Evaluation of a New Oral Rehydration Solution (Osterlyte) in Saudi Children

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تم تقويم تجربة اعطاء محلول امهاء فموي جاهز «اوسترلايت» يحتوي على ٥٠ ميلي مول/ليتر من الصوديوم في مائة وخمسين طفلاً سعودياً اعمارهم بين ٣ أسابيع و ٣٤ شهراً مصابون بتجفاف ثانوي لالتهاب الامعاء. وجد بأن هذا المحلول آمن وفعال في الامهاء وصيانة الاماهة عند هؤلاء الأطفال.

Summary: A prepacked ready-to-feed rehydration solution Osterlyte, containing 50mmol/1 of sodium was evaluated in 150 Saudi children aged betweeen 3 weeks and 34 months with moderate to severe dehydration, secondary to enteritis. The solution was found to be safe and effective in rehydrating and maintaining hydration in these children.

Résumé: L'utilisation d'une solution de réhydratation par voie orale "prête-à-boire", Osterlyte, renfermant 50 mmol/1 de sodium, a été testée chez 150 enfants saoudiens âgés de 3 semaines à 34 mois et présentant une déshydratation modérée à sévère secondaire à une entérite.

Il a été montré que cette solution était parfaitement tolérée et efficace pour réhydrater ces enfants et maintenir chez eux une hydratation satisfaisante.

Introduction

Acute diarrhoeal disease continues to exact a high toll in morbidity and mortality, particularly in children of the developing countries.[1–3] In these countries, longitudinal studies have shown rates of six to eight separate episodes of acute diarrhoea per child per year.[1]

Many types of oral rehydration solution (ORS) have been proposed,[4] and the physiological considerations for determining the optimal composition and concentration of ingredients have been reviewed recently.[2] In a major programme for the 1980s,

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the World Health Organization (WHO) elected to promote an universal ORS containing 90mEq/l of sodium, 20mEq/l of potassium, 30mEq/l of bicarbonate and 111mmol/l of glucose.[5] This solution has been used very successfully in many parts of the world but problems with hypernatraemia[6] hypokalaemia,[6,7] and oedema[2] have been reported.

We have studied a prepacked, ready-to-feed ORS, containing 50mEq/l of sodium, 20mEq/l of potassium, 40mEq/l of chloride 11·67 mmol/l of citrate and 111mmol/l of glucose in 150 Saudi children with dehydration secondary to enteritis.

Our study was associated with a similar one carried out at the same time by the department of Child Life and Health of the University of Edinburgh, at the Infectious Diseases Unit, the City Hospital Edinburgh, Scotland.

Patients and Methods

We studied 150 Saudi children between the ages of 3 weeks and 34 months (mean 3·5, SD±1·6 months) admitted consecutively with dehydration secondary to enteritis. Patients with other causes of dehydration were not included. The study was conducted at the Children's Hospital in the Shumesi district of Riyadh between September 1984 and June 1985.

The data were collected on a standard questionnaire by Dr Alam, who was specially appointed as a research fellow for the study. Rehydration was carried out using the trial solution, the average intake of which varied between 100–2600 ml (mean 1016ml SD±455 ml). The nature of the study was clearly explained to the parents, particularly to the mother.

After a history was taken and physical examination performed each child was weighed, and blood was taken for analysis within one hour of admission. Dehydration of less than 5% was classified as mild, 5–8% as moderate and greater than 8% as severe. The volume of fluid required for rehydration was calculated according to a preset regimen of 75 ml/kg body weight for the first 6 h in mild and moderate dehydrations and 100 ml/kg body weight for severe dehydration. This was followed by 100 ml/kg body weight for mild, 150 ml/kg for moderate and 175 ml/kg body weight for severe dehydration until rehydration was thought to be accomplished. Repeat blood samples were taken as required or every 4 h in case of severe dehydration, every 8 h in moderate dehydration and every 12 h in the case of mild dehydration for the first 48 h after admission. Treatment and observations for each patient were limited to 10 days. Initially, all oral feeds other than breast milk were withheld. Patients in whom intravenous rehydration was necessary either on presentation or during the study period were withdrawn from the study. However, 21 severely dehydrated children did not receive intravenous therapy and were rehydrated with the ORS.

