

Comparison of the effect of regular diet and low-fiber diet on bowel cleansing before colonoscopy

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Research article

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Abstract

BACKGROUND

High quality bowel preparation is essential for colonoscopy. A low-fiber diet (LFD), changing people's dietary habit, is recommended for the day before colonoscopy. The aim of this study was to compare the quality of bowel preparation of regular diet (RD) with that of LFD.

METHODS

Patients undergoing colonoscopy in the morning were randomly to LFD group, which took a LFD the day before the procedure, or RD group. All patients received a split dose of 3L PEG regimen. The diet satisfaction and adverse events were recorded by a questionnaire before colonoscopy. The quality of the bowel preparation was ranked according to the Boston Bowel Preparation Scale (BBPS) by the endoscopists. Per-protocol (PP) and intention-to-treat (ITT) analyses were conducted for the clinical outcomes. A non-inferiority analysis was performed to prove the quality of bowel preparation of RD was not inferior to that of LFD.

RESULTS

400 patients (200 in RD group, 200 in LFD group) were included. In PP analysis ($n = 357$), no significant difference was found in the quality of the bowel preparation between the RD group and the LFD group ($P = 0.440$). The diet satisfaction ($P = 0.978$), polyp detection rate (PDR) ($P = 0.763$) and adenoma detection rate (ADR) ($P = 0.800$) were not significantly different between the two groups. Similar results were found in the ITT analysis ($n = 400$, $P = 0.440, 0.778, 0.724, 0.893$). Hunger in RD group was significantly lower than that in LFD group ($P = 0.010$), especially in young patients ($P = 0.029$) and inpatients ($P = 0.036$).

CONCLUSION

The quality of the bowel preparation of RD is comparable to that of LFD. RD could reduce hunger, especially in young patients and inpatients. Without changing patients' eating habits, RD may be more acceptable for patients before undergoing colonoscopy.

Trial registration: Current Controlled Trials ChiCTR1900021836 on 12 March 2019.

Background

Colonoscopy is the standard and valuable tool for screening colorectal precancerous lesion and cancer. It is widely acknowledged that high quality of the bowel preparation is essential for diagnostic accuracy and therapeutic safety of colonoscopy [1]. Bowel preparation regimens typically include dietary restriction and oral cathartics. Traditionally, a clear liquid diet (CLD) is recommended for the day before colonoscopy [2], but patient's compliance may be poor because of the unpleasant dietary restriction. Large prospective studies have demonstrated that a low-fiber diet (LFD) is comparable to or even better

than CLD in the quality of bowel preparation and has better tolerability [2–5]. Both the American Society for Gastrointestinal Endoscopy (ASGE) Guideline in 2015 and the European Society of Gastrointestinal Endoscopy (ESGE) Guideline in 2019 recommend LFD with FDA-approved purgatives for bowel preparation [6, 7]. However, a LFD is considered as too restrictive to provide enough calories, leading to starvation, fatigue and hypoglycemia-induced side effects. In view of these facts, regular diet (RD) may contribute to increasing patients' willingness to undergo colonoscopy. A multicenter randomized study from Korea has demonstrated that for healthy outpatients with the avoidance of high-fiber foods for 3 days before colonoscopy, the quality of bowel preparation is not significantly different between the CLD group and RD group [8]. A randomized single-blind trial has found out that RD with split-dose polyethylene glycol electrolyte (PEG) provides better quality of bowel preparation than LFD with whole dose PEG, and no significant difference on patient tolerability and side effects is found between the two groups [9]. Above all, this study was designed as a non-inferiority trial, aimed to test a hypothesis that the quality of the bowel preparation of RD would be comparable to that of LFD.

In Chinese population, 3-L split-dose PEG is superior to 2-L PEG in bowel cleansing, compliance and adenoma detection rate (ADR) of rightward colon [10]. Based on meta-analysis, split-dose preparations are superior to day-before bowel cleansing regimens [11]. Therefore, we chose 3L split-dose PEG for the bowel preparation. In this study, we attempted to investigate the quality of bowel preparation, tolerability and safety between a RD and LFD on the day before colonoscopy, followed by a 3L split-dose PEG.

