

## Efficacy of *Saccharomyces Boulardii* in the Treatment of Acute Diarrhea

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### Abstract

**Objective:** To evaluate efficacy of *Saccharomyces boulardii* in infantile diarrhea.

**Material and Methods:** It was a comparative cross-sectional study conducted in Children Hospital Lahore. The duration of this study was of four months. 70 infants suffering from acute diarrhea were divided randomly into study group and control group. The control group was given standard treatment of diarrhea while study group also received *Saccharomyces boulardii* for five days in addition to standard treatment. Both groups were monitored for five days. Frequency of diarrhea was monitored in both groups for five days.

**Results:** There was reduction in frequency of diarrhea in study group. *Saccharomyces boulardii* significantly decreased the stool output in study group.

**Keywords:** Diarrhea, Infants, *Saccharomyces Boulardii*

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### Introduction

Diarrhea is the significant health problem throughout the world. It is the significant cause of mortality in infants and in children below 5 years of age, approximately 2195 children die each day due to diarrhea. This shows 8% of all mortality and is second important reason of mortality in children below five years of age.<sup>1</sup> Pakistan has been ranked 23 by The World Health Organization (WHO) due to mortality in childhood caused by diarrhea and records showing 6.4 million diarrheal cases in pediatric population each year.<sup>2</sup> The common disorder of gastrointestinal tract is the acute diarrhea as it is important reason for dehydration in young children. In acute diarrhea, the

individual passes three or more loose and watery stools each day for seven to ten days but not more than fourteen days. Acute diarrhea most commonly occurs in children below five years of age.<sup>3</sup> Rotavirus and *Escherichia coli* are important causative agents of diarrhea in developing nations whereas *Campylobacter* spp. is the significant cause of diarrhea in developed countries.<sup>4</sup> Globally, significant mortality linked with diarrhea is due to drinking of unsafe water besides other reasons. The ratio of hospitalization and deaths due to diarrhea is greater in people having poor social background and also in cases of unhygienic conditions.<sup>2</sup> The WHO recommends the use of oral rehydration solutions (ORS) as well as zinc supplements in the treatment of diarrhea. Intravenous solution (IV) should be administered if the patient shows severe dehydration.<sup>5</sup> The addition of probiotics can reduce the duration of diarrheal illness and days of hospital stay in the management of acute diarrhea. However, further good quality RCT studies in hospital settings are required to verify the results.<sup>6</sup> Probiotics are the products made of food or supplements which contain beneficial microorganisms like yeast and bacteria. They colonize the gastrointestinal tract and can provide health benefits to the host.<sup>7</sup> *Saccharomyces*

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boulardii belongs to the yeast family and it has proved immune modulating activities in the gastrointestinal tract. There is not enough data from the developing countries on the role of S.boulardii in the management of diarrhea.<sup>8</sup> This trial was conducted to evaluate efficacy of S.boulardii in infantile diarrhea.

Material and Methods

It was a comparative cross-sectional study. The study was done in tertiary care, Children Hospital Lahore. The clinical study was approved by Ethical Committee Ref: 01/159/16 Dated: 11-072016 of Children Hospital Lahore. The duration of this study was of four months. The study was conducted from July 2016 to October 2016. The age of the infants in this study was from 6 months to 1 year. The infants were enrolled in the study after taking proper consent from parents. Non probability purposive sampling was used as sampling technique in the study. In this study, inclusion criteria were infants from 6 months to 1 year suffering from acute diarrhea having mild, moderate and severe dehydration. The exclusion criteria were infants suffering from malnutrition, chronic diarrhea, typhoid fever, dysentery and other co-morbid conditions. According to WHO, “acute diarrhea is defined as the passage of three or more loose stools per day, lasting less than 14 days”. The infants enrolled in the study were divided into two groups, study group and control group. The sample size was calculated having 5% level of significance and 90% power of study with help of previous published study<sup>9</sup>. According to that study sample size should be 15 in each group. In our study, we have enrolled 35 infants in each group. 70 infants suffering from acute diarrhea were enrolled in this clinical trial. They were divided into study group and control group having 35 infants in control group and 35 infants in study group. Standard treatment of diarrhea was given to infants of control group. Standard treatment included ORS, Zn supplements and IV fluids in case of moderate to severe dehydration. S.boulardii was given to infants of study group in addition to standard treatment. S.boulardii was in capsule form and its contents were mixed with water for feeding. The dose of S.boulardii was 250 mg and it was given twice daily for five days. We monitored the infants for 5 days. Primary parameter of the study was frequency

of diarrhea or number of stools per day. Episodes of vomiting and duration of fever were the secondary parameters. Infant was said to be recovered if he or she passed less than three stools per day and consistency of the stool also improved.

The data of the trial was processed by SPSS 20. Quantitative variables like number of stools were presented as mean and SD. ANOVA was used for analyzing significance among control group and study group. To compare pairwise among the groups, post hoc Tukey test was used. For qualitative variables, chi square test was applied. P value less than 0.05 was significant.

Results

The number of infants in the study were 70 having 35 infants in each group. The mean age of infants in the control group was 8.64 ± 2.37 months and the mean age of infants in the study group was 9.3 ± 2.4 months. The mean weight of infants in the control group was 7.4 ± 0.93 and the mean weight of infants in the study group was 7.67 ± 0.85. All the infants were given IV fluids as they were showing signs of moderate to severe dehydration.

