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Comparison of Clinical Efficacy of Saccharomyces Boulardii with Yogurt in Children with Acute Watery Diarrhea

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ABSTRACT

Objective: To compare the clinical efficacy of Saccharomyces Boulardii versus yogurt in the treatment of acute watery diarrhea in children aged 6–24 months.

Study Design: Quasi-experimental Study.

Place and Duration of Study: Department of Paediatrics, Combined Military Hospital (CMH) Rawalpindi, Pakistan from Jan to May 2024.

Methodology: Fifty children with acute watery diarrhea were randomly allocated to receive either S. boulardii 250 mg twice daily (Group-A, n = 25) or plain yogurt 200 mL twice daily (Group-B, n = 25), in addition to standard oral rehydration and zinc. Primary outcomes were stool frequency at 48 h and time to recovery (≤3 formed stools in 24 h).

Results: Baseline characteristics were comparable between groups. Group-A showed significantly shorter duration of diarrhea (median 3.0 vs. 4.0 days), vomiting (1.0 vs. 3.0 days) and hospital stay (3.0 vs. 4.0 days) compared to Group-B (p=0.001 for all). Although recovery at 48 hours was higher in the Group-A (64.0% vs. 40.0%), the difference was not statistically significant (p=0.089). No significant difference was observed in recovery at 72 hours (p=0.747).

Conclusion: Saccharomyces Boulardii shortened the clinical course of acute watery diarrhea more effectively than yogurt, nearly doubling the 48-hour recovery rate without added adverse effects. Its routine use may therefore be considered in this age group.

Keywords: Acute Disease, Diarrhea, Probiotics; Saccharomyces boulardii, Yogurt.

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INTRODUCTION

Acute watery diarrhea, defined by the World Health Organization (WHO) as three or more loose stools in 24 h, remains the second leading cause of mortality in children < 5 years worldwide, accounting for an estimated 740,000 deaths annually.[1] In Pakistan alone, diarrheal illnesses are responsible for roughly 200,000 childhood deaths each year, with enterotoxigenic Escherichia coli and Vibrio cholerae among the most common etiological agents.[2,3] Standard WHO-recommended therapy combines oral rehydration solution (ORS), supplemental zinc and continued age-appropriate feeding, interventions that are highly effective at preventing dehydration yet have limited impact on shortening the duration or severity of symptoms.[4]

To accelerate recovery, interest has grown in adjunctive probiotic therapies.[5] Fermented milk products, such as yoghurt, contain live Lactobacillus spp. that can inhibit enteric pathogens, improve mucosal immunity, and modestly reduce diarrheal duration in children.[6] Saccharomyces boulardii, a non-pathogenic yeast first isolated from tropical fruit skins, has distinct advantages: it is acid- and bile-resistant, requires no refrigeration, produces antimicrobial factors that neutralise toxins and competes with pathogenic bacteria for binding sites in the gut.[7,8] Meta-analyses show that S. boulardii shortens diarrhea by 24–30 h and lowers the risk of persistent disease, with an excellent safety record even in infants.[9] Despite these data, yoghurt remains the culturally preferred home remedy in South Asia, and head-to-head comparisons with S. boulardii are scarce.[10]

Diarrheal diseases continue to be a major public health concern in Pakistan, particularly among children under five years of age, where access to advanced healthcare remains limited. Yogurt is widely available and culturally accepted, while Saccharomyces Boulardii has shown promising results in international studies due to its stability and specific anti-diarrheal mechanisms. This study was conducted to compare the effectiveness of Saccharomyces

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Boulardii with yogurt in reducing the duration and severity of acute watery diarrhea in children.

METHODOLOGY

This quasi-experimental study was carried out at the Department of Paediatrics, Combined Military Hospital (CMH) Rawalpindi, Pakistan, from January to May 2024. The study was approved by the Institutional Ethical Review Board of Army Medical College/CMH Rawalpindi (Approval No. 706).

Inclusion Criteria: Children of either gender aged 5 to 24 months, admitted to or attending the paediatric ward/outpatient clinic with acute watery diarrhoea, defined as ≥3 loose or watery stools per day lasting <14 days, were included.

Exclusion Criteria: Children with visible blood in stool, known chronic intestinal disorders such as coeliac disease, cystic fibrosis or inflammatory bowel disease, those with clinically evident parasitic infestation, severe malnutrition (weight-for-age z-score < -3 SD), systemic antibiotic use within the preceding seven days documented immunodeficiency, or any concurrent condition requiring intensive care were excluded.

