



Retrospective Study

Application effect of linaclotide capsules combined with compound polyethylene glycol in colonoscopy bowel preparation

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Abstract

BACKGROUND

In the field of clinical intestinal preparation, compound polyethylene glycol electrolyte solution (SF-PEG) is a commonly used intestinal cleaner. However, practice has shown that using only a single polyethylene glycol formulation often fails to achieve the desired intestinal preparation effect. Linaclotide has a unique mechanism of action, which can effectively enhance the secretion of small intestinal fluid and promote intestinal peristalsis. The combination of linaclotide and SF-PEG may provide a better solution for intestinal preparation and improve the quality of intestinal cleaning. Therefore, exploring the application value and clinical efficacy of linaclotide capsules combined with SF-PEG in intestinal preparation is of great clinical significance.

AIM

To explore the effects of the combination of linaclotide capsules and SF-PEG, including its efficacy in intestinal preparation and patient tolerance.

METHODS

To investigate the differences in the effectiveness of different bowel preparation plans in colonoscopy, this article conducted a comprehensive and detailed retrospective analysis of the medical records of patients who underwent colonoscopy from January 2023 to December 2023. In this study, 116 patients were accurately divided into three groups based on the different intestinal preparation drugs used before colonoscopy. Among them, group A consisted of 29 patients who underwent intestinal preparation using 3 liters of SF-PEG combined with linaclotide; group B consists of 50 patients who underwent intestinal preparation using 3 liters of SF-PEG; group C consisted of 37 patients who underwent intestinal pre-

paration using a combination of 2-liter SF-PEG and linaclotide. Subsequently, this article evaluated the quality of intestinal preparation in these three groups of patients, using the Boston bowel preparation scale (BBPS) as a quantitative indicator, while comparing multiple indicators such as intestinal preparation completion rate and detection of positive lesions, providing a strong basis for optimizing clinical intestinal preparation plans.

RESULTS

No statistically significant differences were found in BBPS scores (7.75 ± 1.23 , 7.69 ± 1.14 , and 7.66 ± 1.31 ; $P = 0.240$), bowel preparation completion rates (96.55%, 90.00%, and 97.30%; $P = 0.293$), adenoma detection rates (20.69%, 38.00%, and 32.43%; $P = 0.281$), polyp detection rates (34.48%, 50.00%, 37.84%; $P = 0.326$), insertion time (6.03 ± 4.34 , 6.12 ± 3.60 , and 5.33 ± 2.42 ; $P = 0.584$), and patient satisfaction rates (89.66%, 84.00%, and 97.30%; $P = 0.398$) among the three groups. However, statistically significant differences were observed in withdrawal time (7.45 ± 2.91 , 9.02 ± 3.54 , and 6.86 ± 2.66 ; $P = 0.027$) and adverse reaction rates (6.90%, 20.00%, and 2.70%; $P = 0.029$) among the three groups. Multiple comparisons showed that group C had significantly lower withdrawal time and adverse reaction rates than group B ($P = 0.013$, $P = 0.016$).

CONCLUSION

Linaclotide capsules show a trend in improving bowel preparation quality and reducing the dosage of SF-PEG.

Key Words: Colonoscopy; Bowel preparation; Compound polyethylene glycol electrolyte solution; Linaclotide; Boston bowel preparation scale; Curative effect

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Core Tip: Compound polyethylene glycol electrolyte powder (SF-PEG) is a commonly used intestinal cleaner, but some elderly patients have poor tolerance to it. Linalotide can improve intestinal preparation by increasing small intestinal fluid secretion and intestinal peristalsis. In this study, group C (bowel preparation with 2 L of SF-PEG combined with linaclotide) had significantly lower withdrawal time and incidence of adverse reactions compared to group B (bowel preparation with 3 L of SF-PEG), indicating that linaclotide capsules have a tendency to improve intestinal preparation quality, reduce SF-PEG dosage, help reduce patient discomfort, and make colonoscopy easier for patients.

