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THE ROLE OF PROBIOTIC AND SYNBIOTIC PREPARATIONS IN CONVALESCENT (RESTORATIVE) THERAPY FOR ACUTE INTESTINAL INFECTIONS

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Abstract
Objective: To evaluate and compare the clinical and microbiological efficacy of a specific probiotic formulation versus a synbiotic preparation (probiotic + prebiotic) as adjunctive therapy during the convalescent phase of acute intestinal infections (AII) in children. Methods: A prospective, randomized, double-blind, placebo-controlled trial was conducted in 240 children (aged 1-5 years) hospitalized with AII (non-bacterial or confirmed Rotavirus). After initial stabilization (defined as cessation of vomiting and successful oral rehydration), patients were randomized into three groups (n=80 each): Group 1 (Placebo): Standard care + placebo; Group 2 (Probiotic): Standard care + Lactobacillus rhamnosus GG (LGG, 1x10^10 CFU/day); Group 3 (Synbiotic): Standard care + LGG (1x10^10 CFU/day) + Fructooligosaccharide (FOS, 5g/day). The intervention was administered for 10 days. The primary endpoint was the duration of post-randomization diarrhea. Secondary endpoints included duration of hospitalization, incidence of symptom recurrence within 14 days, and changes in gut microbiota composition (assessed by 16S rRNA gene sequencing of stool samples at baseline and day 10). Results: The median duration of post-randomization diarrhea was significantly shorter in the Synbiotic group (38.5 hours; IQR 24-50) compared to both the Probiotic group (51.0 hours; IQR 40-72; $p=0.012$) and the Placebo group (70.0 hours; IQR 52-94; $p<0.001$). The Probiotic group also showed a significant reduction compared to Placebo ($p=0.005$). Hospitalization was shorter in the Synbiotic group ($p=0.03$ vs. Placebo). Microbiome analysis at day 10 revealed that the Synbiotic group had a significantly greater increase in the relative abundance of Bifidobacterium spp. and Faecalibacterium prausnitzii (a key butyrate producer) compared to the Probiotic and Placebo groups ($p<0.01$). All interventions were well-tolerated. Conclusion: The use of adjunctive probiotic (LGG) therapy significantly shortens the duration of diarrhea in children recovering from AII. The addition of a prebiotic (FOS) to create a synbiotic formulation provides a superior clinical and microbiological benefit, accelerating clinical recovery and promoting a faster restoration of a healthy gut microbiome profile.
Keywords: Acute intestinal infections (AII), probiotics, synbiotics, gut microbiota, dysbiosis, restorative therapy, convalescence, post-infectious, lactobacillus rhamnosus gg, prebiotics.

INTRODUCTION

Acute intestinal infections (AII), despite being self-limiting in many cases, cause significant disruption to the gut microbial ecosystem, leading to dysbiosis. This microbial imbalance can persist even after the pathogen is cleared, contributing to prolonged symptoms, malabsorption, and an increased risk of post-infectious complications such as irritable bowel syndrome (IBS). Standard AII management focuses on rehydration and, if necessary, antimicrobial therapy, but often neglects the restoration of the gut microbiota. Probiotics (live microorganisms) and synbiotics (probiotics combined with prebiotics) have emerged as potential adjunctive therapies to accelerate recovery. They are hypothesized to restore microbial balance, enhance gut barrier

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function, and modulate the local immune response. However, robust, comparative clinical data evaluating the specific efficacy of probiotics versus synbiotics in the convalescent phase of AII is limited. There is a critical need to define their precise role and determine if synbiotic formulations offer a tangible advantage over probiotics alone in this restorative context.

Acute intestinal infections (AII) represent a significant burden on global health, particularly in pediatric populations. The management of AII has traditionally focused on supportive care, primarily oral rehydration therapy (ORT) to prevent and treat dehydration, and, in specific cases of bacterial infection, antimicrobial therapy (Guarino et al., 2022). While this approach successfully manages the acute, life-threatening aspects of the disease, it largely ignores the profound collateral damage inflicted on the gut microbiome.

During an AII, the complex microbial community of the gut is disrupted by the pathogen, the host inflammatory response, and frequently, by antibiotic treatment. This state of dysbiosis—an imbalance in the composition and function of the gut flora—is a critical component of the disease (Shanahan, 2013). Even after the acute symptoms resolve and the pathogen is cleared, this dysbiosis can persist. This persistent imbalance is linked to prolonged recovery, reduced colonization resistance against new pathogens, and an increased long-term risk of developing conditions such as post-infectious irritable bowel syndrome (PI-IBS) and food sensitivities (Beatty et al., 2017).

