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Bacillus Clausii As An Adjuvant Therapy In Acute Childhood Diarrhoea

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Abstract:*We conducted a prospective study of children suffering from acute diarrhoea, at a private tertiary care hospital in Navi Mumbai. Children were divided into 2 groups: Group 1 included children on oral rehydration therapy (ORT) + Zinc + Bacillus Clausii (Probiotic) and Group 2 comprised of children on ORT+ Zinc. We studied 131 cases admitted to the paediatric ward of whom 83 (63.4%) were males and 48 (36.6%) were females. Children less than 2 years, 2-6 years and 6-12 years were 73 (55.7%), 35(26.7%) and 23(17.5%) respectively.The duration of diarrhoea in Group 1 was 22.64 hours and Group 2 was 47.05 hours (p< 0.01). The frequency of diarrhoea showed improvement within 24 and 60 hours in Group 1 and Group 2 respectively (p<0.01).Similarly, the mean duration of hospital stay was 2.78 days in Group 1 and 4.30 days in Group 2. The treatment cost was INR 779 & INR 944whilesocial cost was INR 937 & 1409 in Group 1 & 2 respectively. Thus Group 1 & 2 spent INR 1716 and INR 2353 respectively.*
Bacillus Clausii reduced the duration, frequency and hospital stay of diarrhoea thereby reducing the treatment and social costs.
Keywords: *Childhood diarrhoea, Bacillus Clausii, therapy.*

I. Introduction

Potable water and sanitation can save millions of children suffering from diarrhoea across the globe. Probiotics are "live microorganisms, which when administered in adequate amounts confer a health benefit on the host" (1). Bacteriotherapy is known to play an important role in intestinal dysbiosis and judicious use of probiotics could reduce the duration and frequency of diarrhoea.

There is Level 1 evidence in prospective, randomized, controlled trials and meta-analysis with systemic reviews in children with acute diarrhoea (2, 3).

ORT and Zinc would remain the mainstay in the management of acute diarrhoea. However, stabilizing the gut microbiota would also be an integral part in the management and we envisage the beneficial effects of probiotics in assisting the healing process of the leaky gut.

We studied Bacillus Clausii (probiotic) as an add-on therapy to ORT and Zinc in acute diarrhoea.

Aims and Objectives:
To evaluate the role of Bacillus Clausii related to:

- Duration of diarrhoea
- Frequency of diarrhoea
- Hospital stay
- Direct and indirect costs

II. Material and Methods

We studied 131 children admitted to the paediatric ward of a private tertiary care hospital. Cases were divided into two groups: Group 1 comprised of children who were administered oral rehydration therapy (ORT) with Zinc and Bacillus Clausii and Group 2 was treated with ORT and Zinc. It was a prospective, randomized, open label, comparative study. Data was filled in a pre-designed proforma and statistical analysis was done using the Chi square test and sample t test of proportion. Institutional Ethics Committee approval was taken and an informed consent with assent was obtained before enrolling the subjects in the study.
Children were administered one mini bottle containing 2 billion spores of Bacillus Clausii 12 hourly for 5 days. They were followed up at 6 hours, 12 hours, 24, 36, 48, 60 and 72 hours.

Inclusion Criteria:

- Age between 6 months to 12 years
- Children with mild to moderate dehydration
- No prior probiotic administration

Exclusion Criteria:

- Age < 6 months
- Cases with chronic diarrhoea
- Children transferred to PICU
- Parents not consenting to participate in the study

Observation and Results: We studied 131 cases of whom Group 1 and Group 2 comprised of 69 cases and 62 cases respectively of whom 83 (63.4%) were males and 48 (36.6%) were females. Children less than 2 years were 73 (55.7%); 2-6 years were 35 (26.7%) and 6-12 years were 23 (17.6%).The duration of diarrhoea in Group 1 was 22.64 hours and Group 2 was 47.05 hours ($p<0.01$). The frequency of stool in Group 1 and Group 2 reduced within 24 and 60 hours respectively ($p<0.01$).The mean duration of hospital stay was 2.78 days when compared to 4.30 days in Group 1&2. The cost of treatment was INR 779 in Group 1 and INR 944 in Group 2. The indirect and social cost was INR 937 and INR 1409 in the above groups respectively.

III. Discussion

The normal gut microbiota in acute diarrhoea is disrupted in children and in the present study; we have tried to highlight the therapeutic efficacy of Bacillus Clausii. The duration of diarrhoea was significantly altered in Group 1; 22.64 hours when compared to Group 2; 47.05 hours ($p<0.001$, t test= 16.014) (Fig 1)

The result of t test revealed that the mean frequency of stool in Group 1 was significantly less as compared to Group 2 ($p<0.001$) and improved within 24-36 hours, (Fig 2) thus preventing fluid loss and electrolyte imbalance. The patients in Group 1 were discharged within 3 days while Group 2 had a longer stay of 5 days ($p<0.001$)The Cochrane review of meta-analysis has shown a decrease in duration and frequency of acute diarrhoea within 24 hours (4). Lahiri et al in 2008 in a phase III, controlled, open label, randomized, parallel, comparative graph using Bacillus Clausii spore in acute diarrhoea, showed that the mean duration of diarrhoea in the study Group 1 was 44.8 hours as compared to 74.5 hours in Group 2 (5).

