



## Bowel Preparation for a Better Colonoscopy Using Polyethylene Glycol or C-lax: A Double Blind Randomized Clinical Trial

Rose Khorasanynejad<sup>1</sup>, Alireza Norouzi<sup>2\*</sup>, Gholamreza Roshandel<sup>3</sup>, Sima Besharat<sup>4</sup>

1. Assistant of cardiology, Department of Cardiology, Mashhad University of Medical Sciences, Mashhad, Iran
2. Gastroenterologist, Golestan Research Center of Gastroenterology and Hepatology, Golestan University of Medical Sciences, Gorgan, Iran
3. Epidemiologist, Golestan Research Center of Gastroenterology and Hepatology, Golestan University of Medical Sciences, Gorgan, Iran
4. PhD of Biomedicine, Golestan Research Center of Gastroenterology and Hepatology, Golestan University of Medical Sciences, Gorgan, Iran

### ABSTRACT

#### BACKGROUND

Ideal bowel preparation regimen for a suitable colonoscopy should be safe, and well tolerated, and should rapidly clear gastrointestinal tract. Soluble polyethylene glycol (PEG) is the most common cleansing drug and Senna or C-Lax (Cassia angustifolia Vahl) is an alternative herbal one. This study was designed to compare the efficacy of PEG and C-lax in bowel preparation.

#### METHODS

In this randomized double blind trial (registry number in IRCT.ir: IRCT201601161264N7), 320 patients were randomly assigned in PEG or C-lax groups. PEG solution was prepared from 5×70 gr sachets in 20×250cc water (250 ml every 15 minutes), prescribed 24h before the colonoscopy. In the other group 3×60 ml C-lax syrup glasses (each containing 90 mg senozid B) was given in two divided doses (1.5 glasses of 250cc every 12 hours), 24h before the colonoscopy. Ottawa score was used to evaluate the quality of bowel preparation. Chi-square test, Student t test, Mann-Whitney test and multivariate analysis were used to analyze the data.

#### RESULTS

Of these patients with the mean (SD) age of 50 (15.16) years, 162 (50.8%) were men. Mean (SD) Ottawa score was 2.57 (0.2) and 3.15 (0.31) in the PEG and C-lax group, respectively (p value = 0.81). Multivariate analysis showed that less opium consumption (p < 0.001) and higher educational level (p = 0.005) were associated with better bowel preparation.

#### CONCLUSION

C-Lax is non-inferior to PEG solution in cleansing colon. The quality of bowel preparation was lower in opium consumers and better in those with higher educational level.

#### KEYWORDS:

Bowel preparation, Polyethylene glycol, C-Lax, Double blind clinical trial, Ottawa score

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### INTRODUCTION

Colonoscopic examination necessitates a well prepared fecal-matter-free bowel for a diagnostic and therapeutic approach.<sup>1</sup> A good colonoscopy may have three main characteristics: a skilled gastroenterologist, a cooperative patient, and a glossy clean bowel.<sup>2</sup> Bowel preparation most commonly involves oral ingestion of a large volume of a cathartic agent with laxative properties over a defined period of time.<sup>1,3</sup>

Administering a good tasty tolerable oral agent to patients willing to undergo a colonoscopic examination may seem no big deal to clinicians but is a key factor for patients to decide whether to avoid or accept the procedure.<sup>4</sup> Efficacy, tolerance, and safety are among the most important factors that a

#### \* Corresponding Author:

Alireza Norouzi, MD  
Golestan Research Center of Gastroenterology and Hepatology, Third floor, Research Centers' Complex, Sayyad-e-Shirazi Hospital, Sayyad-e-Shirazi Boulevard, Gorgan, Iran  
Telefax: + 98 17 32251910  
Email: norouzi54@gmail.com

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cleansing agent should have when chosen.<sup>4</sup>

Inadequate bowel cleanliness has been reported in one third of patients who have been candidate for colonoscopy<sup>5</sup>, leading to a higher rate of repeat colonoscopy, increased rate of complications, and a longer duration of the procedure.<sup>4,6,7</sup>

There are several factors affecting bowel preparation such as face-to-face patients' education, patients' general health condition like elderly, or childhood, inflammatory bowel disease in active phase, or concurrent renal failure, heart failure, acute gastrointestinal bleeding, and urgent colonoscopy. Such factors can affect the ability of patients to tolerate and adhere to the preparation regimen.<sup>1,4</sup>

