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Rice-based oral rehydration solution for treating diarrhoea

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ABSTRACT

Background

Oral rehydration therapy is used to treat dehydration caused by diarrhoea. However the rehydration solution does not reduce stool loss or length of illness. A solution able to do this may lessen the use of ineffective diarrhoea treatments as well as improve morbidity and mortality related to diarrhoea.

Objectives

The objective of this review was to assess the effects of rice-based oral rehydration salts solution compared with glucose-based oral rehydration salts solution on reduction of stool output and duration of diarrhoea in patients with acute watery diarrhoea.

Search methods

We searched the Cochrane Infectious Diseases Group trials register, the Cochrane Controlled Trials Register, Medline, Embase, Lilacs and the reference lists of relevant articles. We also contacted researchers in the field.

Selection criteria

Randomized trials comparing standard World Health Organization oral rehydration solution with an experimental oral rehydration salts solution in which glucose (20 grams per litre) was replaced by 50-80 grams per litre of rice powder, with the electrolytes remaining unchanged.

Data collection and analysis

Data were extracted independently by a statistician and a clinician.

Main results

Twenty-two trials were included. Concealment of allocation was adequate in 15 of these trials. Irrespective of age, people with cholera who were given rice oral rehydration salts solution had substantially lower rates of stool loss than those given oral rehydration salts solution in the first 24 hours. Mean stool outputs in the first 24 hours were lower by 67 millilitres/kg of body weight (weighted mean difference -67.40, 95% confidence interval -94.26 to -41.53) in children, and by 51 millilitres/kg of body weight (weighted mean difference -51.07, 95% confidence interval -65.87 to -36.27) in adults. The rate of stool loss in infants and children with acute non-cholera diarrhoea was reduced by only four millilitres/kg of body weight (weighted mean difference -4.29, 95% confidence interval -9.36 to 0.78).

Authors' conclusions

Rice-based oral rehydration appears to be effective in reducing stool output in people with cholera. This effect was not apparent in infants and children with non-cholera diarrhoea.

PLAIN LANGUAGE SUMMARY

Rice-based oral rehydration solution for treating diarrhoea

Plain language summary pending.

BACKGROUND

Oral rehydration therapy with glucose and electrolyte solution recommended by the World Health Organization and Unicef is used to treat children with dehydration caused by diarrhoea, provided they are able to drink and do not have signs of shock (1). Although the solution is both safe and effective (D. Mahalanabis, unpublished document), it has important limitations: it neither reduces the rate of stool loss nor shortens the duration of illness (2-5). Mothers often do not understand the relation between diarrhoea and dehydration, and their primary concern, shared by many health workers, is to see the diarrhoea stop. This probably accounts for the continuing widespread use of ineffective "anti-diarrhoeal" drugs and antibiotics to treat diarrhoea instead of, or in addition to, oral rehydration salts solution (WHO diarrhoeal diseases control programme, seventh programme report, 1988-89, 1990).

If a packaged oral rehydration salts formulation could be developed that not only had the positive features of WHO formulation, including low cost and safety and stability during prolonged storage, but also substantially reduced the duration of diarrhoea or the rate of stool loss, it would have considerable advantages. In particular, it could be promoted as having real antidiarrhoeal effect. This should improve its acceptance and use by both health workers and mothers, especially if its benefits were sufficiently great to be evident to them. It might also result in less use of ineffective drugs and antibiotics. Such changes would represent a major advance in efforts to control morbidity and mortality associated with diarrhoea through effective case management.

Several clinical trials have shown that an oral rehydration salts solution containing cooked rice powder (50-80g/l) in place of the usual glucose (20g/l) substantially reduces the rate of stool loss due to acute diarrhoea (6-10). Other studies, however, have reported no significant benefit (11-14). The patients in these studies varied considerably and included infants, children, and adults both with

diarrhoea associated with cholera and with acute diarrhoea not associated with cholera. Moreover, in some studies the number of patients evaluated was probably insufficient to support firm conclusions. To define more precisely the true benefit of rice oral rehydration salts solution in relation to the WHO oral rehydration salts solution and to determine whether this benefit is related to the patient's age or the aetiology of diarrhoea we performed a systematic review using data from all available randomized clinical trials that compared these two formulations.

OBJECTIVES

To compare rice oral rehydration salts solution (containing 50-80 g/l of rice powder) with glucose oral rehydration salts solution (WHO standard).

Explore the hypotheses:

Benefit is related to the patient's age

Benefit is related to whether or not the diarrhoea is caused by cholera

METHODS

Criteria for considering studies for this review

Types of studies

Randomized trials. Trials with alternate allocation were excluded.

Types of participants

Children or adults with signs of dehydration due to acute diarrhoea.

