

Original Research Article

## **Safety and Efficacy of *Saccharomyces Boulardii* in Acute Adult Diarrhea**

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**Abstract:** Probiotics are defined as “live micro-organisms that confer a health benefits on the host when administered in adequate amounts.” The only yeast, *saccharomyces boulardii* is used in many countries as both preventive and therapeutic agent for diarrhea and other gastrointestinal disorders. This study was planned to demonstrate clinical efficacy and safety of *Saccharomyces boulardii* in acute adult diarrhea. This is a retrospective study conducted at Department of General Medicine of a tertiary care centre. All adult patients (age >18 years) who presented with diarrhea of less than 2 weeks duration were evaluated for possible inclusion in this study. In *S. boulardii* group, patients were managed by WHO-CDD protocol for diarrhea plus *S. boulardii* (250 mg bid) for 5 days. In the control group patients were managed by WHO-CDD protocol only. The target criteria were the changes in the frequency of stools over the preceding 24 hours and its consistency. At the two check-up, patients were asked about any side-effects, tolerability and general well being. Under *S. boulardii* group, patients had significant reduction in the score for stool frequency and stool quality than control group after two days treatment. In secondary variables, significant advantage of *S. boulardii* over control: improvement in nausea and positive assessment of treatment by patients on day 3. No severe side effects were observed in any patient and the tolerance of the active medication was described by both doctor and patient as very good or good. *S. boulardii* has been used as probiotic since last 6 decades, and it has been investigated in several clinical trials worldwide. *S. boulardii* is significantly effective for the prevention of acute adult diarrhea.

**Keywords:** Probiotic, diarrhea, *sacchromyces*.

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### **INTRODUCTION**

Probiotics are defined as “live micro-organisms that confer a health benefits on the host when administered in adequate amounts.” The only yeast, *saccharomyces boulardii* is used in many countries as both preventive and therapeutic agent for diarrhea and other gastrointestinal disorders [1]. *S. boulardii* is a tropical strain of yeast first isolated from lychee and mangosteen fruit in 1923 by French scientist Henri Boulard. He first isolated the yeast after he observed natives of Southeast Asia chewing the skin of lychee and mangosteen in an attempt to control the symptoms of cholera. *S. boulardii* has been shown to be non-pathogenic, non-systemic (it remains in the gastrointestinal tract rather than spreading elsewhere in the body), and grows at the unusually high temperature of 37°C. *S. boulardii* has several different types of

mechanisms of action which may be classified into three main areas: Luminal action, trophic action and mucosal anti-inflammatory effects. *S. boulardii* has antitoxin effects (inhibit toxins of *Clostridium difficile*, enteropathogenic *E. coli*, Cholera), inhibits growth of pathogens (*Candida albicans*, *Salmonella typhimurum*, *Yersinia enterocolitum*, *Aeromonashemolysin*) and maintain epithelial integrity by preventing distribution of adhesive proteins between intestinal epithelium. *S. boulardii* exerts trophic effects restoring the intestinal homeostasis. *S. boulardii* also interferes with the host cell signaling pathways and decreases the expression of inflammation-associated cytokines such as IL-8, TNF- $\alpha$ . *S. boulardii* also exerts prebiotic effects as its cell wall consists of glucans, mannoproteins and chitins, which serve as excellent substrates for microbial fermentation.

Acute adult diarrhea is a broad classification for diarrhea that includes illnesses that may develop quickly, but are typically short lived and sporadic. The etiologies of acute adult diarrhea may include infectious agents (Bacteria, viruses or amoeba) or may be idiopathic. This study was planned to demonstrate clinical efficacy and safety of *Saccharomyces boulardii* in acute adult diarrhea.

### MATERIALS & METHODS

**Study Design:** This is a retrospective study.

**Study Setup:** This study is conducted at Department of General Medicine of a tertiary care centre.

**Study Duration:** The duration of study was two years; November-2014 to October-2016.

**Sampling:** Purposive sampling technique is used for selection of desired samples according to inclusion criterion.

**Inclusion criteria:** All adult patients (age >18 years) who presented with diarrhea of less than 2 weeks duration were evaluated for possible inclusion in this study.

We retrospectively evaluated case files of all adult patients of eithersex who admitted in hospital with diarrhea in last two years. We have divided study population in two groups; In *S. boulardii* group, patients were managed by WHO-CDD protocol for diarrhea [2] plus *S. boulardii* (250 mg bid) administered orally either in liquid form or capsule form for 5 days. In the control group patients were managed by WHO-CDD protocol only. Out of 250 patients of diarrhea, 128 patients had been treated with *S. boulardii* and 122 patients had been treated with routine supportive treatment only. Demographic characters like age, sex,

weight, date of onset of diarrhea, previous treatment (where applicable), number and consistency of stools, vomiting, body temperature, sign of dehydration and any other data by clinical examination of all subjects were noted. Routine investigations including complete blood counts, random blood glucose, serum creatinine, serum electrolytes and stool examination were recorded. Data of both groups was recorded before the first treatment (day 1) and during treatment on days 3 and 7. The target criteria were the changes in the frequency of stools over the preceding 24 hours and its consistency. At the two check-up, patients were asked about any side-effects, tolerability and general well being.

