

Efficacy and Outcome of Locally Available Probiotics in Children with Acute Watery Diarrhea: A Case-Control Study in Bangladesh

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Abstract

Background: Acute watery diarrhea is common in children and is often caused by viral or bacterial infections. It leads to dehydration and electrolyte imbalances. Probiotics have gained attention as a potential therapeutic option, as they may help restore gut flora balance and reduce the duration and severity of watery diarrhea. This study aimed to assess the efficacy of probiotics in managing children with acute watery diarrhea.

Methods: This case-control study was conducted at the Lifeline Diagnostic Center, Dhaka, Bangladesh from April 2023 to September 2023. The data were sourced from the patient database of a registered physician practicing at his chamber at the diagnostic center. In total 120 children with acute watery diarrhea were enrolled and divided into two equal groups. The case group received probiotics alongside the oral rehydration solution, while the control group received the oral rehydration solution only. The data were analyzed using SPSS version 26.0 software.

Results: In both groups, stool frequency significantly decreased from initial values to lower values by day five ($p < 0.001$). On day one, the mean stool frequency showed no significant difference ($p = 0.238$) but on day two, it indicated a significant difference ($p = 0.021$). Starting on day three, the case group showed a marked frequency reduction (3.1 ± 1.1) compared to controls (5.4 ± 1.9 , $p < 0.001$). By day five, frequencies were 1.2 ± 0.5 (case) versus 2.2 ± 0.7 (control, $p < 0.001$). Overall diarrhea duration was shorter in the case group (3.3 ± 0.4 days) compared to controls (4.3 ± 1.3 days, $p < 0.001$).

Conclusion: Probiotics are highly effective in managing acute watery diarrhea in children. When combined with oral rehydration solutions (ORS), probiotics can enhance efficacy and lead to faster recovery by reducing stool frequency and the duration of diarrhea in children.

Keywords: Acute watery diarrhea, Children, Dehydration Efficacy, ORS, Probiotics

1. INTRODUCTION

Acute watery diarrhea remains a leading cause of morbidity and mortality in children, particularly in developing nations, where it ranks as the second leading cause of death [1]. Diarrhea is a common symptom in children and often resolves without the need for medical intervention in developed countries, where it is

generally considered a self-limiting condition that does not require specific treatment [2]. However, in developing countries, it can lead to severe complications such as malnutrition, morbidities, and even death, primarily due to dehydration and electrolyte imbalances [3].

Anti-diarrheal drugs, commonly used in adults to slow intestinal transit, are not recommended

for children under 2 years of age due to the risks of central nervous system effects, such as respiratory depression, coma, and ileus [4]. The primary objective of treatment in children with diarrhea is to reduce its duration and morbidity while minimizing potential side effects [5]. As a result, alternative treatments based on the study of the intestinal flora have been explored, including the use of probiotics and symbiotics [6]. Probiotics consist of beneficial intestinal microorganisms [7], and numerous studies highlight their effectiveness in restoring gut microbiota following an intestinal disturbance. Gibson and Roberfroid introduced the concept of 'probiotics', describing them as additives or non-digestible ingredients, primarily polysaccharides, that positively affect the host by selectively stimulating the growth or activity of beneficial bacteria [8]. Several clinical trials have evaluated the use of probiotics as an adjunct to oral rehydration therapy (ORT) in various settings, demonstrating a reduction in the duration of illness [9]. *Saccharomyces boulardii*, a non-pathogenic yeast, has shown efficacy in multiple studies involving children with acute watery diarrhea [10]. *Bacillus clausii* has also proven effective in a phase III trial, though additional studies are needed to confirm these findings. Despite this, both probiotics are widely prescribed by pediatricians for managing acute watery diarrhea in children [9]. The objective of this current study was to assess the efficacy of probiotics in managing acute watery diarrhea in children.

