



COMPARATIVE STUDY ON EFFICACY OF SACCHAROMYCES BOULARDII WITH LACTOBACILLUS SPOROGENES IN CHILDREN WITH ACUTE GASTROENTERITIS

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ABSTRACT

Aim and Objectives: The aim of this study was to compare the efficacy of *Saccharomyces boulardii* with *Lactobacillus sporogenes* in children with acute gastroenteritis by studying the usefulness of probiotic in children in reducing the stool frequency, improving stool consistency and also to assess the duration of hospital-stay with the use of probiotic. **Materials and Methods:** A prospective randomized observational study was conducted in gastroenteritic patients (from 2 months to 5 years of age) to compare the efficacy of two probiotics in the department of pediatrics, Durgabai Deshmukh Hospital. The study conducted for a period of six months from September 2017 to March 2018. **Results:** Among the total number of patients 60, *S.boulardii* was prescribed to 30 patients whereas remaining 30 administered *L.sporogenes* irrespective of their age, sex and degree of dehydration. The efficacy of drugs is assessed based on its frequency, consistency and duration of hospital stay in mild, moderate and severe dehydration stages. By comparing all the results *Saccharomyces boulardii* showed more efficacies compared to *Lactobacillus sporogenes* in all three factors (frequency, consistency and hospital stay duration). The efficacy in decreasing frequency is calculated by Two-way Anova method whereas hospital stays duration calculated by using T-test. **Conclusion:** From this study, we have concluded that, *Saccharomyces boulardii* is more efficacious than *Lactobacillus sporogenes* in decreasing the frequency, improving in consistency and decrease in hospital stay.

INTRODUCTION

Acute gastroenteritis is a sudden onset of diarrhoea or vomiting, which is due to infection or irritation of the digestive tract particularly stomach and intestine^[1]. The main symptoms of Gastroenteritis include Diarrhoea, Vomiting, Abdominal pain, Fever, lack of energy and dehydration may also occur.^{[2][3]} It is a main cause of morbidity and mortality in children over the world⁴. Many of deaths are caused by dehydration, resulting from loss of water and electrolytes. The replacement of these losses

By oral rehydration solution is the mainstay of therapy for children with acute gastroenteritis^[5]. The Degree of Dehydration is severe when the patient shows any two of the following signs which include lethargic or unconscious, sunken eyes, not able to drink or drinking poorly, skin pinch goes back very slowly and the patient is considered as some dehydrated .

Probiotics: These are non-pathogenic living microorganisms, when administered in sufficient quantities have a beneficial effect

on the host. They are mostly anaerobic organisms also prevent pathogenic microorganisms from increase in the human gut. [9] These probiotics are derived from food sources such as-

- Cultured milk products - Lactic acid bacteria (*Lactobacillus* and *Bifidobacteria*).
- A non-pathogenic strain of *Escherichia coli* (*E. coli* Nissle, 1917); *Clostridium butyricum*; *Streptococcus salivarius*.
- *Saccharomyces boulardii* (a non-pathogenic strain of yeast) [10].

Drugs in the study:

Saccharomyces boulardii:

S. boulardii has different types of action it can be classified into three main areas: Luminal action, Trophic action and Mucosal-anti-inflammatory signaling effects [11-14]. In intestinal lumen, *S. boulardii* can impede with pathogenic toxins, preserve cellular physiology, impede by pathogen connect, interact with normal microbiota or help out in re-establishing short chain fatty acid levels. *S. boulardii* also may act as an immune regulator, both within the lumen and systemically.

