e-ISSN: 0976-822X, p-ISSN:2961-6042

Available online on http://www.ijcpr.com/

International Journal of Current Pharmaceutical Review and Research 2026; 18(2); 1466-1470

Original Research Article

Probiotic Characterization of *Saccharomyces boulardii* and its Effect on Infantile Diarrhoea: A Prospective Interventional Study from a Tertiary Care Centre in Eastern India

Siddhartha Kumar[1], Deepak Kumar Pintu[2], Kanhaiya Jha[3], Nitu Kumari[4]

[1]Tutor, Department of Microbiology, Darbhanga Medical College & Hospital, Darbhanga, Bihar, India
[2]Tutor, Department of Microbiology, Darbhanga Medical College & Hospital, Darbhanga, Bihar, India
[3]Professor, Department of Microbiology, Darbhanga Medical College & Hospital, Darbhanga, Bihar, India
[4]Tutor, Department of Microbiology, Darbhanga Medical College & Hospital, Darbhanga, Bihar, India

Received: 01-12-2025 / Revised: 16-01-2026 / Accepted: 06-02-2026
Corresponding Author: Dr. Nitu Kumari
Conflict of interest: Nil

Abstract

Background: Infantile diarrhoea remains a leading cause of morbidity in developing countries. Probiotics such as Saccharomyces boulardii have demonstrated therapeutic potential in reducing duration and severity of diarrhoeal illness. However, region-specific clinical and microbiological characterization studies remain limited.

Aim: To characterize the probiotic properties of Saccharomyces boulardii and evaluate its clinical efficacy in the management of infantile diarrhoea.

Methods: A prospective interventional study was conducted involving 160 infants aged 6–24 months diagnosed with acute diarrhoea. Participants were randomized into two groups: standard therapy (ORS + zinc) and standard therapy plus S. boulardii (250 mg twice daily for 5 days). Probiotic characterization included acid tolerance, bile salt resistance, antimicrobial activity, and adhesion assay. Clinical parameters such as duration of diarrhoea, stool frequency, hospital stay, and recurrence rate were analyzed. Statistical evaluation was performed using Student's t-test and chi-square test.

Results: S. boulardii demonstrated high acid tolerance (87.3% survival at pH 2.0), bile resistance (82.1% at 0.3% bile salts), and significant antimicrobial activity against enteropathogens. The probiotic group showed a significant reduction in mean duration of diarrhoea (48.6 ± 12.4 hours vs 72.8 ± 16.1 hours, $p<0.001$), stool frequency, and hospital stay. Recurrence within 14 days was lower in the probiotic group (6.3% vs 18.8%, $p=0.02$).

Conclusion: Saccharomyces boulardii is a potent probiotic with significant therapeutic benefit in infantile diarrhoea. Its inclusion as adjunct therapy may improve clinical outcomes in resource-limited settings.

Keywords: Saccharomyces boulardii; Infantile diarrhoea; Probiotic characterization; Acute pediatric gastroenteritis; Acid and bile tolerance.

DOI: 10.25258/ijcpr.18.2.242

Introduction

Infantile diarrhoea remains one of the most significant contributors to pediatric morbidity and mortality globally, particularly in low- and middle-income countries. According to the World Health Organization, diarrhoeal diseases account for nearly 525,000 deaths annually among children under five years of age [1]. In India, diarrhoea continues to pose a substantial healthcare burden despite improvements in sanitation and vaccination programs [2].The pathophysiology of acute diarrhoea in infants involves intestinal inflammation, disruption of epithelial integrity, and alteration of gut microbiota composition. Recent advances in microbiome research have emphasized the therapeutic role of probiotics in restoring intestinal homeostasis [3]. Probiotics are defined as live microorganisms which, when administered in adequate amounts, confer a health benefit on the host [4]. Among the various probiotic strains studied, Saccharomyces boulardii, a non-pathogenic yeast first isolated by Henri Boulard in 1923, has emerged as a promising therapeutic agent. Unlike bacterial probiotics, this yeast is resistant to antibiotics, allowing concomitant administration during antimicrobial therapy [5]. Mechanistically, S. boulardii exerts beneficial effects through modulation of immune responses, inhibition of pathogen adhesion, secretion of proteases that neutralize bacterial toxins, and enhancement of mucosal barrier function

[6,7].Multiple meta-analyses have demonstrated reduced duration of acute infectious diarrhoea with S. boulardii supplementation [8,9]. It has also shown efficacy in antibiotic-associated diarrhoea and recurrent Clostridioides difficile infection [10]. However, variations in strain characterization, dosage, and regional microbial ecology necessitate locally conducted clinical trials.

