



## Research Paper

# A randomized controlled trial on comparison of colon cleansing for colonoscopy bowel preparation using one-day or two-day regimen methods

Saleh Azadbakht <sup>a, \*\*</sup>, Morteza Azadbakht <sup>b</sup>, Salehe Azadbakht <sup>c</sup>, Alireza Esmaili <sup>a</sup>, Parisa Rahmani <sup>d, \*</sup>

<sup>a</sup> Department of Internal Medicine, School of Medicine, Lorestan University of Medical Sciences, Khorramabad, Iran

<sup>b</sup> Department of Surgery, School of Medicine, Tehran University of Medical Sciences, Tehran, Iran

<sup>c</sup> Student Research Committee, Lorestan University of Medical Sciences, Khorramabad, Iran

<sup>d</sup> Pediatric Gastroenterology and Hepatology Research Center, Tehran University of Medical Sciences, Tehran, Iran

## ARTICLE INFO

## Article history:

Received 27 October 2020

Received in revised form

10 November 2020

Accepted 11 November 2020

Available online 16 November 2020

## Keywords:

Colonoscopy

Regimens

Bowel

Colon cleansing

Lower gastrointestinal tract

Small intestine

## ABSTRACT

**Background:** Adequate bowel cleansing prior to colonoscopy is important to achieve clearer view of the bowel and ease diagnosis.

**Objective:** This study was performed to compare colon cleansing prior to colonoscopy using one-day and two-day regimens.

**Method:** This study is a randomized controlled clinical trial, the patients were randomly allotted in one-day or two-day colon cleansing groups Polyethylene glycol was used as a laxative agent and colonoscopy was performed either on one-day following the bowel cleansing or non-next day (two-day) after the bowel cleansing. Statistical analysis was performed by SPSS software (version 22).

**Results:** Overall, the two groups had 52 patients and were not significantly different in terms of age and gender. The mean duration of colonoscopy in the one-day group was 9.44 min and in the two-day diet group was 10.5 min, which was also not significantly different,  $P = 0.098$ . Total colon cleansing in one-day was acceptable in 94.2% and unacceptable in 5.8% patients. The two-day clearance rate was 80.8% and unacceptable clearance 19.2% patients, which was statistically significant,  $p = 0.038$ .

**Conclusion:** The total colon cleansing was better in one-day regime group. The two groups did not differ in terms of side effects and these effects were not associated with age and the gender of the patients.

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## 1. Introduction

Colonoscopy is a type of endoscopic procedure in the lower gastrointestinal tract, which is specifically used to examine the large intestine and distal part of small intestine [1]. Bowel preparation including bowel cleansing is an important prerequisite for colonoscopy whereas, inadequate bowel cleansing can effect up to 30% of the colonoscopies in the United State. This can lead to poor detection of polyps and increased surgical complications.

This study was approved by the Research Ethics Board of Lorestan University of Medical Sciences (IR.LUMS.REC.1398.229). <https://ethics.research.ac.ir/ProposalCertificateEn.php?id=102315&Print=true&NoPrintHeader=true&NoPrintFooter=true&NoPrintPageBorder=true&LetterPrint=true>.

\* Corresponding author.

\*\* Corresponding author.

E-mail addresses: [md.azadbakht.s@gmail.com](mailto:md.azadbakht.s@gmail.com), [azadbakht.saleh@yahoo.com](mailto:azadbakht.saleh@yahoo.com) (S. Azadbakht), [md.p.rahmani@gmail.com](mailto:md.p.rahmani@gmail.com) (P. Rahmani).

<https://doi.org/10.1016/j.ijso.2020.11.011>

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Inadequate bowel cleansing also exerts economic burden on health care system [2].

Mechanical bowel preparation (MBP) is one of the effective ways of bowel cleansing that is associated with reduced complications and mortality. It also reduces the risk of postoperative infections following colorectal surgery. In some cases, bowel cleansing can lead to electrolyte imbalance, nausea and vomiting, lesions and dehydration [3]. A number of studies have been conducted to optimize bowel cleansing methods that are well-tolerated, have minimal side effects, cleanse the bowel adequately and do not obscure the diagnosis. Some of the common bowel cleansing agents includes Polyethylene Glycol (PEG), sodium phosphate, mannitol, milk of magnesia and liquid paraffin [4]. The time lapse between colonoscopy and bowel cleansing is also play a significant role in achieving the quality of cleansing and obtaining adequate diagnosis [5].

