

The Effectiveness of Triple Medications Bowel Preparation for Colonoscopy in Elderly Patients

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Abstract

Introduction: Colonoscopy is critical in colorectal cancer screening and the effect of intestinal preparation affects the accuracy of diagnosis, especially in elderly patients. The commonly used Polyethylene Glycol Electrolyte, PEG, is found inadequate in bowel cleansing for the elderly patients. And the internal environment of those is easily disturbed. Thus, the exploration of an optimal method with effectiveness and safety in bowel preparation for those people is crucial in the setting.

Methods: This is a single-center, single-blind, and randomized controlled study. The patients between 60 to 74 years old meeting the inclusion criteria were randomly divided into four groups: Group A (Polyethylene Glycol Electrolyte, PEG), Group B (PEG plus mosapride), Group C (PEG plus simethicone), and Group D (PEG plus mosapride and simethicone). Serum electrolytes were compared before and after the preparation. The intolerance, safety, adverse reactions and Boston Bowel Preparation Scale (BBPS) were evaluated among the groups. Three endoscopists were assigned to avoid individual discrepancy in BBPS scores evaluation.

Discussion and conclusion: The BBPS scores of Group D were significantly higher than the other groups ($p < 0.05$). And the electrolytes tests did not show a significant difference. The homeostasis of the elderly patients can be maintained. There were no significant difference in adverse reactions, intolerance, and safety. The triple medications administration presented an excellent bowel preparation, and showed effectiveness and safety in elderly patients.

Keywords: Bowel preparation; Elderly patients; Colonoscopy; Intestinal cleansing.

Abbreviations: PEG: Polyethylene Glycol Electrolyte; BBPS: Boston Bowel Preparation Scale.

Introduction

Colonoscopy examination becomes crucial in colorectal cancer screening and polyp treatment [1-3]. The bowel preparation before the examination is indispensable, and the quality of colorectal cleanliness can effectively affect the accuracy of diagnosis and colorectal polyp treatment [4-6]. Besides, geriatric becomes a concern in bowel preparation. When the body is getting old, the vital organ functions will become compro-

mised comparatively. The laxative may cause severe internal environment imbalance, that can seriously cause safety issue. Polyethylene Glycol Electrolyte, PEG, is the commonly used medical agent for bowel preparation [7,8]. Yet, the cleansing effect of single application is unsatisfied in elderly patients in clinical practice [9]. So far, there is lack of consensus on optimal bowel preparation regimen for those patients. This study aims to explore an effective and safe way in elderly patients bowel preparation.

Methods

Sample size and research subjects

A total of 800 eligible patients who underwent colonoscopy in our hospital from January 2021 to November 2022 were selected. The research subjects were randomly divided into four groups: Group A (Polyethylene Glycol Electrolyte, PEG), Group B (PEG plus mosapride), Group C (PEG plus simethicone), and Group D (PEG plus mosapride and simethicone).

Inclusion and exclusion criteria, and withdrawal of subjects

Inclusion criteria: 60 to 74 years old; painless colonoscopy; no contraindication for bowel preparation and colonoscopy; ability to communicate and complete consent form.

Exclusion criteria: Compromised vital organs functions that contraindicate bowel preparation and colonoscopy; a known history of allergy to anesthesia and bowel preparation medications; use of purgative, antidiarrheal and gastrointestinal motility disorder drugs within 2 weeks; Hepatitis B and C, syphilis, AIDS, tuberculosis and other infectious diseases and malignant tumors; a history of gastrointestinal surgery.

Withdrawal: The amount of water intake do not reach 75% of requirements, and vomiting exceeds 50% of the water intake. For other reasons, the patients cannot continue the study.

Diet and medications preparation

A Fermentable Oligosaccharides Disaccharides Monosaccharides and Polyols (FODMAP) [10] diet was taken. Foods and medications that could affect the color of feces were avoided. Nothing by mouth was initiated from 8 hours prior to the colonoscopy.

Experimental design

Group A: 2 boxes of PEG with 1500 ml warm water were taken within 2 hours at 6 to 8 pm on the prior night; then another round of 2 boxes of PEG with 1500 ml warm water were repeated within 2 hours at 1 to 3 am on the day of examination.

Group B: PEG plus mosapride were administrated. Specifically, the above PEG preparations were used plus 5 mg mosapride taken three times before the three diets on the prior day.

Group C: PEG plus simethicone were applied. 15 ml of simethicone oil taken at 8 pm was added to PEG preparations.

