

Clinical effectiveness of *Bacillus clausii* and *Lactic acid bacillus* in acute diarrhea

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Received - 04 February 2020

Initial Review - 15 February 2020

Accepted - 09 March 2020

ABSTRACT

Background: Depending on the duration, acute diarrhea is defined as the passage of three or more loose or liquid stools per day lasting for <14 days. To combat diarrheal diseases, many treatment options have been made available. Probiotics are one of the most researched subjects in the pediatric discipline. **Objective:** The objective of the study was to compare the effectiveness of two different species of probiotic bacteria, *Bacillus clausii* and *Lactic acid bacillus*, in acute diarrhea. **Materials and Methods:** The sample size was 150 with 75 patients each divided into two groups. Groups A and B patients were administered probiotic *B. clausii* (2 billion spores) and *L. bacillus* (1.5 billion spores) respectively, along with ORS+Zinc given orally twice a day. The data were analyzed for details of diarrhea before and after probiotic administration. **Results:** In Group A, 20 patients recovered within 3 days, whereas 22 Group B patients recovered in 4 days after probiotic administration. For achieving normal stool frequency, the mean number of days was 3.76 ± 1.44 and 3.99 ± 1.52 among Groups A and B patients, respectively, and to achieve normal stool consistency, the values were 3.54 ± 1.34 and 3.65 ± 1.33 days, respectively ($p > 0.05$). **Conclusion:** Both probiotic preparations were almost equally effective in achieving normal stool consistency and frequency in patients with acute diarrhea.

Key words: Acute diarrhea, Probiotics, Stool consistency, Stool frequency

Adults and children commonly present with acute diarrhea due to various etiologies. Depending on the duration, acute diarrhea is defined as, the passage of three or more loose or liquid stools per day lasting for <14 days (<2 weeks) in duration [1]. It is of concern since acute diarrhea in children is one of the biggest public health problems related to higher morbidity and mortality rates. It is also the second leading cause of death in children under 5 years worldwide [1,2]. To combat diarrheal diseases, many treatment options have been made available. Recently, probiotics are one of the most researched subjects in the pediatric discipline. Probiotics are defined as, non-pathogenic live microorganism which, when administered in adequate amounts, confer a health benefit to the host [3]. They basically affect the intestinal microbial balance of the host and improve his/her immunity, thus showing preventive as well as curative effects on diarrhea of different etiologies [4,5]. This study was carried out with an aim to compare the effectiveness of two different species of probiotic bacteria, *Bacillus clausii* and *Lactic acid bacillus*, in acute diarrhea.

MATERIALS AND METHODS

This prospective, single centric, parallel group, single blind, and randomized clinical study commenced after obtaining approval from Institutional Ethics Committee. It was conducted

from January 2018 to June 2019 at the Department of Pediatrics of a Tertiary Care Teaching Hospital. The sample size was 150 patients which were calculated using Cochran's formula. Among these, 75 patients each were included in two Groups A and B. This randomization was carried out through a lottery method by a random allocator who was not associated with the study.

The data were collected on a case record form after the informed written consent was obtained from parent or guardian. Infants and children between 6 months and 5 years, suffering from acute diarrhea and seeking treatment at this set-up, were included in the study. Infants and children whose parents or guardian were not willing to give their written informed consent, those with other co-morbid conditions such as the presence of blood/mucus in stool, co-existing acute systemic illness, shock, any infection, immune-deficiency states, severe dehydration, lactose intolerance, severe acute malnutrition or those who were already on probiotic before the hospital visit were excluded from the study.

Groups A and B patients were administered probiotics – *Bacillus clausii* (2 billion spores) and *Lactic acid bacillus* (1.5 billion spores), respectively, along with ORS+Zinc orally twice a day. They were followed-up until they passed three consecutive stools with normal consistency and/or frequency to calculate the effectiveness of probiotics in acute diarrhea with respect

to duration of diarrhea, stool frequency per day, and stool consistency. During the course of study, they were not given any medication other than their respective probiotic preparation, ORS, Zinc, and other drugs such as anti-emetic (Ondansetron) and anti-pyretic (Paracetamol) if necessary.

The data was analyzed for details of diarrhea. The statistical analysis was done using Microsoft Excel Office 365 and SPSS (version 26.0). p-value >0.05 was considered as statistically non-significant.

RESULTS

A total of 150 patients were studied and Groups A and B consisted of 75 patients each. Fig. 1 shows that among 75 patients in Group A, a maximum 42 (56%) patients had loose stool for 1 day. Among 75 patients in Group B, 36 (48%) patients had loose stool for 2 days.

With respect to stool frequency per day, the majority of 18 (24%) patients in Group A experienced 6 loose stools/day followed by 16 (21.33%) and 15 (20%) patients having 5 and 4 loose stools/day. In Group B, 22 (29.33%) patients had 5 loose stools/day. The details are given in Table 1.