Methods

Patients

This was a randomized, non-inferiority and single-blind prospective cohort trial and conducted from March 2019 to July 2019 at the Sixth Affiliated Hospital of Guangzhou Medical University. Both outpatients and inpatients who were scheduled for colonoscopy were enrolled in this study. All enrolled patients were given written informed consent. Patients under the age of 18 or over 75, or present with a severe illness (cardiopulmonary, cerebral, renal, metabolic), acute abdomen (including acute pancreatitis, acute appendicitis, acute cholecystitis, gastrointestinal perforation or acute intestinal obstruction), cirrhosis ascites, active inflammatory bowel disease, imaging indicating colorectal cancer (CRC), diabetes, previous history of abdominal surgery, major psychiatric illness, and women who are pregnant, menstruating or breastfeeding were excluded from the study.

The study was reviewed and approved by the Institutional Review Board of The Sixth Affiliated Hospital of Guangzhou Medical University. This study is registered at <http://www.chictr.org.cn>, and the registration identification number is ChiCTR1900021836. All study participants, or their legal guardian, provided informed written consent prior to study enrollment.

Bowel Preparation

Patients were randomized by a random number table to receive a split dose of 3L PEG preparation either with LFD (the LFD group) or RD (the RD group). On the day before the colonoscopy (until 8:00PM), patients in the LFD group were instructed by oral notification and written notice to have a LFD (including rice, milk, noodles, eggs, meat, or other dairy products, excluding high-fiber food, such as vegetables, fruits, seaweeds and mushrooms). Patients randomized to the RD group were allowed to have a RD without any restriction. All patients received 3 sachets of PEG, each containing 59 g macrogol 4000, 1.46 g sodium chloride, 5.68 g anhydrous sodium sulfate, 0.74 g potassium chloride, and 1.68 g sodium bicarbonate. These 3 sachets were to be dissolved in 3 L water: 2 L PEG solution was consumed at 8:00 PM before the day of colonoscopy (250 ml/15 min) and the remaining 1 L PEG solution was consumed within 4 to 6 h before procedure, and then, 5 g dimethicone powder mixed with 50 ml water was consumed 30 minutes later. All colonoscopies were performed between 9:00 AM and 12:00 PM.

Data collection

Before colonoscopy, we collected patient information, such as gender, age, height, weight, body mass index (BMI), history of constipation and diarrhea, hypertension, history of smoking and alcohol, family history of CRC. Just before procedure, all participants were interviewed by an independent investigator to complete a questionnaire detailing their diet plan, overall preparation process (medicine and diet), dietary satisfaction, and common adverse events (including hunger, sleep disturbance, dizziness, fatigue, vomiting, abdominal pain, nausea, acid regurgitation, anal orifice, bloating, palpitation, heartburn, cough, dry mouth) during the preparation process. Endoscopists, who were blinded to the type of diet preparation, used the Boston Bowel Preparation Scale (BBPS) [12] to assess the quality of the bowel preparation. Adequate bowel cleansing was defined as a BBPS score ≥ 2 in all three colon segments and ≥ 6 in the total colon. We measured the amount of foam and bubbles of the overall impact on mucosal visualization in each bowel segment [13]. We also collected the results of colonoscopy and the histopathology of the polyps. The polyp detection rate (PDR) and ADR were defined as the proportion of procedures detecting at least one polyp and one adenoma respectively. The clinical outcomes were the quality of bowel preparation, dietary satisfaction, PDR and ADR. All the colonoscopy withdrawal time was more than 6 minutes.

Statistical analysis

The calculation for sample size was based on the assumption of a 90% adequate preparation in LFD group versus 75% in RD group. Using an α level of 0.05 and statistical power of 95%, considering a 10% dropout rate, the sample size was 180 patients per group. The software SPSS version 24 was used for statistical analyses. The normal distribute data (BMI) was expressed as mean \pm SD and test by the Student`s t-test, while the skew distribution data (Age) were described by median and quartile spacing, and tested by rank sum test statistics. The chi-square or Fisher exact test was used to compare counting data. Analyses on the clinical outcomes (the quality of bowel preparation, dietary satisfaction, PDR and ADR) were done both by intention-to-treat (ITT) and per-protocol (PP). All other analyses were done on a PP cohort. P -value < 0.05 was considered statistically significant.

