Biological and Clinical Sciences Research Journal

eISSN: 2708-2261; pISSN: 2958-4728

www.bcsrj.com

DOI: https://doi.org/10.54112/bcsrj.v6i6.1798
Biol. Clin. Sci. Res. J., Volume 6(6), 2025: 1798

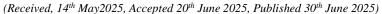
Original Research Article

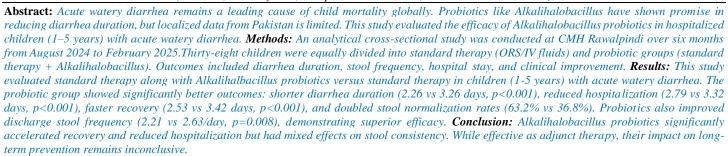


Effect of Probiotic (Alkalihalobacillus) in the Outcome of Acute Watery Diarrhea in Children Admitted in Combined Military Hospital Rawalpindi, Pakistan

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Keywords: Acute watery diarrhea, probiotics, Alkalihalobacillus, children, Pakistan

[How to Cite: Iqbal J, Anwar S, Hasan S, Naveed M, Ikram F, Sahaf. Effect of probiotic (alkalihalobacillus) in the outcome of acute watery diarrhea in children admitted in combined military hospital Rawalpindi, Pakistan. Biol. Clin. Sci. Res. J., 2025; 6(6): 148-151. doi: https://doi.org/10.54112/bcsrj.v6i6.1798

Introduction

disease is the third leading cause of death in children under 5 years old and is responsible for killing around 4,43,832 children every year. Probiotics are live, beneficial microorganisms, mostly bacteria, that improve gut microbial balance. Taken as supplements or in food, they work by lowering intestinal pH, hindering pathogen colonization, and modulating the immune system(1). According to a study conducted at Gotong Royong Hospital in Surabaya Indonesia, the difference between the duration of diarrhea with and without the use of probiotics was significant(p<0.001). It was observed that the use of probiotics reduced the duration of diarrhea by two days as compared to those patients who were not given probiotics(2). Another study evaluated the probiotic Alkalihalobacillus clausii for treating diarrhea in 120 patients in different age groups. Results showed that probiotc use significantly improved diarrhea in all age groups, reducing time to last unformed stool and diarrheal frequency(3). Another study showed that probiotics offer a promising treatment due to their impact on gut function, immunity, and microbiome however, strain and indication specificity are crucial(4). Another study, which was conducted at Combined Military Hospital, Quetta from January 2017 to June 2018, investigated the effect of Saccharomyces boulardii for acute watery diarrhea in children aged 2 months to 5 years. Significant reduction in diarrhea duration and stool frequency were observed (p<0.05). A statistically significant difference

(p=0.021) was noted in recovery rates, with 53% of the probiotic group

(114 children) showing improvement compared to 47% of the control

group (101 children). This study concluded that probiotic use

World Health Organization (WHO) defines diarrhoea as "the passage of

3 or more loose or liquid stools per day (or more frequent passage than is

normal for the individual)." According to the WHO factsheet, diarrhoeal

significantly reduces the duration of acute diarrhea and stool frequency in children(5). A randomized controlled trial was conducted at Khyber Teaching Hospital, Peshawar from May to November 2019. It investigated the outcome of probiotics in treating acute diarrhea in 200 children aged 6 months to 5 years divided into 2 groups i.e. control (Oral Rehydratory Salts (ORS)) and intervention(probiotic) groups. Results showed improvement in 92 (92%) patients in the probiotic group (Group A) compared to 71 (71%) patients in the ORS-only group (Group B) which indicates that probiotics are more effective in the treatment of acute diarrhea as compared to standard ORS therapy(6). Another study showed that there was no significant association between probiotic use and age, weight or doze per kilogram of the patients in the treatment of acute diarrhea(7).

There have been many studies suggesting that probiotics may reduce the duration and severity of diarrhea. However, there is a literature gap regarding effect of probiotics on acute watery diarrhea in Pakistan especially Rawalpindi District. Our study aims to assess the effects of probiotics in acute watery diarrhea in admitted children in context to local population of Rawalpindi District.

The objective of the study is **t**o evaluate the effect of probiotics (Alkalihalobacillus) on the duration and severity of acute watery diarrhea in hospitalized children.

