Is rice based oral rehydration therapy effective in young infants?

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Abstract

Rice based oral rehydration therapy (ORT) solutions have been shown to be superior to glucose oral rehydration salts (World Health Organisation (WHO) ORS) in reducing stool volume and duration of diarrhoea in children and adults. Rice based ORT has been used only sparingly in young infants, however, because of theoretical concerns about digestibility. A randomised controlled trial of rice based ORT (50 g rice and electrolytes identical to WHO ORS) and WHO ORS was carried out in 52 male infants less than 6 months old with moderately severe acute diarrhoea to evaluate efficacy and digestibility. Nineteen (70%) of 27 children who received rice based ORT and 18 (72%) of 25 children who received WHO ORS were treated successfully.

The mean (SD) diarrhoeal stool output for the first 24 hours of treatment was significantly lower in the infants receiving the rice based ORT than in those receiving WHO ORS (101.0 (60.5) v 137.1 (74.6) g/kg). The stool output was also significantly less in the rice based ORT group in the second 24 hours. Infants in the rice based ORT group drank significantly less rehydration solution than infants in the WHO ORS group (mean (SD) 165.4 (77.4) v 217.9 (86.1)) during the first 24 hours of treatment. There was no difference in the duration of diarrhoea between the groups. The volume of breast and formula feeding was similar in the two groups. No difference was seen in the frequency of finding reducing substances or acid pH in the stools of either group of children. The results suggest that rice based ORT is as effective as WHO ORS in infants with moderately severe diarrhoea and that rice based ORT is as well tolerated as WHO ORS in infants.

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The worldwide use of oral rehydration therapy (ORT), primarily the glucose based oral rehydration salts (ORS) solution advocated by the World Health Organisation (WHO) and Unicef has greatly improved the outlook for millions of patients with acute diarrhoeal disease.¹ These solutions are used in only about 20% of diarrhoeal episodes, however.¹ One important reason proposed for this low rate of use is that glucose based ORT replaces

fluid and electrolyte losses but does not decrease stool volume nor shorten the duration of diarrhoea. Research has focused on methods to improve ORT formulations by replacing glucose with organic solutes such as starches to reduce the osmolality and increase the co-transport molecules for the coupled transport of sodium.² A variety of starches has been used successfully including rice, wheat, maize, and sorghum.³ The greatest experience has been with rice based solutions containing 50-80 g rice for each litre of water.⁴⁻⁷ These solutions have been shown to reduce stool volume by up to 45% in children with cholera-like diarrhoea and by up to 30% in non-cholera diarrhoea.⁸

These solutions have been little used in the youngest infants because of the theoretical concern about their digestibility.⁹ Young infants have incompletely developed mechanisms to digest starch, including low levels of pancreatic amylase.¹⁰ Despite the low enzyme levels, previous studies have shown that infants as young as 1 month can digest and absorb substantial amounts of rice.^{11 12} This digestion and absorption probably occurs through the use of salivary and breastmilk amylases and brush border disaccharidases.¹¹⁻¹³ To evaluate the efficacy and digestibility of rice based ORT in infants less than 6 months old compared with WHO ORS, we carried out a prospective, randomised controlled trial.

Patients and methods

SELECTION OF PATIENTS

This study was carried out from March 1989 to April 1990 at the National Institute of Child Health, Pakistan. Infants who were evaluated in the institute's diarrhoea training unit for acute diarrhoea were considered for the study. Boys younger than 6 months were enrolled if they had (a) more than four loose or watery stools without visible blood in the preceding 24 hours, (b) duration of diarrhoea less than four days, (c) clinical signs of mild or moderate dehydration based on clinical criteria,¹⁴ and (d) weight for age greater than 75% of 50th centile of the National Center for Health Statistics standard. Boys were chosen because of the greater accuracy in collecting stool and urine volumes. Children were excluded if they had bloody diarrhoea, a history of treatment with antibiotics or antidiarrhoeal drugs within 48 hours of admission, fever greater than 39°C, serious concurrent illness such as sepsis, shock, meningitis, pneumonia, evidence of intestinal obstruction, or refusal of the parents to sign the informed consent form.

