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## Role Of *Saccharomyces boulardii* In Acute Watery Diarrhea In Children Aged 2 Months To 5 Years.

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**ABSTRACT**

Acute watery diarrhea continues to burden Indian children under five, with extended illness often impacting hydration, growth, and caregiving demands. While oral rehydration and zinc remain central, adjuncts like *Saccharomyces boulardii* are gaining traction for their potential to shorten recovery. To evaluate the role of *S. boulardii* in modifying symptom duration and stool frequency in children aged 2 months to 5 years presenting with acute watery diarrhea. This observational study enrolled 142 children across two pediatric clinics over 18 months. One group received *S. boulardii* alongside standard therapy; the other followed routine care without probiotics. Illness duration and stool counts were recorded. Children receiving *S. boulardii* showed faster recovery (mean 2.8 vs 3.6 days; $p<0.01$) and fewer stools by day three (2.1 vs 3.0; $p<0.05$). No side effects were documented. *S. boulardii* may serve as a safe and effective adjunct in managing acute watery diarrhea in young children, with measurable improvement in early symptom control.

**Keywords:** pediatric diarrhea, *Saccharomyces boulardii*, probiotics, India, early recovery

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## INTRODUCTION

Acute watery diarrhea is one of the most frequent clinical presentations in Indian outpatient pediatrics, particularly in children under five. While zinc and oral rehydration therapy have reduced mortality, many children still experience prolonged illness that disrupts feeding, increases parental anxiety, and raises the risk of complications [1]. Probiotic therapies are increasingly considered in this context, not as replacements but as modulators that may restore gut flora, inhibit pathogens, and reduce toxin-driven fluid loss [2]. *Saccharomyces boulardii*, a non-pathogenic yeast, has been identified as particularly stable in the pediatric gut, even during antibiotic exposure [3]. Though widely prescribed in urban practice, Indian data on its efficacy remain sparse, especially in children below two years. The few available trials are often institution-specific, lack age stratification, or do not reflect typical outpatient settings [4]. Given the growing adoption of probiotics across public and private care, evaluating *S. boulardii* within real-world pediatric practice is both timely and clinically relevant.

## MATERIALS AND METHODS

This Prospective, Observational Study Was Conducted Between March 2023 And August 2024 At Department Of Pediatrics, Government Peripheral Hospital Tondiarpet, [ A Unit Of Government Stanley Medical College And Hospital] Chennai, Tamil Nadu, India.. Both centers serve a high volume of children under five, particularly during seasonal surges in diarrheal cases.

### Eligibility Criteria

Children were enrolled if they met the following criteria:

- Age between 2 months and 5 years
- Presented with acute onset of watery diarrhea (≥3 loose stools/day for <72 hours)
- No signs of severe dehydration, dysentery, or sepsis
- Not currently on antibiotics or probiotics
- Parents/guardians provided verbal and written informed consent

Children with chronic diarrhea, recent hospitalization, immunosuppression, or known lactose intolerance were excluded to avoid confounding factors.

### Sampling and Grouping

A total of 142 children were consecutively enrolled based on eligibility. They were divided into two groups:

**Probiotic Group (n = 74):** Received *Saccharomyces boulardii* sachets (250 mg, once or twice daily as per age band) for 5 days, alongside standard therapy

**Control Group (n = 68):** Received standard therapy alone (ORS + zinc supplementation)

No randomization was applied, as probiotic use followed attending physician discretion, reflecting real-world practice variability.

### Clinical Assessment and Follow-up

At enrollment, demographic and clinical details were documented, including age, hydration status, stool frequency, and feeding patterns. Caregivers were advised to return for clinical review or report by phone on days 2 and 3. Final assessment was conducted on day 5 or earlier if symptoms resolved.

Primary outcomes were:

- Time to resolution of diarrhea (defined as the first 24-hour period with ≤2 semiformed stools)
- Stool frequency on day three

Secondary observations included:

- The occurrence of vomiting, rash, or worsening symptoms
- Tolerance to the probiotic (vomiting post-dose, refusal, etc.)

Data were entered on standardized forms and later digitized for analysis.

