

Original Research Article

Effect of probiotic supplement (kidilact) on prevention of acute diarrhea in children: a double-blind randomized clinical trial

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ABSTRACT

Background: Acute viral diarrhea is one of the most common diseases in children, which is associated with high risk of mortality. The present study aimed to determine the effect of Kidilact on the treatment of children with acute diarrhea.

Methods: This double-blind randomized clinical trial was conducted on 84 children aged 6-60 months with diarrhea, hospitalized in pediatric ward of Amir al-Mu'minin hospital of Zabol, Iran. The patients who met the inclusion criteria were included and assigned to the control and treatment groups (42 patients in each group). Data collection instruments included clinical examination of participants in terms of gender, medication, diet, stool test, weight, average heart rate, average respiratory rate, average body temperature, and average frequency of defecation. Data was analyzed with descriptive and analytical tests (chi-square, Fisher's exact test, t-test, etc.) in SPSS-21.

Results: Body temperature, heart rate, and frequency of defecation significantly reduced in the intervention group after three days ($p < 0.05$). In addition, weight gain presented an improving trend in the intervention group, but not significantly different from the control group ($p < 0.05$).

Conclusions: Findings indicated that the use of Kidilact may be helpful in the treatment of acute viral diarrhea in children and play a key role in early recovery, reduction of disease severity, and improvement of vital signs in these patients.

Keywords: Acute viral diarrhea, Kidilact, ORS powder, Probiotic

INTRODUCTION

Probiotics are dietary supplements containing live bacteria with beneficial effects on the host body by establishing a microbial balance. Currently, the World Health Organization's (WHO) recommended treatment for diarrhea in children includes the use of ORS powder, continuation of feeding for the prevention and treatment of dehydration, and administration of zinc to decrease the duration and severity of the disease.¹ Although the use of probiotics is very common for the treatment of diarrhea in many countries, it is not recommended by WHO.^{2,3} FAO and WHO define probiotics as "Live microorganisms which when administered in adequate

amounts confer a health benefit on the host".⁴ These non-pathogenic living microorganisms can survive in the stomach and small intestine after being swallowed.^{3,5} The use of probiotics for the treatment of acute infectious diarrhea is based on the assumption that they combat with intestinal pathogens. Although probiotic mechanism of action is not clear, it probably includes synthesis of pathogen removing or inhibiting compounds, competition for nutrients required for the growth of pathogens, contribution to the re-establishment of disrupted intestinal flora, increasing the intestinal acidity, competitive inhibition of pathogen adhesion, modification of toxic substance or recipient, and stimulation of specific and non-specific immune system of the host against

pathogens.⁵⁻⁷ Numerous studies have been conducted on the effectiveness of probiotics in the treatment and prevention of acute diarrhea. Meta-analysis studies have reported a significant reduction in the average duration of diarrhea and frequency of defecation following the prescription of probiotics.^{3,8,9}

Large-scale randomized trials have provided relatively scant evidence (statistically significant but clinically controversial) of some probiotic strains, such as *Lactobacillus rhamnosus*, and some *reuteri* species and *Bifidobacterium animalis* in the prevention of acquired diarrhea in children.¹⁰⁻¹⁴ However, few studies have been conducted in developing countries on the use of probiotics, as adjunctive therapy, in the treatment of acute diarrhea.³ Hence, the present study aimed to determine the effect of probiotics, as an adjuvant therapy, on the treatment of diarrhea in children.

METHODS

This double-blind randomized clinical trial was conducted on 84 children aged 6-60 months with diarrhea hospitalized in pediatric ward of Amir al-Mu'minin hospital of Zabol, Iran during the first 6 months of 2014. The inclusion and exclusion criteria are presented below. A written informed consent was obtained from parents of children who participated in this study.

Inclusion criteria

- Acute non-bloody diarrhea
- Passage of liquid stool more than three times a day in less than 14 days
- Mild to moderate dehydration.

Exclusion criteria

- Severe malnutrition (Grades 2 and 3)
- Continuation of diarrhea despite 7 days of antibiotic treatment
- Intestinal diseases such as celiac, IBD, and CF
- Pancreatic insufficiency
- Parasitic infection
- Leukocytes and erythrocytes in the stool 2-3 hours after admission to the emergency ward
- Affliction with the immunodeficiency disease.

According to previous studies and considering $d=0.23\%$, $p=0.38\%$, and $\alpha=0.05$, the sample size in each group was determined to be 42. Eligible patients were assigned to the control and test groups, using the random number table. The probiotic used in this study was Kidilact, the trade name of a specific probiotic compound containing high amounts of 7 beneficial bacterial strains, including *Lactobacillus casei*, *Lactobacillus acidophilus*, *Lactobacillus rhamnosus*, *Lactobacillus bulgaricus*, *Bifidobacterium infantis*, and *Streptococcus thermophilus*. Data was analyzed with descriptive and analytical tests (chi-square, Fisher's exact test, t-test, etc.) in SPSS-21.

