

COMPARISON OF LACTOSE FREE FORMULA MILK WITH LACTOSE CONTAINING MILK IN THE MANAGEMENT OF ACUTE WATERY DIARRHEA

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Abstract

Objectives: To compare the role of lactose free formula milk versus lactose containing milk in the management of acute watery diarrhea.

Study Design: "Quasi-experimental study".

Place and Duration of Study: "CMH, Rawalpindi from 15 Oct 2023 to 15 March 2024"

Patients & Methods: 68 infants who were admitted with diagnosis of "acute watery diarrhea (AWD)" were included in the study and were divided into "Lactose-free milk group" and "Lactose-containing milk group". Patients were assessed for duration required for achieving diarrhea resolution and frequency of patients who achieved diarrhea resolution in ≤ 3 days and the results were compared between groups. Data was analyzed by SPSS 20.00.

Results: Mean age was 11.89 ± 6.28 months. There were 43 (63.24%) males and 25 (36.76%) were females. Mean duration of diarrhea was 13.63 ± 3.21 hours. Mean number of stools per day was 8.16 ± 1.32 episodes. 49 (72.06%) patients lived in rural area while 19 (27.94%) patients lived in urban area. Mean duration taken to achieve diarrhea resolution in "lactose-free milk group" was 3.52 ± 1.23 days while in "lactose-containing milk group" it was 5.50 ± 1.67 days, ($p < 0.001$). Frequency of patients who achieved diarrhea resolution in ≤ 3 days in "lactose-free milk group" was 19 (55.88%) while in "lactose-containing milk group" it was 7 (20.59%), ($p = 0.003$).

Conclusion: "Lactose-free milk" significantly reduces duration of achieving diarrhea resolution and increases the frequency of patients who achieve diarrhea resolution in ≤ 3 days.

INTRODUCTION

"Acute watery diarrhea (AWD) is a condition that is defined by "passage of looser consistency stools with increased volume, frequency or weight".¹ One of the major cause of developing this

gastrointestinal condition, particularly in the underdeveloped nations, is the consumption of water from the underground source that is contaminated with the excremental matter.²

Deadliness of diarrheal illness can be estimated with the fact that daily more than 2000 children die of this disease daily and more than 800,000 pediatric deaths occur due to diarrhea every year.

³ In Pakistan, 15% of the population is made up by the children who are aged five years or less and the mortality rate related to “acute watery diarrhea (AWD)” in this particular pediatric population reaches as high as 50% posing a major threat to pediatric healthcare. ⁴

Primary mechanism by which diarrhea results in death of a child is due to dehydration that results in major alterations in the levels of a variety of electrolytes and the acid-base balance through fluctuations in levels of sodium (Na+), chloride (Cl-), potassium (K+), blood pH and bicarbonate (HCO3-). ⁵ Main goal of treatment of acute diarrheal illness is to achieve the complete resolution of diarrhea as early as possible, reduce the duration for which child has to be hospitalized and to correct the electrolyte abnormalities. To achieve this, preliminary management intervention is fluid resuscitation of the child with crystalloid fluid (either ringer lactate or normal saline). ⁶ Another important factor that influences the outcome of acute diarrhea in infants is their feed, major portion of which is the milk that contains “lactose” which has been considered to have tendency to increase the duration for which a child suffers from diarrhea. ⁷ In order to overcome this, researchers hypothesized that “lactose free milk” may be beneficial to improve patient outcome in cases of “acute watery diarrhea (AWD)”. ⁸ However, there are studies that also suggest no statistically significant role of using “lactose free milk” instead lactose containing dairy product (i.e., yogurt) provides much better outcome in children suffering from “acute watery diarrhea (AWD)”. ⁹

To address this disparity, this study was conducted with the primary aim of comparing the outcome of “acute watery diarrhea (AWD)” in children who were given “lactose free milk” with those given “lactose containing milk” during the course of disease.

