Journal of Rawalpindi Medical College (JRMC); 2016;20(4):292-295

Original Article

Efficacy of Reduced Osmolarity Oral Rehydration Solution in Children with Acute Diarrhoea

Ayesha Fayyaz, Israr Liaquat, Qaiser Shahzad Humayun
Department of Paediatrics, Holy Family Hospital and Rawalpindi Medical College

Abstract

Background: To compare the efficacy of reduced osmolarity ORS with standard WHO ORS in children with acute diarrhoea.

Methods: In this comparative study 1080 children suffering from acute diarrhoea were selected from emergency. Children were divided randomly into 2 groups. Group A was given reduced osmolarity ORS and Group B was given standard WHO ORS. Proforma was filled at the time of admission and after every four hours till there was no dehydration. Criteria of treatment efficacy was, need of unscheduled IV infusions, number of stools, improvement in number of episodes of vomiting and duration of hospital stay in hours.

Results: A total of 1080 children with acute diarrhoea were included in the study. 540 children in group A were given reduced osmolarity ORS and 540 children in group B were given WHO ORS. Efficacy of treatment was significantly good in group A (75%) as compared to group B (34%). Unscheduled IV infusion was less in group A as compared to group B. Number of stools were significantly reduced in group A as compared to group B. Vomiting during rehydration was also lesser in group A as compared to group B. Patients in group A had significantly reduced average duration of hospital stay as compared to group B.

Conclusion: Reduced osmolarity ORS reduced the duration and severity of symptoms in children with acute diarrhea and treatment was well tolerated with no side effects.

Key Words: Acute diarrhea, reduced osmolarity ORS. standard WHO ORS, unscheduled IV infusion.

Introduction

Diarrhoea emerges as major cause of mortality in children in developing countries. Diarrhoea is characterized by passing of three or more loose, watery stools per day.A large number of diarrheal deaths occur due to dehydration. Dehydration was treated with IV infusion initially. Dehydration must be evaluated rapidly and corrected in 4-6 hours according to degree of dehydration and estimated daily requirements. Oral rehydration therapy is the basis in the treatment of diarrheal episodes and in recent years, low osmolarity oral rehydration solution (ORS) has been recommended for rehydration. These electrolyte solutions can be used for rehydration as well as maintenance and can prevent most diarrhoea-related complications. Laboratory work suggests that lower concentrations of sodium and glucose enhance solute induced water absorption. So, reduced osmolarity ORS might be advantageous for children with acute diarrhoea. [1]

Acute diarrhoea is defined as the passage of three or more stools per day with consistency softer than usual for a child or one watery stool per day[1]. Diarrhoea is a leading cause of childhood death in developing countries. It accounts for nearly 18% of childhood deaths, with almost 1.8 million deaths/year globally.[2] In 2008 diarrhea was estimated to have caused 1.1 million deaths in children aged five and over and 1.5 million deaths in children under the age of five in developing countries. Worldwide, children younger than 5 years have an estimated 1.7 billion episodes of diarrhoea each year, leading to 124 million clinic visits, 9 million hospitalizations, and 1.34 million deaths, with more than 98% of these deaths occurring in the developing world.[3,4,5,6]

Lack of a system able to generate representative quality data regularly is one of the major obstacles for international and national planning to reduce under 5 mortality[7]. Diarrheal illness may have a significant impact on the psychomotor and cognitive development in young children.[8] WHO suspects that there are > 700 million episodes of diarrhoea/year in children < 5 years of age in developing countries.[9] Major risks are environmental contamination and increased exposure to enteropathogens.[10] The main complication is dehydration, which until early 1960s was treated with IV infusion. Dehydration must be evaluated rapidly and corrected in 4-6 hours according to degree of dehydration and estimated daily requirements. [11,12]

