

# Effect of Oral *Saccharomyces Boulardii* Supplementation on the Duration of Acute Watery Diarrhea in Children

ASIF JAVEED<sup>1</sup>, SAIMA MANZOOR<sup>2</sup>, SABA WAMIQ<sup>3</sup>

## ABSTRACT

**Aim:** To compare the mean duration of acute watery diarrhea in hospitalized children, 6 months to 5 years of age, with moderate dehydration and normal nutritional status managed with and without *Saccharomyces boulardii*.

**Study Design:** Randomized controlled trial.

**Duration of study:** Study was conducted for a period of 6 months from January 2017 to June 2017

**Place of study:** Multan Medical and Dental College/Ibn-e-Seina Hospital & Research Institute Multan.

**Methods:** A total of 314 children 6 months to 5 years of age with acute watery diarrhea were hospitalized and included in the study. Patient was divided randomly into two groups (A and B) by Draws method. Two draws were made, one for group A and other for group B..

One hundred and fifty seven patients were included in each group. Patients included in group A were given oral *saccharomyces houlardii* supplementation and the patients in group B were not given oral *saccharomyces boulardii*.

**Results:** Mean duration of illness was 4.37+0.11 days in patients of group A (who were given *saccharomyces boulardii* supplementation), while in group B (who were not given *Saccharomyces Boulardii*), mean duration of illness was 4.59+.12 days. All the patients recovered, no death occurred.

**Conclusion:** According to my study, oral *saccharomyces boulatdii* has significant role in reducing the duration of acute watery diarrhea.

**Key words:** Oral *Saccharomyces Boulardii*, duration of illness, acute watery diarrhea, ORS, Mortality,

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## INTRODUCTION

Acute diarrhea remains one of the leading killers of young children, causing > 700 million episodes of illness and 1.8 million deaths annually worldwide in children below 5 years of age<sup>1</sup>. Diarrhea is also a common cause of hospital admission in Pakistan. On average, every child gets 5-6 episodes of diarrhea per year and over 200,000 children die every year in Pakistan<sup>2</sup>.

The use of oral rehydration salt (ORS) in acute diarrhea in children has reduced the mortality associated with it, however severity and duration remains unaffected<sup>3</sup>.

Different probiotic strains are being used as prophylactic and therapeutic management of acute watery diarrhea in children. Among those, *Saccharomyces boulardii*, *Lactobacillus GG* and *Bifidobacterium* are more important<sup>4</sup>. These probiotics are living micro-organisms (bacteria and yeast) resistant to digestion and reaching the colon alive and when ingested in adequate amount, have a health benefit for host<sup>5</sup>. These friendly micro-

organisms enhance the brush border enzyme expression, neutralize the bacterial toxins and enhance the cell ability to restore the intestinal permeability<sup>6</sup>.

Among different probiotics used now-a-days, 250mg BID of *Saccharomyces boulardii* for 5 days is most effective and duration of illness<sup>2</sup>. It is non-pathogenic yeast first isolated from lychee fruit in Indonesia and used first in France to treat diarrhea, in the beginning of 1950. It reduces the frequency of stools and duration of illness<sup>2</sup>.

In one study conducted by Galliano zanella et al Institute National de la Recherche Agronomique, France, *Saccharomyces boulardii* treatment for 5 days reduced the mean duration of disease (3.07+1.5 vs. 4.08+2.04 days in placebo group), the frequency of stools (on day 2: 54% in placebo group) and normalized stool consistency (on day 3: 76% vs. 24% in placebo group)<sup>6</sup>.

In another study the mean duration of diarrhea was 3.08 days in *S. boulardii* group with population no of 48(96%) out of 50(P< 0/05)<sup>7</sup> and by Kurugöl Z, Koturoğlu G. Duration of diarrhea significantly reduced in the *S. boulardii* group compared with the placebo group (4.7+2.5 vs. 5.5+3.2d, p = 0.03)<sup>8</sup>.

As there are many studies performed in different countries with different results, so we decided to conduct a study in our setup to see the results locally,

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<sup>1</sup>Assistant Professor Paediatric Medicine

<sup>2</sup>Associate Professor Paediatric Medicine

<sup>3</sup>Senior Registrar Paediatrics Medicine, Multan Medical & Dental College, Multan

Correspondence to Dr. Asif Javeed

Email: sheheryar.sial@gmail.com

in terms of shortening the duration of diarrhea. It will reduce the hospital stay which result social and economic benefits for the patients as well as for health department.

## METHODOLOGY

A total of 314 children 6 months to 5 years of age with acute watery diarrhea were hospitalized and included in the study. Patient was divided randomly into two groups (A and B) by Draws method. Two draws were made, one for group A and other for group B. Each patient was asked to pick one draw and patient was included in that group (A or B).

One hundred and fifty seven patients were included in each group. Patients included in group A were given oral *sachharomyces houlardii* supplementation and the patients in group B were not given oral *sachharomyces boulardii*. Both the groups were given similar hospital treatment for acute watery diarrhea including oral rehydration solution and intravenous fluids.

Patient were followed daily for the number of stools passed by the child. Duration of illness was analyzed for both groups. Approval from institutional ethical committee was taken. Informed consent from parents or attendants was taken. Children reporting to Pediatric Unit-II with acute watery diarrhea were registered. Children meeting the inclusion criteria, stated above, were included in the study. The basic demographic information including name, age, sex and address was recorded.

Children enrolled in the study were divided into two groups; study and control, randomly by using opaque envelopes containing group assignment based on which group children were assigned to each group. Oral *Saccharomyces boulardii* 250mg BID for 5 days were given only to the children in the study group. Same hospital treatment was given to the children in both groups. This was included oral rehydration fluids on admission and intravenous fluids if severe dehydration develops. Ciprofloxacin was given in children with bacterial infection (high fever and/or presence of blood or pus on stool examination). Outcome was measured as duration of diarrhea ( number of days with 3 or more watery stool) for five days the observer. The findings were noted in Performa attached at the end of 5<sup>th</sup> day.

