

Assessment of Efficacy of Regular and Probiotic Yogurt in Patients with Acute Watery Diarrhea: A Comparative Study.

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ABSTRACT

Background: Diarrhea is the second most common infectious disease in children, and causes a significant number of hospitalizations, morbidity and mortality. Probiotics are live microorganisms that, when administered in adequate amounts, confer a health benefit on the host while enhancing the properties of intestinal flora. Nowadays, probiotics use is increasingly widespread; however, indication of their use has been evidenced since ancient times. Aim of the study: To compare the efficacy of regular yogurt and probiotic yogurt in patients with acute watery diarrhea. **Materials & methods:** The study was conducted in the department of general medicine of the Government D.B. General Hospital, Churu, Rajasthan, India.. For the study, we included patients admitting to general medicine ward with acute watery diarrhea. Acute diarrhea was defined as the presence of 3 or more liquid or loose stools per day lasting for less than 14 days. A total of 120 patients were included. The patients were randomly grouped into Group 1 and Group 2. Group 1 patients were advised to consume regular yogurt (250 mg twice a day) and Group 2 patients were advised to consume probiotic yogurt (250 mg twice a day). **Results** A total of 120 patients were included in the study. Group 1 had 32 males and 28 females. Group 2 had 37 males and 23 females. Mean age of the patients in Group 1 was 32.33 years whereas Group 2 patients were 36.21 years. The duration for significant reduction of stools in group 1 was 2.12 days and in group 2 was 1.32 days. Duration for normalization of stools in group 1 was 4.12 days and in group 2 was 3.18 days. **Conclusion:** The overall duration of diarrhea in group 2 was shorter as compared to group 1. Normalization of stool composition and frequency was more rapid in the group 2 patients. These results should be confirmed with a large scale placebo controlled clinical trial evaluating the efficacy of probiotic yogurt.

Keywords: probiotic, yogurt, diarrhea, stools.

INTRODUCTION

Diarrhoea is the second most common infectious disease in children, and causes a significant number of hospitalizations, morbidity and mortality. In both developed and developing countries, viruses are the leading cause of the episodes of acute diarrhoea, with rotavirus predominating. Worldwide rotavirus-associated diarrhoea is responsible for about 600,000 deaths annually and approximately 40% of the hospitalizations for diarrhoea in children under 5 years of age. Probiotics are live microorganisms that, when administered in adequate amounts, confer a health benefit on the host while enhancing the properties of intestinal flora.^[1,2] It should be emphasized that the FAO/WHO definition of

probiotics provided by the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO) does not mention the human origin of the bacterial strain among the criteria for the selection and definition of probiotics, but instead classify according to effect caused. Nowadays, probiotics use is increasingly widespread; however, indication of their use has been evidenced since ancient times. Probiotics are often recommended on the assumption that ingestion of 'healthy' bacteria will reduce the disturbance of gut microbiota and subsequent diarrhoea. Like pharmaceuticals, different probiotics exert different actions and have different effects.^[3,4]

A number of clinical trials have used probiotics for the prevention of AAD. These studies have used a range of probiotics and have shown variable results. Meta-analyses show equivocal results due to the lack of homogeneity between studies. Sub-group analyses of the meta-analyses showed a significant reduction in AAD with the use of probiotics, namely *Lactobacillus rhamnosus* GG (LGG) and *Saccharomyces boulardii*.^[5,6] A number of methods

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have been used to administer these probiotics, including capsules, tablets and yogurts. The organisms used vary from a single species to multi-species cocktails, and the doses vary between studies, from 107 to 1010 colony-forming units (CFU).^[7,8] Hence, the present study was planned to compare the efficacy of regular yogurt and probiotic yogurt in patients with acute watery diarrhea.

MATERIALS AND METHODS

The study was conducted in the department of general medicine of the Government D.B. General Hospital, Churu, Rajasthan, India. The ethical clearance for the study was obtained from the ethical board of the institute prior to commencement of the study. For the study, we included patients admitting to general medicine ward with acute watery diarrhea. Acute diarrhea was defined as the presence of 3 or more liquid or loose stools per day lasting for less than 14 days. The exclusion criteria were: severely malnourished patients, antibiotic treatment during the preceding 7 days, known chronic uncontrolled intestinal disease such as celiac disease, pancreatic insufficiency, parasitic infestations, and bacterial diarrhea suspected by the presence of leukocyte and erythrocyte in stool examination in 2–3 hours of admission. A total of 120 patients were included. The patients were randomly grouped into Group 1 and Group 2. Group 1 patients were advised to consume regular yogurt (250 mg twice a day) and Group 2 patients were advised to consume probiotic yogurt (250 mg twice a day). All patients were examined by 1 pediatric gastroenterologist on admission and re-evaluated every morning by the same doctor until resolution of diarrhea and discharge. Demographic data, nutritional status, dehydration stage, duration of diarrhea, number and consistency of the stools, duration and number of episodes of vomiting, and duration of hospitalization were recorded.

