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Original Research Article

A Prospective Open-Labeled Study on Efficacy of Probiotic Use in Pediatric Acute Diarrhea at Tertiary Care Hospital

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Abstract:

Background: Acute diarrhea is defined as more than three stools per day in less than 14 days, combined with loose stools. Pediatric diarrhea is most often caused by viral illnesses, and replacing lost fluid and electrolyte balance is the most popular treatment. Supplementing with probiotics while traditional therapy is probably going to produce better results. This study aimed to investigate the efficacy of Saccharomyces boulardii, a probiotic, as a supplemental treatment for acute diarrhea in children.

Methods: This was a prospective, open-label trial. Forty children (n = 40) who matched the entrance requirements for inclusion were divided into two groups at random. Group 2 (n = 20) received probiotics in addition to conventional treatment, while group 1 (n = 20) received standard treatment alone. The parents were instructed to mix the probiotic powder with some milk or water prior to giving it to the children. As outcome markers, the length of the diarrhea and the stools' consistency were measured.

Results: The probiotic-treated group experienced diarrhea for 3.8 days, while the usual therapy group experienced diarrhea for 5.1 days. In the standard therapy group, the first semi-liquid stools usually occur after 3.3–1.6 days, but in the probiotic treatment group, they appear after 2.0–0.56 days. The results showed statistical significance.

Conclusion: The probiotic S. boulardii helps reduce diarrhea duration and the time it takes for the first semi-liquid stools to appear by one day.

Keywords: Pediatric Diarrhea, Probiotic Saccharomyces boulardii, Efficacy.

Introduction

Acute diarrhea is defined as more than three stools per day in less than 14 days, combined with loose stools. Acute respiratory tract infections account for the majority of infant deaths in India[1], with acute diarrhea following in second.[2] Diarrhea primarily arises from viral (rotavirus), bacterial (Escherichia coli), and parasite diseases; however, medication side effects, starvation, food allergies, and gastrointestinal abnormalities can also be contributing factors.[3]

The World Health Organization (WHO) recommends that children with acute diarrhea should be treated with oral rehydration solution (ORS) or intravenous fluids as soon as possible, and that the infant should continue to nurse or feed early throughout the episode. Diarrhea should be treated with ORS, a solution made of purified water, sugar, and salt.[4] The risk of getting sick can be decreased by taking steps to prevent diarrhea, such as washing your hands with soap, employing better sanitation techniques, and drinking safe water.[4] This conventional therapy lessens dehydration without changing the frequency, intensity, or length of diarrheal episodes.[5]

Adjuvant therapy, which includes (1) micronutrient zinc supplementation, (2) probiotics, (3) anti-motility agents like loperamide and diphenoxylate, (4) anti-secretarial agents like racecadotril, and (5) adsorbent agents like diosmectide, can be used in addition to ORS to lessen the duration and severity of symptoms.[1] One option for additional therapy in addition to the conventional treatment for diarrhea is probiotics. Probiotics are live bacteria that, when given in adequate amounts, improve the health of the host.[6] They work by preventing

harmful germs from growing in a competitive manner.[7] Probiotics such as Lactobacillus GG and Saccharomyces boulardii have been shown in numerous studies to be effective when used in addition to other therapies for acute pediatric diarrhea in industrialized nations. However, the paucity of research in underdeveloped nations, where enteral infections are common, highlights the necessity for ongoing investigations.[8]

For the past 30 years, the non-pathogenic yeast S. boulardii has been suggested as a preventive and therapeutic measure against bacterial diarrheal illnesses. Recent evidence from animal models of inflammation and clinical trials suggests that this probiotic yeast may be beneficial for individuals with inflammatory bowel disease (IBD). The fact that S. boulardii has shown therapeutic efficacy for gastrointestinal illnesses primarily characterized by inflammation in both clinical and experimental settings is noteworthy. This suggests that the probiotic may disrupt cellular signaling pathways that are shared by a variety of inflammatory conditions.[9]

In this particular context, the aim of this study was to investigate the efficacy of the probiotic S. boulardii in treating children with acute diarrhea. In comparison to usual treatment, the efficacy was evaluated in terms of (1) shortening the duration of diarrhea. (2) To alter stool consistency earlier than would be expected with a typical course of treatment.