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The study was approved by the ethical review committees of the Aga Khan University, the National Institute of Child Health, Pakistan, and Harvard University, USA. Informed consent was obtained from the parents or legal guardians of the patients before inclusion in the study. Once included in the study, the patients were randomly assigned to receive rice based ORT (group A) or WHO ORS (group B) using a permuted block randomisation technique.

Packets of rice based ORT were made in the paediatric research laboratory of Aga Khan University. Twin packets were made. One packet contained 50 g rice powder (basmati rice) and the other contained sodium chloride 3.5 g, trisodium citrate dihydrate 2.9 g, and potassium chloride 1.5 g. The packets were used within one week of their preparation. To constitute the solution, 50 g rice powder was boiled in 1100 ml water (100 ml extra water was added to allow for evaporative loss) for approximately six to seven minutes while stirring continuously. The solution was brought to room temperature and the electrolytes were added before administration. Patients in the control group received WHO/Unicef recommended glucose ORS (table 1).

TREATMENT SCHEDULE

After the initial history and physical examination, the degree of dehydration was assessed. Each infant's fluid deficit was determined by multiplying his weight at admission by the percentage dehydration estimated from clinical signs.¹⁴ Initial rehydration was accomplished within six hours. Each infant was reassessed clinically for dehydration after the ingestion of the calculated fluid deficit. The ongoing losses of stool and vomitus were replaced volume for volume with rice based ORT or ORS. Mothers were trained to feed oral rehydration solution to their infants under the supervision of research nurses and doctors. After rehydration, *ad libitum* feeding was begun by breast for those infants who were breast fed before admission or by a standard cows' milk formula (S-25, Wyeth) for children already receiving animal milk. The milk was offered at half strength (33 kcal/100 ml) at 120 ml/kg/24 hours for two days and then full strength thereafter. Plain water was also offered *ad libitum* after rehydration. Breastmilk intake was measured by weighing the child before and after breast feeding. Intake and output measurements were recorded every hour until

the diarrhoea had stopped. This was defined as the passage of the last diarrhoeal stool followed by two consecutive semiformed stools or an absence of stool for at least 12 hours. The weights of stool and vomitus were measured using tared diapers and cotton wool and a digital electronic balance sensitive to ± 1 mg (Tanita, Tokyo, Japan). Adhesive urine bags were used to collect urine and the volume was measured with a graduated cylinder. Vital signs were assessed every six hours. Nude body weights were taken on admission, on completion of rehydration, and then every 12 hours until the diarrhoea had stopped using a double beam balance (Detecto) accurate to ± 20 g.

Treatment failure was defined as the need for intravenous treatment after initial rehydration had been achieved, or the persistence of diarrhoea (defined as watery or liquid stool >30 g/kg/day) in children removed from the study by their parents after at least 72 hours of admission to hospital. Successful treatment was defined as maintenance of hydration status until formed stools appeared.

LABORATORY INVESTIGATIONS

On admission, a complete blood count, serum specific gravity, and electrolytes were determined before the start of treatment. Repeat values were obtained 24 hours after rehydration. Stool specimens were tested by microscopy for leucocytes, red cells, and ova and parasites. Stool pH (Universal Indicator paper, range pH 1–10), osmolality (osmometer), and reducing substances (Clinitest tablets, Miles Laboratories, Indiana) were determined once daily until the diarrhoea stopped.

Rectal swabs were obtained on admission and placed in phosphate buffered saline transport media before being tested for salmonella, shigella, enteropathogenic and enterotoxigenic *Escherichia coli* and *Vibrio cholerae* using standard techniques.¹⁵ Stool samples were also tested for rotavirus using an enzyme linked immunosorbent assay.