Results

Figure 1 shows a flow chart of this study. A total of 400 patients were included and randomized to either LFD group (n = 200) or RD group (n = 200). In the RD group, 25 patients were excluded from the PP analysis, for not taking laxatives as required (n = 6), not following the diet preparation (n = 18) and not finishing colonoscopy (n = 1), while in the LFD group, 18 patients were excluded from the per-protocol analysis, for not taking laxatives as required (n = 14), not following the diet preparation (n = 2) and not finishing colonoscopy (n = 2). Ultimately, 357 patients (175 in the RD group and 182 in the LFD group) had finished a complete procedure in PP population.

The demographic and clinic characteristics of patients in the two groups are listed in Table 1. Among the 357 patients, 174 (48.7%) were men and 183 (51.3%) were women. Patients' age ranged from 18 to 75 years old, with a median age of 49 (40, 57). No significant differences were observed between the two groups in terms of gender, age, BMI, history of smoking and alcohol, family history of CRC, Hypertension, constipation, diarrhea, and mixed bowel habits.

Table 1
Demographic data and indication for colonoscopy

	RD group (n = 175)	LFD group (n = 182)	<i>P-value</i>
Gender (Male/Female)	91/84	83/99	0.227
Age	48 (39, 56)	51 (40, 57)	0.177
BMI ($\bar{x} \pm SD$)	22.46 \pm 0.21	22.36 \pm 0.24	0.742
History of smoking (n, %)	40 (22.9%)	39 (21.4%)	0.745
History of alcohol (n, %)	33 (18.9%)	27 (14.8%)	0.310
Family history of CRC (n, %)	10 (5.7%)	8 (4.4%)	0.569
Hypertension (n, %)	22 (12.6%)	23 (12.6%)	0.985
Constipation (n, %)	33 (18.9%)	36 (19.8%)	0.825
Diarrhea (n, %)	28 (16.0%)	29 (15.9%)	0.986
Mixed bowel habits (n, %)	11 (6.3%)	7 (3.8%)	0.292

Clinical outcomes in different groups

The clinical outcomes in the two groups are shown in Table 2. The bowel preparation quality was evaluated by the BBPS and the bubble scale. The RD group had a similar portion of adequate bowel preparation (PP analysis 97.1% vs 98.4%, $P = 0.440$; ITT analysis 96.5% vs 99.6%, $P = 0.792$) and 0 score in bubble scale (PP analysis 97.1% vs 98.4%, $P = 0.440$; ITT analysis 97.1% vs 98.4%, $P = 1.000$) with the LFD group. The ADR in PP population was 17.1% (23.6% in men, 10.9% in women). No differences were

observed in terms of dietary satisfaction (PP analysis 99.4% vs 99.9%, $P=0.097$; ITT analysis 97.0% vs 96.5%, $P=0.778$), PDR (PP analysis 25.6% vs 27.1%, $P=0.641$; ITT analysis 24.5% vs 23.0%, $P=0.724$) and ADR (PP analysis 16.0% vs 17.42%, $P=0.619$; ITT analysis 17.0% vs 16.5%, $P=0.893$) between the two groups.

Table 2
Clinical outcomes according to different diet types (n, %)

	RD group	LFD group	<i>P-value</i>
PP analysis	n = 175	n = 182	
Adequate bowel preparation ^a	170 (97.1%)	179 (98.4%)	0.440
Bubble scale = 0	170 (97.1%)	179 (98.4%)	0.440
Dietary satisfaction	174 (99.4%)	181 (99.5%)	0.978
PDR	39 (22.3%)	43 (23.6%)	0.763
ADR	29 (16.6%)	32 (17.6%)	0.800
ITT analysis	n = 200	n = 200	
Adequate bowel preparation ^a	193 (96.5%)	192 (96.0%)	0.792
Bubble scale = 0	194 (97.0%)	194 (97.0%)	1.000
Dietary satisfaction	194 (97.0%)	193 (96.5%)	0.778
PDR	49 (24.5%)	46 (23.0%)	0.724
ADR	34 (17.0%)	33 (16.5%)	0.893
^a BBPS score ≥ 2 in all three colon segments and ≥ 6 in the total colon			

Adverse events

The adverse events during the bowel preparation in the two groups are shown in Table 3. There were no significant differences in adverse events between the two groups, except hunger, which in the RD group was significantly lower than that in the LFD group ($P=0.010$).