Advent of oral rehydration salts (ORS) solution for the treatment of dehydration due to diarrhoea is considered to be one of the greatest achievements of medical research in the 20th century.[13] Since it was

recommended by the World Health Organization (WHO) in 1978 for the management of all types of diarrhoea in all age-groups, numerous studies have been undertaken to develop an 'improved' ORS. The goal was to discover a product that would be at least as safe and effective as standard ORS solution for preventing or treating dehydration from all types of diarrhoea but which, in addition, would reduce stool output or have other important clinical benefits. . Oral rehydration therapy is the mainstay in the treatment of diarrheal episodes, and in recent years, low osmolarity oral rehydration solution (ORS) has been recommended for rehydration.[14] For more than two decades, WHO has recommended a standard formulation of glucose based ORS with 90 mmol/l of sodium and 111 mmol/l of glucose and a total osmolarity of 311 mmol/l. It remains unclear, however, if this is the optimum sodium concentration. Some studies have found patients with blood sodium concentrations above the normal level of 150 mmol/l.[15] Laboratory work suggests that lower concentrations of sodium and glucose enhance solute induced water absorption. [16] In one study it was observed that in first 24 hrs, mean stool output (g/kg) was 114 vs. 125, vomiting occurs in 58% vs. 62%, duration of hospital stay was similar and proportion of children who required unscheduled IV therapy was 10% vs. 15% in children who received reduced osmolarity ORS as compared to those who received the WHO ORS respectively.[17]

Patients and Methods

This study was done in Department of Paediatrics , Holy Family Hospital Rawalpindi from 9th August 2015 to 15th September 2015. Using WHO sample size criteria, the sample size was 1080. In randomized clinical trial there were 540 children in each group. Power of study was 80%. Significance level was taken as 10 %. $p1^9$ was 10 % and $p2^9$ was 15% . Children of either gender with acute diarrhoea having, age 3 months to 2 years, diarrhoea of duration less than 5 days and with some dehydration with consecutive non-probability sampling were studied and children having other systemic illnesses or cholera, children who are immunocompromised and third degree malnourished children (wt. <60% expected for that age) were excluded from the study. Total 1080 children suffering from acute diarrhoea were selected from emergency. Parents were informed about aims of study. Risks and benefits of reduced osmolarity and standard WHO ORS were explained to the parents. Informed written consent was taken from parents .The study protocol was reviewed and approved by the ethical committee. Children were divided randomly using random number table into 2 groups. Group A was given reduced osmolarity ORS and group B were given standard WHO ORS under supervision of nurse incharge. Proforma was filled at the time of admission and after every four hours , till there was no dehydration. Criteria of treatment efficacy was taken as need of unscheduled IV infusions, improvement in number of episodes of vomiting, number of stools and duration of hospital stay in hours. Data analysis was done using Statistical Package for Social Sciences version 10. Quantitative variables i.e. age, number of stools, vomiting during rehydration and duration of hospital stay in hours were presented as mean and SD. Qualitative variables i.e. gender, need for unscheduled IV infusions and efficacy were presented as frequencies and percentages. Test of significance was applied. For qualitative data i.e. gender, need for unscheduled intravenous infusions and efficacy, Chi square test was used. For quantitative data i.e. age, no. of stools, vomiting during rehydration and duration of hospital stay in hours, t-test was applied and p value less than .05 was taken as statistically significant.

Results

A total of 1080 children with acute diarrhea were included in the study. We analyzed the record of 540 children in group A (Reduced osmolarity ORS given) and 540 children in group B (WHO ORS given). The clinical parameters of both groups at the time of admission including age, weight, duration of illness, signs and symptoms and their distribution were not statistically different. Mean age was 14.51±6.90 months, ranging from 3 months to 24 months. Of these 620(57.4%) were from 3-13 months(316 in group A and 304 in group B) and 460 (42.6%) were from 14-24 months(224 in group A and 236 in group B). Of the total patients, 595 were males (55.1%) and 485 were females (44.9%).(Table 1 &2). Efficacy was significantly improved in group A (75%) as compared to group B (34%), having Chi square value of 182.394 , df value 1 and one sided p value <0.00005.(Table 3) Unscheduled IV infusion was given in 45.5% patients . In group A, only 25 %(135) patients needed IV infusion as compared to group B in which 65.95% (356) were given IV infusion (Chi square 182.394, df 1 and one sided p value of<0.00005).(Table 4) Average numbers of stools was 4 ±2.17 in group A as compared to 5.35±2.58 in group B. (t- test -0.458, df 1047.6 and one sided p value =0.00005). Average episodes of vomiting were 0.57±0.78 in group A as compared to 1.21±1.05 in

group B (t test -11.505, df 997.454 and one sided p value =0.00005). Average duration of hospital stay was also significantly reduced in patients of group A 7.79±4.41 as compared to group B 10.78±5.18 (t test -10.197, df 1050.97 and one sided p value =0.00005)(Table 5&6)