Group D: PEG plus mosapride and simethicone.

Lab tests and Boston Bowel Preparation Scale (BBPS)

All included subjects' venous blood was drawn before and after the examination. Serum electrolytes of sodium, potassium, calcium, chlorine, magnesium and phosphorus were evaluated.

A 9-point assessment scale of BBPS [11] was used to evaluate the quality of bowel preparation. The structure of colon is divided into three segments: the right colon, the transverse colon, and the left colon. Each segment is rated from 0 to 3 based on the degree of soiling. The three scales are classified specifically as: scale 0 - being full of colorectal excretion, that severely affect inspection and prohibit the continuing of colonoscopy; scale 1 - lots of colorectal excretion, that limit the visibility of some intestinal mucosa; scale 2 - minor amounts of residual stool with a rather clear view of the colorectal mucosa; scale 3 - no residual soiling with a perfect and clear sight of the entire

colorectal mucosa. Intestinal bubbles were also scored: point 1- full of bubbles that severely inhibit a clear view of colon mucosa; point 2- some bubble that moderately affect a good view of colon mucosa; point 3- no bubble and the colon mucosa being seen well.

Statistics

SPSS 27.0 was applied for data analysis. The normal distribution data were described as mean± standard deviation ($\bar{x}\pm s$); and the counting data as rate/component ratio. The normal distribution data among the four groups were compared through one-way ANOVA on homogeneity of variance test and further analysis of LSD-t test, and the comparison of counting data was conducted by R x C Chi-square test. P Value <0.05 was interpreted as showing significant difference in comparisons.

Results

Characteristics of research subjects

There were 27 subjects (6 from Group A, 9 from Group B, 8 from Group C and 4 from Group D) withdrawing from the study due to certain reasons. Finally, a total of 773 subjects completed the study with 194 patients in Group A, 191 in Group B, 192 in Group C, and 196 in Group D. There were 377 males (48.77%) and 396 females (51.23%), with an average age of (67.39±5.97) years old, height of (165.86±7.46) cm and weight of (59.36±8.42) kg. There were no significant differences in age, gender, height and weight ($P>0.05$) (Table 1).

Comparison of serum electrolytes

There were no statistically significant differences in serum sodium, potassium, calcium, chlorine, magnesium and phosphorus among the four groups before and after taking medication ($P>0.05$), as shown in Table 2 and Table 3.

Comparisons of the intestinal cleanliness scores of the four groups

Results of one-way ANOVA indicated statistically significant differences among the four groups in each of the four intestinal segments and overall cleanliness (Table 4). Further LSD-t tests indicated that the transverse colon scores were not statistically significant between group A and group B (2.07±0.41 vs 2.07±0.44, $P=0.93$); in the right half colon, no significant difference was revealed between group A and group C (1.86±0.68 vs 1.88±0.61, $P=0.80$); in the overall score and each of the remaining segments the scores of group A were significantly lower than the other groups ($P<0.05$); Significant difference was found between groups B and C in each of the colon segments ($P<0.05$), but no statistical significance in the overall score (6.29±1.02 vs 6.27±0.97, $P=0.78$); the scores of group D were significantly higher than the other groups in all colon segments and overall score ($P<0.05$).

Comparison of intestinal bubble volume scores among the four groups

There were significant differences in the scores of each intestinal segment and the whole intestinal bubble volume among the four groups ($p<0.05$). The scores of all intestinal segments and the whole bubble volume in group D were statistically significant as compared with the other three groups ($p<0.005$). (Table 5).

Table 1: Characteristics of research subjects.

	Group A (n=194)	Group B (n=191)	Group C (n=192)	Group D (n=196)	F/ χ^2	p
Age (years)	66.54 +/- 7.20	67.35 +/- 4.88	67.17 +/- 6.26	68.51 +/- 5.53	0.535	0.637
Gender n(%)					0.928	0.387
Male	98 (50.52)	91 (47.64)	98 (51.04)	90 (45.92)		
Female	96 (49.48)	100 (52.36)	94 (48.96)	106 (54.08)		
Height (cm)	166.24 +/- 8.15	165.77 +/- 7.57	165.53 +/- 6.68	165.88 +/- 7.45	0.128	0.889
Weight (kg)	60.81 +/- 8.38	58.72 +/- 8.35	57.15 +/- 8.30	60.76 +/- 8.66	0.213	0.810

Table 2: Comparison of serum electrolytes among the four groups before taking medication ($\bar{x} \pm s$).