Three types of bowel preparation agents are available so far: a- polyethylene glycol (PEG) solutions, b-osmotic agents, such as sodium phosphate, magnesium citrate, lactulose, and mannitol, and c- stimulants, such as castor oil, Senna, sodium picosulfate, and bisacodyl.<sup>2</sup>

PEG is a balanced isotonic oral, non-digestible, and non-absorbable solution, of which usually 4 liters are administered for bowel preparation. In some patients, the unpleasant taste and smell and drinking a large volume in short time intervals could not be well tolerated.<sup>1,4</sup>

Stimulants affect the epithelial transport of water and electrolytes and stimulate the intestinal motility. They are cheaper, safe, and easy to ingest. Senna (*Cassia angustifolia* Vahl, Leguminosae, Indian Senna, Tinnevely Senna) is a laxative from this group.<sup>8</sup>

In the present study, we compared the quality of bowel preparation with either PEG solution or Senna in two groups of patients who were candidate for colonoscopy in our academic center, in northeast Iran.

## MATERIALS AND METHODS

### Randomization

In this double blind randomized clinical trial, 320 eligible patients were recruited from the candidates with any indications of colonoscopy such as screening, polyp surveillance, etc who were referred to our academic hospital in Gorgan city, northeast Iran. All the patients were randomly allocated in either PEG (N = 160) or C-lax (N = 160) group by the endoscopy ward technician. Neither the gastroenterologist nor the one who evaluated the Ottawa score was aware of the group randomization. Age and sex were matched in both groups using frequency

matching method.

A soft clear liquid regimen without any solid residues (bread, rice, vegetables or fruits) was administered to all the patients the day before the procedure. In PEG group, 5L of PEG fluid was administered (sachets of PEG powder were rinsed in water, each sachet contains 70 grams of PEG rinsed in 4 glasses of water), and the patients were asked to drink 250 mL of the solution every 15 minutes starting 24 hours before the procedure.

In C-lax group, three bottles of C-lax syrup (each 60 mL bottle contains 90 mg Senozoids) in two split doses beginning from 24 hours before the procedure (1.5 bottles at 9 am and 1.5 bottles at 5 pm the day before colonoscopy) were prescribed.

Cases were suggested to drink lots of liquids. More liquid food and beverage were suggested for those with long-lasting constipation. A written permission from a cardiologist was also necessary for those with a history of heart disease (in addition to self-informed consent).

Exclusion criteria were as following: age less than 18 years, a history of colectomy, any contraindication for colonoscopy, severe mental disease, pregnancy, lactation, and patients' not willing to participate.

A single gastroenterologist (principle investigator of the study) performed all colonoscopies and scored the bowel preparation using Ottawa bowel preparation quality scale (table 1). This system evaluates the bowel cleansing and fluid volume separately for the right colon (secum and ascending colon), mid colon (descending and transverse colon) and rectosigmoid colon. Each part of the colon would be scored from 0 to 4 and the liquid is scored from 0 to 2 (0: minimal liquid, 1: moderate, and 2: lots of liquid). Total score would be from 0 to 14 (solid stool in entire colon and lots of liquid, no preparation). Lower score means the better preparation and 14 means the worst.

### Outcome measure

The quality of bowel preparation by either methods (PEG or C-Lax) measured by Ottawa score was considered as the primary outcome. Adequate bowel preparation was defined as a total Ottawa score of  $\leq 4$ , while inadequate bowel preparation was defined as a score of more than 5, based on the previous studies.<sup>7</sup>

**Table 1:** Comparing baseline characteristics of the two studied groups receiving either PEG or C-Lax

Variables	Intervention group		Total
	PEG (N = 160)	C-Lax (N = 151)	
<b>Sex</b>			
Male/ Female	83.77	75.76	0.619
<b>Education level</b>			
Illiterate	50 (30.7)*	47 (30.1)	0.994
High school	65 (39.9)	63 (40.4)	
College	48 (29.4)	46 (29.5)	
<b>Ethnicity</b>			
Fars	10 (6.1)	7 (4.5)	0.691
Turkmen	122 (74.8)	114 (73.5)	
Other	31 (19)	34 (21.9)	
<b>Smoking history</b>			
No	138 (88.5)	144 (94.1)	0.078
Yes	18 (11.5)	9 (5.9)	
<b>Opium consumption</b>			
No	132 (83)	128 (83.7)	0.879
Yes	27 (17)	25 (16.3)	

\*number (%)

### Ethical considerations

The study protocol was approved by the local Ethics Committee of Golestan University of Medical Sciences (Reference number: 32189210226). This clinical trial was registered in Iranian registry of clinical trials (www.IRCT.ir) and assigned a code as: IRCT201601161264N7. Informed consent was obtained from all the participants after verbal consent and explaining the study protocol by the principle investigator.