2. METHODOLOGY

This Case-Control Study Was Held At The Lifeline Diagnostic Center, Dhaka, Bangladesh, From April 2023 To September 2023, Using Data From The Clinic's Patient Database. A Total Of 120 Children With Acute Watery Diarrhea, Aged 1 To 5 Years, Were Enrolled And Divided Equally Into Two Groups. The Case Group Received Probiotics And Oral Rehydration Solution (ORS), While The Control Group Received Only ORS. In The Case Group, Either *Bacillus Subtilis* HU58 (2 Billion CFU/5 MI) or *Bacillus Clausii* Spores' Suspension (2 Billion/5 MI) Was Administered Within the Recommended Doses. For Dehydration Management, Both Groups Received Oral Rehydration Solutions. Children Under 2 Years Were Given 50–100 MI After Each Loose Stool, While Children Aged 2–5 Years Received 100–200 MI After Each Loose Stool. Informed Consent Was Obtained From All Participants

Before Data Collection. As Per The Inclusion Criteria, Only Children Aged 1 To 5 Years Who Presented With Acute Watery Diarrhea, Regardless Of Gender, Were Included In The Study. Exclusion Criteria Comprised Patients With Diarrhea Lasting More Than 14 Days, Blood In Stools, Co-Morbidities, Chronic Disorders, Immunosuppression, Recent Probiotic Treatment Within The Preceding Two Weeks, Diarrhea Caused By Drug Intake Or Allergies, And Post-Surgical Patients. All Children Were Followed Up On Day 5 To Assess Treatment Outcomes. The Outcomes Were Evaluated By Measuring The Duration Of Diarrhea And The Frequencies of the Number Of Stools Per Day By The 5th Day After Presentation. Data Analysis Was Carried Out Using SPSS Version 26.0.

3. RESULT

The baseline characteristics of the participants showed that both the case and control groups (n=60 each) had similar age distributions, with 62% of cases and 60% of controls being under 2 years old. In terms of gender distribution, 57% of the cases were male compared to 55% of the controls. Nutritional status indicated that 60% of cases and 58% of controls had no malnutrition, while 32% of cases and 35% of controls were classified as Grade 1 malnutrition. Grade 2 malnutrition was observed in 8% of cases and 7% of controls. The mean duration of diarrhea was similar for both groups, with cases averaging 29.14 ± 11.76 hours and controls averaging 28.93 ± 11.66 hours. The treatment tenure of five days significantly reduced stool frequency in both groups. In the case group, the mean stool frequency decreased from 7.6 ± 2.4 on the first day to 1.2 ± 0.5 on the fifth day ($p < 0.001$). Similarly, the control group experienced a reduction from 8.2 ± 3.1 to 2.2 ± 0.7 over the same period, with a p-value also less than 0.001, indicating that the treatment was effective in both groups. On the first day, the mean stool frequency was 7.6 ± 2.4 for the case group and 8.2 ± 3.1 for the control group, with a p-value of 0.238, indicating no significant difference. However, on the second day, the case group had a mean frequency of 6.8 ± 2.3 compared to 7.8 ± 2.4 in the control group ($p = 0.021$). From the third day onward, the case group exhibited a marked reduction in frequency, with a mean of 3.1 ± 1.1 compared to 5.4 ± 1.9 in the control group ($p < 0.001$). The fourth day reflected a similar trend, with frequencies of 2.1 ± 0.6 for the case group and 3.8 ± 1.1 for the control

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group ($p < 0.001$). On the fifth day, the case group showed a frequency of 1.2 ± 0.5 , while the control group had 2.2 ± 0.7 ($p < 0.001$). The overall duration of diarrhea was significantly

shorter in the case group (3.3 ± 0.4 days) compared to the control group (4.3 ± 1.3 days) with a p-value of < 0.001 .

