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Efficacy of resomal versus low osmolar ORS in severe acute malnutrition children with diarrhea age 6 months to 59 months

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ABSTRACT

Objective: To compare the efficacy of Resomal versus low Osmolar ORS in severe acute malnutrition in children with diarrhea age 6 months to 59 months.

Methodology: This Randomized Control Trial was carried out at the Nutrition stabilization Centre pediatrics Department, Liaquat university hospital, Hyderabad, with duration of one year from April-2016 to March-2017. All the children having severe acute Malnutrition were included. After admission, severity of diarrhea was assessed on a clinical basis. After informed consent, patients of Severe Acute Malnutrition were divided into two groups i.e Group-A and Group-B on randomized selection. Group A was given Resomal and Group–B was given low Osmolar ORS. Electrolytes were sent on admission then again after 12 hours of giving rehydration solution, response of diarrhea was assessed based on laboratory investigations and clinical assessment.

Results: Mean age of the children was 20.83 months and the standard deviation was 3.52 months. Female children were in the majority of 172 as compared to males 152 out of 324 cases. No significant difference was found in Z-score of both groups, P-value 0.07. Acute diarrhea was the most common in both groups, Diarrhea frequency-1 was found significantly more in both groups, having p-value 0.001, while frequency 2 and 3 were found without significant difference in both groups. Statistically, there was a significant difference in pre rehydration electrolytes in both groups, having p-value 0.001. After rehydration no significant difference was found in electrolytes in both groups.

Conclusion: It was concluded that resomal and low osmolar ORS were similarly efficacious in the rehydration of severely malnourished children with diarrhea and dehydration after rehydration.

Keywords: Diarrhea, Severe Acute Malnutrition, Resomal, ORS.

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Introduction

Globally it is estimated that nearly 20 million children are severely acutely malnourished,[1] most of them live in South Asia & Sub Saharan Africa. In September 2011, Sindh statistics shows that nearly 17% of children under 5 years are malnourished with 7% having Severe Acute Malnutrition. Malnutrition is associated with both macro- and micronutrient deficiencies[2], and directly or indirectly related to 35% of all deaths among under-five children.[3] Severe malnutrition is often associated with life-threatening consequences such as hypoglycemia, hypothermia, hypernatremia, severe chest infection, sepsis, and severe electrolyte disturbances.[4] Childhood malnutrition remains an important public health problem in the Asian subcontinent; although most of the countries in this region have experienced rapid economic development in recent years.[2] Each of the different types of nutritional deficits such as underweight, stunting, and wasting is associated with increased deaths from diarrhea, respiratory infections, and other infectious diseases such as measles.[5] A 4-year prospective study among severely acutely malnourished children aged 6 months to 12 years,

hospitalized with diarrhea experienced higher deaths compared to the children who did not have diarrhea during their hospital stay.[6] A cohort study of 430 Zambian children aged 6 - 59 months with severe acute malnutrition noted 2.5 times higher deaths in those with diarrhea on admission compared to those who did not have diarrhea.[7] Demographic and Health Survey 2011, the prevalence of childhood stunting, underweight, and wasting were 43%, 41%, and 17% respectively.[8] Most of the earlier studies have identified the association between malnutrition and diarrhea and examined the association of etiologic agents of diarrhea with malnutrition.[9,10] Dehydration is defined as the condition that results from excessive loss of body water.[11] In severe acute malnutrition, dehydration is caused by untreated diarrhoeal disease which leads to the loss of water and electrolytes.[12] Dehydration with severe acute malnutrition can be difficult to identify, as many of the typical signs such as skin elasticity are not reliable.[13] Useful indicators include restless/irritable, lethargic, thirsty, sunken eyes, dry mouth/tongue concerning the history of recent fluid loss, that is, diarrhea or vomiting.

