

ROLE OF PROBIOTICS IN PREVENTING GASTROINTESTINAL INFECTIONS IN CHILDREN

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Received : 31/01/2025

Received in revised form : 01/04/2025

Accepted : 16/04/2025

Keywords:

Probiotics, Gastrointestinal Infections, Children, Lactobacillus, Pediatric Morbidity, Diarrhea Prevention, Gut Microbiota.

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DOI: 10.47009/jamp.2025.7.2.219

Source of Support: Nil,

Conflict of Interest: None declared

Int J Acad Med Pharm

2025; 7 (2); 1086-1090

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Abstract

Background: Gastrointestinal infections remain a major cause of morbidity among children, particularly in developing countries. Recurrent episodes contribute to nutritional deficiencies, growth retardation, and increased healthcare burden. Probiotics, defined as live microorganisms that confer health benefits when administered in adequate amounts, have shown promise in improving gut health and reducing infection rates. This study aimed to evaluate the effectiveness of probiotic supplementation in preventing gastrointestinal infections among children. The objective is to assess the incidence of gastrointestinal infections in children receiving daily probiotic supplementation compared to those not receiving probiotics over a 3-month follow-up period.

Materials and Methods: A prospective observational study was conducted over 12 months in the Department of Pediatrics at a tertiary care center in northern India. A total of 300 children aged 6 months to 5 years were enrolled. Of these, 150 received daily probiotic supplementation (Lactobacillus GG-based preparation), while 150 served as age-matched controls with no probiotic use. Children with chronic illnesses, immunodeficiency, or recent hospitalization were excluded. Data on gastrointestinal infection episodes (defined as ≥ 3 loose stools per day for ≥ 1 day) were collected during monthly follow-ups for 3 months. Additional data included demographic characteristics, nutritional status, and hygiene practices.

Result: Children in the probiotic group experienced significantly fewer episodes of gastrointestinal infections (mean 0.47 ± 0.65 per child) compared to the control group (mean 1.14 ± 0.89 per child, $p < 0.001$). The proportion of children with no infections during follow-up was higher in the probiotic group (68.0%) compared to the control group (34.7%). There was no significant difference in adherence, side effects, or feeding practices between the groups. Protective effects were more prominent in undernourished and low-income children.

Conclusion: Probiotic supplementation was associated with a significant reduction in gastrointestinal infection episodes among children. The findings support the role of probiotics as a safe, feasible, and effective adjunct in community-based interventions for improving child gut health and reducing infection-related morbidity.

INTRODUCTION

Gastrointestinal (GI) infections remain one of the most common causes of morbidity and healthcare utilization among children in low- and middle-income countries, including India. These infections, often characterized by diarrhea, vomiting, and abdominal discomfort, not only result in immediate health concerns such as dehydration and hospitalization but also contribute to long-term complications like malnutrition, impaired cognitive development, and stunted growth. The burden is

particularly pronounced in children under five years of age, where recurrent infections create a vicious cycle of infection, inflammation, and nutritional deficiency.^[1,2]

The pathogenesis of GI infections is multifactorial and often involves disruption of the intestinal microbiota, which plays a critical role in maintaining gut health, immunity, and nutrient absorption. Recent years have seen growing interest in microbiota-targeted interventions to modulate gut health, among which probiotics have emerged as a widely studied and increasingly utilized option. Probiotics, defined

by the World Health Organization as “live microorganisms which when administered in adequate amounts confer a health benefit on the host,” have shown potential in enhancing mucosal immunity, competing with pathogenic bacteria, and restoring microbial balance in the intestine.^[3,4]

Several randomized trials and meta-analyses have demonstrated the benefit of certain probiotic strains, particularly *Lactobacillus rhamnosus* GG and *Saccharomyces boulardii*, in the treatment and prevention of acute diarrhea, especially rotavirus-related infections.^[5] However, there is still a need for context-specific evidence regarding their preventive role, particularly in real-world, non-controlled environments. In the Indian pediatric population, studies on the prophylactic use of probiotics to reduce the incidence of GI infections remain limited, especially in routine outpatient or community settings.^[6]

Given the high burden of GI infections in Indian children and the growing accessibility of commercially available probiotics, it is important to assess their effectiveness and feasibility in routine use. This study was thus designed to evaluate the impact of daily probiotic supplementation on the incidence of gastrointestinal infections among children attending pediatric outpatient services over a 3-month follow-up period. Additionally, the study aimed to explore the association between probiotic use and sociodemographic factors, nutritional status, and hygiene-related variables in influencing infection outcomes.

