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Clinical Trial

Patient-directed vs. fixed-volume PEG for colonoscopy preparation: a randomized controlled trial

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ABSTRACT

Background: Individualization using different volumes of polyethylene glycol is widely regarded as the optimal solution for bowel preparation, while the patient-directed regimen we propose may serve as a reliable individual solution. This study aimed to assess the efficacy, safety, and satisfaction of bowel preparation with a patient-directed regimen.

Methods: Patients in the fixed-volume group ingested the same amount of PEG, while those in patient-directed group ingested different amount according to stool consistency or stool water content.

Results: After filtering by exclusion criteria, 428 individuals in the fixed-volume group and 103 in the patient-directed group were successfully enrolled and analyzed. Eighty-three (80.6%) individuals in the patient-directed group had a reduced polyethylene glycol volume. There was no significant difference in the bowel preparation efficacy between the two groups (90.0% vs. 90.3%, $\chi^2 = 0.01$; $p = 0.918$). Patients in the patient-directed group complained of fewer adverse effects (53.0% vs. 36.9%, $\chi^2 = 8.655$; $p = 0.003$), especially vomiting (13.6% vs. 1.0%, $\chi^2 = 13.304$; $p < 0.001$). Regarding comfort during bowel preparation, the degree of comfort was not significantly different between groups. Furthermore, the willingness rate for further colonoscopy in the patient-directed group was significantly higher than that in the fixed-volume group (90.3% vs. 77.1%, $\chi^2 = 8.912$; $p < 0.05$). Multivariable logistic regression analysis showed that the body mass index served as an independent factor impacting quality of bowel preparation with the patient-directed regimen (OR 1.16, 95% CI 1.00–1.34; $p = 0.043$).

Conclusions: Without decreasing the bowel preparation efficacy, the patient-directed regimen increased the safety and satisfaction of bowel preparation and is expected to be a regular and individual solution for bowel preparation. Individuals with a lower body mass index are more likely to undertake this new regimen.

Trial registration number: ChiCTR1900022072 at ChiClinicalTrials.gov

Keywords: bowel preparation, patient-directed, individualization, efficacy, safety

Introduction

Colonoscopy plays a crucial role in detecting precancerous or cancerous lesions in the colon and evaluating the treatment efficacy of intestinal diseases including inflammatory bowel disease.[1,2] The effectiveness of screening colonoscopy is influenced by many factors, including the quality of bowel preparation and rate of participation among the population.[3] Inadequate bowel preparation results in low adenoma detection rate, long cecal intubation time, and reexamination within 1 year.[1,4,5] A poor level of bowel cleansing may also increase the burden of public health care.[6,7] Therefore, an optimal regimen for bowel preparation is essential to increase the quality of colonoscopy.[8]

Polyethylene glycol (PEG), an osmotic laxative, is currently the most effective agent for bowel preparation.[8] Recent studies have shown that a high-volume PEG solution (≥ 3 L) is equally or more effective than a low volume of PEG. However, the poor performance of high-volume PEG in terms of tolerability and refusal to reuse this regimen may lead to low participation in colonoscopy screening.[9] Several factors influence bowel preparation, including dietary habits,[10] use of medication, stool frequency, and concomitant diseases.[11] Individuals who prefer a low-residue and clear liquid diet and have a lower body mass index (BMI) are more likely to achieve adequate bowel preparation with a lower volume of PEG than those who have higher BMI and a high fiber diet or complain of chronic constipation.[8,12,13] Moreover, sleep disturbance during bowel preparation may cause psychological factors and influence bowl movement.[14] However, specific psychological factors are difficult to control in clinical practice and few related clinical trials have demonstrated this. Although several studies have attempted to build a predictive model for inadequate bowel preparation, there remain some drawbacks and there is currently no widely acceptable model for bowel cleansing.[11,13,15] Therefore,

