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Original Article

Clinical Efficacy of Bacillus Clausii Probiotic in the Management of Acute Diarrhoea in Children

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Abstract

Background: *Diarrhoea is the second most common cause of under five mortality especially in developing world. Very few studies have been conducted so far on bacillus clausii probiotic with inconsistent result. So, the aim of the present study is to determine the clinical efficacy of Bacillus Clausii probiotic formulation as adjunct treatment of acute diarrhoea.*

Materials and methods: *This prospective single blind randomized controlled trial included 310 infants and children between 6 months to 6 years of age admitted in a tertiary care hospital Sylhet, Bangladesh with acute watery diarrhoea having varied dehydration status ranging from no to severe dehydration excluding shocked state. Cases were randomly assigned to two groups: Group A (n=150) comprised of children who were treated with standard treatment (According to WHO guideline) only as control group and Group B who received standard treatment plus Bacillus Clausii as probiotic. Clinical responses were evaluated in terms of improvement of outcome variables such as duration and frequency of diarrhoea and duration of hospital stay.*

Results: *Mean duration of diarrhoea was 3.3(±1.1) days in Group A and 3.2(±1.3) days in Group B which was not statistically significant. Frequency of diarrhoea decreased significantly at day 4 of treatment in both study groups showing no statistical difference. Mean duration of hospital stay in both groups was 3.8 days showing no significance.*

Conclusion: *Bacillus Clausii is ineffective in reducing the duration, frequency of diarrhoea and duration of hospital stay.*

Key words: Diarrhoea; Probiotic; Bacillus Clausii.

INTRODUCTION

Acute diarrhoea is still a major health problem worldwide and a frequent cause of death, especially in developing countries[1]. This is usually treated according to WHO guideline using oral rehydration solution, intravenous fluid as indicated, and zinc supplementation[2]. This treatment doesn't halt the progression of the disease, but to minimize the complications which are the causes of death in diarrhoea. The concept of using probiotic as an adjuvant therapy in existing diarrhoeal treatment has been introduced decades ago and till now studies are being taken in both developed and developing countries to evaluate its beneficial effect[3]. Probiotics are live microorganisms which when administered in adequate amounts confer a health benefit on the host[3]. The rationale for using probiotics in acute infectious diarrhoea is based on the assumption that they act against intestinal pathogens and possible

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mechanisms include the synthesis of antimicrobial substances, competitive inhibition of adhesion of pathogens, modification of toxin and non toxin receptors and stimulation of non specific and specific immune responses to pathogens[3,4]. Scientific evidence points to the fact that the ability of a probiotic bacterium to confer a health effect largely depends on the particular strain being used[4]. While some probiotic strains have shown benefit others have demonstrated no visible difference. Most of the studies conducted so far evaluating multistrain probiotics, especially Lactobacillus species came up with favorable outcome[5]. Studies conducted using Bacillus Clausii probiotic were very few and most of them did not recommend its use[5]. So the aim of the present study is to determine the clinical efficacy of a specific probiotic strain named as Bacillus Clausii probiotic formulation as adjunct treatment of acute diarrhoea.

MATERIALS AND METHODS

This prospective single blind randomized controlled trial was carried out in a tertiary care hospital in Sylhet, Bangladesh over a period of 1year from March 2017 to February 2018. Previously healthy 6 months to 6 years old infants and children diagnosed as acute watery diarrhoea with no to severe dehydration excluding shocked state clinically on the basis of history and physical examination were included in the study. Children with dysentery, chronic diarrhoea, other acute systemic illness, severe malnutrition and/or immunosuppressive state, use of probiotic or antibiotic in previous three weeks were excluded from the study. Informed consent was obtained from parents/guardians of individual participant included in the study. Ethical clearance was taken from the institution's ethical clearance committee before study.

We analyze total 310 patients fulfilling the inclusion criteria. Cases were randomly assigned to two groups: Group A (n=150) comprised of children who were treated with standard treatment only as control group and Group B who received standard treatment plus Bacillus Clausii as probiotic. Standard treatment was used according to WHO guideline; the use of oral rehydration solution, intravenous fluid as indicated, and zinc supplementation. Probiotic formulation administered was 2 billion spores of Bacillus Clausii contained in a small bottle given 12 hourly for 5 days. Data were entered into prepared proforma, which included the information regarding baseline characteristics of patients (Age, sex, nutritional status, and dehydration status), duration of symptoms of study groups before admission (Duration and frequency of diarrhoea) and outcome variables (Duration, frequency of diarrhoea and duration of hospital stay).

Patients were followed up daily. During hospital stay, clinical responses were evaluated in terms of improvement of outcome variables. Data were processed and analyzed by using SPSS statistical software version 17 employing appropriate statistical tests. Any probability value of less than 0.05 was considered statistically significant.

RESULTS

Mean age of patients was14.67 (±9.7) months in group A and 16.20 (±8.5) months in group B. Most of the patients in both study groups were male (M: F=1.5:1 in group A versus 2.1:1 in group B). More than half of the patients in both groups had no malnutrition. While 28% in Group A and 30% in Group B had grade 1 malnutrition, fewer percentages had grade 2 malnutrition in both groups. Regarding dehydration status, most of the patients in both study groups suffered from some dehydration.

