
ORIGINAL ARTICLE

Oral Rehydration Solution

An Appropriate Formula for Acute Infantile Diarrhoea*

by

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Abstract

A new formula of oral rehydration solution (kristalyte R) with the following composition: Na 51.2, K 25.0, Cl 37.5, Citrate 57.5 mEq/L, dextrose 100 and sucrose 52.0 mMol/L with the osmolality of 323 mOsm/L were tried in 21 acute infantile gastroenteritis with mild and moderate dehydration. The age of the patients varied from 2.5 to 36 months with the average of 13.4 months.

As a control were used 21 children with the same age, same diagnosis and same nutritional state treated with oralyte with the composition of Na 90, K 15, Cl 75, HCO₃ 30 mEq/L and glucose 120 mMol/L with the osmolality of 330 mOsm/L.

Clinical observation and chemical observation were done before and after rehydration which usually occurred after 24 hours of treatment.

Stool culture, WBC count and urinalysis were done on admission only.

The results of the trial revealed that in kristalyte group better results were obtained in gaining the body weight, reducing the frequency of diarrhoea or fluid loss, acceptance of the solution and reducing the risk of periorbital oedema.

No hypernatremia and neurological manifestations were found in both groups and all of the children were discharged on the third day in good condition.

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Introduction

Oral rehydraton for the treatment and prevention of acute diarrhoeal disease with or without dehydration has become popular in the last few years. It has been established to be effective in preventing and correcting lifethreatening dehydration.

Several kinds of oral electrolyte solution with various compositions have been used in previous studies (Nalin et al., 1970; Pierce, 1971; Hirschhorn and Wesley, 1972; Hirschhorn et al., 1972; Pierce., 1973; Hirschhorn et al., 1973; Ludan and Del Mundo, 1973; Pitono Suparto et al., 1974; Nalin 1975; Pitono Suparto et al., 1976; Naik and Shah, 1976; Chakabarti et al., Sunoto et al., 1976; 1977).

The most commonly used for oral rehydration in Indonesia up till now is Cholera Oral Solution (COS). A single universal oral rehydration solution has been recommended by WHO/UNICEF (1976). This solution consisted of NaCl 3.5 g/L, NaHCO₃ 2.5 g/L, KCl 1.5 g/L and glucose 20 g/L or equivalent to Na 90 mEq/L, K 15 mEq/L, Cl 75 mEq/L and glucose 120 mOsm/L. This solution was originally used in pediatric patients with cholera mainly according to the composition of the stool of cholera patients, i.e. Na 105 mEq/L, K 26 mEq/L, Cl 95 mEq/L and HCO₃ 3 mEq/L.

But it has been shown stool composition of pediatric diarrhoea consisted of Na 56 mEq/L, K 26 mEq/L, Cl 55 mEq/L and HCO₃ 14 mEq/L (Pierce,

1971). As it also known, epidemic diarrhoea or suspected cholera cases in Indonesia are only about 50.000 cases per year, whereas the number of pediatric diarrhoea is about 50 million cases per year or 1000 times the suspected cholera cases (Brotowasisto et al., 1978).

The disadvantage of this WHO/UNICEF solution is the high concentration of the Na (90 mEq/L), which is harmful to children particularly to infants. The risk of hypernatremia, which can cause convulsion, is more frequently found in periorbital oedema and dilatation of the gut particularly in neonatal and low birth weight infants with diarrhoea. After using this solution and knowing the complications, its wider acceptance by paediatrician was limited.

Second disadvantage of this solution is the taste and the flavour of this solution which is not so attractive for the children so that there is a report concerning the rejection of this solution by the patients (Brotowasisto et al., 1978).

The third disadvantage of the present solution is the volume of packaging. Up till now in Indonesia there are 2 kinds of volume of packaging and those are : for one litre or 5 glasses solution and for 200 ml or 1 glass solution. But the problem is that, there are only a few people or mothers who exactly know how much is 200 ml and 1 litre, while in their home there is no measurement for that purpose. And there are so many kinds of glasses in the community with various volumes ranging from 100 ml up to 300 ml.