Lactobacillus sporogenes:

Despite the transient nature of this organism in the digestive tract, it shifts the

intestinal environment in support of a complex gastrointestinal flora. It results in improving gastrointestinal ecology by replenishing the quantity of desirable obligate microorganisms and antagonizing pathogenic microbes. [15-17]

MATERIALS AND METHODS:

This prospective observational study was conducted for 6 months in department of pediatrics, Durgabai Deshmukh Hospital, a 300 bedded multi-specialty hospital to assess patients (male and female) with Acute gastroenteritis. Baseline demographic data will be collected from the patient case report. The sample size is 60 in which patients with age group of 1 month to 5 years (except new-borns) were included and Patients with duration of Acute gastroenteritis more than seven days, blood in stools, malnourished children beyond grade 1 PEM were excluded. All the relevant and necessary data will be collected from inpatient records, laboratory records, by interviewing patient and patient representative and prescription..

Statistical analysis: All the data was analysed using GraphPad Prism software version 5. Comparison among two groups was performed using unpaired ‘t’ test and p-value < 0.05 was considered statistically significant.

Table-1 Assessment of Dehydration [7]

Symptom or Sign	No or Minimal Dehydration	Mild-to-Moderate Dehydration	Severe Dehydration
Mental status	Alert	Restless, irritable	Lethargic, unconscious
Thirst	Drinks normally	Drinks eagerly	Drinks poorly
Heart rate	Normal	Normal to increased	Tachycardia
Quality of pulse	Normal	Normal - decreased	Weak /palpable
Breathing	Normal	Normal or fast	Deep
Eyes	Normal	Slightly sunken	Deeply sunken
Tears	Present	Decreased	Absent
Mouth and tongue	Moist	Dry	Parched
Capillary refill	Normal	Prolonged	Prolonged or minimal
Extremities	Warm	Cool	Cold, mottled, cyanotic
Urine output	Normal	Decreased	Minimal

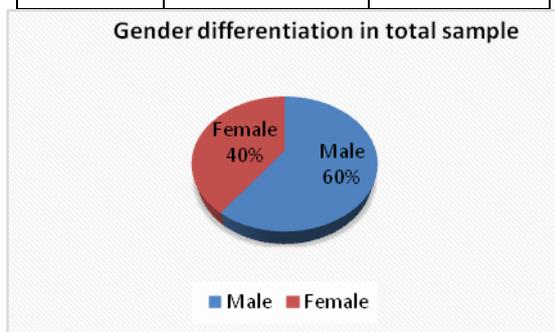
RESULTS AND DISCUSSIONS:

A total of 60 patients of either sex who fulfilled inclusion criteria were taken for the study at paediatric department, Durgabai Deshmukh Hospital.

5.1 Based on Gender:

Table 5.1: Number of patients based on Gender.

Gender	No. of Patients	Percentage
Male	36	60%
Female	24	40%

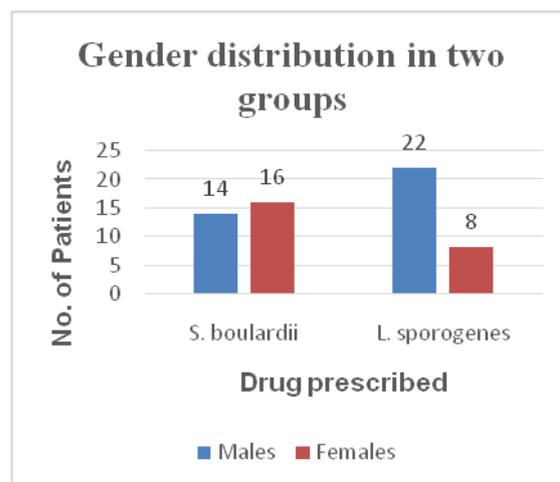


Graph 5.1 Gender differentiation.

