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Original Research Article

Comparative Study on the Effect of Zinc and Probiotic Therapy Versus Zinc Supplementation Alone on the Duration of Acute Watery Diarrhea in Children

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Abstract: *Diarrhea remains a leading cause of morbidity and mortality among children worldwide. Numerous studies have investigated the effects of zinc and probiotics in reducing the duration and severity of acute watery diarrhea.* ***Objective:*** *This study aimed to compare the efficacy of zinc-probiotic combination therapy with zinc-only therapy in managing acute watery diarrhea in pediatric patients.* ***Methodology:*** *Conducted at the Department of Pediatrics, Sughra Shafi Medical Complex, Narowal, from March 10, 2023, to August 10, 2024, the study enrolled 80 children diagnosed with acute watery diarrhea, who were randomly assigned into two groups. Group A received oral zinc, low osmolarity ORS, and continued nutritious feeding, while Group B was given Enflor sachets in addition to zinc and ORS. The duration of diarrhea was recorded, and data analysis was performed using SPSS v25.0. A t-test was used to compare the duration of diarrhea between the two groups, with statistical significance set at $p \leq 0.05$.* ***Results:*** *The average age in Group A was 38.3±10.5 months, and in Group B, it was 38.6±10.1 months. The duration of diarrhea in Group A was 31.35±2.338 hours, compared to 24.08±2.495 hours in Group B, with a significant difference ($p = 0.0001$).* ***Conclusion:*** *The combination of probiotics and zinc was more effective than zinc alone in reducing the duration of acute diarrhea in children, suggesting a significant improvement in treatment outcomes.*

Keywords: Acute Watery Diarrhea, Zinc Supplementation, Probiotics

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Introduction

Diarrhea-related morbidities represent a significant public health concern on a global scale, particularly prevalent in developing nations. It has been theorized that within the pediatric demographic aged under five years, a noteworthy 21% of mortality cases can be attributed to untreated diarrhea. This statistic translates to a staggering 2.5 million fatalities occurring within the under-five age bracket. The impact of unmanaged diarrhea on young children underscores the urgent need for targeted interventions and improved healthcare infrastructure in affected regions (1).

Various studies conducted during the 1800s indicated that the mortality rate among children due to gastroenteritis was estimated to be around 4.6 million. These researches from the nineteenth century focused on evaluating the number of deaths within the pediatric population caused by this gastrointestinal infection (2). Throughout the world, gastroenteritis remains a prominent cause of mortality among children, accounting for nearly a hundred million cases annually and an estimated ten to twenty thousand deaths per year in children under the age of five. This highlights the urgent need for effective preventive measures and interventions to reduce the burden of this disease on pediatric populations globally (3).

The World Health Organization has included oral rehydration solution (ORS) in the guidelines for managing diarrhea, resulting in a significant reduction in children's mortality rates. Despite the progress made with oral rehydration therapy (ORS), acute gastroenteritis continues to make a significant contribution to the mortality rate among children. This could be attributed to the fact that while ORS helps improve hydration levels, it does not have any impact on the regulation of diarrheal episodes and their overall duration. As a result, there is a need for other treatment modalities to enhance the effectiveness of ORS in managing diarrhea (4).

Numerous advancements have been achieved in this particular area through the integration of zinc and probiotics into the guidelines for managing pediatric diarrhea, showcasing the continuous evolution and improvement in treatment protocols for such cases (5). The decline in the prevalence of diseases related to diarrhea and the decrease in mortality rates among children have been linked to the implementation of two therapeutic approaches, namely oral rehydration solution (ORS) and the provision of zinc supplements. These interventions have played a significant role in reducing the impact of diarrhea on child health outcomes and have been recognized for their effectiveness in improving overall well-being (6).

Zinc plays a crucial role in nutrition as it serves as a vital component that helps in preventing oxidative harm to the cell. Unlike some other nutrients, zinc is not retained in the body over time, thus making it essential to ensure an adequate intake through diet or supplementation. In cases of children suffering from diarrhea, the loss of zinc through the damaged gut can lead to a deficiency, highlighting the importance of timely intervention and replenishment of this micronutrient. The therapeutic benefits of zinc in treating diarrhea may stem from its ability to enhance the overall absorptive capacity of the intestine and facilitate a quicker restoration of the damaged epithelial lining, thereby aiding in the recovery process (7).

The use of probiotics in therapy has been examined in various trials, highlighting their positive effects in pediatric acute diarrhea. Consequently, the European Society for Pediatric Infectious Diseases has included probiotics in the guidelines for managing gastroenteritis in children. Saccharomyces boulardii, a beneficial yeast, is a probiotic that was first discovered in fruits. In the prevention and treatment of acute pediatric gastroenteritis, S. boulardii has demonstrated clinical efficacy, as evidenced by various clinical studies (8, 9).