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INTRODUCTION

In clinical medical practice, colonoscopy has become the preferred method for screening and diagnosing intestinal diseases. This is mainly because the cleanliness of intestinal preparation has a direct and critical impact on the accuracy of colonoscopy diagnosis and the safety of treatment. If the intestinal preparation is insufficient, it may affect the diagnostic results and even delay the timing of treatment. Relevant statistical data shows that about 18%-35% of colonoscopies have insufficient bowel preparation[1]. The consequences of inadequate intestinal preparation are very serious, which can lead to missed diagnosis of adenomas[2]. This means that many potential risks of intestinal diseases are overlooked, and patients may miss the best treatment opportunity as a result. The domestic guidelines[3] explicitly recommend the use of compound polyethylene glycol electrolyte (PEG) powder (SF-PEG) for intestinal preparation. Numerous studies have shown that 3 L SF-PEG significantly improves the detection rate of colon polyps (especially the right colon) and the rate of cecal intubation[4,5]. However, this approach is not perfect. Many patients, especially elderly patients, have poor tolerance to it. During the process of taking it, they may experience discomfort symptoms such as nausea, bloating, and vomiting. More seriously, due to the need to consume large amounts of SF-PEG in a short period of time, some patients may even experience life-threatening conditions such as tearing of the cardiac mucosa. Therefore, how to improve patient tolerance while ensuring the effectiveness of intestinal preparation has become an urgent clinical problem to be solved.

Linalotide capsules are a medication approved by the United States Food and Drug Administration specifically for the treatment of constipation. It has a unique pharmacological mechanism of action that can enhance the secretion of chloride and bicarbonate in the intestinal lumen. This effect increases the active secretion of small intestinal fluid and accelerates the transport speed of the colon[6]. Based on this, this study focuses on the application value and clinical effects of linaclotide capsules in combination with SF-PEG for intestinal preparation, aiming to provide a better solution for intestinal preparation.

MATERIALS AND METHODS

General information

This study focused on the medical records of patients who underwent colonoscopy between January 2023 and December 2023, and conducts a comprehensive and in-depth retrospective analysis. To ensure the accuracy and reliability of the research results, this article had established strict inclusion and exclusion criteria. In terms of inclusion criteria, patients were required to be between 18 and 75 years old and undergo relevant examinations to make the research results more universal and representative. The exclusion criteria were: (1) Patients with severe cardiopulmonary dysfunction, renal failure, or a history of stroke or heart attack within 6 months; (2) Patients with a history of abdominal or pelvic surgery; (3) Pregnant and lactating women; (4) Patients with a body mass index between 18.5 and 28 but suffering from inflammatory bowel disease, intestinal obstruction, or other high-risk factors for intestinal preparation; (5) Patients with coagulation abnormalities or those who have used antiplatelet or anticoagulant drugs within 7 days; (6) Patients diagnosed with colon polyps; (7) Bristol stool score of 7 indicates patients with diarrhea; and (8) Patients who participate in other interventional clinical trials within 60 days prior to colonoscopy examination. This study has been approved by the Ethics Committee of Rui'an People's Hospital/The Third Affiliated Hospital of Wenzhou Medical University, and the Ethics Committee has agreed to waive the informed consent form (YJ2024044), providing ethical protection for the smooth progress of the study.

After strictly following the established inclusion and exclusion criteria, this study ultimately successfully enrolled 116 patients. To investigate the differences in the effectiveness of different bowel preparation plans, these 116 patients were carefully divided into three groups based on the bowel preparation drugs used by patients before colonoscopy. Among them, group A consisted of 29 patients who underwent intestinal preparation using 3 Liters of SF-PEG combined with linaclotide; group B consists of 50 patients who underwent intestinal preparation using 3 Liters of SF-PEG; group C had 37 patients who underwent intestinal preparation using 2 Liters of SF-PEG combined with linaclotide, laying the foundation for subsequent research. No statistically significant differences ($P > 0.05$) were found in general characteristics, such as gender, age, and reasons for colonoscopy examination, among the three groups, ensuring comparability (Table 1).