Out of 60 Acute GE patients 24 (40%) are female and 36(60%) are male

5.2 Gender differentiation in two groups.

Out of 30 patients in Group-A 16 (53.3%5) are female and 14 (46.6%) are male. Out of 30 patients in Group-B 8 (26.6%) are female and 22 (73.3%) are male



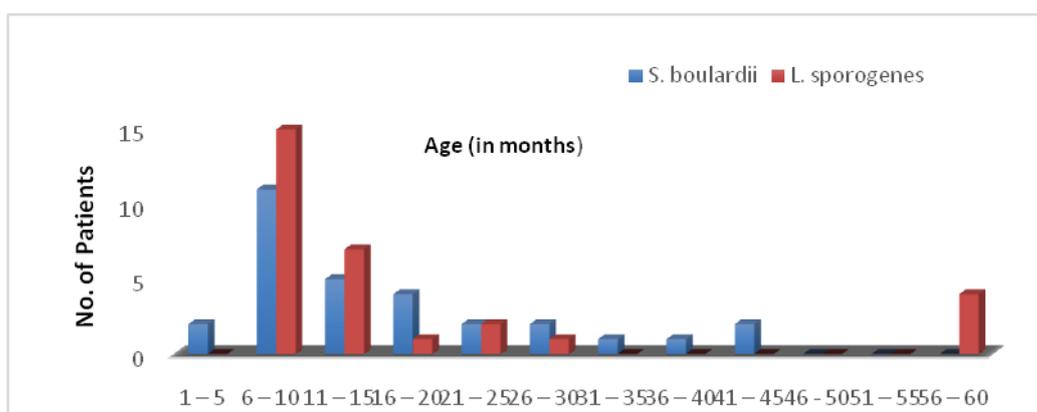
Graph 5.2 Gender distribution of in S. boulardii and L. Sporogenes

The major effected age group of Acute Gastroenteritis patients was seen in 6 to 10months of age.

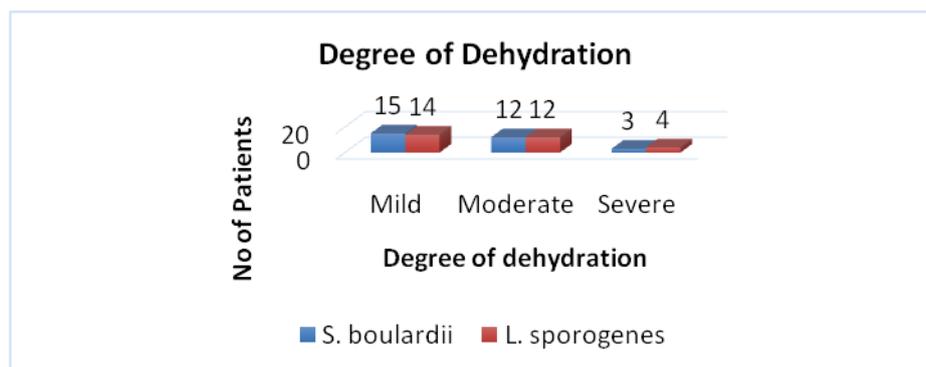
5.4 Degree of dehydration:

No significant differences regarding nutritional status, feeding status or duration of diarrhea before admission were found between the study groups.

Severity of diarrhea, as determined by the number of stools per day, Degree of dehydration and associated symptoms like fever, vomiting did not differ between the two groups.



Graph.5.3 Age distribution in two groups. The major effected age group of Acute Gastroenteritis patients was seen in 6 to 10months of age.



Graph 5.4 Degree of dehydration

Out of 60 GE patients 29 were mild dehydrated, 24 were moderately dehydrated and 7 were severely dehydrated. S. boulardii was given to 15, 12, 3 patients who are of mild, moderate and severely dehydrated respectively.

Table 5.2: Gender Distribution according to drug prescribed

Drug Given	Males	Females	Total (60)
S. boulardii	14 (46.6%)	16 (53.3%)	30
L. Sporogenes	22 (73.3%)	8 (26.6%)	30

Table 5.3 Age distribution in two groups

Age (in months)	S. boulardii	L. sporogenes
1 – 5	2	0
6 – 10	11	15
11 – 15	5	7
16 – 20	4	1
21 – 25	2	2
26 – 30	2	1
31 – 35	1	0
36 – 40	1	0
41 – 45	2	0
46 - 50	0	0
51 – 55	0	0
56 – 60	0	4
Total	30	30

