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Comparative Study Of Oral Zinc Supplementation Versus Placebo In Reducing The Duration Of Acute Diarrhoea In Under-Five Children.

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ABSTRACT

Acute diarrhoea continues to be a major cause of morbidity and mortality in under-five children worldwide, especially in developing countries. While oral rehydration therapy (ORT) prevents dehydration, it does not reduce the duration or severity of illness. Zinc supplementation has been recommended by WHO and UNICEF as an adjunct therapy, but variability in outcomes across populations warrants further evaluation. This comparative study was conducted in the Department of Pediatrics at a tertiary care hospital over one year. A total of 54 children aged less than five years with acute diarrhoea were randomized into two groups. Group A received oral zinc supplementation (10–20 mg/day for 14 days) along with standard therapy, while Group B received placebo with standard therapy. Clinical outcomes including duration of diarrhoea, stool frequency, hospitalization, and adverse events were recorded. Data were analyzed using chi-square and Student's t-tests. Zinc significantly reduced the mean duration of diarrhoea (54.8 ± 12.6 hours vs. 72.3 ± 14.2 hours, p=0.001) and stool frequency. Recovery by day 5 was higher in the zinc group (85.2% vs. 55.6%). No major adverse events were noted. Oral zinc supplementation was safe, well-tolerated, and significantly reduced both duration and severity of acute diarrhoea in under-five children.

Keywords: Zinc supplementation, Acute diarrhoea, Under-five children

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INTRODUCTION

Acute diarrhoea remains a leading cause of morbidity and mortality among children under five years of age, particularly in developing countries [1]. Despite significant advancements in healthcare and sanitation, diarrhoeal diseases continue to contribute substantially to under-five mortality worldwide. According to the World Health Organization (WHO), diarrhoea accounts for nearly half a million child deaths annually, highlighting the urgent need for effective, low-cost interventions. While oral rehydration therapy (ORT) and continued feeding have significantly reduced diarrhoea-related deaths, these measures do not shorten the duration or severity of the illness. Therefore, adjunct therapies that can improve clinical outcomes are of great public health importance [2-3].

Zinc plays a crucial role in immune function, intestinal mucosal integrity, and cellular repair mechanisms. Zinc deficiency is prevalent among children in low- and middle-income countries and has been associated with increased susceptibility to diarrhoeal diseases. Clinical studies have suggested that zinc supplementation can reduce both the duration and severity of acute diarrhoeal episodes. On this basis, WHO and UNICEF recommend zinc supplementation as an adjunct to ORT in the management of acute diarrhoea in children. However, variability in outcomes across different populations necessitates further evaluation [4-6]. Our study aims to compare the effectiveness of oral zinc supplementation versus placebo in reducing the duration of acute diarrhoea in under-five children.

METHODOLOGY

This comparative study was conducted in the Department of Pediatrics at a tertiary care hospital over a period of one year. A total of 54 children under five years of age, presenting with acute diarrhoea of less than 14 days duration, were enrolled. The diagnosis of acute diarrhoea was made on the basis of history of passage of three or more abnormally loose or watery stools in a 24-hour period. Children with persistent diarrhoea, dysentery, severe malnutrition, systemic illnesses, or those already receiving zinc supplementation were excluded from the study. Written informed consent was obtained from the parents or guardians of all participants prior to inclusion.

The enrolled children were randomly allocated into two groups using a simple randomization method. Group A received oral zinc supplementation in the form of zinc sulphate syrup (20 mg/day for children above 6 months and 10 mg/day for infants below 6 months) for a duration of 14 days, along with standard treatment including oral rehydration solution (ORS) and continued feeding. Group B received a placebo syrup identical in appearance and taste, along with standard treatment. Both groups were managed according to WHO guidelines for diarrhoea management, ensuring uniformity of care except for the intervention under study.

Baseline demographic details such as age, gender, weight, and nutritional status were recorded. Clinical parameters including duration of diarrhoea before enrollment, frequency of stools, associated symptoms, and hydration status were documented. Daily follow-up was done in the hospital for admitted children and by telephonic contact for outpatients until recovery. The primary outcome variable was the duration of acute diarrhoea measured in hours from the start of intervention until the last abnormal stool, followed by return to normal stool consistency. Secondary outcomes included frequency of stools per day, need for hospitalization, and any adverse effects related to zinc supplementation.

All data were entered in a predesigned proforma and later transferred into Microsoft Excel for analysis. Descriptive statistics were used to summarize baseline characteristics. Comparison between the zinc and placebo groups was carried out using the chi-square test for categorical variables and Student's t-test for continuous variables. A p-value of less than 0.05 was considered statistically significant. The study was approved by the Institutional Ethics Committee, and confidentiality of patient information was maintained throughout the research process.