Table I : Baseline characteristics of study groups

Parameter	Group A (n=150)	Group B (n=160)
Mean age (Months±SD)	14.67(±9.7)	16.20(±8.5)
Sex		
Male No (%)	90(60%)	109(68%)
Female No (%)	60(40%)	51(32%)
Nutritional status		
No malnutrition	78(52%)	90(56%)
Grade 1 malnutrition	42(28%)	48(30%)
Grade 2 malnutrition	30(20%)	22(14%)
Dehydration status		
No dehydration	13(09%)	13(08%)
Some dehydration	108(72%)	114(71%)
Severe dehydration	29(19%)	33(21%)

Before admission, duration of diarrhoea in Group A was 3.5(±1.7) days while in Group B was 3.8(±1.6) days. No significant difference was found (p =0.579). Frequency of diarrhoea was 7.2(±2.7) per day and 7.6(±2.9) per day in Group A and Group B respectively. This was also not statistically significant (p=0.716).

Table II : Duration of symptoms of study groups before admission

Symptoms (Mean±SD)	Group A (n=150)	Group B (n=160)	p value
Duration of diarrhoea (Days)	3.5(±1.7)	3.8(±1.6)	0.579
Frequency of diarrhoea (Per day)	7.2(±2.7)	7.6(±2.9)	0.716

After intervention, mean duration of diarrhoea was 3.3(±1.1) days in Group A and 3.2(±1.3) days in Group B which was not statistically significant (p =0.432). Frequency of diarrhoea decreased significantly at day 4 of treatment in both study groups (p=0.506) showing no statistical difference. Mean duration of hospital stay in both groups was 3.8 days showing no significance (p=0.885).

Table III : Outcome variables of study groups

Outcome (Mean±SD)	Group A (n=150)	Group B (n=160)	p value
Duration of diarrhoea (Days)	3.3(±1.1)	3.2(±1.3)	0.432
Frequency of diarrhoea			
Day 1	6.9(±2.5)	6.9(±2.6)	0.902
Day 2	6.0(±1.7)	5.8(±2.0)	0.410
Day 3	3.9(±1.2)	4.0(±1.2)	0.405
Day 4	2.0(±0.9)	2.0(±0.8)	0.506
Day 5	0.7(±0.6)	0.8(±0.6)	0.328
Duration of hospital stay (Days)	3.8(±1.0)	3.8(±1.4)	0.885

DISCUSSION

Outcome measures are duration, frequency of diarrhoea and duration of hospital stay. In our study, the duration of diarrhoea in group A was 3.3(±1.1) days and in group B was 3.2(±1.3) days. No significant difference was found (p value=0.432). This study also showed that both groups reduced the frequency of diarrhoea on Day 4 of treatment and statistically insignificant (p value=0.506). This result was consistent with the study conducted by Sinchana Bhat et al which showed that Bacillus Clausii did not significantly affect duration and frequency of diarrhoea in comparison to control and Saccharomyces Boulardii group[6]. This was supported by Canani RB et al evaluating five probiotic preparations in children with acute diarrhoea proved that only two preperations : L. rhamnosus (LGG) and the mix of (L bulgaricus, L acidophilus, S thermophilus and B bifidum) had a significant effect on reducing the severity and duration of diarrhoea after the first day of administration. Bacillus clausii did not show any significant effect[7]. Another study conducted by Maugo BM in under 5 children in Kenya concluded that there was a significant decrease in the frequency of stool on Day 3&4 of treatment but no significant difference in reduction of duration of diarrhoea and duration of hospital stay with Bacillus Clausii[8]. Present study also did not show any significant difference for duration of hospital stay in both study groups. However, a recent study on Bacillus clausii done by Gianluca Ianiro et al in Italy showed promising result. It concluded that Bacillus Clausii might represent an effective therapeutic option in acute childhood diarrhoea[9]. Another study conducted by Jayanthi N et al supported the use of Bacillus Clausii in pediatric diarrhoea[10]. Lahiri et al conducted a study on bacillus clausii in pediatric acute diarrhoea and it showed reduction of diarrhoeal duration, and hospital stay but it was regarded as poor quality by meta analysis done by Gianluca Ianiro et al[11,9].

Data extrapolated from different western studies testing the efficacy of probiotics in treating diarrhoea concluded that different strains of Lactobacillus species and Saccharomyces Boulardii showed effective efficacy to varying degree. But, Bacillus Clausii probiotic showed no improvement at all[12-15]. A review by the European Society for Paediatric Gastro-enterology, Hepatology and Nutrition (ESPGHAN) was published in 2014 on the use of probiotic in diarrhoea reporting that Lactobacillus GG and S Boulardii are very potent, while L reutrri and L acidophilus have a lower recommendation. Bacillus clausii and other probiotics cannot be recommended[12]. Szajewska H et al conducted meta-analysis revealed that probiotic (L. GG, L.reuteri and S. boulardii) compared with placebo significantly reduce the risk of diarrhoea.[13] A Cochrane review suggests that probiotics mainly combination of Lactobacillus species and S boulardii may appear to be a useful adjunct to rehydration therapy when managing both adults and children[14]. Applegate JA et al evaluated eight RCTs which studied different combination of probiotics and individual probiotic showed reduction in duration and frequency of diarrhoea with Lactobacillus GG with other combination but not with Bacillus Clausii[15].

CONCLUSION

Single strain probiotic, Bacillus Clausii as an adjunctive treatment in acute diarrhoea cannot be recommended from the present study. Although very few study results favored its role in diarrhoea, most of the well recognized studies did not advocate its use. Multicentre randomized controlled trials need to be undertaken using single strain Bacillus Clausii probiotic to actually evaluate its role in diarrhoea.

DISCLOSURE

All the authors declared no competing interest.

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