As shown in Table 2, a maximum of 41 (54.67%) patients experienced Grade 3 watery loose stools whereas 34 (45.34%) experienced Grade 2 semi-liquid loose stools in Group A. In case of Group B, 44 (58.67%) experienced Grade 2 stool consistency while Grade 3 stool consistency was noted in 31 (41.34%) patients.

All 150 patients included in the study were given ORS+Zinc therapy irrespective of the probiotic being administered. Fig. 2 shows that in Group A, maximum 20 (26.67%) patients recovered within 3 days while in Group B, maximum 22 (29.45%) patients recovered within 4 days. A total of 5 (6.67%) patients in Group A recovered in 1 day, whereas 3 (4%) took 7 days to recover. In Group B, 6 (8%) patients recovered in 1 day while 5 (6.67%) recovered in 7 days.

Table 1: Frequency of loose stool per day before probiotic administration

Frequency of loose stool (per day)	Total number of patients, n (%)	
	Group A	Group B
3	14 (18.67)	8 (10.67)
4	15 (20)	17 (22.67)
5	16 (21.33)	22 (29.33)
6	18 (24)	17 (22.67)
7	12 (16)	11 (14.67)
Total	75	75

Table 2: Consistency of loose stool before probiotic administration

Consistency of loose stool	Total number of patients, n (%)	
	Group A	Group B
Grade 2 (semi-liquid)	34 (45.34)	44 (58.67)
Grade 3 (watery)	41 (54.67)	31 (41.34)
Total	75	75

As shown in Fig. 3, maximum 21 (28%) Group A patients achieved normal stool frequency in 3 days followed by 19 (25.34%) in 4 days and 16 (21.34%) in 5 days whereas maximum patients in Group B, i.e., 23 (30.67%) achieved in 4 days followed by 16 (21.34%) and 13 (17.34%) patients in 3 and 5 days, respectively. The mean number of days were 3.76±1.44 and 3.99±1.52 days among Groups A and B patients, respectively (p=0.35).

Fig. 4 shows that among patients in Group A, normal stool consistency was achieved in 3 days in 23 (30.67%) patients, whereas among patients in Group B, maximum 24 (32%) patients reached normal stool consistency in 4 days. Mean number of days were 3.54±1.34 and 3.65±1.33 days among Groups A and B, respectively (p=0.58).

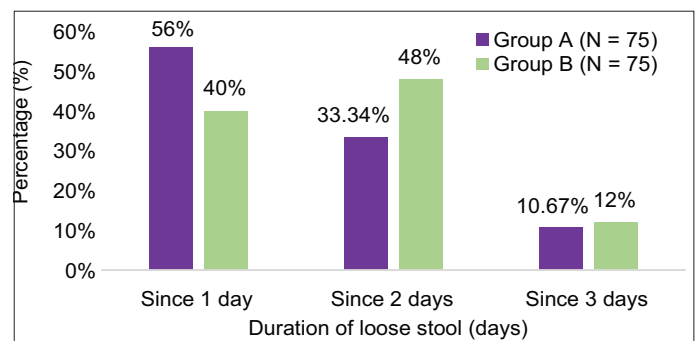


Figure 1: Duration of loose stool in patients before probiotic administration

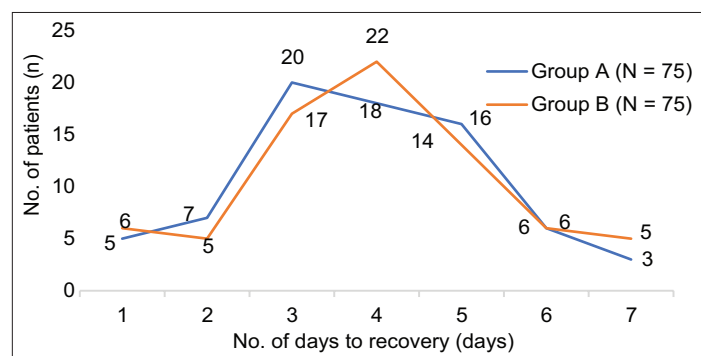


Figure 2: Total duration of loose stool after probiotic administration

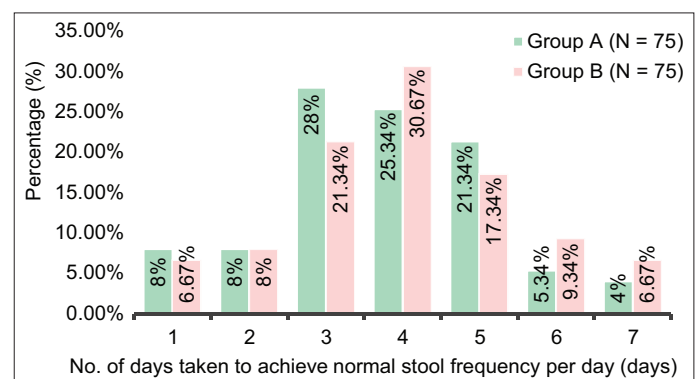


Figure 3: Days taken to achieve normal stool frequency after probiotic administration

