Original Article

Triple-Dose vs. Split-Dose PEG-ELS Bowel Preparation before Colonoscopy in Constipated Patients: A Prospective, Endoscopist-Blinded, Randomized Controlled Trial

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Background: There is no data available on the efficacy of bowel preparation among constipated patients. This study aims to compare the bowel cleansing efficacy, safety, tolerability, acceptability, compliance, and satisfaction of triple-dose and split-dose polyethylene glycol electrolyte lavage solution (PEG-ELS) before colonoscopy in patients with constipation.

Materials and Methods: A prospective, multicenter, endoscopist-blinded, randomized controlled trial was conducted in 4 hospitals in northeast Thailand. Seventy-six participants who were eligible for colonoscopy were randomly allocated to either triple-dose or split-dose PEG-ELS before colonoscopy. The quality of bowel preparation was assessed using the Ottawa Bowel Preparation Scale (OBPS).

Results: The mean overall OBPS score and the rate of successful bowel cleansing (total OBPS score ≤6) in the per-protocol analysis were significantly superior in the triple-dose group compared with the split-dose group (4.1±2.4 vs. 5.4±1.9, p = 0.014, and 91.4% vs. 73.0%, p = 0.042, respectively). There were no clinically significant differences in renal function, electrolyte abnormalities, adverse events, or patient acceptance, compliance, or mean satisfaction between the two groups.

Conclusion: The triple-dose PEG-ELS was found to be superior to the split-dose bowel preparation before colonoscopy in constipated patients, and there were no serious side effects.

Keywords: Colonic bowel preparation, Colonoscopy, Ottawa bowel preparation scale, Polyethylene glycol electrolyte lavage solution

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Colorectal cancer is the fourth most common cancer in the world[1]. In Thailand; it is the third most common cancer in men and the fifth most common in women[2]. Only 10% of cases are diagnosed in the early stages of the disease[3] due to both lack of awareness and the cost of endoscopy[4]. Colonoscopy has been shown to have a 30 to 40% adenoma detection rate in Western countries but only 10% in Asia[5]. In Thailand, the rate of high-risk adenoma as diagnosed by colonoscopy is up to 7% and that of colon cancer is 1.3%[6]. This makes the risk of colon cancer in Thailand as high as it is in Western countries. The most effective screening tool for colorectal cancer is the detection and removal of colonic polyps[7]. Screening colonoscopy with polypectomy to remove precancerous lesions (i.e. adenomatous polyps) can help reduce the risk of colorectal cancer[8-10].

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The effectiveness of the colonoscopy in detecting colorectal cancer depends on the endoscopist's skill and the quality of the bowel preparation before colonoscopy[11,12]. Inadequate bowel preparation occurs in up to 20 to 30% of colonoscopy in clinical practice and is associated with a high rate of missed adenoma, shortened surveillance intervals, and greater discomfort for the patient[13-16].

Constipation is a risk factor of inadequate bowel preparation for colonoscopy. In Thailand, the prevalence of constipation is about one-fourth of the population. Despite intensive patient education, a previous study found that the rate of inadequate bowel preparation in the endoscopic unit at Srinagarind Hospital (Thailand) was 39% with constipation as a risk factor[17]. A randomized study in Italy found that the use of split 4-liter polyethylene glycol for colonoscopy bowel cleansing in patients with chronic constipation resulted in an 81% successful cleansing rate[18]. As recent studies tend to increase the volume and laxatives to be closer to the endoscopic time and there are currently no data available on the efficacy of bowel preparation among constipated patients in Thailand. The purpose of this study was to compare the

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bowel cleansing efficacy, safety, tolerability, acceptability, compliance, and satisfaction between triple-dose and split-dose polyethylene glycol electrolyte lavage solution (PEG-ELS) before colonoscopy in patients with constipation.