Material and Methods

This study was an open-label prospective investigation carried out in the Department of Pharmacology at Jawaharlal Nehru Medical College and Hospital in Bhagalpur, Bihar, in cooperation with the Pediatrics department. The youngsters admitted to the pediatric department throughout three-month periods (January 2023 and March 2023) comprised the study population.

Children between the ages of two months and twelve years who were admitted to the hospital with acute diarrhea and dehydration were included in the study. The study excluded children who had diarrhea, systemic disease, gastrointestinal problems, immunodeficiency, or malnutrition. Out of the 55 children who were admitted to the ward for this trial, two did not provide informed consent; twenty got standard care and twenty got probiotics a long with usual care; three children passed away from extreme dehydration; and ten of the children were under weight. In the end, forty children were counted and divided into two groups. Group 1 (n=20) received regular medical care (ORS/IV fluids), while group 2 (n=20) received probiotic S. boulardii in addition to standard care. The probiotic was 250mg of S. boulardii sporesinsachets (Econorm, Dr. Reddy's laboratory). For five days, the parents were in structed to give their infants these probiotics twice a day in 20milliliters of water or breast milk.

The duration of the diarrhea and the consistency of the stool were used to measure the results. Prior to beginning treatment, baseline data including age, sex, duration of diarrhea, consistency of stool, and level of hydration were recorded. Daily notes on outcome measures were made until the day of hospital discharge.

Before any data was collected, parents or legal guardians gave their informed consent.

Microsoft Excel was used to enter the data that was collected. The qualitative data were presented as numbers and percentages. For quantitative data, the mean and standard deviation were calculated. To determine the significance of the difference in proportions, a chi-square test or a Fisher's exact test, as appropriate, was performed.

The data's normality was examined using the Shapiro–Wilk test. A student's t-test was used to determine whether there is a significant difference between the means when the data is normally distributed. Mann–Whitney's U test was applied if the data were not normally distributed. Version 26.0 of IBM SPSS Statistics for Windows IBM Corp., Armonk, New York, was employed for the analysis. Statistical significance was considered to be $P < 0.05$.

Results

The two groups' baseline measurements, which included dehydration, age and sex distribution, mean duration of diarrhea prior to therapy, and stool consistency, were similar.

Most of the children in both groups ranged in age from two months to two years. When both groups were admitted, the duration of diarrhea and the consistency of their stools were roughly the same [Table 1].

Table 1: Baseline parameters comparison among both groups

Baseline Readings	Group 1 (n=20) Standard treatment Number (%)	Group 2 (n=20) Standard treatment+probiotic Number (%)	p-value
Age			
• 2 months – 2 years	15 (75%)	14 (70%)	0.928
• 2 years – 5 years	4 (20%)	5 (25%)	
• 5 years – 12 years	1 (5%)	1 (5%)	

Sex • Male • Female	 11 (55%) 9 (45%)	 12 (60%) 8 (40%)	 0.749
The mean duration of diarrhea (Days)	3.75±1.97	3.95±2.06	0.755
Stool consistency	Loose watery	Loose waterly	
Dehydration status • No dehydration • Some dehydration • Severe dehydration	 0 (0%) 12 (60%) 8 (40%)	 0 (0%) 14 (70%) 6 (30%)	 0.507

The mean ± standard deviation was used to compare the outcome measures between the two groups. After therapy, the probiotic-treated group (group 2) experienced diarrhea for 3.8 ± 2.0 days, while the standard treatment group (group 1) experienced diarrhea for 5.1 ± 1.7 days. In the probiotic-treated group (group 2), the first semi-formed stools emerged after 2.0 ± 0.6 days, but in the control group, they came after 3.3 ± 1.6 days [Table 2].

