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Comparison of a Clear Liquid Diet Versus a Low-Fiber Diet Regimen in Pediatric Colonoscopy: A Randomized Clinical Trial

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ABSTRACT

Background & Objective: Colonoscopy serves as a diagnostic and therapeutic tool for children. However, the process of bowel preparation presents a considerable challenge. This study aimed to compare the effectiveness of a clear liquid diet (CLD) versus a low-residue diet (LRD) in bowel preparation for colonoscopy among children aged 2-14 years.

Materials & Methods: In this single-blind clinical trial, a total of 110 children aged 2-14 years undergoing colonoscopy were randomly assigned to two groups: the CLD group and the LRD group. Along with their assigned diets, all participants received 2 g/kg of polyethylene glycol in two or three divided doses, as well as a single dose of 5-mg bisacodyl prior to colonoscopy. The primary outcome was the adequacy of bowel cleansing for colonoscopy, evaluated using the Boston Bowel Preparation Scale (BBPS) in both groups. The secondary outcomes included the tolerability of bowel preparation diets and adverse effects.

Results: According to the physician's assessment, the CLD group had favorable BBPS scores (BBPS ≥5) in 96.5% (55/57) of cases, while the LRD group had favorable scores in 98.1% (52/53) of cases. There were no significant differences between the two groups in terms of the mean BBPS score, regimen tolerability, and adverse effects.

Conclusion: This study demonstrated that both CLD and LRD regimens were effective in bowel preparation and were well-tolerated by children aged 2-14 years.
Keywords: Low-fiber diet, Clear liquid diet, Colon cleansing, Colonoscopy, Children

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1. Introduction

Colonoscopy, a diagnostic and therapeutic technique used for both adults and children (1), necessitates thorough bowel cleansing. This is particularly important in children, who often exhibit increased resistance and decreased tolerance to medical procedures. Insufficient bowel preparation can lead to compromised visibility during colonoscopy, extended procedure duration, and potential oversight of certain lesions (2). Therefore, thorough bowel preparation is crucial for the successful execution of a colonoscopy (1). Moreover, factors, such as patient acceptance and tolerance, adherence to the bowel-cleansing protocol, sufficient sedation, and the expertise of the colonoscopy team, significantly contribute to the success rate of the procedure (3-5).

Annually, numerous colonoscopies are conducted on children for a variety of reasons. The effectiveness of various drugs, including macrogols, senna, bisacodyl, sodium phosphate, magnesium citrate, and polyethylene glycol (PEG) with electrolytes, administered in regimens spanning 1-4 days, has been extensively researched and studied (4, 6). However, currently, there are no established or standardized protocols for bowel preparation prior to colonoscopy (7). Traditionally, to prepare the colon for a colonoscopy, patients are advised to follow a large-volume clear liquid diet (CLD) a day prior to the procedure (8). Nevertheless, this approach, in addition to imposing dietary restrictions, can be time-consuming and unpleasant for the patient, inevitably impacting their compliance (1, 3).

Recent studies have proposed a low-residue diet (LRD) as an alternative to the CLD regimen. A meta-analysis and trial sequential analysis of randomized controlled trials (8)

found that the LRD regimen was comparable to the CLD in terms of bowel preparation quality prior to colonoscopy. Furthermore, side effects, such as nausea, vomiting, hunger, and headache, were reported less frequently in the LRD group. A greater number of patients also expressed comfort with the LRD and indicated a willingness to repeat the regimen (8).

Given the limited research on bowel preparation for colonoscopy in children, this study aimed to compare the effectiveness of the CLD and LRD regimens, in conjunction with PEG plus bisacodyl, in preparing both younger and older children for diagnostic or therapeutic colonoscopy. Additionally, the study sought to assess the tolerability of both bowel preparation regimens.

2. Materials and Methods

2.1 Study design and population

This single-blinded, placebo-controlled, randomized clinical trial was carried out over a one-year period (from April 2020 to April 2021) at the tertiary-level Amirkola Children's Hospital in northern Iran. The study included all children aged 2-14 years, who were eligible for outpatient colonoscopy and whose parents had provided informed consent. The exclusion criteria were as follows: a positive history of cardiac, renal, or metabolic diseases; a known allergy to PEG; use of medications inhibiting bowel movements; alterations in the number of bisacodyl tablets administered; and children in need of an emergency colonoscopy. Furthermore, children who were uncooperative during the colonoscopy or did not comply with the diet were excluded from the study.

2.2 Sample size and test power

All eligible colonoscopy candidates were included in the study through sequential sampling over the course of one year.

