old; mean age = 51.33 years old; SD=17.37years) scheduled to undergo a screening colonoscopy were selected for admittance into the study. Results indicated that 64% of patients in group 1, 58% of patients in group 2had good preparation rating by the endoscopist for left and right colon. (p = .9)Conclusions The overall performances of all preparations were considered to be acceptable to perform colonoscopy according to the endoscopist's standards. This information is useful in supporting alternatives to traditional clear liquid diet restrictions for patients requiring bowel preparation.

#### **BACKGROUND**

Bowel cleansing is a critical step obtains to diagnostic efficacy during colonoscopy procedures. There are various Colon cleansing methods and may require one to three days of a clear liquid diet in addition to laxative administration. These preparations provide an adequately cleansed colon; however, they are time-consuming, inconvenient, uncomfortable for the patient, and often lead to poor patient compliance (Abuksis et al., 2001). Noncompliance by patients is cited as one of the primary reasons for inadequate bowel preparation leading to failed colonoscopies and the need to repeat procedures (Cohen et al., 1994; Ness, Manam, Hoen, & Chalasani, 2001).

A clear liquid diet consists of transparent drinkable liquids and excludes all solid foods, including milk and citrus juices an effort to minimize the load of food needing digestion in the intestines. Although the clear liquid diet is beneficial in helping to clear the bowels of residual contents, it is often difficult for the patient not to eat any solid food for a long period of time required for bowel cleansing.

Polyethylene glycol (PEG) lavage solution is one of the

standard regimens used to prepare patients for colonoscopy. Since introduction in 1980 (Davis, Santa Ana, & Morawski, 1980), PEG solutions have become the most widely used laxatives for bowel cleansing. Despite proven efficacy, this large-volume laxative, in addition to a clear liquid diet, is usually difficult for patients to tolerate and therefore decreases patient compliance (Kastenberg et al., 2001).

As a low volume alternative, oral sodium phosphate bowel cleansing solutions have been found to be equally or better tolerated or as effective as PEG in preparation for outpatient colonoscopy (Hwang et al., 2005). The Food and Drug Administration (FDA) and Health Canada have recently released warnings, however, concerning the potential toxicity of these solutions (FDA, 2002; Maher & MacDonald, 2002). Most of the reported oral sodium phosphate toxicities have been the result of inappropriate dosing (Hookey, Depew, & Vanner, 2002).apparently, oral laxative tablet is better tolerable by patients.

The purpose of this study was to compare the effectiveness and patient tolerability of the two Bowel Preparations for Colonoscopy including PEG and liquid diet (standard regimen) compared to bisacodyL tablet and liquid diet.

### **METHODS**

This study was conducted between August 2003 and July 2006 at Emam reza hospital of AJA University of Medical Sciences. The study protocol was s approved by the university research qualification office. All patients provided written informed consent.

This study was a prospective, single-blinded, randomized evaluation of outpatients scheduled for screening colonoscopies. Patients 18 years of age and older were recruited to participate in the study. The patients were asked to participate in the study when they called the endoscopy center to make an appointment. At the time of patient enrollment, the endoscopy nurse obtained written informed consent and provided the patient with the appropriate verbal and written instructions. All preparation materials were given to the patient by the study coordinator free of charge. Patients that were insulin dependent diabetics, on renal dialysis, pregnant, had colostomies, contraindications to colonoscopy (i.e., gastrointestinal obstruction, bowel perforation, etc.), or partial resection of colons were excluded from the study.

After obtaining informed consent, subjects were prospectively randomly assigned to one of the two bowel preparation groups according to a computer generated randomization schedule: group 1 received instructions for a clear liquid diet and a PEG to be administered on the day of the procedure at least two hours prior to examination; group 2 received clear liquid diet as Group 1 and bisacodyL tablet. All procedures were performed by the same endoscopist who was blinded to the type of bowel preparation used by the patient. Comparative data was collected for colonic cleansing and patient tolerance. Colonic cleansing was assessed on a three-point scale by the endoscopist during the procedure. Points on the scale were defined as: 1) good, no fecal residue present; 2) fair, moderate fecal residue easily removed by suction; and 3) poor, substantial fecal residue requiring a repeat examination (Delegge & Kaplan, 2005; El-Baba et al., 2006).

Prior to colonoscopy, the subjects were asked about their preparation experience by the study coordinator. The study coordinator recorded the verbal responses of the patient regarding the number of trips to the bathroom during the night, any associated side effects, and tolerance of the preparations. The preparations were ranked by patients for tolerance by choosing one of four categories: 1) tolerable, 2) intolerable.

Numerical data were analyzed using the t-test. The Chisquare test was used to compare the assessment of colonic cleansing and patient tolerance. A P-value of <.05 was considered significant. Statistical software SPSS Version 10.0 (SPSS, Inc., Chicago, Illinois) was used.

#### **RESULTS**

A total of 100 patients (59male, 41female; 19to 84 years old; mean age = 51.33 years old; SD=17.37years) scheduled to undergo a screening colonoscopy were selected for admittance into the study. Two 50 subjects (31 males 19 female) in group 1, 50 subjects (28 male 22 female) in group 2. The characteristics of all subjects were similar between the Two groups (see Table 1).

Figure 1
Table 1- subjects demographics

	Group 1	Group 2	P- value
Number of patient	50	50	
	21.10	28.22	0.21
Gender-male female	31.19	28.22	0.21
Mean age	49.12	53.54	0.28
Mean age	49.12	53.54	0.28

Results indicated that 64% of patients in group 1, 58% of patients in group 2had good preparation rating by the endoscopist for left and right colon. (p = .9) (see table2).

Figure 2
Table 2- bowel cleansing in left and right colon(l.t = left, r.t = right)

preparation	Group1(l.t/r.t colon)	Group2(l.t/ r.t colon)
good	64/62	58/50
fair	20/28	32/30
poor	16/10	10/20

There was no difference in tolerance between the two regimens:

(see table 3). 45 subjects (90%) in group 1 rated the preparation to be "tolerable" compared to 42 subjects (84%) in group 2 (p = .82). two preparation regimens were well tolerated, and no patients reported any adverse experiences or other complaints attributed to the bowel preparations.

**Figure 3**Table 3- tolerability of bowel preparation regimen

	Group 1	Group2
tolerable	90	84
Non tolerable	10	16

#### **DISCUSSION**

A clear liquid diet, in combination with various laxative preparations, is the conventional method used for preparation of the colon prior to colonoscopy. The traditional methods used for bowel preparation provide a relatively clean colon; however, they are time-consuming, inconvenient, and uncomfortable for the patient. The inability of patients to comply with these methods, specifically with regard to the usual liquid diet, the laxative preparation taste, and laxative preparation volume can result in a poorly cleaned colon, thus decreasing the sensitivity of the procedure by missing pathological lesions or resulting in cancelled procedures (Ness et al., 2001). In this study, we have shown that a oral laxative tablet, in combination with low and high volume clear liquid regimens, is as effective as the traditional method to adequately clean the colon for colonoscopy and is also well tolerated by the patient.

# CONCLUSIONS

The use of a better tasting, lower volume preparation in combination with a oral laxative tablet evaluated in this study offers a dependable, safe, and effective way of improving

patient satisfaction and compliance, which resulted in clinically improving the quality of the diagnostic procedure and decreasing the need for repeated procedures in this sample. Although there were no significant statistical significances reported in the study, the overall performances of all preparations were considered to be acceptable to perform colonoscopy according to the endoscopist's standards. This information is useful in supporting alternatives to traditional clear liquid diet restrictions for patients requiring bowel preparation.

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