The aim of this study to compare the outcomes of two different colon cleansing regimens; one-day regimen (given a day before

colonoscopy) and two-day regimen (colonoscopy performed on non-next day of the bowel cleansing).

## 2. Methods

This study is a randomized controlled clinical trial that like any quasi-experimental study has an intervention factor and two control and test groups where conventional methods (two-day method) is an independent variable and colon clearance is a dependent variable. Samples were randomly selected based on age at a time point. In this study, 8 patients were excluded due to non-compliance with the intestinal preparation protocol. Sampling for control and experimental groups was done randomly based on age among the candidates for colonoscopy. In this way, four age groups were determined based on the WHO age division and patients were added to the experimental and control groups alternately based on age, (age groups according to WHO classification including 18–25 years, 26–44 years, 45–64 years, 65 years and above) A detailed explanation of the study and methods was provided to all the patients and a written consent for participation was obtained from all the patients. Finally, 52 people were in the control group and 52 people were in the experimental group.

Inclusion criteria of the study included: patients aged over 18 years, patients without symptomatic ischemic heart disease during the last 6 months, liver disease (clinically significant ascites), creatinine above 2 mg/dL, high blood pressure (diastolic blood pressure above 105 mm Hg), the history of insulin-dependent diabetes, pregnancy and lactation, medical evidence of obstruction of the stomach or intestines, the usage iron derivatives during the last 4 days, constipation during the last 12 h and history of opium use, history of colectomy more than or equal to 50% of the intestine, severe constipation (less than or equal to once a week), the suspicion or known gastroparesis and severe nausea and vomiting. Patients other than this and those who did not consent to participate in the study were excluded.

A researcher provided the necessary training on how to prepare the intestine, including the diet, and the usage of oral PEG powder and in writing (educational pamphlet) to the patients in both groups. The training was as follows:

Experimental group: one-day diet

- The day before colonoscopy: Consumption of a diet based on clear liquids + Senagraph syrup once at 8 am + 1 tablet of bisacodyl every 6 h (6 am - 12 noon, 6 pm–12 pm).
- 6 packs of PEG powder (Pidrolax), each pack is dissolved in 4 glasses of water and one glass is taken every 30 min.
- After finishing the powder, if clear liquids are not excreted, one or two more packs of PEG powder using the above-mentioned method.

Control group: two-day diet

- 2 days before colonoscopy: Diet of clear liquids + Senagraph syrup once at 8 am + Bisacodyl tablets 1 every 6 h (6 am - 12 noon, 6 pm–12 pm) and 5 packs of Pidrolax powder
- 1 day before colonoscopy: Take a diet of clear liquids + bisacodyl tablets 1 every 6 h (6 am - 12 noon, 6 pm–12 pm) and 5 packs of Pidrolax powder

Patients in both groups are advised to drink plenty of fluids up to 3 h before colonoscopy.

- How to use Pidrolax powder: Dissolve each package of 75 g of Pidrolax powder in 1 L of water (4 glasses) and drink a glass (250 cc) every 15 min.

A questionnaire comprising of three parts was filled for each participant. The first part of the questionnaire included name, sex, age, contact number, start and end date of colonoscopy, time of colonoscopy and duration of colonoscopy. The information in the second and third parts included the table of exclusion criteria and complications during the preparation diet and a table regarding admission details of the patients such as the presence of symptoms including nausea, vomiting, bloating, abdominal cramps, sweating, tremors, headache, dizziness, anal pain and sleep disturbance. The endoscopist specialist recorded the quality of colon cleansing based on the following classification and entered it in the third table of the questionnaire: (Ottawa Scale).

Excellent: mucosal details are clearly visible, almost no stool remains. If liquid is present, details are clear = Score 0.

Good: There is some turbid fluid or stool residue, but mucosal details are still visible without the need for rinsing/suction = Score 1.

Fair enough: There is some turbid liquid or stool residue. However, mucosal details become visible by suction, no washing required = Score 2.

Poor: Stool residue causes the mucous details to not be seen well, but good vision is achieved by suction and washing = Score 3.

Inadequate: Solid stools hide mucosal details and are not cleared by washing and suction = Score 4.