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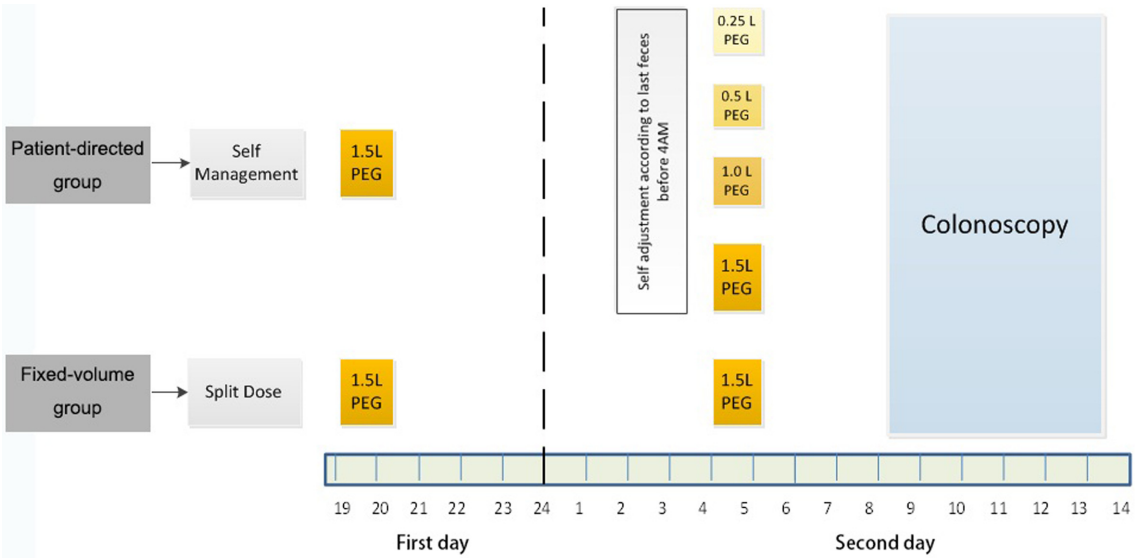

Figure 1. Protocol for bowel preparation in the fixed-volume and patient-directed groups.

individualization of bowel cleansing regimens may serve as an alternative to improve the tolerability and willingness of bowel cleansing, while also providing adequate bowel preparation. Furthermore, in clinical practice some individuals cannot assess the level of stool fluency suitable for colonoscopy, and colonoscopists have found that a certain number of individuals who reported clear stool fluid before colonoscopy had poor bowel preparation. These patient populations must withdraw from examination and retake the agent. Therefore, it is crucial for patients to be able to evaluate whether their stool traits before colonoscopy are successful bowel preparations by themselves.

To the best of our knowledge, this is the first study to propose the concept of a patient-directed regimen. We aimed to compare the efficacy, safety profile, and tolerance between patient-directed and standard fixed-volume regimens in subjects undergoing colonoscopy. We also analyzed the most suitable population and factors associated with efficacy of bowel preparation.

Methods

Patients

The enrolled patients comprised females and males who ranged in age from 18 to 80 years and who were scheduled for colonoscopy examination at the digestive endoscopy center of Renmin Hospital of Wuhan University. The subjects were recruited from December 2020 to September 2021. Participants who met the following criteria were excluded: (1) medical history of bowel resection; (2) incomplete colonoscopy due to stricturing bowel; (3) bowel obstruction, and (4) intolerance to colonoscopy. This study was approved by the Ethics Commission at Renmin Hospital of Wuhan University (2019 CK01). Eligible patients were randomized to one of the two bowel preparations using concealed allocation by a scheduling assistant (blinded) in a 1 : 1 allocation ratio.

Protocol

The bowel cleansing protocol is shown in Fig. 1. In the fixed-volume group, participants were instructed to ingest 1.5 L of PEG at 19:00–21:00 hours the day before the colonoscopy; after several hours' break, the remaining 1.5 L of PEG were taken at 4:00–5:00 AM. Subjects in the patient-directed group took a 1.5 L of PEG solution, similar to those in the standard group. The volume of the remaining PEG ingested by participants was determined by stool consistency or stool water content before 4:00 AM: those with clear bowel effluent and no solid pieces were given 250 ml of PEG; those with watery stool and no solid pieces (Type 7 in Bristol Scale) were given 500 ml of PEG; those with fluffy pieces (Type 6) or soft blobs (Type 5) were given 1000 ml of PEG; and those with sausage-shaped smooth or soft stool (Type 4), sausage-shaped stool with cracks on surface (Type 3), sausage-shaped lumpy stool (Type 2), or hard lumps (Type 1) were given 1500 ml of PEG. [16]

All participants were given picture instructions to help with bowel preparation. Colonoscopy was performed between 8:00 and 13:00 hours. Five experienced colonoscopists who had performed >2000 cases were blinded to the bowel preparation protocol. This study was registered at ChiClinicalTrials.gov. (ChiCTR1900022072, Registered 23 March 2019, https://www.chictr.org.cn/historyversionpub.aspx?regno = ChiCTR1900022072).