The sample size for this study was calculated using OpenEpi online calculator, applying the formula for comparing two independent proportions. Reference values reported a 48.5% recovery rate at 48 hours in children treated with Saccharomyces Boulardii compared to a 25.5% recovery rate in those treated with yogurt fluid. With an equal allocation ratio (1:1), the required sample size was calculated to be 50 participants (approximately 25 in each group).[11]

Participants were enrolled through consecutive non-probability sampling after fulfilling the inclusion criteria. Upon obtaining informed consent from parents or guardians, eligible children were randomized into two groups using block randomization (block size=4) with sealed opaque envelopes to ensure allocation concealment. Data collection was carried out prospectively by trained pediatric residents under the supervision of a pediatric gastroenterologist.

Upon admission, each child underwent a clinical evaluation, including documentation of baseline demographic data, nutritional status, and degree of dehydration. Stool samples were collected and examined for the presence of bacteria, fungi, or protozoa to rule out invasive or parasitic causes of diarrhea. All children with mild to moderate dehydration were managed with standard WHO-recommended therapy, including oral rehydration salts (ORS) and zinc supplements (10 mg daily for children ≤6 months and 20 mg daily for those >6 months).

Group-A received lyophilized Saccharomyces Boulardii at a dose of 250 mg twice daily for children aged ≥1 year, and 125 mg twice daily for those <1 year. Group-B received yogurt fluid (YF) containing Lactobacillus bulgaricus and Streptococcus thermophilus, freshly prepared daily, administered as 30 mL twice daily for children ≥1 year, and 15 mL twice daily for children <1 year. Patient flow can be seen in Figure. The use of any other probiotics or fermented milk products was not allowed during the treatment period.

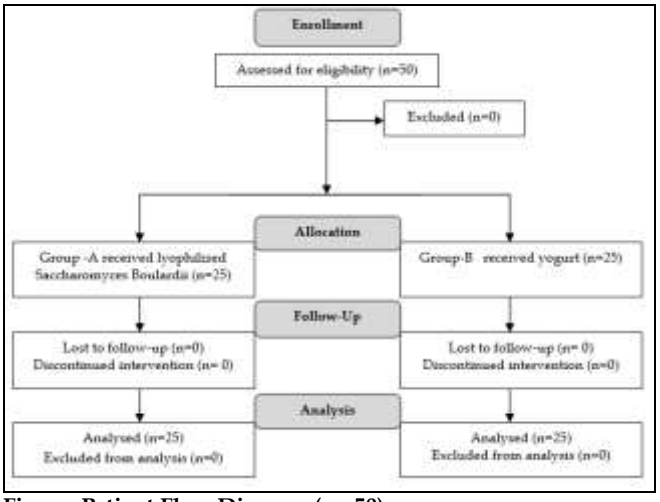

Figure: Patient Flow Diagram (n= 50)

Patients were monitored daily by the same physician to ensure consistency in clinical assessment. Daily evaluations included stool frequency, consistency (using the Bristol Stool Scale), episodes of vomiting, hydration status, and tolerance to oral intake.[12] The duration of diarrhea (time until stool returned to a Bristol score <5), duration of vomiting, and length of hospital stay were recorded as outcome variables.

All data were analyzed with Statistical Package for the Social Sciences (SPSS) version 25. Normality was assessed with the Shapiro–Wilk test: age, weight-for-age z-score and baseline serum sodium were normally distributed, whereas stool frequency, duration of diarrhoea, duration of vomiting and length of hospital stay were non-normally distributed. Accordingly, normally distributed continuous

variables are reported as Mean±SD and were compared between groups with an independent-samples t-test, while non-normal variables are expressed as median (IQR) and compared with the Mann-Whitney U test. Categorical variables (e.g., recovery status at 48 hour and 72 hour) were analysed with the Chi square or Fisher's exact test, as appropriate. A *p*-value ≤ 0.05 was considered statistically significant for all comparisons.

RESULTS

A total of 50 children aged 5 to 24 months with acute watery diarrhea were enrolled, with 25 participants in each treatment group. The baseline characteristics of the two groups were comparable (Table-I). The mean age was 14.5±5.7 months in Group-A and 15.2±6.0 months in Group-B (*p*=0.682). Baseline serum sodium levels did not differ significantly between groups (*p*=0.204). Similarly, the mean stool frequency on day 1 was comparable between groups (*p*=0.837).

Table-I: Baseline Characteristics of Study Participants (n=50)

Variable	Group-A (n=25) Mean±SD	Group-B (n=25) Mean±SD	*p*-value
Age (months)	14.5±5.7	15.2±6.0	0.682
Serum Sodium (mmol/L)	136.4±2.9	137.4±2.5	0.204
Stool Frequency (Day 1)	6.6±1.4	6.7±1.3	0.837

Clinical outcomes demonstrated a statistically significant benefit in favor of S. boulardii across all primary endpoints (Table-II). The median duration of diarrhea was significantly shorter in Group-A (3.0 [IQR: 2.0–3.0] days) compared to Group-B (4.0 [IQR: 3.0–5.0] days), with a *p*-value of 0.001. A similar trend was observed in the duration of vomiting (1.0 [1.0–2.0] vs. 3.0 [2.0–3.0] days; *p*=0.001) and length of hospital stay (3.0 [2.0–3.0] vs. 4.0 [3.0–4.0] days; *p*=0.001).

