



## Article Appraisal

**Article:** Effect of Dilute Apple Juice and Preferred Fluids vs. Electrolyte Maintenance Solution on Treatment Failure Among Children With Mild Gastroenteritis: A Randomized Clinical Trial

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### Background and Study Objective(s):

To determine if oral hydration with dilute apple juice/preferred fluids is non-inferior to oral electrolyte maintenance solution in children with mild gastroenteritis.

According to the study authors, most evidence for oral rehydration solutions comes from low and middle-income countries where significant dehydration and hyponatremia are more prevalent than in developed countries. The need for strictly balanced salt and glucose solutions may not be the same in high-income countries where diseases like cholera and rotavirus are less prevalent. Furthermore, electrolyte solutions do not taste good to many children and are expensive. Both the AAP (American Academy of Pediatrics) and CPS (Canadian Pediatrics Society) recommended using an oral electrolyte solution such as Pedialyte although surveys shows this recommendation is not universally followed in both the USA and Canada.

### Study Design:

This was a randomized, single blind non-inferiority trial in a pediatric tertiary care centre in Toronto (Sick Kids). The non-inferiority cut-off was based on focus group data and chosen to be a treatment failure rate 7.5% above the oral electrolyte solution group. Patients' eligibility and randomization were done at triage in the ED. Study participants were aged 6-60 months, diagnosed with gastroenteritis and minimally dehydrated according to the Clinical Dehydration Scale (score 0-4 out of a possible 8). Kids with complicating gastrointestinal comorbidities or red flags such as an acute abdomen or hematochezia were excluded from the study.

Patients and healthcare providers were blinded in the ED; however, caregivers were unblinded after discharge as they were given a sealed letter to open at home that advised them which type of oral solution to keep using.

Patients were phoned daily by a study nurse until asymptomatic for 24 hours and were offered a 72-hour

re-assessment at the hospital by a study nurse, with physician reassessment if clinical criteria were met. The daily phone calls recorded relevant study outcomes (see below) and clinical course.

The primary outcome was “treatment failure” of the oral solution given (dilute apple juice or oral electrolyte solution). This was a composite outcome that included any of the following within 7 days of the index visit: (1) hospitalization or (2) intravenous fluid resuscitation at any time, (3) a >3% weight loss or >5 clinical dehydration scale score at re-assessment visit 72-84h after presentation, (4) unscheduled healthcare visit, (5) crossover into the other group, or (6) extended symptomatology beyond 7 days from index visit. An intention-to-treat analysis was used.

Parents mailed final details regarding symptoms and repeat healthcare visits in to the hospital or dropped them off in person. Data verification was done with two provincial registries.

## Results:

Dilute apple juice was found to be not only non-inferior, but also superior ( $p=0.006$ ) to an oral electrolyte solution in treating mild gastroenteritis in this patient population. Subgroup analysis shows benefit mainly was seen in patients older than 24 months.

## Validity of Results:

As a single-blinded study, there was potential for bias from parents that were aware of the solution given after leaving the ED. Similarly, children that are old enough to discriminate may also have disclosed the study solution to caregivers and healthcare providers. Blocks of 8 were used for randomization, meaning that if participants became unblinded during the process they potentially would know the status of all the other patients in that block. Selection bias exists in that patients were only recruited 6 days a week, for 12 hours per day from October to April. There was excellent follow-up achieved (99.5%) in both groups. While some outcomes were self-reported by parents, all health services utilization outcome measures were verified using reliable provincial administrative data.

Both groups were similar in their characteristics after randomization and had both groups had similar rates of ondansetron administration.

## Generalizability of Results:

As a Canadian study done in an urban centre, the results are likely generalizable to our patient population in the Lower Mainland of British Columbia. It is reasonable to expect similar pathogens, demographics and vaccination rates in Vancouver and Toronto. The study was done at a pediatric tertiary care centre, which may mean its results are less generalizable to community hospitals that see patients of all ages.

## The Bottom Line:

Although this study has not been externally validated (including in community hospitals), half-strength apple juice is likely an excellent alternative to oral electrolyte solutions in high-income countries for patients meeting the study inclusion criteria, particularly if they are between 2 and 5 years of age, and is cheaper.