Table 1. Baseline characteristics

Parameter	Case		Control	
	(n=60)		(n=60)	
	Mean \pm SD/n (%)			
	n	%	n	%
Age distribution				
<2 years	37	62%	36	60%
2-5 years	23	38%	24	40%
Gender distribution				
Male	34	57%	33	55%
Female	26	43%	27	45%
Nutritional status				
No malnutrition	36	60%	35	58%
Grade I	19	32%	21	35%
Grade 2	5	8%	4	7%
Duration of diarrhea				
Hour	29.14 \pm 11.76		28.93 \pm 11.66	

Table 2. Stool frequency reduction by 5 days treatment tenure

Group	Frequency		p-value
	1st day	5th day	
Case	7.6 \pm 2.4	1.2 \pm 0.5	<0.001
Control	8.2 \pm 3.1	2.2 \pm 0.7	<0.001

Table 3. Comparative periodic result of both group patients

Variables		Case	Control	p-value
Frequency	Day	Mean \pm SD		
	1 st	7.6 \pm 2.4	8.2 \pm 3.1	0.238
	2 nd	6.8 \pm 2.3	7.8 \pm 2.4	0.021
	3 rd	3.1 \pm 1.1	5.4 \pm 1.9	<0.001
	4 th	2.1 \pm 0.6	3.8 \pm 1.1	<0.001
	5 th	1.2 \pm 0.5	2.2 \pm 0.7	<0.001
Duration (Day)		3.3 \pm 0.4	4.3 \pm 1.3	<0.001

4. DISCUSSION

The baseline characteristics of the participants showed that both the case and control groups had similar age distributions. In most of the studies [8,9], similar trends were observed. In terms of gender distribution in our study, 57% of the cases were male compared to 55% of the controls. Such male predominance was found in some other studies [9,12].

In our study, the nutritional status indicated that most of the case group and control group patients had no malnutrition. In the study [9] conducted by Bhat et al., nearly similar findings were observed. In this study, a five-day treatment period significantly reduced stool frequency in both the case and control groups. Stool frequency in both groups showed a significant decrease from baseline to day five

($p < 0.001$). In this study, in analyzing the stool frequencies, on the first day, there was no substantial difference between the groups ($p = 0.238$). By the second day, a significant difference was observed ($p = 0.021$). From day three, the case group exhibited a notable reduction in stool frequency (3.1 ± 1.1) compared to the control group (5.4 ± 1.9 , $p < 0.001$). By the fifth day, the frequencies were significantly lower in the case group (1.2 ± 0.5) than in the control group (2.2 ± 0.7 , $p < 0.001$). Sharif et al also found nearly similar results [13]. In our study, the overall duration of diarrhea was significantly shorter in the case group (3.3 ± 0.4 days) compared to the control group (4.3 ± 1.3 days) with a p-value of < 0.001 . Comparable findings were observed in other studies [11,13]. Our findings support some of the previous studies, including the research by

Choudhary et al., which evaluated the effects of regular and probiotic yogurts in treating acute childhood diarrhea and found that both types of yogurts were effective in reducing the duration and frequency of diarrhea [14]. Similarly, Heydarian et al. investigated the effects of both types of yogurts and found that probiotic yogurt was effective in managing acute diarrhea, although their results for regular yogurt did not reach statistical significance [15]. Despite this, clinical trials involving probiotics, including probiotic yogurt, continue to show mixed and inconclusive results regarding their effectiveness in treating and improving the outcomes of diarrhea [16,17]. Nonetheless, the findings from this current study may serve as a valuable reference for future research in similar areas.

5. LIMITATION OF THE STUDY

This study was single-centered with a relatively small sample size, and it was conducted over a brief time frame. As a result, the findings may not accurately represent the broader national context.

6. CONCLUSION & RECOMMENDATION

Probiotics are highly effective in managing acute watery diarrhea in children. When combined with oral rehydration solutions (ORS), probiotics can enhance treatment efficacy, promoting faster recovery by reducing both stool frequency and the duration of diarrhea in children. This combination therapy supports gut health and helps restore the balance of beneficial bacteria, providing an efficient and safe approach to treating acute watery diarrhea in children. It is recommended that healthcare providers consider incorporating available probiotics with ORS as a standard treatment protocol for acute watery diarrhea in children to improve outcomes and expedite recovery times.

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