The possible therapeutic benefits of probiotics might stem from their capability to maintain intestinal microbial balance, prevent bacterial invasion of the intestinal lining, modulate the immune response, enhance

gut mucosal function, and improve the absorptive and nutrient processes of the intestine. Pakistan, as a developing nation, has numerous children lacking adequate zinc levels. Consequently, zinc is commonly recommended for managing diarrhea, while some pediatricians use probiotics, though most do not utilize them for treating acute watery diarrhea.

The aim of our research is to evaluate the effects of administering probiotics alongside zinc compared to zinc alone in treating acute watery diarrhea in children under 5 years old. The findings of this research are expected to assist us in deciding if the combination of zinc and probiotics is more effective than using zinc alone.

Methodology

The research investigation was carried out at the Department of Pediatrics Medicine, located within the esteemed Sughra Shafi Medical Complex in Narowal, spanning a time frame from March 10, 2023, to August 10, 2024. During this period, meticulous steps were taken to secure the necessary approval from the Hospital Ethical Committee, ensuring that all ethical considerations were duly met, along with obtaining informed consent from the attendants/parents of the participants.

A total of 80 children, comprising an equal distribution of 40 individuals in each group, encompassing both male and female subjects falling within the age range of 2 months to 5 years, aligning with the specified case definition of acute watery diarrhea, were carefully selected to partake in the research study. The sample size was estimated at 80% power of the test and 95% confidence level and the expected mean duration of diarrhea was 27.63±14.22 hours in the probiotics plus zinc group and 38.86±20.70 hours in the zinc alone group in children with acute watery diarrhea.

Children who exhibit 3rd degree malnutrition as per the Z classification, severe dehydration as per the WHO classification, systemic infection, recent intravenous fluid administration, presence of blood in stools, or any other comorbid conditions like immunodeficiency, systemic infection, and chronic illness necessitating intensive care due to electrolyte imbalance were not included in the study based on history and clinical examination. The study participants were then segregated into two groups through a lottery method. Group A received treatment consisting of oral Zinc at a dosage of 10mg for children under 6 months old and 20mg for those older than 6 months, low osmolarity oral rehydration solution (ORS) at a rate of 5 ml/kg per hour, and maintenance of a nutritious diet. On the other hand, Group B was administered 250mg of Saccharomyces boulardii (Enflor sachet) twice daily in addition to oral Zinc, low osmolarity ORS at a rate of 5 ml/kg per hour, and continuation of a nutritious diet.

Age, gender, and the duration of diarrhea were documented for all pediatric patients. Acute watery diarrhea (AWD) was characterized by the passing of 3 or more stools per day, with a consistency grade III or higher, lasting less than 7 days. The length of diarrhea was noted in hours to days from the start of treatment until the patient recovered. The resolution of diarrhea was characterized by a reduction in both the frequency and quantity of stool. A decrease in diarrhea frequency indicated having passing stools fewer than three times daily.

A reduction in the consistency of diarrhea indicated a shift in stool texture from liquid (watery) to semi-solid (or solid). A decrease in stool volume indicated a lower quantity of stool passed per occasion, varying from 100-150 grams during diarrhea to a typical amount of 5 grams (grape size) to 40 grams (large sausage). The weight of the stool was assessed by measuring the diaper's weight from its dry state to when it is wet (with a typical diaper weight ranging from 20 to 35 grams based on the child's age and weight). The length of diarrhea, based on the operational definition, was noted. Patients were observed in hospital units, and every child received suitable treatment according to established guidelines.

Data was inputted and analyzed using SPSS version 25.0. The quantitative variable, age, was depicted as Mean±Standard Deviation. The qualitative variables, such as gender, socio-economic status, and residence, were displayed as frequency and percentages. A t-test was utilized to compare the duration of diarrhea among different groups. The data was segmented based on gender, age, socio-economic status, and residence to account for any potential effect modifiers. Following segmentation, an Independent sample t-test was conducted. A significance level of $p \leq 0.05$ was considered statistically significant.

Results

In this study, a total of 80 children suffering from acute watery diarrhea were included as participants. The patients were segregated into two distinct groups, namely Group-A receiving Zinc supplementation alone, and Group-B receiving Zinc supplementation in addition to probiotics. Within Group A, there were 19 individuals (47.5%) identified as males and 21 individuals (52.5%) as females, while in Group B, 17 individuals (42.5%) were males and 23 individuals (57.5%) were females (Table 1).

