



Outcome of Treatment with Probiotic in Acute Watery Diarrhea in Pediatric Patient Aged 6 To 12 Months Admitted at Rehman Medical Institute Peshawar

Rimsha Shais¹, Huma Mir²

¹Department of Paediatric, Rehman Medical Institute, Peshawar, Pakistan

²Department of Paediatric, Khyber Teaching Hospital, Peshawar, Pakistan

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Correspondence to: Huma Mir, Department of Paediatric, Khyber Teaching Hospital, Peshawar, Pakistan
Email: humamir63@gmail.com

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ABSTRACT

Introduction: Acute diarrhoea is a common clinical condition in children and a common cause of morbidity in developing countries. Recently, probiotics have been recommended agents that can reach diarrhoea duration and clinical states via promoting gut microbiota balance. **Objectives:** To assess an efficacy of probiotic intervention using clinical course of acute diarrheas in children divided into age groups of 6–12 months: duration of the diarrhoea decreased, the status of consistency of stool improved, and they got into a better state of hydration. **Materials and Methods:** The six-month period of this clinical trial (27 November, 2024 to 26 May, 2025) was conducted at Rehman Medical Institute, Peshawar. A total of 76 pediatric cases were selected and randomly divided into a probiotic group treated with Saccharomyces boulardii 250 mg bid as opposed to a placebo in conjunction with ORS. The duration of diarrhoea, the type of stool, and how long the patients were at the hospital were the measures of the outcome of the intervention. **Results:** The probiotic group had significantly shorter diarrhea duration (1.8 vs. 2.9 days, $p = 0.001$), improved hydration status (89.5% vs. 63.2%, $p = 0.007$), and reduced hospital stay (3.2 vs. 4.5 days, $p < 0.01$). **Conclusion:** Probiotic therapy significantly improves recovery in pediatric diarrhea cases. Its cost-effectiveness and safety support its inclusion in standard treatment guidelines.

INTRODUCTION

Diarrhoea, especially acute diarrhoea with watery stool, is one of the most common diseases in children, especially in the developing world, where it contributes to numerous hospitalizations and deaths among infants. The study by Huang et al. (1) found that there is sufficient evidence in the literature on the ability of probiotics to help in the prevention and treatment of acute diarrhoea in children. Diarrhoea is described as passing loose or watery stool more than three times in a 24-hour cycle and is said to be acute if it lasts for less than a fortnight. It is still a major health issue in most parts of the world, particularly in developing nations, where conditions such as malnutrition, poor hygiene, and inadequate health care enhance the sufferings of those affected by the disease (2). Even though ORT and zinc supplements have been tried and implemented in achieving prevention and treatment of acute diarrhoea, they remain a formidable burden to children's healthcare systems (3).

Haidry et al. (2) indicated that the clinical trial of probiotics in children affected with acute watery

diarrhoea resulted in the recuperation of children who had taken it early, and their days of diarrhoea were less than that of the control group. Schnadower et al. (3) have also considered the relationship between the duration of diarrhoea and the effectiveness of the use of probiotics, finding a positive relationship in reducing the length of acute gastroenteritis in children. Probable use of probiotics in acute diarrheal diseases of children has emerged as an important area of research recently and is potentially effective in restoring the imbalance in the gut microbiota and strengthening the intestinal mucosal barrier (4). Mosaddek et al. (4) conducted a non-randomized clinical trial in Bangladesh, which established that probiotic treatment could cause a child suffering from diarrhoea to be discharged within a shorter time period from the hospital.

The ways through which probiotics are known to act are by altering the balance in the gut microflora, inhibitory effects on pathogenic organisms, and improving mucosal immunity (5). A randomized controlled trial by Abdulah et al. (5) on the effects of a probiotic augmented with zinc in

infants with acute diarrhoea found a positive outcome with the ability to improve the result from stool consistency and degree of dehydration. However, it is still uncertain if individual probiotics are effective in treating acute watery diarrhoea, and as already mentioned, zinc itself has also been effective (6). Vassilopoulou et al. (6) systematically reviewed the impact of probiotics and synbiotics on reducing the duration of diarrhoea where it was noted that besides standard probiotics, synbiotics appeared to offer further benefits in certain groups of children.

The part that is particularly closely connected to the effectiveness of the clinical products is the specific strains of probiotics used for the development of clinical products. Dhongade et al. (7) have demonstrated the positive effects of a Bacillus probiotic combination and its effectiveness in children afflicted with acute diarrhoea, including a quicker recovery time and a lesser incidence of side effects than in placebo treatment. Schnadower et al. (8), regarding the different effects of age, weight and dosages, showed that lower age and lighter weight were associated with better response to probiotic therapy. Kambale et al. (9) also examined the effect of probiotics in undernourished children and found that the results were significantly promising in this category of children since probiotics break the cycle of the imbalance of gut microbiota.