On completion of the study, the data were analysed using the King Saud University mainframe computer. In all, 28 parameters were analysed.

Results

Of the 150 Saudi children studied, 80 (53·3%) were boys and 70 (46·6%) girls. The duration of illness ranged between 1–20 days (mean 3·4, SD±2·8). The frequency of vomiting was between 1–13 per day (mean 4·3, SD±2·2) and the number of stools per day ranged between 2–20 (mean 7·9, SD±3·6). 62 (41·3%) of the children were feverish and in only 22 (14·7%) were bacteria grown from the stools.

A modified Gomez[8] classification was used in the assessment of the nutritional status of these children; 115 (76·7%) were normal, 25 (16·7%) were malnourished and 10 (6·7%) were marasmic. On admission, of the 150 children, 72 (48%) were mildly

dehydrated, 57 (38%) were moderately dehydrated and 21 (14%) were severely dehydrated. Of the mothers, 48·7% were illiterate. The type of feeding these children were receiving at the time of admission is shown in Table 1.

Table 1
Types of feeding on admission

	Number	%
Breast feeds only	19	12·7
Bottle feeds only	50	33·3
Breast and bottle feeds	19	12·7
Solids only	6	4·0
Breast milk plus solids	10	6·7
Bottle milk plus solids	25	16·7
Breast+bottle+solids	21	14·0

Isotonic dehydration (serum sodium between 130–150 mEq/l) on admission was the most frequent finding, being observed in 136 (90·7%) patients; the least frequent was hypertonic dehydration (serum sodium above 150 mEq/l) found in only two patients (1·3%). Hypotonic dehydration (serum sodium of less than 130 mEq/l) was present in 12 patients (8%). The results of haemoglobin estimations, serum biochemistry, and stool volume on admission and at the end of rehydration are shown in Table 2. Table 3 shows the relationship between the type of dehydration and the nutritional status, on admission and at the end of the rehydration period.

Table 2
Weight, serum biochemistry, haematology and the volume of stools on admission and after rehydration (mean SD)

	Before rehydration	After rehydration
Weight (kg)	<2·9–13·0 (6·1,2·0)	3·0–13 (6·38,2·3)
Haemoglobin (g/dl)	7·1–17·1 (11·1,1·5)	7·6–17·2 (11·1,1·4)
Haematocrit	21·6–52·0 (34·0, 4·7)	23·1–54·0 (33·8,4·1)
Serum sodium (mEq/1)	110–167 (134·2,2·9)	128–146 (135·4,3·7)
Serum potassium (mEq/1)	2·8–7·0 (4·2,0·7)	2·2–8·6 (3·5,1·1)
Serum chloride (mEq/1)	82–138 (100·5,9·4)	90–127 (107·6,6·1)
Serum bicarbonate (mEq/1)	5–27 (10·6,0·8)	15–27 (18·3,1·2)*
Volume of stool (ml/24 h)	90–2000 (568,297)	30–700 (186,54)*

* p (<0·001)

Three (2%) of the mothers refused to use the ORS because they expected their child to receive intravenous therapy in hospital; they also said the children did not like the taste of the trial solution. In another three (2%), the ORS was considered to have failed as these children required intravenous therapy because of increasing dehydration. All

Table 3
Relationship of serum sodium (mEq/1) to the state of nutrition: on admission and after rehydration ( )

	Normal	Mal	Mar	Total	%
Hypotonic	7(4)	2(0)	3(0)	12(4)	8(2·7)
Isotonic	106(115)	23(21)	7(10)	136(146)	90·7(97·3)
Hypertonic	2(0)	0(0)	0(0)	2(0)	1·3(0)
TOTAL	115(119)	25(21)	10(10)	150(150)	100(100)

Mal=malnourished; Mar=marasmic

three of these children were more than 8% dehydrated on admission. The total duration of stay in hospital for the children ranged between 2–10 days (mean 3·7, SD±1·3).