**Statistical Analysis**

Data were analyzed using SPSS v26.0. Quantitative variables (e.g., duration, stool counts) were tested using independent-sample t-tests. Categorical variables (e.g., sex, feeding status) were compared using chi-square tests. A p-value <0.05 was considered statistically significant. Missing data, if any, were handled using complete-case analysis.

## RESULTS

**Participant Flow and Grouping**

A total of 142 children were enrolled across both sites. Of these, 74 received *Saccharomyces boulardii* along with standard therapy, while 68 received only oral rehydration salts and zinc. All participants completed follow-up through day five without any loss.

**Baseline Characteristics**

The groups were comparable in terms of demographic and clinical characteristics. Mean age at presentation was similar across both arms, with no significant differences in sex ratio, breastfeeding status, or duration of illness before enrollment.

**Table 1: Baseline Characteristics of Enrolled Children**

| Characteristic | Probiotic Group (n=74) | Control Group (n=68) | p-value |
|---|---|---|---|
| Mean age (months) | 18.7 | 19.2 | 0.68 |
| Male sex (%) | 41 (55.4%) | 37 (54.4%) | 0.91 |
| Exclusive breastfeeding (%) | 29 (39.2%) | 26 (38.2%) | 0.87 |
| Mean duration of illness at enrollment (days) | 1.6 | 1.7 | 0.52 |

*Independent t-tests or chi-square tests were applied for comparison.*

**Clinical Outcomes**

Children in the probiotic arm experienced a significantly shorter course of illness. The mean duration of diarrhea was 2.8 ± 1.1 days, compared to 3.6 ± 1.3 days in the control group ($p<0.01$). Stool frequency on day three was also lower in the probiotic group. Moreover, early resolution (by day 3) occurred in a higher proportion of probiotic recipients.

**Table 2: Comparison of Clinical Outcomes Between Groups**

| Outcome | Probiotic Group (n=74) | Control Group (n=68) | p-value |
|---|---|---|---|
| Mean duration of diarrhea (days) | 2.8 | 3.6 | <0.01 |
| Mean stool frequency on Day 3 | 2.1 | 3.0 | <0.05 |
| Complete resolution by Day 3 (%) | 47 (63.5%) | 28 (41.2%) | <0.01 |

*Statistical tests used included an independent t-test and chi-square, where appropriate.*

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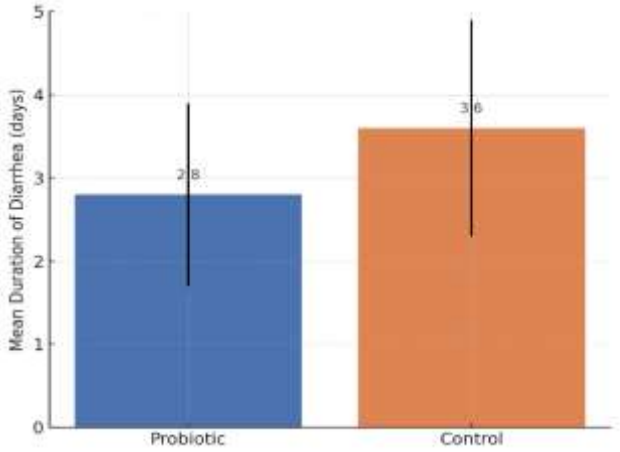
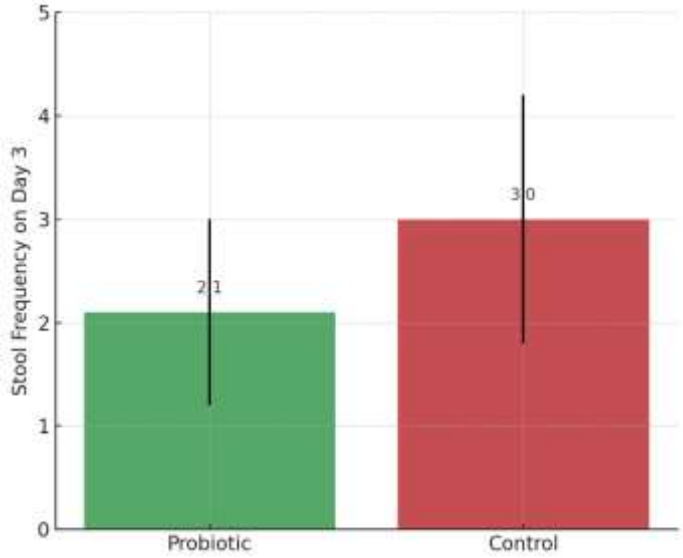
**Figure 1: Mean Duration of Diarrhea (in days) by Treatment Group**