Materials and Methods

Study design

This prospective, multicenter, endoscopist-blinded, randomized controlled trial was conducted in four hospitals in northeast Thailand (Khon Kaen University's Srinagarind hospital and Roi Et, Mahasarakham, and Kalasin provincial hospitals). Our protocol was approved by the Khon Kaen university ethics committee in human research (Reference No. HE601092).

Study population

Outpatients with constipation from April 2017 to December 2017 were enrolled in the study. Those aged 50 to 75 years were admitted for colorectal cancer screening and those <50 years were patients with indication for colonoscopy (blood in stool, abdominal pain, bowel habit change, elevation of CEA, first-degree relatives with colorectal cancer, weight loss, anemia, or abnormal imaging results). Constipation was defined according to the Rome III[19] criteria or as a score of 1 or 2 on the Bristol Stool Form Scale[20]. Subjects with any one of the following criteria were excluded from the study: (1) pregnancy or lactation, (2) known or suspected hypersensitivity to the active ingredients in PEG-ELS, (3) known or suspected intestinal obstruction or perforation, toxic megacolon, or major colonic resection, (4) heart failure (class III or IV) or serious cardiovascular disease, (5) severe liver failure or end-stage renal insufficiency, or (6) contraindication for general anesthesia. All participants provided written informed consent. At the time of enrollment, a complete medical history was taken, a physical examination that included measurement of vital signs was performed, and information regarding previous and concomitant medications was obtained by a physician who was not involved in the evaluation of the bowel preparation. Blood was collected before and after the colonoscopy. All participants could use their laxatives until 2 days before the colonoscopy.

Randomization and blinding

Patients were randomly assigned to receive either triple-dose or a split-dose PEG-ELS with an allocation ratio of 1: 1. A computer-generated randomization list was prepared by a qualified statistician with a block of four and separate lists for each center. Subjects satisfying all of the inclusion criteria were consecutively assigned to the next available number. The study was observer blind in that the endoscopists were not allowed to perform any activities associated with study preparation and had to avoid any discussion with the patients and the staff that might disclose the type of bowel preparation employed.

Bowel preparation and colonoscopy

The preparation used in this study was PEG-ELS (NIFLEC®) powder dissolved in 2 liters of water. Subjects allocated to the triple-dose PEG-ELS were administered 2 liters of the solution at 3.00 PM on each of the two days preceding the colonoscopy and in the early morning 4 to 6 hours before the procedure. The patients were instructed to drink 250 mL in 15 to 20 min (all of the solution in about 1 to 2 hours). As an active control, patients given split doses were administered 2 liters of PEG-ELS at 3.00 PM and in the early morning 4 to 6 h before colonoscopy. All patients were admitted to the hospital one day before the procedure. The bowel preparation was dispensed by the physician (not involved in the evaluation of the preparation) who carefully explained how the products should be taken, emphasizing the importance of complete intake of the solution to ensure a safe and effective procedure. Moreover, each patient was provided with a detailed instruction card explaining the low-residue diet to which they were to adhere for 3 days prior to undergoing colonoscopy. Patients were instructed to consume only clear liquids and no solid food for 1 day before the procedure. They were also instructed to consume nothing orally after midnight on the day of the procedure. Patients also received a telephone call emphasizing the importance of this diet and explaining proper PEG-ELS administration. To avoid variability in the interval between bowel preparation and colonoscopy, all colonoscopies were scheduled for 4 to 6 hours after the patients' last dose of PEG-ELS. All subjects received intravenous anesthesia administered by trained anesthesiologists. The colonoscopies were performed by experienced endoscopists. Images were recorded of the main colonic segment (right, transverse, and left colon) and colonic fluid.

Outcomes measurement

Bowel cleansing efficacy was evaluated by 3 endoscopists who were unaware of method of bowel preparation. The images of the main colonic segment (right, transverse, and left colon) were reviewed using the validated Ottawa Bowel Preparation Scale (OBPS) and given a score of 0 to 4 and the overall colonic fluid was rated according to a 3-point scale (0 to 2). The total score (bowel cleansing total score; primary end point) may range from 0 (best) to 14 (worst). A total OBPS score $\leq$6 was considered to indicate successful bowel preparation[21].