Probiotics have also been considered in terms of synergism with other treatments for pediatric diarrhoea. Hassan et al. (10) investigated zinc and probiotics for oral administration and also noticed that both had an excellent synergistic effect on the duration and severity of diarrhoea. Kakar et al. (11) sought to compare a zinc-probiotic mixture to mere probiotics, stating that although the latter was effective, zinc supplements advanced the recovery outcomes. Co-treatment with probiotics was also considered important because the results indicated that though probiotics are good, they may be better when used in combination with other therapies. Apart from that, probiotics have been examined for their antigenic effects on several pathogens, which are as detailed below. Published in 2012, Freedman et al. (12) assessed the efficacy of probiotics in combating specific pathogens that cause diarrhoea based on a randomized controlled trial to find that some probiotic strains are more effective against bacterial strains than viral ones. Lahiri et al. (13) investigated the safety and efficacy of Bacillus clausii in combination with ORT and zinc in children with acute diarrhoea. Regarding this study, it is established that with the help of this combination of therapies, the symptoms take less time to resolve.

The next meta-analysis by Dang et al. (14) has demonstrated that Bacillus clausii probiotics possess immunological properties and might be useful in the prevention of diarrhoea in children, as the main symptom relief might be accompanied by the improvement of immune response and no repeated diarrhoea indications of the examined children. Lastly, Sāsāran et al. (15) have also conducted an updated bibliographic review regarding the use of probiotic and synbiotic activity in childhood gastroenteritis, emphasizing that the different strains of probiotics offer diverse efficacy depending on the type of diarrhoea. Since there is sufficient epidemiological data for

the implementation of probiotics to cure acute diarrhoea cases in children, this research is designed to assess the clinical performance of children below 12 months of age admitted at Rehman Medical Institute, Peshawar, with acute watery diarrhoea. Unlike other studies that have examined the effects of probiotics with zinc or antibiotics, this particular research is a systematic review that addresses the outcomes of the administration of probiotics. The findings of this study related to stool consistency and time to recovery shall supplement the literature in pediatric gastroenterology and develop low-cost treatment plans.

Objective

The objective of this study is to evaluate the clinical outcome of probiotic treatment in pediatric patients aged 6 to 12 months with acute watery diarrhea, assessing its efficacy in reducing diarrhea duration and improving stool consistency.

METHODOLOGY

Study Design: Randomized Controlled Trial.

Study setting: The study was conducted at Rehman Medical Institute, Peshawar having a comprehensive children's care facility.

Duration of the study: The study was conducted over a six-month period covering the months from 27 November, 2024 to 26 May, 2025.

Inclusion Criteria

This study was carried out among children aged 6 to 12 months with confirmed acute watery diarrhoea on presentation. Patients enrolled in this study only had diarrhoea of less than 14 days duration as defined according to WHO criteria. Children who were free of antibiotic and anti-diarrheal medicines used within the past 48 hours were allowed to enroll in the study. Participants had no history of chronic gastrointestinal diseases except being included in acute cases and no other condition besides the acute case. The study was conducted according to the guidelines of the existing institution review board, and subjects were asked for parental consent before participating.

Exclusion Criteria

Patients who had taken antibiotics or anti-diarrhoea drugs within the last 48 hours were omitted from the study in order to exclude interferences that may have arisen from the drugs on the effectiveness of the probiotics. Freely screened children having chronic diarrhoea, celiac disease or other gastrointestinal diseases were also excluded. Secondly, patients with bloody diarrheal disorder, severe enema signs that warranted intensive care, and patients who had compromised immune systems were excluded from the study. The exclusion criteria helped minimize external confounding factors affecting the study to ensure the effectiveness of probiotic treatment on uncomplicated acute watery diarrhoea was effectively established.

Methods

According to the recommendation of the hospital's research committee, after obtaining ethical approval, pediatric patients aged between six to twelve months, admitted with acute watery diarrhoea at Rehman Medical

Institute, Peshawar, were recruited for this study. Parents or guardians voluntarily consented to the participants since they were all requested to provide written informed consent. The participants were randomly divided into two groups using a randomly generated number list on the computer. The drugs used in group A were probiotic *Saccharomyces boulardii* 250 mg two times per day for two days in conjunction with the ORT based on the severity of diarrhoea. Only Group B received a placebo together with ORT, which was administered in the same way as those in Group A. The only other medical procedures were done in the hospital after analyzing the patients. Basic characteristics of the patients were noted down, such as age, sex, duration of diarrhoea, and presence or absence of dehydration or malnutrition. The patient's stool frequency and consistency were recorded at the interval of 12 hours. The success was evaluated as the resolution of diarrhoea, which was characterized as normal stool consistency in a patient within 48 hours of treatment. The study data were analyzed using SPSS version 22 statistical software, and statistical significance was at a level of $p < 0.05$.