Methodology

This analytical cross-sectional study was conducted in the Department of Pediatrics at Combined Military Hospital (CMH), Rawalpindi, Pakistan, over a period of six months from August 2024 to February 2025 following ethical approval from the institutional review board. The study population included children aged 1 to 5 years who were admitted to the pediatric

ward of CMH, Rawalpindi. Participants were selected using a non-probability convenience sampling technique, allowing for efficient recruitment based on accessibility and availability during the study period. A total of 38 participants were included for the study, divided in a 1:1 ratio of 19 each for the standard therapy group and standard therapy + probiotic group. Children aged 1 year to 5 years old admitted to the pediatrics department with acute watery diarrhea were included while Children with chronic diarrhea or underlying medical conditions were excluded.

Ethical approval was obtained from the institutional ethical review board. The parents/guardians of the eligible participants was briefed regarding the steps and purpose of the study and informed consent was taken. Group 1 was given the standard therapy for acute watery diarrhea i.e. ORS/Intravenous Fluids while Group 2 was given the Probiotic (Alkalihalobacillus) in a dose of 1 vial 2 times a day (1 vial carries 2x109 spores) after test dose along with the standard treatment as explained above. Both Groups were assessed before the start of the treatment for base line values and after 3 days of treatment. Reassessment was done after 5 days of treatment. Variables such as mean weight, no. of stool episodes per day, duration of diarrhea and stool consistency was measured before and after the treatment.

Results

The gender distribution between the two treatment groups showed some variation while maintaining relative balance. In the standard therapy group, female patients predominated at 63.2% (12 of 19), with males comprising 36.8% (7 of 19). The probiotics group females accounted for 52.6% (10 of 19) and males made up 47.4% (9 of 19). At the time of admission, stool consistency patterns revealed important differences between the treatment groups. The majority of children in the standard therapy group presented with watery stools (73.7%, 14 of 19), indicating more severe diarrhea, compared to 57.9% (11 of 19) in the probiotics group. Conversely, a higher proportion of patients in the probiotics group exhibited soft stools (42.1%, 8 of 19) versus the standard therapy group (26.3%, 5 of 19). Frequency of vomiting was identical between both treatment groups at admission, with 42.1% of children (8 out of 19) in both the standard therapy and probiotics groups experiencing vomiting. Conversely, 57.9% of patients (11 out of 19) in each group did not present with vomiting at baseline. The prevalence of fever differed notably between the treatment groups at baseline. In the standard therapy group, 31.6% of children (6 out of 19) presented with fever, while a significantly higher proportion - 52.6% (10 out of 19) - in the probiotics group exhibited febrile symptoms. Conversely, afebrile patients constituted 68.4% (13 out of 19) of the standard therapy group compared to 47.4% (9 out of 19) in the probiotics group. The presence of blood in stools was identical between both treatment groups, with 15.8% of children (3 out of 19) in each group showing this clinical sign. The vast majority of patients in both groups, 84.2% (16 out of 19) did not exhibit bloody stools at admission. At the time of discharge, significant differences emerged in

stool consistency patterns between the treatment groups. While both groups achieved complete resolution of watery stools (0% in each), their recovery trajectories diverged markedly. In the standard therapy group, 63.2% of children (12 out of 19) still had soft stools, while only 36.8% (7 out of 19) achieved full normalization of stool consistency. The probiotics group showed a reversed and more favorable pattern: 63.2% (12 out of 19) attained normal stools, with just 36.8% (7 out of 19) remaining at the soft stool stage. This striking contrast demonstrates that the probiotics group exhibited superior recovery, with nearly twice as many children reaching complete normalization of bowel function compared to standard therapy alone (Table 1).