Legitimate criticisms of meta-analysis include small sample sizes, heterogeneity related to the probiotic strains, clinical methods and endpoints (6). Our study could be regarded as a proof of concept to support the original definition of probiotics.

IV. Conclusion

Bacillus Clausii, probiotic in the spore form appeared to have a promising role as an add-on therapy to ORT and Zinc in the management of acute diarrhoea in children. It significantly reduced the duration and frequency of diarrhoea. In addition, it lowered the hospital stay thereby downscaling the financial burden to the family.

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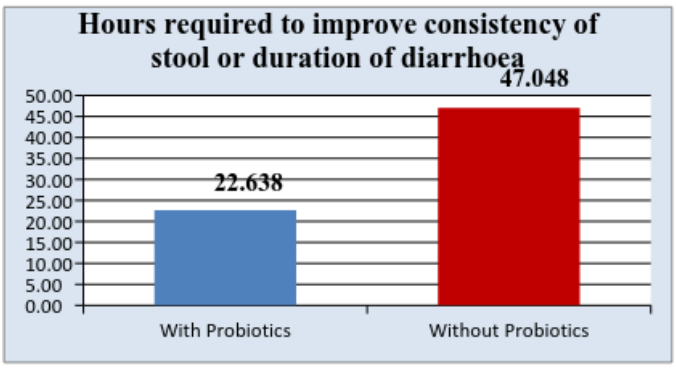

Fig 1: Duration of diarrhea

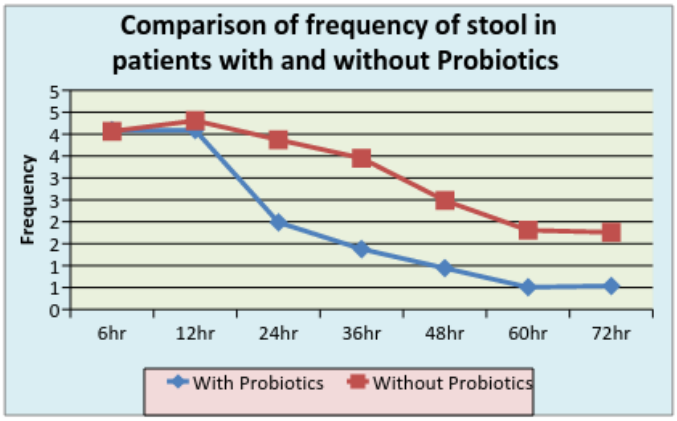

Fig 2: Frequency of stool

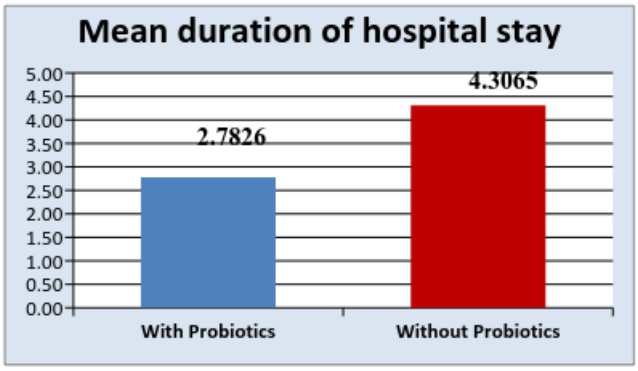

Fig 3: Duration of hospital stay

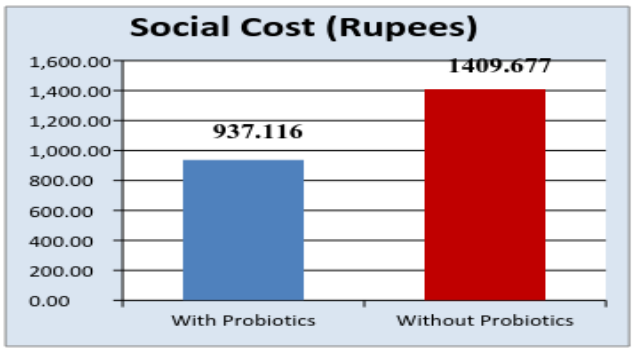

Fig 4: Social cost of diarrhoeal illness

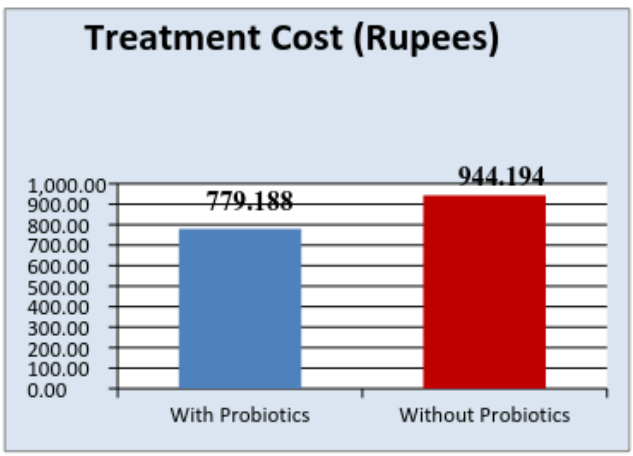

Fig 5: Treatment cost of diarrhoeal illness.