Bowel preparation efficacy

The primary endpoint of the study was the efficacy of bowel preparation, as evaluated using the Ottawa bowel preparation scale (OBPS).[17] Three bowel segments were assessed using the OBPS, with scores ranging between 0 and 4, where 0, 1, 2, 3, and 4 represent excellent, good, adequate, poor and inadequate levels of bowel cleansing, respectively. The fluid score was also assessed using the OBPS, where 0, 1, and 2 refer to little or no fluid, moderate fluid, and much fluid, respectively. Successful bowel preparation was defined as an overall OBPS score ≤ 7. Excellent bowel preparation was defined as an overall OBPS score ≤ 4. Successful and excellent bowel cleansing rates were compared between the fixed-volume and patient-directed groups. A score of <2 in each colon segment was considered successful cleansing.

Tolerability and safety

A questionnaire was used to evaluate the safety profile and tolerability. Before colonoscopy, all subjects were required to complete the questionnaire, which included the following: (1) basic demographic information including age, weight, height, level of education, medical history, previous surgery history, and

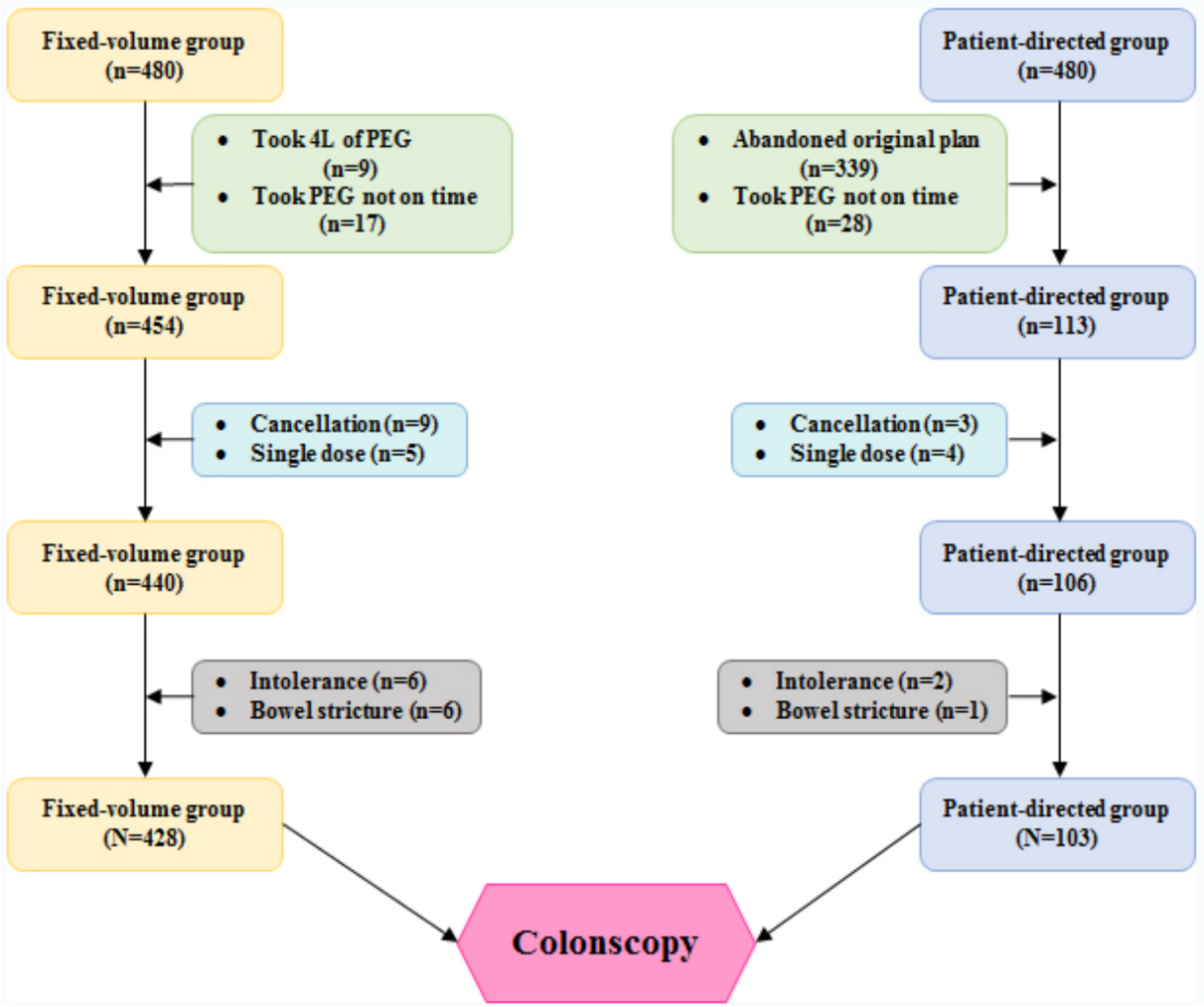

Figure 2. Flowchart of this study.

indications for colonoscopy; (2) adverse events including nausea, abdominal pain, abdominal distension, vomiting, or other reported symptoms during bowel preparation; (3) tolerability assessment including the level of satisfaction during bowel cleansing (0 = satisfactory, no pain or discomfort including dizziness, fatigue, nausea, vomiting, bloating and so on; 1 = mild discomfort, mild or intermittently moderate pain, or other discomfort that can be easily tolerated; 2 = moderate discomfort, continuous moderate pain or other discomfort that can be tolerated; and 3 = severe discomfort; severe pain or discomfort that cannot be tolerated) and willingness to reuse this regimen for further colonoscopy. For individuals complaining of bloody stools and those with colitis, the tolerability and safety of the subgroups were compared.

Statistical analysis

Statistical analyses were conducted using SPSS (version 19.0). Categorical variables are reported as percentages and were compared using the χ^2 test. Fisher's exact test was also used to estimate categorical variables if one set contained <5. Continuous variables conforming to a normal distribution are shown as mean and standard deviation and compared using the t-test. Variables conforming to a non-normal