

## Original Article

## Efficacy of Bovine Colostrum in The Treatment of Acute Diarrhoea in Infants and Children

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## Abstract

**Objective:** The objective of this study was to determine the efficacy of bovine colostrum for the treatment of acute diarrhoea among infants and children admitted to a tertiary care hospital in Islamabad, Pakistan.

**Methods:** This interventional study was conducted at a tertiary care hospital, Islamabad. Infants and children admitted to the hospital with acute diarrhoea were selected through consecutive sampling. Group A received bovine colostrum along with the standard treatment, whereas group B received standard treatment alone. Number of days to achieve defecation frequency of <3 Times per day, normal stool consistency, and duration of hospital stay were the main outcomes of interest. SPSS version 21 was used for statistical analysis.

**Result:** Mean recovery time in Group A was 1.4865+ 0.506 days and in Group B was 1.2174 + days. The mean number of days remaining for patients admitted in Group A was 3.8919 + 1.629 days, while in Group B it was 3.8261+ 1.64 days. The efficacy was 33.59 in group A, while 25.52 in group B. This difference was not statistically significant (p=0.738).

**Conclusion:** There was no difference between the group taking standard treatment and the one taking standard treatment plus bovine colostrum in terms of recovery time and efficacy but the difference was significant in terms of the number of days patients remained admitted where bovine colostrum group had increased no of days of admission so conclusion is there is not much role of bovine colostrum in treatment of acute diarrhea when combined with standard care.

**Keywords:** Children, Colostrum, Defecation, Diarrhoea, Hospitalised

## Introduction

Diarrhoea is one of the main public health problems in infants and toddlers, especially in low-resource settings.<sup>1</sup> Diarrhoea can be due to viral, bacterial, parasitic and fungal infections, with viral infections being the most common aetiology.<sup>2</sup> According to WHO, it is a condition manifested as the passing of  $\geq 3$  loose stools/ day or too frequent stools for an individual.<sup>3</sup> Annual reported deaths from diarrhoea are 525,000 per year.<sup>4</sup>

Despite Oral Rehydration Therapy's proven efficacy and advocacy by AAP (American Academy of Paediatrics), CDC (Centres for Disease Control and Prevention), WHO (World Health Organisation) and European Society for Pediatric Gastroenterology and Nutrition, only 33% of children with diarrhoea receive ORT.<sup>5</sup> The efficacy of certain other therapeutic agents has also been established in preventing and treating diarrheal diseases. It is important to develop a therapeutic method that is safe and effective, and, along with the standard treatment, accelerates the recovery time and reduces the length of hospital stay.<sup>6-8</sup>

Colostrum contains growth factors, immunoglobulins and antimicrobial peptides. It is known to boost neonatal immunogenic defence.<sup>9</sup> Bovine colostrum is commercially available colostrum abstract containing antibodies against bacterial, fungal, parasitic and viral infections.<sup>10</sup> Use of colostrum in treating various illnesses dates back thousands of years: There are published studies that have reported efficacy in children for the treatment of acute diarrhoea. WHO or the FDA have not recommended any specific dose. Most clinical trials have reported very few minor side effects, and generally, bovine colostrum is tolerated well. The frequently associated side effects are sensitivity to milk proteins and lactose intolerance.<sup>11</sup> Therefore, possibly nutraceutical approach of bovine colostrum will improve the treatment of diarrhoea patients.<sup>12</sup>

Though studies are being conducted to determine the efficacy of certain adjuvant therapies along with the standard treatment. However, there is a dearth of literature both nationally and internationally on the efficacy of BC in the treatment of acute diarrhoea. In particular, our search has revealed that no study is available from Pakistan; therefore, this randomised controlled trial is planned.

## Contributions:

HM, AR, RZ, SA, AZ - Conception, Design

NT, - Acquisition, Analysis, Interpretation

HM, AR - Drafting

NT, RZ, SA, AZ - Critical Review

All authors approved the final version to be published & agreed to be accountable for all aspects of the work.

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**Potential Competing Interests:**

None to report

## Institutional Review Board Approval

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To determine the efficacy of bovine colostrum for the treatment of acute diarrhoea among infants and children admitted to a tertiary care hospital in Islamabad, Pakistan.

The bovine colostrum, in addition to the standard treatment, is more effective as compared to the standard treatment alone in infants and children aged less than 5 years.

#### Operational Definitions

Acute Diarrhoea is defined as a diarrheal illness of less than 7 days duration presenting with 4 or more watery loose stools per day. Efficacy is measured in terms of recovery time and length of hospital stay.