The statistical analysis of the data was done using SPSS version 20.0 for windows. The Student’s t-test and Chi-square test were used to check the significance of the data. The p-value less than 0.05 was predetermined as statistically significant.

RESULTS

A total of 120 patients were included in the study. Table 1 shows the demographic data and clinical findings at the admission. Group 1 had 32 males and 28 females. Group 2 had 37 males and 23 females. Mean age of the patients in Group 1 was 32.33 years whereas Group 2 patients was 36.21 years. Malnutrition was seen I 15 patients in Group 1 and 13 patients in Group 2. Dehydration was seen in 36 patients in Group 1 and 48 patients in Group 2. Frequency of stools at admission was 7.32 per day in Group 1 and 6.89 per day in Group 2. Table 2 shows

the characteristics of the patients after consuming regular yogurt and probiotic yogurt. The duration for significant reduction of stools in group 1 was 2.12 days and in group 2 was 1.32 days. Duration for normalization of stools in group 1 was 4.12 days and in group 2 was 3.18 days. The duration of diarrhea in group 1 was 4.06 days and in group 2 was 3.02 days. The results were found to be statistically significant (p<0.05).

Table 1: Demographic data and clinical findings at the admission

Variables	Group 1 (n=60)	Group 2 (n=60)	p-value
Gender (M/F)	32/28	37/23	
Mean age (years)	32.33	36.21	
Malnutrition (%)	15	13	
Dehydration (%)	36	48	
Frequency of stools per day	7.32	6.89	

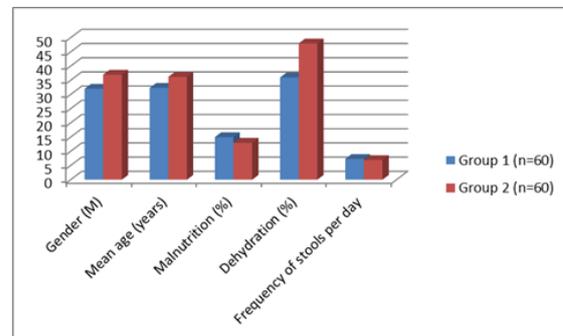


Figure 1: Demographic data and clinical findings at the admission

Table 2: Characteristics of the patients after consuming regular yogurt and probiotic yogurt

Characteristics	Group 1	Group 2	p-value
Duration for significant reduction of stools (days)	2.12	1.32	0.03
Duration for normalization of stools(days)	4.12	3.18	
Duration of diarrhea (days)	4.06	3.02	

DISCUSSION

In the present study we compared the efficacy of regular yogurt and probiotic yogurt in patients with acute watery diarrhea. We observed that symptoms were resolved earlier in Group 2 patients that were patients who were given 250 mg of probiotic yogurt twice a day. The group 1 patients who were given 250 mg of regular yogurt also had significant efficiency in resolving the symptoms but probiotic yogurt was more efficient in resolving the symptoms. The results were found to be statistically significant. The results were compared to previous studies and results were found to be significant. Grandy G et al reported the use of a locally prepared