### Statistical analysis

SPSS software version 16 was used for analysis. Chi square test was used to analyze qualitative variables and t test was used for quantitative ones after testing for the normality of the variables by Kolmogorov–Smirnov test.  $p$  value less than 0.05 was considered as statistically significant.

### RESULTS

In this randomized clinical trial, 320 eligible cases were randomized into either PEG or C-Lax group. Nine cases from C-Lax group did not present in the scheduled date, despite phone calls and follow-ups and were excluded

from the study. So, all analyses were done on 151 cases in C-lax group and 160 cases in PEG group.

The mean (SD) age of the studied patients was 50 (15.2) years. 158 (51%) patients were male and 153 (49%) were female. There were no significant differences between the groups receiving PEG or C-Lax regarding the demographic variables (table 1).

Mean (SD) Ottawa score was not significantly different between PEG and C-Lax groups, 2.6 (2.5) versus 3.15 (3.75), respectively ( $p = 0.110$ ).

As shown in table 2, in PEG group there was a significant higher Ottawa score in illiterates and opium consumers ( $p < 0.005$ ). And in C-Lax group, elder patients ( $\geq 51$  years), illiterate cases, ethnic groups other than Fars and Turkmen and opium consumers had significantly higher Ottawa score ( $p < 0.005$ , table 2).

Multivariate analysis showed that opium consumption and education level were the strongest variables related to the bowel preparation. Opium increased the Ottawa score (worse bowel preparation) but higher education level decreased the Ottawa score (better bowel preparation, table 3).

As shown in table 4, mean (SE) Ottawa score was not significantly different in different segments of the colon in both groups, although the score was lower for the entire colon in PEG group compared with the C-lax group (table 4).

### DISCUSSION

In this randomized clinical trial, we found no significant differences in bowel preparation scores between those cases taking PEG or C-Lax. However, opium consumers and those with lower formal educational level showed significant lower bowel preparation quality in both groups.

According to the literature, some studies reported the superiority and effectiveness of PEG solution<sup>9,10</sup> and some showed equal<sup>11-13</sup> or inferior effects<sup>14,15</sup> for PEG group compared with Sennosides.

Radaelli and colleagues compared the efficacy and overall quality of colon cleansing of 24 tablets of 12-mg Senna (divided into two doses at 1 p.m. and 9 p.m. [Senna group,  $n = 191$ ]) with standard 4-L Polyethylene glycol-electrolyte solution (PEG-ES group,  $n = 92$ ). Consumption of Senna revealed significantly better quality

**Table 2: Comparing mean (SE) Ottawa score regards to the baseline characteristics of the studied population**

Variables		PEG (N = 160)	p-value	C-Lax (N = 151)	p-value
Sex	Male	2.45 (0.24)	0.78	3.39 (0.41)	0.12
	Female	2.71 (0.31)		2.91 (0.44)	
Age group	< 51	2.16 (0.22)	0.07	2.66 (0.40)	0.03
	≥ 51	2.95 (0.3)		3.65 (0.45)	
Education level	Illiterate	3.32 (0.41)	0.002	4.82 (0.75)	0.004
	High school	2.66 (0.3)		2.91 (0.39)	
	College	1.68 (0.24)		1.84 (0.34)	
Ethnicity	Fars	2.17 (0.8)	0.47	2.75 (0.52)	0.004
	Turkmen	2.39 (0.19)		2.60 (0.31)	
	Others	3.4 (6.4)		4.99 (0.81)	
Cigarette smoking	Yes	3.03 (0.46)	0.12	4.89 (1.72)	0.14
	No	2.53 (0.22)		2.97 (0.30)	
Opium	Yes	4.89 (0.71)	0.001	5.73 (1.01)	0.001
	No	2.10 (0.16)		2.58 (0.29)	

