ORIGINAL ARTICLE

Comparison of Lactose Free With Lactose Containing Formula Milk in the Management of Acute Watery Diarrhoea in Infants

ASMA NOREEN[1], AMIR JALAL[2], QUDSIA[3], *RAKHSHANDA JABEEN[4], SAMINA QAMAR[5]*

ABSTRACT

Acute gastroenteritis is a major cause of pediatric morbidity and mortality, accounting for 15% of all childhood deaths worldwide. Evidence from developed countries suggests that intake of lactose-free milk during diarrheal episodes may reduce the duration of the illness in pediatric inpatients. In this study we compare the outcome of lactose free milk with lactose containing formula milk in terms of mean time to resolution of diarrhea in the management of acute watery diarrhea in infants. In randomized controlled trial a total of 69 children, between 1-12 months of either gender with acute diarrhea for less than 14 days were included in the study after a written informed consent. These patients were included from Department of Pediatric Medicine, Sheikh Zayed Hospital, Lahore. Patients were divided into two groups randomly by lottery method, group 1 and group 2, group 1 was given lactose free milk and the group 2 was given lactose containing milk (5-8 feed/day) .The patients were assessed for time to resolution of diarrhea as per operational definition. All the patients were managed as per hospital protocol with ORS & antibiotics. In our study, 35(46.675%) in Group-1 and 34(45.33%) in Group-2 were between 1-12 months, mean±sd was calculated as 13.35±5.94 , mean time to resolution of diarrhea was calculated as 4.52±1.16 in Group-1 and 3.16±0.94 days in Group-2, p value was calculated as 0.001 showing a significant difference. We concluded that the outcome of lactose free milk is significantly better when compared with lactose containing formula milk in terms of mean time to resolution of diarrhea in the management of acute watery diarrhea in children.

Keywords: Lactose, watery diarrhea, formula milk

INTRODUCTION

More than 2 decades ago, the World Health Organization (WHO) estimated an annual occurrence of 800 million episodes of diarrhea and 4.6 million diarrhea-related deaths among children younger than 5 years in developing countries[1].

It is observed in the previous literature that there is some evidence that a lactose-free diet may decrease the duration of diarrhea in children[2].

Diarrheal disease remains an important cause of morbidity and mortality throughout our region and despite advances in nutrition and hygiene, the incidence remains high[3.] Existing literature showed that the mean difference between lactose free and lactose containing milk is found (MD -17.7, with 95% CI -25.32 to -10.21). It showed that lactose free milk had reduced the duration of diarrhea by an average time of about 18 hours. Lactose-free products resulted in early resolution of diarrhea (RR 0.52, 95% CI 0.39 to 0.68)[4].

[1]PG Trainee(pediatrics) Sheikh Zayed Hospital, Lahore.
[2]Assistant Professor Biochemistry, Sahara Medical College, Narowal.
[3]Demonstrator(Histopathology) Sahara Medical College,Narowal.
[4]Associate Professor(Anatomy). Sahara Medical College,Narowal
[5]Assistant Professor Pathology, K. E. Medical University, Lahore
Correspondence to Dr. Qudsia Email dr.qudsia00@gmail.com, cell: 03314855029

In a controlled clinical trial it was observed that lactose-free formula had a significantly shorter time to diarrhea resolution compared with the lactose containing (1.7±0.7 vs. 2.6±0.7 days, P<0.001)[5].

The rationale of our study is to compare the effect of lactose free milk with lactose containing formula milk in the management of acute watery diarrhea in infants. Most studies favour the use of lactose free milk but according to Dalgic N the difference in the duration of resolution of diarrhea was not significant lactose containing (5.35+1.80),lactose free(4.46+1.22)[2].

Moreover this study has not been conducted in Pakistan so I want to compare the results in our population where the incidence of rotavirus diarrhea and its associated lactase deficiency is high.

MATERIAL AND METHODS

Study was conducted in Sheikh Zayed Hospital, Lahore in duration of six months in 12-5-2015 to 11-11-2015 .The sample size is calculated as total 69 subjects (35 in each group) considering 95% level of significance and study power=80% and expecting percentage of time of resolution of diarrhea i.e., 5.35±1.80[2] in lactose containing formula milk versus 4.46±1.22 in lactose free formula milk in management of acute watery diarrhoea

Both male and female infants aged 1 to 12 months and Infants with acute diarrhea as per operational definition for less than 14 days are included. Children who had sepsis (CRP>6, total leukocyte count>14000),severe dehydration(sunken eyes, skin pinch goes back very slowly i.e., >2 sec) and history of antibiotic therapy were excluded.