Scoring before suction and washing was done for three part: right colon (ascending), mid-colon (transverse) and rectosigmoid.

Statistical data were analyzed using SPSS version 22 using descriptive statistics (mean, standard deviation and frequencies) and analytical statistics (Chi-square). Significance level was considered to be less than 0.05. This study was approved by the Research Ethics Board of (XXX).

## 3. Results

In the present study, 104 candidates of colonoscopy were equally divided in the two groups of 1-day cleansing regimen and 2-day cleansing regimen. In the one-day cleansing group, 18 female patients (34.6%) and 34 male patients (65.4%) were included whereas in two-day cleansing group 23 patients (44.2%) were female and 29 patients (%). 8/55 were male. These differences were not statistically significant,  $p = 0.316$ .

In 1-day cleansing group, the highest frequency of the patients was in age group of 45–59 years (40.4%) and in the group receiving 2-day cleansing the age group of 45–59 years had the highest frequency of the patients 36.5%. According to chi-square test, the difference in the relative frequency distribution of the two groups based on the age was not statistically significant ( $p = 0.882$ ). Based on the results in the independent  $t$ -test, the difference between the mean age of the two groups was not statistically significant  $p = 0.726$ .

The mean duration of colonoscopy in the group receiving the one-day diet was 9.44 min and, in the group, receiving the two-day diet was 10.5 min, which according to the independent  $t$ -test, was not statistically significant,  $p = 0.890$ .

In the study of rectosigmoid clearance status in the two groups, the clearance rate in the group receiving the one-day clearance diet was acceptable in 96.2% and unacceptable in 3.8%. In the group receiving the two-day clearance diet, the acceptable clearance rate was 88.5% and the unacceptable clearance rate was 11.5%. According to the Fischer's exact test, this difference was not statistically significant,  $p = 0.141$ .

For transverse colon, the clearance rate was acceptable in 94.2% in the one-day diet group and unacceptable in 5.8%. In the two-day diet group, the acceptable clearance rate was 84.6% and unacceptable clearance was 15.4%. According to the Fischer's exact test, this difference was not statistically significant,  $p = 0.111$ .

In ascending colon, the cleansing in the group receiving a one-day diet was acceptable in 94.2% patients and unacceptable in 5.8%. In the group receiving a two-day diet, the amount of acceptable cleansing was 84.6% and unacceptable clearance was 15.4%. The difference in the two groups was not statistically significant,  $p = 0.111$ .

The total colon cleansing in one-day cleansing diet group was acceptable in 94.2% patients and unacceptable in 5.8%. In the group receiving the two-day diet, the amount of acceptable cleansing was 80.8% and unacceptable cleansing was 19.2%. The Fischer's exact test showed that this difference was not statistically significant,  $p = 0.038$  (Table 1).

Based on chi-square test, there was no statistically significant difference in the frequency distribution of cleansing side effects in the group receiving the one-day diet and the group receiving the two-day diet (Table 2).

The frequency distribution of colon cleansing status in patients receiving one-day diet by age and sex is reported in Table 3. The rate of acceptable cleansing in men (94.1%) and women (94.4%) that based on Fischer's exact test, was not statistically significant,  $p = 0.962$ .

Also, the rate of acceptable clearance in the one-day diet in the age groups under 30 years, 30–44 years, 45–59 years and 60 years and above were 100%, 90%, 95.2% and 90%, respectively. Based on Chi-square test, the difference was not statistically significant,  $p = 0.712$ .

The frequency distribution of colon cleansing status in patients receiving two-day diet by age and sex has been presented in Table 4. The rate of acceptable cleansing in two-day diet in men (79.3%) and women (82.6%) was not statistically significant,  $p = 0.764$ .

Also, the acceptable clearance rate in the two-day diet in the age groups under 30 years, 30–44 years, 45–59 years and 60 years and above was 77.8%, 91.7%, 89.5% and 3%, respectively. According to Chi-square test, the difference in colon clearance in the two-day diet based on age groups of patients was not statistically significant,  $p = 0.123$ .

#### 4. Discussion

Colonoscopy is commonly used procedure for bowel examination to determine the signs of the disease or pathology [6]. One of the significant challenges faced during colonoscopy is inappropriate or vague diagnosis due to improperly prepared bowel [7]. Commonly, bowel preparation is achieved by one, two or four-day PEG regime [8].