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RESULTS

Table 1: Baseline Demographic and Clinical Characteristics of Study Population (N = 54)

Parameter	Zinc Group (n = 27)	Placebo Group (n = 27)	p-value
Mean Age (months)	28.6 ± 12.4	29.3 ± 13.1	0.81
Male : Female ratio	16:11	15:12	0.78
Mean Weight (kg)	11.2 ± 2.8	10.9 ± 3.1	0.69
Nutritional Status (Normal / Underweight)	18 / 9	17 / 10	0.79
Mean Duration of Diarrhoea before enrollment (hours)	34.2 ± 10.5	33.7 ± 11.3	0.87

Table 2: Clinical Outcomes – Duration and Frequency of Diarrhoea

Outcome Measure	Zinc Group (n = 27)	Placebo Group (n = 27)	p-value
Mean Duration of Diarrhoea (hours)	54.8 ± 12.6	72.3 ± 14.2	0.001*
Mean Stool Frequency on Day 1	7.8 ± 1.5	7.6 ± 1.7	0.72
Mean Stool Frequency on Day 3	3.2 ± 1.1	4.8 ± 1.3	0.002*
Mean Stool Frequency on Day 5	1.1 ± 0.6	2.5 ± 0.9	0.001*
Proportion Recovered by Day 5	23 (85.2%)	15 (55.6%)	0.01*

Table 3: Secondary Outcomes and Adverse Events

Parameter	Zinc Group (n = 27)	Placebo Group (n = 27)	p-value
Hospitalization Required	4 (14.8%)	9 (33.3%)	0.08
Mean Duration of Hospital Stay (days)	2.4 ± 0.9	3.1 ± 1.2	0.04*
Any Adverse Events (nausea, vomiting)	3 (11.1%)	2 (7.4%)	0.64
Compliance with Intervention	25 (92.6%)	26 (96.3%)	0.55

DISCUSSION

The present comparative study evaluated the role of oral zinc supplementation versus placebo in reducing the duration and severity of acute diarrhoea among under-five children. A total of 54 children were studied, equally distributed into zinc and placebo groups. The findings demonstrated that zinc supplementation significantly shortened the duration of diarrhoeal episodes and reduced stool frequency when compared with placebo, while being safe and well-tolerated [7].

In our study, the mean duration of diarrhoea in the zinc group was 54.8 ± 12.6 hours, which was significantly lower than the placebo group (72.3 ± 14.2 hours). This aligns with the results of large-scale meta-analyses and WHO-supported clinical trials, which have consistently reported a reduction of approximately 20–25% in the duration of acute diarrhoea with zinc supplementation. The observed benefit can be attributed to zinc's role in enhancing intestinal mucosal repair, promoting epithelial regeneration, and boosting immune function. Zinc deficiency is common in undernourished children in low- and middle-income countries, which may partly explain the greater therapeutic impact of supplementation in this age group [8-12].

Stool frequency trends in our study further support the efficacy of zinc. On day 3, the mean stool frequency reduced to 3.2 ± 1.1 in the zinc group compared with 4.8 ± 1.3 in the placebo group, indicating faster clinical recovery. By day 5, 85.2% of children in the zinc group had completely recovered, compared to only 55.6% in the placebo group. This outcome is particularly important in reducing caregiver burden, hospital stay, and overall cost of treatment. Similar findings were reported by Bhatnagar et al. and Roy et al., who noted that zinc not only reduced diarrhoea duration but also decreased stool output and improved recovery rates.

The secondary outcomes in our study revealed that hospitalization requirements were lower in the zinc group (14.8%) compared with the placebo group (33.3%), though the difference did not reach statistical significance (p = 0.08), possibly due to the modest sample size. However, the mean hospital

stay was significantly shorter in the zinc group (2.4 days) than in the placebo group (3.1 days), suggesting a clinically relevant benefit. This reduction in hospital stay duration is important for healthcare resource optimization, especially in resource-limited settings.

Adverse events were minimal and comparable between the groups, with mild nausea and vomiting observed in a few cases. Importantly, compliance was high in both groups, reinforcing the practicality of zinc supplementation in community and hospital-based programs. These findings corroborate the recommendations by WHO and UNICEF, which advocate for zinc supplementation (10–20 mg daily for 10–14 days) as an adjunct to ORT in children with acute diarrhoea.

The results of this study highlight the importance of incorporating zinc into routine diarrhoeal management protocols. Beyond reducing disease burden, zinc supplementation may also have long-term benefits by lowering the incidence of subsequent diarrhoeal episodes, as documented in earlier studies. However, limitations of our study include a relatively small sample size and single-center design, which may restrict generalizability. Future studies with larger populations and longer follow-up are warranted to assess the sustained benefits and cost-effectiveness of zinc supplementation.

CONCLUSION

In conclusion, this study demonstrated that oral zinc supplementation significantly reduced the duration and severity of acute diarrhoea in under-five children compared with placebo. Given its safety, affordability, and effectiveness, zinc should be promoted as an essential adjunct in the standard management of acute diarrhoeal diseases in children.

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