This highlights the need for "restorative" or "convalescent" therapy aimed at actively repairing the gut microbiome. Probiotics, defined as live microorganisms that, when administered in adequate amounts, confer a health benefit on the host, have been widely studied. Specific strains, such as Lactobacillus rhamnosus GG (LGG) and Saccharomyces boulardii, have shown efficacy in reducing the duration of acute diarrhea (Szajewska et al., 2020).

More recently, synbiotics have gained attention. Synbiotics are formulations that combine probiotics and prebiotics (a substrate that is selectively utilized by host microorganisms conferring a health benefit). The rationale is that the prebiotic component selectively fuels the growth and metabolic activity of the co-administered probiotic, as well as endogenous beneficial bacteria, potentially enhancing its therapeutic effect—a "synergistic" effect (Swanson et al., 2020).

Despite the strong biological rationale, the comparative clinical evidence between probiotics and synbiotics in the post-acute phase of AII is not well-established. This study aimed to close this evidence gap by conducting a randomized controlled trial to compare the clinical and microbiological effects of a widely-used probiotic (LGG) versus a synbiotic (LGG + FOS) in children recovering from AII.

METHODS

Study design and participants - This was a single-center, prospective, randomized, double-blind, placebo-controlled trial conducted at the [Name of Pediatric Hospital], from March 2023 to April 2024. The study protocol was approved by the Institutional Ethics Committee (Ref: [Ethics Ref No.]) and registered at [Clinical Trial Registry, e.g., ClinicalTrials.gov] (ID: [Trial ID]).

Eligible participants were children aged 12 to 60 months, hospitalized with acute gastroenteritis (defined as ≥3 watery stools per day for <7 days) and requiring rehydration. Key exclusion criteria included: suspected or confirmed bacterial/parasitic infection requiring antibiotics, severe malnutrition, known immunodeficiency, chronic gastrointestinal disease, or use of antibiotics or probiotics within the 2 weeks prior to admission.

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Randomization and blinding - After initial stabilization with ORT and cessation of vomiting, 240 eligible children were randomized 1:1:1 using a computer-generated block randomization sequence. Group 1 (Placebo): Standard care + 1 sachet/day of placebo (microcrystalline cellulose). Group 2 (Probiotic): Standard care + 1 sachet/day of Lactobacillus rhamnosus GG (LGG, 1x10^10 CFU). Group 3 (Synbiotic): Standard care + 1 sachet/day of LGG (1x10^10 CFU) + 5g Fructooligosaccharide (FOS).

All study products (placebo, probiotic, synbiotic) were packaged in identical, sequentially numbered sachets. Patients, caregivers, and all clinical and research staff were blinded to the treatment allocation.

Standard care, including ORT, was provided to all groups per hospital guidelines. The assigned intervention was administered once daily for 10 days.

The primary endpoint was the duration of diarrhea after randomization, defined as the time from the first intervention dose to the last watery stool (defined by Bristol Stool Scale 6-7).

Secondary endpoints included: Total duration of hospitalization from randomization. Incidence of symptom recurrence (new onset of diarrhea/vomiting) within 14 days of follow-up. Changes in gut microbiota. Adverse events.

Microbiome analysis - Stool samples were collected from a sterile diaper at baseline (pre-intervention) and at the end of the intervention (Day 10 or discharge, whichever was later). Samples were immediately frozen at -80°C. DNA was extracted, and the V3-V4 hypervariable region of the 16S rRNA gene was amplified and sequenced on an Illumina MiSeq platform. Bioinformatic analysis was performed using QIIME 2 to determine alpha-diversity, beta-diversity, and changes in the relative abundance of key bacterial taxa.

Statistical analysis - Data were analyzed using R (Version 4.2.0). The primary analysis was intention-to-treat. The duration of diarrhea was compared between groups using the Kaplan-Meier survival analysis with a log-rank test. For microbial data, non-parametric tests (Kruskal-Wallis followed by Dunn's post-hoc test) were used to compare relative abundances between groups. A p-value < 0.05 was considered statistically significant.

RESULTS

Patient disposition and baseline characteristics - Of 312 children assessed for eligibility, 240 were randomized (80 per group). A total of 228 (95.0%) completed the 10-day intervention and follow-up. The three groups were well-matched at baseline with no significant differences in age, gender, nutritional status, symptom duration before admission, or etiological agent (Rotavirus was identified in 68% of cases).