Patients were directly questioned about adverse events associated their regimen on the day of the colonoscopy. New symptoms and exacerbation of pre-existing symptoms occurring after the treatment were assumed to be related to the bowel preparation. Patients were questioned about tolerability, acceptability, and compliance. The endoscopist was not allowed to take part in the interview or to supervise the filling out of the questionnaire before the procedure. Tolerability assessment was based on recorded GI symptoms and adverse effects. Each patient was questioned about the occurrence and severity of nausea, bloating, abdominal pain/cramps, dizziness, chest pain, sleep disturbance, and itching sensation in the anus. A 4-point ordinal scale (1 = no distress, 2 = mild distress, 3 = moderate distress, and 4 = severe

distress) was used to score tolerability. In order to evaluate the acceptability of the PEG-ELS, intake difficulty was scored using a 3-point scale (1 = easy to ingest, 2 = strange taste but tolerable, 3 = difficult to ingest). Compliance was scored using a 3-point scale based on the percentage of the solution ingested (Optimal: complete intake of the solution; Good: intake of at least 60% of the solution; poor: intake of <60% of the solution). Satisfaction was scored using a 10-point numeric rating scale from 0 (very bad) to 10 (excellent), and the causes of dissatisfaction were recorded.

The primary efficacy end-point was overall colon cleansing, which was defined as the rate of 'successful' cleansing (i.e. OBPS, ≤6 points). Secondary end-points also included the proportion of patients with no predefined gastrointestinal symptoms, distress, or adverse effects and high acceptability, compliance, and satisfaction.

Statistical analysis

Baseline colonoscopy-related characteristics and quality indicators were compared between the two bowel preparation regimens using descriptive statistics. Statistical differences in the rate of successful cleansing, adverse events during the bowel preparation process, acceptance, compliance, and dissatisfaction were assessed using a Chi-squared test, and an independent t-test was used to compare participants' mean overall OBPS and satisfaction scores between the two regimens. The blood chemistry before and after colonoscopy in cases in which the bowel preparation had adverse effects was compared using a paired t-test. A *p*-value <0.05 was considered to be statistically significant. Statistical analyses were performed using the STATA software (College Station, Texas, USA).

Results

Seventy-six randomized patients were included in the study, 37 of whom were assigned to the triple-dose PEG-ELS group and 39 of whom were assigned to the split-dose PEG-ELS group. The flow of patients through the study is shown in Figure 1. No differences were observed in terms of baseline characteristics, bowel preparation factors (Table 1), or quality indicators (Table 2) between the two groups. In addition, all patients in both groups completed caecal intubation (Table 2). The adenoma detection rates in the triple-dose group, split-dose group, and overall were 25.7%, 29.7%, and 27.8%, respectively. The prevalence of colorectal cancer was 2.6%.

Efficacy of bowel cleansing

The primary endpoint of bowel cleansing score differed significantly between the two groups. The triple-dose preparation was found to be superior to the split-dose preparation in terms of mean overall OBPS score (4.1±2.4 vs. 5.4±1.9, 95% CI of difference 2.264 to 0.265, $p = 0.014$. The rate of successful bowel cleansing (total OBPS score ≤6) also differed significantly according to the per protocol analysis (91.4% vs. 73.0%, $p = 0.042$). However, the OBPS scores at each segment did not differ significantly between the two

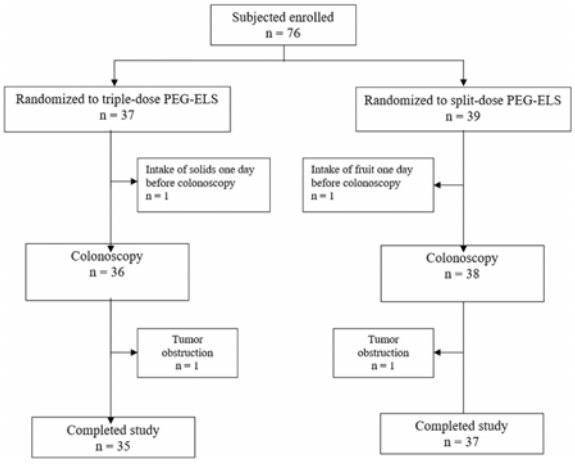

Figure 1. Flow chart of patients during the study.

