



Research Article

## EFFICACY OF PROBIOTICS IN ACUTE GASTROENTERITIS IN PAEDIATRIC AGE GROUP

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### ABSTRACT

**Background:** Gastroenteritis remains the second leading cause of death in children below 5 years of age; in addition it is also responsible for a huge burden on human society globally. Objective of this study was to investigate and compare the efficacy of probiotics in the treatment of acute gastroenteritis in children.

**Methods:** This was a hospital based prospective observational study conducted in a tertiary care hospital in Jamshedpur for 1 year. 80 children aged 6 months to 5 years admitted with gastroenteritis were enrolled in the study who fulfil the inclusion criteria and divided into two group (40 for each along with oral rehydration solution and zinc)- Group 1 received oral rehydration therapy and zinc, Group 2 received probiotics. Both groups underwent a thorough physical examination and duration of diarrhoea during hospital stay measured. Chi square test were used for analysis.

**Results:** The duration of diarrhoea significantly reduced (45.2 hrs) in Group2 as compared to Group 1 (52.8 hrs) ( $p < 0.05$ ).

**Conclusions:** Probiotics is effective in reducing the duration of diarrhoea and hospital stay in children with acute gastroenteritis.

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### INTRODUCTION

Gastroenteritis is the second leading cause of death among children under five globally and remains a major public health problem worldwide [1]. Incidence of gastroenteritis is highest in the first two years of life. In India about 10% of infants and 14% of 0-4 years children mortality due to diarrhoea.[2]

Rotavirus is the most common cause of severe, dehydrating acute gastroenteritis (AGE) among children under five years of age in India. Low osmolarity oral rehydration solution (ORS) and zinc are the effective interventions for diarrhoea management. However, its use neither shortens the duration nor reduces frequency of the stool loss. Several trials on probiotics, as an adjuvant to oral rehydration therapy (ORT) have been conducted in the recent years and have been found to reduce the duration of illness. Probiotics are live or attenuated microorganisms that can offer health benefits on their host when they are consumed in sufficient quantities. The concept of probiotics evolved after Metchnikoff observations of Bulgarian peasants who lived longer consumed large quantities of sour milk containing *Lactobacillus bulgaricus*. [3] Probiotics have an antimicrobial effect through modifying gut microflora, secreting antibacterial substances, competing with pathogens to prevent their adhesion to the intestinal epithelium, competing for nutrients necessary for pathogen survival, producing an antitoxin effect. It also capable of modulating the immune system and reducing cell proliferation in cancer.

With the increasing availability and widespread use of probiotics randomized controlled trials in Indian children are required before a particular strain is recommended to the patients. There is scanty data to establish the efficacy of the probiotics available in the Indian market. Hence we conduct this study.

### MATERIAL AND METHOD

**Study Design:** This was a Hospital based prospective observational study on efficacy of probiotic in diarrhoea patients.

**Study Setting:** This study was conducted in a tertiary care hospital and teaching institute in Jamshedpur.

**Study Period:** The present study was conducted over one years (march 2018-march 2019) and data was analysed after that.

**Source of Data:** Patients admitted in paediatric wards of the tertiary care hospital with diagnosis of diarrhoea and who fulfil the inclusion criteria were enrolled in the study.

**Sample Size:** Total 80 participants were included in the study (40 for each group).

**Aim and Objectives:** To study the efficacy of probiotics in acute diarrhoea in children

Children belonging to different socioeconomic status and from different parts of the city came to the hospital for paediatric services.

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Inclusion criteria: Acute gastroenteritis (AGE) subjects are eligible for enrolment in the study if they meet all of the following criteria:

- Are between 6 month to 5 years of age.
- Present for treatment of AGE\*.

\*AGE is defined as the occurrence of  $\geq 3$  episodes of diarrhea (stools of a less formed character than usual) within a 24-hour period, less than 7 days prior to hospital visit that is not explained by an underlying medical condition.

**Exclusion criteria:** Patients should be excluded from enrolment if any of the following apply:

- Are >5 years of age
- Unable to contact parent/ obtain written informed consent.
- Admitted to another hospital for >24 hours (and subsequently transferred to the current hospital).
- Presence of blood or pus in stools
- severe dehydration
- severely malnourished patients (grade III and IV) IAP classification
- history of immunodeficiency (AIDS, drug therapy with steroids, anticancer drugs etc.)
- presence of acute systemic illness (sepsis, meningitis, pneumonia.)
- chronic diarrhoea

We selected 80 patients which was divided into two groups. Both groups underwent a thorough physical examination, assessment of vital signs, assessment of hydration, frequency and severity of diarrhoea, and nutritional status. Group 1 managed with oral rehydration therapy or intravenous fluid and zinc but group 2 with oral rehydration therapy or intravenous fluid, zinc and probiotics. Total duration of diarrhoea after admission: time calculated in hours from the time of admission to the time the child passed the last abnormal stools.