Despite its established global evidence, data from Eastern India, particularly Bihar, are sparse. Regional differences in gut microbiota composition, nutritional status, and pathogen prevalence may influence probiotic efficacy [11]. Therefore, a combined microbiological and clinical evaluation of S. boulardii is essential to validate its therapeutic application in this population. The present study aims to characterize probiotic attributes of Saccharomyces boulardii and evaluate its effect on infantile diarrhoea in a tertiary care hospital setting in Bihar, India.

Materials and Methods

This prospective randomized interventional study was conducted in the Department of Microbiology and Pediatrics at Darbhanga Medical College & Hospital from 05th February 2025 to 25th November 2025. Ethical clearance was obtained from the Institutional Ethics Committee. Informed consent was obtained from parents or guardians. A total of 160 infants aged 6–24 months presenting with acute diarrhoea (≥3 loose stools per day, duration <72 hours) were enrolled. Exclusion criteria included severe dehydration requiring ICU admission, chronic gastrointestinal disorders, immunodeficiency, and prior probiotic use within two weeks. Participants were randomized into two equal groups. Group A received standard therapy consisting of oral rehydration solution and zinc supplementation. Group B received standard therapy plus Saccharomyces boulardii (250 mg sachet twice daily for 5 days). For probiotic characterization, commercially available S. boulardii was subjected to in vitro acid tolerance testing at pH 2.0 for 2 hours, bile salt resistance at 0.3% concentration, antimicrobial activity by agar well diffusion method against Escherichia coli, Salmonella typhi, and Shigella flexneri, and adhesion assay using Caco-2 cell lines.

Clinical parameters recorded included duration of diarrhoea, stool frequency per 24 hours, time to rehydration, length of hospital stay, and recurrence within 14 days. Statistical analysis was performed using SPSS v26. Continuous variables were expressed as mean ± SD and compared using Student's t-test. Categorical variables were analyzed using chi-square test. A p-value <0.05 was considered statistically significant.

Results

Table 1 presents the baseline demographic and clinical profile of infants enrolled in the study comparing standard therapy (Group A) and standard therapy plus Saccharomyces boulardii supplementation (Group B).The mean age of participants was comparable between Group A (14.2 ± 5.1 months) and Group B (13.8 ± 4.8 months), with no statistically significant difference ($p = 0.62$). Gender distribution was also similar, with male predominance observed in both groups (52.5% in Group A and 55% in Group B; $p = 0.74$).Regarding clinical presentation, the proportion of infants presenting with moderate dehydration was nearly equivalent in both groups (41.2% vs 38.7%; $p = 0.71$). The mean baseline stool frequency per 24 hours was 6.8 ± 1.4 in Group A and 6.9 ± 1.6 in Group B ($p = 0.83$), indicating uniform severity of diarrhoeal illness at enrollment. Overall, there were no statistically significant differences in demographic or clinical parameters between the two groups at baseline, confirming appropriate randomization and ensuring that subsequent differences in clinical outcomes could be attributed to the probiotic intervention rather than confounding variables.

Table 1: Baseline Demographic and Clinical Characteristics

Parameter	Group A (n=80)	Group B (n=80)	p-value
Mean Age (months)	14.2 ± 5.1	13.8 ± 4.8	0.62
Male (%)	52.5%	55%	0.74
Moderate dehydration (%)	41.2%	38.7%	0.71
Mean Stool Frequency/day	6.8 ± 1.4	6.9 ± 1.6	0.83

Table 2 summarizes the in vitro probiotic characterization of Saccharomyces boulardii used in the study. The strain demonstrated strong acid tolerance with 87.3% survival at pH 2.0 after 2 hours of incubation, indicating its ability to withstand gastric acidity. It also showed substantial bile salt resistance, with 82.1% survival at 0.3% bile concentration, supporting its viability in the small intestine. Antimicrobial testing revealed measurable inhibitory zones against common enteropathogens, particularly Escherichia coli (14 ± 1.2 mm), confirming antagonistic activity. The adhesion assay demonstrated a 28% adherence index to Caco-2 intestinal epithelial cells, suggesting adequate colonization potential. Overall, the findings confirm that the tested strain fulfills key probiotic criteria, including gastrointestinal

survivability, pathogen inhibition, and epithelial adherence capacity.