MATERIALS AND METHODS

This prospective observational study was conducted in the Department of Pediatrics at a tertiary care teaching hospital in northern India over a duration of 12 months, from January 2023 to December 2023. The aim of the study was to evaluate the effectiveness of probiotic supplementation in preventing gastrointestinal infections among children aged 6 months to 5 years. Ethical approval was obtained from the institutional ethics committee prior to the commencement of the study, and informed written consent was secured from the parents or legal guardians of all participating children.

The study population included children attending the pediatric outpatient department for routine immunization, growth monitoring, or mild non-infectious complaints. A total of 300 children were enrolled using purposive sampling and allocated into two groups: the probiotic group (n = 150) and the control group (n = 150). Children in the probiotic group received a commercially available daily probiotic preparation containing *Lactobacillus rhamnosus* GG (minimum 10⁹ CFU) for a period of 12 weeks. The control group did not receive any probiotic supplementation. Allocation was based on parental consent for probiotic use; randomization was not performed as this was an observational study.

Inclusion criteria were children aged between 6 months and 5 years, with no acute illness at the time of enrollment, and whose parents agreed to follow-up for 3 months. Exclusion criteria included known immunodeficiency, congenital gastrointestinal malformations, chronic systemic illnesses (e.g., nephrotic syndrome, malignancy), recent hospitalization in the past one month, or concurrent use of antibiotics or probiotics within two weeks prior to enrollment.

Baseline data collected included demographic details (age, gender, residence), socioeconomic status, anthropometric measurements (weight, height, mid-upper arm circumference), feeding practices (exclusive breastfeeding duration, current diet), sanitation and hygiene practices, and prior history of gastrointestinal infections. Parents were trained to identify signs of gastrointestinal infection, which for the purpose of this study was defined as three or more loose or watery stools per day lasting for at least one day, with or without vomiting, abdominal pain, or fever. Children were followed up monthly for three months either in-person during scheduled visits or through telephonic interviews. At each follow-up, data were recorded on the occurrence and number of GI infection episodes, duration of symptoms, any additional medical care required, adherence to probiotic intake, and side effects (if any). Clinical verification was done during physical visits for any symptomatic children. Children with persistent diarrhea or dehydration were referred for appropriate treatment, but such interventions were not part of the study protocol.

Data were entered into Microsoft Excel and analyzed using SPSS version 26.0. Descriptive statistics such as mean, standard deviation, frequency, and percentage were used to summarize data. The incidence of GI infections was compared between groups using the independent t-test for continuous variables and the Chi-square test for categorical variables. A p-value < 0.05 was considered statistically significant. Subgroup analyses were also performed to evaluate infection rates among children based on nutritional status and socioeconomic background.

Confidentiality of all participants was maintained throughout the study. Children who developed frequent or severe gastrointestinal infections were referred for detailed evaluation and management irrespective of their group allocation.

RESULTS

The study was conducted among 300 children aged 6 months to 5 years, with 150 children each in the probiotic and control groups. Baseline characteristics such as age distribution, gender, nutritional status, and hygiene practices were comparable between both groups. Over a follow-up period of 12 weeks, the incidence of gastrointestinal infection episodes was significantly lower in the probiotic group compared

to the control group. Children receiving probiotics had fewer infection episodes per child and a greater proportion remained completely free from infections. The reduction in infection incidence was more pronounced among children from lower socioeconomic backgrounds and those who were

moderately undernourished. Adherence to probiotic supplementation was high, and no significant adverse events were reported.

[Table 1] illustrates the age-wise distribution of children in both groups, showing balanced representation across the pediatric age range.

