



COMPARATIVE STUDY OF LACTOSE AND LACTOSE FREE MILK FOR ACUTE DIARRHEAL MANAGEMENT IN CHILDREN UPTO 1 YEAR OF AGE.

1. MBBS, FCPS (Pediatric)
Associate Professor
Sargodha Medical College
Sargodha.
2. MBBS, FCPS (Surgery)
Associate Professor Surgery
Sargodha Medical College
Sargodha.
3. MBBS, FCPS (Pediatric)
Assistant Professor Pediatric
Medicine
Multan Medical and Dental College
Multan.
4. MBBS, M.Phil Forensic Medicine
(UK)
Assistant Professor Forensic
Medicine
Sargodha Medical College,
Sargodha.
5. MBBS, M.Phil (Biochemistry)
Assistant Professor Biochemistry
Rai Medical College, Sargodha.
6. MBBS, M.Phil (Anatomy)
Associate Professor Anatomy
Sargodha Medical College,
Sargodha.
7. M.Phil (Food and Technology)
Lecturer
Sargodha Medical College
Sargodha
University of Sargodha.
8. M.Phil (Nutrition)
Lecturer
Sargodha Medical College
University of Sargodha.

Correspondence Address:

Dr. Shoaib Ahmed
Assistant Professor Biochemistry
Rai Medical College, Sargodha.
shoaibahmed745@gmail.com

Article received on:

19/11/2019

Accepted for publication:

03/02/2020

INTRODUCTION

Acute watery diarrhea is usually resolved by itself but still it is connected with considerable healthcare costs & its treatment remains a frequent concern for health care.¹

Major causes are related to gastrointestinal infections (viral or bacterial) but rarely it may occur due to alimentary intoxications or due to other factors.

Since the main complications of acute diarrhea are dehydration and negative nutritive balance but it is evident that immediate replacement of lost body fluids and tolerable diet are the mainstay of

Muhammad Arshad¹, Ahmad Hassan Khan², Masood Mazhar³, Nadir Ali Rana⁴, Shoaib Ahmed⁵, Amna Mubeen⁶, Faiga Chaudhury⁷, Farah Naz Akbar⁸

ABSTRACT... Objectives: The objective of this particular research was to contrast mean duration of acute diarrhea in infants taking lactose free formula versus lactose-containing formula milk along with standard treatment. **Study Design:** Randomized Controlled Trial. **Setting:** Department of Paediatric Medicine DHQ Teaching Hospital Sargodha. **Period:** 6 months from 29 October 2016 to 28 April 2017. **Material & Methods:** This study included 60 infants of both genders who were between 1 month to 1 year of age and presented with acute diarrhea. These infants were separated into two groups. Infants in Group-A were given lactose-free formula milk while those in Group-B received lactose-containing formula milk. Outcome variable was mean duration of diarrhea which was compared between the two groups. Consent was taken in black and white from parents of each infant. **Results:** The average age of the infants was 7.2 ± 3.1 months. Majority ($n=41$, 68.3%) of the infants were aged 6 months and above followed by 19 (31.7%) infants aged between 1-5 months. There were 29 (48.3%) male and 31 (51.7%) female infants with a female to male ratio of 1.1:1 the weight of infants ranged from 2.6 Kg to 11.9 Kg with a mean of 8.1 ± 2.2 Kg. Both study groups were compared in terms of mean age (p -value=0.741), mean weight (p -value=0.932) and age (p -value=0.781), gender (p -value=0.438) and weight (p -value=0.573) groups distribution. The mean period of diarrhea was notably shorter in infants taking lactose-free milk (1.7 ± 0.8 vs. 2.7 ± 0.8 days; $p < 0.001$) as compared to those receiving lactose-containing milk. Similar significant differences were observed across various subgroups based on patient's age, gender and weight. **Conclusion:** Lactose-free formula milk reduces mean duration of diarrhoea significantly when compared to lactose-containing formula milk regardless of patient's age, gender and weight which advocate its preferred use in future practice in infants presenting with acute diarrhea.

Key words: Acute Diarrhea, Lactose-free Formula Milk, Lactose-Containing Formula Milk.