RESULTS

This study was conducted on 84 children with diarrhea. In terms of gender, there were 17 males (54.8%) and 25 females (47.2%) in the intervention group (Kidilact).

There was no significant between-groups difference in terms of diet, stool test, and mean weight in the first visit and 3 days later.

On the other hand, there was a significant between-groups difference in terms of the frequency of medication delivery. In addition, findings demonstrated that Kidilact significantly reduced the average frequency of defecation from the first visit to 3 days later. The study of the mean values of vital signs of patients in the two groups also showed that there was a significant difference between them in heart rate and body temperature 3 days after the first visit Table 1.

DISCUSSION

The present research aimed to study the treatment of acute viral diarrhea using Kidilact, compared to the conventional treatment, in children visiting Pediatric Ward of Amir al-Mu'minin Hospital of Zabol. Although some gastroenterologists believe that the use of probiotics is not an appropriate treatment for acute diarrhea¹⁵, the American Academy of Pediatrics (2010) reported that this treatment can reduce the duration of illness to less than one day and is the most effective method within the first hours after the onset. It has been also stated that the use of probiotics is more effective than other methods in the treatment of acute liquid diarrhea with viral origin.¹⁶ Some studies have also reported that probiotic treatment significantly reduce the severity and duration of illness, compared to other therapies.¹⁷⁻¹⁹ Probiotics can be effective by regulating inflammatory cytokines. Since the duration of viral diarrhea is directly related to the treatment of intestinal tissue inflammation, probiotics can be very effective in combination with other treatments.^{18,20} A study conducted by Sazawal on the use of probiotics in the treatment of children with acute gastroenteritis indicated that the incidence and prevalence of dysentery and fever, and severity of disease significantly decreased in the group treated with probiotics.¹⁷ The study conducted by Guandalini also suggested that *Lactobacillus GG*, *S. boulardii*, and *L. reuteri* have the highest effectiveness in the treatment of children with acute liquid diarrhea.¹⁸ In a study by Vibeke on children with acute diarrhea, it was shown that the recovery was significantly shorter in patients receiving probiotics than in the placebo group.²¹ In the present study, the frequency of defecation in the first visit was significantly lower in the intervention group than in the control group. In addition, vital signs, such as body temperature and heart rate, significantly reduced 3 days after the treatment with Kidilact. Although respiratory rate showed a reduction in the intervention group after treatment, it was not significantly different from the

control group. On the other hand, the weight gain process was accelerated in the intervention group following treatment with Kidilact; however, the two groups were not significantly different in this regard. The findings of Nagata also indicated that treatment with probiotics can remarkably relieve the fever of children with acute viral diarrhea in the first days after treatment.²² Salvatore

stated that treatment with probiotics in combination with zinc syrup seems necessary for children with acute diarrhea.²³ Moreover, some similar studies have shown that treatment with probiotics can positively affect vital signs of patients with acute diarrhea and help them gain normal weight faster.^{17,24,25}

Table 2: Effect of probiotic supplement (kidilact) on prevention of acute diarrhea in participating children.

		Kidilact	Control	P-value
Gender	Male	(47.2) 25	(52.8) 28	0.651
	Female	(54.8) 17	(45.2) 14	
Drug	Yes	(38) 16	(16.6) 7	0.028
	No	(62) 26	(83.3) 35	
Diet	Breastfeeding	(11.9) 5	(7.1) 3	0.646
	Breastfeeding and food	(50) 21	(47.6) 20	
	Infant formula and food	(16.6) 7	(26.2) 11	
	Food	(14.3) 6	(16.6) 7	
	Infant formula	(7.2) 3	(2.5) 1	
Stool test	Positive	0	(9.5) 4	0.116
	Negative	(100) 42	(90.5) 38	
Weight	First visit	8595.24	9140.48	0.266
	3 days later	8654.76	9157.14	0.332
Average heart rate	First visit	129.674	131.5	0.216
	3 days later	122.38	124.52	0.004
Average respiratory rate	First visit	20.93	20.95	0.064
	3 days later	18.55	19.38	0.442
Average body temperature	First visit	37.35	37.44	0.434
	3 days later	36.59	36.7	0.017
Average number of defecation	First visit	10.48	8.29	0.026
	3 days later	2.19	2.93	0.001

CONCLUSION

Findings of the present study suggested that the use of Kidilact can be helpful in the treatment of acute viral diarrhea in children and play a major role in early recovery, reduction of disease severity, and improvement of vital signs.

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