**Table 3: Multivariate analysis of factors predicting the bowel preparation (Ottawa score)**

Variables	Standardized Beta	Unstandardized Beta	95% Confidence Interval for B	p-value
C-Lax or PEG	0.08	0.52	-0.14 - 1.19	0.124
Sex	-0.01	-0.09	-0.80 - 0.61	0.792
Age group	0.03	0.19	-0.60 - 0.98	0.638
Education	-0.17	-0.73	-1.24 - 0.22	0.005
Ethnicity	0.10	0.70	-.01-1.42	0.056
Co-morbidity	-0.03	-0.20	-1.00 - 0.58	0.609
Cigar	0.01	0.15	-1.12 - 1.42	0.817
Opium	0.28	2.39	1.41 - 3.38	0.000

**Table 4: Comparing mean (SE) Ottawa score of different part of colon in two groups of bowel preparation**

	Mean (SE) of Ottawa score				
	Right colon	Mid colon	Rectosigmoid colon	Entire colon	Total score
PEG (N = 160)	1.02 (1.06)	0.6 (1.02)	0.7 (1)	0.3 (0.4)	2.6 (2.5)
C-Lax (N = 151)	1.22 (1.42)	0.7 (1.3)	0.85 (1.22)	0.41 (0.6)	3.15 (3.75)
P-value	0.160	0.443	0.198	0.045	0.110

of colon cleansing (90.6% vs. 79.7%), overall tolerance of the preparation, and compliance ( $p = 0.003$ ).<sup>15</sup>

Shavakhi and co-workers enrolled 322 patients randomized into two groups: Senna group (24 tablets of 11mg Senna in two divided doses 24 hours before colonoscopy) and PEG group (solution of four sachets in four liters of water the day before the procedure and the patients were asked to drink 250 ml every 15 minutes).

The overall quality of colon cleansing was evaluated using the Aronchick scoring scale. Quality of colon cleansing, patients' tolerance, compliance, and the difficulty of the procedure was similar between the two groups ( $p > 0.05$ ).<sup>13</sup>

Performance of colonoscopy in hospital inpatients, bowel habits tend to chronic constipation, opioid dependency, consumption of drugs such as tricyclic antidepressants.

sants (TCA), low socioeconomic status, being overweight or obese especially higher abdominal circumference, male sex, and starting the procedure later in a day are factors predicting a poor colonoscopy.<sup>5,16</sup> Outpatient status has been also considered a difficult entity due to unawareness and poor adherence to the instructions.<sup>5</sup>

Type of cleansing agent, taking adequate water till the colonoscopy time, applying protocol, and the time interval between starting the preparation schedule and the colonoscopy procedure are the most important predictors of adequate bowel preparation.<sup>5,17</sup> Different educational aids such as videos, booklets, questionnaires, telephone calls at the same day of colonoscopy or the short-message services, brief educational sessions and interactive systems have been applied to improve the bowel cleanliness, although inconsistent results have been achieved.<sup>5,7,16,17</sup>

Rosenfeld and colleagues in an interventional study on 38 inpatients, who were candidate for colonoscopy, randomized 16 cases to the intervention and 22 as controls. The patients in the intervention group received a brief counseling session in addition to written instructions outlining the methods and rationale for bowel preparation before colonoscopy. Results showed that a simple, inexpensive and safe method like counseling would significantly improve the outcome of colonoscopy.<sup>17</sup> Prakash and colleagues in a series of outpatients referred for colonoscopy reported an improvement in the quality of bowel preparation scale (Ottawa score) when an additional educational video was added to the applied instruction. Although income level, education level or age had no significant correlation with Ottawa score.<sup>16</sup> Forgetting the key components of the bowel preparation process urge the need to review the whole schedule using any educational facilities can be beneficial in answering the remained questions and empower patients' compliance with the bowel preparation.<sup>16</sup>

Furthermore, understanding the written instructions or counseling sessions are much better when patients have higher formal educational level (high school or more), however this may not be applicable for the visual educations like video tapes. Another interventional study showed that a short 10-minute physician-delivered patient education session along with the written instruction has better effect on the quality of bowel preparation.<sup>5</sup>

Applying a comfortable session to explain the rationale and importance of pre-colonoscopy preparation for patients would be of more importance especially when the educational level is low.

In the present study, we did not assess the effect of education on the quality of bowel preparation, but our results showed that higher educational level decreased the Ottawa score and provide a better bowel preparation.

## CONCLUSION

It seems that PEG solutions and C-Lax syrup have similar effects in bowel preparation. But there are other factors resulting in a well prepared bowel such as the educational level and addiction to opioids. So, sociodemographic situation of the studied population would affect the outcome of even a well-designed colonoscopy. These demographic variables would be further investigated in future projects.

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## CONFLICT OF INTEREST

The authors declare no conflict of interest related to this work.

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