

## A Study of Therapeutic Outcomes of Probiotics Used In Gastroenteritis in Paediatric Patients

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### Abstract:

**Background:** Acute gastroenteritis is defined as the inflammation of the mucus membranes of the gastrointestinal tract and it is characterised by diarrhoea and vomiting which remains a major problem of healthcare till date as there are still approximately 4 billion diarrhoeal episodes every year. Probiotics may be an effective adjunct to the management of diarrhoea that has been used alongside rehydration therapy probiotics appear to be safe and have clear benefits in shortening the duration and reducing stool frequency in gastroenteritis. **Method:** A prospective observational study was conducted in the department of paediatrics at a tertiary care teaching hospital for a period of 6 months. A total of 110 patients were included in the study and their prescription was analysed for the safety and efficacy of probiotics. **Results:** Male infants were more prone to GI infection. We have analysed the prescribing pattern in which bifilac was most commonly prescribed. **Conclusion:** Probiotics were used in all types of GI infections in which bifilac was frequently prescribed. We also studied the efficacy and safety of prescribed probiotics along length of hospital stay of children with GI. Patients had a positive impact on probiotics in the management of Gastroenteritis and enhances the intestinal immune response thereby acting as a prophylaxis to gastroenteritis disease.

**Keywords:** Children, Gastroenteritis, Probiotics, Dehydration.

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### I. Introduction

The European Society children for Paediatric Gastroenterology, Hepatology and Nutrition (ESPGHAN) defines Acute Gastroenteritis as a decrease in the consistency of stools ( loose or liquid ) and/or an increase in the frequency of evacuations (typically  $\geq 3$  in 24 hrs), with or without fever or vomiting. Acute diarrhoea typically lasts for  $< 7$  days and not  $> 14$  days<sup>(1)</sup>. According to WHO, an estimated 2 billion cases of diarrhoea occur among children under 5 years of age each year. The prevalence of rotavirus diarrhoea in India has been found to vary from 5-71 percent in hospitalized children less than 5 years of age with acute gastroenteritis<sup>(2)</sup>. The priority in gastroenteritis therapy is to replace the fluid loss and reduce the severity and duration of diarrhoea.

Probiotics are commonly used in the prevention of Gastroenteritis. The widely accepted scientific definition of probiotics is “ Live microorganisms which when administered in adequate amounts confer health benefits on the host”<sup>(3)</sup>. Current management for Acute Gastroenteritis is primarily supportive, particularly with respect to dehydration, but probiotics are the commonly used therapy. Probiotics have been shown to have a luminal action : Antitoxic effect against specific pathogens, antimicrobial activity, reserving the tight junction, modulation of intestinal flora and metabolic activity. Probiotics also have a tropic effect on the mucosa and inflammatory mucosal effects.

The aim of this research article is to study the present knowledge of impact of probiotics in the prevention and treatment of Gastrointestinal disorder in Paediatrics.

### II. Materials And Methods

**Study type:** Prospective observational study

**Study site:** The study was conducted in the department of paediatrics at Rajah Muthiah Medical College and Hospital, Annamalai University, Chidambaram, Tamilnadu, a 1400 bed Multispecialty tertiary care teaching hospital located in South India.

**Study period and duration:** 6 months (From November 2019 to April 2020)

**Inclusion criteria:**

1. Patients of both gender below 12 years of age.
2. Patients who are admitted in the Department of Paediatrics with Acute Gastroenteritis.
3. Patients who are hospitalized less than 7 days.

**Exclusion criteria:**

1. Patients who are more than 12 years of age.
2. Patients who are hospitalized more than 7 days.
3. Patients who are unwilling to participate.

In this study patients case sheets & medical records were collected. From the above collected data, the commonly prescribed probiotics, their safety & efficacy, duration of diarrhoea, daily number and consistency of stools along with the length of hospital stay in paediatrics prescribed with probiotics and not prescribed with probiotics was analysed and recorded.