Types of interventions

Control: standard WHO oral rehydration salts solution

Experimental: oral rehydration salts solution in which glucose (20g/l) was replaced by 50-80g/l of rice powder, the electrolyte concentrations remaining unchanged.

Types of outcome measures

Stool output during the first 24 hours;
total stool output from admission to cessation of diarrhoea;
duration of diarrhoea from admission in the study until cessation of diarrhoea;
weighted estimates of the difference in mean stool output and mean duration between treatment.

Search methods for identification of studies

The Cochrane Infectious Diseases Group (CIDG) Specialized Register was searched for any trial or reference to a relevant trial (published, in-press or in progress). The topic search terms used were: cholera, dehydration, diarrhea (diarrhoea/diarrhea/diarhea), fluid therapy, oral rehydration therapy, oral rehydration solution, rehydration solutions, rice. Full details of the CIDG methods and the journals searched are published in The Cochrane Library in the section on Collaborative Review Groups.

The reviewer searched The Cochrane Central Register of Controlled Trials (CENTRAL), published in *The Cochrane Library*. This is a compilation of published trials identified by hand-searching by various individuals within The Cochrane Collaboration. Full details of the sources and methods used are published in The Cochrane Library.

The following databases were also searched: MEDLINE ; EMBASE; and LILACS, using the search strategy defined by the Cochrane Collaboration, and detailed in appendix 5c of The Cochrane Handbook. The specific topic search terms used were: cholera, dehydration, diarrhea (diarrhoea/diarrhea/diarhea), fluid therapy, oral rehydration therapy, oral rehydration solution, rehydration solutions, rice.

Dates of searches:

Cochrane Infectious Diseases Group Specialized Register (March 2004)

CENTRAL, *The Cochrane Library* (Issue 1, 2004)

MEDLINE (1966 to March 2004)

EMBASE (1988 to March 2004)

LILACS (March 2004).

Organisations and individual researchers working in the field were contacted for unpublished data, confidential reports and raw data of published trials.

The reviewers also checked the citations of existing reviews and of all trials identified by the above methods.

The external referees were asked to check the completeness of the search strategy and the efforts made to identify unpublished, ongoing and planned trials.

Data collection and analysis

Each trial report was reviewed independently by a statistician and a clinician to determine patient eligibility according to stated selection criteria for age and dehydration status; the number of patients who were randomized and the number of these subsequently excluded from analysis; details of the randomization procedure; and the precise timing of the outcome measurements, such as stool output and intake of oral rehydration salts solution.

In studies where outcomes were presented in two subgroups (patients with *Vibrio cholerae* isolated from the stool, and those where it was not), mean values were combined as a weighted average, to make them comparable with other studies. The highest standard deviation of the two subgroups was taken.

For studies in children, data from girls were excluded because of the difficulty in measuring precisely stool volumes in female children.

RESULTS

Description of studies

Twenty two studies met the inclusion criteria. All were hospital-based clinical trials.

Studies in patients with cholera were conducted in three countries, Bangladesh (3 studies in children with cholera and 2 studies in adults), Indonesia (1 study in children with cholera and 2 studies in adults), and India (1 study in children with cholera). All studies in patients with cholera only included patients with severe dehydration.

A total of 7 clinical trials were conducted in Bangladesh, of which 5 were either directed conducted or supervised by Dr AM Molla. Studies in children with non-cholera diarrhoea were conducted in Asia (Bangladesh, India and Pakistan), Mexico, South America (Chile and Peru), and Africa (Egypt). All studies except two (Mexico and Pakistan) only included children above 4-6 months of age. The studies conducted in Mexico and Pakistan only included patients below 6 month of age to assess the digestibility of rice ORS in this age group.

Eight studies were developed during various proposal development workshops organised by the WHO, and therefore used a

standardized design and similar data collection forms: Bhan 1987, Chea-Woo 1994, El Mougi 1988, Fayad 1993, Guiraldes 1995(a), Maulen 1994, Mochtar 1989, Razafindrakoto 1993.

Risk of bias in included studies

Of the 22 studies, concealment of allocation was adequate in 15. The rest were described as randomized, but details of the method and of any concealment were not given.

Patients should have been randomized immediately before treatment with oral rehydration salts solution was started, and after completion of any intravenous treatment for severe dehydration. However, no trial reported when patients with severe dehydration were randomized and outcome measurement initiated - that is, before or after initial intravenous therapy. Thus it was unclear whether the first 24 hour measurement of stool output began when intravenous rehydration was started or when oral rehydration salts solution was first given, as should have been the case.

In one study patients were randomized irrespective of age, but were stratified into arbitrary age groups during analysis (Molla 1985). Ideally, such stratification should have been part of the randomization plan. Stratification during analysis was also done in two other studies (Mochtar 1989, Alam 1987), but this was based on aetiology and so was unavoidable.