bowel preparations (sigmoid colon and rectum: $p = 0.170$; transverse and descending colon: $p = 0.104$; right sided colon: $p = 0.102$; fluid: $p = 0.476$), as shown in Table 3.

Safety and tolerability

Both regimens significantly improved blood urea nitrogen ($p<0.01$), and there was no significant difference in terms of electrolyte levels between the two groups, as shown in Table 4.

Side effects, including nausea, bloating, abdominal pain, dizziness, sleep disturbance, and itching sensation in the anus, were all mild. No patients experienced vomiting or no chest pain. Bloating was the most common adverse effect reported in both groups (56.7% in the triple-dose group vs. 46.2% in the split-dose group; $p = 0.098$). Side effects did not differ significantly between the two groups, as shown in Table 5.

Acceptability, compliance and satisfaction

No significant difference was observed between the two treatment groups with regard to acceptance or compliance. The majority of patients in both groups gave the solution an acceptability rating of 2 (59.5% in the triple-dose group vs. 66.7% in the split-dose group). The proportion of patients indicating dissatisfaction in the triple-dose group was significantly higher than in the split-dose group (43.2% vs. 15.4%; $p = 0.007$), but there was no significant difference in mean satisfaction score ($p = 0.087$), as shown in Table 6.

Discussion

The results of this study demonstrated statistically significant differences in bowel cleansing efficacy between triple-dose and split-dose PEG-ELS before colonoscopy in patients with constipation. The mean overall OBPS score and the rate of successful bowel cleansing (total OBPS score ≤6) were significantly higher in the triple-dose group than in the split-dose group. Moreover, the results of triple-dose

Table 1. Subjects' baseline characteristics and bowel preparation factors*

Variables	Triple dose (n = 37)	Split dose (n = 39)
Age (years), mean ± SD	57.6±9.4	59.2±7.2
Female, n (%)	23 (62.2)	25 (64.1)
Body mass index (kg/m^2), mean ± SD	24.2±3.1	23.6±3.8
Constipation duration (year), mean ± SD	6.0±7.4	4.6±6.1
Diagnostic criteria of constipation, n (%)		
Rome III	1 (2.7)	5 (12.8)
Bristol stool form scale 1 to 2	36 (97.3)	34 (65.8)
Underlying disease, n (%)		
Hypertension	3 (8.1)	3 (7.7)
Diabetes mellitus	10 (27)	9 (23.1)
Spondylosis	2 (5.4)	2 (5.1)
Others	7 (18.9)	11 (28.2)
No	15 (40.5)	14 (35.9)
Number of laxatives drug used, n (%)		
Yes	24 (64.9)	26 (66.7)
1	15 (40.6)	19 (48.7)
2	6 (16.2)	7 (18)
≥3	3 (8.1)	0
Fecal immunochemical test, n (%)	7 (18.9)	15 (38.5)
Previous abdominal surgery, n (%)	22 (59.5)	20 (51.3)
Indications for colonoscopy, n (%)		
Screening for colorectal neoplasm	30 (81)	35 (89.7)
Blood in stool	0	1 (2.6)
Abdominal pain	6 (16.2)	3 (7.7)
Bowel habit change	1 (2.7)	0
Bowel preparation factors, n (%)		
Low residual diet for 3 days	37 (100)	39 (100)
Clear liquid diet on the previous day	36 (97.3)	38 (97.4)
Minimal delay of colonoscopy	5 (13.5)	3 (7.7)

