Original Article

Evaluation of the Efficacy of Saccharomyces Boulardii in Children with Acute Diarrhea

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ABSTRACT

Objective: To evaluate the efficacy of the yeast Saccharomyces boulardii (SB) as an antidiarrheal agent in 100 children with acute diarhoreal illness.

Study Design: Analytical observational study.

Materials and Methods: Study was conducted From 1st April 2008 31st August 2008, 200 children 6 months to 12 years of age with acute watery diarrhea with duration of less than 07 days without history of fever or blood in stool or severe malnutrition admitted in Paediatric department PMCH were included in the study group.

Results: Evaluation of the results showed reduction in the number of stools and an improvement in their consistency in Saccharomyces boulardii group. After 48h and 96h children treated with Saccharomyces boulardii scored better than controls. It is concluded that in Saccharomyces boulardii group significantly more children recovered and normalized stools than controls without adverse reactions.

Conclusion: It is concluded from our study that in infant and small children with acute diarrhea treatment with SB achieves significant reduction in the duration of diarrhea and number of stool even in the early period of SB preparation use. This yeast (SB) can be used as an adjunct to oral rehydration in treating acute diarrhea in children.

Key Words: Saccharomyces boulardii, efficacy, acute diarrhea.

INTRODUCTION

According to the Food and Agriculture Organization of United Nation and World Health Organization, Probiotics are the live organisms which when consumed in adequate amounts as a part of food confer a health benefit on the host.[1]They function by competing with pathogens for nutrients and receptors, by inducing hydrolysis of toxins and receptors, production of antimicrobial substances (including peptides of the innate immune system) and organic acids and modulation of nitric oxide synthesis.[2]

Saccharomyces boulardii is non-pathogenic probiotic yeast considered to be useful against enteropathogens. Although the exact mechanism by which S. boulardii might exert its activity remains unclear, several possible mechanisms have been proposed, mostly based on results of *in vitro* and animal studies. These include inhibition of pathogen adhesion, [3] strengthening of enterocyte tight junctions, [4, 5] neutralization of bacterial virulence factors[6, 7] and enhancement of the mucosal immune response.[8, 9.]

Saccharomyces boulardii has been shown to reduce the duration of diarrhea[10] and also the duration of hospitalization.[11]It also reduces the frequency of stools and improves consistency of the stools as compared to the children kept on other treatment modalities for acute diarrhea and is well tolerated with almost no adverse effects[12]

As multiple studies on efficacy combining Saccharomyces boulardii along with other probiotics have been conducted with varying results but limited studies are available showing the efficacy of only Saccharomyces boulardii. This study will assess the efficacy of Saccharomyces boulardii for treating the children with acute diarrhea and will be beneficial in adding on to pre-existing data.

MATERIALS AND METHODS

From 1st April 2008 31st August 2008, two hundred children 6 months to 12 years of age (140 below 5 years of age and 60 were more than 5 years of age) with acute watery diarrhea with a duration of less than seven days admitted in the pediatric ward of PMC hospital Nawabshah. Exclusion criteria were; fever > 38.5°C, macroscopic blood in the stools, intake of anti-biotic drugs, or existing severe malnutrition (weight-to-height ratio < 70%). Patients who exhibited during the study deterioration of their diarrhoeal illness or any concomitant disease thus required other drugs were excluded from the study.

Children were divided into 2 groups. First group received 250 mg SB every 24 hour diluted into 5 ml of cold liquid. Second group received 250 mg placebo (glucose) diluted into 5 ml of cold liquid every 24hour. All patients were given World Health Organization low osmolar oral rehydration solution and normal food for their ages.

After 48h and 96h stool frequency and its consistency were recorded. The criterion of treatment efficacy was an absence of liquid stools and progressive reduction of stool frequency.

Statistical analysis was carried out using the Chi-square test and Student's t-test for two independent samples.

RESULTS

Two hundred patients completed the study. Group 1 (100 patients) represented 62 boys and 38 girls (mean age 15 ± 7.4 months), group 2 (100 patients); 58 boys and 42 girls (mean age of 14.1 ± 7.1 months). There were no significant differences between the two groups ($p>0.05$). Patient characteristics at baseline did not differ between the two groups. The mean duration of diarrhea was 3.18 days in S. boulardii group and 4.28 days in the control group ($P < 0.05$). On day 2, the defecation frequency was less than three times a day in 51 (51%) of 100 in the S. boulardii group and 32 (32%) of 100 in the control group ($P = 0.019$) (Table 1). On day 3, S. boulardii and ORS was two times more to reduce the frequency of stools to less than three per day than ORS alone. On day 4, 95 (95%) of 100 in the S. boulardii group had less than three stools per day compared with 80 (80%) of 100 in the control group. On day two, S. boulardii had no significant effect on the consistency of stools. However, after day 3, stool consistency was significantly more solid in the S. boulardii group (Table 2). On day 3, 75 (75%) of 100 patients in the S. boulardii group passed solid stools compared with only 26 (26%) of 100 in the control group ($P < 0.005$). On day 4, patients were 13 times more likely to pass solid stools after receiving S. boulardii plus ORS than patients who received only ORS. After day 5, no patients in the S. boulardii group had liquid stools.

Table No. 1: Stool frequency in the study population

	Controls		Saccharomyces boulardii		
Day	< 3 times	≥3 times	< 3 times	≥3 times	*P-Value*
1	0	100	0	100	NS
2	32	68	55	45	0.019
3	56	44	76	24	0.019
4	80	20	94	6	NS
5	96	4	100	0	NS
6	100	0	100	0	NS
7	100	0	100	0	NS

Table No. 2: Stool consistency in the study population

	Controls		*Saccharomyces boulardii*			
Day	Solid	Liquid	Solid	Liquid	P-Value	Odds Ratio(95%CI)
01	0	100	0	100	--	
02	2	98	4	96	< 0.307	3.167 (1.888 - 5.312)
03	25	75	70	30	< 0.005	13.17 (1.909 – 88.889)
04	63	37	97	3	< 0.005	13.025 (1.909 – 88.889)
05	84	16	100	0	0.001	
06	97	3	100	0	0.001	
07	100	0	100	0	0.001	

DISCUSSION

The efficacy of S. boulardii has been documented in various types of diarrhea such as the prevention of antibiotic-associated diarrhea,[13] Clostridium difficile–associated enteropathies,[14] chronic diarrhea caused by giardiasis[15,16] and amebiasis,[17] prevention of traveler's diarrhea,[18] prevention of diarrhea in critically ill tube-fed patients,[19] and treatment of human immunodeficiency virus–associated diarrhea.[20] However, the major indication is acute diarrhea in children and adults.[21-25]

In the present study we found remarkable reduction of stool frequency in the active treatment group vs placebo and higher percentage of cases cured starting from 48h. Lactose intolerance was recorded in 8% of SB treated cases and in 26% of cases in placebo group; these results are in consistency with other international studies [10, 26].

CONCLUSION

In conclusion, we confirmed that in infant and small children with acute diarrhoea treatment with SB achieves significant reduction in the duration of diarrhoea and number of stool even in the early period of SB preparation use. In the light of these results and the previously established safety, Saccharomyces boulardii preparation might be recommended for routine use in children with acute diarrhoea parallely with oral rehydration solution. As this is a costly practice to introduce the probiotics on national level in developing countries like Pakistan, so still more studies

are needed to look for the efficacy of probiotics in management of acute watery diarrhea.

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