Table 5.4 Degree of dehydration

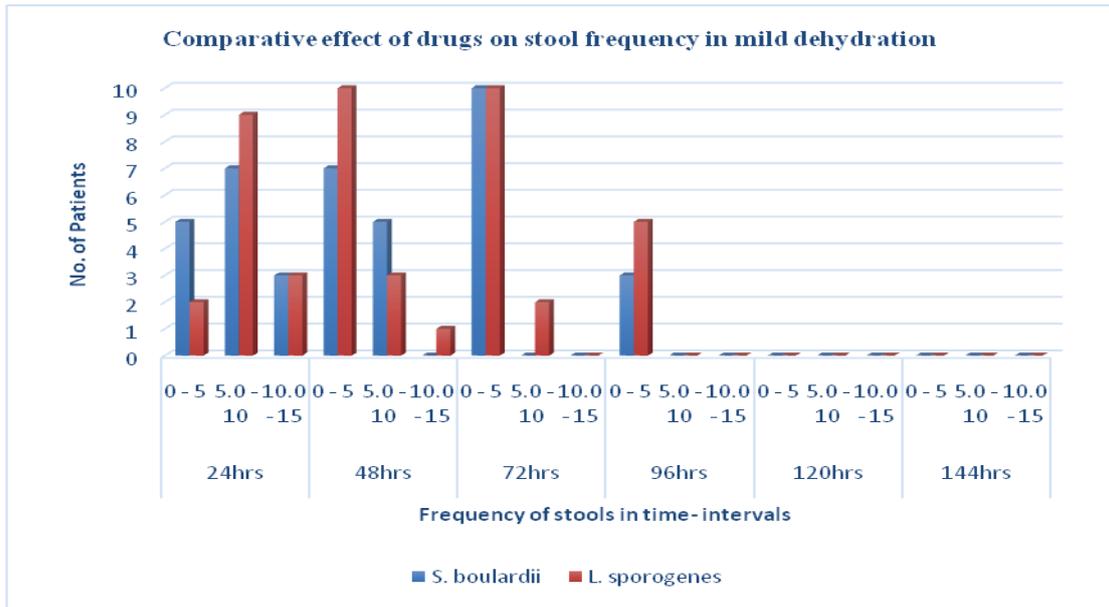
Degree of Dehydration	S. boulardii	L. sporogenes	Total
Mild	15	14	29 (48.33%)
Moderate	12	12	24 (40%)
Severe	3	4	7 (11.6%)

5.5.1 The Effect of drug on Stool Frequency in mild dehydration:

Table 5.5. Effect of drug on Stool Frequency

No. of episodes	No. of patients in 24hrs		No. of patients in 48hrs		No. of patients in 72 hrs		No. of patients in 96 hrs		No. of patients in 120 hrs		No. of patients in 144 hrs	
	DrugA	DrugB	DrugA	DrugB	DrugA	DrugB	DrugA	DrugB	DrugA	DrugB	DrugA	DrugB
0 – 5	5	2	7	10	10	10	3	5	0	0	0	0
5 – 10	7	9	5	3	0	2	0	0	0	0	0	0
10 – 15	3	3	0	1	0	0	0	0	0	0	0	0

Here, Drug A is *Saccharomyces boulardii*., Drug B is *Lactobacillus sporogenes*.