Bowel preparation methods

Group A patients need to strictly follow the prescribed bowel preparation before undergoing colonoscopy examination. Specifically, for 3 consecutive days, take Linalotide capsules (registration number: National Medical Products Administration Approval No. J20200012, manufacturer: Almac Pharma Services Limited, specification: 290 µg) on time 30 minutes before the first meal of each day. They did not take the capsule on the day of the examination. Starting from the day before the examination (breakfast, lunch, and dinner), they followed a low-residue diet and began fasting at 7:00 PM, then consumed 1500 mL of SF-PEG at 8:00 PM (approval number: Guoyozhunzi H20030827, manufacturer: Shenzhen Wanhe Pharmaceutical Co., Ltd., specification: 68.56 g/bag; preparation method: Pour two bags of powder into a measuring cup, add warm water to make 2 L, and stir until completely dissolved), completing intake within 1.5 hours. They orally consumed another 1500 mL of SF-PEG within 1.5 hours after starting, 4-6 hours before the colonoscopy on the examination day. After they took laxatives, they immediately ingested 6 mL of simethicone.

Group B followed the same dietary restrictions as group A the day before the examination. They consumed 1500 mL of SF-PEG at 8:00 PM 4-6 hours before the colonoscopy on the examination day, completing intake within 1.5 hours. They orally consumed another 1500 mL of SF-PEG within 1.5 hours after starting. After they took laxatives, they immediately ingested 6 mL of simethicone.

Group C followed the same linaclotide capsule regimen as group A for 3 days before the colonoscopy. They also followed the same dietary restrictions as groups A on the day before the examination. They consumed 1000 mL of SF-PEG at 8:00 PM (preparation method: Pour one bag of powder into a measuring cup, add warm water to make 1 L, and stir until completely dissolved), completing intake within 1.5 hours. They orally consumed another 1000 mL of SF-PEG within 1.5 hours after starting, 4-6 hours before the colonoscopy on the examination day. After they took laxatives, they immediately ingested 6 mL of simethicone.

Observation indicators

Bowel preparation quality: The Boston bowel preparation scale (BBPS) plays a crucial role in assessing the quality of bowel preparation[7]. In this study, it was used to separately evaluate the cleanliness of the left colon, transverse colon, and right colon in three groups of patients. The scoring range of this scale is set from 0 to 3 points, divided into four levels based on the degree of intestinal cleanliness from the worst to the cleanest, with a total score range of 0-9 points. Specifically, when the score is 0, it means that there is solid fecal residue in the intestine, and the intestinal mucosa is completely covered by pasty feces, making it impossible for doctors to observe effectively. A score of 1 indicates that only a portion of the intestinal segment is visible, and there is obvious fecal residue on the mucosa, which affects the observation field. At 2 minutes, most of the intestinal segments were clearly visible, with only a small amount of fecal residue on the mucosa, which had relatively little interference with observation. A score of 3 is an ideal state of intestinal preparation, with relatively clear intestinal mucosa and only a small amount of intestinal fluid, which does not hinder the doctor's careful observation. Usually, if the total score exceeds 6 points and all parts score ≥ 2 points, it will be judged as sufficient intestinal preparation; Those who do not meet this standard are considered to have insufficient intestinal preparation.

Bowel preparation completion rate and detection of positive lesions: During the examination process, the bowel preparation completion rate of the three groups was documented, calculated as the percentage of laxative intake $\geq 90\%$

Table 1 Patient characteristic among the three groups

Group	Gender		Age (year)	Reason for colonoscopy				
	Male	Female		Abdominal discomfort	Black stool/bloody stool	Constipation	Routine check-up	Other
A (<i>n</i> = 29)	16	13	52.77 ± 6.32	5	7	8	6	3
B (<i>n</i> = 50)	26	24	53.65 ± 7.14	14	12	11	7	6
C (<i>n</i> = 37)	18	19	53.29 ± 8.48	10	6	9	5	7
Statistic	0.28		1.012	3.636				
<i>P</i> value	0.869		0.367	0.888				

cases over the total cases in the group. Following patient examinations, diseased tissues were biopsied, and healthcare personnel recorded the detection of positive lesions (adenomas and polyps) in the three groups.

Colonoscopy examination time: The insertion and withdrawal times of colonoscopy for the three groups were recorded. The time from the anus to the cecum marked the insertion time, whereas the time from the cecum to exiting the anus indicated the withdrawal time.