Table 3
Adverse events (n, %)

	RD group (n = 175)	LFD group (n = 182)	<i>P</i> -value
Adverse event	107 (61.1%)	126 (69.2%)	0.109
Hunger	62 (35.4%)	89 (48.9%)	0.010 ^a
Sleep disturbance	56 (32.0%)	70 (38.0%)	0.202
Abdominal pain	4 (2.3%)	4 (2.2%)	1.000
Bloating	8 (4.6%)	9 (4.9%)	0.868
Nausea	4 (2.3%)	2 (1.1%)	0.645
Acid regurgitation	1 (0.6%)	0 (0.0%)	0.984
Vomiting	3 (1.7%)	1 (0.5%)	0.588
Fatigue	1 (0.6%)	0 (0.0%)	0.984
Palpitation	0 (0.0%)	1 (0.5%)	1.000
Dizziness	1 (0.6%)	0 (0.0%)	0.984
Dry mouth	0 (0.0%)	1 (0.5%)	1.000
^a $P \leq 0.05$			

Evaluation of bowel preparation quality in different age subgroups

We divided the patients into three subgroups according to their ages: young patients (18 to 40 years old), middle-aged patients (41 to 65 years old) and elderly patients (66 to 75 years old). In young patients, there were no differences observed in terms of the portion of adequate bowel preparation (PP analysis 100% vs 93.5%, $P = 0.233$; ITT analysis 100% vs 94.2%, $P = 0.216$), 0 score in bubble scale (PP analysis 95.7% vs 97.8%, $P = 1.000$; ITT analysis 96.4% vs 98.1%, $P = 1.000$), dietary satisfaction (100.0% vs 97.8%, $P = 0.991$; ITT analysis 100% vs 98.4%, $P = 1.000$), PDR (PP analysis 8.5% vs 10.9%, $P = 0.973$; ITT analysis 8.9% vs 9.6%, $P = 1.000$) and ADR (PP analysis 8.5% vs 6.5%, $P = 1.000$; ITT analysis 8.9% vs 5.8%, $P = 0.718$) in the two groups (Table 4). Similar results were found in middle-aged patients and elderly patients. Hunger in RD group was significantly lower than LFD group in young patient ($P = 0.029$).

Table 4
Patients' bowel preparation quality in different ages (n, %)

	RD group	LFD group	<i>P-value</i>
Young patients			
PP analysis	n = 47	n = 46	
Adequate bowel preparation ^a	47 (100%)	43 (93.5%)	0.233
Bubble scale = 0	45 (95.7%)	45 (97.8%)	1.000
Dietary satisfaction	47 (100%)	45 (97.8%)	0.991
PDR	4 (8.5%)	5 (10.9%)	0.973
ADR	4 (8.5%)	3 (6.5%)	1.000
ITT analysis	n = 56	n = 52	
Adequate bowel preparation ^a	56 (100%)	49 (94.2%)	0.216
Bubble scale = 0	54 (96.4%)	51 (98.1%)	1.000
Dietary satisfaction	56 (100%)	51 (98.1%)	0.970
PDR	5 (8.9%)	5 (9.6%)	1.000
ADR	5 (8.9%)	3 (5.8%)	0.718
Middle-aged patients			
PP analysis	n = 119	n = 124	
Adequate bowel preparation ^a	115 (96.6%)	124 (100%)	0.120
Bubble scale = 0	117 (98.3%)	122 (98.4%)	1.000
Dietary satisfaction	118 (99.2%)	124 (100%)	0.984
PDR	32 (26.9%)	32 (25.8%)	0.848
ADR	22 (18.5%)	24 (19.4%)	0.863
ITT analysis	n = 133	n = 136	
Adequate bowel preparation ^a	127 (95.5%)	132 (97.1%)	0.720
Bubble scale = 0	131 (98.5%)	131 (96.3%)	0.462
Dietary satisfaction	132 (99.2%)	136 (100%)	0.991
PDR	40 (30.1%)	36 (26.5%)	0.511

	RD group	LFD group	<i>P</i>-value
ADR	26 (19.5%)	25 (18.4%)	0.807
Elderly patients			
PP analysis	n = 9	n = 12	
Adequate bowel preparation ^a	8 (88.9%)	12 (100%)	0.429
Bubble scale = 0	8 (88.9%)	12 (100%)	0.429
Dietary satisfaction	9 (100%)	12 (100%)	1.000
PDR	3 (33.3%)	6 (50.0%)	0.660
ADR	3 (33.3%)	5 (41.7%)	1.000
ITT analysis	n = 11	n = 12	
Adequate bowel preparation ^a	10 (90.9%)	12 (100%)	0.965
Bubble scale = 0	10 (90.9%)	12 (100%)	0.965
Dietary satisfaction	10 (90.9%)	12 (100%)	0.965
PDR	5 (45.5%)	6 (50.0%)	0.827
ADR	3 (27.3%)	5 (41.7%)	0.667
^a BBPS score \geq 2 in all three colon segments and \geq 6 in the total colon			