STATISTICAL ANALYSIS

The sample size (30 patients in each treatment group) was calculated as being sufficient to detect a 40% decrease in stool output with a type I error of 0.05 and type II error of 0.20.¹⁶ All data were entered into a personal computer using the StatPack Gold package, and analysis was aided by the use of the SPSS/PC+ (Chicago, Illinois, USA) software package. The two tailed Student's *t* test was used to compare mean values, whereas the χ^2 test was used to compare the percentage difference. When distributions were skewed, the Mann-Whitney U test was used for comparison of median values between groups. Log transformation analysis was also performed on the major outcome variables.

Results

Table 2 gives the clinical characteristics at

Table 1 Composition of rice ORT and glucose ORS used to treat infants ≤ 6 months old with acute diarrhoea

	Rice ORT	Glucose ORS
Sodium chloride (g)	3.5	3.5
Trisodium citrate dihydrate (g)	2.9	2.9
Potassium chloride (g)	1.5	1.5
Glucose (g)	—	20.0
Rice powder (g)	50	—
Water (ml)	1100*	1000
Osmolality (mOsm/kg)	288	331

*100 ml extra water to meet evaporative loss during boiling of rice ORS.

Table 2 General characteristics of the patients at admission

	Rice ORT (n=27)	Glucose ORS (n=25)
No (%) in each age group		
≤2 Months	10 (37)	5 (20)
3-4 Months	11 (41)	12 (48)
5-6 Months	6 (22)	8 (32)
Mean (SD) weight on admission (kg)	5.06 (1.1)	5.1 (1.3)
Mean (SD) nutritional status Z score*	1.1 (0.8)	1.4 (0.8)
Mean (SD) duration of diarrhoea before admission (days)	3.2 (2.1)	3.2 (1.7)
No (%) with vomiting	21 (78)	17 (68)
Dehydration status (No (%))		
Mild	20 (74)	17 (68)
Moderate	7 (26)	8 (32)
Feeding history (No (%))		
Exclusively or predominantly breast fed	21 (78)	17 (68)
Exclusively or predominantly formula or animal milk fed	6 (22)	8 (32)
No with pathogens isolated		
Enteropathogenic <i>E coli</i>	7	7
<i>Vibrio cholerae</i>	1	6
Rotavirus	1	6

No statistically significant differences exist between the groups (χ^2 for proportion and t test for mean).

*Z score for weight for age using National Center for Health Statistics standard.

the time of admission for the 52 infants. The two groups were comparable with respect to age, weight, nutritional status, duration of diarrhoea before admission, history of vomiting, degree of dehydration, and feeding practices. Thirty eight infants (73%) were less than or equal to 4 months old: 21/27 (78%) in group A (rice based ORT) and 17/25 (68%) in group B (glucose ORS).

Table 3 compares the major outcome variables. Because of the skewed distribution of stool volumes recorded, median and log transformation methods were used to evaluate the data. There was significantly less stool volume at 24 and 48 hours in group A infants, but no significant difference was found during the rehydration period or for the total stool output during the study.

Group A infants required significantly less oral rehydration fluid than those in group B at 24 and 48 hours. There was no difference between the groups with respect to intake of water, breast milk, or formula milk. The percentage of children who vomited during treatment was similar in the two groups (52% in group A *v* 68% in group B; $p<0.36$). The mean (SD) duration of diarrhoea in the children successfully treated was 3.2 (2.0) days in group A compared with 3.6 (1.4) days in group B ($p<0.5$).