Adverse reactions: Adverse reactions during bowel preparation were recorded for all three groups, including nausea, abdominal pain, palpitations, vomiting, and dizziness, and the rate of adverse reactions was calculated.

Patient satisfaction: Patient satisfaction was assessed in accordance with the “Chinese Digestive Endoscopy Diagnosis and Treatment Related Bowel Preparation Guidelines (2019, Shanghai)” [3]. Satisfaction scores were categorized as follows: Satisfied: Score > 90 points; average: Score 66-90 points; and dissatisfied: Score ≤ 65 points. The satisfaction rate was calculated on the basis of the percentage of satisfied and average cases out of the total cases.

Statistical analysis

This study conducted statistical analysis using SPSS (version 26.0) software. For continuous data, it was presented in the form of mean (mean ± SD), and independent sample *t*-test is used for inter group comparison. And the categorical data was represented in the form of *n* (%), and the χ^2 test was used to compare the differences between groups. When determining whether the results had statistical significance, a significance level of *P* < 0.05 was set to ensure the scientific and reliable nature of the research conclusions.

RESULTS

Comparison of BBPS among the three groups

After rigorous statistical analysis, it was found that there was no statistically significant difference in the total BBPS score, as well as the scores of the left colon, transverse colon, and right colon, among the three groups of patients (see Table 2 for specific data).

Comparison of bowel preparation completion rate and detection of positive lesions among the three groups

As shown in Table 3, no statistically significant differences were observed in the bowel preparation completion rates (96.55%, 90.00%, and 97.30%; *P* = 0.293); adenoma detection rates (20.69%, 38.00%, and 32.43%, *P* = 0.281); and polyp detection rates (34.48%, 50.00%, and 37.84%; *P* = 0.326) among the three groups.

Comparison of colonoscopy examination time among the three groups

No statistically significant difference was found in insertion time among the three groups (*P* = 0.584). However, a significant difference was noted in withdrawal time (*P* = 0.027). Further multiple comparisons revealed that the difference in withdrawal time was mainly between groups B and C (*P* = 0.013), A and B (*P* = 0.111), and A and C (*P* = 0.405), with no statistical significance in withdrawal time differences (Table 4).

Comparison of adverse reaction rates among the three groups

After in-depth analysis of the incidence of adverse reactions in three groups of patients, the results showed that there was a statistically significant difference in the incidence of adverse reactions among the three groups (*P* = 0.029). To further clarify the differences, multiple comparisons were conducted. The results showed that the differences in the incidence of adverse reactions were mainly concentrated between group B and group C (*P* = 0.016), group A and group B (*P* = 0.118), and group A and group C (*P* = 0.417). However, the incidence of adverse reactions between the groups was not statistically significant (see Table 5 for specific data).

Table 2 Comparison of Boston bowel preparation scale scores among the three groups

Group	Left colon	Transverse colon	Right colon	Total score
A (<i>n</i> = 29)	2.78 ± 0.45	2.70 ± 0.51	2.41 ± 0.55	7.75 ± 1.23
B (<i>n</i> = 50)	2.74 ± 0.41	2.69 ± 0.48	2.32 ± 0.59	7.69 ± 1.14
C (<i>n</i> = 37)	2.76 ± 0.49	2.56 ± 0.64	2.35 ± 0.66	7.66 ± 1.31
Statistic	0.203	0.954	1.042	1.446
<i>P</i> value	0.816	0.388	0.356	0.240

Table 3 Comparison of bowel preparation completion rate and detection of positive lesions among the three groups, *n* (%)

Group	Bowel preparation completion rate	Adenoma detection rate	Polyp detection rate
A (<i>n</i> = 29)	28 (96.55)	6 (20.69)	10 (34.48)
B (<i>n</i> = 50)	45 (90.00)	19 (38.00)	25 (50.00)
C (<i>n</i> = 37)	36 (97.30)	12 (32.43)	14 (37.84)
Statistic	2.453	2.539	2.243
<i>P</i> value	0.293	0.281	0.326

Table 4 Comparison of colonoscopy examination time among the three groups

Group	Insertion time (minute)	Withdrawal time (minute)
A (<i>n</i> = 29)	6.03 ± 4.34	7.45 ± 2.91
B (<i>n</i> = 50)	6.12 ± 3.60	9.02 ± 3.54
C (<i>n</i> = 37)	5.33 ± 2.42	6.86 ± 2.66 ^a
Statistic	0.541	3.717
<i>P</i> value	0.584	0.027

^a*P* < 0.05, statistically significant difference compared with group B.

