Acta Pædiatr 86: 1047–51. 1997

Oral rehydration with a plantain flour-based solution in children dehydrated by acute diarrhea: a clinical trial

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Arias MM, Alcaráz GM, Bernal C, González G. Oral rehydration with a plantain flour-based solution in children dehydrated by acute diarrhea: a clinical trial. Acta Pædiatr 1997; 86: 1047–51. Stockholm. ISSN 0803–5253

A clinical trial was conducted in order to prove the efficacy of a solution containing 50 g/l of plantain flour and 3.5 g/l of sodium chloride (NaCl) for the rehydration of children with acute diarrheal diseases. 121 children were given WHO–ORS (Group A) and 117 a plantain flour-based solution (Group B). Rehydration was successful in 85.9% in Group A and 88.0% in Group B ($p = 0.634$). Rehydration was completed in 5.28 h (SD 1.99) in Group A and in 4.88 h (SD 2.11) in Group B ($p = 0.132$). The average solution intake for rehydration was 24.56 ml/kg/h (SD 10.12) in Group A and 21.17 ml/kg/h (SD 9.35) in Group B ($p = 0.00782$). The mean stool output during rehydration was 8.45 g/kg/h (SD 9.72) in Group A and 4.69 g/kg/h (SD 4.98) in Group B ($p = 0.00053$). Decrease in blood levels of sodium and potassium occurred in some children in group B. The plantain flour-based solution proved effective for the treatment of dehydration due to acute diarrheal diseases and should be considered as an alternative when standard WHO–ORS is not available. □ *Dehydration, diarrhea, oral rehydration, plantain flour*

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Diarrheal diseases are among the major causes of morbidity and mortality in children of developing countries (1).

Despite success obtained by the World Health Organization (WHO) Program for the Control of Diarrheal Diseases (CDD) and the confirmation of ORS formula as an effective remedy, limitations in its availability and use are still evident. Geographic, cultural and economic limitations affect the availability of ORS especially among rural and Indian communities. Despite its advantages, ORS does not reduce the volume of stool loss or the duration of diarrhea, which is the primary concern of both parents and health workers when dealing with children with diarrheal diseases.

The search for an improved solution has lead to studies with aminoacids, rice and other cereals, maltodextrines, hydrolysed proteins, low osmolarity solutions, and short polymers of glucose (2–13).

Study background

Colombian culture has used plantain as a basis for homemade medicines for the treatment of diarrhea under the belief of having "antidiarrheal properties".

In the Indian communities of Antioquia, one of Colombia's largest provinces, diarrheal diseases stand among the first causes of morbimortality in children, while the availability and use of ORS solution is low (14). Several different varieties of plantains (musa sp.) are available all year round and have become the nutritional staple of these Indian groups.

In 1991, a biochemical study was performed on four varieties of green plantain, in order to obtain a solution prepared with native community resources for the prevention and treatment of dehydration. There are 83.3 g of glucose and 3.7 g of protein with low contents of electrolytes in 100 g of plantain flour. Once hydrolysed, these proteins produce the following amino acids: glycine, lysine, leucine, glutamic acid, valine, phenyl alanine, tryptophan, aspartic acid, histidine, arginine and alanine (15).

The following homemade recipe for a plantain flour-based solution was standardized in this study using green hartón plantain (*musa paradisiaca*): the peel of the plantain is removed. The plantain is cut it into very thin slices, dried in the sun and powdered in a home mill. Fifty grams of the plantain flour are added to 1100 ml of water and 3.5 g of sodium chloride, mixed and then boiled for 12 min. The mean osmolarity ($n = 16$) of the solution was 134.37 mOsml/l (SD 12.32).

Objective

The objective of the present clinical trial was to prove whether a homemade plantain flour-based solution could be an effective and safe alternative for the prevention and treatment of dehydration.

Material and methods

The study was conducted in the Oral Rehydration Service at the San Vicente de Paúl University Hospital in Medellín, Colombia. Two hundred and thirty-eight patients were studied (149M, 89F), ranging between 4 months and 5 y of age, who presented mild to moderate dehydration due to diarrheal disease of less than 14 days from onset (acute diarrhea), and had no other severe clinical findings or diseases associated with sepsis, pneumonia, or meningitis. The hydration state on admission was established according to the clinical criteria of the WHO Program for the Control of Diarrheal Diseases (CDD) (16).

