

Role of Probiotics in Acute Diarrhea in Children

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Submitted for Publication

21-04-2016

Accepted for Publication

26-05-2016

ABSTRACT

Objective: To determine the effect of Bifidobacterium BB12 on mean change in stool frequency and hospital stay in the management of acute diarrhea. **Study Design:** Randomized controlled trial. **Place and duration of study:** Study was conducted at department of pediatrics, DHQ hospital, Faisalabad from 1st July 2013 to 31st December 2013. **Patients and methods:** Ninety eight patients after fulfilling inclusion criteria were registered and sorted out into group A (study) and Group B (Control) randomly (By lottery method). Group A patients were given Bifidobacterium BB12 (6 Billion units BD for five days) diluted in ORS while group B patients were given ORS only. The cases were assessed daily for decrease in frequency of stool and total duration of illness at discharge. **Results:** Mean age at the time of admission was 17.6±7 months for study group and 14.6±7.4 months for controls. Duration of hospital admission was 1.88±0.21 days in the probiotic group compared with 3.38±0.13 days in the control group (P = 0.02). Mean reduction in the frequency of stool per day was 5.08±0.34 times for study group and 2.3±0.35 times for the control group (P = 0.05). **Conclusion:** We conclude that effect of Bifidobacterium bifidum is statistically significant in reducing the mean change in stool frequency and hospital stay in management of acute diarrhea in children.

Keywords: Acute diarrhea, Probiotics, Children, Bifidobacterium (BB12).

Article Citation: Taseer AA, Anjum ZM, Zafar S, Subhani S, Ayesha H. Role of Probiotics in Acute Diarrhea in Children. APMC 2016;10(2):97-100.

INTRODUCTION

Diarrhea means increase in number or fluid content of stools due to increased intestinal motility¹. According to WHO greater than seven hundred million episodes of diarrhea occur annually in children of less than five years of age. On an average diarrhea causes 18% of childhood death, with an estimated 1.8 million deaths per year². In Pakistan, mortality from diarrhea is 0.2 million deaths per year (six hundred deaths per day) and up to 5-6 episodes occur in each child annually³. Rotavirus, Enterotoxigenic E. Coli and Vibrio cholera are the most common pathogen causing acute diarrhea in our country while acidosis, shock, septicemia and electrolyte derangements are the major complications⁴.

Conventionally, diarrhea is managed by rehydrating the patient according to the degree of dehydration, either by oral rehydration solution or intravenous fluids. In addition zinc, antiemetics, adequate nutrition and antibiotics in special circumstances like cholera can also be given⁵.

World over, there has been an intense on-going research to find a safer alternative adjunctive

treatment for this common ailment. The use of hypo-osmolar ORS and probiotics have yielded promising results in this respect⁵.

Probiotics produce a beneficial effect on health of the host⁶ when administered in adequate amounts and they are microbial cell preparations or components of microbial cells. They act by positively changing the intestinal flora, stimulating the local immunity, inhibiting the growth of pathogenic bacteria, promoting proper digestion, and increasing resistance to infection. Bacteria including Lactobacillus GG, Lactobacillus reuteri, Bifidobacteria and a yeast called Saccharomyces boulardii are the probiotics that have been studied in various clinical trials^{3,6}.

Various strains of probiotics differ in their efficacy and future clinical trials are needed to find the strain with the most desirable effects in acute diarrhea. In our setup, majority of studies on probiotics have been done on Saccharomyces boulardii in treatment of acute diarrhea and limited work on Bifidobacterium^{3,5}. so this study was done to prove the efficacy of Bifidobacterium BB12, to be used

as supportive evidence for prescription of Bifidobacterium in treatment of acute diarrhea and able to decrease diarrhea related mortality, morbidity, hospital stay and economic burden.

METHODOLOGY

The present study took place at department of Pediatrics, DHQ hospital Faisalabad from 1st July 2013 to 31st December 2013. It was randomized, controlled trial and Ninety eight hospital in-patients aged 6 to 24 months with acute non-bloody diarrhea of a less than 14 days duration were enrolled. The exclusion criteria were cases of diarrhea who have received antibiotics in the last 48 hours, cases of diarrhea having serious co-morbid conditions like cardiac, renal or respiratory disease, intake of anti-diarrheal drugs, cases of diarrhea in patients who are critically ill or have third degree malnutrition, patients with diarrhea who have blood in their stool were not enrolled in the study.

OPERATIONAL DEFINITIONS:

1. **Acute Diarrhea:** Diarrhea of less than two weeks duration.
2. **Effect:** Effect was assessed in terms of
 - a) Mean change in number of stools at discharge from the baseline.
 - b) Mean number of days from admission to discharge.
(Patient was discharged when there was no dehydration and number of stools was reduced to at least half from the baseline.

Their demographic information (name, age and sex) and history of present illness with regard to type of symptoms, frequency of stools per day and duration of symptoms were recorded. They were examined for signs of dehydration along with complete systemic examination.

Cases were randomly (by lottery method) divided into two groups, (A) and (B), with 49 cases in each group. Group A patients was given Bifidobacterium BB12 (6 billion units BD for five days) diluted in ORS while group B patients were given ORS only. Rehydration, adequate nutrition and zinc was provided to both groups. The cases were assessed daily for decrease in frequency of stool and total duration of illness at discharge.

