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The Effect of G-ORS Along With Rice Soup in the Treatment of Acute Diarrhea in Children: A Single-Blind Randomized Controlled Trial

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Abstract

Background: The world health organization guidelines for treatment of diarrhea in children emphasize on continued feeding together with prescription of oral rehydration solution (ORS) and supplementary zinc therapy. However, conflicting viewpoints exist regarding the optimal diet and dietary ingredients for children with diarrhea. Moreover, few studies have investigated the effect of rice soup along with ORS in the treatment of this disease.
Objectives: This study aimed to explore effects of simultaneous taking of glucose oral rehydration solution (G-ORS) and rice soup in the treatment of acute diarrhea in 8 to 24-month-old children.
Patients and Methods: This single-blind controlled clinical trial was conducted in the pediatric ward of 22nd of Bahman hospital, Gonabad, Iran between June 2013 and February 2014. Forty children aged 8-24 months with acute diarrhea were randomly assigned into an intervention group (G-ORS plus rice soup group) comprising 20 babies and a control group (G-ORS) of 20 children based on balanced blocking randomization. The variables under investigation were diarrhea duration, patient hospitalization, need for intravenous (IV) fluids and stool output frequency. Data was analyzed using independent samples t and chi-square test.
Results: At the end of study, the time for treating acute watery diarrhea in the intervention and control groups were 21.10 ± 8.81 and 34.55 ± 5.82 hours ($P < 0.001$) and hospital stay were 34.05 ± 6.62 and 40.20 ± 6.32 hours ($P = 0.005$). Moreover, stool output frequency were 4.20 ± 0.95 and 8.00 ± 1.37 ($P < 0.001$) in the first 24 hours, and 2.18 ± 0.60 and 2.80 ± 0.76 ($P = 0.03$) in the second 24 hours of treatment in intervention and control groups, respectively.
Conclusions: Rice soup regimen was highly effective and inexpensive in the treatment of acute diarrhea in children. Thus, in addition to the common treatment by G-ORS, rice soup can be consumed simultaneously with G-ORS.

Keywords: ORS, Rice, Diarrhea, Children

1. Background

A diarrhea lasting for seven days or less is classified as acute diarrhea (1). Accounting for an annual 1.7 million deaths worldwide, diarrhea is the leading cause of mortality in children under 5 years old (2). It is responsible for over a quarter of all childhood mortality worldwide (3). This disease negatively impacts quality of life and could lead to high health costs (4). Dehydration is the immediate cause of death in most cases and if appropriately treated, mortality can be averted almost completely (5). Despite this fact, mortality due to diarrhea is still considerably high (5, 6).

Diarrhea dehydration was treated by intravenous (IV) infusion of fluids until the 1970s, but it was costly and impractical in low-resource settings (5). Therefore, oral rehydration solution (ORS) was introduced and developed for widespread use and since then millions of children and adults with diarrhea were saved (7). ORS has been termed as "the most important advance in this century" and has kept its fame even after the turn of the century. However, there have been controversies regarding its ideal composition due to the fact that its formulation does not seem universal for children of all ages with gastroenteritis or other causes within all geographical regions (8).

As nations launched diarrhea control programs, they faced with many problems in making ORS accessible with high coverage levels, which was partly due to inadequate manufacturing capacity. Control programs promoted using additional fluids and home-made solutions like rice water to prevent development of dehydration in an attempt to improve fluid provision in early diarrhea episodes (9). As diarrhea can cause serious short- and long-

term complications, it is necessary to educate women on how to prevent the disease and to take care of children with diarrhea (10) as most diarrhea episodes are treated at home by mothers (11).

Accordingly, various research and experiments have been performed to alter the composition of ORS to achieve an ideal formula (9). Moreover, appropriate nutrition habits play an important role in controlling diarrhea (12). Rice-based oral rehydration solution has proved to be effective in the treatment of diarrhea and dehydration (13, 14). Some studies have altered the composition of current ORS formula replacing glucose with rice components, which has also been effective in treating diarrhea (13).

In previous studies, rice-based ORS (R-ORS) has been compared with the world health organization (WHO) recommended glucose-based ORS (G-ORS) in treating children with acute diarrhea and contradictory results have been reported. In a research to investigate the efficacy of R-ORS compared to G-ORS, in treating children with acute watery diarrhea, R-ORS was more effective in reducing the duration of diarrhea and hospital stay, although no significant effect was found on stool output or intravenous fluid administering frequency (15). Some other studies have found no significant difference between R-ORS and G-ORS in the treatment of children with diarrhea (13-16).