Upon obtaining parental consent, eligible patients were randomly assigned to one of the two study groups, using permutation blocks of variable length. One hundred and twenty-one patients were included in Group A, which received standard WHO–ORS solution and 117 in Group B, which received plantain flour-based solution.

Group A patients were given the ORS solution formula recommended by WHO, which contains 90 mmol/l sodium, 80 mmol/l chloride, 20 mmol/l potassium and 10 mmol/l citrate, with an osmolarity of 311 mOsm/l. Group B patients were given a plantain flour-based solution prepared according to the above recipe.

The composition of the solution was controlled twice a week by measuring the sodium and potassium levels in the mixture. The mean concentration of sodium was 60.52 mmol/l (SD 8.87) and that of potassium 9.32 mmol/l (SD 1.4).

All patients were evaluated by a physician and nurse upon admission and followed up until rehydration or failure of oral rehydrating therapy was declared. Children were weighed on admission and at the end of the rehydration session. The state of hydration, physical findings of the children, the amount of oral solution received, stool output, and losses due to vomiting and urine were recorded hourly. Stool output was quantified by using previously weighed disposable diapers, urine loss by using collecting bags, and loss due to vomiting by using previously weighed absorbent napkins. Blood samples were obtained for sodium and potassium levels on admission and at the end of the rehydration session.

Fecal specimens were collected for bacterial agents, Rotavirus, ova and cysts of protozoa.

Patients were removed from the study because of parental request or failure of the rehydration therapy. Failure was declared when: (i) Rehydration was not obtained within a maximum period of 9 h; or (ii) there was no improvement in the state of hydration within the first 4 h.

The protocol was studied and approved by the Ethics Committee at San Vicente de Paúl University Hospital

Sample size was determined by Pocock equation (17), which is used when no difference between the two therapies is to be proven.

Statistical analysis

Descriptive statistics of variables and independence tests were calculated with a 5% significance level using χ^2 and Snedecor F distributions, in version 6.0 EPI INFO and EPIDAT. Stargraphics 5.0 was used for variance analysis procedures on totally randomized Tukey's designs for the selected variables according to the objectives. The Snedecor F, normal and t distribution tests was also used for these procedures. The Bonferroni correction was made for multiple comparisons.

Results

No statistically significant differences were obtained between both groups of patients according to their characteristics on admission or the infectious agents identified (Table 1). Rehydration was successful in 104 patients (85.9%) in Group A, and 103 patients (88%) in group B ($p = 0.634$).

The use of nasogastric probes was similar in both groups and the major indication for their use was the refusal of oral solution intake.

Weight gain and the time required for rehydration were similar in both groups ($p = 0.8581$ and $p = 0.132$, respectively) (Table 2).

The volume of solution required for rehydration was significantly less in group B ($p = 0.0001$) (Table 2).

The average stool output during rehydration was quantified for 98 children in group A and 106 in group B, being 8.45 g/kg/h (SD 9.72) for children in Group A and 4.69 g/kg/h (SD 4.98) for those in Group B ($p = 0.00782$) (Table 2).

The total stool output during rehydration was 44.72 g/kg (SD 49.56) in Group A and 22.56 g/kg (SD 26.85) in Group B ($p = 0.000081$) (Table 2).

The average stool frequency during rehydration was 3.62 (SD 2.74) in Group A and 2.47 (SD 2.26) in Group B ($p = 0.000474$) (Table 2).

No statistically significant differences were obtained for urinary elimination or vomit output.

There were no statistically significant differences in average blood levels of sodium on admission. Potassium blood levels were significantly lower in group B on admission ($p = 0.0155682$) (Table 4).

Admission and final blood levels of sodium did not show statistically significant differences in Group A ($p = 0.25824$). Sodium blood levels in group B decreased in a statistically significant manner ($p = 0.000008$) (Table 3). Ten patients who had normal sodium blood levels on admission (average of 134.4 mmol/l, SD 2.37) presented levels below normal (average of 128.80, SD 4.10) upon rehydration. These patients did not present clinical symptoms of hyponatremia and showed satisfactory evolution.

Average blood levels of potassium of children in group B decreased in a non statistically significant manner ($p = 0.20565$). Eleven children who had potassium levels within low but normal values upon admission (average of 3.87 mmol/l, SD 0.29) showed values below normal

Table 1. Patient characteristics on admission.