* Intention-to-treat population
SD = standard deviation

Table 2. Quality indicators for colonoscopy*

	Triple dose (n = 35)	Split dose (n = 37)
Procedure time		
Complete caecal intubation, n (%)	35 (100)	37 (100)
Caecal intubation time (min), mean ± SD	10.2±4.3	9±4
Withdrawal time (min), mean ± SD	8.7±3	8.5±2.5
Findings of colonoscopy		
No abnormalities, n (%)	7 (20)	9 (24.3)
Polyps, n (%)	17 (48.6)	17 (46)
<1 cm	16	17
≥1 cm	1	0
Adenomas, n	9	11
Adenoma detection rate (%)	25.7	29.7
Diverticular disease, n (%)	4 (11.4)	2 (5.4)
Internal hemorrhoid, n (%)	5 (14.3)	6 (16.2)
Other, n (%)	2 (5.7)	3 (8.1)

* Per-protocol population

regimen also show that the effectiveness of bowel preparation is better than previous study comparing 2-L polyethylene-glycol-citrate-simethicone plus 2-day bisacodyl and 4-litre PEG[18], 91.4% vs. 80.2% and 81.4%, respectively. The cleansing efficacy in the split-dose group in this study was lower than in a previous study (73% vs. 81.4%)[17]. This was because most of the patients in our study were diagnosed with constipation based on a Bristol Stool Form Scale score

of 1 to 2, whereas the previous study used the Rome III criteria.

Both regimens significantly improved blood urea nitrogen, which might be explained by that both groups of patients receiving intravenous fluid before colonoscopy. The triple-dose preparation regimen did not result in increased nephrotoxicity, electrolyte abnormalities, or adverse events. There was also no significant difference between the two groups in terms of acceptance and compliance. Although the proportion of patients indicating dissatisfaction in the triple-dose group was significantly higher than in the split-dose group due to excessive laxative intake, the mean satisfaction scores did not differ significantly between the two groups.

This study found a 27.8% adenoma detection rate and 2.6% colorectal cancer in an average-risk population, suggesting that the quality of colonoscopy was good. This

Table 3. Quality of bowel preparation*

	Triple dose (n = 35)	Split dose (n = 37)	*p*-value
Overall OBPS score, mean ± SD	4.1±2.4	5.4±1.9	0.014
Successful (OBPS ≤6), n (%)	32 (91.4)	27 (73)	0.042
OBPS score at each segment, n (%)			
Sigmoid colon and rectum			0.170
0	11 (31.4)	5 (13.5)	
1	18 (51.4)	21 (56.8)	
2	6 (17.2)	9 (24.3)	
3	0	2 (5.4)	
4	0	0	
Transverse and descending colon			0.104
0	8 (22.9)	2 (5.4)	
1	10 (28.6)	12 (32.4)	
2	17 (48.5)	21 (56.8)	
3	0	2 (5.4)	
4	0	0	
Right side colon			0.102
0	4 (11.4)	0	
1	13 (37.1)	12 (32.4)	
2	17 (48.6)	21 (56.8)	
3	1 (2.9)	4 (10.8)	
4	0	0	
Fluid			0.476
0	16 (45.7)	13 (35.1)	
1	18 (51.4)	21 (56.8)	
2	1 (2.9)	3 (8.1)	

* Per-protocol population
OBPS = Ottawa bowel preparation scale

Table 4. Blood chemistry before and after bowel preparation in the two treatment groups*