Table 5 Comparison of adverse reaction rates among the three groups, *n* (%)

Group	Nausea	Abdominal pain	Palpitations	Vomiting	Dizziness	Total occurrence rate
A (<i>n</i> = 29)	1 (3.45)	0 (0.00)	1 (3.45)	1 (3.45)	1 (3.45)	2 (6.90)
B (<i>n</i> = 50)	5 (10.00)	2 (4.00)	1 (2.00)	5 (10.00)	3 (6.00)	10 (20.00)
C (<i>n</i> = 37)	1 (2.70)	0 (0.00)	0 (0.00)	1 (2.70)	0 (0.00)	1 (2.70) ^a
Statistic						7.116
<i>P</i> value						0.029

^a*P* < 0.05, statistically significant difference compared with group B.

Comparison of patient satisfaction among the three groups

In terms of satisfaction, there were significant differences between different groups of samples (see Table 6 for details).

DISCUSSION

Colorectal lesions pose a serious threat to human health, and colonoscopy is the preferred method for screening such lesions. The quality of intestinal preparation is related to the accuracy and success rate of colonoscopy examination. High quality intestinal preparation allows endoscopists to have good visibility during the examination process, greatly

Table 6 Comparison of patient satisfaction among the three groups, *n* (%)

Group	Satisfied	Neutral	Not satisfied	Total satisfaction rate
A (<i>n</i> = 29)	16 (55.17)	10 (34.48)	3 (10.34)	26 (89.66)
B (<i>n</i> = 50)	26 (52.00)	16 (32.00)	8 (16.00)	42 (84.00)
C (<i>n</i> = 37)	22 (59.46)	14 (37.84)	1 (2.70)	36 (97.30)
Statistic				4.059
<i>P</i> value				0.398

improving the success rate of insertion, and thereby increasing the detection rate of polyps and disease diagnosis rate. It can be considered that the quality of intestinal preparation plays a crucial role in colonoscopy[8]. In clinical practice, PEG is a widely used intestinal cleaner. PEG is an inert polymer that does not affect electrolyte exchange in the intestine and does not undergo biological metabolism in the body. Therefore, PEG has high safety and wide applicability, providing reliable assurance for intestinal preparation during colonoscopy[9]. The cleansing effect of PEG is dose-dependent, with previous studies showing that the cleansing effect of 4 L PEG is significantly higher than that of 2 L[10]. However, with the increasing dosage of PEG, patients need to consume a large amount of water, which can easily cause discomfort such as nausea, vomiting, and abdominal distension, leading to decreased tolerance and compliance. A single cleansing effect may not be ideal, especially for patients with slow intestinal motility and constipation. Therefore, researchers domestically and internationally have explored studies combining SF-PEG with lactulose, enemas, and vitamin C, among others. However, these approaches have been limited in their promotion due to adverse reactions, target population suitability, and patient tolerability[11,12]. Linaclotide capsules are a novel medication for the treatment of refractory constipation. Approved by relevant departments, certain drugs are mainly used to treat constipation predominant irritable bowel syndrome (IBS-C), *etc.*[13]. The mechanism of action of these drugs is relatively unique, as they can act on intestinal epithelial cells and activate receptors expressed on their luminal side. Once the receptor is activated, it induces intestinal epithelial cells to produce cyclic guanosine monophosphate (cGMP) and release it into the extracellular space, thereby exerting therapeutic effects. The increase in intracellular cGMP leads to the secretion of chloride ions and bicarbonate ions along with water into the intestinal lumen, increasing the water content of feces and accelerating intestinal motility[14]. Studies have shown that linaclotide can reduce visceral sensitivity and improve the severity of abdominal pain and bloating in patients, making it more favorable for patients with constipation[15].

