EFFICACY OF SACCHAROMYCES BOULARDII IN THE MANAGEMENT OF ACUTE WATERY DIARRHEA

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ABSTRACT

Objective: To determine the Efficacy of probiotic (saccharomyces boulardii) in children (2 months to 5 years) with acute watery diarrhea.

Study Design: Comparative cross sectional study.

Place and Duration of Study: This study was carried out in the department of pediatrics, Combined Military Hospital, Quetta, from Jan 2017 to Jun 2018.

Methodology: All children (2 months to 5 years) with acute watery diarrhea presenting within 24 hour of illness with no dehydration and some dehydration were enrolled and divided into two groups, study group and control group. Efficacy was assessed by reduced frequency of stools(less than 3 per day) and duration during the study period.

Results: Mean age of the children in probiotic saccharomyces boulardii group was 3.42 ± 1.36 years, while mean age in control group was 3.91 ± 1.16 years (p-value 0.002). Significant difference was also observed in duration of stool and frequency of stool at day 1-5 (p-value <0.05). Statistically significant difference was observed among children in probiotic saccharomyces boulardii group 114 (53%) as compared to controls 101 (47%) (p-value 0.021).

Conclusion: The Efficacy of probiotic (saccharomyces boulardii) was found satisfactory in children (2 months to 5 years) with acute watery diarrhea. In children with acute watery diarrhea saccharomyces boulardii may be recommended for better outcome.

Keywords: Acute watery diarrhea, Children, Dehydration, Probiotics, Saccharomyces boulardii.

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INTRODUCTION

As per World Health Organization (WHO) definition, stool emission with a frequency of 3 or more loose stool per day is termed as diarrhea. Quantification of stool in children especially in diaper babies may be difficult1,2. Different mechanisms have been presumed for diarrhea. The final result of all the mechanisms is either increase in the volume of stool or there may be increase in stool frequency. Multiple factors are involved in water balance across the intestine mucosal membrane3-5. Diarrheal diseases are considered the fifth most leading cause of mortality in under 5 years children and the 8th leading cause of death among all ages, worldwide6. It is also the main cause of childhood mortality and morbidity in Pakistan: highest mortality from moderate to severe diarrhea reported from some part of Pakistan among south Asian countries7-8.

Different etiological factors are involved in causing diarrhea. The most common cause of diarrhea is infection, with viruses top of the list. About 20% of infectious diarrhea is due to bacteria. Common strain of bacteria responsible for diarrhea are E.Coli, Salmonella and campylobacter species etc. Besides bacterial infections, diarrhea may be caused by parasites and fungal infections. There are non-infectious causes of diarrhea as well like antibiotic associated diarrhea, diarrhea caused by toxins and some non-organic metals (Magnesium) etc. At time diarrhea may be a manifestation of systemic illness, particularly in children. Children with otitis media, encephalitis and pneumonia may present with loose motion. Route of transmission in most cases is oro-fecal. The spread of infections is due to unhygienic environment9. Infection may spread from person to person by direct contact or by taking contaminated food and water. The infection may remain localize to the intestine or may spread to other organs. The sign and symptoms then depend on the pathogenicity of the bacteria and the organ involved. The patients may present only with loose motion and vomiting or sometime may be having systemic symptoms as well like fever, malaise, respiratory and renal symptoms. Some organisms may result in fatal outcome, like Clostridium difficile, which may lead to life threatening colitis10.

We carried out our study with the aim to prove whether probiotics are efficacious in acute watery diarrhea or not. If proved to be efficacious, then
probiotics would be recommended for acute watery diarrhea so as to decrease duration of disease, hospital stay and overall cost of the disease.

**METHODOLOGY**

This comparative cross sectional study was conducted in the department of Pediatric Medicine, Combined Military Hospital, Quetta, from Jan 2017 to Jun 2018. The sample size of 126 was required for each group. Sampling Technique used was non probability consecutive sampling. Inclusion criteria included Children (2 months to 5 years) with acute watery diarrhea presenting within 24 hour of illness with no dehydration and some dehydration. Children with severe intercurrent illnesses, children with malnutrition, children with antibiotic associated diarrhea, children with chronic and persist-tent diarrhea, children with known food allergies and metabolic diseases, children with dysentery (blood and mucous in stool) and children with severe Dehydration were excluded from the study. Dehydration was classi-fied into no, some and severe on the basis of clinical symptoms (using integrated management of childhood illnesses). The following operational definitions were used.