The WHO guidelines for treatment of diarrhea in children emphasize on continued feeding together with prescription of ORS and supplementary zinc therapy. However, conflicting viewpoints exist regarding optimal diet and dietary ingredients for children with diarrhea (1). Nonetheless, we found no studies investigating the effect of rice soup along with ORS in the treatment of diarrhea; therefore, the question still comes to mind whether rice soup ORS is effective in treating children with acute diarrhea.

2. Objectives

This study aimed to investigate the effects of simultaneous consumption of G-ORS and rice soup compared with consumption of G-ORS only in the treatment of acute diarrhea in 8 to 24-month- old children.

3. Patients and Methods

This study was a single blind randomized controlled clinical trial conducted from June 2013 to February 2014. The sample population included children hospitalized in the pediatric ward of 22nd of Bahman hospital, Gonabad, Iran with acute diarrhea and having normal sodium and potassium ion ranges in their blood serum. To decide on the number of patients needed, a pilot study was performed on 10 children (5 in each group). The stool output frequency in the second 24 hours was considered and the following results were obtained: $\mu_1 = 2.8$, $\mu_2 = 2.1$, $S_1 = 0.25$, $S_2 = 0.94$. Accordingly, with a type I error probability of 0.05 and a power of 0.80, the sample size was estimated as 16 patients for each group. However, we recruited 20 patients in each group, with a total of 40 patients for the two groups (Figure 1).

Children hospitalized with acute diarrhea and fulfilling the inclusion criteria were assigned into two groups of control (G-ORS) and experimental (G-ORS along with rice soup) in 10 blocks of 4 using balanced block randomization (five blocks for each group).

The inclusion criteria were age of 8 to 24 months, having no comorbidities, experiencing an acute diarrhea and having a normal range of sodium and potassium in serum. Moreover, during the study children were not supposed to consume anything that would aggravate diarrhea (such as artificial fruit juices, very sweet foodstuffs, etc.) and were to adhere to the prescribed regimen.

The exclusion criteria included: the child being incapable to continue the study from a medical point of view, child's parents unwillingness to continue the study, nonadherence of child to the prescribed regimen, diarrhea being associated with severe vomiting (of more than 2 times per day) and requirement of antibiotics administration.

3.1. The Procedures

The treatment protocol was as per the recommendation of the WHO chart in which the need for intravenous fluids and G-ORS has been determined based on the severity of diarrhea (17). The control group received recommended treatment with G-ORS (produced by Daroopakhsh Drug Manufacturing Co., Iran). The experimental group received rice soup (25 mL for children under one and 50 mL for those older than one year old) based on per stool output or vomiting besides receiving the same G-ORS protocol. To consider the fluid intake amount not to exceed the recommended levels, G-ORS volume was decreased in proportion to the amount of rice soup added.

The rice soup was prepared by the hospital cook for hospitalized children every day. To prepare the soup, 100 g Iranian rice plus 6 g salt with 1.2 L of boiled water was cooked by simmering at a low flame for one hour and stirring from time to time until the final soup volume reached 1 L. The prepared soup and a measuring container were given to each mother to feed the child with the required amount of soup per stool output or vomiting. The extra soup was kept in the fridge but fresh soup was prepared and kept at the disposal of the mothers the next day.