The average age of patients in Group A was calculated as 38.3±10.5 months, whereas in Group B, it was slightly higher at 38.6±10.1 months. Within Group A, there were 3 children (7.5%) falling within the age group of 2-12 months, 19 children (47.5%) in the 13-36 months age category, and 18 children (45.0%) in the 37-60 months age bracket. On the other hand, in Group B, 5 children (12.5%) were in the 2-12 months age range, 17 children (42.5%) in the 13-36 months age group, and 18 children (45.0%) in the 37-60 months age range (Table 2).

Analysis of the residency status revealed that in Group A, 19 participants (47.5%) were classified as rural residents and 21 participants (52.5%) as urban residents. Conversely, in Group B, 18 participants (45.0%) were rural residents and 22 participants (55.0%) were urban residents. Furthermore, in Group A, 15 children (37.5%) were reported to have low income, 10 children (25.0%) had middle income, and 15 children (37.5%) had high income. In comparison, within Group B, 12 children (30.0%) had low income, 15 children (37.5%) had middle income, and 13 children (32.5%) had high income.

Examining the duration of diarrhea, it was found that the mean duration in the Zinc supplementation alone group was calculated to be 31.35±2.338 hours, while in the Zinc supplementation plus probiotics group, it was slightly lower at 24.08±2.495 hours, yielding a statistically significant p-value of 0.0001. Stratification of the mean duration of diarrhea between the groups based on different factors was conducted, revealing a significant variance in duration between the groups. (Table 5,9)

Table 1: Frequency distribution of gender between groups

Gender	Groups		Total
	Zinc supplementation alone	Zinc supplementation plus probiotics	
Male	19	17	36
	47.5%	42.5%	45.0%
Female	21	23	44
	52.4%	57.5%	55.0%
Total	40	40	80
	100.0%	100.0%	100.0%

Table 2: Frequency distribution of age groups between groups

Age groups	Groups		Total
	Zinc supplementation alone	Zinc supplementation plus probiotics	
2 months – 12 months	3	5	8
	7.5%	12.5%	10.0%
13-36 months	19	17	36
	47.5%	42.5%	45.0%
37-60 months	18	18	36
	45.0%	45.0%	45.0%
Total	40	40	80
	100.0%	100.0%	100.0%

Table 3: Frequency distribution of residence between groups

Residence	Groups		Total
	Zinc supplementation alone	Zinc supplementation plus probiotics	
Rural	19	18	37
	47.5%	45.0%	46.3%
Urban	21	22	43
	52.5%	55.0%	53.8%
Total	40	40	80
	100.0%	100.0%	100.0%

Table 4: Frequency distribution of socio-economic status between groups

SES	Groups		Total
	Zinc supplementation alone	Zinc supplementation plus probiotics	
Low	15	12	27
	37.5%	30.0%	33.8%
Middle	10	15	25
	25.0%	37.5%	31.3%
High	15	13	28
	37.5%	32.5%	35.0%
Total	40	40	80
	100.0%	100.0%	100.0%

Table 5: Comparison of duration of diarrhea between groups

	Groups	n	Mean	Std. Deviation	p-value
Duration of diarrhea (hours)	Zinc supplementation alone	40	31.35	2.338	0.0001
	Zinc supplementation plus probiotics	40	24.08	2.495	

Table 6: Stratification of duration of diarrhea between groups concerning gender

	Gender	Groups	n	Mean	Std. Deviation	p-value
Duration of diarrhea (hours)	Male	Zinc supplementation alone	19	31.74	1.968	0.001
		Zinc supplementation plus probiotics	17	23.35	2.090	
	Female	Zinc supplementation alone	21	31.00	2.627	0.001
		Zinc supplementation plus probiotics	23	24.61	2.675	

Table 7: Stratification of duration of diarrhea between groups concerning age

	Age	Groups	n	Mean	Std. Deviation	p-value
Duration of diarrhea (hours)	2-12 months	Zinc supplementation alone	3	31.67	3.215	0.013
		Zinc supplementation plus probiotics	5	23.80	3.033	
	13-36 months	Zinc supplementation alone	19	30.95	2.392	0.001

		Zinc supplementation plus probiotics	17	23.71	2.392	
	37-60 months	Zinc supplementation alone	18	31.72	2.218	0.001
		Zinc supplementation plus probiotics	18	24.50	2.526	

Table 8: Stratification of duration of diarrhea between groups concerning residence

	Residence	Groups	n	Mean	Std. Deviation	p-value
Duration of diarrhea (hours)	Rural	Zinc supplementation alone	19	31.05	2.272	0.001
		Zinc supplementation plus probiotics	18	24.50	2.176	
	Urban	Zinc supplementation alone	21	31.62	2.418	0.001
		Zinc supplementation plus probiotics	22	23.73	2.729	

