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RESEARCH PAPER

COMPARISON OF EFFECTIVENESS OF ZINC SUPPLEMENTATION WITH ORS AND BACILLUS CLAUSII VS ZINC SUPPLEMENTATION WITH ORS AND SACCHAROMYCES BOULARDII IN ACUTE WATERY DIARRHOEA IN PAEDIATRIC PATIENTS

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ABSTRACT

BACKGROUND: Gastroenteritis is a major public health problem worldwide and remains the second leading cause of death among the children under five globally. About 10% of infants and 14% of 0-4 year's children die due to diarrhea in India.

OBJECTIVE: objective of this study was to improve the symptoms of diarrhea and compare the effectiveness of commonly available probiotics with zinc and ORS in treatment of acute watery diarrhea in children.

METHOD: This was a comparative study conducted between two probiotic (BACILLUS CLAUSII, SACCHROMYCES BOULARDII) along with zinc and ORS in a hospital at Hyderabad for 6 months. 100 children of aged 6months-5years admitted with acute watery diarrhea of less than or equal to 48 hours duration were divided into two groups; Group-A received *Bacillus Clausii* along with zinc and ORS and Group-B received *SaccharomycesBoulardi i*along with zinc and ORS. The primary outcome measures were mean number of stools per day, consistency of stools, duration of diarrhea. The secondary outcome were duration of vomiting, fever and hospital stay. ANOVA, student t test, were used for analysis.

RESULTS: The duration of diarrhea and hospital stay significantly reduced in Group-A compared to Group-B

CONCLUSION: From the results it can be said that *Bacillus Clausii* along with zinc and ORS is effective in reducing the duration of diarrhea in children with acute gastro enteritis.

KEY WORDS : Bacillus Clausii, Saccharomyces Boulardii, diarrhea.

INTRODUCTION

Acute watery diarrhea is one of the common causes of death among infants and adults and is defined as increased stool frequency with increased water content. Usually, this frequency lasts less than two weeks however, if it lasts more than two weeks, it is called protracted diarrhea (1). Acute watery diarrhea accounts for about 2.5 million deaths annually worldwide. In the United States, it was estimated that about 48 million foodborne diarrheal illnesses are being recorded annually resulting in more than 128,000 hospitalizations and 3,000 deaths (2, 3). The common causes of diarrhea are viruses (rotaviruses) and bacteria (salmonella, shigella yersinia, clostridium or pathogenic E. coli). Based on the physiological conditions, acute infectious diarrhea is classified into non-inflammatory (viral) and inflammatory

(toxin-producing bacteria) (4,5). In general, viral infections are the common cause of acute watery diarrhea (6)whereas bacterial infections are often associated with contaminated food, travel and comorbidities.The clinical manifestations of acute watery diarrhea include watery stools, rarely mixed with blood, vomiting and fever. The further complications may depend on the degree of dehydration, i.e., the degree of fluids or electrolyte loss.

The common treatment strategy for acute watery diarrhea is replacement of fluids and electrolytes and the enteric administration of food toprecise maintenance of catabolic state and to promoteenterocyte regeneration.Anti-diarrheal drugs such as loperamide and bismuth subsalicylate are used to control severe symptoms, and includes bismuth subsalicylate however, over usage of these drugs may lead to complications of hemolytic uremic syndrome if the patients id infected with Shiga-toxin *E. coli*. Along with these drugs, clinicians prefer some probiotics to alleviate the severe symptoms.Probiotics stimulate the immune system thereby competing for binding sites on intestinal epithelial cells. Previous studies have been reported the association between the usage of probiotics and reduced severity in acute diarrhea patients (7,8,9,10).

Though, probiotics are thought to be a promising agentsto treat acute diarrhea, knowledge about the efficacy of the agents is still lacking as various strains of probiotic bacteria have distinct mode of action with gut microbes. Proper understanding of each probiotic action and their efficacy in minimizing the symptoms may contribute to give a better treatment for diarrhea patients. Hence, the present study aimed to study the efficacy of two probiotics namely Econorm and Enterogeminain acute watery diarrhea patients.