Article Citation: Arshad M, Khan AH, Mazhar M, Rana NA, Ahmed S, Mubeen A, Chaudhury F, Akbar FN. Comparative study of lactose and lactose free milk for acute diarrheal management in children upto 1 year of age. Professional Med J 2020; 27(8):1631-1635. DOI: 10.29309/TPMJ/2020.27.08.4350

management.²

Every year 25 Million cases of acute gastroenteritis are reported in children who are below 5 years of age, and approximately over one thousand die due to acute diarrhea.³ Escherichia coli (EAEC) and rotavirus are the main causative organisms causing acute gastroenteritis in children. 9.4% infants need admission in intensive care unit, while 4.9% infants die due to severe dehydration.⁴

About 20% of infants in Pakistan reported with acute diarrhea.⁵ In different study it is observed that Rotavirus is the major culprit of acute diarrhea. About 30.5% of the children presenting

with acute diarrhea are infected with rotavirus and 61% of these infected children are under the age of 1 year.⁶

Saneian et al. Conducted a study in 2011 in infants suffering from acute diarrhea and found that infants who took lactose-free formula showed significant reduction in mean time of diarrhea relief when compared to those taking lactose-containing formula (1.7 ± 0.7 vs. 2.6 ± 0.7 days,/ $T < 0.001$) respectively.⁶

The results of this randomized controlled trial are promising and lactose-free formula can thus reduce the duration of diarrhea in infants. However, no local published data is available on this topic. The frequency of acute diarrhea is high in Pakistan due to the poor education of mothers regarding use of hygienic methods and also because 60% of the population of Pakistan lives in rural areas. Therefore the purpose of the current study is to repeat this trial and confirm the role of lactose-free formula in infants with acute diarrhea in local population. If its use is associated with early recovery from acute diarrhea in infants, this study will enable routine use of lactose-free formula in future which will enable us to decrease morbidity and mortality associated with acute diarrhea.

MATERIAL & METHODS

Infants of both sex groups with ages in the range of 1-12 months and suffering from acute diarrhea were included in our study. Infants who had blood in stool, had taken antibiotics in last 8 weeks, had 2 or more episodes of vomiting, had renal failure (serum creatinine ≥ 1.2 mg/dl as per investigations) or liver failure (serum bilirubin ≥ 1.2 mg/dl as per investigations) at the time of presentation and whose body weight was ≤ 60 percentile of their age were expelled from our study. After endorsement from ERC, 60 infants (30 in each group) who presented in the emergency department of Pediatrics, DHQ Sargodha Hospital, Sargodha and who fulfilled the above criteria were considered in the study. Parents of these infants were counseled and explained about the details of the study. Detailed history and written informed consent was taken

from each parent. These infants were separated into following two groups randomly.

- Group A: Infants using lactose-free formula
- Group-B: Infants using lactose-containing formula

Infants in both the groups received same antibiotics, and intravenous fluid replacement according to the Department protocol. Duration of acute diarrhea was calculated starting from the day of admission. These patients were rehydrated orally or intravenously according to the severity of dehydration. Mean duration of acute diarrhea was noted and recorded by the candidate into the attached proforma along with demographic details of the patient. The history, physical examination and naked eye examination of the stool consistency and frequency of stools upon presentation at the time of settlement of acute diarrhea were recorded by the candidate to eliminate bias and confounding variables were controlled by exclusion. Entire collected data was analyzed through SPSS version 20.0. Quantitative variables; age, weight & duration of acute diarrhea have been presented by mean \pm SD. Independent sample t-test has been applied for comparison of mean duration of acute diarrhea between the two groups taking $p \leq 0.05$ as significant. Categorical variables; gender has been presented by frequency and percentage. Data has been stratified for age, gender and weight to address the effect modifiers. Post stratification independent sample t-test has been applied taking p value of ≤ 0.05 as statistically significant.

RESULTS

Infant's age ranged from 1 month to 1 year with a mean of 7.2 ± 3.1 months. Majority ($n=41$, 68.3%) of the infants were aged 6 months and above followed by 19 (31.7%) patients aged between 1-5 months. There were 29 (48.3%) male and 31 (51.7%) female patients with a female to male ratio of 1.1:1. The weight of infants ranged from 2.6 Kg to 11.9 Kg with a mean of 8.1 ± 2.2 Kg. Both the study groups were then compared in terms of mean age (p -value=0.741), mean weight (p -value=0.932) and age (p -value=0.781), gender

(p-value=0.438) and weight (p-value=0.573) groups distribution. The mean period of diarrhea was notably shorter in infants receiving lactose-free milk (1.7 ± 0.8 vs. 2.7 ± 0.8 days; $p < 0.001$) as compared to those taking lactose-containing milk as shown in Table 9.3. Similar significant difference was observed across various subgroups based on patient's age, gender and weight.

Characteristics	Participants N=60
Age (months)	7.2 ± 3.1
≤5 months	19 (31.7%)
6-12 months	41 (68.3%)
Gender	
Male	29 (48.3%)
Female	31 (51.7%)
Weight (Kg)	8.1 ± 2.2
<7 Kg	18 (30.0%)
≥7 Kg	42 (70.0%)

Table-I. Baseline characteristics of study sample.