The results of this study showed that the relative frequency distribution in terms of sex and age, mean duration of colonoscopy, rectosigmoid, ascending and transverse colon clearance status, by polyethylene glycol using one-day and two-day methods did not show any statistically significant difference. However, the total colon cleansing among the two groups were statistically significant, which is, it was more acceptable in one-day regime group. The colon cleansing rate was independent of age and gender distribution among the groups. Despite some studies have reported that advanced age and male gender as independent predictors of inadequate bowel cleansing [9], the frequency of geriatric participants in our study was less and we also predict that male population in our study adhered to cleansing regime similar to female patients.

A study by Laura Ramos and colleagues compared the one-day and two-day colon preparation methods. Colon cleansing was sufficient in 94% of patients in one-day group compared with 80% in two-day group ( $P = 0.27$ ). There was no significant difference between the two groups in terms of intestinal cleansing [10]. In a randomized control trial, Sorser, Konanki [11] compared the one-day and three-day colon cleansing method using Polyethylene Glycol 3350 in children undergoing elective colonoscopy. The study concluded that both the methods are well-tolerated and there is no significant difference in the efficacy and the safety of the two methods.

Parra-Blanco, Nicolas-Perez [12] reported that the quality of bowel cleansing and the identification of polyps and superficial lesions is correlated with the time interval between colonoscopies and better bowel cleansing on the day of colonoscopy ( $P = 0.02$ ). In our study, a significant difference was observed in the outcomes of one-day and two-day PEG cleansing regimes. It has been known that the quality of bowel cleansing is correlated with the better diagnosis of intestinal polyps [13]. Furthermore, Eun, Han [14] concluded that the shorter duration between bowel cleansing and colonoscopy is associated with better cleansing outcomes, irrespective of the time cleansing regime is taken (day or evening time).

The studies have also shown that in addition to separate doses of polyethylene glycol being more effective than a single dose, the time of administration (less than 5 h before colonoscopy) is effective to achieve cleansing than that of more than 19 h before the procedure and is more important in colon preparation than diet restriction [15]. The findings of these studies confirm the results of our study, that polyethylene glycol at one-day shows more acceptable results compared to two-day cleansing regime.

**Table 1**  
Comparing the frequency distribution of total colon cleansing status in the studied patients.

Groups	Total colon cleansing status			p-value
	Acceptable (N%)	Non-acceptable (N%)	Total (N%)	
one-day cleansing group	49 (94.2%)	3 (5.8%)	52 (100%)	0.038
two-day cleansing group	42 (80.8%)	10 (19.2%)	52 (100%)	

\*Statistical test: Fisher's exact test.

**Table 2**  
Comparative table comparing the frequency distribution of intestinal cleansing side effects in the studied patients.

Side effects/ study groups	Nausea	Sweating	Vomit	shiver	Headache	cramp	bloat	Nausea & headache	Nausea & vomit	Nausea & shiver	Vomit & Sweating	Headache & cramp	Nausea & cramp	Headache & shiver	p
one-day cleansing group	4 (28.6)	2 (14.3)	3 (21.4)	0 (0)	2 (14.3)	0 (0)	0 (0)	2 (14.3)	0 (0)	1 (7.1)	0 (0)	0 (0)	0 (0)	0 (0)	0.283
two-day cleansing group	7 (30.4)	1 (4.3)	0 (0)	1 (4.3)	3 (13)	2 (8.7)	1 (4.3)	1 (4.3)	3 (13)	0 (0)	1 (4.3)	1 (4.3)	1 (4.3)	1 (4.3)	

\*Statistical test: Chi-square Tests.

**Table 3**

Agreement table comparing the frequency distribution of total colon cleansing status in patients receiving one-day diet by age and sex.

Properties	Total colon cleansing status			p-value
	Acceptable (N%)	Non-acceptable (N%)	Total (N%)	
Male	32 (94.1%)	2 (5.9%)	34 (100%)	0/962 <sup>a</sup>
Female	17 (94.4%)	1 (5.6%)	18 (100%)	
<30	11 (100%)	0 (0%)	11 (100%)	0/712 <sup>b</sup>
30–44	9 (90%)	1 (10%)	10 (100%)	
45–59	20 (95.2%)	1 (4.8%)	21 (100%)	
≥60	9 (90%)	1 (10%)	10 (100%)	

<sup>a</sup> Statistical test: Fisher's exact test.