Table 1 .Distribution of cases by age

Age(Months)	Number	Percentage%
3-13	620	57.4
14-24	460	42.6
Total	1080	100
Mean SD	14.51±6.90	

Table 2.Distribution of cases by gender

Gender	Number	Percentage%
Male	595	55.1
Female	485	44.9
Total	1080	100

Table 3.Efficacy of treatment

Treatment	Present	Not Present
Reduced osmolarity ORS	405(75%)	135(25%)
WHO ORS	184(34%)	356(65.9%)
	589(54.5%)	491(45.5%)
Chi sq 182.394, df 1, one sided p <0.00005		

Table 4. Frequency of unscheduled IV infusion

Group	Given	Not Given
A	135(25%)	405(75%)
B	356(65.9%)	184(34.1%)
	491(45.5%)	589(54.5%)

Table 5. Secondary outcome measures

Group	Number Of Stools	Vomiting	Duration Of Hospital Stay
A	4±2.17	0.57±0.78	7.79±4.41
B	5.35±2.58	1.21±1.05	10.78±5.18

Table 6. t- test

Study Variables	t value	df	One sided p- value	Mean Difference	SD
Number of Stools	-9.318	1047.6	0.00005	-1.35	0.14
Vomiting Episodes	-11.505	997.45	0.00005	-0.65	5.63E-02
Duration of Hospital stay	-10.197	1050.9	0.00005	-2.99	0.29

Discussion

In the present study, we wanted to find out whether a reduction in osmolarity would improve the rehydrating properties of the oral rehydration solution. For more than 25 years WHO & UNICEF have recommended single formulation of glucose based ORS to prevent or treat dehydration from diarrhea irrespective of cause or age group affected. This product has proven effective & contributed substantially to the dramatic global reduction in mortality from diarrhea during the period. Based on more than two decades of research & recommendations by an expert group, WHO & UNICEF received the effectiveness of a new ORS formula with reduced concentration of glucose & salts. Reduced osmolarity rehydration solution was associated with reduced need for unscheduled intravenous infusions, lower stool volume and less vomiting compared with standard WHO rehydration solution. [18] Because of the improved effectiveness of this new ORS solution, WHO & UNICEF recommended that countries use and manufacture this new formulation in place of old one.

Therapy of acute watery diarrhoea requires replenishing water and electrolyte losses (rehydration phase) and maintaining water and electrolyte balance after rehydration until diarrhoea ceases (maintenance phase). Oral rehydration is successful when hourly oral intake matches or modestly exceeds fluid losses (regardless of gross stool rate). When the solution contains appropriate amounts of sodium, potassium, and bicarbonate or base-precursor, electrolyte balance is also restored and maintained. Dehydrated patients in shock need rapid intravenous rehydration followed by oral maintenance. If intravenous fluids or skilled personnel are unavailable, oral rehydration and maintenance can be effective even in hypotensive patients. With lesser degrees of dehydration, most patients respond without intravenous fluids, and dehydration can be prevented by early oral maintenance therapy. For years, the WHO has encouraged the use of a single ORS formulation to be used for all ages and all causes of infectious diarrhea and the effectiveness of this approach has been enormous. Laboratory work suggests that lower concentrations of sodium and glucose enhance solute induced water absorption and improves symptoms earlier. Patients with acute diarrhoea might be benefited by use of reduced osmolarity oral rehydration solution.

In our study, we compared treatment efficacy of reduced osmolarity oral rehydration solution with standard WHO oral rehydration solution in patients with acute diarrhoea. There was significant improvement in all the parameters compared. Patient given reduced osmolarity ORS had shown significantly improved treatment efficacy that was

measured in terms of significantly reduced need for unscheduled IV rehydration solution, lesser numbers of stool, lesser episodes of vomiting and shorter duration of hospital stay. There was no significant adverse effect during treatment. There are lot of studies that had been done to measure effectiveness of reduced osmolarity ORS and shown to had good results. Reduced osmolarity ORS is now being recommended as first line treatment in patients of acute diarrhoea worldwide. But in our country still WHO ORS is being used for oral rehydration. Policy makers must take some measures for recommendation of reduced osmolarity oral rehydration solution by its easy availability and awareness of general population regarding its effectiveness. [14-18]

Conclusion

1.Use of reduced osmolarity ORS in acute diarrhoea in children improves symptoms earlier and reducing need of unscheduled IV infusion and duration of hospital stay.