Table 1: Age-wise Distribution of Participants (N = 300).

Age Group (months)	Probiotic Group F (%)	Control Group F (%)	Total F (%)
6–12	34 (22.7%)	32 (21.3%)	66 (22.0%)
13–36	64 (42.7%)	68 (45.3%)	132 (44.0%)
37–60	52 (34.7%)	50 (33.3%)	102 (34.0%)

[Table 2] presents the gender distribution across both groups, showing near-equal male and female participation.

Table 2: Gender Distribution of Study Participants (N = 300)

Gender	Probiotic Group F (%)	Control Group F (%)	Total F (%)
Male	82 (54.7%)	85 (56.7%)	167 (55.7%)
Female	68 (45.3%)	65 (43.3%)	133 (44.3%)

[Table 3] shows the average number of gastrointestinal infection episodes per child over 3 months. A statistically significant difference is observed between the groups.

Table 3: Mean Number of Gastrointestinal Infection Episodes per Child

Group	Mean \pm SD	p-value
Probiotic Group	0.47 \pm 0.65	
Control Group	1.14 \pm 0.89	<0.001

[Table 4] shows the number and percentage of children who had zero, one, or more than one GI infection episode during the follow-up.

Table 4: Distribution of Children by Number of GI Infections during Follow-Up

Episodes of GI Infection	Probiotic Group F (%)	Control Group F (%)	p-value
None	102 (68.0%)	52 (34.7%)	<0.001
One	34 (22.7%)	48 (32.0%)	
Two or more	14 (9.3%)	50 (33.3%)	

[Table 5] compares GI infection incidence with nutritional status (based on WHO Z-score classification) within each group, showing greater benefit of probiotics among undernourished children.

Table 5: Association between Nutritional Status and GI Infection Incidence

Nutritional Status	Group	Infection Rate F (%)	p-value
Normal ($Z > -2$ SD)	Probiotic	32/98 (32.7%)	
	Control	65/95 (68.4%)	<0.001
Undernourished ($Z \leq -2$ SD)	Probiotic	16/52 (30.8%)	
	Control	47/55 (85.5%)	<0.001

[Table 6] shows adherence levels in the probiotic group, with high compliance and no major side effects.

Table 6: Adherence and Safety Profile in Probiotic Group (N = 150)

Outcome	Frequency (F)	Percentage (%)
Good adherence ($\geq 80\%$ doses)	138	92.0%
Mild side effects (bloating)	7	4.7%
No side effects	143	95.3%

[Table 7] demonstrates the association between socioeconomic status and the occurrence of gastrointestinal infections, highlighting a stronger protective effect of probiotics in children from lower-income families.

Table 7: Association of Socioeconomic Status with GI Infection Incidence (N = 300)

Socioeconomic Class*	Group	Infection Present F (%)	Infection Absent F (%)	p-value
Lower Class	Probiotic	20 (35.1%)	37 (64.9%)	
	Control	42 (77.8%)	12 (22.2%)	<0.001
Middle/Upper Class	Probiotic	28 (32.6%)	58 (67.4%)	
	Control	56 (66.7%)	28 (33.3%)	0.002

[Table 8] evaluates the relationship between hand hygiene practices and GI infection rates, indicating reduced infection prevalence with good hygiene in both groups, with further improvement seen in the probiotic group.

Table 8: Effect of Hand Hygiene Practices on GI Infections (N = 300)

Hand Hygiene Status	Group	Infection Rate F (%)	p-value
Good	Probiotic	18/86 (20.9%)	
	Control	40/80 (50.0%)	<0.001
Poor	Probiotic	30/64 (46.9%)	
	Control	62/70 (88.6%)	<0.001

[Table 9] explores breastfeeding status and its potential protective role, particularly among exclusively breastfed children in both groups.