Table 2: Probiotic Characterization of Saccharomyces boulardii

Test	Result
Acid tolerance (pH 2.0)	87.3% survival
Bile resistance (0.3%)	82.1% survival
Antimicrobial zone (E. coli)	14 ± 1.2 mm
Adhesion index	28% adherence

Table 3 demonstrates the comparative clinical outcomes between the standard therapy group (Group A) and the group receiving adjunctive Saccharomyces boulardii (Group B).A statistically significant reduction in the mean duration of diarrhoea was observed in Group B (48.6 ± 12.4 hours) compared to Group A (72.8 ± 16.1 hours), with $p < 0.001$. Stool frequency on Day 2 of treatment was markedly lower in the probiotic group (3.1 ± 1.0 episodes/day) than in the control group (5.2 ± 1.3 episodes/day), also highly significant ($p < 0.001$).Additionally, the mean duration of hospital stay was significantly shorter in Group B (2.9 ± 0.9 days) compared to Group A (4.1 ± 1.2 days), indicating faster clinical recovery ($p < 0.001$).Overall, Table 3 highlights the statistically and clinically meaningful benefit of probiotic supplementation in reducing disease severity and accelerating recovery in infantile diarrhoea.

Table 3: Clinical Outcomes

Parameter	Group A	Group B	p-value
Duration of diarrhoea (hours)	72.8 ± 16.1	48.6 ± 12.4	<0.001
Stool frequency Day 2	5.2 ± 1.3	3.1 ± 1.0	<0.001
Hospital stay (days)	4.1 ± 1.2	2.9 ± 0.9	<0.001

Table 4 outlines the comparison of recurrence rates and complication-related outcomes between the standard therapy group (Group A) and the adjunct probiotic group receiving Saccharomyces boulardii (Group B).The recurrence of diarrhoea within 14 days was significantly lower in Group B (6.3%) compared to Group A (18.8%), with statistical significance ($p = 0.02$). This finding suggests a protective effect of the probiotic in restoring gut microbial balance and preventing early relapse. Additionally, the requirement for antibiotic therapy during the course of illness was reduced in the probiotic group (10%) compared to the control group (21.3%), which was statistically significant ($p = 0.04$). This indicates a potential reduction in secondary bacterial complications and overall disease severity. Overall, Table 4 demonstrates that adjunctive Saccharomyces boulardii therapy not only improves acute recovery but also reduces recurrence and the need for additional medical interventions

.

Table 4: Recurrence and Complications

Outcome	Group A	Group B	P Value
Recurrence (14 days)	18.8%	6.3%	0.02
Antibiotic requirement	21.3%	10%	0.04

Figure 1 illustrates the comparative mean duration of diarrhoea between infants receiving standard therapy alone (Group A) and those treated with adjunctive Saccharomyces boulardii (Group B).The bar diagram clearly demonstrates a significantly shorter duration of diarrhoeal episodes in the probiotic group (48.6 hours) compared to the control group (72.8 hours). The difference of approximately 24 hours reflects a statistically highly significant improvement ($p < 0.001$).This graphical representation emphasizes the substantial clinical benefit of Saccharomyces boulardii supplementation in accelerating recovery from infantile diarrhoea.

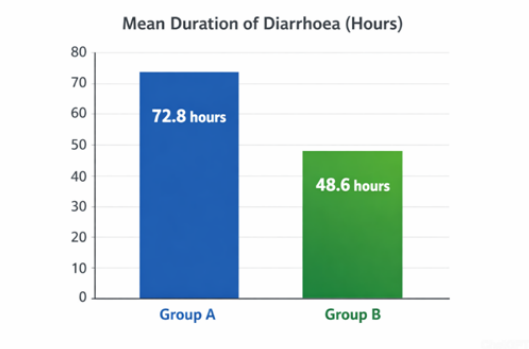

Figure 1: Mean Duration of Diarrhoea (Hours)

Discussion

The present study demonstrates significant probiotic potential and clinical efficacy of Saccharomyces boulardii in infantile diarrhoea. The yeast showed high survival under acidic and bile conditions, confirming its ability to withstand gastrointestinal transit, consistent with findings reported by McFarland [12]. Its antimicrobial activity against enteric pathogens supports previous experimental evidence indicating toxin-neutralizing and anti-inflammatory properties [6].