The laboratory evaluations of the two

Table 3 Comparison of outcome variables in the rice ORT and glucose ORS groups. Results are mean (SD) values

Period (hours)	Rice ORT (n=27)	Glucose ORS (n=25)	p Value
Cumulative stool weight (g/kg body weight)			
0-6	32.3 (20.3)	39.0 (23.0)	0.20
0-24	101.0 (60.5)*	137.1 (14.6)	0.04
0-48	179.4 (106.4)*	226.3 (172.6)	0.04
Total output	451.2 (399.7)	642.2 (608.2)	0.20
ORT (ml/kg)			
0-6	82.5 (29.0)	101.1 (36.2)	0.05
0-24	164.5 (77.4)	217.9 (86.1)	0.02
0-48	249.7 (117.2)	355.8 (177.5)	0.01
Total intake	519.1 (370.0)	698.2 (487.2)	0.14
Breastmilk intake (g/kg)			
0-24	35.5 (27.2)	40.6 (48.3)	0.64
0-48	86.5 (79.9)	83.9 (85.1)	0.90
Formula milk intake (g/kg)			
0-24	37.7 (50.9)	59.9 (55.9)	0.14
0-48	91.9 (98.8)	144.1 (126.0)	0.10

*Significant differences were found between the groups at 24 hours and 48 hours after log transformation.

groups were also similar. There was no difference in the admission haemoglobin or the initial and follow up electrolyte values. Stool microscopy showed no parasitic or protozoal infections. No patients were noted to have blood in the stool. Enteric pathogens were found in 10 (37%) group A and 18 (72%) group B patients. The most commonly found pathogen was enteropathogenic *E coli* (seven children in each group). *Vibrio cholerae* was found in seven patients (one in group A and six in group B) and rotavirus was found in seven patients (one in group A and six in group B).

Treatment was unsuccessful in eight (30%) of the 27 infants in group A and seven (28%) of the 25 infants in group B (table 4). Of these 15 children, eight (53%) required intravenous treatment (five in group A and three in group B), six were removed from the study by their parents with continuing diarrhoea of >30 g/kg/day (three in each group) after at least 72 hours of treatment, and one developed sepsis and died. The mean (SD) duration of treatment before intravenous fluids were started was 55.4 (53.6) hours.

There was no difference in stool output during the rehydration period in children in whom treatment was successful or unsuccessful; however, the children in whom treatment failed had more vomiting than the children who were treated successfully (14/15 *v* 18/37; $p<0.01$). The presence of enteric pathogens was not increased in the children in whom treatment failed compared with the children in whom treatment was successful.

The tolerance of rice based ORT was assessed by stool pH and reducing substances after 24 and 48 hours of treatment with ORS (table 5). The percentage of infants with more than 0.5% reducing substances and stool pH less than 5 were similar in the two groups. In addition, the presence of reducing sugars in stools and acid stool pH did not correlate with the purging rate of infants receiving rice ORT or glucose ORS.

Discussion

The results of this controlled clinical trial support our hypothesis that rice ORT can be safely and effectively used in the management of acute diarrhoea of infants younger than 6 months. Our study shows that the use of rice based ORT can result in significantly lower stool output and a smaller volume of ORT intake than glucose ORS during the first 48 hours of treatment. These findings are consistent with those of previous studies in older children and adults.⁴⁻⁸ In addition, the rice based ORT appears to be well tolerated, as measured by similar low levels of reducing substances in stools and stool pH in the two groups.

The ability of young infants to digest and absorb rice based oral rehydration solutions is not surprising, as earlier studies have clearly shown that infants can tolerate substantial amounts of rice.^{11 12 17} There are several explanations for the ability of infants to digest and absorb the glucose polymers of starch

Table 4 Evaluations of outcome variables in the children in whom treatment was unsuccessful. Results are mean (SD) values

	Rice ORT (n=8)	Glucose ORS (n=7)
Age in months	3.4 (1.7)	3.4 (1.6)
Weight on admission (kg)*	5.2 (0.9)	4.7 (1.2)
% With emesis during rehydration	37	57
Cumulative stool weight (g/kg)		
Periods (hours)		
0-6	38.5 (16.8)	44.1 (18.2)
0-24	143.2 (65.1)	205.8 (71.7)
0-48	251.3 (114.6)	430.5 (174.4)*
Total output	863.7 (463.4)	1215.9 (808.0)

*p<0.05 (Student's *t* test).