Pragmatic analysis according to intention to treat requires that all randomized patients continue to be monitored and that their data be included in the analysis. Nevertheless, in six trials (Guiraldes 1985 (a), Patra 1982, Molla 1985, Alam 1987, Mohan 1988, El Mougi 1988) 1-15% of randomized patients were excluded from the analysis, either because they were considered "treatment failures" (usually because additional intravenous treatment was required) or because they had been randomized in error. In two trials that used permuted blocks (Molla 1989) or factorial design (Alam 1992) it seems that some patients were randomized but not reported on, as the numbers specified in the different groups differed appreciably. The reasons for these differences were not stated.

Effects of interventions

All studies reported stool output and oral rehydration salts solution intake during the first 24 hours. Only a few reported total stool output until diarrhoea stopped, and only a few reported the duration of diarrhoea. Our analysis therefore focused largely on stool output during the first 24 hours.

Whether the data were for adults with cholera or with cholera-like diarrhoea, children with cholera or cholera-like diarrhoea, or children with non-cholera diarrhoea, the ratios of mean to standard deviation for stool output were roughly constant, averaging 1.6 and ranging from 1.2 to 2.5. This regularity indicates the need for logarithmic transformation; however, only some of the most

recently completed studies reported calculations on that scale. This finding provides a criterion for judging the internal consistency of key outcome data.

In children and in adults with cholera or cholera-like diarrhoea, the mean 24 hour stool output was significantly reduced in those treated with rice ORS compared to those treated with standard WHO ORS.

However, in children with non-cholera diarrhoea the analysis shows that rice ORS caused only a small, statistically non significant, reduction in mean 24 hour stool output.

DISCUSSION

Irrespective of age, patients with cholera who were given rice oral rehydration salts solution had substantially lower rates of stool loss than those who were given WHO oral rehydration salts solution in the first 24 hours.

One biological explanation for this is that a greater amount of glucose (and amino acids) is released when rice powder is fully digested than is present in the WHO solution. Assuming that glucose-facilitated absorption of sodium proceeds on an equimolecular basis, 50-80g/l of rice powder would release sufficient glucose and amino acids to promote the absorption of all the sodium (and water) in the rehydration solution and, in addition, reabsorption of at least part of the sodium (and water) secreted into the bowel as part of the diarrhoeal process, thus diminishing stool output. In contrast, the WHO solution contains only enough glucose (20g/l) to promote the absorption of the sodium and water in the solution, thus leaving the rate of stool loss essentially unaffected. The lower osmolarity of the rice solution (about 200 mmol/l vs 310 mmol/l) would also enhance the intestinal absorption of water, but not of sodium.

To take this explanation further, the lack of effect of rice ORS in children with non-cholera diarrhoea when compared to standard WHO ORS could reflect the benefit of feeding immediately after rehydration, providing large amounts of carbohydrates and amino acids, and thus hiding any benefit the additional carbohydrates (and amino acids) contained in the rice ORS might have had.

AUTHORS' CONCLUSIONS

Implications for practice

Rice oral rehydration salts solution may be more clinically effective for patients with cholera than of WHO standard ORS. This conclusion is based on stool outputs within the first 24 hours.

Rice oral rehydration salts have no advantage over standard ORS in children with non-cholera diarrhoea. At least 95% of all cases

of diarrhoea in children fall into this category in developing countries. Thus rice oral rehydration salts solution, which is more expensive, is not justified in these groups. Food given immediately after rehydration is generally recommended in these groups.

Implications for research

The results from this systematic review contrast with reports of more promising effects of reduced osmolarity glucose-based ORS, where reduced requirements for supplemental infusion and decreased stool output have been reported. It may be more appropriate to pursue this evidence in reduced osmolarity glucose-based ORS as this appears to be more promising than rice-based ORS. A systematic review of reduced osmolarity ORS against standard ORS is required.

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* Indicates the major publication for the study

CHARACTERISTICS OF STUDIES

Characteristics of included studies [ordered by study ID]

Alam 1987

Methods	randomized unblinded clinical trial; permuted blocks	
Participants	39 children aged 1 to 8 years, both male and female, with a history of diarrhoea of less than 72 hours, with moderate to severe dehydration, and V. cholerae isolated from their stools.	
Interventions	rice-based ORS vs standard WHO ORS	
Outcomes	24 hour stool output duration of diarrhoea	
Notes	Bangladesh, conducted in 1984 Cholera endemic area Three cell study	
<i>Risk of bias</i>		
Bias	Authors' judgement	Support for judgement
Allocation concealment?	Low risk	A - Adequate