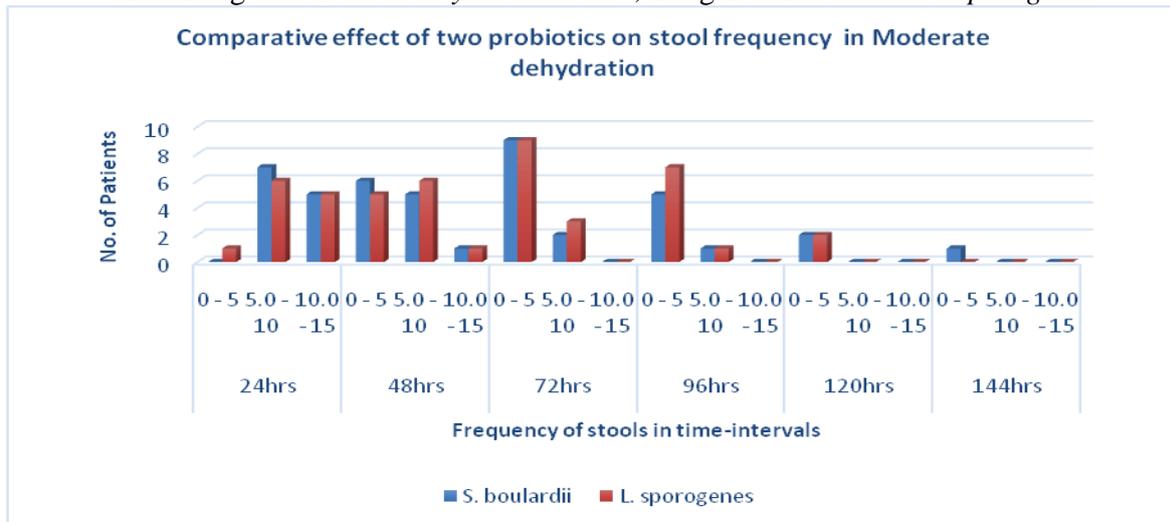
Graph.5.5.1 Comparative effect of two probiotics on Stool Frequency in mild dehydration.

5.5.2 Effect of probiotics on stool frequency in Moderate dehydration:

Table 5.6: Effect of Probiotics on stool frequency in Moderate dehydration

No. of episodes of stools	No. of patients in 24hrs		No. of patients in 48hrs		No. of patients in 72hrs		No. of patients in 96hrs		No. of patients in 120hrs		No. of patients in 144hrs	
	DrugA	DrugB	DrugA	DrugB	DrugA	DrugB	DrugA	DrugB	DrugA	DrugB	DrugA	DrugB
0 – 5	0	1	6	5	9	9	5	7	2	2	1	0
5 – 10	7	6	5	6	2	3	1	1	0	0	0	0
10 – 15	5	5	1	1	0	0	0	0	0	0	0	0

Here Drug-A is *Saccharomyces boulardii* , Drug-B is *Lactobacillus sporogenes*.



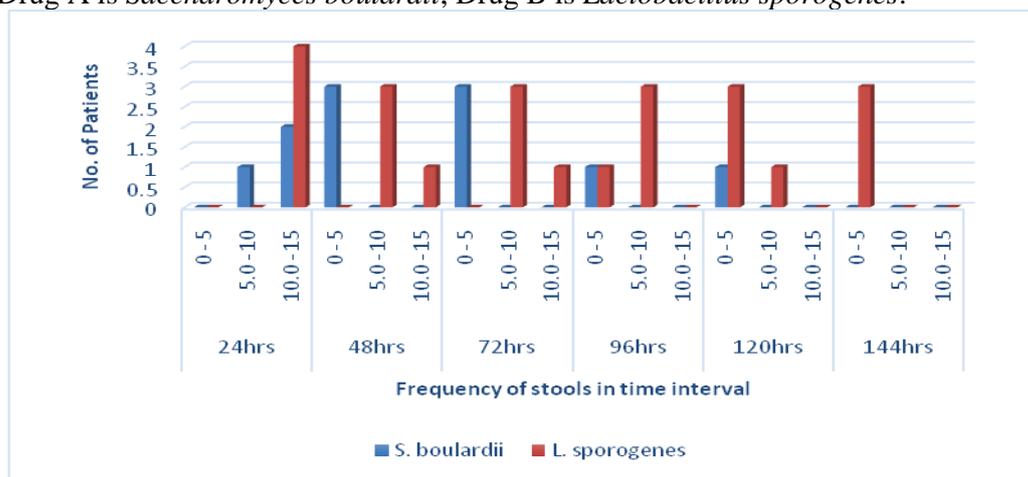
Graph.5.5.2 Comparative effect of two probiotics on stool frequency in Moderate dehydration.