Table 1 shows the frequency of diarrhea in both groups. It shows mean no. of stools ± SD of study group and control group. There was reduction in number of stools per day in study group. There was significant difference among the groups with p-value less than 0.05. Reduction in frequency of diarrhea was observed in study group. Table 2 shows mean temperature ± SD of control group and study group. Significant difference was observed among means of both groups at day 2 having p-value less than 0.05. Infants in control group had high fever than infants in study group at day 2. Table 3 shows episodes of vomiting in control group and study group. No significant difference was observed among control group and study group in terms of vomiting.

Table 1: Frequency of stools in study group and control group

Group	Day 1	Day 2	Day 3	Day 4	Day 5
Control group	10.89 ± 2.94	9.17 ± 2.93	7.46 ± 3.16	6.26 ± 3.00	4.63 ± 2.50
Study group (S.boulardii)	9.46 ± 3.11	6.71 ± 3.19	4.74 ± 2.95	3.77 ± 2.64	2.63 ± 1.97
P-value	0.128	0.003	0.001	0.001	0.001

**Table 2:** Frequency of stools in study group and control group

Group	Day 1	Day 2	Day 3	Day 4	Day 5
Control group	99.55 ± 1.10	99.38 ± 0.80	98.76 ± 0.45	98.64 ± 0.24	98.64 ± 0.24
Study group (S.boulardii)	99.20 ± 0.77	98.95 ± 0.67	98.85 ± 0.82	98.75 ± 0.62	98.65 ± 0.24
P-value	0.08	0.023	0.31	0.19	0.52

**Table 3:** Episodes of vomiting in study group and control group

Group	Day 1	Day 2	Day 3	Day 4	Day 5
Control group	1.94 ± 1.43	0.86 ± 1.06	0.46 ± 0.78	0.14 ± 0.69	0.06 ± 0.23
Study group (S.boulardii)	2.40 ± 1.61	1.23 ± 1.35	0.66 ± 1.21	0.31 ± 0.83	0.17 ± 0.51
P-value	0.464	0.31	0.074	0.251	0.087

## Discussion

Diarrhea is the significant cause of infant mortality, almost 1.3 million children below five years of age are affected every year due to diarrhea. Diarrhea in childhood affect more children below five years of age than measles, malaria or acquired immunodeficiency syndrome.<sup>10</sup> The major complication of diarrhea in infants and young children is dehydration. According to recommendation of WHO, oral rehydration should be done to replace electrolytes and fluids in children suffering from mild to moderate dehydration. For rehydration, oral rehydration solutions (ORS) are available. IV fluids should be administered if the child is suffering from severe dehydration. WHO also recommends Zn supplements in children suffering from gastroenteritis.<sup>11</sup> Probiotics are microorganisms providing benefit to host by making colonies in the human body. They cause growth of good bacteria and improve the immune system of the host. Several researches have explored efficacy of probiotics regarding diarrhea but good quality trials are required in clinical settings for verification of results.<sup>12</sup> *Saccharomyces boulardii* is known as a yeast probiotic. It is used for management of disorders of gastrointestinal tract. It can be used as a probiotic due to its properties like resistance to acidic medium, optimal growth temperature and its viability at low pH.<sup>13</sup>

In this study, infants of control group and study group were given standard management of acute diarrhea. ORS and Zn supplements were given to infants of both groups. All the infants enrolled in the study had

moderate to severe dehydration. To prevent dehydration, they were given IV fluids. Infants of study group were also given *S.boulardii* 250 mg twice daily for five days. There was reduction in frequency of diarrhea in study group. Result was significant from day 2 to day 5. The infants were observed for five days. *S.boulardii* reduced the frequency of diarrhea in study group. No difference was observed regarding episodes of vomiting per day between the groups. Temperature of infants were monitored in both groups for five days. Significant difference was observed at day 2 among the control group and study group. Infants in control group had high fever at day 2 than infants of study group. Previous study conducted in Iran demonstrated the ability of *S.boulardii* to decrease the duration of diarrhea in children of age 2 to 5 years, however *S.boulardii* had no effect on days of hospital stay.<sup>14</sup> Another study was conducted in India for observing effect of *S.boulardii* in acute diarrhea in children of age 3 months to 5 years. Duration of diarrhea was decreased in children who received *S.boulardii*, however there was no impact on duration of fever and vomiting in study group.<sup>8</sup> In one clinical study conducted in Pakistan for evaluating effect of this probiotic in acute diarrhea in children of age 2 months to 5 years showed positive response of this probiotic in decreasing the frequency of diarrhea.<sup>15</sup>

In our study, *S.boulardii* decreased the frequency of diarrhea but there is no impact of *S.boulardii* on vomiting. There was positive response of *S.boulardii* in terms of fever as fever was higher in infants of control group at day 2 than infants of study group. The reduction in frequency of diarrhea is probably related to the mechanism of action of probiotics like decrease in permeability of barrier of intestine, increase in synthesis of short-chain fatty acids in colonocytes or decrease in the number of invading microorganisms.<sup>16</sup>

## Conclusion

*S. boulardi* helped to decrease the frequency of acute infantile diarrhea.

## Conflict of Interest

None

## Funding Source

None

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## Authors Contribution

**FAK:** Conceptualization of Project

**MZK:** Data Collection

**AEZ:** Literature Search

**SJ:** Statistical Analysis

**SM:** Drafting, Revision

**FP:** Writing of Manuscript