Table-II: Clinical Outcomes of the study Participants (n=50)

Outcome	Group-A (n=25) Median [IQR]	Group-B (n=25) Median [IQR]	*p*-value
Duration of Diarrhea (days)	3.0 [2.0–3.0]	4.0 [3.0–5.0]	0.001
Duration of Vomiting (days)	1.0 [1.0–2.0]	3.0 [2.0–3.0]	0.001
Hospital Stay (days)	3.0 [2.0–3.0]	4.0 [3.0–4.0]	0.001

Recovery status at 48 and 72 hours post-treatment is shown in Table-III. At 48 hours, 64.0% of children in Group-A had recovered, compared to 40.0% in yogurt Group-B, however, the difference was not statistically significance (*p*=0.089). By 72 hours, recovery rates improved to 76.0% and 72.0% in groups A and B, respectively (*p*=0.747), with no significant difference observed.

Table-III: Recovery Status at 48 and 72 Hours (n=50)

Time Point	Group	Recovered		*p*-value
		Non (%)	Yes n(%)	
48 hours	Group-A (n=25)	9(36.0%)	16 (64.0%)	0.089
	Group-B (n=25)	15(60.0%)	10(40.0%)	
72 hours	Group-A (n=25)	6(24.0%)	19(76.0%)	0.747
	Group-B (n=25)	7(28.0%)	18 (72.0%)	

DISCUSSION

Our study demonstrates that adjunctive Saccharomyces boulardii significantly shortened the duration of diarrhea, vomiting, and hospital stay when compared to yogurt fluid in children with acute watery diarrhea. These findings align with a previous study where S. boulardii reduced diarrheal duration as compared to placebo, reinforcing our results on accelerated recovery.[13] Another study reported accelerated onset of semiformed stools and shorter diarrhea duration in children given S. boulardii.[14]

Local studies echo these benefits in Pakistan. Munir et al. at CMH Quetta found that S. boulardii significantly reduced stool frequency and diarrheal duration (53% vs. 47%, *p*=0.021), mirroring our clinical outcomes.[15] Similarly, Tabassum *et al*. at Faisalabad reported faster stool reduction by day 5 and a higher recovery rate in those taking S. boulardii (64% vs. 42%; *p*=0.022), supporting our recovery trends.[16]

Rotavirus-specific studies have also confirmed these benefits. A double-blind trial showed reduced median diarrhea duration (60 h vs. 89 h) and shorter hospital stays in children treated with S. boulardii, mirroring our findings in mixed etiology cases.[17] In contrast, large comparative trials between S. boulardii and bacterial probiotics like Lactobacillus rhamnosus have reported no additional advantage of S. boulardii over bacterial strains, suggesting strain-specific effects vary by diarrheal etiology.[18]

One advantage of our study is the direct comparison with yogurt fluid, a culturally familiar yet unstandardized probiotic source. While workspace studies have mostly focused on placebo or bacterial

probiotic comparisons, ours adds real-world value by assessing a locally used intervention.

LIMITATIONS OF STUDY

This study has several limitations that should be acknowledged. First, the sample size was relatively small, which may limit the generalizability of the findings to broader pediatric populations. Second, stool pathogens were not routinely typed; thus, the etiology of diarrhea (e.g., viral vs. bacterial) could not be stratified, which might affect the comparative efficacy of probiotics. Third, while yogurt was used as a comparator due to its local relevance, its probiotic content may vary in potency and viability, unlike standardized formulations. Lastly, the study was conducted at a single tertiary care hospital, which may introduce selection bias and limit external validity.

CONCLUSION

This study demonstrates that Saccharomyces boulardii, when used as an adjunct to standard WHO-recommended therapy, is more effective than yogurt fluid in reducing the duration of diarrhea, vomiting, and hospital stay in children with acute watery diarrhea. Although the difference in recovery rates at 48 and 72 hours did not reach statistical significance, the overall clinical benefit observed supports the use of S. boulardii as a superior probiotic intervention in pediatric diarrheal illness. Its integration into national guidelines and local treatment protocols should be considered, especially in resource-limited settings where rapid recovery can significantly reduce healthcare burden.

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Authors Contribution

Following authors have made substantial contributions to the manuscript as under:

ST & SAS: Conception, study design, drafting the manuscript, approval of the final version to be published.

WN & YZ: Data acquisition, data analysis, data interpretation, critical review, approval of the final version to be published.

SA & AT: Conception, data acquisition, drafting the manuscript, approval of the final version to be published.

Authors agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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