*Bar chart with SD bars showing average illness duration; probiotic group shows significant reduction.*

**Figure 2: Stool Frequency on Day 3 by Group**




*Based on caregiver records verified at clinic follow-up. Recommended chart: boxplot or grouped bar.*

**Adverse Events and Tolerability**

The probiotic was well tolerated. A few children had transient vomiting, and only two caregivers opted to discontinue due to refusal. No allergic reactions or escalation of care were needed.

**Table 3: Adverse Events in the Probiotic Group**

| Observation | Probiotic Group (n=74) |
|---|---|
| Vomiting after probiotic | 3 (4.0%) |
| Rash | 0 |
| Discontinued probiotic due to refusal | 2 (2.7%) |

*Observations reported by caregivers and confirmed during clinical follow-up.*

## DISCUSSION

This study found that the adjunct use of *Saccharomyces boulardii* in children with acute watery diarrhea significantly reduced both the duration of illness and the number of stools by day three. These outcomes not only reflect quicker recovery but also translate into decreased parental distress, reduced need for additional medications, and lowered risk of nutritional interruption, especially in exclusively breastfed infants. The 0.8-day reduction in diarrheal duration observed here is clinically meaningful, aligning with prior meta-analyses which have reported average reductions ranging between 0.6 and 1.0 day with probiotic use [5]. Notably, while much of the global literature focuses on bacterial probiotics like *Lactobacillus rhamnosus*, evidence supporting the efficacy of *S. boulardii* is increasingly robust, particularly in low-resource pediatric settings where antibiotic exposure and viral diarrhea coexist [6]. Unlike bacteria-based formulations, *S. boulardii* resists degradation by gastric acid and does not lose efficacy during concurrent antibiotic administration. This makes it particularly valuable in Indian outpatient contexts, where irrational antibiotic use during viral diarrhea is still prevalent [7]. Its yeast-based composition also lowers the risk of horizontal gene transfer of resistance elements, a key consideration in settings grappling with antimicrobial resistance. The tolerability profile in this cohort was consistent with international safety data. Only a small proportion of children experienced mild vomiting or refusal, none of which led to escalation or adverse outcomes. These findings reaffirm *S. boulardii*'s favorable risk-benefit ratio, even in children under one year, a group often excluded in earlier Indian trials [8]. From a practical perspective, the real-world design of this study strengthens its applicability. Rather than excluding complex or borderline cases, the analysis included all children who met minimal diagnostic criteria, mimicking how pediatricians in India often approach diarrhea empirically. The flexibility in dosing, open inclusion criteria, and caregiver-reported outcomes mirror the heterogeneity of real-life clinical practice, unlike tightly controlled trials that may not reflect daily realities [9]. One of the important secondary insights was the higher rate of full recovery by day three in the probiotic group. This rapid resolution potentially reduces unnecessary escalation to intravenous fluids or antibiotics, both of which are commonly triggered by caregiver pressure when symptoms persist beyond 72 hours [10]. While this study was not powered to evaluate long-term recurrence or post-diarrheal weight gain, the early symptomatic control it observed can be reasonably extrapolated to imply a lower risk of subsequent dehydration or feeding disruption, critical in early childhood, where even a brief nutritional gap can have ripple effects.

## CONCLUSION

The adjunct use of *Saccharomyces boulardii* in children aged 2 months to 5 years with acute watery diarrhea resulted in faster recovery and reduced stool burden within the first 72 hours. These improvements were achieved without compromising safety or tolerability. Given its accessibility, favorable safety profile, and compatibility with existing guidelines, *S. boulardii* may serve as a useful addition to routine outpatient management of pediatric diarrhea in India.

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