RESULTS

The study involved 76 pediatric patients 6 to 12 months of age with 38 assigned to each group. Patients' demographic characteristics such as gender distribution, state of hydration and duration of diarrheal illness at the time of admission did not differ significantly between the two groups.

Demographic and Baseline Characteristics

Table 1 below shows the demographic information of the study participants. The ages of the patients in the study were relatively close, with the mean age being 8.2 ± 1.9 months in the probiotic group and 8.4 ± 2.1 months in the placebo group. Patients' gender was also almost equally distributed, with a slight preference for the male gender in both groups. The mean time length of diarrhoea prior to admission was 3.8 ± 1.2 days in the probiotic group and 3.9 ± 1.4 days in the placebo group.

Table 1

Baseline Characteristics of Study Participants

Characteristic	Probiotic Group (n=38)	Placebo Group (n=38)	p-value
Mean Age (months)	8.2 ± 1.9	8.4 ± 2.1	0.74
Gender (Male/Female)	22/16	21/17	0.81
Mean Duration of Diarrhea (days)	3.8 ± 1.2	3.9 ± 1.4	0.65

Effect of Probiotic Treatment on Diarrhea Duration

The main objective criterion was the improvement of diarrhoea within 48 hours of the onset of therapy. The intergroup comparison depicted that 31 of 38 patients in the probiotic group (81.6%) developed normal stool consistency in 48 hours, while in the placebo group, only 19 out of 38 patients (50.0%) produced normal consistency with a significant p-value of 0.004. Stronger evidence towards treatment effectiveness. Duration of diarrhoea after treatment initiation was also significantly lower in the probiotic group (1.8 ± 0.6 days) as compared to the placebo group (2.9 ± 1.1 days).

Table 2

Treatment Outcomes in Both Groups

Outcome	Probiotic Group (n=38)	Placebo Group (n=38)	p-value
Resolution of diarrhea within 48 hours	31 (81.6%)	19 (50.0%)	0.004
Mean duration of diarrhea after treatment (days)	1.8 ± 0.6	2.9 ± 1.1	0.001

Hydration Status and Hospital Stay

The result of this study reveals that patients in the probiotic group are less likely to have moderate dehydration 48 hours after treatment. Furthermore, hospital stay was also shorter in the probiotic group, equaling 3.2 ± 0.8 , while in the placebo group, it was 4.5 ± 1.2 days ($p < 0.01$).

Table 3

Hydration Status and Hospital Stay

Parameter	Probiotic Group (n=38)	Placebo Group (n=38)	p-value
Improved Hydration at 48 hours	34 (89.5%)	24 (63.2%)	0.007
Mean Hospital Stay (days)	3.2 ± 0.8	4.5 ± 1.2	<0.01

These findings highlight the efficacy of probiotics in enhancing diarrhoea resolution, hydration status, and the length of stay of paediatric patients with acute watery diarrhoea.

DISCUSSION

Acute non-specific diarrhoea is a very serious disease in patients less than 5 years of age, particularly in many countries with high rates of malnutrition, poor personal hygiene and poor access to health care. This study aimed to determine the efficacy of probiotics in decreasing the time of bowel movement and overall outcomes in children aged 6 – 12 months. The results show that if patients are given probiotic treatment instead of placebo treatment, the use of probiotics shortens the duration of diarrhoea, creates less poor-quality stool, increases the percentage of days the patients were hydrated, and reduces the number of days patients were hospitalized. This is consistent with other passive trials showing that probiotics positively impact the management of diarrhoea among children.

There are studies that show that probiotics have an important role in the prevention of acute diarrhoea. Huang et al. (1) conducted a systematic review and meta-analysis study and findingly stated that the overall decrease in diarrhoea duration was significantly lower in children given probiotics. Finally, this also confirmed observation because results showed that 81.6% of the children in the probiotic group had normal stool formation within 48 hours in comparison with 50% in the placebo group. These results support the notion that probiotics improve the rate of natural healing because the inner flora is disturbed in the Scorpio when it has diarrhoea. The shortening period of diarrhoea in the probiotic group was also significant such that the children were better hydrated, which in part meant that the children of the probiotics group were receiving better status in terms of the health economic savings on the cost for the children that admitted to hospitals due to diarrhoea cases.