distribution were reported as medians along with interquartile ranges (IQRs) and compared using the Mann–Whitney U test. Risk factors associated with bowel preparation quality were analyzed using univariate and multivariate logistic regression. Variables that achieved P-values < 0.1 in univariate analyses were entered into a multiple logistic regression model using a forward stepwise method. Statistical significance was set at $P < 0.05$.

Results

Flow of inclusion

A total of 960 subjects were enrolled in the clinical trial. In the fixed-volume group, 9 patients took 4 L of PEG and 17 subjects did not take PEG on time. In the patient-directed group, 339 patients abandoned the original plan and 28 subjects did not take PEG on time. Subsequently, 454 individuals in the fixed-volume group and 113 in the patient-directed group were given identical paper instructions to help with bowel preparation the day before colonoscopy. Among these, 21 subjects were excluded due to cancellation ($n = 12$) or violation of regime ($n = 9$). The remaining 546 individuals arrived at the endoscopy center next day. During the colonoscopy process, 8 subjects did not tolerate the procedure and were withdrawn (6 in the fixed-volume group and 2 in the patient-directed group), while 7 patients had a stricture which the physician could not pass through to complete the colonoscopy

Table 1. Baseline characteristics of the study patients.

	Total (N = 531)	Fixed-volume group (*n* = 428)	Patient-directed group (*n* = 103)	χ^2/t	P-value/t
Age, years, mean ± sd	49.24 ± 11.96	49.75 ± 11.74	47.11 ± 13.60	1.814	0.072
Sex, *n* (%)					
Male	320(60.3%)	254(59.3%)	66(64.1%)	0.776	0.378
Female	211(39.7%)	174(40.7%)	37(35.9%)		
BMI, mean ± sd		23.39 ± 3.06	22.92 ± 3.53	1.343	0.180
Obesity[a], *n* (%)	41(7.7%)	34(7.9%)	7(6.8%)	0.154	0.695
High level of education[b]	409(77.0%)	325(75.9%)	84(81.6%)	1.481	0.224
Past medical history, *n* (%)					
History of colonoscopy ≥ 2	75(14.1%)	63(14.7%)	12(11.7%)	0.645	0.422
History of polypectomy	52(9.8%)	47(11.0%)	5(4.9%)	3.528	0.060
Hypertension	73(13.7%)	59(13.8%)	14(13.6%)	0.003	0.959
Diabete	20(3.8%)	15(3.5%)	5(4.9%)	-	0.563*
Colonoscopy purpose, *n* (%)					
Bloody stool	80(15.1%)	61(14.3%)	19(18.4%)	1.141	0.285
Diarrhea	68(12.8%)	49(11.4%)	19(18.4%)	3.641	0.056
Constipation	43(8.1%)	30(7.0%)	13(12.6%)	3.513	0.061
Physical examination	96(18.1%)	83(19.4%)	13(12.6%)	2.570	0.109

[a]Obesity is defined as BMI ≥ 28. [b]High school level of education and above. *Fisher exact probabilities.