MATERIALS AND METHODS

This is a prospective comparative study as it watches for outcome such as the development of a disease ,during the study period and relates this to other factors such as suspected risk or protection factors .A total of 100 patients were recruited for this study and were separated into group A (n=50) treated with Econorm (probiotic) and group B (n=50) treated with Enterogemina. Demographic

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charecteristics of the patients such as age, gender, past medical history and immunization history were collected. Lab investigations such as Stool for microscopy, stool for microscopy test for cyst, stool for microscopy test for ova, stool for culture and sensitivity, stool for reducing substances and serum electrolytes were collected from lab records.All efforts should be made to avoid sources of bias such as loss of individuals to follow up during study.This study was conducted in In -Patient Department meeting the study criteria.The study was conducted in paediatrics department of princess Esra hospital moghulpurahyderabad. This study was approved by institutional ethics committee, princess Esra hospital, Hyderabad

INCLUSION CRITERIA:

- Age group between 6 months to 5 years of age is included as acute watery diarrhoea occurs mostly in infants and young children
- Mild, Moderate ,Severe dehydration should be included in the study.
- Both healthy and severely malnourished patients should be included .
- Child vaccinated with or without rotavirus should be included.
- Osmotic diarrhoea of all caused except secretary diarrhoea should be included.

EXCLUSION CRITERIA:

- If there is any history of presence of blood or pus in stools as acute bloody diarrhoea is mostly associated with pathogenic bacteria.
- If they have undergone treatment with antibiotics,probiotics, or prebiotics within a period of two weeks before enrolment as we cannot compare effectiveness of probiotic.
- If they have any History of conditions known to producing immune deficiency (AIDS, other congenital immuno deficiency syndrome, drug therapy with steroids, anti cancer drugs etc).
- If there is any Presence of acute systemic illness (meningitis, pneumonia, sepsis)
- Patients suffering from chronic diarrhoea was excluded from the study.
- Parents of patients not willing to participate in the study.

Primary outcomes measures:

The primary outcome measures were the total duration of diarrhoea and number of stools per day and their consistency. duration of diarrhoea shows the time in hours from first to last abnormal (loose or liquid) stools preceding a normal stool output. **Secondary outcome measures** The secondary outcome measures were the incidence and mean duration of vomiting, fever. Data was analyzed using Microsoft Excel to calculate the mean duration. Statistical analysis of the data was performed using one way anova and unpaired t test

RESULTS

DRUG DISTIBUTION IN SUBJECTS:

S.NO	PROBIOTIC	NO. OF SUBJECTS
1	BACILLUS CLAUSII	50
2	SACCHAROMYCESS BOULARDII	50

GENDER WISE DISTRIBUTION:

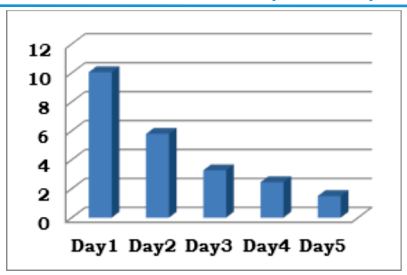
	MALE	FEMALE
BACILLUS CLAUSII	30	20
SACCHAROMYCES BOULARDII	34	16

AGE WISE DISTRIBUTION:

ANOVA TABLE 1

Effect of Econorm on number of stools per day after drug administration

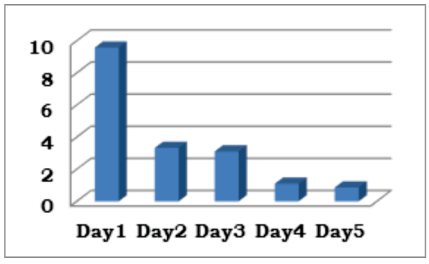
Day 1	Day 2	Day 3	Day 4	Day 5	Total	F value	P value
10.06±5.21	5.80±3.80	3.27±2.53	1.94±1.73	1.84±0.82	6.44±4.21	21.25	0.06