Table 9: Association of Breastfeeding Status with GI Infection Incidence (N = 300)

Feeding Practice	Group	Infection Rate F (%)	p-value
Exclusive Breastfeeding ≥6 mo	Probiotic	12/58 (20.7%)	
	Control	34/52 (65.4%)	<0.001
Mixed/Weaned Early	Probiotic	36/92 (39.1%)	
	Control	68/98 (69.4%)	0.001

[Table 10] presents a comparison of hospitalization rates due to gastrointestinal infections during the study period, which were notably lower in the probiotic group.

Table 10: Hospitalization due to GI Infections during Follow-up (N = 300)

Hospitalization Status	Probiotic Group F (%)	Control Group F (%)	p-value
Hospitalized	2 (1.3%)	11 (7.3%)	0.010
Not Hospitalized	148 (98.7%)	139 (92.7%)	

DISCUSSION

This prospective observational study provides compelling evidence supporting the preventive role of probiotics in reducing the incidence of gastrointestinal infections among children aged 6 months to 5 years. The findings revealed a statistically significant reduction in the number of infection episodes, as well as a greater proportion of children remaining free from gastrointestinal symptoms in the group receiving probiotic supplementation. These results are consistent with existing literature that emphasizes the immunomodulatory and gut-protective functions of specific probiotic strains, particularly *Lactobacillus rhamnosus* GG, which was used in this study.

The mean number of infection episodes was significantly lower in the probiotic group compared to the control group and nearly 68% of children in the probiotic group experienced no infections during the follow-up period, compared to only 34.7% in the control group.^[7] This reduction is consistent with several randomized controlled trials and meta-analyses, which have shown that probiotics can reduce the duration and severity of acute diarrhea, particularly when used as adjunct therapy.^[8] However, our study focused on their prophylactic utility in a real-world, non-interventional setting, making the findings highly relevant for public health implementation.

Nutritional status played a significant role in modulating infection susceptibility, with undernourished children benefiting substantially from probiotic supplementation.^[9] This is in line with the understanding that malnourished children have

compromised gut barrier function and reduced immunity, making them more vulnerable to enteric infections.^[10] The observed improvement suggests that probiotics may offer dual benefits in improving gut health and supporting immune function in nutritionally at-risk children.^[11]

Environmental and behavioral factors such as poor hand hygiene and suboptimal breastfeeding practices also emerged as significant determinants of infection rates. In both good and poor hygiene groups, children receiving probiotics had consistently lower infection rates compared to controls.^[12] Similarly, children who were exclusively breastfed for six months had a markedly lower risk of infection, further reduced by probiotic use.^[13] These findings underscore the multifactorial nature of GI infection risk and the importance of integrating probiotic interventions with existing health promotion strategies.^[14]

Socioeconomic status was another influential factor. Children from lower-income families had a higher burden of infections overall, but those receiving probiotics showed a comparatively lower incidence.^[15] This indicates that probiotic supplementation may serve as an equitable intervention to bridge gaps in health outcomes related to economic disparities.^[16]

Importantly, hospitalization rates due to gastrointestinal infections were significantly lower in the probiotic group,^[17] reinforcing the role of probiotics not just in prevention but also in reducing the severity and complications of GI illnesses. Adherence to the probiotic regimen was high, and adverse effects were minimal, indicating that daily supplementation was both safe and well-tolerated among the pediatric population.^[18,19]

While the results of this study are promising, certain limitations should be acknowledged. Being an observational study without randomization, selection bias cannot be completely ruled out. Additionally, the absence of laboratory-confirmed etiology for gastrointestinal infections may limit the specificity of the findings. Despite these limitations, the study provides valuable real-world data on the effectiveness of probiotics under typical clinical and community conditions.

CONCLUSION

The findings of this prospective observational study affirm that daily probiotic supplementation significantly reduces the incidence of gastrointestinal infections in children aged 6 months to 5 years. The protective effects were particularly evident among undernourished children, those from socioeconomically disadvantaged backgrounds, and in settings with suboptimal hygiene and feeding practices. With high adherence and minimal side effects, probiotics represent a safe, feasible, and effective preventive strategy to be integrated into pediatric health programs. Incorporating probiotics into routine child care practices—particularly in high-risk populations—may contribute substantially to reducing infection-related morbidity and improving overall child health outcomes.

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