Alam 1992

Methods	"randomized" unblinded clinical trial "according to random numbers". No details given
Participants	patients aged 15 to 60 years old, with diarrhoea for 24 hours or less, with moderate to severe dehydration, V.cholerae in fresh stool specimen, and no history of antidiarrhoeal or antimicrobial drug consumption prior admission
Interventions	rice-based ORS vs standard WHO ORS
Outcomes	24 hour stool output total stool output duration of diarrhoea
Notes	Bangladesh, conducted in 1988 This was a four cell study using a factorial design.
<i>Risk of bias</i>	

Alam 1992 (Continued)

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Unclear risk	B - Unclear

Bhan 1987

Methods	randomized unblinded clinical trial
Participants	male children aged 3 months to 5 years, with diarrhoea for less than 5 days, with more than 4 loose stools in previous 24 hours, and with signs of dehydration.
Interventions	pop rice-based ORS vs standard WHO ORS
Outcomes	24 hour stool output total stool output duration of diarrhoea
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Low risk	A - Adequate

Chea-Woo 1994

Methods	randomized unblinded clinical trial
Participants	male children aged 3 to 24 months, with acute watery diarrhoea for less than 5 day duration, with mild to moderate dehydration.
Interventions	pre-cooked rice-based ORS vs standard WHO ORS.
Outcomes	24 hour stool output total stool output duration of diarrhoea
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
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Chea-Woo 1994 (Continued)

Allocation concealment?	Low risk	A - Adequate
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Dutta 1988

Methods	randomized unblinded clinical trial
Participants	male children aged 4 months to 4 years, with acute diarrhoea, and signs of dehydration.
Interventions	pop rice-based ORS vs standard WHO ORS
Outcomes	24 hour stool output total stool output duration of diarrhoea
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Unclear risk	B - Unclear

El Mougi 1988

Methods	randomized unblinded clinical trial
Participants	male children 4 to 18 months old, with acute diarrhoea for less than 5 day duration, with signs of moderate dehydration.
Interventions	rice-based ORS vs standard WHO ORS
Outcomes	24 hour stool output duration of diarrhoea
Notes	In this article, the reported SD are most probably SE: This was corrected in the meta-analysis

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Low risk	A - Adequate

El Mougi 1991

Methods	multicentre randomized unblinded clinical trial	
Participants	male children 4 to 18 months old, with acute diarrhoea for less than 5 day duration, with signs of moderate dehydration.	
Interventions	rice-based ORS vs standard WHO ORS	
Outcomes	24 hour stool output duration of diarrhoea	
Notes		
<i>Risk of bias</i>		
Bias	Authors' judgement	Support for judgement
Allocation concealment?	Unclear risk	B - Unclear

Faruque 1994a

Methods	randomized unblinded clinical trial	
Participants	children of either sex aged 3-35 months, with a history of acute watery diarrhoea for 72 hours or less, with signs of mild to moderate dehydration.	
Interventions	pre-cooked rice-based ORS vs standard WHO ORS	
Outcomes	24 hour stool output	
Notes		
<i>Risk of bias</i>		
Bias	Authors' judgement	Support for judgement
Allocation concealment?	Low risk	A - Adequate

Faruque 1994b

Methods	randomized unblinded clinical trial	
Participants	children of either sex aged 3-35 months, with a history of acute watery diarrhoea for 72 hours or less, with signs of mild to moderate dehydration.	
Interventions	pre-cooked rice-based ORS vs standard WHO ORS	

Faruque 1994b (Continued)

Outcomes	24 hour stool output	
Notes		
<i>Risk of bias</i>		
Bias	Authors' judgement	Support for judgement
Allocation concealment?	Low risk	A - Adequate

Fayad 1993

Methods	randomized unblinded clinical trial	
Participants	male children aged 3-18 months, with acute diarrhoea for less than 72 hours, with five or more watery stools in last 24 hours, and with signs of dehydration.	
Interventions	pre-cooked rice-based ORS vs standard WHO ORS	
Outcomes	24 hour stool output total stool output duration of diarrhoea	
Notes		
<i>Risk of bias</i>		
Bias	Authors' judgement	Support for judgement
Allocation concealment?	Low risk	A - Adequate

Guiraldes 1995a

Methods	randomized unblinded clinical trial	
Participants	male children aged 3 to 18 months, with watery diarrhoea of less than 4 days duration, with moderate dehydration	
Interventions	pre-cooked rice-based ORS vs standard WHO ORS	
Outcomes	24 hour stool output total stool output duration of diarrhoea	

Guiraldes 1995a (Continued)

Notes		
<i>Risk of bias</i>		
Bias	Authors' judgement	Support for judgement
Allocation concealment?	Low risk	A - Adequate

