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A Comparative Study of ORS (Oral Rehydration Solution) with Probiotics versus ORS with Zinc as an Adjunct Therapy in Pediatric Acute Diarrhoeal Diseases

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ABSTRACT

Background: Diarrhea is characterized by abnormally loose or watery stools. Diarrhea causes the body to lose a lot more fluid than normal, infants and toddlers can become dehydrated more quickly than older children when they have diarrhea and vomiting. If dehydration becomes severe it can be dangerous particularly in young babies. We in the current study tried to evaluate the effect of ORS with probiotics and ORS with zinc supplementation as an adjunct therapy to diarrheal disease.

Methods: Based on the inclusion and exclusion criteria n=100 successive cases were identified and included in the study. They were randomly allotted in two groups. Group A (N=50) was given a probiotic sachet consisting of Saccharomyces 2.5 billion spores and Lactic acid bacillus 100 million spores. The powder in the sachet was dissolved in 20 ml of lukewarm water and given to the child twice daily. Group B (n=50) were given 20mg Zinc sulfate tablet once daily along with the usual treatment of fluid replacement.

Results : The mean age was 2.76 years in-group-A and 2.92 years in Group-B. In this study, the mean weight was 10.12 kg of the patients belonging to group-A and the mean weight was 10.16 kg of the patients belonging to group B. The Mean duration of diarrhea to subside after intervention in group A was 75.3 hours and the mean duration of diarrhea after intervention in group B was 56.08 hours. The average time for recovery in patients of group A was 4.5 days and in group B the meantime for recovery was 3.9 days.

Conclusion: There was a significant improvement in the patients treated with the zinc group when compared with the probiotic group in terms of time taken for resolving diarrhea. There was a little difference in the effect of probiotics and zinc in patients in terms of stool frequency and stool consistency. However, the efficacy of zinc was greater compared to probiotics.

KEYWORDS: Zinc, Probiotics, Oral Rehydration Solution, Acute Diarrhoeal Disease

INTRODUCTION

Acute diarrheal disease is a common illness among the pediatric age group across the world. Despite global success in the reduction of all-cause and diarrhea-specific mortality in the past 30 years, diarrhea remains the second leading cause of death due to infections among children under five years of age worldwide, especially in developing countries. [1]Diarrhea is the passage of watery stools at least three times in 24 hours. However, recent updates found a change in the consistency of the stool is considered more important than the frequency. [2]The diarrheal illness is commonly found in infants and children from 6 months to 2 years. Acute diarrhea is a leading cause of under-5 mortality in India. [3]Acute infectious diarrhea occurs due to viral, bacterial, and parasitic infections and most commonly of infectious origin. However, in approximately 40% of cases, no causative agent may be detected. The relative contribution of the different pathogens may vary depending on the specific geographical location. Seasonal variations of acute diarrhea being predominantly of viral origin in winters and of bacterial origin in summer. Bacterial origin diarrhea is commonly found in developing countries. The principal bacterial pathogen responsible is E. coli. The viral pathogens which are frequently seen in developed countries include Noroviruses. They are the emerging viral pathogens thought to be the leading cause of non-bacterial diarrheal diseases across the world. An important development in the treatment of diarrheal diseases has been the discovery that dehydration from acute diarrhea of any etiology and at any age, except when it is severe, can be safely and effectively treated in 90% of cases with simple oral rehydration fluids. Glucose and several salts in a mixture known as Oral Rehydration Salts (ORS) are dissolved in water to form an ORS solution. [4] Oral rehydration therapy (ORT) includes rehydration and maintenance of fluids with ORS solutions, combined with continued age-appropriate nutrition. Oral rehydration therapy has been shown to improve the health outcomes of children in developing countries. Although, ORT has limitations because it does not achieve all the desired goals of therapy.

Diarrhea continues to be a major cause of hospitalization and deaths in under 5-year-old children and has severe economic consequences. There is a strongly felt need among physicians and caretakers of children for additional modalities of treatment which can reduce the duration, severity, failure rates and reduce the need for intravenous fluids (IVF). Recent developments in the science of diarrhoeal disease management have substantially altered case management. The new modalities currently used are new generation Oral rehydration solutions, probiotics, micronutrients (like zinc), and alternate feeding regimens. Physicians now recognize that zinc supplementation can reduce the incidence and severity of diarrheal disease, probiotics can harmonize the intestinal gut flora, and an ORS of reduced osmolarity. These updated recommendations were developed by specialists in managing the diarrhoeal disease. Antibiotic therapy should be reserved only for cases of dysentery and suspected cholera. Diarrhoeal diseases can be prevented to a great extent by improving infant feeding practices and personal and domestic hygiene. [5] This study is aimed at comparing the efficacy of ORS with Probiotics as compared to ORS with Zinc in our tertiary care teaching hospital.