Clinically, the reduction in diarrhoeal duration by approximately 24 hours aligns with a large meta-analysis by Feizizadeh et al. [8], which reported a mean reduction of 1.1 days. Similarly, a Cochrane review demonstrated significant reduction in stool frequency and hospital stay with S. boulardii supplementation [9].

The recurrence rate reduction observed in our study corroborates findings from Surawicz et al. [10], who demonstrated prevention of recurrent diarrhoeal episodes. The mechanism may involve restoration of gut microbiota balance and stimulation of secretory IgA production [7].Unlike bacterial probiotics, S. boulardii is unaffected by antibiotics, making it particularly suitable in settings where empirical antimicrobial use is common. Our findings also align with studies conducted in South Asia showing improved recovery rates among pediatric populations [13].Regional validation is critical, as gut microbial composition varies geographically [11]. The significant outcomes observed in this Eastern Indian cohort suggest that S. boulardii retains efficacy despite environmental and nutritional variations. Overall, our study strengthens the growing body of evidence supporting Saccharomyces boulardii as an effective adjunct in acute infantile diarrhoea management.

Conclusion

Saccharomyces boulardii demonstrates strong probiotic characteristics and significantly reduces duration, severity, and recurrence of infantile diarrhoea. Its incorporation as adjunct therapy alongside ORS and zinc is recommended in tertiary care settings.

Reference

1. World Health Organization. Diarrhoeal disease. Geneva: World Health Organization; 2023.
2. Walker CLF, Rudan I, Liu L, Nair H, Theodoratou E, Bhutta ZA, et al. Global burden of childhood pneumonia and diarrhoea. Lancet. 2013;381(9875):1405–1416.
3. Hill C, Guarner F, Reid G, Gibson GR, Merenstein DJ, Pot B, et al. Expert consensus document: The International Scientific Association for Probiotics and Prebiotics consensus statement on the scope and appropriate use of the term probiotic. Nat Rev Gastroenterol Hepatol. 2014;11(8):506–514.
4. Food and Agriculture Organization of the United Nations; World Health Organization. Guidelines for the evaluation of probiotics in food. London, Ontario, Canada: FAO/WHO Working Group Report; 2002.
5. McFarland LV. Systematic review and meta-analysis of Saccharomyces boulardii in adult patients. World J Gastroenterol. 2010; 16(18): 2202–2222.
6. Czerucka D, Piche T, Rampal P. Review article: yeast as probiotics—Saccharomyces boulardii. Aliment Pharmacol Ther. 2007; 26(6): 767–778.
7. Buts JP, Bernasconi P, Vaerman JP, Dive C. Stimulation of secretory IgA and secretory component of immunoglobulins in small intestine of rats treated with Saccharomyces boulardii. Clin Diagn Lab Immunol. 2003;10(2):318–324.
8. Feizizadeh S, Salehi-Abargouei A, Akbari V. Efficacy and safety of Saccharomyces boulardii for acute diarrhea in children: a systematic review and meta-analysis. Pediatrics. 2014;134(1):e176–e191.
9. Szajewska H, Kołodziej M, Gieruszczak-Białek D, Skórka A, Ruszczyński M, Shamir R. Systematic review with meta-analysis: Saccharomyces boulardii in the prevention of

antibiotic-associated diarrhoea. Aliment Pharmacol Ther. 2015;42(7):793–801.
10. Surawicz CM, McFarland LV, Greenberg RN, Rubin M, Fekety R, Mulligan ME, et al. The search for a better treatment for recurrent Clostridium difficile disease: use of high-dose vancomycin combined with Saccharomyces boulardii. Clin Infect Dis. 2000;31(4):1012–1017.
11. Yatsunenko T, Rey FE, Manary MJ, Trehan I, Dominguez-Bello MG, Contreras M, et al. Human gut microbiome viewed across age and geography. Nature. 2012;486(7402):222–227.
12. McFarland LV. Meta-analysis of probiotics for the prevention of antibiotic-associated diarrhea. Am J Gastroenterol. 2006;101(4):812–822.
13. Dinleyici EC, Eren M, Ozen M, Yargic ZA, Vandenplas Y. Effectiveness and safety of Saccharomyces boulardii for acute infectious diarrhea. J Pediatr Gastroenterol Nutr. 2015;60(3):410–415.