**Ethical Consideration:** Prior to conduct of the present study, the protocol of the study was submitted to ethical and scientific committee of hospital. After getting due approval from these two committees, the present study was initiated.

**Statistical Technique:** Microsoft Excel® and SPSS® 20 for Windows® were used for data storage and analysis. The qualitative data were expressed in percentages and quantitative data were expressed as mean  $\pm$  standard deviation. Student's t test and Chi-Square test were used to determine statistical difference between variables.

### RESULTS

Two hundred fifty patients were included in the study, 128 patients in *S. boulardii* group and 122 patients in control group. Patient baseline characteristics in control and study groups were comparable (Table1).

Under *S. boulardii* group, patients had significant marked reduction in the score for stool frequency and stool quality than under control group after two and five days treatment.(Table 2)

**Table-1: Demographic Characteristics of All Subjects**

Patient characteristics	<i>S. boulardii</i> group (n=128)	Control Subjects (n= 122)	P value
Age ( $\pm$ SD)	23.8 $\pm$ 8.8 years	25.8 $\pm$ 9.2 years	NS
Sex (Female %)	48%	46%	NS
Bacteria Isolated in stool	12%	11%	NS

NS= Nonsignificant

**Table-2: Stool characteristics**

Patient characteristics	S. boulardii group (n=128)	Control Subjects (n= 122)	P value
Duration of diarrhea (days)	4.2	5.1	0.001
Mean number of stools reported on day 0	10.8	10.5	NS
Mean number of stools reported on day 3	3.1	4.5	0.01
Mean number of stools reported on day 6	1.5	3.7	0.001

NS= Nonsignificant

In secondary variables, significant advantage of *S. boulardii* over control was noted in the form of: improvement in nausea and positive assessment of treatment by patients on day 3.

No severe side effects were observed in any patient and the tolerance of the active medication was described by both doctor and patient as very good or good.

## DISCUSSION

Diarrhea is defined by the World Health Organization as 3 or more passages of loose or watery stool and increments in stool frequency in a 24-hours period. The most common cause of diarrhea is a gut infection (viral, bacterial, and parasitic). Other causes include side effects of medicine (especially antibiotics), infections not associated with the gastrointestinal tract, food poisoning, and allergy [3]. Diarrhea is also categorized into acute (lasts several hours or days) and persistent (continues for 14 days or longer). The treatment of choice for dehydration caused by diarrhea is the replacement of the lost fluids and electrolytes by oral rehydration solution. As rehydration therapy does not significantly decrease the frequency/length of diarrhea, scientists are interested in adjunctive treatments [4]. Probiotics as one of the alternative approaches for prevention and treatment of diarrhea are living microorganisms that provide various beneficial health effects in humans. Several studies of *S. boulardii* have been done in children and adults in the treatment of acute diarrhea [5]. The results of our studies are consistent with some of these studies. *S. boulardii* is generally administered in lyophilized powder corresponding to approximately  $3 \times 10^{10}$  cfu/g which unless exogenously administered is not found as part of the intestinal microflora of humans and under normal conditions it does not permanently colonize the gastrointestinal tract [6].

Daily administration as lyophilized powder guarantees vital persistence of yeast along the whole gastrointestinal tract, in fact, this yeast, because of its peculiarity it's not absorbed, it has no systemic impact, is resistant to gastric acids and to bile secretions [7].

## CONCLUSION

*S. boulardii* has been used as probiotic since last 6 decades, and it has been investigated in several clinical trials worldwide. *S. boulardii* is significantly effective for the prevention of acute adult diarrhea.

## REFERENCES

1. Czerucka D, Piche T, Rampal P. yeast as probiotics—*Saccharomyces boulardii*. *Alimentary pharmacology & therapeutics*. 2007 Sep 1;26(6):767-78.
2. Bhan MK, Mahalanabis D, Pierce NF, Rollins N. The treatment of diarrhea. *A Manual for Physicians and other senior health workers*. WHO/CAH/2005:8–16.
3. Pawlowski SW, Warren CA, Guerrant R. Diagnosis and treatment of acute or persistent diarrhea. *Gastroenterology*. 2009 May 31;136(6):1874-86.
4. Guarino A, Vecchio AL, Canani RB. Probiotics as prevention and treatment for diarrhea. *Current opinion in gastroenterology*. 2009 Jan 1;25(1):18-23.
5. Hatakka K, Savilahti E, Ponka A, Meurman JH, Poussa T, Nase L. Effect of long term consumption of probiotic milk on infections in children attending day care centres: double blind, randomised trial. *BMJ* 2001;322:1327.
6. Hooper LV, Xu J, Falk PG, Midtvedt T, Gordon JI. A molecular sensor that allows a gut commensal to control its nutrient foundation in a competitive ecosystem. *Proceedings of the National Academy of Sciences*. 1999 Aug 17;96(17):9833-8.

7. Periti P, Tonelli F. Preclinical and clinical pharmacology of biotherapeutic agents: Saccharomyces boulardii. Journal of chemotherapy. 2001 Jan 1;13(5):473-93.