Data collection procedure: A total of 69 patients were enrolled in this study after a written informed consent. Patients were confirmed for the presence of acute diarrhea. At admission time (first visit), after obtaining the demographic data (like age and gender) and medical history, nude weight was measured with scale with an accuracy of 10g. Patients were divided into two groups randomly by lottery method, group 1 and group 2, group 1 was given lactose free milk and the group 2 was given lactose containing milk(5-8 feed/day)

All the demographic data e.g., age and gender were entered in a pre defined questionnaire. (Annex-I). The patients were assessed for time to resolution of diarrhea as per operational definition. All the patients were managed as per hospital protocol with ORS & antibiotics.

Data analysis: Data was entered on computer software SPSS version 17. Quantitative data like age and time to resolution of diarrhea was presented by mean and standard deviation while qualitative data like gender was presented by frequency and percentages. T-test was used to determine the significant difference between mean time to resolution of diarrhea in both groups. P-value < 0.05 was considered significant. Data was stratified for age, nutritional status, episode and consistency before treatment and socioeconomic status to deal with effect modifiers. Post stratification T-test was applied. P-value ≤0.05 was considered significant.

RESULTS

A total of 69 cases fulfilling the inclusion/exclusion criteria were enrolled to compare the outcome of lactose free milk with lactose containing formula milk in terms of mean time to resolution of diarrhea in the management of acute watery diarrhea in infants.

Patients were distributed according to age, 35(46.675%) in Group-1 and 34(45.33%) in Group-2 were between 1-12 months, mean±sd was calculated as 13.35±5.94 (Table 1)**.**

Mean time to resolution of diarrhea was calculated as 4.52±1.16 in Group-1 and 3.16±0.94 days in Group-2, p value was calculated as 0.001 showing a significant difference (Table 2).

The data was stratified for age, episode and consistency before treatment and socioeconomic status to deal with effect modifiers (Table 2,3,4).

Table 1: Age distribution (n=69)

Age (months)	**Group 1**	**Group 2**
1-12	35(46.67%)	34(45.33%
mean±SD	13.35±5.94	13.43±6.18

Table 2: Mean time to resolution of diarrhea (n=69)

Mean time	**Group 1 (n=35)**		**Group 2 (n=34)**	
	Mean	**SD**	**Mean**	**SD**
	4.52	1.16	3.16	0.94

P value=0.0001

Table 3: Stratification for age for mean time to resolution of diarrhea (n=69) Age: 1-12 months

Mean time	**Group 1 (n=35)**		**Group 2 (n=34)**	
	Mean	**SD**	**Mean**	**SD**
	4.29	1.07	3.09	0.87

P value=0.0001

Table 4: Stratification for no. of stools for mean time to resolution of diarrhea (n=69)

Mean time	**Group 1 (n=35)**		**Group 2 (n=34)**	
	Mean	**SD**	**Mean**	**SD**
	3.94	1.13	3.12	0.98

P value=0.0001

DISCUSSION

Acute gastroenteritis is a major cause of pediatric morbidity and mortality, accounting for 15% of all childhood deaths worldwide. In developing countries, diarrheal diseases continue to be a major public health burden. Evidence from developed countries suggests that intake of lactose-free milk during diarrheal episodes may reduce the duration of the illness in pediatric inpatients.

We planned this study with the view to compare the effect of lactose free milk with lactose containing formula milk in the management of acute watery diarrhea in infants.

In our study, 35(46.675%) in Group-1 and 34(45.33%) in Group-2 were between 1-12 months, mean time to resolution of diarrhea was calculated as 4.52±1.16 in Group-1 and 3.16±0.94 days in Group-2, p value was calculated as 0.001 showing a significant difference.

Existing literature showed that the mean difference between lactose free and lactose containing milk is found (MD -17.7, with 95% CI -25.32 to -10.21)[4]. It showed that lactose free milk had reduced the duration of diarrhea by an average time of about 18 hours. Lactose-free products resulted in early resolution of diarrhea (RR 0.52, 95% CI 0.39 to 0.68)[5].

The findings of our study in support with other studies conclude that lactose free milk is effective for the management of acute watery diarrhea with regards to time of resolution of diarrhea.

As, no previous study has been conducted in Pakistan so, our findings are primary and some other trials are required to validate our findings.

CONCLUSION

We concluded that the outcome of lactose free milk is significantly better when compared with lactose containing formula milk in terms of mean time to resolution of diarrhea in the management of acute watery diarrhea in infants.

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