Haidry et al. (2) supported this by pointing out that they

also experienced a remarkable decrease in the instances of loose stool among their patients after probiotic therapy. The fact that the probiotics produce positive effects on gut microbiota and inhibit the growth of pathogenic bacteria may account for the Do's effectiveness in causing faster diarrheal resolution. Schnadower et al. (3) and Mosaddek et al. (4) also pinpoint the fact that probiotics enhance diarrheal outcomes, and this has helped in encouraging the use of probiotics in clinical practice. Similarly, in their study, Abdulah et al. (5) observed even higher effectiveness of recovery rates by the use of both zinc supplements in combination with probiotics.

The ability of probiotics to act beneficially by improving the function of the mucosal barrier in the gastrointestinal tract. The gut microbiota is involved in the modulation of the immune system and acts as a barrier against pathogenic microorganisms while keeping epithelial tissue healthy. According to the study conducted by Vassilopoulou et al. (6), the roles of probiotics are as follows: they aid in improving the normal microorganism count by suppressing the growth of negative bacteria. The results support this theory as the patients in the probiotic group had improved stool consistency, which is the parameter that would be a clear pointer to the recovery of the intestine. Dhongade et al. (7) took the stand to expand on the information that diverse strains of probiotics differ in efficacy, with *Bacillus* probiotics being highly effective in treating diarrhoea. For the purposes of study, *Saccharomyces boulardii* was chosen for its established efficacy in acute gastroenteritis, according to Schnadower et al. (8).

Another factor that would influence the outcome of the therapy is the age and nutritional status of the patients. According to Kambale et al. (9), diarrhoeal morbidity and academic performance were found to benefit from probiotics, especially for undernourished children, which may have led to enhanced gut microbial flora balance. Probiotics may have an added advantage due to their role in better nutrient absorption and enhancing the immune system because diarrhoea in children is usually accompanied by malnutrition. Hassan et al. (10) observed the use of zinc and probiotics synergistically and concluded that the combination has a better impact on improving the state of hydration and the frequency of bowel movements. Since the study did not have zinc supplementation, the observed improvement in conditions that are associated with the use of probiotics suggests that the probiotics can work on their own to improve clinical results.

The clinical trials of the probiotic as an adjunct to conventional therapy appear to be inconclusive concerning the dose and strain differences. Kakar et al. (11) conducted a study, which is comparing the efficacy of zinc-probiotic combination therapy to that of just probiotics only, and the results of the study showed that while both of the treatments are effective, the combined treatment is much more effective. However, the authors of the study by Freedman et al. (12) observed that the efficiency of the probiotics depends on the cause of

diarrhoea, where certain strains are efficient in the management of the bacterial causes of diarrhoea compared to a viral cause. These observations show the need for proper identification of the right probiotic strain for each group of patients. Lahiri et al. (13) and Dang et al. (14) partly elaborated on the target-directed symptoms concerning the effects of probiotics on the pathogens, which proved that *Bacillus clausii* and *Lactobacillus reuteri* could be effective for different types of diarrhoea. However, to date, there remain certain difficulties in the application of probiotics in the therapy of patients with UC, including issues related to the standardization of treatment regimens. According to Sāsāran et al. (15), further large-scale trials, multi-centric trials in this context, need to be carried out to set norms for probiotic treatment of diarrhoea in children. The evidence obtained in this study is informative regarding the use of *Saccharomyces boulardii*, but further research is necessary regarding dosage, administration time, and effectiveness in different patient subpopulations. In addition, concern about the safety of the probiotics in patients with immunocompromised conditions includes the fact that adverse effects of probiotics have been reported in immunocompromised patients. According to study, clinical effectiveness is enhanced through the use of probiotics in children suffering from acute watery diarrhoea. Probiotics decrease the symptom duration, which lowers the cost and duration of the hospitalization and hence can be seen as an effective and feasible intervention for childhood gastroenteritis. Therefore, the positive findings of the current study endorse the use of probiotics in standard treatment protocol as outlined in current treatment policies, especially for regions or facilities with high diarrhoea disease burden.

CONCLUSION

This study provides evidence that probiotic therapy helps reduce the clinical severity and duration of diarrhoea, stool frequency, and vomiting in children aged between 6 and 12 months experiencing acute watery diarrhoea. The study further revealed that children in the *Saccharomyces boulardii* group experienced a lower duration of diarrhoea, better-formed stools as well as better hydration state and hence shorter hospital stay compared to the placebo group. These results are consistent with other studies that pointed out that probiotics have benefits in acute diarrhoea, such as rebalancing the microbial imbalance and modulating the tight junction proteins. Therefore, considering the fact that probiotics are cheaper and safer, they should be included in the routine treatment of diarrhoea in childhood, especially in developing countries. Therefore, subsequent large-scale trials can help identify the appropriate bacterial strains, dosage, and programme length to generate significant improvement. Lastly, this research provides evidence for the opportunities regarding the usage of probiotics in pediatric gastroenterology as a rather non-invasive and effective approach to enhance the treatment of children suffering from such diseases.

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