Efficacy was labeled if frequency of stool (less than 3 per day) and duration of diarrhea decreases on 5th day as compared to controlled group.

Probiotic yeast (Saccharomyces Boulardii)

Acute watery diarrhea Passage of more than 3 loose stools per day.

Administrative permission from the concerned authorities and ethics committee was sought. Parents were explained about the risks and benefits of the study and informed written consent was obtained for examination of their children and intervention. Permis-sion was also obtained from parents regarding use of data for research and publication. All those children, meeting inclusion criteria, were divided in two gro-ups, study group and control group. The study group was managed with WHO standard therapy i.e. ORS plus oral administration of a probiotic Saccharomyces Boulardii (250mg in two divided doses less than three months and 250mg twice a day in infants more than 3 months) diluted in water around two teaspoon full or mixed with semi-solid food while the control group was managed with WHO standard therapy ORS alone. Efficacy was assessed by reduced frequency of stools (less than 3 per day) and duration on 5th day of the study period. Data regarding age and sex of patient and efficacy of treatment was recorded. Data was coll-

ected through a structured proforma. Confidentiality of the patient record was maintained.

All data was entered and analyzed using SPSS-21. Descriptive statistics was used to analyze and describe data. Frequencies were calculated for categorical (qua-litative) variables. Mean and Standard Deviation (SD) were calculated for numerical (quantitative) variables. Efficacy was noted on 5th day of treatment. Chi-square test was applied to see the association of group with efficacy. Post stratification chi square test was also applied and p-value ≤0.05 was taken as significant.

**RESULTS**

Total numbers of patients in the study were 252 with 126 in study group and 126 patients in control group. Mean age of the children in probiotic sacchar-amycyces boulardii group was 3.42 ± 1.36 years. while mean age in control group was 3.91 ± 1.16 years (p-value 0.002). Majority of the children were females, 134 (53.2%) as compared to males, 118 (46.8%). Mean weight of the children in probiotic saccharamyces boulardii group was 14.91 ± 4.14 Kg while mean weight in control group was 15.94 ± 3.22 Kg (p-value 0.029). Significant difference was also observed in duration of stool and frequency of stool at day 1-5. Overall efficacy was observed in 215 (85.30%) children. Efficacy was significantly higher 114 (53%) among children in probiotic saccharamyces boulardii group as compared to controls 101 (47%) (p-value 0.021) as shown in table-I.

| Table-I: Efficacy with respect to group (n=252). | Group | Efficacy | p-value |
|---|---|---|---|
| | Yes | No |
| Probiotic Saccharomyces Boulardii | 114 (53%) | 12 (32.4%) | 0.021 |
| Control | 101 (47%) | 25 (67.6%) | |

| Table-II: Age ≤3 years & Efficacy with respect to group (n=252). |
|---|---|---|
| Group | Efficacy | p-value |
| | Yes | No |
| Probiotic Saccharomyces Boulardii | 50 (69.4%) | 0 (0%) | 0.021 |
| Control | 22 (30.6%) | 5 (100%) | |

| Table-III: Age >3 years & Efficacy with respect to group (n=252). |
|---|---|---|
| Group | Efficacy | p-value |
| | Yes | No |
| Probiotic Saccharomyces Boulardii | 54 (54.5%) | 0 (0%) | <0.001 |
| Control | 45 (45.5%) | 19 (100%) | |
Stratification was done with respect to age and gender of the patients as shown in table-II-V.