Evaluation of bowel preparation quality in inpatients and outpatient subgroups

According to recent researches, inpatient was an independent risk for inadequate bowel preparation, therefore we divided patient into inpatient and outpatient subgroups to analyze the quality of bowel preparation. As shown in Table 5, in inpatients, there were no significant differences between the RD group and the LFD group in terms of the portion of adequate bowel preparation (PP analysis 92.5% vs 100%, $P = 0.055$; ITT analysis 91.0% vs 98.8%, $P = 0.072$), 0 score in bubble scale (PP analysis 100% vs 97.4%, $P = 0.641$; ITT analysis 100% vs 97.5%, $P = 0.556$), dietary satisfaction (PP analysis 100.0% vs 98.7%, $P = 1.000$; ITT analysis 100% vs 98.82%, $P = 1.000$), PDR (PP analysis 34.0% vs 27.6%, $P = 0.441$; ITT analysis 40.3% vs 27.5%, $P = 0.101$) and ADR (PP analysis 28.3% vs 18.4%, $P = 0.186$; ITT analysis 28.4% vs 18.8%, $P = 0.169$) among the inpatients. Similar results were found in the outpatients. Hunger in RD group was significantly lower than LFD group in inpatients ($P = 0.036$).

Table 5
 Inpatients and outpatients bowel preparation quality (n, %)

	RD group	LFD group	<i>P</i> -value
Inpatients			
PP analysis	n = 53	n = 76	
Adequate bowel preparation ^a	49 (92.5%)	76 (100%)	0.055
Bubble scale = 0	53 (100%)	74 (97.4%)	0.641
Dietary satisfaction	53 (100%)	75 (98.7%)	1.000
PDR	18 (34.0%)	21 (27.6%)	0.441
ADR	15 (28.3%)	14 (18.4%)	0.186
ITT analysis	n = 67	n = 80	
Adequate bowel preparation ^a	61 (91.0%)	79 (98.8%)	0.072
Bubble scale = 0	67 (100%)	78 (97.5%)	0.556
Dietary satisfaction	67 (100%)	79 (98.8%)	1.000
PDR	27 (40.3%)	22 (27.5%)	0.101
ADR	19 (28.4%)	15 (18.8%)	0.169
Outpatients			
PP analysis	n = 122	n = 106	
Adequate bowel preparation ^a	121 (99.3%)	103 (97.2%)	0.517
Bubble scale = 0	117 (95.9%)	105 (99.1%)	0.285
Dietary satisfaction	121 (99.6%)	106 (100%)	1.000
PDR	21 (17.2%)	22 (20.8%)	0.495
ADR	14 (11.5%)	18 (17.0%)	0.233
ITT analysis	n = 133	n = 120	
Adequate bowel preparation ^a	132 (99.2%)	115 (95.8%)	0.171
Bubble scale = 0	128 (96.2%)	118 (98.3%)	0.529
Dietary satisfaction	132 (99.2%)	120 (100%)	1.000
PDR	23 (17.3%)	25 (20.8%)	0.473

	RD group	LFD group	<i>P</i> -value
ADR	15 (11.3%)	18 (15.0%)	0.380
^a BBPS score ≥ 2 in all three colon segments and ≥ 6 in the total colon			