**Statistical analysis:** Data collected during the study tools will be converted into a computer based spreadsheet. The structural analysis will comprise of calculating mean and standard deviation. Collected data were entered into excel sheet & analysed with help of SPSS.

## RESULTS

Out of the 80 cases of diarrhoea, 46 cases were male and 34 cases were female. The overall male: female ratio was 1.35:1 with a mean age of 28.1 months (range: 8–58 month). There was no significant difference between mean age and male: female ratio between the two groups.

The nutritional status was comparable in both the groups but there was no significant difference between both the groups (p value >0.05) as mentioned in table. The degree of dehydration status also compared between these groups and found no significant difference between both the groups (p value >0.05). None of the patients had severe dehydration.

The mean duration of stay after admission in group 1 was 52.8 hours but in group 2 was 45.2 hours. We found the duration of diarrhoea/ duration of hospital stays was 7.6 hours lesser in Group II (probiotic group) when compared with the group 1. On statistical analysis, duration of diarrhoea/ duration of

hospital stays were significant difference between both groups (p=0.03).

## DISCUSSION

The primary outcome of our study was duration of hospital stay or duration of diarrhoea will be decreased when we were using probiotic in addition to ORS and zinc in the management of acute gastroenteritis. This was consistent with the results of a study done by Billoo *et al* from Pakistan which showed that duration of diarrhoea was lesser by 1.3 days in children who were treated with probiotic (*Saccharomyces boulardii*) for diarrhoea.[4] A double blinded randomized controlled trial done by Grandy *et al* on Bolivian children also showed that the duration of diarrhoea was significantly lower by 26.5 hours in the group treated with *Saccharomyces boulardii* (58 hours in cases vs 84.5 hours in controls).[5]

Szajewska H *et al* done a randomised, double blind trial to know the efficacy of orally administered probiotics *Lactobacillus* GG in the prevention of nosocomial diarrhoea in young children.[6] they found *Lactobacillus* GG reduced the incidence of nosocomial diarrhoea in comparison with placebo (6.7% versus 33.3%). The *Lactobacillus* strain GG (ATCC 53103) as fermented milk or as freeze dried powder, significantly reduced the duration of diarrhoea compared to a placebo group.[7] The result has since been confirmed in studies carried out in a similar population[8] as well as in different populations.[9] The effect has been explained by reduction in the duration of rotavirus shedding, [10] stabilisation of the indigenous microflora, and reduction in increased gut permeability caused by rotavirus infection. [11] A meta-analysis of 23 randomized controlled studies in adults and children with a total of 1917 subjects came to the conclusion that probiotics reduce the mean duration of diarrhoea by 30.5 h and appear to be useful in the treatment of acute infectious diarrhoea [12].

A 2010 Cochrane database of systematic review provides a meta-analysis of 63 studies of probiotic agents involving more than 8000 participants, mostly children, and suggest that probiotics shorten the duration of diarrhoea by 24 hours [13].

## CONCLUSION

A low-cost probiotic intervention capable of reducing the duration of diarrhoea and hospital stay in children with acute gastroenteritis, even with modest efficacy, would have an enormous impact on the developing world. A great deal of study will be needed for broad implementation of probiotic in the management of acute gastroenteritis.

**Table** Comparison of baseline characteristics and outcome variables between groups

		Group 1	Group 2	P value
Gender	Male	24(60%)	22(55%)	0.65
	Female	16(40%)	18(45%)	
Age (mean±SD) months		27.8±14.2	28.4±14.93	0.85
Nutritional status	No malnutrition	14(35%)	15(37.5%)	0.81
	Grade 1	14(35%)	15(37.5%)	0.81
	Grade 2	12(30%)	10(25%)	0.61
Dehydration status	No dehydration	22(55%)	18(45%)	0.37
	Some dehydration	18(45%)	22(55%)	
Duration of stay in hospital (mean±SD)		52.8±15.69	45.2±15.69	0.03

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