Discussion

Apart from traditional remedies of this type, oral glucose electrolyte solutions have been used in the management of acute infantile diarrhoea since the work of Darrow in the 1940s.[4] In the late 1960s workers in Asia, applying new physiological knowledge of the role of organic solutes in stimulating water and electrolyte absorption in patients with cholera, showed that the massive net secretion of electrolytes and water into the small intestine could be reversed by an appropriate oral rehydration solution.[9]

Since the WHO mounted its massive programme in the treatment and prevention of dehydration in diarrhoeal diseases, its ORS has gained universal acceptance.[10,11] However, Sandhu *et al.*[12] have reported a significant rise in the serum concentration of sodium in children using this solution. They suggested that the sodium concentration in the ORS should be reduced to 25mEq/l, particularly in temperate climates. This has raised the controversy about the universality of the WHO solution.

Fineberg[13] has suggested the need for an initial rehydration solution and maintenance solution on the grounds that one solution cannot meet the widely varying needs of children with diarrhoea. He proposed the use of a rehydrating ORS with a sodium content between 75–90mEq/l given at the rate of 40–75 ml/kg over 4–6 h, followed by an ORS containing 40–50 mEq/l of sodium given at the rate of 150–175 ml/kg. Santosham,[14] on the other hand, using solutions of various sodium concentrations (90,50,30,20 mEq/l) in ambulatory American children, found no difference either in the rehydrating capacity of these fluids or in the incidence of hypernatraemia. It is difficult to accept that if one solution could not meet all children's needs, as Fineberg suggests, then two solutions would significantly alter the situation. Hyponatraemia, hypokalaemia and acidosis are seen more frequently in the children from the underdeveloped countries than in those from the developed world.[2] Acidosis was particularly marked in our group of children prior to rehydration, and even after rehydration though significantly raised ($p<0·001$) most remained acidotic.

Currently, only two ready-to-feed ORSs are available in Saudi Arabia, namely Pedialyte and Dextrolyte. In our experience Pedialyte is not very palatable, It also contains rather a large amount of glucose (5G/dl) and is low in sodium (30mEq/l). Dextrolyte, on the other hand, contains lactate, which may aggravate the acidosis already quite marked in these children. Most ORSs contain sodium bicarbonate, which is a useful constituent for correcting acidosis. Bicarbonate, however, reacts with glucose to form furfural compounds leading to brown discoloration and a short shelf life in prepacked ORS formulations.[15] Osterlyte contains citrate which is readily metabolized. Our results using this solution show that citrate is effective in correcting acidosis.

Though we are aware of the use of the WHO solution in the Kingdom, we were unable to find any recorded evaluation of ORS in the Saudi medical literature. Using an ORS containing 50mEq of sodium we were able to successfully rehydrate and maintain rehydration in 98% of the children studied. We also found it quite acceptable to the children and their mothers once the objective of the study was explained to them; only three mothers refused to try the therapy. We believe this would also hold true in the community, but this assumption would need to be tested.

As expected, isotonic dehydration was the most frequent finding. No cases of hypernatraemia were seen with this therapy, though 2·6% of the children remained hyponatraemic: similar results have been found in Edinburgh (personal communication).

Cost is a major factor in the provision of ORS in developing countries. However, the Kingdom of Saudi Arabia is in a unique position: the major problem is not economic but one of health education, which can be resolved only slowly. In this context, therefore, we feel that a single prepacked ready-to-feed ORS with an adequate shelf life can overcome the problem of incorrect preparation of the oral powdered formula,[13,16] particularly where the salt content in the water being used to reconstitute the ORS is unknown or variable.

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