



Impact of prebiotic, probiotic, and postbiotic combination on acute gastroenteritis in pediatric patients

Pre/pro/postbiotics & gastroenteritis

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Abstract

Aim: This study investigated whether a new supplement combining prebiotics, probiotics, and postbiotics could help children recover faster from acute gastroenteritis (AGE), a common illness that often leads to dehydration and hospitalization.

Methods: In a randomized, single-masked, placebo-controlled trial, 120 children aged 1–10 years with AGE were assigned to receive either the combined supplement or a placebo, in addition to standard oral rehydration therapy. The study group received one sachet per day containing a combined preparation of 5×10^9 CFU heat-killed (tyndallized) *Lactobacillus acidophilus*, 2.1×10^9 CFU live bacteria (*L. acidophilus*, *L. plantarum*, *Streptococcus thermophilus*, *Bifidobacterium lactis*), and 133.37 mg fructo-oligosaccharides. Researchers monitored children for 5 days, tracking the frequency of diarrhea and vomiting, and changes in stool consistency using the Bristol Stool Scale.

Results: Of the 120 children, 106 completed the study. The group receiving the supplement had a significantly shorter duration of diarrhea (7 vs. 8 days, $P = .043$), faster resolution of vomiting ($P < .001$), and better stool consistency starting from the second day. Importantly, no adverse effects were observed among any participants.

Conclusion: These findings suggest that the combined prebiotic, probiotic, and postbiotic supplement is both safe and effective for children with AGE, helping reduce symptom duration and severity when used alongside standard rehydration therapy.

Keywords

postbiotic, tyndallized lactobacillus acidophilus, acute gastroenteritis, children

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Introduction

Gastroenteritis is a reversible inflammation of the intestinal mucosa caused by various bacterial, viral, and parasitic organisms. Abdominal pain, nausea, vomiting, or diarrhea lasting less than 14 days is defined as acute gastroenteritis (AGE).¹ Although it is a preventable and treatable cause, it is still the 3rd most common cause of death in children worldwide. In the last year, 1.7 million children were diagnosed with acute gastroenteritis, and approximately 500,000 children under the age of 5 died.² The spread of infection from person to person through contaminated food or drinking water, or poor hygiene, is a factor that significantly increases transmission and epidemic frequency.

Nutritional deficiencies due to reduced intake from nausea, along with dehydration resulting from fluid loss through vomiting and diarrhea, are the primary causes of morbidity and mortality in acute gastroenteritis. The foundation of treatment involves the rapid restoration of fluid and electrolyte balance through oral or parenteral rehydration.^{3,4} Considering the fast and devastating effects of dehydration in children, studies for adjunctive treatment options continue. For this purpose, the impact of probiotic use on the course of AGE has been investigated for years.^{5–8} Probiotics, as defined by the Food and Agriculture Organization of the United Nations and the World Health Organization, are living microorganisms that provide health benefits to the host when administered in adequate amounts.⁹ The ESPGHAN study group concluded that probiotics offer a limited yet statistically significant benefit in the treatment of acute diarrhea in children. It has been reported that the effect depends on strain and dose, and is more pronounced when it begins early in the disease course.¹⁰

The mechanisms underlying the benefits of probiotics include gut barrier enhancement, immune response modulation, and competitive inhibition of pathogen colonization of the gut.^{11,12} Some of these effects have been shown to be due to metabolic by-products produced by the probiotic, described as “postbiotic” mediators.¹³ Postbiotics are defined as products or metabolic by-products secreted by living bacteria or released after bacterial lysis. These molecules are of particular interest due to their well-defined chemical structures, safe dosing parameters, long shelf life, and content of various signaling molecules that may exhibit anti-inflammatory and immunomodulatory activities. These properties suggest that postbiotics may enhance host health by modulating specific physiological functions, although the precise mechanisms remain to be fully elucidated.¹⁴ Nevertheless, the extant literature on postbiotics is limited, particularly regarding the pediatric population.

This study aimed to evaluate the efficacy and safety of a combined prebiotic, probiotic, and postbiotic preparation including tyndallized *Lactobacillus acidophilus*, live *Lactobacillus acidophilus*, *Streptococcus thermophilus*, *Lactobacillus plantarum*, *Bifidobacterium lactis*, and fructo-oligosaccharide as an adjunct to standard rehydration therapy in children with AGE.