Table 2. Efficacy of bowel preparation of patients in the fixed-volume and the patient-directed groups.

	Fixed-volume group (*n* = 428)	Patient-directed group (*n* = 103)	χ^2/t	P-value
OBPS, mean ± sd				
OBPS-overall	4.75 ± 2.13	4.69 ± 2.12	0.250	0.803
OBPS-right-side colon	1.54 ± 0.78	1.54 ± 0.81	− 0.100	0.921
OBPS-transverse colon	1.54 ± 0.77	1.57 ± 0.76	− 0.422	0.673
OBPS-left-side colon	1.04 ± 0.70	0.93 ± 0.70	1.458	0.145
OBPS-fluid	0.63 ± 0.71	0.64 ± 0.71	− 0.187	0.852
Adequate bowel preparation, *n* (%)				
Successful bowel preparation	385(90.0%)	93(90.3%)	0.011	0.918
Excellent bowel preparation	214(50.0%)	53(51.5%)	0.07	0.791
OBPS-right-side colon ≤ 1	222(51.9%)	59(57.3%)	0.976	0.323
OBPS-transverse colon ≤ 1	223(52.1%)	51(49.5%)	0.223	0.637
OBPS-left-side colon ≤ 1	354(82.7%)	88(85.4%)	0.442	0.506
OBPS-fluid = 0	218(50.9%)	51(49.5%)	0.067	0.796

(6 in the fixed-volume group and 1 in the patient-directed group). Finally, 428 individuals in the standard fixed-volume group and 103 in the patient-directed group were enrolled and completed the trial (Fig. 2).

Baseline characteristics

The baseline characteristics of the subjects are presented in Table 1. Comparisons of age, sex, body mass index (BMI) distribution, and level of education showed no significant difference between groups. No significant differences were observed in terms of medical history (polypectomy, hypertension, and diabetes), previous colonoscopy, or proportion of individuals with diarrhea, constipation, or screening colonoscopy.

In the patient-directed group, for the second 1.5 L of PEG, 9 subjects who had clear bowel effluent ingested 250 ml of PEG solution, 25 subjects who had watery stool with no solid pieces ingested 500 ml of PEG solution, 49 subjects in subgroup B ingested 1000 ml of PEG, and 20 subjects with type 4–1 stool in Bristol Scale ingested 1500 ml of PEG solution. The baseline characteristics were compared between the low- and large-volume subgroups.

Bowel preparation efficacy

Among the 428 patients in the fixed-volume group, 385 achieved successful bowel preparation (90.0%), while in the patient-directed group 93/103 patients (90.3%) attained this quality of bowel cleansing. There was no significant difference between the two groups ($\chi^2 = 0.01$; $P = 0.918$). Additionally, there was a comparable proportion of excellent bowel cleansing in the fixed-volume and the patient-directed groups (50.0% vs.51.5%, $\chi^2 = 0.07$; $P = 0.791$). The mean OBPS overall score in the fixed-volume group was 4.75 ± 2.13, while in the patient-directed group it was 4.69 ± 2.12. (t = 0.250; $P = 0.803$). Subsequently, the OBPS scores of each colon segment were compared. The results showed no significant difference between the right side, transverse colon, and left colon (Table 2). As colonoscopy was performed between 8:00 and 13:00 hours, there were obvious differences in the time interval since the last PEG was performed. To analyze whether the

Table 3. Impacts of time interval since the last PEG taken on efficacy and safety of bowel preparation.

