Does oral rehydration therapy work for acute gastroenteritis?

Spandorfer et al. Oral versus intravenous rehydration of moderately dehydrated children: a randomized, controlled trial. Pediatrics 2005; 115:295-301.

Take Home Message: Oral rehydration therapy (ORT) is as effective as intravenous fluids (IVF) in rehydration of moderately dehydrated children due to gastroenteritis.

Highlights: The AAP and WHO recommend ORT as first-line therapy for children with mild to moderate dehydration; however, many providers continue to use IV fluids for rehydration. Prior studies investigating ORT vs. IVF lacked masking or a standardized definition of dehydration, and many of them took place in inpatient settings or developing countries. Spandorfer et al. published this randomized, single-masked (the ED physicians were masked to study assignment) study[i] in 2005, in which children with moderate dehydration from presumed viral gastroenteritis in an urban academic hospital emergency room were randomized to be rehydrated with either ORT or IVF. There was no difference between the two groups in the primary outcome defined as resolution of the moderate dehydration. In fact, ORT was superior in some aspects – the time to initiate therapy was shorter. There were also fewer hospitalizations in the ORT group (though this was not found to be significant). This study provides further evidence to support the AAP and WHO's recommendations that ORT, a simple, low-cost and less painful treatment, should be the first-line in rehydrating mild to moderately dehydrated children. Interestingly, a multicenter retrospective study that came out in 2014[ii] revealed that IV rehydration rates were unchanged between 2002 and 2011.

The Nitty-Gritty:

- **Design:**

- Randomized, single-blind, controlled clinical trial (noninferiority study design)
- N= 73
  - ORT group (n=36)
  - IVF group (n=37)
- Setting: Children's Hospital of Philadelphia Emergency Room
- Enrollment: 2001-2003
- Primary outcome: success of treatment in the ED at 4 hours, defined as resolution of moderate dehydration (based on a dehydration score that would indicate mild to no dehydration), weight gain, production of urine output during the trial, and absence of severe emesis
- Analysis: intention-to-treat

- **Population:**
  - **Inclusion Criteria:**
    - Children 8 weeks – 3 years old
    - Moderately dehydrated (based on a 10-point dehydration score found to have excellent interrater reliability, corresponding to 5-10% dehydrated)

- § Diagnosis of probable viral gastroenteritis (defined as ≥3 loose or watery stools in the previous 24 hours)
- § Parent or legal guardian available to remain with patient
- § Phone number at which they could be contacted at 72 hours for follow-up

- o **Exclusion Criteria**
  - § Hypotension (systolic BP ≥2SDs below the mean for age on 2 repeated measures)
  - § Duration of illness > 5 days
  - § History of chronic illness that would influence fluid status
  - § Malnutrition/failure to thrive
  - § Impaired oromotor skills
  - § Received treatment at any ED within the preceding 12 hours

- o **Baseline Characteristics –** values are means from the ORT group if one value listed, otherwise ORT vs. IVF
  - § Age: 15.8 months
  - § Gender: 52.8% vs. 75.7% male

§ Race: 19.4% vs. 16.2% non-Hispanic white; 72.2% vs. 81.1% black, 8.3% vs. 2.7% other

§ # of emesis episodes in previous 24 h: 7.3

§ # of diarrhea episodes in previous 24 h: 6.8 vs. 8.9

§ Baseline dehydration score (3-7 is moderately dehydrated): 4.3

§ Referred by primary medical doctor: 36.1% vs. 48.7%

§ Triage heart rate: 142 bpm

§ Triage temperature: 37.7 degrees Celsius

§ Saw primary medical doctor prior to coming to ED: 30.6%

§ Accompanied by:

- Mother only: 63.9% vs. 70.3%
- Father only: 0% vs. 8.1%
- Both parents: 36.1% vs. 21.6%

§ First-born child: 38.9%

§ Mother employed: 45.5% vs. 62.2%

- § Maternal education: 12.9 months

- **Intervention**: Children who met inclusion criteria were randomized to either ORT or IVF treatment group and rehydrated during a 4-hour study period. Patients in the ORT group received Pedialyte at 50-75 ml/kg orally over 4 hours in equal 5-minute aliquots by the parents after instruction on proper ORT techniques from a formally trained nurse or NP. Patients in the IVF group had an IV placed and received two 20 ml/kg normal saline boluses within the first hour. The treating physician was masked to the assignment of the patients

- **Outcomes:** comparisons are ORT vs. IVF

  - **Primary outcome:** success of treatment in the ED at 4 hours, defined as resolution of moderate dehydration, weight gain, production of urine output during the trial, and absence of severe emesis

    - § 55.6% vs. 56.8% (risk difference -1.2%, 95%CI -24.0% to 21.6%)

    - § ORT-treated patients demonstrated noninferiority in individual measures: resolution of moderate dehydration, production of urine, absence of severe emesis. More patients treated with IVF had weight gain:

      - Weight gain: 82.8% vs. 100% (difference -17.2%, 95%CI -31.0 to -3.5%)

  - **Secondary outcomes:**

    - § **Time to initiate therapy (minutes):** 19.9 +- 13.4 vs. 41.2 +- 29.4 (difference of 21.2 minutes, 95% CI 10.3 to 32.1)

§ **Improvement in the dehydration score after 2 hours of therapy:** 78.8% vs. 80% (difference of -1.2%, 95% CI -20.5% to 18%)

§ **Hospitalization rate:** 30.6% vs. 48.7% (difference of -18.1%, 95% CI -40.1% to 4.0%)

§ **Parental preference for same therapy next time:** 61.3% vs. 51.4% (difference of 9.9%, 95% CI -14 to 33.7)

§ **72-hour ED revisits**: 9.1% vs. 8.3% (difference of 0.8%, 95% CI -12.6% to 14.1%)

- **Criticisms**

o Patients were not enrolled after 8pm when children and parents may be too tired to to perform ORT[iii]

o 15.2% were unable to perform ORT suggesting that ORT is not as predictably usefuliii

[i] Spandorfer et al. Oral versus intravenous rehydration of moderately dehydrated children: a randomized, controlled trial. Pediatrics 2005; 115:295-301.

[ii] Freedman et al. Impact of increasing ondansetron use on clinical outcomes in children with gastroenteritis. JAMA Pediatr 2014; 168(4): 321-329.

[iii] Reid S. Comment on Oral versus intravenous rehydration of moderately dehydrated children. Pediatrics 2005; 115:1788