Materials and Methods

This prospective, randomized, single-blind trial was conducted at our outpatient clinic and included 120 patients aged 1 to 10 years presenting with acute diarrhea. The participants, their caregivers, and outcome assessors were blinded. Children with an episode of acute diarrhea—defined as at least three watery stools per day (Bristol Stool Scale ≥ 6)—of likely infectious origin, with mild to moderate dehydration or no dehydration (body weight loss not exceeding 10% of normal) were included.

Any antibiotic or probiotic use within the last 3 months, severe malnutrition, and children with severe chronic underlying diseases, including immunocompromised conditions, were excluded from the study. Any patient who would require hospitalization due to any acute diarrhea-related complications or any other reasons was planned to be excluded from the study. Eligible participants were randomized sequentially according to their order of presentation: the first patient was assigned to the study group, the second to the control group, and so on. All participants received standard care (oral rehydration and maintenance fluids), oral zinc (10–15 mg/day), and age-appropriate dietary recommendations. Patients in the study group received NBL Probiotic Comfort® (Nobel, Türkiye) sachets containing a combined preparation of 5×10^9 CFU heat-killed (tyndallized) *Lactobacillus acidophilus*, 2.1×10^9 CFU live bacteria (*L. acidophilus*, *L. plantarum*, *Streptococcus thermophilus*, *Bifidobacterium lactis*), and 133.37 mg fructo-oligosaccharides. The control group received a placebo sachet, identical in appearance and taste to the study products, containing 100 mg of indistinguishable powder. Both the combined preparation and placebos were provided to the patients by the study authors. Stool consistency and frequency in both groups were assessed by telephone for 5 days. In addition, during the telephone visits, it was determined whether the patients were receiving appropriate nutrition and using zinc and diarrhea medications. All patients were evaluated at the outpatient clinic on the 5th day, with a physical examination. Patients who still had diarrhea on the fifth day were interviewed by phone on the 10th and 15th days to learn about their general condition and whether their diarrhea continued. The primary outcomes assessed were changes in diarrhea duration, vomiting frequency, and stool consistency. The sociodemographic and clinical characteristics of all participants were recorded over a five-day period. Adverse events were also monitored and recorded throughout the study.

The sample size was determined based on an a priori power analysis. Assuming a two-tailed alpha of 0.05, a power of 80% ($\beta = 0.20$), and an expected difference of 25% in the proportion of clinical improvement between the intervention and control groups, a minimum of 52 participants per group was required. To account for potential dropouts and missing data, we included 120 children (60 in the intervention group and 60 in the control group). This sample size provides adequate statistical power to detect clinically meaningful differences between groups.

Ethical Approval

This study was approved by the Ethics Committee of Adnan Menderes University (Date: 16.04.2024, Decision No: 546270).

Statistical Analysis

Statistical analysis was performed using IBM SPSS Statistics for Windows, Version 27.0 (IBM Corp., Armonk, NY, USA). Since continuous variables did not follow a normal distribution, descriptive statistics were presented as medians and interquartile ranges (IQR) (25th–75th percentiles), while categorical variables were summarized as frequencies and percentages. Normality of continuous variables was assessed using descriptive statistics, skewness and kurtosis coefficients, histograms, and the Shapiro-Wilk test. For group comparisons, the chi-square test was used for categorical variables, and the Mann-Whitney U test was applied for comparisons between two independent groups. A *P* value of less than 0.05 was considered statistically significant.

Reporting Guidelines

This study was reported in accordance with the CONSORT 2010 Statement.

Table 1. Comparison of demographic properties, duration of diarrhea, and degree of dehydration of the patients

Parameters		Control group	Study group	P value
Age, mo, median (IQR)		63 (39.5-90.5)	65 (39-90)	.965
Gender, n (%)	Girl	26 (50)	27 (50)	1.000
	Boy	26 (50)	27 (50)	
Duration of diarrhea, ho, median (IQR)		24 (12-48)	24 (12-36)	.818
Degree of dehydration (Vesikari Score)	Mild n (%)	33 (63.5)	33 (61.1)	.803
	Moderate n (%)	19 (36.5)	21 (38.9)	

Results

A total of 120 patients were enrolled in the study. Of these, four children from the study group and six from the control group were excluded due to familial noncompliance, while two children from each group were excluded due to missing data. Ultimately, data from 106 children were analyzed: 54 in the study group and 52 in the control group (Figure 1). The median age in the study group was 65 months (IQR: 39–90), with 50% being male. There were no significant differences between the two groups regarding sociodemographic characteristics, degree of dehydration, or the number and duration of diarrhea and vomiting prior to study enrollment (Table 1).