Guiraldes 1995b

Methods	randomized unblinded clinical trial	
Participants	children of both genders aged 3-24 months, with a history of less than 4 day of watery diarrhoea, and with moderate dehydration.	
Interventions	pre-cooked rice-based ORS vs standard WHO ORS	
Outcomes	24 hour stool output total stool output duration of diarrhoea	
Notes		
<i>Risk of bias</i>		
Bias	Authors' judgement	Support for judgement
Allocation concealment?	Low risk	A - Adequate

Islam 1994

Methods	randomized unblinded clinical trial
Participants	male infants less than 6 months old, with more than 4 loose stools in previous 24 hours, with diarrhoea for less than 4 day duration, and signs of mild to moderate dehydration.
Interventions	rice based ORS vs standard WHO ORS
Outcomes	24 hour stool output total stool output
Notes	
<i>Risk of bias</i>	

Islam 1994 (Continued)

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Low risk	A - Adequate

Maulen 1994

Methods	randomized unblinded clinical trial	
Participants	male infants aged 1 to 6 months, with acute diarrhoea defined as three or more watery stools in previous 24 hours, and with signs of mild to dehydration.	
Interventions	pre-cooked rice-based ORS vs standard WHO ORS	
Outcomes	24 hour stool output total stool output duration of diarrhoea	
Notes		
<i>Risk of bias</i>		
Bias	Authors' judgement	Support for judgement
Allocation concealment?	Low risk	A - Adequate

Mochtar 1989

Indonesia 1988-9		
Methods	Randomized unblinded clinical trial, using block randomization (6-12) with sealed envelopes	
Participants	patients 12 or more years old, with at least 3 watery stools inthe last 12 hours, diarrhoea for no more than 24 hours, and severe dehydration.	
Interventions	pre-cooked rice-based ORS vs standard WHO ORS	
Outcomes	24 hour stool output total stool output duration of diarrhoea	
Notes	Indonesia 1988-9 Cholera endemic	
<i>Risk of bias</i>		
Bias	Authors' judgement	Support for judgement

Mochtar 1989 (Continued)

Allocation concealment?	Low risk	A - Adequate
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Mohan 1988

Methods	randomized unblinded clinical trial	
Participants	male children aged 3 months to 3 years, with acute diarrhoea of less than 5 days duration, and with signs of dehydration.	
Interventions	rice-based ORS vs standard WHO ORS	
Outcomes	24 hour stool output 48 hour stool output	
Notes		
<i>Risk of bias</i>		
Bias	Authors' judgement	Support for judgement
Allocation concealment?	Unclear risk	B - Unclear

Molla 1983

Methods	hospital-based unblinded randomized trial; ”random numbers“-no other details given	
Participants	children aged 2 to 5 years (gender mix not clear), with diarrhoea for less than 24 hours prior to admission, due to cholera, no sign of systemic illness, and moderate to severe degree of dehydration	
Interventions	rice-based ORS vs standard WHO-ORS	
Outcomes	24 hour stool output 48 hour stool output	
Notes	Bangladesh 1981 Cholera endemic area 80% participants Vibrio cholera positive	
<i>Risk of bias</i>		
Bias	Authors’ judgement	Support for judgement
Allocation concealment?	Unclear risk	B - Unclear

Molla 1985

Methods	hospital-based unblinded randomized clinical trial	
Participants	children (males and girls) under 10 years of age, adults, with diarrhoea for less than 24 hours (most probably due to cholera), and signs of moderate to severe dehydration.	
Interventions	rice-based ORS vs standard WHO-ORS	
Outcomes	24 hour stool output 48 hour stool output	
Notes	This trial included in fact two separate studies: one in adults and one in children. The results from these two groups of patients were analysed separately	
<i>Risk of bias</i>		
Bias	Authors' judgement	Support for judgement
Allocation concealment?	Unclear risk	B - Unclear

Molla 1994

Methods	randomized unblinded clinical trial	
Participants	male children aged 3-18 months, with acute diarrhoea for less than 72 hours, with five or more watery stools in last 24 hours, and with signs of dehydration.	
Interventions	pre-cooked rice-based ORS vs standard WHO ORS	
Outcomes	24 hour stool output total stool output duration of diarrhoea	
Notes		
<i>Risk of bias</i>		
Bias	Authors' judgement	Support for judgement
Allocation concealment?	Low risk	A - Adequate

Northrup 1992

Methods	randomized unblinded clinical trial	
Participants	adults (>12 years of age) and children (males and girls, 24 months to 59 months), with duration of diarrhoea no longer than 3 days, with a history of diarrhoea more than 3 times in the last 12 hours	
Interventions	pre-cooked rice-based ORS vs standard WHO ORS	
Outcomes	24 hour stool output total stool output duration of diarrhoea	
Notes	Children and adults were analyzed separately.	
<i>Risk of bias</i>		
Bias	Authors' judgement	Support for judgement
Allocation concealment?	Unclear risk	B - Unclear