**Study subject recruitment procedure:**

The recruitment of subjects was carried out with the help of physicians who has knowledge of patients’s medical history. The patient information form includes the details such as patient age, gender, IP number, past medical history, medication history, drug chart details, prescribed dosage, frequency, route of administration and clinical diagnosis. The study procedure was completely explained to the patient / patient’s care taker and patient consent form will be collected from them. Subjects were selected based on inclusion and exclusion criteria.

**III. Results**

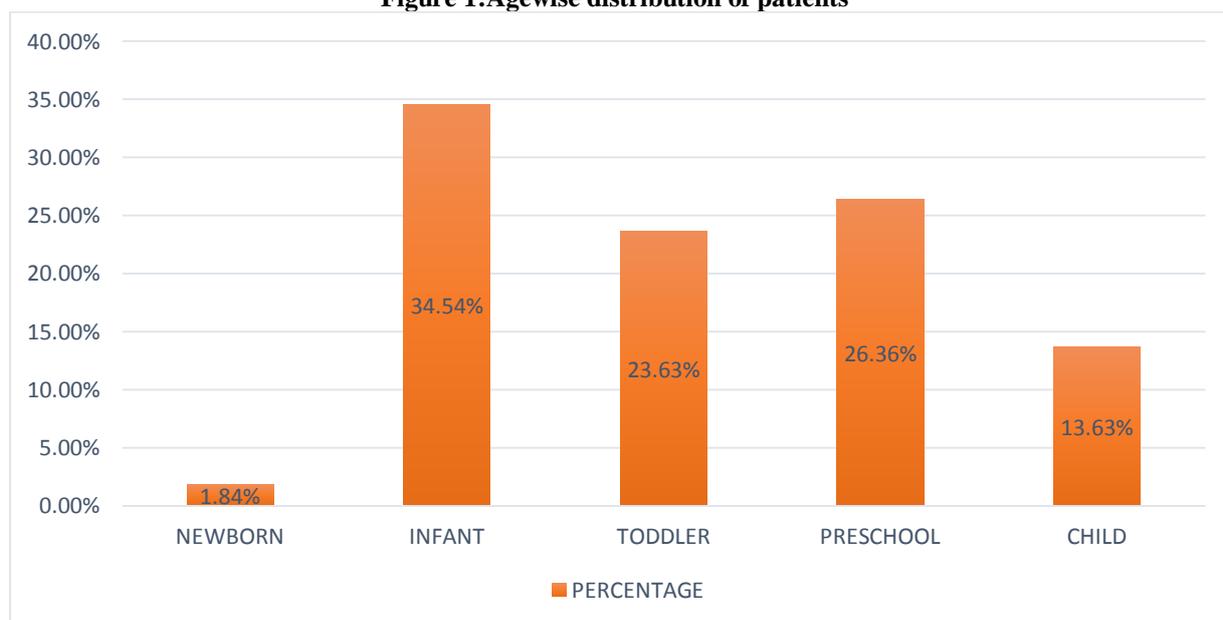
A total of 110 Acute Gastroenteritis patients data were collected among which 60% were males (Table 1)

**Table 1: Gender wise distribution of patients**

GENDER	NUMBER OF PATIENTS	PERCENTAGE(%)
MALE	66	60
FEMALE	44	40
TOTAL	110	100

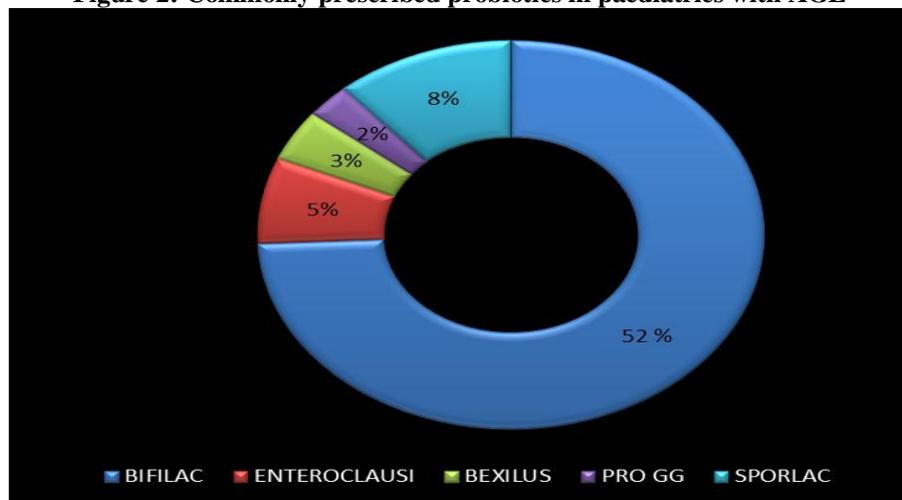
Acute Gastroenteritis are more common in Infants. In the 110 acute gastroenteritis patients 34.54% were infants (1 month – 1 year) (Figure 1)