	Triple dose (n = 37)		*p*-value	Split dose (n = 39)		*p*-value
	Pre	Post		Pre	Post	
BUN (mg/dL)	11.99±2.72	7.78±2.27	<0.01	13.21±4.94	10.64±4.68	<0.01
Creatinine (mg/dL)	0.81±0.18	0.75±0.16	<0.01	0.90±0.18	0.86±0.23	0.04
Sodium (mEq/L)	139.58±3.11	139.64±3.43	0.92	139.62±3.11	139.03±3.73	0.35
Potassium (mEq/L)	4.05±0.28	4.15±0.31	0.051	4.23±0.39	4.12±0.42	0.073
Bicarbonate (mEq/L)	25.20±2.29	25.02±2.51	0.68	24.85±2.46	24.77±2.00	0.83
Chloride (mEq/L)	101.08±2.79	100.91±3.31	0.72	101.13±3.19	100.35±3.90	0.22
Calcium (mg/dL)	9.24±0.37	9.30±0.41	0.38	9.31±0.41	9.25±0.45	0.44
Magnesium (mg/dL)	2.07±0.16	2.10±0.20	0.51	2.09±0.18	2.10±0.17	0.81
Phosphorus (mg/dL)	3.50±0.52	3.61±0.40	0.28	3.50±0.54	3.60±0.50	0.29

* Intention-to-treat population; data are expressed as mean ± SD
BUN = blood urea nitrogen

study was limited in terms of sample size. Future studies should include much larger populations, as this will lead to more accurate results.

Conclusion

Triple-dose PEG-ELS was superior to split-dose bowel preparation before colonoscopy in constipated patients. There was no increase in nephrotoxicity, electrolyte abnormalities, or adverse events. There was no significant difference in terms of patient acceptance, compliance, or overall satisfaction.

What is already known on this topic?

Constipation is a risk factor of inadequate bowel preparation for colonoscopy. Studies from overseas have found an 81% successful cleansing rate using split 4-liter polyethylene glycol for colonoscopy bowel cleansing in patients with chronic constipation.

Table 5. Adverse events during the bowel preparation process*

	Triple dose (n = 37)	Split dose (n = 39)	*p*-value
Nausea			
No distress	30 (81.1)	25 (64.1)	0.10
Mild distress	6 (16.2)	14 (35.9)	
Moderate distress	1 (2.7)	0	
Vomiting			
No distress	37 (100)	39 (100)	
Bloating			0.098
No distress	16 (43.3)	21 (53.8)	
Mild distress	17 (45.9)	18 (46.2)	
Moderate distress	4 (10.8)	0	
Abdominal pain			0.377
No distress	33 (89.2)	32 (82.1)	
Mild distress	4 (10.8)	7 (17.9)	
Dizziness			0.817
No distress	32 (86.5)	33 (84.6)	
Mild distress	5 (13.5)	6 (15.4)	
Chest pain			
No distress	37 (100)	39 (100)	
Sleep disturbance			0.104
No distress	28 (75.7)	35 (89.7)	
Mild distress	9 (24.3)	4 (10.3)	
Itching sensation in the anus			0.587
No distress	36 (97.3)	37 (94.9)	
Mild distress	1 (2.7)	2 (5.1)	

* Intention-to-treat population

Table 6. Acceptance, compliance and satisfaction of the participants*

	Triple dose (n = 37)	Split dose (n = 39)	*p*-value
Acceptance (difficulty in taking study agent), n (%)			0.515
None: easy to ingest	15 (40.5)	13 (33.3)	
Some: strange taste but tolerable	22 (59.5)	26 (66.7)	
Much: difficult to ingest	0	0	
Compliance (% intake of study agent), n (%)			0.087
Optimal (100%)	37 (100)	39 (100)	
Good (≥60%)	0	0	
Poor (<60%)	0	0	
Satisfaction, mean ± SD	9.27±0.99	9.64±0.87	
Dissatisfaction, n (%)	16 (43.2)	6 (15.4)	0.007
Excessive laxative intake	9 (24.3)	2 (5.1)	
Frequent of defecation	1 (2.7)	1 (2.6)	
Other	6 (16.2)	3 (7.7)	

* Intention-to-treat population
SD = standard deviation

What this study adds?

The triple-dose PEG-ELS was found to be superior to split-dose bowel preparation before colonoscopy in constipated Thai patients (91% vs. 73%).

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Potential conflicts of interest

The authors declare no conflicts of interest.

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