Patra 1982

Methods	Hospital based randomized clinical trial; sealed envelopes	
Participants	Children 3 months to 5 years old (gender mix not mentioned); with diarrhoea (length prior to admission not clear), and signs of moderate to severe dehydration	
Interventions	pop rice-based ORS vs standard WHO-ORS	
Outcomes	24 hour stool output total stool output duration of diarrhoea	
Notes	India 1981 Cholera endemic area 50% positive for Vibrio cholera	
<i>Risk of bias</i>		
Bias	Authors' judgement	Support for judgement
Allocation concealment?	Low risk	A - Adequate

Razafindrakoto 1993

Methods	randomized unblinded clinical trial	
Participants	male and girls aged 6 months to 3 years, severely malnourished (W-f-H <70% NCHS), with acute diarrhoea for less than 5 day duration, and with more than 3 watery stools in the last 24 hours.	
Interventions	rice based ORS vs standard WHO ORS	
Outcomes	24 hour stool output total stool output duration of diarrhoea	
Notes		
<i>Risk of bias</i>		
Bias	Authors' judgement	Support for judgement
Allocation concealment?	Low risk	A - Adequate

Characteristics of excluded studies [ordered by study ID]

Study	Reason for exclusion
Bhattacharya 1995	No 24 hour output; total stool output not compatible with hospitalised cholera patients
Cohen 1995	This study is not using rice ORS. The experimental solution tested in this study does not contain rice but some type of carbohydrates obtained by the hydrolysis of rice usually called "glucose syrup solids". However, in this study the authors called it "rice syrup solids"
Haider 1994	The population evaluated (diabetic patients) is quite different from the population of interest (childhood diarrhoea or cholera) in this review. It was felt that the two types of diarrhoea had little in common
Jirapinyo 1996	This study is not using rice ORS. The experimental solution tested in this study does not contain rice but some type of carbohydrates obtained by the hydrolysis of rice usually called "glucose syrup solids". However, in this study the authors called it "rice syrup solids"
Kenya 1989	The ratio mean/sd is totally out of range when compared with other studies. The problem here is similar to that of the Mustafa 1995 study
Khin Maung U 1986	In this study the authors compared standard WHO ORS solution with standard WHO ORS plus "boiled rice feeding". No group was given rice based ORS solution
Lebenthal 1995	This study is testing a chemical (amylite) that hydrolyses large quantities of rice into glucose or short chain carbohydrates. The final ORS obtained by this procedure contains essentially glucose

(Continued)

Mehta 1986	This is not a randomized study. In addition, the three outcome variables measured in the study (stool frequency, volume of stool expressed as large, moderate and small, duration of stay) cannot be compared with the outcome variables from the other studies
Molina 1995	The rice ORS evaluated in this study only contains 37 g/l of rice
Molla 1989a	Ratio of mean stool output per standard deviation was very high, incompatible with normal biological variation
Molla 1989b	No treatment group received rice based ORS.
Mota-Hernandez 1991	The authors just gave rice water, without any salts, to patients who were significantly dehydrated. So the solution is not rice ORS. In addition, this study raises a number of ethical issues, because the patients admitted to this study received less than adequate treatment
Murtaza 1987	The rice based ORS solution evaluated in this study contained only 30g/l of rice. In addition, the study was not randomized and the ratio stool output/SD is much larger than those reported in other studies
Mustafa 1995	The ratio mean/sd for stool output is out of range with the other studies. Usually the ratio is very close to one. In this study the standard deviation is very small, much smaller than in any other such study. On the other hand, the ratio mean/sd for ORS intake is what is usually reported, suggesting that ORS intake was well measured, but that the authors had some difficulties in measuring stool output accurately
Pizarro 1991	No treatment group received rice based ORS.
Prasad 1993	The two outcome variables reported in this article are stool frequency and volume of ORS consumed
Santosham 1990	The complicated design of this study makes it impossible to clearly identify a control group and a study group
Wall 1997	The electrolyte content of the rice ORS as well as the control glucose ORS differs significantly from the electrolyte content of the standard WHO ORS solution

DATA AND ANALYSES

Comparison 1. Rice vs. glucose rehydration solution in cholera cases

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 24 hour stool output	7		Mean Difference (IV, Fixed, 95% CI)	Subtotals only
1.1 Children (<12 yrs)	4	337	Mean Difference (IV, Fixed, 95% CI)	-67.40 [-94.26, -40.53]
1.2 Adults	4	694	Mean Difference (IV, Fixed, 95% CI)	-51.07 [-65.87, -36.27]
2 Total stool output	1		Mean Difference (IV, Fixed, 95% CI)	Subtotals only
2.1 Children (<12 yrs)	1	48	Mean Difference (IV, Fixed, 95% CI)	-124.0 [-248.60, 0.60]
2.2 Adults	0	0	Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
3 Duration of diarrhoea	1		Mean Difference (IV, Fixed, 95% CI)	Subtotals only
3.1 Children (<12 yrs)	1	48	Mean Difference (IV, Fixed, 95% CI)	-13.0 [-24.90, -1.10]
3.2 Adults	0	0	Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]