Table-IV: Male Gender & Efficacy with respect to group (n=252).

| Group                  | Efficacy | p-value |
|------------------------|----------|---------|
|                        | Yes      | No      |         |
| Probiotic Saccharomyces Boulardii | 54 (54.5%) | 0 (0%)  | <0.001  |
| Control                | 45 (45.5%) | 19 (100%) |         |

Table-V: Female Gender & Efficacy with respect to group (n=252).

| Group                  | Efficacy | p-value |
|------------------------|----------|---------|
|                        | Yes      | No      |         |
| Probiotic Saccharomyces Boulardii | 60 (51.7%) | 12 (66.7%) | 0.237   |
| Control                | 56 (48.3%) | 6 (33.3%) |         |

DISCUSSION

Diarrhea is also classified as acute, persistent and chronic diarrhea depending on duration of onset. Similarly, diarrhea may be classified depending on stool characteristic like mostly watery, containing fats and having inflammatory cells etc. The most fearing aspect of diarrhea is dehydration, which occur if the fluid losses are not compensated. Dehydration may also result in fluid electrolytes imbalances, which then manifest in the form of different signs and symptoms.

In pediatric populations, over the past several years probiotics have been largely studied for treatment of diarrheal diseases. The probiotic is a living microorganism when administered proves to be beneficial for the health and wellbeing of host by interactions between immune cells and intestinal flora present in the intestinal mucosal barrier. The advantages are that it is, less invasive and have better efficacy. Various probiotic agents like Lactobacilus GG, Lactobacillus Reuteri and Sacchromyces Boulardii have been used for the treatment of acute watery diarrhea. Sacchromyces boulardii has proven efficacy, from literature, in the treatment of acute diarrhoea with no adverse effects. In our study too we used saccharomyces boulardii as a probiotic. In this study, efficacy was significantly higher 114 (53%) among children in probiotic saccharomyces boulardii group as compared to controls 101 (47%) (p-value 0.021).

Acute diarrhoea is the most investigated disease in the area of probiotic use, especially in children and many systematic reviews described the probiotics role. Probiotics demonstrated a good safety profile, significantly reduction of diarrhoea duration, reduction of stool frequency and reduction of hospitalization period. A study done by Sharif MR enrolled 100 patients in each control and study groups. Both the groups were given standard treatment for diarrhea but the study group was given Sacchromyces Boulardii and the control group only placebo and no probiotics. The mother was asked about the duration and frequency of diarrhea every day after start of treatment. Significant improvement in term of frequency and duration of disease was reported in probiotic group as compared to control group. Dinleyici et al studied the effectiveness of saccharomyces boulardii was studied in acute diarrhea patients reporting to emergency department, outdoor patients department and in admitted patients. The effectiveness was measured in term of frequency of stool, hospital stay and emergency department stay. Duration of diarrhea was significantly lower in probiotic group. Similarly, hospital stay and emergency department stay was also significantly lower in probiotic group as compared to control group. No adverse event was reported in probiotic group.

The most studied diseases for probiotic use are acute diarrhea, diarrhea due to antibiotic use and necrotizing enterocolitis. But not all researchers agree with probiotic use for these diseases. Also, not all strains of probiotics may be equally effective. Conflicting results have been reported regarding probiotic use even for acute gastroenteritis. For necrotizing enterocolitis and antibiotic associated diarrhea further trials have been recommended before probiotic may be routinely advised in these conditions. Especially in our country where most of the time the diarrhea is due to infectious causes, probiotic should not be prescribed as a sole treatment. Guarino et al review, regarding probiotic use for acute gastroenteritis, 7 studies did not recommen-
end probiotic use for gastroenteritis and 5 studies recommended its use. *Saccharomyces boulardii* and *Lactobacillus rhamnosus* were found to be the most effective strains to be used as a probiotics18.

All these studies and trials may provide understandings into the clinical application of probiotics, but it is important to elucidate the mechanisms of probiotics to maximize their health benefits. Limitation of our study was that we defined diarrhea clinically. We didn’t went for stool culture. Similarly, we could not differentiate whether the watery diarrhea was infectious or noninfectious. We therefore recommend that further trials should be carried out which should elucidate the role of probiotics in infectious and non-infectious diarrhea.

**CONCLUSION**

The Efficacy of probiotic (saccharomyces boulardii) was found satisfactory in children (2 months to 5 years) with acute watery diarrhea. Probiotics may be prescribed to children with acute watery diarrhea as it decreases the severity of the disease.

**CONFLICT OF INTEREST**

This study has no conflict of interest to be declared by any authors.

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