Discussion

The quality of bowel preparation plays a fundamental role in performing a high-quality colonoscopy to observe the colon mucosa [14]. Despite of the various methods for bowel preparation, the rates of inadequate bowel preparation are recorded to be between 20% and 30% [15, 16]. The European Society of Gastrointestinal Endoscopy Guideline in 2019 suggested that the minimum standard for adequate bowel preparation should not be less than 90% [7]. Therefore, it's necessary for us to improve the rates of adequate bowel preparation. Ideally, bowel preparation for colonoscopy should reliably clear all solid and liquid material of the colon, and be well tolerated without disorder of water and electrolyte. Previous studies have showed that there is no significant difference in the quality of the bowel preparation between patients eating a LFD and a CLD [2]. In a recent prospective study from the American University of Beirut Medical Center demonstrated that colonic preparation with no dietary restriction provides better quality of colon cleansing than a liquid diet, with no significant impact on patient tolerability and adverse effects [9]. However, there were two variables in this study: patient having a liquid diet received 4L PEG while those having a RD received 2L PEG, which may affect the results. Accordingly, our study aimed to test the hypothesis that a RD on the day before colonoscopy has comparable efficacy in bowel preparation with a traditional LFD. To our knowledge, this is the first randomized and single-blind study to compare the quality of bowel preparation, ADR and overall adverse events between RD group and LFD group undergoing morning colonoscopy with a split dose of 3L PEG.

Our study confirmed that the quality of bowel preparation and ADR in the RD group are comparable to those in the LFD group. Considering RD doesn't change the eating habits of patients and can provide sufficient energy, which may improve the patient's compliance and the convenience of colonoscopy, we suggest that RD should be recommended for bowel preparation. The guideline in ESGE indicated that ADR should be more than 25% [1]. Zhang reported [17] that the ADR was 14–15% in Chinese, the same as Bai [18]. In this study, the ADR was 17.1% (23.6% in men, 10.9% in women), which was consistent with Zhang [17] and Bai [18]. There was a significantly lower incidence of hunger in RD group ($P = 0.010$), especially in young patients ($P = 0.029$) and inpatients ($P = 0.036$). Perhaps young patients have a faster metabolism and need more energy, and RD can provide enough energy to reduce their hunger. For inpatients, an enormous number of them with chronic diseases will deplete energy rapidly, and LFD could not offer enough calorie that inpatients felt hunger easily.

In addition, there are several factors influencing quality of bowel preparation for colonoscopy, such as age, inpatient [19]. Several researches showed that older age is an important independent factor of inadequate bowel preparation [20, 21]. Elderly patients might have disease such as chronic constipation,

and noncompliance with dietary instruction before colonoscopy [21, 22]. In our result, among young patients, middle-aged patients and elderly patients, no significant differences were observed in the adequacy of bowel preparation, bubble scales, dietary satisfaction, PDR and ADR between the two groups. Thus, for the patients aged 18 to 75 years old, it should be recommended to take RD for bowel preparation. Almadi [23] compared the quality of bowel preparation between inpatient and outpatient, and found that inpatient was a risk factor for inadequate bowel preparation. For the inpatients, they are more likely to have gastrointestinal symptoms and less activity, and these may be the reasons that cause inadequate bowel preparation. Our results showed that either in inpatients or outpatients, the bowel preparation, adverse effects, PDR and ADR were not significantly different in the RD group and LFD group. This suggested that even for inpatients, they can take a RD before colonoscopy with adequate bowel preparation.

Conclusion

This study showed that the quality of the bowel preparation, adverse events, PDR and ADR in the RD group were similar to those in the LFD group, while hunger was significantly lower than LFD group. Without changing patients' eating habits, RD is more convenient, reducing hunger and may be more acceptable for patients before undergoing the colonoscopy. As this study is in a single institution and the sample size may not be large enough, a further multicenter study involving larger sample may be needed to confirm the effectiveness and safety of RD for colonoscopy preparation.

Abbreviations

ADR

Adenoma detection rate

BBPS

the Boston Bowel Preparation Scale

CRC

Colorectal cancer

ITT

Intention-to-treat

PDR

Polyp detection rate

PEG

Polyethylene glycol electrolyte

PP

Per-protocol

Declarations

Ethics approval and consent to participate:

The study was reviewed and approved by the Institutional Review Board of The Sixth Affiliated Hospital of Guangzhou Medical University. This study is registered at <http://www.chictr.org.cn> (Chinese Clinical Trial Registry, 12 March 2019), and the registration identification number is ChiCTR1900021836. All study participants, or their legal guardian, provided informed written consent prior to study enrollment.

Consent for publication:

Both of authors agree to publish this manuscript in BMC Gastroenterology.

Competing interests:

Danlei Liu, Hanxian Zhang, Donglian Liu and Tieli Peng have no conflict of interest or financial ties to disclose.