METHODOLOGY

This “quasi-experimental study” was conducted at “CMH, Rawalpindi from ___ 2023 to ___ 2024” after taking approval from the institutional ethical review board of “CMH, Rawalpindi” (IERB #: _____). Appropriate sample size was calculated using following formula:

$$n = \frac{\left\{ z_{1-\alpha/2} \sqrt{2\bar{P}(1-\bar{P})} + z_{1-\beta} \sqrt{P_1(1-P_1) + P_2(1-P_2)} \right\}^2}{(P_1 - P_2)^2}$$

For calculations, following assumptions were used; “level of significance of 5%”, “power of 80%”, “anticipated frequency of patients achieving diarrhea resolution in ≤ 3 days in lactose-free milk group” of 36.5% and “anticipated frequency of patients achieving diarrhea resolution in ≤ 3 days in lactose-containing milk group” of 8.5%. ¹⁰ This gave a sample size of 68 (34 in each group).

Inclusion criteria: Patients who had the age 1 to 24 months, both males and females, who were admitted in pediatrics ward with “acute watery diarrhea (AWD)” were included in the study.

Exclusion criteria: Patients who had history of chronic diarrhea, gluten allergy, lactose intolerance, had severe dehydration and who were given antibiotic therapy due to sepsis were excluded from the study.

Patients were selected by using “non-probability consecutive sampling technique”. Baseline characteristics of the patients including age (in months), gender, duration of diarrhea (in hours), number of stools per day, parental educational status, area of residence and parental socioeconomic status were documented. All the patients, after taking the informed consent of parents, were admitted in pediatric indoor department and were divided into two equal groups based on their medical registration numbers. Children with MR number ending at an even number were placed in “Lactose-free milk group” in which patients were given 5-8 feeds of lactose -free formula (NAN ®) while those who had their MR number ending at an odd number

were placed in “Lactose-containing milk group” who were given mother’s milk. In both the groups, essential management for diarrhea including oral rehydrating solution and body temperature regulation were provided. Patients were monitored daily and number of patients who achieved diarrhea resolution in ≤ 3 days was documented. In addition, total duration taken to achieve diarrhea resolution was also documented. “Data analysis was performed using Statistical package for Social Sciences version 20.00. Quantitative data was represented using mean \pm standard deviation. Qualitative data was represented by using percentage and frequency. Comparison of qualitative variables between groups was performed using Chi-square test while for quantitative variables, Sample t-test was used. A $p \leq 0.05$ was taken as significant”.

RESULTS

In this study, 68 patients (34 in each group) were included. Mean age was 11.89 ± 6.28 months. There were 43 (63.24%) males and 25 (36.76%) were females. Mean duration of diarrhea was 13.63 ± 3.21 hours. Mean number of stools per day was 8.16 ± 1.32 episodes. In terms of parental education status, 40 (58.82%) parents were illiterate while 28 (41.18%) parents had school education or above. 49 (72.06%) patients lived in rural area while 19 (27.94%) patients lived in urban area. 10 (14.71%) parents belonged to upper socioeconomic class, 23 (33.82%) to middle class and 35 (51.47%) to lower socioeconomic status. Comparison of baseline characteristics between groups is summarized in tabulated form below in table I:

Table I: Comparison of baseline characteristics between groups (n = 68)

Characteristic	Lactose-free milk group (n = 34)	Lactose-containing milk group (n = 34)	p-value
Mean age	11.52 \pm 6.16 months	12.26 \pm 6.47 months	0.633
Gender			
Male	23 (67.65%)	20 (58.82%)	0.451
Female	11 (32.35%)	14 (41.18%)	
Mean duration of diarrhea	13.61 \pm 3.18 hours	13.64 \pm 3.29 hours	0.970
Mean number of stools per day	8.08 \pm 1.31 episodes/day	8.23 \pm 1.34 episodes/day	0.650
Parental education status			
Illiterate	19 (55.88%)	21 (61.76%)	0.622
School education or above	15 (44.18%)	13 (38.24%)	
Area of residence			
Rural	23 (67.65%)	26 (76.47%)	0.417
Urban	11 (32.35%)	8 (23.53%)	
Parental Socioeconomic status			
Upper	5 (14.71%)	5 (14.71%)	0.965
Middle	12 (35.29%)	11 (32.35%)	
Lower	17 (50.00%)	18 (52.94%)	