MATERIAL AND METHODS

This cross-sectional study was conducted in the Department of Pediatrics, Prathima Institute of Medical Sciences, Naganoor, Karimnagar. Institutional Ethical committee permission was obtained for the study. Written consent was obtained from the parents/guardian of the patients of the study. Information on their demographic characteristics, medical history, and previous current medications were collected. A thorough physical examination and necessary laboratory investigations Stool examination (mucus, blood, leukocytes, Serum electrolytes, Ova Cysts) were carried out on selected cases.

Inclusion criteria of the patient were the patient with acute diarroehal disease in the age group of 1 to 5 year of either sex, and the time interval between the onset of diarrhea and hospitalization <72 hrs, Presenting with an episode of more than >3 watery or looser than normal, Stools within a 24 hrs period.

Exclusion criteria were Severe Dehydration, Exclusively Breast Feeding, Children with Acute Renal Failure, Children with Shock, Children with Electrolyte imbalances, Children with other existing Co morbidity like Respiratory infection or Urinary Infection, Children with any other severe medical illness like Cardiovascular or Neurological problems.

Based on the inclusion and exclusion criteria n=100 successive cases were identified and included in the study. They were randomly allotted in two groups. Group A (N=50)was given a probiotic sachet consisting of Saccharomyces 2.5 billion spores and Lactic acid bacillus 100 million spores. The powder in the sachet was dissolved in 20 ml of lukewarm water and given to the child twice daily. Group B (n=50) were given 20 mg Zinc sulfate tablet once daily along with the usual treatment of fluid replacement. The tablet was powdered and dissolved in 10ml of water and given to the child. Children in all the two groups we retreated with ORS fluids accordingly to correct the initial dehydration, to maintain the hydration, and for replacement of fluid loss in stools or vomitus. Parents of the children were instructed to note down the frequency and consistency of stools and the number of episodes of vomiting in a printed format. The details noted by the parent were collected and checked every 24 hours. Statistical analysis was done the Interval data have been expressed as Mean $\pm$ SD and categorical data in percentage. P-value < 0.05 was considered statistically significant.

RESULTS

Following the inclusion criteria, out of a total of n=100 patients aged 1-5 years were included. In our study n=29 of the patients belonging to group-A and n=28 of the patients belonging to group B come under the age group of 2 yrs. The mean age was 2.76 years in-group-A and 2.92 years in Group B in this study, the mean weight was 10.12 kg of the patients belonging to the group-A and the mean weight was 10.16 kg of the patients belonging to group B. In the study n=29, were female and n=21, were male of the patients belonging to the group-A and n=19, were female and n=31, were male of the patients belonging to the group-B. In our study n=48, were female, and n=52 were male of the overall patients who were included in the study. The frequency of stools was measured in both groups of patients and is as shown in Table 1

Time (in hours)	Group A	Group B	p values
	Mean (SD)	Mean (SD)	
Day 1 (0 – 24)	7.52 (1.89)	7.46 (2.10)	0.88
Day 2 (25 – 48)	4.90 (1.78)	3.72 (2.26)	0.004*
Day 3 (49 – 72)	3.26 (1.41)	1.85 (1.36)	<0.001*
Day 4 (73 – 96)	1.57 (0.71)	1.32 (0.69)	0.07
Day 5 (97– 120)	1.13 (0.28)	1.00 (00)	-

* Significant

Table 1: Frequency of stool in two groups

The Mean duration of diarrhea to subside after intervention in group A was 75.3 hours and the mean duration of diarrhea after intervention in group B was 56.08 hours given in table 2. Stool consistency was evaluated through a scoring system in which feces were graded as 1 (normal), 2 (loose), 3 (semiliquid), and 4 (liquid), in which different combinations of probiotics were assessed in improving the stool consistency in cases of acute diarrhea. The average stool consistency in group A was at the end of 24 hours was 3. Between 24 – 48 hours were 2.07 and between 49 and 72 hours were 2.06 and at end of 96 hours was 1.40 and at the end of 5 days was 1.04. Similarly, in group B the values were at the end of

24 hours 3, between 24 – 48 hours were 2.36 and between 49 and 72 hours were 2.06 and at end of 72 hours 1.51 and end of 96 hours was 1.15 and at the end of 5 days was 1. The data is as shown inTable 2

Group	Duration of diarrhea		P values
Group A	Mean	75.3	0.0127*
	SD	16.57	
Group B	Mean	56.08	
	SD	17.20	

*Significant

Table 2: Mean duration of diarrhea following intervention

The average time for recovery in patients of group A was 4.5 days and in group B the meantime for recovery was 3.9 days details depicted in Table 3