All the information was entered in the SPSS version 11 and analyzed. Significance was calculated using independent sample t-test for mean change in stool

frequency and hospital stay. P-value of less than 0.05 considered as significant.

RESULTS

Mean age at the time of admission was 17.6±7 months for the study group and 14.6±7.4 months for controls (Table-I).

Table 1: Age distribution

Characteristic	Case	Control
Age (months)	17.6 ± 7	14.6 ± 7

Table 2: Frequency of stools (per day) at admission

Characteristic	Case	Control
Frequency of stools (per day)	14.46 ± 0.52	12.0 ± 0.44

The duration of diarrhea before admission was 1.88±0.21 days and 3.38±0.13 days for case and control respectively (Table-III).

Table 3: Duration of illness before admission

Characteristic	Case	Control
Duration of diarrhea (days)*	1.8 ± 1.2*	1.65 ± 0.8

The mean difference in hospital stay between the two groups was 1.5 days (Table IV) (P = 0.02). Mean reduction in the frequency of stool was 5.08±0.34 for the case group and 2.3±0.35 for the control group respectively; the difference of 2.78 stools was statistically significant (P = 0.05), Table-IV.

Table 4: Duration of hospital stay and reduction in stool frequency

Characteristic	Case	Control	P-value
Duration of hospital stay (days)	1.88 ± 0.21	3.38 ± 0.13	0.02
Mean reduction in frequency of stool	5.08 ± 0.34	2.3 ± 0.35	0.05

DISCUSSION

Acute watery diarrhea is a self-limiting illness in the developed world; however, in developing Countries

it may lead to significant malnutrition, morbidity, and sometimes even death.

The probiotic bacteria such as *Bifidobacterium* and *Lactobacillus* have very important role in intestinal barrier function and modulating mucosal and systemic immune responses.⁷ Yet more work is needed in this regard to investigate the role of probiotics in reducing morbidity, mortality and the cost of disease in developing countries. It is important to note that not all commercially available probiotics preparations are effective in children with acute diarrhea, and pediatricians should choose bacterial preparations based on available effectiveness data.⁷ In our study mean age is 17.6 ± 7 months in study group and 14.6 ± 7 in control group. Duration of hospital admission reduces to 1.5 days and mean duration of diarrhea was 1.88 ± 0.21 in probiotic group and 3.38 ± 0.13 in control group. ($p=0.02$). Average reduction in stool frequency is 5.08 ± 0.34 in probiotic group and 2.3 ± 0.35 in control group. The difference of 2.7 stools is statistically significant ($p=0.05$). Our study results are consistent with study done in Iran on *Bifidobacterium* in treatment of acute diarrhea which shows that the duration of hospital admission reduces to 0.6 day and mean duration of diarrhea was 3.4 ± 0.8 days in probiotics group and 4.5 ± 0.8 days in control group ($P=0.027$). Average reduction of daily frequency of diarrhea 4.4 ± 1.5 times for the case group and 3.6 ± 1.3 times for the control group ($P=0.042$).⁷

In a recently published Cochrane systematic review, including 56 studies with children, the authors conclude that probiotics have clear beneficial effects in shortening the duration of acute infectious diarrhea by a median of 24.76 hours (95% CI: 15.9–33.6 hours; 35 trials; >4500 participants) and in reducing mean stool frequency on day 2 (mean difference 0.8; 0.45–1.14; 20 trials; >2700 participants).⁸ Results from an updated meta-analysis of RCTs investigating the impact of *Saccharomyces boulardii* on treatment of acute (viral) gastroenteritis in children also demonstrated a reduction in the duration of diarrhea by a median of 1.08 days (95% CI: –1.64 to –0.53); 5 RCTs; 944 participants) in the probiotic intervention group compared with the control group.⁹

Some well-controlled clinical studies have shown that probiotics shorten the duration of Acute diarrhea^{10,11} whereas in other trials probiotics had no effect on duration.¹² These inconsistent results

might be caused by differences in study populations, ethnic varieties, type of the probiotic, or differences in the dosage of the probiotic and duration of treatment.

The present study showed that administration of *B. bifidum* for 5 days to children with acute diarrhea can decrease the duration and frequency of diarrhea as well as the hospital stay.

We also detected better weight gain in the case group compared with the control group. Because of the small sample size and lack of data on the etiology of diarrhea (particularly on the involvement of rotaviruses), we were not able to assess which type of diarrhea responded best to treatment with the probiotic. Although rare, bacteremia and fungemia have been reported as adverse effects of probiotics administration.¹³ None of our patients experienced these adverse effect.

CONCLUSION

We conclude that *Bifidobacterium bifidum* is effective in acute diarrhea in young children, however we suggest that more such studies with different strains of probiotics should be conducted with large sample size for uniform consequences over use of probiotics in management of acute diarrhea in children.

ACKNOWLEDGEMENT

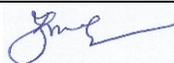
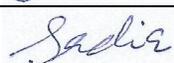
We are very much thankful to Muhammad Amjad for statistical analysis and other technical guidance according to guidelines.

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Samra Subhani	Data Analysis, Proof Reading	
Prof. Dr. Hina Ayesha	Supervise the study	