Previous study in the community about the composition of the oral electrolyte solution made by mothers, revealed that the range of solution is from 50 mEq/L up to 130 mEq per litre (Suhar-yono et al., 1978).

This new composition is namely kristalyte and has the following advantages:

1. Content of lower sodium (51 mEq/L) which is more or less similar with the stool composition of the Na in pediatric diarrhoea, in the hope that this low Na will reduce the risk of the unexpected complication.
2. One sachet of the solution is used for 600 ml, volume of which is similar with one bottle of beer. In Indonesia bottle of beer is very popular and always available in every home, whereas the range of the volume is almost constant that is about 600 ml. Beer-bottle is also popular as a coconut oil-bottle or soya sauce-bottle. With this measurement it is hoped that the range of the solution will be more accurately than use of glasses.
3. Use the citrate instead of bicarbonate, since this remedy is orange taste and orange colour which is similar with the colour of "greenspot", a popular soft drink in Indonesia, in the hope that it will be more accepted by children than the oralyte solution.
4. With all the above advantages it is hoped that this solution will be accep-

ted by all children of all ages with all kinds of diarrhoea and all kinds of nutritional state too (it is known Sodium concentration for malnourished children should be in low concentration), and will be accepted by pediatricians who have a strong confidence in promoting the use of this solution.

Material and method

Sixty children with acute diarrhoeal diseases of all ages, all kinds of cause and all kinds of nutritional state, with mild and moderate dehydration according to the clinical adjustment or scoring system of King (1974) as seen in Table 1 were included in the trial. The patients were admitted in the hospital for at least 72 hours where clinical and chemical observations were made.

They were divided into 2 groups. Group 1 was treated with kristalyte solution and the other group with standard oral electrolyte solution. They were treated randomized as follows:

Patients with unequal numbers (1, 3, 5, etc.) were treated with kristalyte solution and patient with equal numbers (2, 4, 6, etc.) were treated with standard oral electrolyte solution as controle. Both oral glucose electrolyte powder was put in the similar sachets and had a code number unknown to the investigator. The answer of the composition was put in an envelope and just opened after the trial was finished.

The composition of both solutions per 1 litre was as follows :

<u>K r i s t a l y t e</u>		<u>O r a l y t e</u>	
Sodium	51.2 mEq/L	Sodium	90 mEq/L
Potassium	25.0 mEq/L	Potassium	15 mEq/L
Chloride	37.5 mEq/L	Chloride	75 mEq/L
Citrate	57.5 mEq/L	Bicarbonate	30 mEq/L
Dextrose	100.0 mMol/L	Glucose	120 mMol/L
Sucrose	52.0 mMol/L		
Osmolality	323 mOsm/L	Osmolality	330 mOsm/L

The average amount of the solution to be given per day was as follows :

Weight (Kg)	Mild dehydration	Moderate dehydration
3 — 10	150 ml/Kg/day or 2 sachets	175 ml/Kg/day or 3 sachets
10 — 20	125 ml/Kg/day or 3 sachets	150 ml/Kg/day or 5 sachets
20 — 30	100 ml/Kg/day or 6 sachets	125 ml/Kg/day or 8 sachets

Initial solution intake was divided into small and frequent feeds of 60 - 120 ml every 2 - 3 hours. The amount increased gradually as the patient is able to drink and tolerate the solution. Only oral solution was given as the source of liquids for the first 24 hours. After which all the patients were allowed to drink or eat the usual food as a regular refeeding according to their age and their habit (breast milk, formula milk, low lactose milk solid food, etc.

Clinical observation was done before admission and after rehydration which usually occurs after 24 hours of the treatment. These included body weight, state of hydration, frequency of stool, urine

and vomiting and the acceptance of the solution.

Chemical observation was done before and after 24 hours. These included sodium, potassium, chloride, CO_2 content and blood sugar. Routine blood examination, hematocrit, urinalysis and stool including pH and clintest were done as usual.

Stool cultures and sensitivity test were done on admission only. Antibiotics were not given in all of the patients as it has been done in previous study that these antibiotics were of little or no value in the treatment of acute diarrhoeal disease (Sunoto et al., 1976; 1978; Bachtin et al., 1976).