**Figure 1: Agewise distribution of patients**



Among all the probiotics, Bifilac was the most commonly prescribed in paediatrics with Acute Gastroenteritis. (Figure 2)

**Figure 2: Commonly prescribed probiotics in paediatrics with AGE**



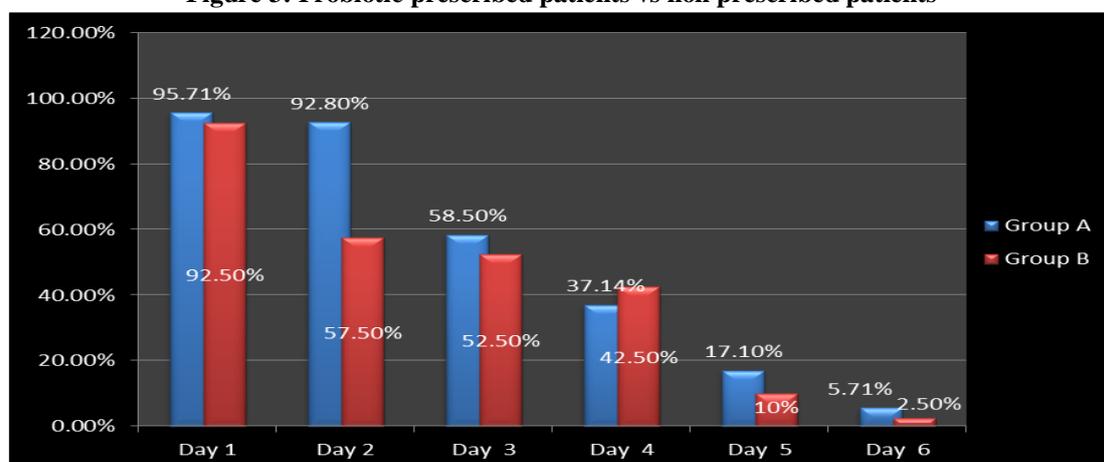
Probiotics prescribed over the study (Table 2)

**Table 2: Prescribed probiotics over the study**

PROBIOTICS	COMPOSITION	DOSAGE FORM	STRENGTH
<b>BIFILAC</b>	Clostridium butyrcum Bacillus mesentricus Streptococcus faecalis Lactobacillus sporogens	Syrup Sachet	5 gm \ 50 ml 1 gm
<b>ENTEROCLAUSI FFS</b>	Bacillus clause	Suspension Sachet	5 ml 1 gm
<b>SPORLAC</b>	Lactobacillus acidophillus Lactobacillus sporogens	Syrup Sachet	23 gm \ 50 ml 1 gm
<b>PRO GG</b>	Bifidobacterium bifidum Lactobacillus acidophillus Lactobacillus rhamnosus	Sachet	1 gm
<b>BEXILUS</b>	Bacillus subtilis Bacillus coagulans	Syrup	5 ml \ 30 ml

Probiotics prescribed patients showed quick improvement in duration of diarrhoea, daily number, consistency of stools and other symptoms of gastroenteritis than patients not prescribed with probiotics. (Figure 3)