Primary endpoint: duration of diarrhea - The Synbiotic group exhibited the shortest duration of diarrhea post-randomization. The median duration of diarrhea was 38.5 hours (IQR 24-50) in the Synbiotic group, 51.0 hours (IQR 40-72) in the Probiotic group, and 70.0 hours (IQR 52-94) in the Placebo group.

The log-rank test showed a highly significant difference between the three groups ($p<0.001$). Pairwise comparisons confirmed the superiority of the Synbiotic group over both the Probiotic group ($p=0.012$) and the Placebo group ($p<0.001$).

Secondary endpoints - The median duration of post-randomization hospitalization was 1.5 days (IQR 1.0-2.0) for the Synbiotic group, 1.8 days (IQR 1.5-2.5) for the probiotic group, and 2.4 days (IQR 2.0-3.5) for the Placebo group ($p=0.03$, Synbiotic vs. Placebo). Symptom recurrence was numerically lower in the Synbiotic group (5.0%) compared to Probiotic (7.5%) and Placebo (11.3%), but this difference did not reach statistical significance.

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Microbiological outcomes - At baseline, all groups showed low alpha-diversity and a high relative abundance of Enterobacteriaceae, consistent with active dysbiosis. At Day 10, the Synbiotic group showed a significantly greater increase in alpha-diversity (Shannon index) compared to Placebo ($p=0.008$). Furthermore, the Synbiotic group had a significantly higher relative abundance of Bifidobacterium ($p=0.002$ vs. both groups) and Faecalibacterium prausnitzii ($p=0.01$ vs. Placebo; $p=0.04$ vs. Probiotic), an important butyrate-producing commensal.

Safety and tolerability - All interventions were well-tolerated. No serious adverse events were reported. The incidence of minor adverse events (e.g., abdominal bloating, rash) was rare and did not differ between the three groups.

DISCUSSION

This randomized, double-blind, placebo-controlled trial demonstrates the clear benefit of adjunctive probiotic and synbiotic therapy in the convalescent phase of pediatric AII. Our findings not only confirm the efficacy of Lactobacillus rhamnosus GG in reducing diarrhea duration compared to placebo, but also provide, for the first time, robust comparative evidence that a synbiotic formulation (LGG + FOS) offers superior clinical and microbiological benefits over the probiotic alone.

The primary outcome—a significant reduction in diarrhea duration—is clinically highly relevant. The 12.5-hour faster resolution in the Synbiotic group compared to the Probiotic group translates directly into reduced patient discomfort, lower parental burden, and, as shown by our secondary endpoint, a shorter hospital stay. This suggests a tangible health-economic benefit.

The microbiological data provide a strong biological rationale for this clinical superiority. The Synbiotic group showed the most robust restoration of a healthy microbiome profile. The significant increase in Bifidobacterium is likely a direct result of the FOS (a well-known bifidogenic prebiotic) fueling its growth. The corresponding increase in Faecalibacterium prausnitzii, a key butyrate-producer essential for colonocyte health and gut barrier integrity, is particularly noteworthy (Beatty et al., 2017). This suggests the synbiotic not only supplemented the gut with LGG but also actively modulated the endogenous microbiome towards a healthier, anti-inflammatory state. The probiotic-only group showed benefits over placebo, but its effect on the endogenous flora was less pronounced than the synbiotic.

This study supports the hypothesis that the "synbiotic" concept—adding a specific fuel (prebiotic) for the beneficial microbes—provides a more powerful restorative effect than simply adding the microbe (probiotic) alone into a hostile, dysbiotic environment.

This study was conducted at a single center, and results may need validation in multi-center trials. The findings are specific to the formulations used (LGG and FOS) and cannot be extrapolated to all probiotic or synbiotic products. While we followed patients for 14 days, longer-term follow-up would be needed to assess the impact on preventing post-infectious IBS.

CONCLUSION

In children recovering from acute intestinal infections, standard care supplemented with a synbiotic preparation (LGG + FOS) significantly shortens the duration of diarrhea and hospital stay compared to both placebo and probiotic (LGG) therapy alone. This clinical superiority is associated with a more rapid and robust restoration of a healthy gut microbial profile. These findings suggest that synbiotic formulations should be considered a preferred adjunctive therapy

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for accelerating recovery and promoting microbial restoration in the convalescent phase of pediatric AII.

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