	Group A	Group B	Group C	Group D	F	P value
Sodium (mmol/L)	139.21 +/- 4.01	141.22 +/- 4.20	140.22 +/- 3.18	140.68 +/- 3.94	0.365	0.718
Potassium (mmol/L)	4.43 +/- 1.81	4.30 +/- 1.45	4.39 +/- 1.05	4.18 +/- 1.77	0.569	0.427
Calcium (mmol/L)	2.25 +/- 0.27	2.38 +/- 0.51	2.31 +/- 0.30	2.31 +/- 0.46	0.647	0.289
Chlorine (mmol/L)	100.21 +/- 5.51	98.66 +/- 5.20	98.19 +/- 5.84	99.55 +/- 5.72	0.498	0.617
Magnesium (mmol/L)	0.99 +/- 0.15	0.87 +/- 0.24	0.91 +/- 0.11	0.98 +/- 0.20	0.810	0.266
Phosphorus (mmol/L)	1.31 +/- 0.46	1.47 +/- 0.63	1.09 +/- 0.55	1.24 +/- 0.50	0.875	0.273

Table 3: Comparison of serum electrolytes among the four groups after medication ($\bar{x} \pm s$).

	Group A	Group B	Group C	Group D	F	P value
Sodium (mmol/L)	141.09 +/- 4.75	141.05 +/- 4.66	139.76 +/- 4.11	139.68 +/- 4.04	0.498	0.605
Potassium (mmol/L)	4.27 +/- 2.10	4.15 +/- 1.55	4.22 +/- 1.95	4.10 +/- 1.78	0.513	0.557
Calcium (mmol/L)	2.21 +/- 0.20	2.33 +/- 0.46	2.22 +/- 0.56	2.27 +/- 0.36	0.699	0.213
Chlorine (mmol/L)	104.45 +/- 5.41	98.67 +/- 5.27	99.19 +/- 5.24	102.55 +/- 5.12	0.558	0.517
Magnesium (mmol/L)	0.97 +/- 0.15	0.97 +/- 0.24	0.95 +/- 0.21	0.95 +/- 0.31	0.756	0.289
Phosphorus (mmol/L)	1.37 +/- 0.46	1.39 +/- 0.73	1.15 +/- 0.75	1.23 +/- 0.41	0.809	0.315

Table 4: Comparison of intestinal readiness cleanliness scores among the four groups ($\bar{x} \pm s$).

	Left semicolon	Transverse colon	Right semicolon	Overall score
Group A	1.94 +/- 0.58	2.07 +/- 0.41	1.86 +/- 0.68	5.87 +/- 0.89
Group B	2.12 +/- 0.43	2.07 +/- 0.44	2.18 +/- 0.54	6.29 +/- 1.02
Group C	2.21 +/- 0.56	2.18 +/- 0.54	1.88 +/- 0.61	6.27 +/- 0.97
Group D	2.54 +/- 0.41	2.36 +/- 0.48	2.50 +/- 0.40	7.40 +/- 0.71
F	9.257	10.507	11.354	12.375
p	< 0.05	< 0.05	< 0.05	< 0.05

Table 6: Comparison of the incidence of adverse reactions among the four groups n(%).

	Nausea	Vomiting	Abdominal pain	Bloating
Group A (n=194)	29 (14.9)	20 (10.3)	24 (12.4)	35 (18.0)
Group B (n=191)	24 (12.6)	16 (8.4)	22 (11.5)	20 (10.5)
Group C (n=192)	22 (11.5)	21 (11.0)	24 (12.5)	29 (15.1)
Group D (n=196)	20 (10.2)	17 (8.7)	16 (8.2)	18 (9.2)
χ^2	3.090	11.203	18.471	30.338
p	0.135	0.028	0.013	0.001

Table 5: Comparison of intestinal preparation bubble volume scores among the four groups ($\bar{x} \pm s$).