Period (in hours)	Group A Number of the cases remaining	Group B Number of the cases remaining
Day 1 (0 – 24)	50	50
Day 2 (25 – 48)	50	50
Day 3 (49 – 72)	50	49
Day 4 (73 – 96)	47	25
Day 5 (97– 120)	24	6

Table 3: Number of Patients Remaining in each Group for every 24 hours duration following treatment

DISCUSSION

In the present study, among the n=50 patients of Group A, the minimum age of the patient is 2 years and the maximum age is 5 years. The number of patients in each age group (2, 3, 4, 5 years) is 32, 3, 10, 5 respectively. Similarly, among the n=50 patients of Group B, the number of patients in each age group (2, 3, 4, 5 years) are 28, 5, 11, 6 respectively. Yazar S et al.[6]conducted a single-center, randomized, parallel-group, controlled, clinical trial in outpatient children (6 – 120 months) with acute infectious diarrhea in Turkey. P. Packasieelli et al.[7] in their study found the range of 6-24 months. Dalgic et al in a similar study found the patients of 3-36 months age were affected with diarrhea. The average stool frequency in patients of group A in the present study on1stday, 2nd day, 3rd day, 4th day, and 5th day is 7.52, 4.9, 3.26, 1.57, and 1.08respectively. The average stool frequency in patients of group B in the present study on 1st day, 2nd day, 3rd day, 4th day, and 5th day was 7.46, 3.72, 1.85, 1.32, and 1 respectively. The effects of treatment in terms of frequency of diarrhea started to be observed by 1st day after intervention. Zinc supplementation had a faster effect than probiotic supplementation. P-value after being calculated by Chi-Square Test inpatients of both group A and group B in the present study on 1st day, 2nd day, 3rd day, 4th day, and 5th day was 0.88, 0.0047, <0.0001, 0.07, and 0 respectively as shown in Table 1. Our results are in concordance to observations by Yazar S et al.,[6] P. Packasieelli et al. [7]. This is probably because of zinc that inhibits the cAMP-induced, chloride-dependent fluid secretion and improving the levels of brush border enzymes. In the study by Dalgic et al,[8]different combinations of adjunct therapies did not seem to bring additional value to rehydration therapy in children with rota virus diarrhea except for in those receiving only zinc and zinc plus S.boulardii. Results of various other studies showed a trend towards a reduced proportion of episodes lasting more than seven days in children receiving zinc supplementation, and in one study, the reduction was statistically significant.[9–11] Again, the pooled analysis of these studies showed that zinc supplementation can decrease by about 25% the proportion of episodes lasting more than seven days, therefore significantly reducing the proportion of diarrhea episodes becoming persistent. In the present stool consistency improved in both the groups but, it was faster in the group to which zinc was supplemented as an adjunct therapy along with ORS for treating acute diarrhea.P. Packasieelli et al, [7] the stool consistency was the same in all the groups on the first day. On the 2nd, 3rd, 4th, the day the zinc group showed a more significant improvement towards normal than the other two groups. This also correlates with the study by P Dutta et al,[12]showing fewer liquid stools in zinc therapy. This is due to the role of zinc in the regeneration of epithelial cells lining the GIT and better absorption of water and electrolytes. In the present study, the same number (50) of patients remained in both the study groups at the end of the first and second days after the intervention. In group A, at the end of the 3rd, 4th, and 5th day, the number of patients with persisting diarrhea were 50, 47 and 24 respectively as shown in Table 3. In group A, at the end of the 3rd, 4th, and 5th day, several patients with persisting diarrhea were 49, 25, and 6 respectively as shown in Table 3. This showed a significant difference improvement in children treated with zinc as an adjunct therapy for acute diarrhea. This correlates with the study by Yazar S et al,[6]in which the effect of treatment started after 48 hours of intervention in the study groups to which symbiotics and zinc were given respectively. On Day 3, 61.8% of the children receiving symbiotic still had watery diarrhea while 83.6% of the controls had watery diarrhea (p=0.01). The Mean duration of diarrhea after the intervention was significantly reduced in the zinc group than in the control group. This correlates with the studies of Sazawal et al, [13] the duration of diarrhea in children treated with zinc were about 19 hrs shorter than the probiotics group. This difference was significant. This correlates with the study of Dalgic et

al., [8]where the duration of diarrhea was much reduced in the groups with zinc included in therapy, compared to groups with saccharomyces alone or with lactose-free formula. This may be because zinc improves the regeneration of intestinal epithelium and enhances the immune response allowing for better clearance of pathogens.

CONCLUSION

Within the limitations of the present study, it can be concluded that there was a significant improvement in the patients treated with the zinc group when compared with the probiotic group in terms of time taken for resolving diarrhea. There was a little difference in the effect of probiotics and zinc in patients in terms of stool frequency and stool consistency. However, the efficacy of zinc was greater compared to probiotics.

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