5.5.3 Effect of probiotics on stool frequency in severe dehydration:

Table 5.7: Effect of probiotics on stool frequency in Severe dehydration

No. of episodes of stools	No. of Patients in 24hrs		No. of Patients in 48hrs		No. of Patients in 72hrs		No. of Patients in 96hrs		No. of Patients in 120hrs		No. of Patients in 144hrs	
	DrugA	DrugB	DrugA	DrugB	DrugA	DrugB	DrugA	DrugB	DrugA	DrugB	DrugA	DrugB
0 – 5	0	0	3	0	3	0	1	1	1	3	0	3
5 – 10	1	0	0	3	0	3	0	3	0	1	0	0
10 – 15	2	4	0	1	0	1	0	0	0	0	0	0

Here, Drug A is *Saccharomyces boulardii*, Drug B is *Lactobacillus sporogenes*.

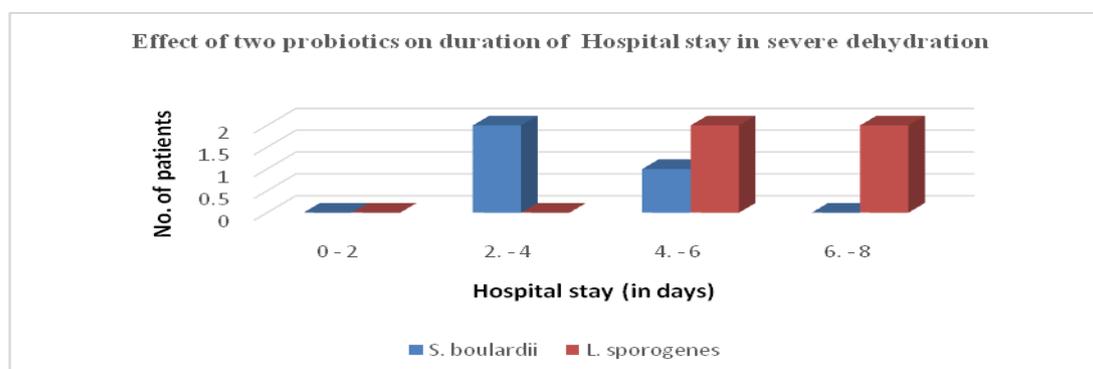


Graph.5.5.3Comparative effect of two probiotics onstool frequency of stools in Severe dehydration

5.4 The effect of two probiotics on duration of hospital stay in severe dehydrated patients:

Table 5.8.Effect of two probiotics on duration of hospital stay in severe dehydrated patients

Drugs prescribed	No. of patients discharged in 0-2 days	No. of patients discharged in 2-4 days	No. of patients discharged in 4-6 days	No. of patients discharged in 6-8 days
S. boulardii	0	2	1	0
L. sporogenes	0	0	2	2



Graph 5.7.3 Comparison of two probiotics on duration of hospital stay in severe dehydration

**In our study, *Saccharomyces boulardii* demonstrated more effectiveness as compared to the *Lactobacillus sporogenes* in the evaluated parameters such duration of diarrhoea, frequency of diarrhoea and duration of hospital stay. It indicates *Saccharomyces boulardii* can be used in the overall management of diarrhoea as compared to the *Lactobacillus sporogenes*

CONCLUSION:

In this study, *Saccharomyces boulardii* demonstrated more effect in comparison to the *L. sporogenes* in terms of reduction of duration of diarrhoea, frequency of diarrhoea and duration of hospital stay. However, therapeutic strategy for acute gastroenteritis need to be assessed in different settings and it should be based on the nutritional status of the children. Hence, use of probiotic should be based on locally generated data

Ethics and consent

The entire study was conducted according to the ethical committee guidelines of durgabai deshmukh hospital. All the relevant and necessary data was collected from in patient records, laboratory reports, prescriptions and by interviewing the patients.

Conflicts of interest: None.

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