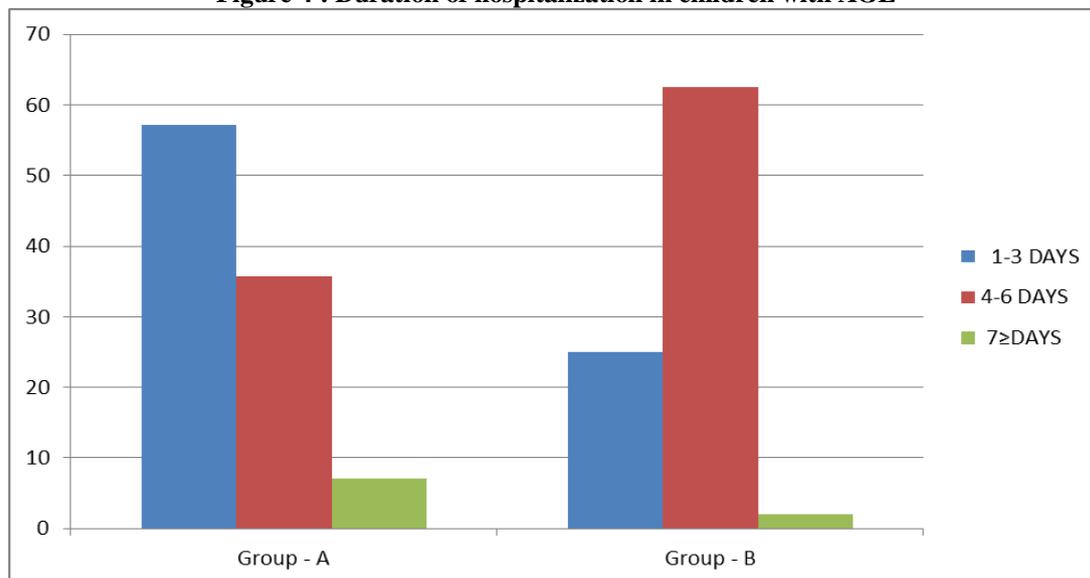
**Figure 3: Probiotic prescribed patients vs non prescribed patients**



**Group A :** Probiotic prescribed patients **Group B :** Probiotic non prescribed patients

Patients prescribed with probiotics showed better control of gastroenteritis, that the hospitalization was less than probiotics non-prescribed patients. (Figure 4)

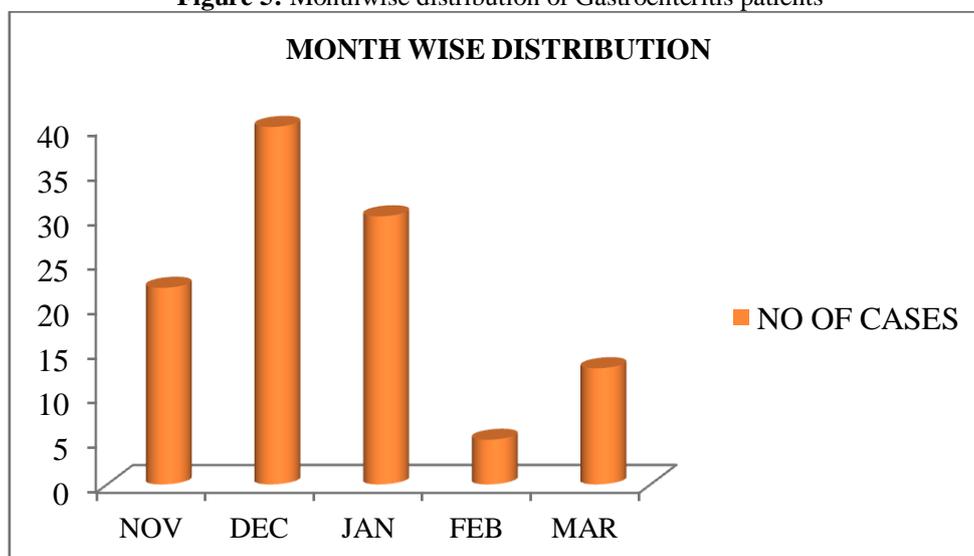
**Figure 4 : Duration of hospitalization in children with AGE**



**Group A :** Probiotic prescribed patients **Group B :** Probiotic non prescribed patients

The data also demonstrates that the illness peaked during the winter season (December) (Figure 5)

**Figure 5: Monthwise distribution of Gastroenteritis patients**



#### IV. Discussion

A total number of 110 patients were enrolled in the study. The demographic data shows that among these patients, male patients ( 60% ) were more than the female patients ( 40% ). Majority of patients 34.54% belong to ( 1 month – 1 year ) age group, they were most prone for the occurrence of Acute Gastroenteritis, focused in the study. The data also demonstrates that the illness peaked during the winter season ( i.e. December and January ).