In children with severe acute malnutrition, dehydration should be immediately treated with oral rehydration salts (ORS).[14] ORS is a fluid that contains salt, sugar, potassium chloride and citrate to replenish the lost fluids and electrolytes during diarrheal episodes.[5] Dehydration in severe acute malnutrition caused by diarrheal diseases, is treated with an altered version of ORS called ReSoMal, which stands for rehydration solution for severely malnourished children. The difference between ORS and Resomal is that the ORS has high sodium contents and Resomal has low sodium contents. Recently, to minimize the risk of sodium overload and compensate for potassium and other micronutrient deficiencies of malnourished children with diarrhea, WHO designed a new oral rehydration solution, Resomal, for malnourished children. Compared with the standard glucose-containing ORS, Resomal contains a reduced concentration of sodium and increased concentration of potassium and other electrolytes and micronutrients. However, the use of ORS depends upon the integrity of the intestinal functions, including energy-driven sodium absorption. Whether or not these are intact in malnourished and dehydrated children is not clear.[15]

Methodology

This Analytical comparative study was conducted at Nutrition stabilization centre pediatrics Department, Liaquat university hospital, Hyderabad, during one year from 2017 to 2018. Children with age 6 months to 59 months, both gender, having severe acute Malnutrition, some dehydration, those for whom written informed consent was given by the parent were included. Children having severe acute malnutrition with severe dehydration and shock, acute malnutrition with diarrhea and life-threatening complications, and those who did not agree to participate in the study were excluded. Sample size calculation was done, by using the Raosoft software taking the proportion 69.72% of diarrhea[9] with 95% confidential interval and 5% of margin of error. The sample size stands to be 324 (162 in each). This study was conducted after the approval of a synopsis from the ethical committee at LUMHS. Patients of Severe Acute Malnutrition were divided into two groups i.e Group-A and Group-B on randomized selection. Group A was given Resomal and Group–B was given low Osmolar ORS. Electrolytes were assessed on admission then again after 12 hours of giving rehydration solution, response of diarrhea was assessed based on laboratory investigations and clinical assessment. All the data was collected via study proforma and data analysis was done by SPSS version 20.

The data collected in the study was analyzed by using SPSS version 18. Mean and standard deviation were calculated for quantitative data. Frequency and percentage were calculated for qualitative data. Chi-square test was applied to compare the qualitative variables and T-test was applied to compare the quantitative variables. P-value $\leq$ 0.05 was considered as significant.

Results

In this study mean age of the children was 20.83 months and standard deviation was 3.52 months. Female children were in the majority 172 as compare to males 152 out of 324 cases. No significant difference was found between age, height, weight and MUAC in both groups. (Table I)

Table 1: Age, height, weight and MUAC comparison in both groups (n=324)

	Study groups	Statistics	P-value
Age	Resomal	21.13±17.0	0.728
	low Osmolar ORS	20.54±13.4	
Gender	Male	76(49.91%)	1.00
	Female	86(50.09%)	
	Male	76(49.91%)	
	Female	86(50.09%)	
Height(cm)	Resomal	69.09±9.2	0.511
	low Osmolar ORS	69.76±9.0	
Weight (kg)	Resomal	5.68±1.6	0.982
	low Osmolar ORS	5.69±1.3	
MUAC	Resomal	10.36±0.6	0.968
	low Osmolar ORS	10.36±0.7	
Diarrhea duration	Resomal	3.04±1.8days	0.005
	low Osmolar ORS	3.56±1.4days	

In this study, no significant difference was found in Z-score in both groups P-value 0.07. (Table II)

Diarrhea frequency-1 was found significantly more in both groups, p-value 0.001, while frequency 2 and 3 were found without significant difference in both groups (Table III)

In this study, statistically, there was a significant difference in pre rehydration electrolytes in both groups p-value 0.001. After rehydration no significant difference was found in electrolytes in both groups, the result shows in (Table IV)

Table II: Z- score comparison in both groups (n=324)

z-score	Study Group		P-Value
	Resomal	Low Osmolar ORS	
<-1SD	01	00	0.07
<-2SD	07	00	
<-3SD	53	47	
<-4SD	101	115	

Table III: Case distribution according to diarrhea frequency in both groups (n=324)

	Study groups	Mean± SD	P-Value
Diarrhea frequency-1	Resomal	4.74±1.04	0.001
	low Osmolar ORS	5.37±1.69	
Diarrhea frequency_2	Resomal	2.64±0.99	0.58
	low Osmolar ORS	2.81±1.16	
Diarrhea frequency_3	Resomal	2.23±0.34	0.62
	low Osmolar ORS	2.15±0.98	

Table IV: Electrolytes comparison according to pre and post rehydration in both groups (n=324)