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Authors' contributions:

TP designed the study; DL (Danlei Liu) and HZ performed the study and analyzed the data; DL (Danlei Liu), DL (Donglian Liu) and TP drafted the manuscript. All authors have read and approved the manuscript.

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Availability of data and material:

The datasets generated and/or analysed during the current study are not publicly available due its confidential nature and to prevent deductive disclosure of the identity of the study participants but are available from the corresponding author on reasonable request.

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Figures

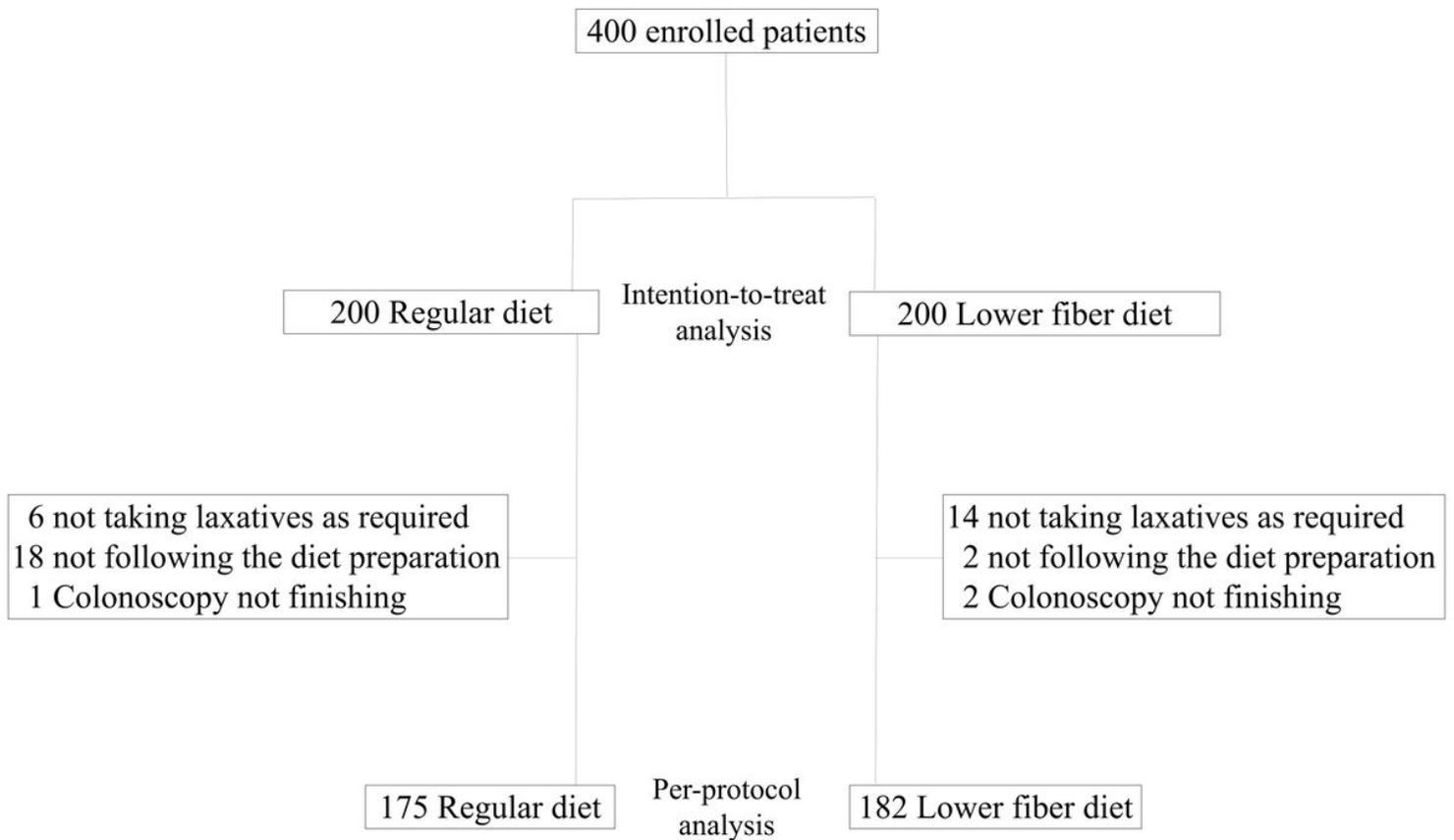


Figure 1

Enrollment flow chart

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