Subsequently, the study's power was determined post hoc with the following parameters: mean LRD=6.96; mean CLD=6.75; SD LRD=1.31; SD CLD=1.22; N LRD=57; N CLD=57; α=0.05; and P-value=0.14.

2.3 Intervention

Children were randomly allocated to either the CLD or LRD groups, using a computer-generated randomization code. The CLD regimen included chicken juice, broth, strained soup, water, and tea, while the LRD regimen comprised milk, dairy products, soup, soft bread, and honey. Both groups commenced their respective diets on the evening prior to the colonoscopy, starting at 16:00 pm.

In addition to their assigned diets, both groups were administered 2 g/kg of PEG (Sepidaj Pharmaceutical Company, Iran). This involved dissolving 70 g of PEG powder in 1 L of a non-red beverage, which was then administered in two or three divided doses. Additionally, a single dose of 5-mg bisacodyl tablets (Tolid Daru Co., Iran) was administered prior to colonoscopy. Following a minimum fasting period of six hours, colonoscopy was performed under general anesthesia by a pediatric gastroenterologist (the corresponding author), using an Olympus CE-H170L device (Japan

2.4 Outcome measures and follow-up

The primary outcome was the adequacy of bowel cleansing for colonoscopy, as evaluated using the Boston Bowel Preparation Scale (BBPS) in both groups (9). The BBPS employs a scoring system ranging from 0 to 9. It uses a four-point scale (0-3 points) for each of the three regions of the colon: right, transverse, and left. The total BBPS score is the sum of the scores for these three regions. Notably, individuals with scores of ≥5 are classified as having a 'favorable' preparation, while those with scores <5 are deemed 'unfavorable'. The secondary outcomes included the tolerability of the bowel preparation diets and any adverse effects. Both parents and children rated tolerability using a 10-point Visual Analog Scale (VAS) (10). Adverse effects, including nausea, vomiting, abdominal pain, and bloating, were documented if they occurred post-colonoscopy. The study was conducted in a single-blinded manner. The assigned diet was administered to the children by a nurse, and the specialist performing the endoscopy and completing the BBPS questionnaire was unaware of the diet type. The outcomes were determined by a specialist and a pediatric assistant in a blinded procedure. For a subgroup analysis, children were categorized into two age groups: (a) 2-6 years old and (b) 6-12 years old (due to a lack of research on the age group of 2-6 years).

2.5 Statistical analysis

Data analysis was performed using SPSS Version 16 (SPSS Inc., Chicago, IL, USA). The results were evaluated based on each protocol. Data were presented as either number (percentage) or mean±SD. Prior to analysis, the Kolmogorov-Smirnov test was utilized to verify the normal distribution of data. Group comparisons were conducted using the Chi-square test and independent t-test. When required, equivalent non-parametric tests were employed. For all analyses, a two-sided P-value of <0.05 was considered statistically significant.

2.6 Ethical considerations

The current study was approved by the Ethics Committee of Babol University of Medical Sciences (MUBABOL.HRI.REC.1398.021) and registered in the Iranian Registry of Clinical Trials (IRCT20210505051185N1).

3. Results

Out of 114 eligible children, 57 were randomly allocated to the CLD group and 53 to the LFD group. Four participants from the LFD group were excluded due to non-cooperation. The mean age and body mass index (BMI) of the total participants, including 35 (31.8%) females, were 9.01±3.54 years and 17.82±5.86 kg/m2, respectively. There were no significant differences

between the two groups in terms of age, BMI, and sex (Table 1).

Table 1. Comparison of the baseline characteristics between the two groups

	CLD[1]	LRD[2]	P-value
Age, mean±SD*, y*	9.66±3.43	8.40±3.55	0.07
Male/female, n*/n	39/18	36/17	0.95
BMI, mean±SD	18.51±6.26	17.08±5.36	0.13

1CLD: Clear liquid diet, 2LRD: Low-residue diet.
***N: Number, Y: Year, SD: Standard deviation.**

The mean BBPS scores were 6.75±1.22 and 7.72±1.23 in the CLD group and 6.96±1.31 and 7.08±1.29 in the LRD group, as assessed by the nurse and physician, respectively. There was no significant difference between the two groups regarding the BBPS score assessment by either the nurse (P=0.31) or the physician (P=0.42). According to the physician's assessment, a favorable BBPS score (BBPS ≥5 points) was achieved by 96.5% (55/57) of the CLD group and 98.1% (52/53) of the LRD group. There were no significant differences between the two groups in terms of regimen tolerability and adverse effects (Table 2).

