A Randomized Trial of Oral vs Intravenous Rehydration in a Pediatric Emergency Department

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Background: Physicians report several barriers to the use of oral rehydration therapy (ORT) for dehydration in children due to acute gastroenteritis.

Objectives: To compare ORT with intravenous therapy for the treatment of moderate dehydration in children with acute gastroenteritis and to determine whether the factors reported as barriers to the use of ORT would be substantiated in practice.

Methods: Randomized controlled trial in an urban pediatric emergency department. Children with moderate dehydration due to acute gastroenteritis were randomly assigned to ORT (group 1) or intravenous therapy (group 2). The primary outcome was length of stay in the emergency department. Secondary outcomes included hospital admission rate, staff time, relapse after discharge from the hospital, and parental satisfaction. Two days after discharge, parents were surveyed by telephone to assess the relapse and their satisfaction with the visit.

Results: Eighteen patients were enrolled in group 1 and 16 in group 2. The mean length of stay in group 1 was 225 vs 358 minutes in group 2 (P<.01). Mean staff time was 35.8 minutes in group 1 compared with 65 minutes in group 2 (P=.03). Three patients failed ORT and required intravenous therapy. Two patients (11%) in group 1 vs 4 (25%) in group 2 required admission to the hospital (P=.20). No patients relapsed after being discharged from the hospital. Fourteen parents (77%) in group 1 compared with 6 (37.5%) in group 2 reported that they were highly satisfied with all aspects of the visit (P=.01).

Conclusions: Reported barriers to ORT were not supported by our data. Moreover, ORT performed better than intravenous therapy on all measured outcomes.

Arch Pediatr Adolesc Med. 2002;156:1240-1243
drowsiness, thirst, and postural hypotension. Patients with chronic illness, severe dehydration or shock, protracted vomiting, absent bowel sounds, no accompanying guardian, or no contact telephone number, and those requiring intravenous access for reasons other than hydration, were excluded. The study was approved by the Committee on Clinical Investigations at the Albert Einstein College of Medicine, Bronx, NY.

After parental consent, eligible patients were randomly assigned to receive ORT or IVT. Randomization was accomplished by placing odd and even numbers in a sealed, opaque container. A clerical staff member drew a number that was then assigned to the child. Children assigned even numbers underwent treatment with ORT; children given odd numbers underwent treatment with IVT. Children assigned to the IVT group received an initial bolus of 20 mL/kg of an isotonic sodium chloride solution over a 30-minute period. A second bolus of an isotonic sodium chloride solution was administered if necessary, as determined by the treating physician. This was followed by an intravenous solution of 5% dextrose in 0.45% saline in children 2 years and older, and 5% dextrose in 0.33% saline in children younger than 2 years. The dextrose-saline solution was administered at a rate of 1 1/2 times daily maintenance. Commercially prepared oral maintenance electrolyte solutions were introduced during maintenance therapy, at a rate of 5 mL or 10 mL every 5 minutes, depending on the age of the child. Children assigned to the ORT group received commercially prepared oral maintenance electrolyte solutions at a rate of 5 mL every 5 minutes if they were younger than 4 years, and 10 mL every 5 minutes if they were 4 years or older. If the child did not vomit during the first hour of ORT, intake was advanced to twice the initial volume and given every 5 minutes. Oral fluids were withheld for 30 minutes if the patient vomited, and then were restarted at the initial rate. Oral fluids were administered by a parent or guardian. Patients who vomited 3 or more times after the initiation of oral therapy were considered to have failed ORT and IVT was started. Because this was an intention-to-treat study, these patients remained in the ORT group for data analysis.

All patients were evaluated at 30- to 60-minute intervals. Stool cultures and serum chemistry studies were obtained at the discretion of the treating attending physician. The decision to discharge the patient from the PED was made by the attending physician when the patient's presenting signs and symptoms of dehydration were reversed and vomiting had ceased. Patients who continued to vomit despite IVT and withholding of oral fluids were hospitalized.

