A Comparative Study of Probiotic Lactic Acid Bacilli alone and in Combination with Bifidobacterium and Saccharomyces as Adjuvants to ORS and Zinc in the Management of Acute Pediatric Diarrhea

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ABSTRACT

Introduction: Pediatric diarrhoea is the second leading cause of childhood mortality. It is a major global health problem, particularly affecting children under the age of 5 years. It is managed with oral rehydration salt, and zinc supplements. Recently, there has been a trend of prescribing probiotics which help in reducing the frequency and duration of diarrhoea. As India is fast emerging as a potential market for probiotics, scientific studies are required to ensure their efficacy. With this background, this study was undertaken to evaluate the role of probiotics in the treatment of acute onset mild and moderate pediatric diarrhea.

Materials and Methods: This was an observational, prospective, open label, comparative study. It was conducted on 90 children after obtaining informed consent from their guardian. The participants were allocated to one of three study groups as follows; Group A: ORS & zinc; Group B: ORS, Zinc and lactic acid bacilli; Group C: ORS, Zinc and combination of lactic acid bacilli acidophilus, Bifidobacterium lactis and Saccharomyces boulardii. They were followed up for 72 hours after receiving the treatment and after 7 days. The outcome measures were reduction in mean duration and mean frequency of diarrhoea. Data was collected in case report forms. Statistical analysis was done using ANOVA followed by Dunnet’s test.

Results: The mean frequency of diarrhoea on day 1 in Group A, B and C were 5.87±1.23; 6.5±1.15 and 6.63±1.42 respectively. On day 2, in Group A it was 2.93±0.82; Group B, 3.23±0.99 and in Group C, 2.73±0.89 respectively. On day 3, in Group A it was 1.33±0.47; Group B, 0.86±0.5 and in Group C, 0.53±0.5 respectively. The mean duration of diarrhoea in Group A, B and C were 4.5±0.76, 3.47±0.5 and 3.17±0.37 days respectively. There was significant reduction in mean frequency and duration of diarrhoea in Group B and C compared to Group A (p<0.05).

Conclusion: Probiotics when used alone or in combination as adjuvant to ORS and Zinc in the treatment of acute pediatric diarrhoea results in significant reduction in mean frequency and mean duration of diarrhoea.

Key words: Bifidobacterium, Diarrhea, ORS

INTRODUCTION

Pediatric diarrhoea is the second leading cause of childhood mortality. It is a major global health problem, particularly affecting children under the age of 5 years. The overall prevalence of pediatric diarrhoea under 5 years was 37.6% in India in the year 2011.¹,² Out of those cases, acute watery diarrhoea was most common (58.9%) followed by dysentery (24.2%) and persistent diarrhoea (16.9%). The prevalence of acute pediatric diarrhoea was found to be highest in the lower socio-economic class (41%). Pediatric diarrhoea is classified into acute, persistent and chronic diarrhoea. Acute diarrhoea is defined as the passage of liquid or watery stool more than three times a day. Persistent diarrhoea is defined as diarrhoea of presumed infectious origin that begins acutely and lasts for 14 days or more. Diarrhoea that lasts for 2-4 weeks is termed as chronic diarrhoea. Based on the severity and frequency,
The participants were allocated one of the three study groups. Each study group included 30 participants. The groups envisaged received treatment as follows:

1. ORS and Zinc
2. ORS, zinc and Lactic acid bacilli acidophilus
3. ORS, zinc and combination of Lactic acid bacilli acidophilus with Bifidobacterium lactis and Sacharromyces boulardii.

They were given the study drugs after screening the inclusion and exclusion criteria. They were followed up for a period of 72 hours. A detailed history of all children particularly with respect to demographics was recorded. A thorough clinical examination was done for all children including weight, height, body mass index (BMI), pulse rate, respiratory rate and signs of dehydration. They were given a dairy and advised to come for follow up. In case they fail to return they were contacted over telephone. Investigations like complete blood count, serum electrolytes, stool routine and stool culture were done and recorded for all children during the study. Statistical analysis was performed using ANOVA followed by Dunnet’s t test.