	Fix-volume group (n = 428)		P-value	Patient-directed group (n = 103)		P-value
	8:00–10:30	10:30–13:00		8:00–10:30	10:30–13:00	
OBPS, mean ± sd						
OBPS-overall	4.57 ± 2.18	4.64 ± 2.17	0.387	4.80 ± 2.23	4.50 ± 1.89	0.658
OBPS-fluid	0.56 ± 0.69	0.71 ± 0.68	0.999	0.71 ± 0.75	0.67 ± 0.62	0.834
Adequate bowel preparation, *n* (%)						
Successful bowel preparation	278(90.8%)	107(87.7%)	0.329	81(89.0%)	12(100%)	0.601*
Excellent bowel preparation	155(50.6%)	59(48.3%)	0.668	47(51.6%)	6(50.0%)	0.914
Adverse events, *n* (%)	159(52.0%)	68(55.7%)	0.480	33(36.2%)	5(41.7%)	0.715
Discomfort, *n* (%)	190(62.1%)	81(66.4%)	0.404	48(52.7%)	7(58.3%)	0.715
Willingness to repeat the regimen, *n* (%)	240(78.4%)	90(73.8%)	0.300	81(89.0%)	12(100.0%)	0.601*

*Fisher exact probabilities.

Table 4. Safety and tolerance of bowel preparation of patients in the fixed-volume and the patient-directed groups.

	Fixed-volume group (n = 428)	Patient-directed group (n = 103)	χ^2	P-value
Adverse events, *n* (%)	227(53.0%)	38(36.9%)	8.655	0.003
Nausea	143(33.4%)	25(24.3%)	3.206	0.073
Vomitting	58(13.6%)	1(1.0%)	13.304	<0.001
Abdominal pain	34(7.9%)	7(6.8%)	0.154	0.695
Abdominal distension	60(14.0%)	16(15.5%)	0.155	0.693
Severity of adverse events, *n* (%)				0.890
Mild	188(43.9%)	31(30.1%)	6.551	0.010
Moderate	24(5.6%)	5(4.9%)	0.091	0.763
Severe	15(3.5%)	2(1.9%)		0.547*
Discomfort degree, *n* (%)				0.064
Comfortable	157(36.7%)	48(46.6%)	3.447	0.063
Mild discomfort	223(52.1%)	46(44.7%)	1.840	0.175
Moderate discomfort	37(8.6%)	9(8.7%)	0.001	0.976
Severe discomfort	11(2.6%)	0(0.0%)	–	0.134*
Willingness to repeat the regimen, *n* (%)	330(77.1%)	93(90.3%)	8.912	0.003

*Fisher exact probabilities.

time interval since the last PEG had an impact on bowel cleansing effectiveness and patient satisfaction, patients were divided into 8:00–10:30 and 10:30–13:00 hours groups. The time interval since the last PEG taken before colonscopy had no obvious impact on the OBPS score (Table 3).

Safety profile

Compared to fixed-volume group, patients in the patient-directed group complained of fewer adverse effects (53.0% vs. 36.9%, χ^2 = 8.655; P = 0.003). In particular, only one percent of people experienced vomiting in the patient-directed group (13.6% vs. 1.0%, χ^2 = 13.304; P < 0.001). Although more subjects experienced nausea in the fixed-volume group, no significant difference was observed (33.4% vs. 24.3%, χ^2 = 3.206; P = 0.073). The proportions of abdominal pain and distension were comparable between the two groups (Table 4). In addition, the time interval since the last PEG had no obvious impact on adverse effects (P = 0.480 in the fixed-volume group and P = 0.715 in the patients-directed group; Table 3).

Tolerability and compliance

In terms of comfort during bowel preparation, the degree of comfort was not significantly different. However, the willingness rate for further colonoscopy in the patient-directed was significantly higher than that in the fixed-volume group (90.3% vs. 77.1%, χ^2 = 8.912; P < 0.05) (Table 4). There was no difference in the degree of comfort and willingness to reuse this regimen for further colonoscopy between 8:00–10:30 and 10:30–13:00 hours groups (Table 3).

Factors impacting excellent bowel preparation in the patient-directed group

Given the comparable efficacy, fewer adverse effects, and more compliance with the patient-directed regimen, univariate and multivariate logistic regression analyses were conducted to explore the most suitable population for patient-directed regimens. Multivariable logistic regression analysis showed that BMI served as an independent factor affect preparation (odds ratio (OR) 1.16, 95% confidence interval (CI) 1.00–1.34; P = 0.043) (Table 5). ROC,

Table 5. Logistic regression modeling evaluating factors impacting the efficacy of bowel preparation in patient-directed group.