According to the ESPGHAN working group on probiotics and prebiotics, the use of the following probiotics maybe considered in the management of children with AGE in addition to rehydration therapy: *L rhamnosusGG* , *S boulardii* . Another heat killed lactobacillus strain which cannot be defined a probiotic strain demonstrated some efficacy in reducing AGE – related symptoms in paediatric age<sup>(4)</sup>.

A Cochrane review concluded that the probiotics tested reduce the duration of diarrhoea within 24.76 hours ( 95% confidence interval [CI], 15.9 – 33.6 hrs; n =4,555 , trials = 35 ). According to same Cochrane review the frequency of stool decreased on day 2 ( Mean difference, 0.80; 0.45 – 1.14; n = 2,751, trials = 20 )<sup>(5)</sup>.

Probiotics were reported to reduce the duration of acute diarrhoea by 14.0% and stool frequency on the second day of treatment by 13.1%

Based on Cochrane review from 2010 LGG was investigated in 11 RCT's ( n = 2,072 ) and this meta-analysis found that use of LGG reduced the duration of diarrhoea for mean of 27 hours ( 95% confidence interval [CI], -41 to -13). Subsequent systematic review performed by Szajewska et al. <sup>(6)</sup>.

Collinson S, et.al. independently assessed the methodological quality of the trial and extracted data. 63 studies met the inclusion criteria with a total of 8014 participants. Of these, 56 trials recruited infants and young children. No adverse events were attributed to the probiotic intervention. The average of the effect was significant for mean duration of diarrhoea (95% confidence interval 15.9 to 33.6 hours; n = 4555, trials = 35) diarrhoea lasting  $\geq$  4 days (risk ratio 0.41; 0.32 to 0.53; n = 2853, trials = 29) stool frequency on day 2 (mean difference 0.80; 0.45 to 1.14; n = 2751, trials = 20 )<sup>(7)</sup>.

In our study probiotics improved the balance of the intestinal micro flora. Hypothesized outcomes include suppression of growth or invasion by pathogenic bacteria, improvement of intestinal barrier function and effects on immune function, and thereby acts as a prophylactic to prevent GI diseases. It is also observed that the duration of diarrhoea, daily number and consistency of stools in paediatrics shows quick improvement in patients prescribed with probiotics, whereas the probiotics non prescribed patients showed delayed improvement and has longer hospital stay than the patients prescribed with probiotics. This study shows that the patients were mostly prescribed with probiotic bifilac( 52% ), while only a fewer patients were treated with other probiotics like sporlac ( 8% ), enteroclausi ( 5% ), bexilus ( 3% ), and pro GG ( 2%).

## V. Conclusion

In the present study entitled “A study of therapeutic outcomes of probiotics used in gastroenteritis in paediatric patients” We have made an attempt to study the efficacy and safety of prescribed probiotics along length of hospital stay of children with gastroenteritis.

The study findings showed that Bifilac is the most commonly prescribed probiotic in RMMCH for gastroenteritis and the patients prescribed with probiotics showed quick improvement in duration of diarrhoea, daily number, consistency of stools and other symptoms of gastroenteritis.

Patients prescribed with probiotics showed better control of gastroenteritis. By the end of the study duration of hospitalization was less than the patients non -prescribed with probiotics and are considered as safe and adjunct to rehydration therapy in the treatment of gastroenteritis.

By the conclusion, patients had a positive impact on probiotics in the management of gastroenteritis and it enhances the intestinal immune response thereby acting as a prophylaxis to gastroenteritis disease.

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## DECLARATION

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