2. It is likely to reduce the disease burden and financial burden on parents and hospital. It can also help in removing the problem like cross infection with other microorganisms during prolonged hospital stay, drug resistance and opportunistic infections.

References

1. Johnston BC, Shamseer L, da Costa BR, Tsuyuki RT. Measurement issues in trials of pediatric acute diarrheal diseases. Pediatrics 2010; 126: 222-31.
2. Bryce J, Pinto CB, Shibuya K, Black RE; WHO Child Health Epidemiology Reference Group. WHO estimates of the causes of death in children. Lancet 2005; 365:1147-52.
3. Black RE, Cousens S, Johnson HL, Lawn JE, Rudan I. Global, regional, and national causes of child mortality in 2008: a systematic analysis. Lancet 2010; 375(9730):1969-87.
4. Fischer Walker CL, Perin J, Aryee MJ. Diarrhea incidence in low- and middle-income countries in 1990 and 2010: a systematic review. BMC Public Health 2012; 12:220-24.
5. Parashar UD, Hummelman EG, Bresee JS, Miller MA, Glass RI. Global illness and deaths caused by rotavirus disease in children. Emerg Infect Dis 2003; 9(5):565-72.
6. Boschi-Pinto C, Velebit L, Shibuya K. Estimating child mortality due to diarrhoea in developing countries. Bull World Health Organ 2008; 86(9):710-17.
7. Pinto CB, Velebit L, Shibuya K. Estimating child mortality due to diarrhoea in developing countries. Bull WHO 2008; 86: 710-17.
8. Kazemi A, Tabatabaie F, Ghazvini MRA, Kelishadi R. The role of rotavirus in acute pediatric diarrhea in Isfahan, Iran. Pak J Med Sci 2006; 22: 282-85.
9. Imhoff B, Morse D, Shiferaw B, Hawkins M, Vuqia D. Burden of self-reported acute diahrreal illness in Food Net surveillance areas,1998-1999.Clin Infect Dis 2004; 38: 219-26.
10. Al-Gallas N, Bahri O, Bouratbeen A. Etiology of acute diarrhoea in children and adults in Tunis, Tunisia, with emphasis on diarrheagenic E.coli. Am J Trop Med Hyg 2007; 77: 571-82.
11. Madati PJ, Bachur R. Development of an emergency department triage tool to predict acidosis among children with gastroenteritis. Pediatric Emerg Care 2008; 24: 822-30.
12. Armon K, Stephenson T, Mac Faul R, Eccleston P, Werneke U. An evidence and consensus based guideline for acute diarrhoea management. Arch Dis Child 2001; 85: 132-42.
13. Pulungsih SP, Punjabi NH, Rafli K. Standard WHO-ORS Versus Reduced-osmolarity ORS in the Management of Cholera . J Health Popul Nutr 2006 ;24(1):107-12
14. Khan AM, Sarkar SA, Alam NH. Low osmolar oral rehydration salts solution in the treatment of acute watery diarrhoea in neonates and young infants: a randomized, controlled clinical trial. J Health Popul Nutr 2005; 23:52-57.
15. Chouchan S, Fehri H, Chouchane C, Merchaoui Z, Seket B. Hypernatremic dehydration in children. Arch Pediatric 2005; 12: 1697-02.
16. Nutrition Committee, Canadian Paediatric Society. Oral rehydration therapy and early refeeding in the management of childhood gastroenteritis. Paediatric Child Health. 2006; 11: 527-31.
17. Alam NH, Bhatnagar S, Chea-woo E, Fontaine O. Multicenter, randomized, double blind clinical trial to evaluate the efficacy and safety of a reduced osmolarity oral rehydration solution in children with acute watery diarrhoea. J Pediatr 2001; 107: 613-8.
18. Hahn S, Kim Y, Garner P. Reduced osmolarity oral rehydration solution for treating dehydration due to diarrhoea in children. Br Med J. 2001; 323: 81-85.