<sup>b</sup> Statistical test: Chi-square Tests.

**Table 4**

Agreement table comparing the frequency distribution of total colon cleansing status in patients receiving a two-day diet by age and sex.

Properties	Total colon cleansing status			p-value
	Acceptable (N%)	Non-acceptable (N%)	Total (N%)	
Male	23 (79.3%)	6 (20.7%)	29 (100%)	0/764 <sup>a</sup>
Female	19 (82.6%)	4 (17.4%)	23 (100%)	
<30	7 (77.8%)	2 (22.2%)	9 (100%)	0/123 <sup>b</sup>
30–44	11 (91.7%)	1 (8.3%)	12 (100%)	
45–59	17 (89.5%)	2 (10.5%)	19 (100%)	
≥60	7 (58.3%)	5 (41.7%)	12 (100%)	

<sup>a</sup> Statistical test: Fisher's exact test.

<sup>b</sup> Statistical test: Chi-square Tests.

Colonoscopy is performed for the diagnosis and follow-up of colon-related diseases and disorders and requires intestinal preparation before the test [16]. More than half a million colonoscopies are performed each year in the United States, which has been proven to be a very useful, safe, and durable, however, is associated with a number of limitations. One of these limitations is poor or incomplete intestinal preparation, which in many cases leads to the inability to reach the cecum and even if it reaches the cecum, it weakens the observation of the mucous membrane [17]. Unfortunately, preparation for colonoscopy is often a major source of dissatisfaction [18]. In fact, poor bowel preparation is a common problem in most parts of the gastrointestinal tract. In our study, cleansing with polyethylene glycol was performed at one-day and two-day intervals, where, one-day cleansing was more effective than two-day method. The side effects using the two methods were not statistically significant. Although proper bowel lavage is an important factor in determining the accuracy of a diagnostic test; But there is still no standard method for preparing the intestine. Patients often suffer from dietary restrictions for 2–3 days and in most cases complain of severe side effects in the abdomen during rapid preparation [19]. However, the ideal bowel cleansing diet is the one that is easily prescribed, well tolerated, safe, and satisfactorily cleanses the bowel in all patients [20].

## 5. Conclusion

The results of our study indicate that one-day bowel cleansing using PEG is a tolerable and safe method and is more effective than the two-day method. Our study also shows that age and sex have no effects on colon cleansing and the one-day method can be used at any age and for any gender.

## 6. Limitations

The patients and endoscopist were not blinded in our study for which objective parameter was used to define bowel emptying. Our

study does not include any biochemical (lab-based) parameters to evaluate side effects of the regimes such as electrolyte profile and renal function.

## Provenance and peer review

Not commissioned, externally peer-reviewed.

## Ethical approval

All procedures performed in this study involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

## Funding

No funding was secured for this study.

## Author contribution

Dr. Saleh Azadbakht: Conceptualized and designed the study, drafted the initial manuscript, and reviewed and revised the manuscript.

Dr. Salehe Azadbakht and Dr. Morteza Azadbakht: Designed the data collection instruments, collected data, carried out the initial analyses, and reviewed and revised the manuscript.

Dr. Alireza Esmaili and Parisa Rahmani: Coordinated and supervised data collection, and critically reviewed the manuscript for important intellectual content.

## Conflict of interest statement

The authors deny any conflict of interest in any terms or by any means during the study.

## Guarantor

Saleh Azadbakht.

## Research registration number

Name of the registry: Lorestan University of Medical Sciences, Khorramabad, Iran.

Unique Identifying number or registration ID: (IR.LUMS.REC.1398.229).

Hyperlink to the registration (must be publicly accessible): <https://ethics.research.ac.ir/ProposalCertificateEn.php?id=102315&Print=true&NoPrintHeader=true&NoPrintFooter=true&NoPrintPageBorder=true&LetterPrint=true>.

## Consent to participate

From the under 16 years old was given by a parent or legal guardian.

## Consent for publication

Not applicable.

## Availability of data and material

Data sharing is not applicable to this article as no datasets were generated or analyzed during the current study.

## Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.ijso.2020.11.011>.

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