	WHO–ORS	Plantain flour-based formula	Statistic	*p*
No. of patients	121	117		
Mean age (months)	12.9 (6.7)	15.5 (9.9)	0.30*	0.954
Sex				
Male	77 (63.6%)	72 (61.5%)	0.11*	0.738
Female	44 (36.4%)	45 (38.5%)		
Weight (kg)	8.3 (1.8)	8.7 (2.3)	2.18**	0.140
Duration of diarrhea (days)	3.8 (2.3)	3.8 (2.7)	0.00**	0.951
Average stool frequency 24 h previous	11.3 (7.2)	11.0 (8.6)	0.06**	0.799
Blood in stool	8 (6.6%)	18 (15.3%)	4.70*	0.030
Vomiting	107 (88.4%)	105 (89.7%)	0.10*	0.745
Fever	53 (43.8%)	60 (51.2%)	2.44*	0.295
Weight-to-height	95.7 (10.6)	95.2 (11.6)	0.10**	0.751
Salmonella enteritidis	21/100	10/105	5.88*	0.015
Shigella sp.	1/100	4/105	***	0.20
Rotavirus	44/84	35/85	2.13*	0.144

Values are mean (SE) or number (%).
* χ^2 test; ** F statistic. *** Fisher exact test.
Bonferroni correction 0.05/12 = 0.004.

upon rehydration (average of 3.28 mmol/l, SD 0.19), although no symptoms of hypokalemia were found.

Discussion

The purpose of this study was to prove whether a plantain flour-based formula prepared according to a home recipe could be as effective as standard oral rehydration solution for the correction of dehydration produced by acute diarrheal disease. From a clinical viewpoint, the plantain flour-based formula seems to be quite effective. The probability of success or failure for rehydration, the time required for rehydration, and weight gain were similar for both solutions. The most important finding was the decrease in diarrheal volume. Stool output was practically halved.

Table 4 summarizes the categories of clinical studies performed solutions other than WHO–ORS.

Secretory diarrhea such as cholera may benefit from solutions such as rice-based ORS possibly because of its high starch concentration, which is over twice that of glucose concentration in standard ORS. This glucose is freed slowly upon starch digestion in the intestinal lumen, allowing the absorption of the sodium present in the solution and part of that secreted. This mechanism favors the reabsorption of water in the intestinal tract.

This advantage is not maintained when there is structural compromise of the intestinal mucosa, which impairs carbohydrate digestion and glucose absorption. Solution osmolarity seems to be fundamental in these cases. Low osmolarity ORS contain lower concentrations of sodium and glucose although maintaing a sodium:glucose ratio

Table 2. Results obtained for WHO–ORS and plantain flour-based formula.

	WHO–ORS (n = 117)		Plantain flour-based formula (n = 117)			
	Average	SD	Average	SD	F	*p*
Weight gain (g)	427.28	249.4	421.61	229.91	0.03	0.858
Percent weight gain (g/kg)	4.94	2.7	4.79	2.60	0.25	0.616
Time (h) for rehydration	5.28	1.99	4.88	2.11	2.33	0.132
Solution intake during rehydration (ml/kg/h)	24.56	10.12	21.17	9.35	7.19	0.007
Total solution intake during rehydration (ml/kg)	128.03	63.05	98.88	49.55	15.65	0.0001
Stool output during rehydration (g/kg/h)*	8.45	9.72	4.69	4.98	12.39	0.0005
Total stool output during rehydration (g/kg)*	44.71	49.97	22.56	26.85	16.17	0.00008

*Stool output and urine volume during rehydration therapy was measured for 98 children in the standard ORS group and in 106 children in the plantain flour-based formula group.

Table 3. Plasma sodium and potassium values.

	WHO–ORS ($n = 116$)		Plantain flour-based formula ($n = 112$)			
	Average	SD	Average	SD	F	*p*
Initial Na	139.3	7.93	137.7	7.52	2.35	0.126
Final Na	138.2	6.42	133.6	5.14	36.02	0.000008
Initial K	4.16	0.81	3.91	0.76	5.92	0.015682
Final K	4.22	0.74	3.78	0.79	19.02	0.000019
Ranges of sodium and potassium concentration						
	#	%	#	%	χ^2	*p*
Initial Na						
< 120 mmol/l	13	11.2	10	8.9	2.09	0.3508
120–149 mmol/l	89	76.7	94	83.9		
> 149 mmol/l	14	12.1	8	7.2		
Final Na						
< 120 mmol/l	6	5.2	15	13.4	10.03	0.0066
120–149 mmol/l	104	89.6	97	86.6		
> 149 mmol/l	6	5.2	0	0.0		
Initial K						
< 3.5 mmol/l	27	23.5	33	28.4	1.37	0.5044
3.5–5.49 mmol/l	83	72.2	76	67.9		
> 5.49 mmol/l	5	4.3	3	2.7		
Final K						
< 3.5 mmol/l	24	20.9	40	35.7	6.23	0.0443
3.5–5.49 mmo/l	89	77.4	70	62.5		
> 5.49 mmol/l	2	1.7	2	1.8		