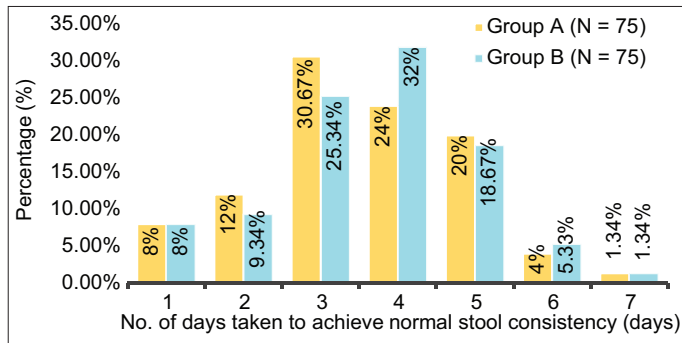


Figure 4: Days taken to achieve normal stool consistency after probiotic administration

DISCUSSION

The clinical benefits that are observed with the usage of probiotics are understood to be mainly due to mechanisms such as immunological tolerance, producing bacteriocins to act as local antibiotics, inhibiting pathogen growth by luminal pH, improving mucosal integrity by stimulating mucin production and by decreasing potent pro-inflammatory cytokines, and enhancing the production of anti-inflammatory cytokines [6-8]. They are also called friendly or good bacteria [9,10]. Thus, the role of probiotics in diarrheal management is highly advocated.

In present study, duration of diarrhea before starting the treatment ranged from 1 to 3 days. This is consistent in the study from Ghana by Reither *et al.* [11], in which the mean duration of diarrhea at presentation was 72 h. In a study by Francavilla *et al.* [12], the duration of diarrhea before admission was 1.5 days. With respect to our study, the frequency of loose stool per day in diarrheal patients before treatment ranged from 3 to 7 loose stools/day. Taseer *et al.* [13] showed that the frequency of stools per day at admission was 14.46 ± 0.52 and 12.0 ± 0.44 among cases and control. The consistency of loose stool before treatment also varied and observations were recorded after subjecting the patient's parents to Bristol stool chart. Majority patients in Group A had loose stool while Group B had semi-liquid stool consistency in our study.

In present study, the primary outcome measures after probiotic use were improvement in stool frequency per day, stool consistency, and decrease in the duration of loose stool. For majority Group A patients, duration of loose stool decreased to 3 days after probiotics whereas in Group B, it became 4 days for a maximum patients.

With respect to normal stool frequency, Group A and B patients required approximately 3 to 4 days. This meant that both the probiotic preparations, *B. clausii* and *Lactic acid bacillus*, were almost equally effective in achieving normal stool frequency per day. Similarly, for normal stool consistency, the mean number of days required in Groups A and B were 3.5 days approximately, indicating that both the preparations were similar in their effectiveness.

Various previous studies also suggested the similar effectiveness of probiotic preparations. In a study by Raza *et al.* [14], there was a reduction in the frequency of vomiting

and loose stools on day 2 with *Lactobacillus* therapy. Ritchie *et al.* [15] in their study showed that probiotics did not change the duration of diarrhea, total stools, or diarrhea score compared with placebo, but there was a significant ($p < 0.05$) difference in diarrhea frequency on day 2 between probiotics (3.3 loose stools; 2.5, 4.3 confidence interval [C.I.]); and placebo (4.7 loose stools/day; 3.8, 5.7 C.I) groups.

In a study by Taseer *et al.* [13], the mean reduction in the frequency of stool per day was 5.08 ± 0.34 times for the probiotic group than 2.3 ± 0.35 times for the control group ($p < 0.05$). Data arising from the pooled analysis also showed that *B. clausii* significantly reduced the duration of diarrhea with a mean difference of -9.12 h only compared with control. Stool frequency was not significantly different after *B. clausii* administration compared with the control group [16]. This superiority of probiotic was observed in a case-control study. In the present study, there were no adverse effects noted with probiotic administration in both the study groups.

Our study had a few limitations. Infants and children aged 6 months–5 years were studied while other pediatric age groups were excluded from the study. Children included in both the study groups were not matched with respect to age, gender, or severity of diarrhea. It was a single centric study. The sample size was small. Since the present study was not a case-control study, it could not be concluded that whether probiotic changed the course of illness or there was natural resolution.

CONCLUSION

Thus, it can be proposed that probiotics might be useful as an adjuvant in acute diarrhea. The probiotic preparations, *B. clausii* and *Lactic acid bacillus*, were almost equally effective in achieving normal stool consistency and frequency in patients with acute diarrhea. The results from this study might help the clinicians in the selection of appropriate probiotic preparation for the treatment of acute diarrhea.

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Funding: None; Conflict of Interest: None Stated.

How to cite this article: Shah AC, Goyal DK, Sareen D. Clinical effectiveness of *Bacillus clausii* and *Lactic acid bacillus* in acute diarrhea. *Indian J Child Health*. 2020; 7(3):109-112.

Doi: 10.32677/IJCH.2020.v07.i03.004