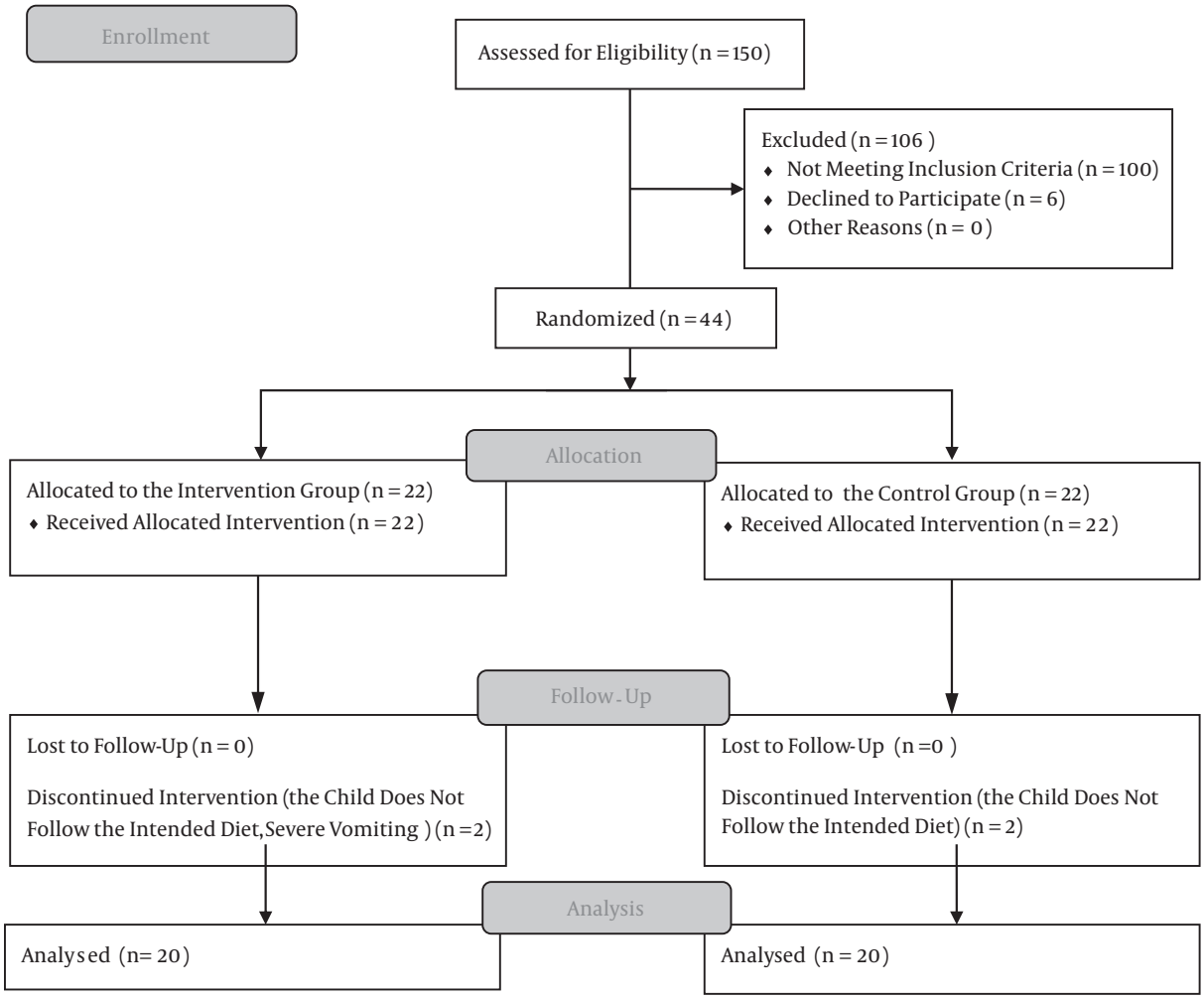

Figure 1. Flow Diagram of the Participants

On the first day of hospitalization and prior to the treatment, sodium and potassium in blood serum were measured using Photometer Model PFP7 (manufactured by Jenwey Company, England) and urine specific gravity was measured using a refractometer Model SPR-T2 (manufactured by Erma company, Japan).

The checklist for demographic information such as age, gender, weight and nutrition type was filled out by the researcher before treatment on the first day of patient's hospitalization. The weight was measured using weighing scale Model 61907 (produced in Germany) and the mother was asked regarding child's age and nutrition type eating habits. Other variables and measurements are defined in Box 1.

All children were examined by a pediatrician who did not know groups (experimental or control) assignment. The assistant researcher who collected the data regarding hospitalization duration, diarrhea duration, stool output frequency and amount of needed intravenous fluids or the person conducting paraclinical tests did not know about children grouping.

3.2. Ethical Considerations

The study was approved by the institutional committee of research Eehics (code: EC/1391/1/4) at Gonabad University of Medical Sciences and registered by the Iranian clinical trial centre under No. IRCT201310169459N1. At the

Box 1. Definitions of the Variables and Outcome Measures

Variable	Definition
Diarrhea	Passage of loose or watery stools or an increased frequency of stools in the child. The diagnosis was made by a pediatrician.
Diarrhea Duration Before Intervention	The period during which the patient had diarrhea before admission per hour reported by mothers, at the time of admission in the hospital.
Diarrhea Duration After Intervention	The number of hours after admission until stool retained its shape, did not stick to the container and was characterized by absence of mucus. This procedure was observed by the same assistant researcher.
Hospital Stay	Was registered at the end of treatment in the number of hours or days the patient stayed in hospital.
The Need for IV Fluids	Was registered based on mL per 24 hours from the nurse's report.
Stool Output Frequency	Was observed by mothers and they were required to report every child's stool output to the assistant researcher. By observing stool, the assistant researcher filled in the checklist and reported the stool frequency based on the number of stool output per 24 hours.
Dehydration Rate (Based on the Recommended Chart by the WHO) (18)	
None (< 5%)	Mentation: Alert, Eyes: Normal, Skin turgor: Normal recoil, Pulse: Normal Rapid, Thirst: Drinks normally.
Mild (5% - 10%)	Mentation: Restless- irritable, Eyes: Sunken, Skin turgor: Slow recoil, Pulse: Rapid- low volume, Thirst: Thirsty- drinks eagerly
Severe (> 10%):	Mentation: Lethargic or unconscious, Eyes: Sunken, Skin turgor: Very slow recoil (> 2 seconds), Pulse: Weak or absent, Thirst: Drinks poorly or unable to drink.