Children receiving standard therapy had a mean age of 2.94 years (± 0.49), while those in the probiotics group had a mean age of 2.10 (± 0.26) years. The duration of diarrhea showed a clinically and statistically significant difference between treatment groups. Children receiving standard therapy alone experienced diarrhea for a mean duration of 3.26 days (±0.56), while those supplemented with probiotics had a substantially shorter diarrheal episode lasting only 2.26 days (± 0.65). The difference in duration of diarrhea between both groups was highly statistically significant (p < 0.001). The narrow standard deviations in both groups indicate consistent findings across study participants. These results demonstrate that probiotic supplementation significantly shortens the course of acute watery diarrhea in children, potentially leading to faster clinical recovery. At the time of admission, both treatment groups showed comparable stool frequency patterns, indicating similar baseline disease severity. The standard therapy group reported a mean of 5.37 (± 0.68) stools per day, while the probiotics group averaged at 5.11 (± 0.93) stools daily. This modest difference of 0.26 stools per day between groups was not statistically significant (p = 0.329). Children receiving standard therapy required hospitalization for an average of 3.32 days (± 0.74), while those in the probiotics group demonstrated a significantly shorter mean hospital stay of 2.79 days (± 0.78). This reduction in the probiotics group achieved high statistical significance (p < 0.001). The time to resolution of diarrheal symptoms demonstrated a significant treatment effect favoring probiotic supplementation. Children in the standard therapy group took an average of 3.42 days (±0.50) to achieve complete symptom resolution, whereas those receiving probiotics recovered nearly a full day faster, with a mean resolution time of just 2.53 days (± 0.51). This substantial difference in recovery time was highly statistically significant (p < 0.001). The statistical significance (p < 0.001) strongly supports the therapeutic benefit of probiotics as an adjunct to standard diarrhea management. The frequency of stools (per day) at discharge revealed a statistically significant improvement in the probiotic group. Children receiving standard treatment had a mean stool frequency of 2.63 (± 0.49) bowel movements per day at discharge, while those in the probiotics group showed better recovery with significantly fewer stools (2.21 ± 0.41 per day). This reduction of 0.42 stools per day achieved statistical significance (p=0.008) (Table 2).

Table 1 Clinical features

		Treatment Groups	
		Standard Therapy n(%)	Standard Therapy + Probiotics n(%)
Gender	Female	12 (63.2)	10 (52.6)
	Male	7 (36.8)	9 (47.4)
Stool Consistency at admission	Watery	14 (73.7)	11 (57.9)
	Soft	5 (26.3)	8 (42.1)
	Normal	0 (0)	0 (0)
Vomiting	Yes	8 (42.1)	8 (42.1)
	No	11 (57.9)	11 (57.9)
Fever	Yes	6 (31.6)	10 (52.6)
	No	13 (68.4)	9 (47.4)
Blood in Stools	Yes	3 (15.8)	3 (15.8)

	No	16 (84.2)	16 (84.2)
Stool Consistency at Discharge	Watery	0 (0)	0 (0)
	Soft	12 (63.2)	7 (36.8)
	Normal	7 (36.8)	12(63.2)

Table 2 Comparison of standard and probiotic groups

	Treatment Groups	P-Value	
	Standard Therapy Mean ± SD	Standard Therapy + Probiotics Mean ± SD	(Independent T-Test)
Age in Years	3.1 ± 0.90	2.45 ± 0.64	< 0.001
Duration of Diarrhea (in days)	3.47 ± 1.07	1.79 ± .078	< 0.001
Frequency of stools on admission (per day)	6.47 ± 1.07	4.79 ± 0.78	< 0.001
Duration of Hospital Stay (in Days)	4.47 ± 1.07	2.79 ± 0.78	< 0.001
Time to Resolution (in Days)	3.72 ± 0.92	1.92 ± 0.71	< 0.001
Frequency of stools at Discharge	3.68 ± 0.82	1.58 ± 0.507	< 0.001

Discussion

Our study compared Alkalihalbacillus probiotics versus standard therapy in children (1-5 years) with acute watery diarrhea. Baseline characteristics showed balanced gender distribution (standard: 63.2% female; probiotics: 52.6%) and similar vomiting rates (42.1% in both). However, the probiotics group had more febrile cases (52.6% vs. 31.6%) and fewer watery stools at admission (57.9% vs. 73.7%). Children receiving probiotics experienced a notable reduction in diarrhea duration, decreasing from 3.26 days to just 2.26 days (p<0.001). Hospital stays were similarly shortened, dropping from 3.32 days to 2.79 days (p<0.001). Recovery times showed marked improvement, with resolution occurring in 2.53 days compared to 3.42 days for standard therapy (p<0.001). Most impressively, stool normalization rates nearly doubled, with 63.2% of probiotic-treated children achieving normal bowel function versus only 36.8% in the standard therapy group. These robust findings consistently favored probiotic supplementation across all measured outcomes. The probiotics group also showed better stool frequency at discharge (2.21 vs. 2.63/day, p=0.008).