Given the lack of research on the age group of <6 years, a subgroup analysis was conducted that divided the children into two age groups: (a) 2-6 years old and (b) 6-12 years old. Subsequently, a comparison of the BBPS and VAS scores was performed between these two age groups (Table 3).

Table 2. Tolerability and adverse effects of the evaluated diets in the study groups

	CLD	LRD	P-value
VAS score			
Physician	8.21±0.92	8.19±1.07	0.92
Nurse	8.18±0.90	8.15±1.08	0.84
Adverse effects			
Nausea, N (%)	1 (1.75%)	1 (1.88%)	0.95
Vomiting, N (%)	0	2 (3.8%)	0.13
Abdominal pain, N (%)	6 (10.5%)	7 (13.2%)	0.66
Bloating, N (%)	0	0	-
Need for an enema			
Yes, N (%)	5 (8.8%)	4 (7.5%)	0.81

Table 3. Comparison of the Boston Bowel Preparation Scale (BBPS) scores in children according to the age groups

Age groups		Diet	N[1]	Mean±SD[2]	P-value
<6 Years	Physician	CLD[3]	10	6.80±1.55	0.82
		LRD[4]	19	6.68±1.20	
	Nurse	CLD	10	6.80±1.39	0.98
		LRD	19	6.78±1.32	
>6 Years	Physician	CLD	47	6.66±1.25	0.07
		LRD	34	7.21±1.43	
	Nurse	CLD	47	6.74±1.21	0.27
		LRD	34	7.06±1.32	

[1]N: Number, [2]SD: Standard deviation, [3]CLD: Clear liquid diet, [4]LRD: Low-residue diet.

In group A, the mean VAS score was 8.10±1.73 in the CLD group and 7.74±1.15 in the LRD group, as assessed by the physician (P=0.50). According to the nurse's assessment, the mean VAS score was 8.50±0.97 in the CLD group and 7.78±1.18 in the LRD group (P=0.11). Similarly, in group B, the mean VAS score was 8.06±1.09 in the CLD group and 8.29±1.22 in the LRD group, according to the physician's assessment (P=0.37). Also, the nurse-assessed score was 8.11±0.89 in the CLD group and 8.35±0.98 in the LRD group (P=0.24).

4. Discussion

This study found no significant difference between the CLD and LRD regimens administered one day before colonoscopy in terms of achieving adequate bowel preparation in children aged 2-14 years. While most research in this field focuses on adults, some studies suggest that the LRD regiment is superior to the CLD in terms of bowel preparation (3, 11-15), whereas others suggest no significant difference between the two diets (1, 3, 15). In this regard, a study conducted by Gómez-Reyes (11) on patients aged over 18 years (average age, 55.6 years) found that the effectiveness of colon cleansing, as measured by the BBPS score, was comparable between the LRD and CLD groups; however, the LRD regimen was better tolerated by the patients. Moreover, Stolpman et al. (16) reported that 96.5% of patients achieved a good colon preparation score according to the BBPS. Nevertheless, the quality of colon preparation was slightly lower with the LRD regimen, compared to the CLD (LRD, 7.8 vs. CLD, 8.1).

An investigation involving adults (14) found that the Ottawa Bowel Preparation Scale (OBPS) ratings for bowel cleansing were comparable between the LRD and clear fluid diet (CFD) groups, with scores of 4.62±2.99 and 4.47±2.76, respectively (P=0.72). However, the LRD was found to be more acceptable than the CFD (75% vs. 60% acceptability). In another study, Park et al. (3) examined a low-fiber diet and CLD in adult participants (minimum age,

18 years; average age, 54.1 years) using the OBPS. Both groups consumed 4 L of PEG solution along with their respective diets. The findings indicated that both diets were effective in bowel preparation, and the efficacy of LRD in bowel cleansing was similar to that of the liquid diet, with scores of 2.97±2.0 and 2.46±1.78, respectively (P=0.06).

Additionally, a comprehensive systematic review and meta-analysis conducted by Song et al. (1) incorporated primary studies that utilized both BBSP and OBPS for bowel preparation. The analysis revealed no significant difference in the efficacy of bowel preparation between the two diets (SMD, -0.04; -0.27 to 0.18; P=0.70). However, there was moderate evidence indicating that patients on the LRD diet had a higher tolerability (RR, 1.06; 95% CI, 1.02–1.11; P=0.00). In a different systematic review and meta-analysis, a comparison was made between a low-fiber diet and CLD to assess the adequacy of bowel preparation. The findings showed that the overall rate of adequate bowel preparation was 86.4% for the low-fiber diet group and 83.5% for the CLD group. Nevertheless, no significant difference was observed in the quality of bowel preparation between the two diets (5).