Table 9: Stratification of duration of diarrhea between groups concerning socioeconomic status

	SES	Groups	n	Mean	Std. Deviation	p-value
Duration of diarrhea (hours)	Low	Zinc supplementation alone	15	31.33	2.093	0.001
		Zinc supplementation plus probiotics	12	24.83	2.125	
	Middle	Zinc supplementation alone	10	30.90	2.807	0.001
		Zinc supplementation plus probiotics	15	23.33	2.440	
	High	Zinc supplementation alone	15	31.67	2.350	0.001
		Zinc supplementation plus probiotics	13	24.23	2.803	

Discussion

The children of nations in the process of development often encounter high rates of morbidity and mortality caused by diarrhea, a common health issue in such regions. The occurrence of diarrhea can result in various severe complications such as dehydration, acidosis, renal dysfunction, and secondary infections, all of which contribute significantly to the mortality rates within the pediatric population. It is crucial to address these underlying factors and implement effective interventions to reduce the burden of diarrheal diseases and improve the overall health outcomes of children in developing countries (13-15).

It is approximated that 17.3% of the global population faces the issue of being potentially deficient in zinc, a vital mineral for human health. In regions with strong economic standing, the prevalence of inadequate zinc intake is estimated at 7.5%, a concerning statistic that climbs significantly to 30% for the South Asian region, indicating a higher susceptibility to zinc deficiency in this area. While zinc-rich foods such as meat and fish are known to be excellent sources of this essential mineral, they are often priced at a premium, making them less accessible to individuals who may need them the most due to economic constraints (16-18).

Nuts, legumes, seeds, and whole grain cereals are sources of zinc; however, the absorption of this essential mineral is affected by the presence of phytate in these food items. It is important to note that zinc is not stored in the human body, leading to approximately 50% of zinc being eliminated through the gastrointestinal tract. Furthermore, in cases of diarrhea, the excretion of zinc is heightened, exacerbating the risk of zinc deficiency in individuals experiencing such episodes (19, 20).

In the current investigation, the average age of children experiencing acute diarrhea was found to be 38.6±10.1 months in the combination group, slightly higher than the mean age of 38.3±10.5 months in the Zinc group. This finding aligns with previous research conducted by Azim M et al., and Nguyen TV et al., indicating a consistency in the prevalence of acute diarrhea caused by rotavirus among children aged 0-36 months (21, 22).

In the current investigation, the period required for diarrhea to resolve was notably shorter in the cohort receiving combination therapy, with a mean duration of 24.08±2.495 hours compared to 31.35±2.338 hours in the group solely treated with zinc. An examination conducted by Szajewska and Mrukowicz scrutinized ten randomized, double-blind, placebo-controlled trials and determined that the duration of symptoms associated with acute diarrhea experienced a significant decrease to an average of 20 hours through the consumption of probiotics. This evidence underscores the potential efficacy of probiotics in alleviating the manifestations of acute diarrhea, as supported by the findings in the reviewed studies (23).

In a recent investigation, the length of time that diarrhea persisted was documented to be 27.63±14.22 hours among participants receiving a combination of probiotics and zinc, whereas it was measured at 38.86±20.70 hours in individuals solely administered zinc, with a statistically significant difference denoted by a p-value of less than 0.001 (10).

Furthermore, in a separate experimental analysis, it was observed that the duration of diarrhea stood at 52.1±22.4 hours for those subjected to probiotics in conjunction with zinc supplementation, compared to 72.6±23.9 hours for those who received zinc alone, the disparity being statistically significant with a p-value less than 0.001 (11). Another study explored the same variables, revealing that the duration of diarrhea was recorded at 53.5±30.5 hours for the probiotics plus zinc cohort and

57.6±34.3 hours for the zinc-only group, however, the discrepancy was deemed statistically insignificant with a p-value greater than 0.001 (12).

Conclusion

The combination of probiotics and zinc demonstrated enhanced efficacy when contrasted with zinc administered independently in managing acute diarrhea among children, indicating a more favorable outcome with the combined approach due to the potential synergistic effects of the two interventions on gastrointestinal health.

Declarations

Data Availability statement
All data generated or analyzed during the study are included in the manuscript.
Ethics approval and consent to participate
Approved by the department concerned. (IRBEC-SMCN-0879-24)
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Conflict of interest

The authors declared the absence of a conflict of interest.

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MKH (SR Pediatric Medicine**),**
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All authors reviewed the results and approved the final version of the manuscript. They are also accountable for the integrity of the study.

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