ANOVA TABLE 2

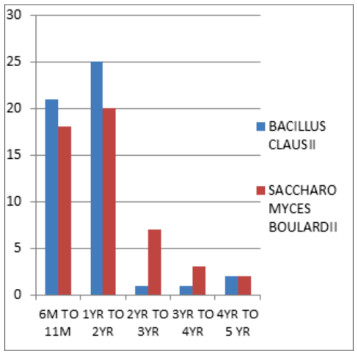
Effect of Enterogemina on number of stools per day after drug administration

Day 1	Day 2	Day 3	Day 4	Day 5	Total	F value	P value
9.58±5.41	5.0±2.21	2.22±1.10	1.74±0.61	1.62±0.41	5.10±2.42	32.14	0.05*



AGE WISE DISTRIBUTION

AGE GROUP	BACILLLUS CLAUSII	SACCHAROMYCES BOULARDII
6M-11M	21	18
1Y-2Y	25	20
2Y-3Y	1	7
3Y-4Y	1	3
4Y-5Y	2	2



Comparison between two drugs with respect to hospital stay:

Day	Econorm	Enterogemina	T	P valve
Day 1	10.06±5.21	11.59±5.42	1.44	0.15
Day 2	5.80±3.81	4.33±2.21	1.90	**0.05***
Day 3	3.28±2.53	3.11±2.87	0.79	0.43
Day 4	2.45±1.74	1.10±0.54	2.64	**0.04***
Day 5	2.50±1.12	0.86±0.35	2.14	**0.05***
Hospital stay				
	3.66±1.31	1.08±0.80	2.37	**0.05***

DISCUSSION:

The mean age of group A was 16.92 whereas for group B it was 13.92. The percentage of male and female patients in group A was 68.00% and 32.00% whereas in group B it was 60.79% and 39.21. The mean birth weight of group A was 9.75 and in group B it was 8.88. Patients with P/A soft and soft GIT were more or less percentage in both groups. Similar trend was observed with respect to mean PR and mean RR in both groups. We observed that patients with below 5 vomiting episodes were more in group B compared to group A however, it was observed that patients with above 5 episodes were less in group B. Patients with below 5 episodes of loose stool were more in group B compared to group A.

Though, the mean number of stools at day 1 was more or less equal in both groups, the number was steeply declined as the duration of the treatment increased in group B. Further, we analyzed the data to evaluate the effect of Econorm and Enterogemina on number of stools per day after drug administration. We did not find any significant mean difference with respect to number of stool per each day when we treated with Econorm however, it was observed that the number of stools per each day was significantly reduces in patients when we treated with Enterogemina.

Acute watery diarrhoea disease is the leading cause of death among children under five years old. Diarrhoea can last for 14 days, and lead to severe dehydration.. Several probiotics are widely used to treat the acute watery diarrhea. However, only few probiotics are effectively replace the beneficial microorganisms. In our study, we studied the effect of two probiotics on Acute watery diarrhea. We observed that patients treated with Enterogemina showed to be more effective than econorm. This might be due to the increased number of beneficial bacteria which fight with harmful bacteria for nutrients and thus starve them off than Econorm. Our results were in accordance with previous study (8) where they observed improved stool consistency in children suffering from acute watery diarrhea when they were treated with specific mix of probiotics. Moreover, it can be attributed that enterogemina might be showed better probiotic activities such as lactic acid production and hydrogen peroxide which lower intraluminal pH thereby contributing development of hostile environment for other potentially pathogenic bacteria. In conclusion, Enterogemina shows more efficacyin terms of improving stool consistency than Econorm. Enterogemina might be a useful probiotic to treat the acute watery diarrhea.

CONCLUSION:

From the data collected and results obtained it can be concluded that *Bacillus Clausii* + zinc+ORS is effective than *Saccharomyces Boulardii* +zinc+ORS as probiotic when given with other anti-diarrheal medication in reducing the duration of diarrhea.

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