

Comparison Between Oral Versus Intravenous Rehydration to Treat Dehydration in Pediatric Gastroenteritis

EBEM Commentator Contact

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SYSTEMATIC REVIEW SOURCE

This is a systematic review abstract, a regular feature of the *Annals'* Evidence-Based Emergency Medicine (EBEM) series. Each features an abstract of a systematic review from the Cochrane Database of Systematic Reviews and a commentary by an emergency physician knowledgeable in the subject area.

The source of this systematic review abstract is: Hartling L, Bellemare S, Wiebe N, et al. Oral versus intravenous rehydration for treating dehydration due to gastroenteritis in children (review). *Cochrane Database Syst Rev*. 2006;(3):CD004390. DOI:10.1002/14651858.

The *Annals'* EBEM editors assisted in the preparation of the abstract of this Cochrane systematic review, as well as the Evidence-Based Medicine Teaching points.

OBJECTIVE

The objective of this review was to compare the efficacy of oral rehydration therapy in treating dehydration caused by gastroenteritis in children.

DATA SOURCES

The authors searched the Cochrane Infectious Disease Group Specialized Register (March 2006), Cochrane Central Register of Controlled Trials (Central, Issue 1, 2006), MEDLINE (1966 to March 2006), EMBASE (1974 to March 2006), and LILACS (1982 to March 2006). In addition, the authors contacted researchers, pharmaceutical companies, and relevant organizations for any unpublished reports, confidential reports, and raw data. Finally, the authors reviewed the reference list from the trials.

STUDY SELECTION

The authors included randomized and quasi-randomized controlled trials for the review. Children aged 18 years or younger and with dehydration caused by acute gastroenteritis were selected as study participants. Acute gastroenteritis is

defined as diarrhea lasting longer than 14 days that may or may not be associated with nausea, vomiting, fever, or abdominal pain. Diarrhea is the increased frequency and volume of loose or watery stool. Finally, dehydration is a deficit of water and salt, often described as percentage of weight loss.

The primary outcome was the failure either of achieving rehydration or maintaining hydration after the initial rehydration attempts, described by the studies. Secondary outcomes are weight gain, length of inpatient hospital stays, hypernatremia, hyponatremia, duration of diarrhea, total fluid intake, sodium intake and sodium levels, and complication and adverse events.

DATA EXTRACTION AND ANALYSIS

Two authors independently selected trials for the review. When relevant articles were identified, 2 authors independently assessed for inclusion with an a priori inclusion criteria. The authors also assessed the effectiveness of randomization and allocation for the selected studies. Extraction of data from selected trials and verification of data completeness were performed by 2 independent reviewers.

Risk difference between treatment groups was used to determine efficacy of therapy for each group in each study. To quantify the benefits of intravenous therapy, the authors calculated number needed to treat, in which the number of oral rehydration therapy patients successfully treated was compared with 1 successfully treated intravenous therapy patient.

MAIN RESULTS

There were 17 trials in the review, of which 2 were quasi-randomized trials. One study was analyzed as 2 separate studies because patients were concurrently enrolled in 2 different countries and in 2 slightly different study designs. There were 1,811 study participants, whereas 1,015 patients (56%) were randomized to the oral rehydration therapy. There was a statistical difference favoring intravenous therapy for rehydration or maintenance of hydration. The risk difference was 4% (95% CI 1% to 7%). The number needed to treat was

Table 1. Comparison of risk difference of failure to rehydrate between oral rehydration therapy (any solution) versus intravenous therapy.

Study, y	ORT, n/N	IVT, n/N	Risk Difference, Random Effects (95% CI)
Inpatient, subtotal	44/882	5/669	0.04 (0.00 to 0.07)
Outpatient, subtotal	22/133	18/127	0.03 (−0.05 to 0.1)
Total	66/1015	23/796	0.04 (0.01 to 0.07)

ORT, Oral rehydration therapy; IVT, intravenous therapy.

25 (95% CI 14 to 100). The failure rate for oral rehydration therapy was 4.9% compared with 1.3% for intravenous therapy (Table 1).

Death was identified as the other primary endpoint by the authors. They identified only 4 trials reporting this outcome and the causes. All deaths occurred in trials in which the study was conducted in low- to middle-income countries.

When the secondary outcomes were analyzed, the authors showed there was no statistical significance for differences in weight gain at discharge, hyponatremia, hypernatremia, duration of dehydration, total fluid intake at 6 hours and 24 hours, or amount of sodium intake and sodium levels. There was one exception, the length of stay in the hospital. Children treated with oral rehydration therapy spent less time in the hospital (weighted mean difference=1.20 days, 95% CI −2.38 to −0.02).

There were 2 identified complications of therapy. Paralytic ileus was identified more often in the oral rehydration therapy group (risk difference=3%; 95% CI 1% to 5%). The number needed to treat to prevent 1 case of paralytic ileus was 33. The second complication was phlebitis, which occurred more frequently in the intravenous therapy group (risk difference=2%; 95% CI 1 to 4).