Variables		Study groups	Mean± SD	P-Value
Pre-rehydration	Na	Resomal	1.32±6.56	0.001
		low Osmolar ORS	1.34±3.58	
	K	Resomal	3.10±0.64	0.008
		low Osmolar ORS	3.25±0.27	
	HCO3	Resomal	19.95±3.41	0.001
		low Osmolar ORS	21.7±2.13	
Post-rehydration	Na	Resomal	1.36±3.86	0.897
		low Osmolar ORS	1.36±4.99	
	K	Resomal	3.47±0.26	0.512
		low Osmolar ORS	3.49±0.48	
	HCO3	Resomal	24.48±1.16	0.071
		low Osmolar ORS	24.04±1.90	

Discussion

The present study was conducted to evaluate the efficacy of Resomal and compared with low Osmolar ORS in the children having diarrhea with severe acute malnutrition and findings of my study show that the efficacy and safety of Resomal is the same as low Osmolar ORS in the correction of dehydration and electrolytes in severely malnourished children with diarrhea. While many studies currently recommended that there is little experience with Resomal in the treatment of diarrhea in severely malnourished children, and its efficacy about patient characteristics has not been previously reported.[16,17] In an experimental absorption study using perfusion techniques in human adult volunteers, water and sodium absorption was less efficient with ORS containing low compared with higher concentrations of sodium.[18] While in this study, water and sodium absorption with resomal did not seem to be less efficient than with low osmolar ORS as evidenced by correction of dehydration and stool output. Similar findings were demonstrated by Alam NH et al.[19]

In our study on pre assessment electrolytes were decreased in low osmolar group children, and after rehydration electrolytes were almost equally found in both groups, it mean resomal showed good efficacy in the adequate concentration of electrolytes like low osmolar ORS but non-significant, when it was significantly decreased as compare to low osmolar ORS group before rehydration, and after rehydration electrolytes were found equally in both groups without significant difference P-value 0.51. While findings of Alam NH et al.[19] provides an increase in the concentration of potassium in a modified ORS such as resomal for use in these children. Potassium depletion universally accompanies severe malnutrition and is believed to represent a significant risk for sudden death in malnourished children. Compared with WHO-ORS, resomal therapy has corrected hypokalemia in a much greater proportion of children and in a shorter time.

In our study hyponatremia is equally covered in both groups, no significant difference was found p-value 0.89. While Water low JC et al.[20] reported that. Severely malnourished children have an excess total body and intracellular sodium even in the presence of reduced-sodium concentration in the blood, ie, hyponatremia. Alam NH et al.[19] suggested that the rate of urinary sodium excretion surpasses that of intracellular to extracellular shift of sodium in a clinically significant manner. An ORS with sodium concentration reduced to the level contained in resomal does not seem to be supported by the results of our study. In recent years, there has been growing interest in the use of hypotonic or reduced osmolarity ORS (lower sodium and lower glucose ORS) in the treatment of diarrhea, because some clinical studies have demonstrated

better efficacy, especially in a reduced need for unscheduled intravenous fluids.[21-23] Based on these findings, a WHO/UNICEF expert committee meeting[24] recommended a revised formulation of reduced-osmolarity ORS (Na 75, Cl 65, K 20, citrate 20, glucose 75 mosmol/L, osmolarity 245 mosmol/L) for use in children and adults for all causes of diarrhea, including cholera; however, the issue of the best ORS remains controversial, and criticism persists.[24,25] Reduced osmolarity ORS with higher potassium and added micronutrients has never been evaluated in the treatment of severely malnourished children with diarrhea. The rationale for other micronutrients in resomal including magnesium, zinc, and copper is mainly to replace those micronutrients in which severely malnourished children are known to be deficient and in which deficiency is known to increase risk of adverse outcome.[17] These micronutrients (especially zinc) may influence recovery from diarrhea; however, we were unable to evaluate this possibility, because the standard WHO-ORS group also received supplements as part of our routine practice for the treatment of severely malnourished children.[26,27]

Conclusion

We conclude that resomal and low osmolar ORS were similarly efficacious in the rehydration of severely malnourished children with diarrhea and dehydration. Furthermore, in both resomal and low osmolar ORS groups children were found without significant difference in electrolytes after rehydration.

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