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SHORT COMMUNICATION

Effect of Zinc in Tablet and Suspension Formulations in The Treatment of Acute Diarrhoea Among Young Children in an Emergency Setting of Earthquake Affected Region of Pakistan

Muhammad Atif Habib, Sajid Bashir Soofi and Zulfigar A. Bhutta

ABSTRACT

A longitudinal cohort study was conducted at Camp Hospital Batagram in August 2006 to ascertain the effect of Zinc utilization in tablet and suspension formulations on the frequency and recovery rates of diarrhoea among young children in the emergency settings of earthquake affected region of Pakistan. Two hundred patients were recruited and followed-up, the patients were allocated either of the 2 groups i.e. A (Zinc in tablets form) and B (Zinc in suspension form). Both groups also received WHO recommended treatment for diarrhoea. Most of the cases recovered from the illness within 3 days after presentation. Significant p-values were established among Zinc use and reduction in frequency of stools on Day 2 and 3, with better outcome in group B. The study supports the notion that Zinc reduces the frequency and improves recovery rates of diarrhoea in any form and has better compliance and outcomes with the use in suspension form.

Key words: Zinc. Formulations. Acute diarrhoea. Suspension. Tablets.

Diarrhoeal diseases are still the major paediatric health concern worldwide which contributes to 2.5 million annual deaths in children.¹ The therapy of using Oral Rehydration Solution (ORS) and nutritional management are considered to be the best choice for the management of diarrhoea in young children.² The ORS reduces the risk of mortality by averting the dehydration but it does not help in reducing the frequency and consistency of stools.³

Zinc supplementation along with ORS has emerged as a potent approach to treat diarrhoea and studies have endorsed the fact that use of Zinc is associated with a significant reduction in duration of diarrhoea. The World Health Organization (WHO) also recommended daily Zinc supplements for 10-14 days for children with acute diarrhoea. However, there are still some enduring gaps in the information about dose and intake of Zinc supplementation, it is not clear what form of Zinc is more acceptable and effective.

A longitudinal cohort study was conducted among children to measure the impact of daily Zinc administration in different formulations. There were two groups in the study; one group received Zinc in the form of suspension whereas the other group received Zinc in the form of

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dispersible tablets. Zinc was given in a dose of 3 RDA (1 RDA = 5 mg per day for infant and 10 mg per day for children) as per standard recommendations. The standard WHO treatment for the management of acute diarrhoea was also provided to the enrolled cases.

A sample size of 200 patients was calculated assuming 80% Power, 95% CI and 20% Improved recovery rates, by using the approximate sample size formula. The enrolled children were brought to the hospital with acute gastroenteritis both from inpatient and outpatient units. Diarrhoea was defined as the passage of 3 or more loose or watery stools in the 24-hour period before enrolment. Eligible children were screened by a physician and recruited in the study, after the screening a verbal consent was obtained from the parents or caretaker and the patient was randomized in one of the two groups. Children were randomized either of the 2 intervention using block randomization.

Patients were examined and daily information on morbidity and general health at the time of recruitment and on follow-up days 1, 2 and 3 was recorded. Follow-ups were done only for 3 days due to limited resources, short stay of patients at Camp Hospital and reluctance of patient to come back for follow-up. Data was collected on illness characteristics, frequency of stools and vomiting, hydration status and the use of the supplement per day since the last visit was noted. Compliance was measured by reported intake and by measuring the remaining volume of syrup in the returned bottles and tablets in the strips respectively.

Data was entered in Visual FoxPro version 7 and statistical analysis was conducted using SPSS 14 (SPSS Inc.

Chicago, IL, USA). Mean and standard deviation were calculated for continuous variables and frequency and percentages were computed for categorical variables. Chi-square test was used to see association among categorical variables.

The baseline characteristics of the patients in both groups were similar. All the cases were recruited in the study and randomized in one of the two groups to receive the Zinc formulation along with the conventional treatment of diarrhoea. It was intended to treat all the cases with Zinc suspension but 15% of cases were dropped out during the study and could not receive the Zinc formulations. Those cases were excluded from analysis because the compliance of Zinc could not be analysed on them. So the effectiveness of Zinc formulations were analysed among 190 cases, 81 and 109 respectively in group A and B. The main reasons for the drop outs were cultural beliefs, left against medical advice, referrals and refusal for the treatment.

The mean of total frequency of stool during the last 24 hours were 12, almost equal in both groups and the frequency of stools after starting supplementation were 7.2 ± 4.4 and 6.0 ± 3.8 on day 1, 4.2 ± 3.4 and 2.6 ± 2.4 on day 2, and 2.4 ± 1.6 and 1.6 ± 1.1 on day 3 in group A and B respectively. Significant p-values were established among Zinc use and reduction in frequency of stools on Day 2 and Day 3, with comparatively better outcome in group B. Furthermore about 90% of the patients recovered from diarrhoea within 3 days of presentation, 82% from group A and 96% from group B. On comparison of group A and B the recovery rates for group B was found to be significantly higher up to 4.76 (1.63 - 13.90) with p-values of 0.001 (Table I). Therefore, a considerable effect of Zinc on duration and frequency of diarrhoea was found in both groups but more favourably in group B which received Zinc in the form of suspension.

The results of the study support the notion that Zinc reduced the duration and frequency of diarrhoea in children as seen in both groups. In both groups most of patients recovered within 3 days after institution of Zinc treatment. On comparing both groups, Zinc suspension was easier to reconstitute and administer in young infants while the tablets were a bit difficult to utilize especially in the young ones as it had to be crushed and

Table I: Day wise diarrhoea recovery rates.

	Group A	Group B	Total	p-value	RR (95% CI of RR)
	15	33	48		
Day 1	19.2%	31.1%	26.1%	0.06	1.17 (0.99-1.39)
	45	84	129		
Day 2	57.7%	79.2%	70.1%	0.001	2.04 (1.3-3.21)
	63	102	164		
Day 3	80.8%	96.2%	89.1%	0.001	4.76 (1.63-13.90)

mixed with water or milk. Although the role of the Zinc suspension is statistically significant but has cost implications.

The study supports the fact that Zinc is beneficial in the treatment of acute diarrhoea and can help in reduction of morbidity and mortality associated with diarrhoeal illnesses. Moreover, it explores the use of Zinc in different formulations and delivery mechanism and supports the suspension form. It appears that the suspension form is more easy and handy to use especially in emergency settings. But the cost of syrups may possibly limit its use as the conventional treatment of diarrhoea. But before establishing any conclusion more controlled studies and trials are needed to establish more evidence in favour of Zinc suspension.

Specific suggestion concerning the utilization of Zinc supplementation in any kind of supplementation for the treatment of acute diarrhoea must look forward to further population-based studies measuring the role of Zinc supplementation in diverse formulations for the treatment of acute diarrhoea.

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