After the first day of treatment, the study group had lower diarrhea frequency (daily diarrhea numbers) and Bristol stool scores, as well as fewer episodes of vomiting on days 2, 3, and 5, compared to the placebo group (Table 2, Figure 2). The median duration of diarrhea was significantly shorter in the study group than in the control group (7 [6.5–8] vs. 8 ⁷⁻⁹ days; *P* = .043). Among children who presented with vomiting, resolution occurred more rapidly in the study group compared to the control group (median 1 ¹⁻² vs. 2.5 ²⁻³ days; *P* < .001). No significant adverse effects were observed during the study period. No patients needed to be hospitalized during the study period for any reason.

Table 2. Comparison of patients’ diarrhea and vomiting characteristics; median (interquartile range)

		Placebo group (n = 52)	Study group (n = 54)	P value
Daily diarrhea numbers				
1.	day	7 (6-9)	8 (7-9)	.262
2.	day	7 (6-8)	6 (6-8)	.043
3.	day	6 (5-8)	6 (5-7)	.039
4.	day	6 (4-7)	5 (4-6)	.033
5.	day	5 (4-6.5)	4 (3-5)	.005
Bristol scores				
1.	day	7 (7-7)	7 (7-7)	.940
2.	day	7 (7-7)	7 (6-7)	.034
3.	day	7 (6-7)	6 (6-7)	.002
4.	day	6 (6-7)	6 (6-6)	< .001
5.	day	5 (5-6)	5 (5-5)	.003
Daily vomiting numbers				
1.	day	1 (0-2.5)	1 (1-2)	.348
2.	day	1 (0-2)	0 (0-1)	.001
3.	day	0 (0-1)	0 (0-0)	.001
4.	day	0 (0-0)	0 (0-0)	.129
5.	day	0 (0-0)	0 (0-0)	.039

Discussion

In recent years, postbiotics have gained increasing attention as safe and stable adjuncts in the management of gastrointestinal diseases. Compared with live probiotics, postbiotics offer advantages in safety, stability, and storage, making them particularly suitable for pediatric use and in low-resource settings. In our study, a combined prebiotic, probiotic, and postbiotic preparation produced statistically significant improvements in stool frequency, stool consistency, and vomiting duration compared to placebo, without any adverse effects. These findings suggest that such preparations may contribute to faster symptom resolution and improved recovery in children with acute gastroenteritis.

Similarly, a double-blind, placebo-controlled study using a synbiotic preparation with comparable probiotic content reported a 1-day reduction in the duration of diarrhea and improved stool consistency on days 2 and 3. However, vomiting was not specifically evaluated.¹⁵ Consistent with these results, we observed fewer vomiting episodes on days 2, 3, and 5 in the treatment group, potentially reducing the need for antiemetics. Another study in children aged 3–24 months using heat-killed *L. acidophilus* LB showed a significant reduction in the duration of diarrhea, particularly among those not previously treated with antibiotics, again without safety concerns.¹⁶

In our study, the rapid improvement in Bristol stool scores after the first day may reflect the reduction of intestinal fluid secretion demonstrated experimentally for heat-killed lactobacilli.¹⁷ Previous research also indicates that both live and inactivated forms can reduce the duration of bacterial, non-rotavirus diarrhea, possibly due to heat-stable bioactive molecules in the culture supernatant.¹⁷⁻¹⁹ However, data on postbiotic use in children remain limited. A systematic review found that heat-killed *L. acidophilus* LB reduced the duration of diarrhea, while other non-viable strains showed inconsistent effects.¹⁸