Item	Univariate logistic regression			Multivariate logistic regression		
	OR	95% CI	*P*-value	OR	95% CI	*P*-value
BMI	1.13	0.99–1.29	0.056	1.16	1.00–1.34	0.043
Female	1.99	0.88–4.51	0.099			
High level of education	0.42	0.16–1.09	0.074			

receiver operating characteristic curve and cut-off values were calculated (Area Under Curve (AUC) = 0.596, CI = 0.486–0.706, cut-off value = 27.030).

Factors impacting successful bowel preparation in the fixed-volume group

Among the 428 patients in the fixed-volume group, 385 (90.0%) achieved adequate bowel cleansing. Univariate logistic regression was conducted to determine the specific factors affecting quality of bowel preparation (Table 6). Multivariate logistic regression analysis revealed that the factors affecting bowel cleansing efficacy were medical history of colonoscopic polypectomy (previous polypectomy vs. non-polypectomy OR 1.98, 95% CI 1.04–3.78; $P = 0.039$), complaining of abdominal distension (abdominal distension vs. non-abdominal distension OR 0.44, 95%CI 0.21–0.95; $P = 0.037$), and the purpose of screening during colonoscopy (screening vs. non-screening OR 0.55, 95%CI 0.34–0.91; $P = 0.02$) (Table 6).

Discussion

This study is the first to propose the concept of a patient-directed regimen. According to our study, colon cleansing efficacy and tolerability were comparable between the two groups. However, fewer patients in the patient-directed group experienced adverse effects, particularly vomiting. In terms of compliance, more patient-directed individuals were willing to reuse this method for colonoscopy, if applicable in the future. We also confirmed that individuals with a higher BMI were more likely to have inadequate bowel preparation for a patient-directed regimen.

The rate of sufficient bowel preparation, 90% among all participants, usually served as an indicator of high-quality colonoscopy. In this trial, 90.0% of individuals attained successful bowel preparation (overall OBPS $\leq$ 7) in the fixed-volume group, whereas in the patient-directed group the rate was up to 90.3%. Our results showed that previous bowel preparation plays an important role in adequate bowel preparation for factors affecting the efficacy of bowel cleansing. Although there was no significant difference in terms of the number of previous colonoscopies between the fixed-volume and the patient-directed groups, multivariate logistic regression results indicated that those with a previous colonoscopic polypectomy had a higher chance of adequate bowel cleansing. Colonscopy surveillance is generally recommended for patients undergoing colonoscopic polypectomy as they have more instances of bowel preparation and colonoscopy than the ordinary population.[18] In addition, we found that individuals with lower bowel movement, e.g. people complaining of abdominal distension, are more likely to have unsuccessful bowel preparation. Interestingly, people undergoing routine colonoscopy screening usually have inadequate bowel preparation, which may compromise the effectiveness of colonoscopy in colorectal cancer screening. Therefore, awareness campaigns for adequate bowel preparation are essential to enhance adequate bowel cleansing and effectiveness of colorectal cancer screening.[19–21]

Regarding safety profile, the proportion of individuals who complained of adverse effects, including nausea, vomiting, abdominal pain, and distension, was significantly lower in the patient-directed group than in the fixed-volume group. Fewer individuals in the patient-directed group experienced ingestion-related vomiting than those in the standard fixed-volume group. This is partly due to fewer solutions being taken by individuals in the patient-directed group. In addition, potentially less PEG at 4:00 AM can relieve the pressure of large volumes. The results also showed that 9 subjects had moderate to severe levels of vomiting, which may have a negative effect on bowel preparation, especially for those who actually require greater volumes of PEG solution for adequate bowel cleansing.

One point that prioritizes the patient-directed regimen is that this method can significantly increase the willingness to reuse PEG when undergoing colonoscopy. Individuals' willingness is important in colonoscopy screening. Subjects reject further bowel preparation because of its volume, uncomfortable taste, and disturbance of sleep. These factors could help researchers to explore new methods to increase compliance with colonoscopy screening. Our results also showed that among these factors, a higher BMI was the independent risk factor for inadequate bowel cleansing. This analysis was consistent with that of a previous meta-analysis for a standard fixed-volume regimen.[11]