beginning of study, parents were informed about the objective of research and a written consent for their child's participation was obtained. The parents were free to discontinue at any stage of research. They were also assured of confidentiality of all personal information.

3.3. Data Analysis

To analyze the data, normality test for data distribution was performed using Kolmogorov-Smirnov test. As data was distributed normally, independent samples t-test for the two groups was performed for comparing quantitative variables of age, weight, urine specific gravity, sodium and potassium levels in blood serum, diarrhea duration, hospital stay, stool output frequency and the rate of intravenous fluids received. Moreover, Chi-square test was used to investigate the relation between qualitative variables of gender, nutrition type and degree of dehydration. Analysis of covariance was used for adjusting confounding effect of serum sodium variable. P-value below 0.05 was considered statistically significant.

4. Results

From a total of 40 children, 19 (47.5%) were male and 21 (52.5%) female. The mean age was 14.35 $\pm$ 5.63 months with a minimum of 8 months and a maximum of 24 months. Twelve (30%) children had slight dehydration, 28 (70%) moderate dehydration, and no case had severe dehydration.

No significant difference was found between the groups regarding age, gender, admission weight and nutrition type (breastfeeding or formula), the degree of dehydration (mild or moderate), serum sodium and potassium levels, urine specific gravity at the onset of hospitalization, vomiting, pulse rate and respiratory rate (Table 1).

Also, no significant difference was observed between the two groups regarding diarrhea duration prior to the treatment. However, the duration of diarrhea was significantly shorted in G-ORS + rice soup group than that of the G-ORS group (22.30 $\pm$ 4.78 hours vs. 34.55 $\pm$ 5.82 hours, $P < 0.001$) (Table 2).

Furthermore, a significant difference was found between the groups for stool output during the first 24 hours ($P < 0.001$) and the second 24 hours ($P = 0.03$) after the treatment. Moreover, the stool output of G-ORS + rice soup group was less than that of G-ORS group during the first and second 24 hours (Table 2). For receiving intravenous fluids, the results showed no significant difference between the groups during the first 24 hours ($P = 0.95$) as well as in the second 24 hours ($P = 0.87$) after the treatment (Table 2). In analysis of covariance, no significant difference was found between the two group averages for stool output during the first 24 hours ($P < 0.001$) and the second 24 hours ($P = 0.03$), diarrhea duration ($P < 0.001$) and hos-

Table 1. Baseline Characteristics in Control and Intervention Groups[z,a]

Variable	Group				
	Control	Intervention	Test Result		
			T	P	X^2
Age, Month	14.10 ± 6.09	14.60 ± 5.28	0.28	0.78	NA
Gender			NA	0.75	0.10
Female	11 (55)	10 (50)			
Male	9 (45)	10 (50)			
Weight, g	9871.40 ± 1666.48	9973.30 ± 1468.80	0.21	0.84	NA
Nutrition Type			NA	0.73	0.11
Breast Feeding	13 (65)	14 (70)			
Formula Feeding	7 (35)	6 (30)			
Serum Na	141.05 ± 2.79	139.20 ± 3.31	1.90	0.06	NA
Serum K	4.06 ± 0.27	4.01 ± 0.26	0.58	0.56	NA
Urine Specific Gravity	1017.95 ± 4.14	1020.45 ± 6.73	1.41	0.17	NA
Dehydration Degree			NA	0.49	0.48
Mild	13 (65)	15 (75)			
Moderate	7 (35)	5 (25)			
Vomiting	1.05 ± 0.68	0.80 ± 0.69	1.14	0.26	NA
Pulse Rate	126.70 ± 10.95	130.95 ± 11.36	1.20	0.23	NA
Respiratory Rate	32.50 ± 5.03	32.90 ± 3.98	0.28	0.78	NA

Abbreviation: NA, not available.