Recovery time is assessed by the number of days needed to achieve defecation frequency  $\leq 3$  times/day

## Materials And Methods

This interventional study was conducted at Akbar Niazi Teaching Hospital for six months after approval of the synopsis on infants and children admitted to the hospital with acute diarrhoea. A non-probability consecutive sampling was conducted.

The Open Epi sample size calculator was used for the estimation of sample size, taking a confidence interval of 95%, power 80%, ratio of sample size 1:1, mean length of hospital stay in treatment group  $2.89 \pm 0.78$  days,<sup>14</sup> mean length of hospital stay in control group  $3.94 \pm 1.53$  days.<sup>13</sup> The total estimated sample size came out to be 42, i.e., 21 in each group.

Children between 6 months to 5 years of any gender with acute diarrhoea were included in the study.

Children with severe malnutrition receiving medication such as antibiotics, anti-parasite, antiviral, antifungal, and or symptomatic drugs for acute diarrhoea, those Acute diarrhoea that lasted for >48 hours and Non-consenting parents/guardians were excluded from the study.

The study was conducted after getting approval from the ethical review committee of Islamabad Medical and Dental College. All patients meeting the inclusion criteria were enrolled. All patients were randomly divided into two groups through a lottery method. Group A received bovine colostrum along with the standard treatment, whereas group B received standard treatment alone. The baseline characteristics, such as patients' age, weight, gender, residence, and number of days diarrhoea before admission, were noted in a pre-structured proforma. Clinical characteristics such as fever were noted. Number of days to achieve defecation frequency of  $< 3$  Times per day, normal stool consistency, and duration of hospital stay were the main outcomes of interest.

SPSS version 21 was used for statistical analysis. Normality of the data was assessed by plotting a histogram for individual variables. Mean  $\pm$ SD was reported for quantitative variables like age, current weight, number of days diarrhoea before admission, number of days to achieve defecation frequency of  $< 3$  Times per day, normal stool consistency, and duration of hospital stay. Frequency and percentages were computed for socio-demographic variables. Mann-Whitney U test was used to see the mean difference of the number of days to achieve defecation frequency of  $< 3$  Times per day, normal stool consistency, and duration of hospital stay in the treatment versus control group. Fisher's exact test was used to find the association between the treatment group and weight. The p-value of  $\leq 0.05$  was considered significant.

The study was conducted by all the ethical guidelines. No personal or confidential information, including the photograph, was obtained. No risk was reported with the use of bovine colostrum in the intervention arm. The data was password-protected.

## Results

In our study sample, 15% (n=9) of the participants were 6 months to less than 1 year old, 41.7% (n=25) were 1-3 years old, and 43.3% (n=26) were more than 3 to 5 years old. Males were 53.3% (n=32) and females 46.7% (n=28). Participants included in the first group (A) were 61.7% (n=37) and in the second (B) 38.3% (n=23). Mean recovery time in Group A was  $1.4865 \pm 0.506$  days, and in Group B was  $1.2174 \pm$  days. The mean number of days needed to achieve defecation frequency  $< 3$  times/ day in Group A was  $2.8919 \pm 1.62$  days, while in Group B it was  $2.5652 \pm 1.532$  days. The mean number of days patients remained admitted in Group A was  $3.8919 \pm 1.629$  days, while in Group B it was  $3.8261 \pm 1.64$  days. 18.9% (n=7) of children in group A and 17.3% (n=4) in group B had a weight less than the 5<sup>th</sup> centile. Children with weights between the 5<sup>th</sup> to 95<sup>th</sup> centile were 75.6% (n=28) in group A and 78.2% (n=18) in group B, while only 5.40% (n=2) children in group A and 4.3% (n=1) in group B were at the 95<sup>th</sup> centile. The data was not normally distributed.

The mean rank of the number of days needed to achieve defecation frequency  $< 3$  times per day was 31.93 and 28.20 in group A and B, respectively, with no statistically significant difference between the two groups (p=0.409). The mean rank of recovery time  $< 3$  days plus hospital stay  $< 3$  days was 33.59 in group A, while 25.52 in group B.

This difference was statistically significant (p=0.039). The mean rank for the number of days the patient remained admitted was 31.05 for group B and 29.61 for group A, with no significant difference. (p=0.738). There was no significant difference in the weight of children between the two groups (p 0.969).

The first-formed milk in cows after birth is known as bovine colostrum (BC), which is nutritionally significant and may be used as a supplement in humans and other species to promote a healthy gut. According to various studies, BC, if given at a proper time, in adequate levels and at an optimal age, can be both safe and effective.<sup>14</sup> Treatment with bovine colostrum and associated reductions in the frequency and occurrence of stools in comparison to the placebo have been established by a meta-analysis of randomised control trials conducted by Li et al.