despite the relative absence of pancreatic amylase. Brush border disaccharidases, including glycoamylase, are plentiful at birth, as is salivary amylase.¹³⁻¹⁸ In addition, glycoamylase is well preserved compared with the other disaccharidases during intestinal inflammation.¹⁰ Breast fed infants also receive breast milk amylase, which may be the most important form of amylase in infants.¹⁹ Bacterial fermentation in the colon may also play an important part in carbohydrate digestion and absorption by converting malabsorbed sugars to hydrogen gas and short chain fatty acids.²⁰ This mechanism of colonic salvage is present in normal premature and young infants.²¹

The reduction of stool volume with rice based ORT is probably due to several factors. The use of starch instead of glucose decreases the intraluminal concentration of solute, reducing the chance for the net flow of fluid and electrolytes from the intestinal mucosa.² Starch can also provide more glucose molecules at the brush border membrane, facilitating greater coupled transport with sodium.² This increased effectiveness of starch has been shown during in vivo perfusion studies in rats where a short chain glucose polymer of rice was more effective than D glucose in correcting abnormal water and ion secretion induced by dibutyl cyclic AMP.²²

As feeding was restarted at the end of rehydration, the impact of treatment on stool volume at 24 and 48 hours was influenced by diet as well as ORT. This is especially important in this study as the mean stool volume during the rehydration period was similar in those in whom treatment was successful and unsuccessful. The data do not

Table 5 Comparison of digestibility of rice ORT with glucose ORS. Values are number (%)

	Rice ORT (n=27)	Glucose ORS (n=25)
Stool reducing substance positive (>0.5 g %)		
Admission	9 (33)	7 (28)
24 Hours	2 (7)	6 (24)
48 Hours	0	7 (28)
Stool pH <5.0		
Admission	0	1 (4)
24 Hours	1 (4)	2 (8)
48 Hours	1 (4)	4 (16)

No significant difference between groups.

provide an obvious link between feeding and treatment failure, however. The number of children exclusively or predominantly breast and formula fed was similar in the two groups. Also, ORT comprised the majority of the intake during the first two days; breast milk and formula intake averaged less than 8-10 oz (226-283 g) per child each day.

These findings indicate that when ORT comprises the majority of intake, especially early in the treatment process, the use of cereal based solutions can be of particular advantage. Recent evidence has shown, however, that when substantial early feeding of a cereal based diet occurs, glucose ORS can be even more effective than cereal based ORT.²³

The overall rate of successful treatment was comparable (70% v 72%) in the two treatment groups but was lower than the rates reported in similar previous studies.^{7-9, 24-25} Several factors may explain the differences. The mean age of the patients in earlier studies of cereal based ORT were all at least twice that of the patients in this study.^{7-9, 24-25} In the study with the youngest patients (mean age 7 months), El Mougi *et al* reported a success rate of 83%,⁹ which more closely approximates the rate in our study. These workers also found a close association with treatment failure and vomiting after admission. In addition, our conservative estimate of stool volume to define diarrhoea at discharge from the study (>30 g/kg/day) is lower than that used in other studies.²⁴⁻²⁵

One limitation of our study was the unequal distribution of patients with enteric pathogens. This occurred despite randomisation, which resulted in a comparable distribution of patients by age, weight, Z score, duration of diarrhoea, dehydration status, and feeding. The impact of this unequal distribution is likely to be small as ORT has been proved to be effective in diarrhoea caused by the wide range of enteric pathogens found in this study.²⁶ In addition, there was no increased risk of treatment failure in those infants in whom cholera or rotavirus was isolated. As the children presented after a mean of about three days of illness, the pattern of clinical severity was likely to have been established by the time of admission in most patients.

In conclusion, our results indicate that rice based ORT can be effective and well tolerated in young infants with acute diarrhoea and mild to moderate dehydration. These findings suggest that the use of these solutions can expand the effective armamentarium for treating acute diarrhoea at home. Our results also provide a reminder that young infants must be monitored closely during treatment for diarrhoea because treatment can be unsuccessful regardless of the type of ORT used.

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