yogurt with a lyophilized probiotic added. It was a randomized, double-blind and controlled clinical trial in children hospitalized with acute diarrhoea carried out at the Paediatric Centre Albina Patiño in Cochabamba, Bolivia with children 10 to 35 months participating. Children were randomly assigned to receive an oral rehydration solution and *Saccharomyces boulardii* (positive control) or the same solution plus yogurt preparation containing *Lactobacillus rhamnosus* (yogurt group). The primary outcome was the duration of diarrhea. Secondary outcomes were the duration of fever, vomiting and hospitalization. Of the 74 children incorporated 42 completed the protocol; baseline characteristics were similar in both groups. The median duration of diarrhea was similar in children who received yogurt (71 hours) and controls (79 hours). The mean duration of fever was also similar in both groups: *S. boulardii* (24 hours) or yogurt (11 hours), as was the duration of vomiting: 17 hours vs. 32 hours in the control group. A significant difference in the numbers of daily bowel movements was observed in the third day, the probiotic group was lower. There was no effect on the duration of hospitalization. It was concluded that the use of a yogurt containing *L. rhamnosus* has an effect comparable to *S. boulardii*. Introduction of yoghurt with a probiotic in the diet of patients hospitalized with acute diarrhoea may help reduce its duration, regardless of its etiology. Fox MJ et al estimated the efficacy of a probiotic yogurt compared to a pasteurized yogurt for the prevention of antibiotic-associated diarrhea in children. This was a multisite, randomised, double-blind, placebo-controlled clinical trial conducted between September 2009 and 2012. The study was conducted through general practices and pharmacies in Launceston, Tasmania, Australia. Children (aged 1–12 years) prescribed antibiotics, were randomised to receive 200 g/day of either yogurt (probiotic) containing *Lactobacillus rhamnosus* GG (LGG), *Bifidobacterium lactis* (Bb-12) and *Lactobacillus acidophilus* (La-5) or a pasteurised yogurt (placebo) for the same duration as their antibiotic treatment. Stool frequency and consistency were recorded for the duration of treatment plus 1 week. Primary outcome was stool frequency and consistency, classified at different levels of diarrhoea severity. Due to the small number of cases of diarrhoea, comparisons between groups were made using Fisher's exact analysis. 72 children commenced and 70 children (36 placebo and 34 probiotic) completed the trial. There were no incidents of severe diarrhoea (stool consistency ≥ 6 , ≥ 3 stools/day for ≥ 2 consecutive days) in the probiotic group and six in the placebo group. There was also only one episode of minor diarrhoea (stool consistency ≥ 5 , ≥ 2 stools/day for ≥ 2 days in the probiotic group compared to 21 in the placebo group. The probiotic group reported fewer adverse events (1 had abdominal pain, 1 vomited and 1 had

headache) than the placebo group (6 had abdominal pain, 4 had loss of appetite and 1 had nausea). They concluded that a yogurt combination of LGG, La-5 and Bb-12 is an effective method for reducing the incidence of antibiotic-associated diarrhoea in children.^[9,10]

Eren M et al evaluated the clinical efficacy and cost/effectiveness of *Saccharomyces boulardii* compared with yogurt fluid (YF) in acute non-bloody diarrhea in children. This randomized, prospective open-label clinical trial includes 55 children (36 boys, 19 girls; mean age 21.2 ± 28.2 months). Group A (N = 28) received lyophilized *S. boulardii* and group B (N = 27) received YF. The duration of diarrhea was shorter with *S. boulardii* but the hospital stay was reduced with YF, although these differences were not significant. However, diarrhea had resolved in significantly more children on day 3 in the *S. boulardii* group. In outpatient cases, yogurt treatment was cheaper than *S. boulardii* whereas in hospitalized patients, treatment cost was similar. In conclusion, the effect of daily freshly prepared YF was comparable to *S. boulardii* in the treatment of acute non-bloody diarrhea in children. The duration of diarrhea was shorter in the *S. boulardii* group, expressed as a significantly higher number of patients with normal stools on day 3. Szajewska H et al assessed the evidence from randomized controlled trials on effects of probiotics in the treatment and prevention of acute infectious diarrhea in infants and children. A systematic review of published, randomized, double-blind, placebo-controlled trials on probiotics in the treatment or prevention of acute diarrhea defined as >3 loose or watery stools per 24 hours in infants and children. The use of probiotics as compared with placebo was associated with a significantly reduced risk of diarrhea lasting >3 days. The pooled estimate risk was 0.43 with a fixed-effect model, and remained significant in a random-effect model. Only *Lactobacillus* GG showed a consistent effect. Probiotics significantly reduced the duration of diarrhea when compared with placebo, particularly in rotaviral gastroenteritis-the pooled, weighted, mean difference (WMD) assuming the random-effect model was -20.1 hours and -24.8 respectively. A meta-analysis of the prevention studies was not feasible because of significant clinical and statistical heterogeneity. They concluded that there is evidence of a clinically significant benefit of probiotics in the treatment of acute infectious diarrhea in infants and children, particularly in rotaviral gastroenteritis. *Lactobacillus* GG showed the most consistent effect, although other probiotic strains may also be effective. Further research is needed. Clinical and statistical heterogeneity of the prophylactic interventions preclude drawing firm conclusions about the efficacy of probiotics in preventing acute gastroenteritis.^[11,12]

CONCLUSION

Within the limitation of the study we conclude that the overall duration of diarrhea in group 2 was shorter as compared to group 1. Normalization of stool composition and frequency was more rapid in the group 2 patients. These results should be confirmed with a large scale placebo controlled clinical trial evaluating the efficacy of probiotic yogurt.

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