Charac-teristics	Lactose-Free Milk N=30	Lactose-Containing Milk N=30	P-Value
Age (months)	7.4 ± 3.1	7.1 ± 3.1	0.741
≤5 months	9 (30.0%)	10 (33.3%)	0.781
6-12 months	21 (70.0%)	20 (66.7%)	
Gender			
Male	16 (53.3%)	13 (43.3%)	0.438
Female	14 (46.7%)	17 (56.7%)	
Weight (Kg)	8.1 ± 2.3	8.1 ± 2.2	0.932
<7 Kg	10 (33.3%)	8 (26.7%)	0.573
≥7 Kg	20 (66.7%)	22 (73.3%)	

Table-II. Baseline characteristics of study groups. N=60

Charac-teristics	Lactose-Free Milk N=30	Lactose-Containing Milk N=30	P-Value
Age (months)			
≤5 months	1.8 ± 0.8	2.7 ± 0.8	0.027*
6-12 months	1.7 ± 0.8	2.7 ± 0.9	<0.001*
Gender			
Male	1.7 ± 0.7	2.8 ± 0.8	0.001*
Female	1.8 ± 0.9	2.7 ± 0.9	0.011*
Weight (Kg)			
<7 Kg	1.7 ± 0.8	2.6 ± 0.7	0.025*
≥7 Kg	1.8 ± 0.8	2.7 ± 0.9	0.001*

Table-III. Comparison of mean duration of diarrhea between the study groups. N=60.

DISCUSSION

In Developing countries major cause of mortality and morbidity in children is Diarrhea.^{8,10} The objective of this research was to compare mean duration of acute diarrhea in infants taking lactose free formula versus infants taking lactose-containing formula milk along with standard treatment. In this study, the average ages of the infants were between 7.2 ± 3.1 months. A similar mean age of 8.6 ± 4.3 months has been reported by Begum et al. Among infants presenting with diarrhea in Bangladesh.¹¹ Allen et al. reported similar mean age of 7.5 ± 2.5 months among Canadian infants with diarrhea.¹² A similar mean age of 7.8 ± 2.4 months has been reported in Chinese such infants by Wan et al.¹³

We observed that there were 29 (48.3%) male and 31 (51.7%) female infants with a female to male ratio of 1.1:1. A similar female predominance among diarrhea patients has been reported by Allen et al. Who reported male to female ratio of 1:1.3 in Canada.¹² Bener et al. Reported similar female predominance with male to female ratio of 1:1.2 in such infants in Qatar.¹⁴ Begum et al. However reported a male predominance with male to female ratio of 2.1:1 in Bangladesh.¹¹

In the present study, the weight of infants ranged from 2.6 Kg to 11.9 Kg with a mean of 8.1 ± 2.2 Kg. Our study coincides with that of Wan et al. Whose results were similar to our study results with mean weight of 8.3 ± 1.1 Kg among Chinese infants presenting with diarrhea while Allen et al. Reported it to be 7.9 ± 1.3 Kg in Canada.^{12,13}

In the present study, the mean duration of diarrhea was significantly shorter in infants receiving lactose-free milk (1.7 ± 0.8 vs. 2.7 ± 0.8 days; $p < 0.001$) as compared to those receiving lactose-containing milk. Similar significant difference was observed across various subgroups based on patient's age, gender and weight. Our observation is in line with the previously published report from Saneian et al. Who reported similar significant difference in the mean duration of diarrhea (1.7 ± 0.7 vs. 2.6 ± 0.7 days; $p < 0.001$) in infants who received lactose-free formula as compared to those taking lactose-containing formula respectively.⁷

Our study is unique in our local population and has shown that lactose-free formula milk was associated with significant reduction in the mean duration of diarrhea as compared to lactose-containing formula milk regardless of patient's age, gender and weight which advocates its preferred use in future practice in infants presenting with acute diarrhea.

A very strong limitation to the present study was that we only considered the duration of diarrhea, but some other important aspects like weight loss during diarrhea and mortality were not considered which are equally important and should be considered in future before adopting it in routine practice. Such a study is highly recommended in future research.

CONCLUSION








Lactose-free formula milk reduces the mean duration of diarrhea significant when compared to lactose-containing formula milk regardless of patient's age, gender and weight which advocate its preferred use in future practice in infants presenting with acute diarrhea.

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AUTHORSHIP AND CONTRIBUTION DECLARATION

Sr. #	Author(s) Full Name	Contribution to the paper	Author(s) Signature
1	Muhammad Arshad	Abstract, Literature review & methodology.	
2	Ahmad Hassan Khan	Performed experiments & Methodology.	
3	Masood Mazhar	Performed experiments, Compile & analyze results.	
4	Nadir Ali Rana	Typographical error & brief review.	
5	Shoaib Ahmed	Typographical error & brief review.	
6	Amna Mubeen	Literature review helped in finding results.	
7	Faiqa Chaudhury	Helped in performing experiments.	
8	Farah Naz Akbar	Helped in performing experiments.	