This study focuses on the effects of three different treatment options on intestinal preparation in patients undergoing colonoscopy, and the following results are obtained. In terms of intestinal preparation quality, the BBPS scores of the three groups did not show statistically significant differences ($P = 0.240$) after statistical analysis. However, group A performed better than group C. This suggests that after the combined use of linaclotide, the intestinal preparation effect has reached a stable stage when patients take 2 L of SF-PEG solution. In this case, taking an additional 1 Liter of SF-PEG solution did not significantly improve the quality of intestinal preparation. In terms of the completion rate of intestinal preparation, there was no statistically significant difference among the three groups ($P = 0.293$), which means that the three schemes have similar effects in ensuring patients complete intestinal preparation. However, group A (96.55%) was higher than group B (90.00%), indicating a trend of increased bowel preparation completion rate after using linaclotide in combination. Group C (97.30%) was also higher than group B (90.00%), demonstrating that using linaclotide in combination did not have a negative effect on bowel preparation quality despite reducing the amount of 1 L SF-PEG used, thus affirming the role of linaclotide capsules in reducing the amount of SF-PEG used. In terms of colonoscopy operation time, the withdrawal time for group C was significantly lower than that of group B ($P = 0.013$). This difference may be attributed to the higher quality of bowel preparation in group C, reducing the time spent on repeated washing and suctioning of intestinal contents due to poor bowel preparation, leading to a clearer field of vision. A shorter withdrawal time can significantly improve the efficiency of endoscopists and the comfort of patients. Previous studies have shown that there is no significant difference in the detection rate of positive lesions between medium quality and high-quality bowel preparation for adenomas, but low-quality bowel preparation significantly reduces the detection rate of adenomas[16]. In this study, there was no statistically significant difference in the detection rates of adenomas and polyps among the three groups of data after analysis ($P = 0.281$, $P = 0.326$). This further indicates that even if the dosage of SF-PEG is reduced by 1 Liter, the combined use of linaclotide will not have a negative impact on the quality of intestinal preparation. However, there was a statistically significant difference in patient satisfaction among the three groups of patients ($P = 0.398$). However, group A (89.66%) was higher than group B (84.00%), showing an increasing trend in patient satisfaction after using linaclotide in combination. Group C (97.30%) was also higher than group B (84.00%), indicating that using linaclotide in combination not only reduced the amount of 1 L SF-PEG used but also increased patient satisfaction. In terms of adverse reactions, the research results showed that the incidence of adverse reactions in group B was significantly higher than that in group C ($P = 0.016$). In depth analysis revealed that this difference may be related to a decrease in water intake in group C, which leads to an improvement in patient tolerance. It can be inferred that adding linaclotide during intestinal preparation is a feasible strategy that can appropriately reduce the use of SF-PEG. This method can ensure the effectiveness of intestinal preparation and reduce the incidence of adverse reactions during intestinal preparation. This research result is consistent with relevant reports in literature[17-19], providing strong references for clinical practice.

CONCLUSION

Prior to colonoscopy, the use of linaclotide capsules combined with 2 L SF-PEG regimen for intestinal preparation has certain advantages. This plan can effectively shorten the withdrawal time, alleviate the discomfort of patients during intestinal cleansing, and reduce the incidence of adverse reactions. Moreover, it does not affect the quality of intestinal preparation. Therefore, the combination of linaclotide capsules and 2 L SF-PEG regimen is of great value in clinical application, as it can make it easier for patients to undergo colonoscopy. However, it should be clarified that this study belongs to a single center, small sample research, which has certain limitations and is constrained by regional factors. The research conclusion may be biased due to small sample size, uneven distribution of subgroups, or systematic errors, so further confirmation of its reliability and effectiveness is needed through large sample prospective randomized controlled trials.

FOOTNOTES

Author contributions: Xue LW initiated the project; Zhang YQ and Yu WL designed the experiment and conducted clinical data collection, performed postoperative follow-up and recorded data; Xue LW and Wen ZB conducted a number of collation and statistical analysis, and wrote the original manuscript; all authors have read and approved the final manuscript.

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