TABLE 1. Scoring System for Classification of the degree of dehydration according to King (1974).

Part of the body examined	Score for Signs and Symptoms observed		
	0	1	2
General condition	Healthy	Restless, apathetic sleeping or malaise	Delirium, Stupor or Coma
Elasticity of the skin	Normal	Decreased	Very decreased
Eyes	Normal	Sunken	Very sunken
Fontanelle	Normal	Sunken	Very sunken
Mouth	Normal	dry	Very dry or cynosis
Pulse rate per minute	Strong, less than 120	120 — 140	More than 140

Score : 0 — 3 : Mild dehydration
 4 — 6 : Moderate dehydration
 7 — 12 : Severe dehydration

Results

The results of the trial could be seen in Table 2 to 6.

TABLE 2: Summary of the Clinical Data

No of Patients	Age (mo)	Sex		Nutritional state			Kind of hydration			Tonicity of dehydration			Accomp. Disease
		M	F	G	F	U	N	Mi	Mo	Iso	Hypo	Hyper	
Kristalyte Group 21	13.4 (2.5 — 36)	19	2	11	5	5	0	9	12	21	0	0	URTI = 3 LRTI = 2 PEM = 1
Oralyte Group 21	14.0 (3.0 — 36)	17	4	10	6	5	0	12	5	21	0	0	URTI = 4 LRTI = 2 PEM = 1

Note:

M = Male

F = Female

G = Good

F = Fair

U = Undernutrition

N = Normal

Mi = Mild

Mo = Moderate

URTI = Upper Respiratory Tract Infection

LRTI = Lower Respiratory Tract Infection

PEM = Protein Energy Malnutrition

ISO = Isotonic

HYPO = Hypotonic

HYPER = Hypertonic

TABLE 3: Clinical Observation

Kind of Observation	Kristalyte Group		Oralyte Group	
	On admission	After rehydration (24 hrs)	On admission	After rehydration (24 hrs)
1. State of hydration				
Normal	0	21	0	19
Mild	9	0	12	2
Moderate	12	0	9	—
2. Weight (gram)				
Average	7.464	8.145	8.438	8.778
Range	3670-15000	3800 - 15100	6300-17000	6400 - 17350
Average gain in weight	—	681 (9.1%)	—	340 (4.0%)
3. Freq. of micturition				
Average	0.2	3.75 ×	0.46	3.77
Range	(0 - 2 ×)	(2 - 5 ×)	(0 - 2 ×)	(1 - 6)
4. Freq. of Diarrhea				
Average	10.3	2.8	18.69	4.08
Range	(3 - 25 ×)	(1 - 10 ×)	(7 - 40)	(1 - 10 ×)
5. Freq. of Vomiting				
Average	2.7	0	5.38	0.85
Range	(0 - 10 ×)	—	(0 - 15 ×)	(0 - 4)
6. Acceptance of solution				
Good	20	20	15	16
Fair	1	1	6	5
7. Periorbital oedema	0	2	0	5
8. Neurological manifestation	0	0	0	0

TABLE 4: *Chemical Observation*

	Kristalyte Group		Oralyte Group	
	On admission	After rehydration (24 hrs)	On admission	After rehydration (24 hrs)
1. Sodium (mEq/L)				
Mean	135	137	133	137
Range	(121 — 147)	(126 — 150)	(124 — 145)	(120 — 154)
2. Potassium (mEq/L)				
Mean	4.4	4.6	3.73	3.85
Range	(2.6 — 5.5)	(3.0 — 5.6)	(2.2 — 4.8)	(1.8 — 5.7)
3. CO ₂ Comb. Power (vo 1%)				
Mean	30.5	45.2	33.5	42.4
Range	(15.2 — 54.6)	(34.5 — 59.8)	(16.5 — 56.4)	(35.2 — 58.4)
4. Blood Sugar (mg%)				
Mean	73.3	71.0	76.15	78.08
Range	(55 — 115)	(50 — 115)	(50 — 105)	(40 — 115)
5. Serum Osmolality				
Mean	296	287.5	293.15	283.46
Range	(270 — 316)	(270 — 310)	(265 — 301)	(262 — 290)
6. Chloride (mEq/L)				
Average	105	106	99.42	102.59
Range	(81.2 — 122.0)	(99.7 — 115.6)	(66.3 — 106.1)	(96.1 — 115.9)