## RESULTS

In present study, 157 patients of acute watery diarrhea were randomizing to two groups, of 157 each. Group B was treated without *Saccaromyces boulardii* supplementation. Means age of patients was 12.26+1.92 months in group A and 18.26 + 2.58

months in group B respectively (Table 1). There were 100(63.69%) patients in group A and 90(57.32%) cases in group B of the age of 6-30 months while 57(36.30%) in group A and 67(42.67%) children in group B were between 31-60 months respectively as show in table 2.

Gender distribution of the children revealed that there were 80(50.9%) vs 70(44.58%) male in group A and B respectively while female were 77(49%) versus 87(55.42%) in group A and B respectively (Table 3).

There was no difference in days of illness before hospitalization between the groups. Mean duration since diarrhea was 1.58+0.01 days in group A and B respectively. 89.17% children in both groups had 1-2 days illness before hospitalization between the groups (Table 4).

Almost equal no of children in group A and B 15(14%) versus 20(14%) had 3-4 stools per day at admission. There were 90(53.4%) children in group A and 85 (60.4%) children in group B had 5-6 stools per day at admission and 52(32.6%) children in group A versus 52(25.6%) children in group B had 7-8 stools per day at admission (Table 5).

Duration of acute watery diarrhea was 3-4 days in 90(57.33%) children in group A and 72(45.86%) children in group B after treatment. While after treatment , there were 67(42.67%) children in group A and 85 (54.14%) children in group B had 5-6 days duration of acute watery diarrhea, table no. XIV. Mean duration of acute watery diarrhea was 4.3+ 0.11 versus 4.59+ 0.12 days respectively in group A group B (Table 6).

While comparing the groups for significance, there was a difference of 22 hours found between the duration of acute watery diarrhea between the two groups ( $p < 0.05$ ).

Table 1: Age distribution of the patients with acute watery diarrhea

Age (months)	Group A	Group B
6-30	100(63.69%)	90(57.32%)
31-60	57(36.30%)	67(42.67%)
Total	157(100%)	157(100.0%)

**Note:** Age is rounded to the nearest year.

Table 2: Gender Distribution of the Patients with Acute Watery Diarrhea

Gender	Group A	Group B
Male	80(50.9%)	70(44.58%)
Female	77(49.0%)	87(55.41%)
Total	157(100%)	157(100%)

Table 3: Days of illness of the Patients with Acute Watery Diarrhea before Hospitalization

Days	Group A	Group B
1-2	140(89.17%)	140(89.17%)
3-4	17(10.82%)	17(10.82%)
Total	157(100%)	157(100.0%)

Table 4: Stools per day at Admission in Patients with Acute Watery Diarrhea

Stools/Day	Group A	Group B
3-4	15(14.0%)	20(14.0%)
5-6	90(53.4%)	85(60.4%)
7-8	52(32.6%)	52(25.6%)
Total	157(100%)	157(100.0%)

Table 5: Duration of Acute Watery Diarrhea after Treatment

Days	Group A	Group B
3-4	90(57.33%)	72(45.86%)
5-6	67(42.67%)	85(54.14%)
Total	157(100%)	157(100%)

Table 6: Descriptive Statistics

Variable	Mean+SEM in Group A	Mean+SEM in Group B
Age (months)	12.26+1.92	18.26+2.58
Duration since diarrhea (days)	1.58+0.01	1.58+0.01
Duration of acute watery diarrhea (days)	4.37+0.11	4.59+0.12

SEM= Standard error of means.

## DISCUSSION

This study shows oral *saccharomyces boulardii* supplementation has effect on the duration of acute watery diarrhea in children. A total of 314 patients were studied which were divided in two groups, A and B. *Sachharomyces boulardii* supplementation was given to the children in group A only. All the patients in group A and B were comparable with respect to age, nutritional status, severity of symptoms, investigations and rehydration fluid given.

There was a difference of approximately one day (22 Hours) in both groups regarding mean duration of illness, mean duration of hospital stay and mean duration of intravenous fluids given.

Many studies done in different countries of world showed that oral *saccharomyces Boulardii* supplementation has a role on the duration of acute watery diarrhea in children.

Since the 1980s, several series, open prospective studies, and randomized controlled trails have evaluated the efficacy of *Saccharomyces boulardii* in the treatment of acute watery diarrhea associated with gastroenteritis in children. In 2007, Szajewaska and colleagues conducted a meta-analysis of the result from five studies comparing *Saccharomyces boulardii* to placebo or no intervention. A total of 619 children were enrolled in these trials, with *Saccharomyces boulardii* supplementation dose of 250-600 mg per day or placebo given for 4-6 days. Four studies included the

duration of diarrhea as an outcome, with all demonstrating a significant reduction with treatment. The combined data from these studies provided a pooled weighted mean difference of 1.1 days (95% CI:- 1.3 to -0.8).

Single study used in this analysis also documented a reduction in the risk of diarrhea lasting more than 7 days, as well as, reduction in length of hospital stay. The authors concluded that the treatment with *Saccharomyces Boulardii* had a moderate clinical benefit in the treatment of acute diarrhea in otherwise healthy children<sup>9</sup>.

## CONCLUSION

On the basis present study, it is concluded that oral *Saccharomyces Boulardii* supplementation has moderate effect on duration of acute watery diarrhea in children. A re-examination of all available trial results, including this trial, is needed to dissect out the potential contributors to the heterogeneity of trial results before *Sachharomyces Boulardii* can be universally recommended for the treatment of acute watery diarrhea in children.

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