CONCLUSIONS

The authors demonstrated that there was a statistical difference favoring intravenous therapy. However, this statistical difference does not have clinical importance in the treatment of gastroenteritis. Oral rehydration therapy has the advantages of lower cost and ease of use by the provider and allows for moderation of fluids by quantity and rate to match the levels of thirst of the patient. This advantage is observed in patients with mild to moderate gastroenteritis. For those patients with severe dehydration or shock, intravenous therapy is better therapy because ongoing fluid losses from vomiting, diarrhea, or third spacing within the lumen of the gut are matched by a constant fluid infusion.

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COMMENTARY: CLINICAL IMPLICATIONS

Acute gastroenteritis in children is a common disease in which excess fluid losses from vomiting and diarrhea can lead to dehydration. Dehydration causes significant morbidity and mortality. From an epidemiologic standpoint, gastroenteritis is a worldwide problem in which 1.5 billion episodes lead to 2.5 million deaths per year among children younger than 5 years.¹ In the United States, children make more than 1.5 million visits in the outpatient setting, 200,000 require hospitalization, and approximately 200 children die each year from diarrhea-related illnesses.¹

The cornerstone of treatment is rehydration therapy and the controversy clinically is whether to use oral or intravenous fluid therapy. Therapy choices are largely dictated by the degree of dehydration. Severe dehydration is best treated with intravenous fluid therapy that allows for rapid restoration of intravascular volume. The benefit of rapid fluid restoration is counterbalanced by the pain of intravenous catheter placement, risks of rapid electrolyte and fluid imbalances, and infection of skin and vasculature.

Despite the frequency of acute gastroenteritis presentations to EDs, most children with gastroenteritis present with mild to moderate levels of dehydration. Oral rehydration therapy may be the better choice in this group of patients. Children will moderate their fluid intake because their physiologic tolerance will limit its amount and rate of intake. Their physiologic tolerance will minimize rapid electrolyte and fluid imbalances. Successful fluid replacement, however, will often require education and hours of fluid feedings, provided by a diligent and willing caregiver.

Using methods to reduce publication and selection bias, this Cochrane review examined the effectiveness and safety of oral versus intravenous rehydration in acute gastroenteritis. From 17 clinical trials involving 1,801 children, the authors concluded that oral rehydration therapy is an effective treatment for mild to moderate dehydration caused by acute gastroenteritis. Oral rehydration therapy is efficacious in children from high-income, as well as low-income, countries. Children from low-income countries have poorer nutritional states, ie, their gastrointestinal tract does not absorb nutrients as well, tolerate oral fluids readily, and recover from dehydrating effects of gastroenteritis. Finally, oral rehydration therapy is efficacious, despite heterogeneity in the definition of treatment failure among

Table 2. Two-by-two table.

	Outcome	No Outcome
Treatment	a	b
Control	c	d

studies of the review. Oral rehydration therapy is successful for a large number of patients from different populations.

TAKE-HOME MESSAGE

Oral rehydration therapy is effective to rehydrate children with mild to moderate dehydration from acute gastroenteritis. Oral rehydration therapy is comparable to intravenous fluid therapy in terms of fluid replacement success.

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EBEM TEACHING POINT

Readers of clinical studies should understand how results are presented. Results describe a benefit or harm when treatment is compared with a control (standard care or placebo agent[s]). The results are statistically described as risk, risk ratio (relative risk), and risk difference, or odds and odds ratio. When results are tabulated in a 2×2 table, the study population is dichotomized into 2 groups: outcomes (yes/no) and treatment (yes/no) groups (Table 2).

Risk is a probability of disease in a particular patient group. From Table 2, risk is the proportion of patients at risk of disease compared with the total population at risk. In the treated group, the risk of disease is calculated as $a/(a+b)$, whereas in the control group, the risk of disease is calculated as $c/(c+d)$. Odds describe another method to compare events. In clinical research, odds are the number of patients with the outcome compared with the number of patients without the outcome. From Table 2, the odds of the outcome in the treatment group is a/b , whereas the odds of disease in the control group is c/d .

A simple method to compare the risk between 2 groups is to calculate a risk difference. Risk difference is the arithmetic difference between the outcome risk in the treated group and the outcome risk in the control group. The risk difference is $[c/(c+d)] - [a/(a+b)]$ (Table 2). From the concept of risk difference, “number needed to treat” can be derived by taking the reciprocal of the risk difference. The number needed to treat signifies the number of patients who need to be treated to prevent 1 additional patient from developing the outcome. From this Cochrane study, the risk difference is 4%; its reciprocal (number needed to treat) is 25 patients. In other words, 25 patients with acute gastroenteritis would need to be treated with oral rehydration to prevent 1 failure in treatment.

Researchers can measure the relative strength of association of therapy or harm by using RR (relative risk) and odds ratio. A RR is a proportion of patients experiencing the outcome between treated and control groups. RR measures the relative size of difference in event rate between the 2 groups.² From Table 2, the RR is $[a/(a+b)]/[c/(c+d)]$.

On the other hand, an odds ratio compares the ratio of events within the treated (“exposed”) to those within the control (“unexposed”) groups. From Table 2, the odds ratio is $(a/b)/(c/b)$, which is equivalent to the cross-product of $(ad)/(cd)$. Odds ratios are calculated in case-control studies because these studies have a retrospective study design, and they are also calculated to study rare diseases. The further the value of RR or odds ratio is from 1 (unity) in either direction, the stronger the association.³ A RR can directly measure the risk of association, whereas an odds ratio only estimates the association.

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