Clinical guidelines from Western countries recommend that 4 L of PEG is not only appropriate for adequate bowel cleansing but also has good tolerability. However, the volume of PEG used varies among individuals. Given the body size and dietary habits, the guidelines for bowel preparation in China suggest that 3 L of PEG solution is the first choice for bowel preparation, while for some patients 2 L of PEG could also be regarded as an adequate volume during bowel cleansing.[22] In this trial, most enrolled subjects in the patient-directed group consumed 500 ml of PEG solution at the second ingestion time. The results also showed that the proportion of individuals in the different volume groups was comparable in terms of successful bowel cleansing. It was found that a 3-L split-dose of PEG was more likely to attain adequate bowel preparation than a 2-L volume of PEG. However, 2-L of PEG in the previous study was referred to as a single-dose regimen.[22] From the results of our trial, we supposed that a 2-L split-dose of PEG could be feasible for adequate efficacy of bowel cleansing, especially for those who do not require a large volume. Furthermore, we explored the reasons why some people can gain adequate bowel preparation with a low volume. The results showed more females in the large-volume subgroup than in the low-volume subgroup, partly because females may pay more attention to their conditions especially when it comes to patient-directed regimens. Moreover, in a previous meta-analysis, no single patient-related factor associated with unsuccessful bowel cleansing efficacy was

Table 6. Logistic regression modeling evaluating factors impacting the efficacy of bowel preparation in the fixed-volume group.

Item	Univariate logistic regression			Multivariate logistic regression		
	OR	95% CI	P-value	OR	95% CI	P-value
History of polypectomy	0.82	0.69–0.99	0.820	1.98	1.04–3.78	0.039
Patient with abdominal distension	0.47	0.23–1.00	0.05	0.44	0.21–0.95	0.037
Screening colonoscopy	0.64	0.39–1.03	0.068	0.55	0.34–0.91	0.020
Abdominal pain during bowel preparation	0.52	0.25–1.07	0.078			

observed.[11] Therefore, it was hypothesized that some unidentified factors, including psychological factors, may be involved in bowel preparation. Some subjects with irritable bowel disease complained that they become anxious and have diarrhea when suffering from sleep disturbances during bowel cleansing. These psychological factors are currently difficult to include in trials to identify specific reasons for inadequate bowel preparation. Thus, a patient-directed regimen is currently suitable for them to attain adequate bowel preparation.

In this trial, we proposed patient-directed as a potential regimen for bowel preparation, which may increase the safety and willingness to undergo further colonoscopy. Our results may provide new insights into better compliance with bowel preparation before colonoscopy. A range of factors that are difficult to control affect bowel preparation quality.[11] A patient-directed regimen instructs individuals on how to recognize the quality of bowel cleansing and how to adjust the PEG volume by themselves. In addition, this study followed the strict principles of randomized and blinded trials, which provide convincing results of bowel preparation in terms of this new patient-directed concept. Furthermore, we compared the efficacy, safety, and tolerance of bowel cleansing between the fixed-volume and the patient-directed groups and analyzed the most suitable population for patient-directed regimens.

This study has several limitations. First, all bowel preparations were assessed by colonoscopists in routine clinical settings, rather than by the central readers of the OBPS. Therefore, there is potential for variability between the evaluations by different readers.[23] Furthermore, despite the instructions suggesting a low-residue and clear liquid diet for enrolled subjects before colonoscopy, the diets were not specifically recorded and analyzed in this trial, which may have influenced the quality of bowel preparation.[24] Finally, we successfully enrolled only a limited number of patients in the patient-directed group, which was a quarter of the sample size in the fixed-volume group. The asymmetry in the sample size of the two groups may lead to biased statistical results. Hence, further large and multi-center randomized controlled trials are needed to confirm the results of patient-directed regimens.

Conclusions

Most patients can acquire high-quality bowel preparation using a lower volume of PEG. Patient-directed regimens increase the safety and satisfaction rate of bowel preparation without decreasing the bowel preparation efficacy. Individuals with a lower BMI are more likely to undertake this new regimen. Patient-directed regimens are expected to be regular and individualized solutions for bowel preparation.

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Author contributions

Concept and design: J.Z., X.J., and W.D. Acquisition, analysis, or interpretation of data: X.J., Y.G., H.J., J.H., S.W., and B.H. Drafting of the manuscript: J.Z., X.J., and Y.G. Statistical analysis: X.J., W.S., and W.D. Supervision: W.D., X.W., and J.L.

Conflict of interest

None declared.

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