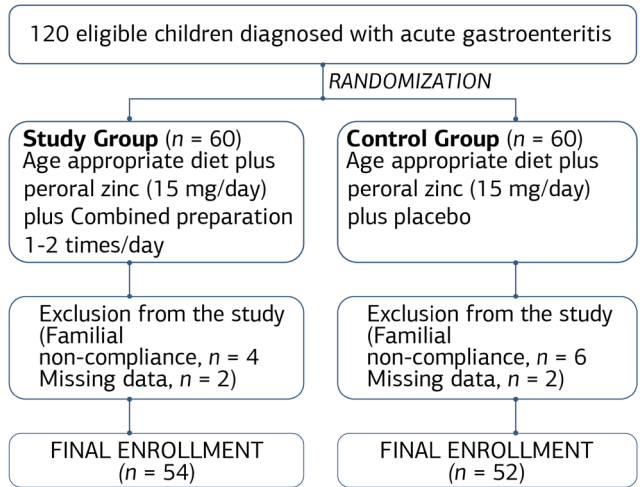


Figure 1. Flow chart of the study population

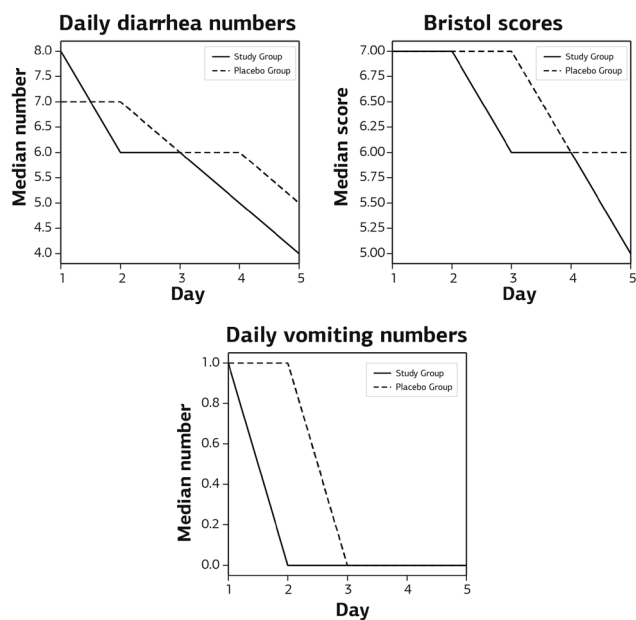


Figure 2. Patients’ diarrhea and vomiting characteristics

The combined preparation used in our study contained *L. plantarum*, *Streptococcus thermophilus*, *Bifidobacterium lactis*, and both live and tyndallized *L. acidophilus*. Several studies have shown that these strains inhibit pathogenic adhesion to intestinal cells and shorten the duration of diarrhea.¹⁹⁻²¹ Our results align with these findings, supporting the potential benefit of multi-strain preparations in pediatric acute gastroenteritis.

This study provides evidence that a combined prebiotic, probiotic, and postbiotic formulation is effective and safe in children with acute gastroenteritis. Its randomized, single-blind design, standardized outcome measures such as the Bristol Stool Chart, and daily symptom monitoring strengthen the reliability of the findings.

Limitations

Some limitations should be acknowledged. We did not identify the specific pathogens responsible for gastroenteritis, which may influence treatment response, as viral, bacterial, and parasitic etiologies could respond differently to such interventions. Without etiological confirmation, it is difficult to determine whether the observed effects are pathogen-specific or reflect general improvements in gastrointestinal function. Future studies incorporating microbiological or molecular diagnostics would allow a more precise evaluation of efficacy. We also did not assess gut microbiota composition or inflammatory markers, which could provide mechanistic insights into the observed benefits. Additionally, the single-center design and relatively small sample size may limit generalizability. As this was a combined formulation, comparative studies assessing the relative effects of combined, probiotic-only, and postbiotic-only preparations are needed. Further research should also examine pathogen-specific efficacy, long-term outcomes, gut barrier function, immune modulation, and cost-effectiveness.

Conclusion

Our findings suggest that a combined prebiotic, probiotic, and postbiotic preparation is a safe and potentially effective adjunctive treatment for pediatric acute gastroenteritis. The observed improvements in diarrhea frequency, stool consistency,

and vomiting resolution—although modest—highlight its clinical utility, particularly where rapid symptom control is essential. Future larger, multicenter studies are warranted to confirm these results and elucidate underlying mechanisms.

Declarations

Animal and Human Rights Statement

All procedures performed in this study were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Declaration of Helsinki and its later amendments, or comparable ethical standards.

Informed Consent

Written informed consent was obtained from all participants before enrollment in the study.

Data Availability

The datasets used and/or analyzed during the current study are not publicly available due to patient privacy reasons, but are available from the corresponding author on reasonable request.

Conflict of Interest

The authors declare no conflict of interest.

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None.

Author Contributions (CRediT Taxonomy)

Conceptualization: D.İ., S.S.K.
Methodology: D.İ., S.S.K., E.S.
Investigation: D.İ., S.S.K., E.S., N.B.B., İ.Ç., Ş.D.
Data Curation: D.İ., E.S.
Formal Analysis: D.İ., S.S.K.
Writing – Original Draft: D.İ.
Writing – Review & Editing: S.S.K., E.S., N.B.B., İ.Ç., Ş.D.
Supervision: S.S.K.

AI Usage Disclosure

The authors declare that no AI-assisted technologies were used.

Abbreviations

AGE: Acute gastroenteritis
CFU: Colony-forming unit
ESPGHAN: European society for paediatric gastroenterology, hepatology and nutrition
IQR: Interquartile range
SPSS: Statistical package for the social sciences

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