similar to that found in the standard solution. Their osmolarity is approximately 240 mOsm/l; previous studies suggest they are better than standard ORS in the treatment of non-choleric diarrhea (9–11).

The decrease of stool output in those children who received the plantain flour-based solution could be related to its low osmolarity or the amino acids contained in the plantain, which might facilitate the coupled transportation

Table 4. Alternatives from standard ORS.

Solutions	Composition	Effects
Rice-ORS (2)	50–80 g of rice flour plus electrolytes similar to those found in standard solution.	More effective in cholera patients. Did not show advantages over standard ORS in patients with not choleric diarrhea
ORS with other foods (3–5)	50–80 g of other starches plus electrolytes similar to those found in standard solution.	No advantages over standard ORS. Few studies
ORS with amino acids (6–7)	Glycine, alanine and gluytamine, either as solitary amino acids or as di- or tripeptides, instead of glucose, with glucose or combined with different proportions of glucose or maltodextrines plus other electrolytes used in ORS.	No advantages over ORS on non-choleric diarrhea, no advantages over Rice-ORS in cholera. More expensive.
ORS with maltodextrines (7)	50 g of maltodextrines plus electrolyte similar to those found in standard ORS.	No advantages over ORS
ORS with hydrolysed proteins (8)	Hydrolysed proteins plus maltodextrines, plus electrolytes similar to those found in standard ORS	No advantages over ORS
Low osmolarity ORS (9–11)	Less sodium and glucose than standard ORS. Lower osmolarity.	More effective in patients with non choleric diarrhea.
ORS with short polymers of glucose (12, 13)	More calories with similar concentrations of electrolytes and osmolarity as ORS.	Less stool output in children with high output diarrhea and allows higher weight gain.
Rice water without electrolytes (15, 16)	Few studies. 50 g of rice flour with or without saccharose.	Hyponatremic and hypokalemic risks. Less stool output in children with high output diarrhea.

of sodium. Other plantain components might have an antidiarrheic effect.

Although the concentration of sodium in the solution was close to 60 mmol/l, a decrease in blood levels of sodium was observed in some children, although no clinical consequences were apparent.

Average blood concentrations of potassium did not decrease significantly although some children showed levels below normal. The concentration of potassium in the solution is lower than that of standard ORS but higher than that of most home made solutions. Some studies have used rice-based solutions, which have very low potassium concentrations, for the treatment of dehydration, apparently without complications (18, 19).

The study "Liquids readily available at home for the prevention of dehydration" performed in Medellin, Colombia identified 70 different home recipes using several varieties of plantain (20).

The reduction in stool output sparks up interest in the popular belief that plantain has "antidiarrheal" effects and poses the need to develop studies in which the quantification of stool output is performed for a long enough period to prove the existence of an antidiarrheal effect. Such studies should be performed with a solution containing the plantain flour based solution and electrolytes in standard concentrations.

Acknowledgments.—This study was sponsored by the Instituto Colombiano para el Desarrollo de la Ciencia y la Tecnología, Francisco José de Caldas, Colciencias of Colombia and the Universidad de Antioquia in Medellín, Colombia. We thank Mr Hugo Grisales for his expert statistical assistance and Carlos Palacio, Gustavo Uribe, Luz Noreña, Adriana Giraldo, Claudia Yepes, Yusbleidy de los Ríos, Carlos Guzmán, Ludy Jaimes, Eneida Galeano, Sol Vélez, Diana Mojica, Luz Mazo, Luz Zapata, Angela Ruiz, Lina Zuleta: physicians and nurses who were directly involved in the study, Ms. Nancy Agudelo and Carmen Zapata for their laboratory assistance, Dr Fernando Montoya of the Universidad de Antioquia and Mr Cristopher Drasbek of the Pan American Health Organization for their review of the manuscript and helpful comments.

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Received Oct. 31, 1996. Accepted in revised form June 12, 1997