Mean duration taken to achieve diarrhea resolution in “lactose-free milk group” was 3.52 ± 1.23 days while in “lactose-containing milk group” it was 5.50 ± 1.67 days, ($p < 0.001$). Frequency of patients who achieved diarrhea

resolution in ≤ 3 days in “lactose-free milk group” was 19 (55.88%) while in “lactose-containing milk group” it was 7 (20.59%), ($p = 0.003$). This data is summarized below in table II:

Table II: Comparison of outcome between groups (n = 68)

Characteristic	Lactose-free milk group (n = 34)	Lactose-containing milk group (n = 34)	p-value
Mean operative time	3.52 ± 1.23 days	5.50 ± 1.67 days	< 0.001
Achievement of diarrhea resolution			
≤ 3 days	19 (55.88%)	7 (20.59%)	0.003
> 3 days	15 (44.12%)	27 (79.41%)	

DISCUSSION

Diarrheal disease persist as a significant healthcare concern in under-developed nations, contributing significantly to the overall mortality and morbidity rates among kids of all ages accounting for approximately 15% of all the deaths in children associated with diarrhea.^{11, 12} Major complication of “acute watery diarrhea (AWD)” in children include negative balance of nutrition and development of moderate to severe dehydration both of which have detrimental effect on the overall health of affected children.^{13, 14} Therefore, preliminary step in formulating a management plan for children suffering from diarrhea is replacement of the lost body fluids through “oral rehydrating solution (ORS)” or intravenous crystalloids or both, depending upon patient’s condition.^{15, 16} Another important aspect of management is use of “lactose-free milk”, role of which in diarrheal illness was focus of present study.

In present study, male-to-female ratio of children suffering from diarrhea was 1.5:1 which was consistent with the findings of multiple studies which reported that in under-developed nations, diarrhea incidence has been found to be much higher in boys as compared to girls.^{17, 18} Among children with diarrhea, majority lived in rural areas with parents having low socioeconomic status and lacking formal education. This finding was consistent with results of a study conducted by Saha et al.¹⁹ who found rural residence, poor socioeconomic status and lack of education being most influential environmental factors affecting diarrhea epidemiology. In terms of outcomes, duration to achieve diarrhea resolution was significantly less in children given “lactose-free milk”, similarly, frequency of patients who achieved diarrhea resolution in ≤ 3 days was

significantly higher in children who were given “lactose-free milk” as compared to those given “lactose-containing milk”. These findings were consistent with the results of multiple studies supporting the use of “lactose-free milk” instead of standard “lactose-containing milk” in children with acute diarrheal illness due to its beneficial effect in significantly shortening the diarrhea resolution time.^{10, 20, 21} In contrast, although quite old, a study conducted by Lozano et al.²² reported no significant effect of consumption of “lactose-free milk” on the diarrheal duration in children suffering from acute diarrhea.

Based on the results of present study, it is strongly recommended that children who suffer from “acute watery diarrhea (AWD)” should be shifted promptly to “lactose-free milk” from standard lactose-containing milk to achieve earlier resolution of diarrhea and improve the health related outcome of the child. There were a few limitations of present study including small sample size, limited age range and non-inclusion of children with infective diarrhea.

CONCLUSION

In conclusion, consumption of “lactose-free milk” significantly reduces duration of achieving diarrhea resolution and increases the frequency of patients who achieve diarrhea resolution in ≤ 3 days.

CONFLICT OF INTEREST

None.

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