Table 2. Comparing the Two Groups Regarding Diarrhea Duration, Hospital Stay, Stool Frequency Output and Intravenous Fluids

Variable	Group				95% CI
	Control	Intervention	Statistics		
			T	P	
Diarrhea Duration, h					
Before Admission	12.60 ± 3.88	11.95 ± 4.51	0.49	0.63	-2.05 - 3.35
After Admission	34.55 ± 5.82	21.10 ± 8.81	5.69	< 0.001	8.67 - 18.23
Hospital Stay, h	40.20 ± 6.32	34.05 ± 6.62	3.01	0.005	2.01 - 10.29
Stool Output Frequency					
The 1st 24 hours	8.00 ± 1.37	4.20 ± 0.95	10.16	< 0.001	3.04 - 4.56
The 2nd 24 hours	2.80 ± 0.76	2.18 ± 0.60	2.30	0.03	0.07 - 1.17
Intravenous Fluids Volume					
The 1st 24 hours	946.00 ± 308.36	951.50 ± 211.61	0.07	0.95	-174.79 - 163.79
The 2nd 24 hours	413.00 ± 203.75	424.54 ± 139.66	0.17	0.87	-152.96 - 129.87

[a]Data are expressed as No. (%) otherwise indicated as Mean ± SD.
Abbreviation: CI, Confidence Interval.

pital stay ($P < 0.004$) after adjusting the confounding variable of serum sodium.

5. Discussion

In the present study, taking G-ORS along with rice soup was more effective in decreasing children's duration of di-

arrhea compared with taking G-ORS. This finding was consistent with some previous studies (15, 19). A randomized clinical trial revealed that although R-ORS is effective in the treatment of diarrhea caused by vibrio cholerae, its effect does not exceed that of G-ORS (16). A study on rats having diarrhea from sorbitol found that the duration of diarrhea in gruel-based and rice-starch groups decreased compared with that of the control group (20). In another study, diarrhea duration in the group received enriched glucose with amylase-resistant starch was less than that of the G-ORS group (21). However, another study did not find any significant difference in diarrhea results between the group receiving G-ORS and the one receiving R-ORS (13). Probably the type of rice or the amounts used in different studies were different from each other. A study conducted on rats pointed out that different types of rice have different effects on diarrhea (22).

Our results revealed no significant difference for administering intravenous fluids during the first and second 24 hours of rehydration between the group received rice soup and G-ORS compared to the G-ORS only group. Therefore, these findings concur with those of another research (15), but in some studies intravenous fluid needed during rehydration in the R-ORS group was significantly less than that in the G-ORS group, which is probably due to the difference in amount and the procedure of preparing rice (14, 23).

In the present study, the frequency of stool output was significantly less in the intervention group both in the first and second days after the treatment. This finding was also in line with some previous investigations that compared the effects of R-ORS and G-ORS (23, 24). Yet, there is another study that showed no significant difference in the stool output frequency of the two groups (15). Glucose in rice is slowly released and quickly absorbed in the small intestine. Then, it increases the water and electrolyte absorption, which consequently decreases stool output, reduces diarrhea duration and shortens the amount of IV fluid replacement. Since glucose available in ORS ingredients is completely present inside the lumen of the small intestine and has no important effect in water and electrolyte intake (9). On the other hand, the pectin available in rice absorbs a large quantity of water in the intestine and consequently causing stool to become fairly hard (25).

Furthermore, the results revealed that the duration of hospital stay in children receiving rice soup was less than that of the control group. This finding corresponds with some other studies (15, 19). As the duration of diarrhea in the experimental group decreased, the duration of hospital stay lessened.

In conclusion, the findings pointed out that stool output frequency and the volume of intravenous transfusion decreased in the both groups, but R-ORS was more effective in lessening diarrhea duration, duration of hospital stay and stool output frequency compared to the use of G-ORS alone. Therefore, since rice soup is rather inexpensive, it can be prescribed with G-ORS to decrease both hospital expenses and complications of acute diarrhea.

One limitation of the study was that diarrhea duration was reported by mothers prior to children's hospital stay. Mothers were required to report a rough estimate of diarrhea duration as we could not practically measure it exactly. Another limitation was that samples only consisted of children from one hospital, which reduces the generalizability of our findings. Thus, performing a multicentral study is recommended. Since the volume of intravenous fluids was registered based on nursing reports, there is the chance of potential error in measurement and registration as another limitation of study.

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Footnotes

Authors' Contribution: Mojtaba Kianmehr designed the study and analyzed data. Ashraf Saber collected clinical data. Jalil Moshari and Reza Ahmadi interpreted data. Mahdi Basiri-Moghadam designed the study and analyzed data. Further, all authors helped to draft the manuscript and involved in final approval of the version to be published.

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