Table 2: Outcome measures comparison among both groups

Outcome measures	Group 1 (n=20) Standard treatment-Number (%)	Group 2 (n=20) Standardtreatment+probiotic Number (%)	p-value
Duration of diarrhea (Days)	5.1±1.6	3.8±2.0	0.037
Time for appearance of first semi-liquid stools (Days)	3.3±1.6	2.0±0.6	0.002

Discussion

Bacterial flora is widely distributed throughout the human stomach. The stomach begins to colonize as soon as a child is born, and by the end of the first two years, the child's gut flora is comparable to that of an average adult. Microorganisms that are balanced between being pro-health (Bifidobacillus) and anti-health (Clostridium) are typical. This balance is lost in disorders that cause diarrhea. By colonizing the gut and displacing the harmful bacteria, probiotics aid in the restoration of this balance.[10]

It has been demonstrated that treating diarrhea with Lactobacillus, Bifidobacterium, and S. boulardii can shorten the illness's duration by 0.5–1.5 days in a number of meta-analyses and systematic reviews. [11,12] The expert panel's evaluation for the Asia-Pacific region states that probiotics such as S. boulardii and Lactobacillus are effective. This effectiveness is especially noticeable in cases of viral gastroenteritis; however, it is not absolutely related to the etiology.[13]

Pathogenic bacteria and the host can interact in a variety of ways. S. boulardii and the protein(s) it releases affect the mitogen-activated protein kinases ERK1/2 and p38, as well as the global mediator of inflammation, nuclear factor B. S. boulardii stimulates the production of peroxisome proliferator-activated receptor-gamma, which guards against intestinal inflammation and IBD. S. boulardii secretes a protease that inhibits "bacteria overgrowth" and host cell adhesion in addition to degrading Clostridium difficile toxin A and its intestinal receptor.It also encourages the development of antibodies that respond with toxin A. According to recent research, S. boulardii may be able to stop IBD from starting by entwining T cells in mesenteric lymph nodes.[9] According to previous studies, the probiotic-treated group experienced diarrhea for approximately two days as opposed to the placebo group's 2.6 days, and the probiotic-treated group experienced the first semiliquid stools 1.5 days earlier than the placebo group did, with 2.3 days.[13]

In comparison to the control group, the duration of diarrhea is lowered from 5.5 days to 4.7 days in research by Kurugol Z et al. done in Turkey. Additionally, the mean length of hospitalization is shortened from 3.9 days to 2.9 days in the S. boulardii group.[14]

In research by Eren et al., by day three, a significantly higher number of patients in the probiotic-treated group were cured than in the control group; nevertheless, the length of diarrhea was similar for both groups overall. Normalization of stool frequency and content was higher in the Saccharomyces group.[15]

According to a study by Asmat et al. carried out in Pakistan, Saccharomyces is more effective than lactic acid in treating 4-5-year-old children when compared to S. boulardii and the lactic acid group.[16] A study by Riaz et al. found that the length of diarrhea reduced by 11.9 hours and the amount of time needed to alter the feces' consistency dropped by 14.7 hours.[8] The diarrheal duration in the S. boulardii group was 15.9 hours shorter than in the control group, per a study by Huang et al.[17] The Das et al. study found that the SB group's median diarrhea duration was approximately 29 hours less than the control group's.[18]

In a multicenter study conducted in India, the probiotic group’s recovery time was significantly shorter than the placebo group’s (95.3 vs. 65.8 h),

and the probiotic group also experienced a faster return to normalcy of stool consistency (23.5 h before the first episode of semisolid stool).[19]

Conclusion

In this study, it was shown that the probiotic S. boulardii can lessen the length of diarrhea. Compared to normal therapy, it took approximately one day to change the consistency of the feces. It was found that the probiotic S. boulardii was effective in reducing the duration of diarrhea in this group by about one day. Therefore, we can reduce the severity of diarrhea and, consequently, the morbidity related to diarrhea in children by employing probiotics.

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