**Table 1: Age & Gender Distribution of the Participants**

Variables	Frequency (n)	Percentage (%)
<b>Age</b>		
6 months-<1 year	9	15
1-3 years	25	41.7
>3-5 years	26	43.3
<b>Gender</b>		
Males	32	53.3
Females	28	46.7

**Table 2: Recovery Time, No of Days of Admission and Efficacy**

Variable	Treatment Groups	Mean Rank	P value
Recovery time (number of days needed to achieve defecation frequency $\leq 3$ times/day)	Group A	31.93	0.409
	Group B	28.20	
The number of days the patient remained admitted	Group A	33.59	0.039*
	Group B	25.52	
Efficacy (recovery time plus no of days the patient remained admitted)	Group A	31.05	0.738
	Group B	29.61	

**Table 3: Cross Tabulation Between Treatment & Weight of Children**

Treatment	Weight			P value
	Less than 5 <sup>th</sup> Centile	Between 5 <sup>th</sup> to 95 <sup>th</sup> Centile	Above 95 <sup>th</sup> Centile	
Group A	7	28	2	0.96
Group B	4	18	1	

## Discussion

The studies included in meta-analysis had various outcomes of interest such as frequency of diarrhea, complications of diarrhea, intestinal permeability etc.<sup>15</sup> None of the studies compared no of days needed to achieve reduced frequency which was the main outcome of interest in our study that reported no significant difference in reducing frequency of defecation between the group receiving standard treatment for diarrhea and the one with supplemental bovine colostrum.

Another meta-analysis revealed no effect of colostrum, whether bovine or human, on the occurrence of severe necrotising enterocolitis, all-cause mortality & feed intolerance as compared to placebo, but mean days to reach full enteral feed were significantly reduced in the intervention group.<sup>16</sup> In a study conducted on preterm infants, use of bovine colostrum has been linked to fewer episodes of sepsis and reduction in length of stay in the hospital as compared to the control group, with the possible explanation of modulating the immune system, enhancing mucosal integrity, tissue repair and reducing gut inflammation.<sup>17</sup> No significant difference was reported in reducing the length of stay between the bovine colostrum group with standard treatment and standard treatment alone in this study. It has been well-established that colostrum is effective in preventing gastrointestinal and respiratory infections based on multiple observational cohort studies, including studies done on children with co-existing health problems, such as allergies or immunodeficiencies. The past reports in the field of Paediatrics present very promising data and hypothesise the effectiveness of BC. Colostrum Supplementation may have a positive effect on the general physical health. Although bovine colostrum has a few benefits nutritionally when given in small doses, as it contains a good amount of some vitamins, minerals and micronutrients, as well as all essential amino acids, which may enhance immunity and aid in replenishing the body's resources.<sup>18</sup>

The colostrum of most species has a good composition of growth factors and immune components in comparison to the mature milk, with a maximum of these components being well preserved in human, bovine and porcine milk. They are considered to be the principal transfer of passive immunity. A major segment of protein in the colostrum is represented by immunoglobulins, with the main immune components, including the isotypes IgG, IgA, IgM, and IgD and their subclasses (IgG1-4 and IgA1-2). Human colostrum is IgA dominant, whereas bovine and porcine colostrum are IgG dominant. There are significant differences in the composition of these isotypes in human, bovine, and porcine colostrum. Secretory IgA characterises 90% of total immunoglobulin in humans compared with BC, where IgA is only 10% of total immunoglobulins.<sup>14</sup>

A meta-analysis showed that bovine colostrum reduced the incidence of diarrhoea, positive pathogen detection and frequency of stool by once per day. The meta-analysis included a study in which children with diarrhoea were administered bovine colostrum, and in another two studies, hyperimmune bovine colostrum, or immunoglobulin from hyperimmune BC. Hyperimmune BC had a significant effect on reducing diarrhoea occurrence.<sup>19</sup> Feeding intolerance, necrotising enterocolitis, late-onset sepsis and pre-term neonatal mortality have been reported to be reduced with colostrum feeding. It also prevents prolonged exercise-induced immunodepression in athletes, reduces vomit frequency and duration and diarrhoea episodes in children 6 months to 2 years old, along with protection against the development of diarrhoea and reduction of abdominal pain complaints in healthy volunteers.<sup>20</sup>

## Conclusions

There was no difference between the group taking standard treatment and the one taking standard treatment plus bovine colostrum in terms of recovery time and efficacy but the difference was significant in terms of the number of days patients remained admitted where bovine colostrum group had increased no of days of admission so conclusion is there is not much role of bovine colostrum in treatment of acute diarrhea when combined with standard care. More studies are needed to support our conclusion.

## Author Information

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