Reduced-osmolarity oral rehydration salts solution shortened the duration of acute diarrhoea

International Study Group on Reduced-osmolarity ORS Solutions. ***Multicentre evaluation of reduced-osmolarity oral rehydration salts solution.*** *Lancet. 1995 Feb 4;345:282-5.*

Objective
To compare the effectiveness of standard and reduced-osmolarity oral rehydration salts (ORS) solutions in boys with acute noncholera diarrhoea.

Design
Randomised, double-blind, controlled trial.

Setting
4 hospitals in Brazil, India, Mexico, and Peru.

Patients
439 boys aged 1 to 24 months (mean age, 10 mo; mean weight on admission, 7.3 kg) with acute noncholera diarrhoea (≥ 3 watery stools in the previous 24 h and no *Vibrio cholerae* in admission stool sample) and signs of mild or moderate dehydration. Exclusion criteria were symptoms lasting for > 5 days, severe malnutrition, systemic infections, other diseases requiring additional treatment, or visible blood in the stool.

Intervention
447 boys were assigned to standard (311 mmol/L) or reduced-osmolarity (224 mmol/L) ORS solution containing 90 and 60 mmol/L of sodium, respectively, and were rehydrated within 4 to 6 hours. Ongoing losses (liquid stools and vomit) were replaced with ORS until diarrhoea stopped. Feeding was resumed immediately after completion of rehydration. In boys who were not exclusively breast-fed, milk formula was given at half strength during the first 24 hours. Supplementary intravenous fluids were prescribed if ORS alone failed to achieve adequate and sustained rehydration.

Main Outcome Measures
Total stool output, need for supplementary intravenous fluid therapy, duration of diarrhoea, and weight gain.

Main Results
395 boys were followed until diarrhoea stopped. 44 patients were withdrawn prematurely and contributed incomplete data. 8 patients were excluded from the analysis. Compared with standard-osmolarity ORS solution, reduced-osmolarity ORS solution decreased total stool output (107 vs. 149 g/kg) and duration of diarrhoea (33 vs. 41 h) ($P < 0.01$). The groups did not differ for the need for supplemental intravenous infusion and weight gain; however, boys who were not breast-fed and who received standard ORS solution were more likely to require intravenous fluids (relative risk, 2.0; 95% CI, 1.0 to 3.8; $P < 0.05$).

Conclusion
Boys who received reduced-osmolarity oral rehydration solution for their acute diarrhoea had less total stool output and a shorter duration of diarrhoea than boys receiving standard ORS solutions.

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Commentary

A fear of hypernatraemia resulting from the use of the standard World Health Organization (WHO) ORS containing 90 mmol/L of sodium has inhibited the use of this solution in developed communities (1). This followed the recognition of a high mortality rate from hypernatraemia in infantile gastroenteritis in the 1970s, although this mortality has now decreased substantially with the advent of low-solute milks (2). The improper use of WHO ORS in Egypt, however, was significantly related to the incidence of hypernatraemia (3). This fear led to a successful clinical trial of hypotonic low-sodium solutions (50 or 60 mmol/L) in Finland (4) and to supportive physiological studies in animals (5) and human volunteers (6).

As a result, the European Society of Paediatric Gastroenterology and Nutrition (ESPGAN) (7) recommended a low osmolarity of 200 to 250 mOsm/kg and a sodium level of 60 mmol/L for "low sodium diarrhoea of European children." Clinical studies in Europe (8) have shown that these solutions are effective, but no large studies of reduced-osmolarity, low-sodium ORS in developing countries were done until this controlled clinical trial by the International Study Group on Reduced-osmolarity ORS Solutions. Only boys were studied because urine is easier to collect and separate from stools in boys than in girls; however, the results should be equally applicable to girls. These observations support the approach of ESPGAN and others that reduced-osmolarity ORS solutions are an effective therapy for noncholera diarrhoea. Whether these solutions are effective in cholera still needs to be proved.

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References

1. **Walker-Smith JA.** Acta Paediatr Scand Suppl. 1989;364:13-6.
2. **Manuel PD, Walker-Smith JA.** Arch Dis Child. 1980;55:124-7.
3. **Fayyad IM.** Diarrhoea Control Newsletter (Egypt). 1985;4:17-9.
4. **Isolauri E.** Acta Paediatr Scand. 1985;74:643-9.
5. **Elliott EJ, Watson AJ, Walker-Smith JA, Farthing MJ.** Gut. 1991;32:1314-20.
6. **Hunt JB, Elliot EJ, Fairclough PD, Clark, ML, Farthing MJ.** Gut. 1992;33:479-83.
7. Report of an ESPGAN Working Group. J Pediatr Gastroenterol Nutr. 1992;14:113-5.
8. **Elliott J, Walker-Smith JA, Farthing MJ, Hunt J, Cameron D.** Clin Therapeutics. 1990;12(Suppl A):86-95.