Comparison 2. Rice vs. glucose rehydration solution in non-cholera diarrhoea in children < 5 years

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 24 hour stool output	15	2777	Mean Difference (IV, Fixed, 95% CI)	-4.29 [-9.36, 0.78]
2 Total stool output	9	1373	Mean Difference (IV, Fixed, 95% CI)	-28.16 [-52.38, -3.94]
3 Duration of diarrhoea	12	2854	Mean Difference (IV, Fixed, 95% CI)	-1.26 [-4.41, 1.89]

Analysis 1.1. Comparison 1 Rice vs. glucose rehydration solution in cholera cases, Outcome 1 24 hour stool output.

Review: Rice-based oral rehydration solution for treating diarrhoea

Comparison: 1 Rice vs. glucose rehydration solution in cholera cases

Outcome: 1 24 hour stool output

Analysis 1.2. Comparison 1 Rice vs. glucose rehydration solution in cholera cases, Outcome 2 Total stool output.

Review: Rice-based oral rehydration solution for treating diarrhoea

Comparison: 1 Rice vs. glucose rehydration solution in cholera cases

Outcome: 2 Total stool output

Analysis 1.3. Comparison 1 Rice vs. glucose rehydration solution in cholera cases, Outcome 3 Duration of diarrhoea.

Review: Rice-based oral rehydration solution for treating diarrhoea

Comparison: 1 Rice vs. glucose rehydration solution in cholera cases

Outcome: 3 Duration of diarrhoea

Analysis 2.1. Comparison 2 Rice vs. glucose rehydration solution in non-cholera diarrhoea in children < 5 years, Outcome 1 24 hour stool output.

Review: Rice-based oral rehydration solution for treating diarrhoea

Comparison: 2 Rice vs. glucose rehydration solution in non-cholera diarrhoea in children < 5 years

Outcome: 1 24 hour stool output

Analysis 2.2. Comparison 2 Rice vs. glucose rehydration solution in non-cholera diarrhoea in children < 5 years, Outcome 2 Total stool output.

Review: Rice-based oral rehydration solution for treating diarrhoea

Comparison: 2 Rice vs. glucose rehydration solution in non-cholera diarrhoea in children < 5 years

Outcome: 2 Total stool output

Analysis 2.3. Comparison 2 Rice vs. glucose rehydration solution in non-cholera diarrhoea in children < 5 years, Outcome 3 Duration of diarrhoea.

Review: Rice-based oral rehydration solution for treating diarrhoea

Comparison: 2 Rice vs. glucose rehydration solution in non-cholera diarrhoea in children < 5 years

Outcome: 3 Duration of diarrhoea

FEEDBACK

Survey of Cochrane Library 1998.4

Summary

Thank you for an informative review on an important topic. We have some minor suggestions to help make the review clearer in some sections.

BACKGROUND/TYPES OF OUTCOMES

The rate of stool loss is mentioned in the background but not >selected as an outcome. An explanation of why this is so would be helpful.

METHODS OF THE REVIEW

It would be helpful to have a description of how the data were

>synthesized and whether heterogeneity was tested.

RESULTS

Under Methodological quality of included studies, the reviewers

>state that intention to treat analysis was not preformed in some of the trials and that some dropouts were treatment failures. We would like to see a subgroup analysis including only trials which reported on all randomised participants, to see if the overall results were different.

CONCLUSIONS

We acknowledge the short follow up period of 24 hours reported in most trials, and suggest that the reviewers might recommend a longer follow up in the "implications for research" or explain why longer follow up is not clinically important.

We certify that we have no affiliations with or involvement in any organisation or entity with a direct financial interest in the subject matter of our criticisms.

Reply

BACKGROUND/TYPES OF OUTCOMES

The expression "rate of stool loss" should be deleted. The sentence in the background section will be modified in the next revision to read as follows: "It neither reduces stool loss nor shortens duration..."

METHODS OF THE REVIEW

The data were either from (i) published articles, or (ii) original data from individual studies available for meta-analysis

Heterogeneity was not tested.