In comparison, in a study by Haidry et al, out of 252 patients, significant differences in stool frequency and consistency were observed on days 3-5 (p < 0.005). Probiotic group assignment was significantly associated with efficacy (p = 0.021). After adjusting for covariates, the probiotic group showed 2.37 times higher efficacy compared to the control group (OR 2.37, 95% CI 1.07-5.24, p = 0.033). Children aged \leq 3 years had 3.23 times higher efficacy than those >3 years (aOR 3.23, 95% CI 1.32-7.91, p = 0.010). Efficacy was significantly lower in children without dehydration (aOR 0.06, 95% CI 0.01-0.52, p = 0.011) and with some dehydration (aOR: 0.09, 95% CI 0.01-0.77, p = 0.028)(8).

In another study conducted by Mosaddek et al, 166 children were enrolled, 98 out of the 166 completed follow-up and were distributed into three treatment groups: probiotics alone (A), antibiotics alone (B), and a combination (C). Baseline characteristics were comparable. The most common causative agents of diarrhea included Rotavirus (69.4%) and E. coli (67.4%), with multiple infections in 45.9% of cases. Group A recovered fastest (3.03 \pm 0.76 days), followed by Group C (3.80 \pm 1.10 days) and Group B (4.11 ± 1.48 days), showing significant differences (p=0.001). By day 30, probiotic-treated groups showed restoration of beneficial gut flora, namely Lactobacillus and Bifidobacterium(9). Another study assessed Bacillus clausii spore probiotics (LiveSpo CLAUSY) for treating persistent diarrhea in children. Results indicated that the probiotic significantly improved treatment outcomes, shortening recovery by 2 days and improving diarrhea symptom reduction by 1.5-1.6 folds. Participants recovered from diarrhea 3 days faster, with a 1.6fold improvement in treatment efficacy(10). Another study by Zhang et

al found that Saccharomyces boulardii and Bifidobacterium groups exhibited lower antibiotic associated diarrhea (AAD) incidence rates compared to the control group (P<0.017), with shorter AAD duration and hospital stays (P<0.05). The control group showed an increased cocci to bacilli ratio in feces from day 1 to days 7, 14, and 21 (P<0.05). Withingroup analysis revealed that Bifidobacterium 14 d and 21 d groups had decreased ratios on day 14 compared to day 1 (P<0.05), and several groups showed decreased ratios on day 14 compared to day 7 (P<0.05). On day 21, the control and Saccharomyces boulardii 21 d groups had lower ratios than on days 7 and 14 (P<0.05). Between-group comparisons indicated that the Saccharomyces boulardii and Bifidobacterium groups had lower cocci to bacilli ratios than the control group on day 7 (P<0.05), and on day 14, the 14 d and 21 d groups had lower ratios than the control and Bifidobacterium 7 d groups (P<0.05)(11).

Limitations & Considerations:

- Small sample size (n=19/group) may inflate effect sizes.
- Younger children may respond differently to probiotics.

Conclusion

This study concludes that probiotic (alkalihalobacillus) reduces the duration and severity of diarrhea in children.

Declarations

Data Availability statement

All data generated or analysed during the study are included in the manuscript.

Ethics approval and consent to participate

Approved by the department concerned. (IRBEC-24)

Consent for publication

Approved

Funding

Not applicable

Conflict of interest

The authors declared the absence of a conflict of interest.

Author Contribution

JI (Postgraduate Resident)

Study design, data collection, data entry, data analysis, and manuscript drafting, Final approval

SA (Postgraduate Resident)

Review of Literature, Data entry

SH (Associate Professor)

Conception of Study, Development of Research Methodology Design

MN (Postgraduate Resident)

Manuscript review, critical input.

FI (Consultant Paediatrics)

Manuscript drafting, Study Design

S (Postgraduate Resident)

Conception of Study, Development of Research Methodology

All authors reviewed the results and approved the final version of the manuscript. They are also accountable for the integrity of the study.

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