ABSTRACT: In a randomized double blind placebo controlled trial of a pre & probiotic formulation (Bifilac), in children in the age group of three months to three years, a statistically significant reduction in the frequency and duration of diarrhea and Rotavirus shedding was observed in those children treated with Bifilac along with oral rehydration solution (ORS). The rehydration solution was as per World health organization recommendation or intravenous fluids, as the case may be. Besides, the duration and volume of oral rehydration solution (ORS) and intravenous fluid therapy were also significantly reduced in those children treated with Bifilac. Bifilac was found to be safe for children in this study.

KEY WORDS: Bifilac, Clinical trial, Placebo, Prebiotic, Probiotic, Rotaviral diarrhea

INTRODUCTION

Worldwide, infectious agents (viruses, bacteria and parasites) have been thought to be responsible for acute gastroenteritis (Burkhart, M., 1999). In developing countries, acute gastroenteritis accounts for millions of death each year among children. On a global basis, three to five billion cases of acute gastroenteritis and nearly two million deaths are reported in children under five years (Elliot, E., 2007). Rotavirus is the most common cause of acute gastroenteritis worldwide (Elliot, E., 2007). Dehydration, which may be associated with electrolyte disturbance and metabolic acidosis, is the frequent and dangerous complication. Optimal management with oral or intravenous fluids minimizes the risk of dehydration and its adverse outcomes. Routine use of antibiotics, antidiarrheal agents and antiemetics is not recommended and may cause harm (Elliot, E., 2007). Clinically significant reduction in the duration of diarrhea and hospital stay has been reported with the use of selected strains of probiotics in acute infectious diarrhea (Vandenplas, Y et al., 2007). However, a combination of a pre and probiotic resulting in the proliferation of Bifidobacterium in the large intestine would be more suitable to stabilize the ecosystem. Hence a study with Bifilac in acute Rotaviral diarrhea was undertaken.

MATERIALS AND METHODS

During the period November 2004 to February 2006, children in the age group of three months to three years visiting the out patient department of JSS Medical College Hospital with symptoms of diarrhea and needing hospitalization were considered for the study.

Children excreting stool positive for rotavirus and negative for bacteria on culture were included. Children with history of malabsorption and other illnesses were excluded. During the trial period, 385 children were admitted with diarrhea. Two hundred and fifty two eligible children were screened and one hundred and one were positive for Rotaviral antigen. But, parents of only 80 out of 101 children who were positive for Rotaviral antigen gave written consent to participate in the trial. For undertaking the above trial, the approval of the “Institutional Ethical Committee” was obtained before the patients were screened.

The eligible children were equally randomized to either the study treatment arm or the placebo arm. Relevant laboratory investigations and clinical assessment were carried out on admission and at discharge. Rotaviral assay was carried twice after admission - once between three to seven days and the next between 10 to 14 days post-treatment.

Study medication/dosage

Bifilac or placebo was dispensed in identical sachets. Each child was given either Bifilac or placebo, one sachet three times a day for a maximum period of 14 days. Oral rehydration solution and / intravenous fluid were given as per the requirement felt by the investigator. Each Bifilac sachet contained:
**RESULTS AND DISCUSSION**

All the 80 children completed the stipulated two weeks treatment. As far as the mean frequency of diarrhea is concerned, the frequency was comparable on day 1 in both the Bifilac and placebo group. However, the frequency declined rapidly in children who were on Bifilac and it touched the zero level on 9th day \((P=0.06)\) whereas in the placebo group, the frequency declined only on the 10th day (Figure 1). The mean duration of diarrhea was 4.35 days in the Bifilac group \((P=0.001)\) and 5.45 days in the placebo group (Figure 2). The results of Rotaviral assay carried out on day 1 and at discharge/early exit is shown in (Figure 3). Only two children in the Bifilac group were positive for Rotaviral shedding \((P=0.04)\) as against 9 in the placebo group.

Diarrheal diseases are responsible for approximately three million deaths among children under five years (Casburn-Jones et al., 2004) with Rotavirus as the highly contagious cause of vomiting and diarrhea (Diggle, 2007). Probiotics, defined as microorganisms that exert beneficial effects on human health when they colonize the bowel, have been proposed as adjunctive therapy in the treatment of acute diarrhea (Canani et al., 2007). Probiotics have been shown to reduce the incidence of diarrheal episodes and facilitate the recovery when used as an adjunct to oral rehydration therapy for acute diarrhea (Sharma et al., 2005). There is evidence of a clinically significant benefit of probiotics in the treatment of acute infectious diarrhea in infants and children, particularly in Rotaviral gastroenteritis (Szajewska et al., 2001). In a systematic review, probiotics – used as an adjunct to oral rehydration therapy – decreased the duration of diarrhea, especially in rotaviral gastroenteritis (Elliott, 2007).

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REFERENCES