RESULTS

In studies conducted on patients with cholera, removing the studies that did not perform "intention to treat analysis" would mean removing 3 out of 4 studies conducted in adults, and 1 out of 4 studies conducted in children. However, as all studies conducted in patients with cholera show a reduction in stool loss in patients treated with rice ORS, removing these 4 studies that did not perform "intention to treat analysis" would not change the overall direction of the conclusion but might change weight of evidence. For studies conducted in patients with acute non-cholera diarrhoea, 3 studies out of 15 did not perform an intention to treat analysis". These three studies represent a total weight of about 5%. In this case again, removing these studies does not change the overall conclusion of the meta-analysis (the reduction in stool loss in the first 24 hours in patients treated with rice ORS goes from 4.3g/kg to 3.1 g/kg).

CONCLUSIONS

Based on previous studies conducted on patients with acute diarrhoea, we can estimate that stool loss in the first 24 hours after admission represent 70% of total stool loss after admission. In the second 24 hours after admission, stool loss represent 20% of the total stool loss, and in the third 24 hour period after admission, the stool loss represent 10% of the total stool loss (Madkour AM et al. Journal of Pediatric Gastroenterology and Nutrition, 1993; 17:176-181). From this, it is clear that the most important period for an "improved ORS solution" to show a clinically significant impact on stool output is the first 24 hour period after admission in the study.

Contributors

The above comment was made as part of a collaborative effort coordinated by Ole Olsen at the Nordic Cochrane Centre. All new reviews on Cochrane Library 1998.4 were selected and critically read by a set of methodologists, comments were coordinated and finally fed back. The general results of the survey will be presented at the Cochrane Colloquium in Rome, October 1999.

We certify that we have no affiliations with or involvement in any organisation or entity with a direct financial interest in the subject matter of our criticisms.

Jeanette Ezzo and Jos Kleijnen

Nate Pierce study

Summary

Regarding the Nate Pierce study, while it is true that there are not clinically significant results with rice-based ORS except (to date) with cholera, it is also true that most rice-based ORS show at least 17% better hydration in non-cholera ORS and rice-ORS is better accepted, can be served warm as well as cold, and never increases fluid losses, as may be the case sometimes with glucose ORS.

Reply

Comment 1: “while it is true that there are not clinically significant results with rice-based ORS except (to date) with cholera, it is also true that most rice-based ORS show at least 17% better hydration in non-cholera ORS”

Reply: In none of the studies we reviewed was “hydration” mentioned as an outcome variable. We are not aware of a direct randomized comparison demonstrating that “most rice ORS show at least 17% better hydration in non-cholera ORS”. What is the definition of “better hydration” and how was it measured and in which studies?

Comment 2: “rice-ORS is better accepted, can be served warm as well as cold”

Reply: The review concentrates on clinically relevant endpoints (i.e., stool output and duration of diarrhoea) and did not include a systematic comparison of acceptance qualities mentioned in Ms Riikonen’s comments.

Comment 3: “[rice-ORS] never increases fluid losses, as may be the case sometimes with glucose ORS”

Reply: Fluid losses can be increased with the use of ORS containing glucose polymers as shown by Dr El-Mougi (El-Mougi M et al. Efficacy of standard glucose based and reduced osmolarity maltodextrin based oral rehydration solutions: effect of sugar malabsorption).

Contributors

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WHAT'S NEW

Date	Event	Description
9 November 2008	Amended	Converted to new review format.

HISTORY

Protocol first published: Issue 4, 1998

Review first published: Issue 4, 1998

Date	Event	Description
21 August 2007	Amended	Details of the protocol for the replacement review added to withdrawn note
21 August 2005	Amended	Review withdrawn as of Issue 4, 2005
29 March 2004	Amended	New studies found but not yet included/excluded
30 May 2000	Amended	Response to comment/criticism added
21 February 2000	Amended	Comment/criticism added
2 August 1998	New citation required and conclusions have changed	Substantive amendment

DECLARATIONS OF INTEREST

We certify that we have no affiliations with or involvement in any organisation or entity with a direct financial interest in the subject matter of the review (e.g. employment, consultancy, stock ownership, honoraria, expert testimony).

SOURCES OF SUPPORT

Internal sources

- World Health Organisation, Switzerland.

External sources

- Department for International Development, UK.
- European Commission (Directorate General XII), Belgium.

NOTES

The Editor withdrew this review as of Issue 4, 2005. This review has been replaced by:

Gregorio GV, Gonzales MLM, Dans LF, Martinez EG. Polymer-based oral rehydration solution for treating acute watery diarrhoea. *Cochrane Database of Systematic Reviews* 2009, Issue 2. Art. No.: CD006519. DOI: 10.1002/14651858.CD006519.pub2.

INDEX TERMS

Medical Subject Headings (MeSH)

*Fluid Therapy; *Phytotherapy; Diarrhea [*therapy]; Oryza; Rehydration Solutions [therapeutic use]

MeSH check words

Adult; Child; Humans