RESULTS

A total of 112 subjects were approached to take part in the study. However, a total of 22 children could not be included due to unwillingness of their guardian to sign the informed consent form. The demographic details are shown in Table 1.

The mean duration of diarrhea in group A was found to be 4.5±0.76; group B, 3.47±0.5; and group C, 3.17±0.37 respectively. The reduction in mean duration of diarrhea in group B and C were found to be statistically significant when compared to group A (p<0.05). The mean frequency of diarrhea on day 1 in Group A was 5.87±1.23, Group B; 6.5±1.15 and Group C, 6.63±1.42 respectively. There was no significant difference between the mean frequency of diarrhea on day 1 in the three groups (p>0.05). In group A, the mean frequency of diarrhea on day 1 was 5.87±1.23, day 2 was 2.93±0.82 and day 3; 1.33±0.47 respectively. In group B, the mean frequency of diarrhea on day 1 was 6.5±1.15, day 2 was 3.93±0.99 and day 3; 0.86±0.5 respectively. In group C, the mean frequency of diarrhea on day 1 was 6.63±1.42, day 2 was 2.73±0.79 and on day 3 was 0.53±0.5 respectively. It was found that combination of probiotics (group C) significantly reduced the mean frequency of diarrhea when compared to group A and B.

MATERIALS AND METHODS

This was a randomized, open labelled, comparative, observational study. It was undertaken in the Department of Pediatrics, Vydehi Institute of Medical Sciences and Research Center, Whitefield, Bangalore. The study was commenced after obtaining approval from the Institutional Ethical Committee. The duration of the study was one year from January 2012 to December 2012. The study was undertaken in 90 children suffering from acute non-infec tive diarrhea of mild to moderate intensity, of age between 6 months to 6 years, after taking informed consent from their guardian. Children suffering from malnutrition, severe dehydration, or if immunocompromised or on any probiotic supplementation were excluded from the study. The participants were allocated one of the three study groups.
respectively (p<0.05). The results are shown in Table 2 and 3.

**Table 2: Mean Duration of diarrhoea in various groups (days)**

<table>
<thead>
<tr>
<th>Group</th>
<th>Group A</th>
<th>Group B</th>
<th>Group C</th>
</tr>
</thead>
<tbody>
<tr>
<td>4.5±0.76</td>
<td>3.47±0.5*</td>
<td>3.17±0.37*</td>
<td></td>
</tr>
</tbody>
</table>

n=30 in each group, df (2,87), F= 44.47, p <0.05

**Table 3: Mean Frequency of diarrhoea in the various groups**

<table>
<thead>
<tr>
<th>Mean frequency of diarrhoea</th>
<th>Group A</th>
<th>Group B</th>
<th>Group C</th>
</tr>
</thead>
<tbody>
<tr>
<td>Day 1</td>
<td>5.87±1.23</td>
<td>6.5±1.15*</td>
<td>6.63±1.42*</td>
</tr>
<tr>
<td>Day 2</td>
<td>2.93±0.82</td>
<td>3.93±0.99*</td>
<td>2.73±0.79*</td>
</tr>
<tr>
<td>Day 3</td>
<td>1.33±0.47</td>
<td>0.86±0.5*</td>
<td>0.53±0.5*</td>
</tr>
</tbody>
</table>

n=30 in each group, df (2,87); F= 2.30, 2.25 & 19.52 respectively, p <0.05

**DISCUSSION**

The study medications were well received and tolerated by all children. No adverse reaction was observed during hospital stay or the follow up period. No study subject discontinued the treatment due to compliance issues.

The study thus states that probiotics have an adjuvant role in the treatment of acute pediatric diarrhoea along with ORS and Zinc. The small sample size is a limitation of the present study. There is thus further need of such studies with more number of children and in different settings. Further studies can also be planned to address the pharmacoeconomics and nutrition economic benefits of probiotics in acute pediatric diarrhoea.

**CONCLUSION**

In this study, it was observed that probiotics reduced the mean duration and mean frequency of acute pediatric diarrhoea.

**REFERENCES**


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