	Left semicolon	Transverse colon	Right semicolon	Overall score
Group A	1.53 +/- 0.70	1.44 +/- 0.83	1.59 +/- 0.66	4.56 +/- 0.72
Group B	2.18 +/- 0.51	2.06 +/- 0.43	2.11 +/- 0.68	6.35 +/- 0.59
Group C	1.81 +/- 0.62	1.97 +/- 0.74	1.86 +/- 0.65	5.64 +/- 0.66
Group D	2.41 +/- 0.35	2.38 +/- 0.40	2.38 +/- 0.31	7.17 +/- 0.38
F	13.869	15.732	15.057	18.303
p	< 0.05	< 0.05	< 0.05	< 0.05

Comparisons of the incidences of adverse reactions among the four groups

The incidences of adverse reactions of vomiting, abdominal pain and bloating were significantly different among the four groups (p<0.05) but no significance of nausea. The average incidences of abdominal pain, and bloating in Group D were 8.7%, and 9.2% respectively, which were lower than the other three groups. The vomiting incidence was 8.7%, which was lower than Group A and Group C, and higher than Group B (Table 6).

Discussion

Studies have explored the effectiveness of PEG, PEG plus mosapride, and simethicone in bowel preparation for colonoscopy [12-14]. Yet, for elderly patients, unideal bowel preparation still exists, and age has been shown as the predictor for inadequate bowel preparation [15]. In this study, we focused on the elderly patients bowel preparation due to the inadequate cleansing and poor quality with the above treatment regimens. We found significant improvement in intestinal cleanliness scores and intestinal bubble scores by combining PEG with mosapride and simethicone in bowel preparation of elderly patients. The intestinal cleanliness and bubble scores were obtained from individual endoscopist's subjective judgement. To avoid assessment discrepancy and error, the colonoscopy examinations were performed separately by 2 experienced endoscopists, and if the difference of scores assessed was more than 2 points a third endoscopist would be assigned to reexamine the endoscopy. After all, the triple medications administration, PEG plus mosapride and simethicone, had gained higher overall intestinal cleanliness scores and bubble scores than single PEG and PEG plus mosapride or simethicone bowel preparation in all three colon segments of the elderly patients. It has provided initial evidence of the effectiveness of triple combination regimen in elderly patients bowel preparation, that could enhance the colon cleansing.

The adverse reaction incidences of abdominal pain and abdominal distension during bowel preparation were significantly reduced by using the three medications preparation in Group D. Interestingly, the vomiting incidence in Group D was similar to Group B, that may be related to the intolerant taste of simethicone oil for some people. In our practice, we have encountered some patients complaining of the bad taste of simethicone, which can even make them throw up. For elderly patients, the vital organs functions and bowel movement may be compromised as the bodies are getting old. Thus, the laxative modulation in bowel cleansing is hard to control. Unlike young patients, the internal environment of elderly patients is comparatively weak and can easily be disordered. The hemodynamic and homeostasis can be hard to maintain. Strong laxative effect can easily cause electrolytes imbalance and affect hemodynamics, but weak cleansing cannot meet the requirement for colonoscopy visibility. Our study showed that blood electrolytes and homeostasis of those elderly patients were able to be maintained, and hemodynamic and vital signs monitored during the colonoscopy examination were stable. This indicates the safety of triple medication administration.

Limitations

This was a single-center and single blinded study, selecting the elderly population, possibly having compromised organ functions and complicated medical conditions, which made it difficult to control all factors. Those potential uncontrollable variables may significantly and negatively affect the results. Further study of multiple center, double-blind, randomized controlled trials can provide more evidence to our findings. That may contribute to the consensus for elderly patient bowel preparation in colonoscopy. In addition, we analyzed the data of the four groups by using one-way ANOVA, on the assumption that the three medications are playing the same effective role of purgative on human body and treated as one factor. Whether a multi-way ANOVA should be adopted, we leave the question to further studies and professional statisticians.

Conclusion

PEG combined with mosapride and simethicone can improve the quality of intestinal preparation in elderly patients, in terms of BBPS scale, and the incidence of adverse reactions. Thus, it has the advantage in bowel preparation for this group of patients in terms of safety and effectiveness.

Ethical approval: Ethical approval and participant signed consent form have been received for this study. The study has followed the guidelines of the Helsinki Declaration.

Disclosure statement: We declare there is no potential conflict of interest.

Author contributions: Dr. XI Miao is the first author, who wrote the manuscript with the help of Dr. LI Fei, and was responsible for statistical analysis of the raw data. Dr LI Fei is the corresponding author, who conceptualized the presented idea with Dr. XI Miao, and reviewed and edited the manuscript. Dr. HUANG Linfei and Dr. PAN Sheng were responsible for data curation. Mr. LUO Limian is a student of Dr. XI Miao, who contributed to the collection of the patients' data.

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