TABLE 5: *Stool Examination*

	Kristalyte Group	Oralyte Group
Leucocyte 5 — 10/HPF	13	4
Leucocyte 10 — 20/HPF	2	9
Ascaris Egg +	1	1
Sugar Intolerance	4	0
Fat Malabsorption	4	1
Fungal Infection	4	1
Salmonella C ₁	4	1

TABLE 6 : *Other Examination*

	Kristalyte Group		Oralyte Group	
	On Admission	After rehydration (24 hrs)	On Admission	After rehydration (24 hrs)
1. Hematocrit				
Mean	37.4	33.2	37	33.3
Range	(26 — 46)	(26 — 40)	(29 — 45)	(26 — 42)
2. W B C				
Mean	7525/cmm	7338/cmm	7323/cmm	7123/cmm
Range	(5800 — 10000)	(5000 — 10600)	(5200 — 10000)	(5200 — 9800)
3. Urinalysis	N.A.D.	N.A.D.	N.A.D.	N.A.D.

N.A.D. = No Abnormality Detected

Discussion

From the clinical observations in Table 3 it can be seen that 9 children admitted with mild dehydration and 12 with moderate dehydration, were rehydrated with kristalyte only after 24 hours of treatment. In the control group 12 children with mild dehydration all of them were became normal, whereas from 9 moderate dehydration 7 were rehydrated but 2 patients were still in mild dehydration, after 24 hours of treatment.

The frequency of diarrhoea was significantly higher in the oralyte group than in the kristalyte group, that is with the average of 4 times versus 2.8 times. The frequency of urination was not significantly different in both groups.

The weight gain was highly significant in kristalyte group than in oralyte group,

that is with the average of 681 gram or 9.1% versus 340 gram or 4.0%. This finding was different with the finding of Chaterejee et al., (1978) who found no difference in both groups.

The acceptance of oralyte was better in the kristalyte group than in the oralyte group, that is good in 20 out of 21 patients or 95% in the kristalyte group, whereas in oralyte group good in 15 out of 21 patients or 71%. This difference could possibly be explained that the kristalyte solution has more delicious taste and more attractive colour than the oralyte solution.

From the biochemical observations in Table 4 it can be seen that the difference in the sodium concentration, potassium, chloride, blood glucose and serum osmolality were not significant.

This finding was more or less similar to the other previous study (Pitono Suparto et al., 1974, 1976; Chaterjee et al., 1978). Hyponatremia was not found in both groups, but periorbital oedema was noted more frequent in oralyte group (5 cases) than in kristalyte group (2 cases). This finding was more or less similar to the finding of Chaterjee et al., (1978) and Hirschhorn et al., (1973). No neurological manifestation was found in both groups. All of the children were recovered and discharged on the third day.

From the stool examination it was found more leucocyte 2+ in oralyte group than in Kristalyte group (9 versus 4), but more Salmonella spp., Fungal Infection, Sugar Intolerance and Fat malabsorption in kristalyte group than in oralyte group (4 versus 1). Nevertheless, the frequency of diarrhoea was more common in oralyte group than in kristalyte group, and the results of the weight gain were higher in the kristalyte group.

The results of the other examination regarding hematocrit, blood analysis and urinalysis were not different in both groups.

Summing up the above results of the treatment in both groups it can be concluded that kristalyte group has better result than oralyte group in gaining the weight, reducing the frequency of diarrhoea or reducing fluid loss, acceptance of the solution, and reducing the risk of peri-orbital oedema.

Though hyponatremia and neurological manifestation were not found, this complication of high Na concentration might occur frequently in younger children, especially children less than 3 months old. Further trial in these group of babies is needed to see the risk of hyponatremia.

Other advantages of this new composition regarding the packaging i.e. by using beer bottle or soya sauce bottle — instead of 1 glass or litre — was not done yet, which needs further evaluation too.

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