Introduction:
Health related quality of life is largely dependent on a healthy gut flora. The intestinal microbiota majorly comprises of the gut associated lymphoid tissue. Probiotics are “live microorganisms, which when administered in adequate amounts confer a health benefit on the host”. [1]
Probiotics are known to play an essential role in regulating and preventing dysbiosis in acute diarrhoea. There is Level 1 evidence in prospective, randomized, controlled trials and meta-analysis with systemic reviews in children with acute diarrhoea. [2,3]
Oral Rehydration Therapy (ORT) and zinc would remain the mainstay in the management of acute diarrhoea. However, stabilizing the gut microbiota in dysbiosis would also be an integral part of the management and we envisage the beneficial effects of probiotics in assisting the healing process of the leaky gut.
We conducted the study at a tertiary care centre in Navi Mumbai, India on the usage of probiotics as an adjuvant to ORS and Zinc in acute childhood diarrhoea.

Aims and Objectives: Primary:
To study the safety and efficacy of Bacillus Clausii in acute childhood diarrhoea.
Secondary:
To evaluate the role of *Bacillus Clausii* related to:
  i. Duration of diarrhoea
  ii. Frequency of diarrhoeal episodes
  iii. Dehydration
  iv. Exclusive breast feeding.

**Material and Methods:** We studied 160 children admitted to the paediatric ward of a private tertiary care hospital. Cases were divided into two groups: Study Group (N=80) comprised of children who were administered oral rehydration therapy (ORT) with Zinc and *Bacillus Clausii* and Control Group (N=80) were 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, p value analysis and sample t test of proportion. Institutional Ethics Committee approval was taken and an informed consent was obtained before enrolling the subjects in the study.

*Bacillus Clausii* is a gram-positive, aerobic, endospore forming, facultative, alkaliphilic rod bacterium. It has four strains O/C, SIN, N/R and T. It is resistant to antibiotics, heat and bile acid. [4] It is colourless, odourless and tasteless hence accepted well by children and can be given in between two doses of antibiotics. 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:**
  i. Age between 6 months to 6 years
  ii. Children with mild to moderate dehydration
  iii. No prior probiotic administration

**Exclusion Criteria:**
  i. Age < 6 months or > 6 years
  ii. Cases of chronic diarrhoea
  iii. Children transferred to PICU
  iv. Severely immune-compromised and malnourished children
  v. Parents not consenting to participate in the study

**Observation and Results:**

**Age & Sex:**
Majority of the patients belonged to 0-2 years age in both the groups and there was no gender bias. (Table 1)

<table>
<thead>
<tr>
<th>AGE (yrs)</th>
<th>CONTROL</th>
<th>STUDY</th>
</tr>
</thead>
<tbody>
<tr>
<td>0-2</td>
<td>60</td>
<td>64</td>
</tr>
<tr>
<td>2-6</td>
<td>20</td>
<td>16</td>
</tr>
<tr>
<td>SEX</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Females</td>
<td>42</td>
<td>34</td>
</tr>
<tr>
<td>Males</td>
<td>38</td>
<td>46</td>
</tr>
</tbody>
</table>

Table 1: maximum children in 0-2 year age group with no gender bias
**Duration:** The duration of diarrhoea was significantly altered in Study Group, 22.26 hours when compared to Control Group, 34.16 hours (p<0.05). (Fig 1)

![Bar chart showing duration of diarrhoea](image)

**Fig 1:** p value <0.05 (significant).

**Frequency:** The result of t test revealed that the mean frequency of stool in Study Group was significantly less as compared to Control Group (p<0.05) after probiotic administration. (Table 2)

<table>
<thead>
<tr>
<th>Group</th>
<th>Before treatment</th>
<th>After treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control Group</td>
<td>6.30</td>
<td>1.70</td>
</tr>
<tr>
<td>Study Group</td>
<td>3.56</td>
<td>1.15</td>
</tr>
</tbody>
</table>

Table 2: p value < 0.05 (significant)
**Dehydration status:** Maximum children in study and control group presented with no dehydration; 74% and 95% respectively, (Fig 2) hence signifying public awareness of the usage of ORS in the general population.

![Graph showing dehydration status](image)

**Fig 2:** no dehydration in most cases; control group (95%) and the study group (74%)

**Exclusive Breast Feeding:** The positive aspect of exclusive breast feeding in majority of the cases in the control group (82.5%) and study group (88.7%) has been highlighted in (Table 3)

**Table 3:** maximum children exclusively breast fed till 6 months of age

<table>
<thead>
<tr>
<th>EBF (months)</th>
<th>Mean</th>
<th>Control Group</th>
<th>Mean</th>
<th>Study Group</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>33.00</td>
<td>3</td>
<td>15.00</td>
<td>2</td>
</tr>
<tr>
<td>3</td>
<td>37.43</td>
<td>7</td>
<td>12.00</td>
<td>1</td>
</tr>
<tr>
<td>4</td>
<td>29.00</td>
<td>4</td>
<td>15.00</td>
<td>2</td>
</tr>
<tr>
<td>6</td>
<td>33.52</td>
<td>66</td>
<td>24.55</td>
<td>71</td>
</tr>
</tbody>
</table>

**Discussion:** Probiotics i.e. Bacteriotherapy is known to play an important role in intestinal dysbiosis caused by acute diarrhoea in children. According to the ESPGHAN guidelines, drugs are generally not necessary in acute diarrhoea; however, probiotics may reduce the duration
and intensity of symptoms. [5]In this study, we have tried to highlight the efficacy of Bacillus Clausii in relation to duration, frequency, degree of dehydration and effect of exclusive breast feeding in acute diarrhoea. The Cochrane review of meta-analysis has shown a decrease in duration and frequency of acute diarrhoea within 24 hours. [6] Recent studies by Lahiri et al revealed the promising role of Bacillus Clausii as an add-on therapy to ORS and Zinc in the management of acute diarrhoea in children. [7, 8]

**Conclusion:** Bacillus Clausii was found to be safe and efficacious in 0-6 years age group. Significant reduction in the duration and frequency of acute diarrhoea was observed in children who received probiotics. Our study reiterated the promising role of Probiotic (Bacillus Clausii) as an adjuvant to ORS and Zinc in the management of acute childhood diarrhoea.

**References:**