There is a limited number of studies focusing on colon preparation for colonoscopy in children. In a clinical report by Pall et al. (7), data were presented on bowel cleansing prior to colonoscopy in children. The findings revealed that among children aged 2-5 years, 59% were given an osmotic laxative, while 36% were given a combination of an osmotic laxative and a stimulant laxative. Interestingly, 93% followed a specific diet in addition to the laxative, with the CLD regimen (one day prior to colonoscopy) being the most commonly followed one. In the age group of 6-11 years, 43% and 50% of pediatric gastroenterologists respectively used one and two types of laxatives for bowel cleansing prior to colonoscopy. Alongside laxative therapy, all children made dietary modifications, with the most frequently adopted measure being the CLD regimen. In a separate study involving children aged 6-18 years, the BBPS scores of ≥5 were reported in 96.6% and 95.1% of the cases, as assessed by physicians in the CLD and low-fiber diet groups, respectively (6). These results align with our findings, which showed corresponding percentages of 96.5% and 98.1% in the CLD and LRD groups, respectively, including 2-14-year-old children. Consequently, both studies concluded that the majority of the pediatric subjects were adequately prepared for colonoscopy using both dietary regimens.

In yet another study (4) focusing on children aged 2-14 years, it was demonstrated that two distinct PEG regimens were suitable for bowel preparation prior to colonoscopy. The BBPS score was rated as excellent and good in 70% and 72% of the cases following one- and two-day diets, respectively. Moreover, a randomized clinical trial comparing four different diets in children aged 2-18 years demonstrated no significant difference in the success of colon cleansing among the four groups, as per the BBPS scores (2). However, it is important to note that the diets used in their study were entirely distinct from ours. Given the higher resistance of children to colonic cleansing compared to adults, the tolerability of the diet used is of particular significance in children, in addition to its correct implementation. This aspect has been less explored in previous studies, indicating a need for further research in this area.

Additionally, in a study conducted on adults (3), it was found that the low-fiber diet was better tolerated than the CLD regimen, with tolerability rates of 53.5% and 30%, respectively (P=0.03). In another study by Mytyk et al. (6), the tolerability of colon preparation was found to be equivalent for both diets (P=0.31), indicating satisfactory tolerability in children; this finding aligns with the results of our study.

The mentioned study also reported no significant difference in side effects between the two diets (P=0.8), a finding that is in agreement with our study. Overall, the majority of the studies conducted on children or adults, including ours, concur that the LRD is comparable to the CLD regimen. However, factors, such as the use of prepackaged LRD or controlled diets, besides the selection of different laxatives in each study, can influence their outcomes and success, including the patients' tolerability and dietary adherence.

The main strengths of the present study include the evaluation of colon preparation and diet tolerability by both a physician and a nurse, ensuring a comprehensive assessment. Moreover, this research is one of the few studies that have explored the age group <6 years, filling a significant gap in the available research. We anticipate that our findings will provide valuable insights for future researchers, aiding in the development of suitable approaches for colonoscopy preparation across all pediatric age groups. Further studies in this area are encouraged to build upon our work.

This study also had some limitations. First, the reasons for undergoing colonoscopy varied among the children, which could have influenced the outcomes. Second, the quantity of digested food differed among the children. In particular, the amount of dietary fiber in the LRD group was not reported, which could potentially impact the study results. Third, the study had a low statistical power due to the small sample size per group, which was a consequence of financial and time constraints. Given these limitations, it is recommended to replicate the study with a larger sample size to enhance the robustness and generalizability of the findings.

5. Conclusion

In the present study, we observed that the colon preparation and tolerability of the regimens were equivalent for both the CLD and LRD groups. Both diets led to appropriate bowel preparation and were well-tolerated across the two studied age groups of children, namely 2-6 years and 6-14 years.

6. Declaration

6.1 Acknowledgments

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6.2 Authors' Contribution

M.S., E.M.R., and K.S. conceived of the idea of the study and designed the experiments. M.S., E.M.R., and K.S. conducted the experiments. H.A.M. processed the experimental data and performed the analyses. M.S. drafted the manuscript and revised the study. All authors read and approved the final version of the manuscript.

6.3 Conflict of Interest

There are no conflicts of interest.

6.34 Funding

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