The primary outcome measure was duration of PED stay, defined as time from enrollment to final disposition. Secondary outcomes included staff time required for patient care, hospital admission rate, relapse after being discharged from the hospital, and parental satisfaction with care. All medical caregivers documented the time spent providing patient care. Two to 4 days after discharge from the PED, an investigator, blinded to the patient's treatment group assignment, surveyed parents by telephone to assess relapse, as well as satisfaction with the visit. Relapse was determined by inquiring whether the patient required additional unscheduled medical intervention for the same complaint. Satisfaction was assessed using the modified Patient Satisfaction Questionnaire. We estimated that 34 patients were needed to detect a difference of 60 minutes in the duration of therapy between the 2 groups, with a power of 80% and an α level of .05.

Data were entered using Epitrope version 6.0 (Centers for Disease Control and Prevention, Stone Mountain, Ga). Means and proportions were calculated using descriptive statistics. Differences in proportions were tested using the χ² test; t tests were used to compare the groups on continuous variables. Analysis of covariance for continuous outcomes and logistic regression analyses for dichotomous outcomes were conducted using SPSS for Windows version 10.0 (SPSS, Chicago, Ill).

RESULTS

Two hundred sixty-nine patients were evaluated for eligibility (Figure). Thirty-four children were enrolled. No parent of an eligible child refused to participate. Eighteen children were randomized to the ORT group, and 16 to the IVT group. Demographic and baseline data are noted in Table 1. The 2 groups were similar for age, sex, and ethnicity. The mean number of dehydration criteria met by the patients in each group was similar (5.1 ORT vs 4.9 IVT).

Differences in outcomes are noted in Table 2. There was a statistically significant difference in the mean duration of PED stay. Compared with children in the IVT group, the mean PED staff time required for children in the ORT group was significantly less. When staff time required for patient care was subtracted from the length of PED stay, the difference in length of PED stay between the 2 groups remained significant. Three patients in the ORT group failed ORT and received IVT. Four patients (25%) in the IVT group required hospital admission for continued symptoms, compared with 2 patients...
Table 2. Outcomes by Treatment Group

<table>
<thead>
<tr>
<th>Outcome</th>
<th>ORT (n = 18)</th>
<th>IVT (n = 16)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>LOS, min</td>
<td>224.7 (77.8)</td>
<td>358.0 (160.0)</td>
<td>&lt;.01</td>
</tr>
<tr>
<td>PED staff time, min</td>
<td>35.8 (32.0)</td>
<td>65.0 (44.0)</td>
<td>.03</td>
</tr>
<tr>
<td>LOS-PED staff time, min</td>
<td>188.9 (86)</td>
<td>293.0 (174)</td>
<td>.03</td>
</tr>
<tr>
<td>Patients who were highly satisfied with the visit, % (95% CI)</td>
<td>77.7 (52.4-93.6)</td>
<td>37.5 (15.2-64.6)</td>
<td>.01</td>
</tr>
<tr>
<td>Patients who were hospitalized, % (95% CI)</td>
<td>11.1 (1.4-34.7)</td>
<td>25.0 (4.5-36.1)</td>
<td>.2</td>
</tr>
<tr>
<td>Patients who relapsed, %</td>
<td>0</td>
<td>0</td>
<td></td>
</tr>
</tbody>
</table>

*Data are given as mean (SD) unless otherwise indicated. ORT indicates oral rehydration therapy; IVT, intravenous therapy; LOS, length of stay; PED, pediatric emergency department; and CI, confidence interval.

(11%) in the ORT group, but this difference was not statistically significant. No patients in either group were reported to have relapsed after discharge. Parents of children in the ORT group were significantly more likely to report that they were highly satisfied with all aspects of the visit compared with parents of children in the IVT group. After controlling for length of PED stay, parents of children in the ORT group were 6.5 times more likely to report they were highly satisfied with all aspects of the visit than parents of children in the IVT group (95% confidence interval, 15.0-36.8) (P = .03).

For many decades, traditional therapy for diarrhea and dehydration was hospital admission and withholding of feedings until the diarrhea ceased. Early attempts at using oral rehydration solutions were unsuccessful, largely because of an inappropriate glucose-sodium ratio. In 1960, the combined transport of glucose and sodium was elucidated, leading to a renewed interest in the use of oral rehydration solution for the treatment of dehydration.12

The First International Conference on Oral Rehydration Therapy (ICORT I) was conducted in 1983. Over the next 3 years, there was a concerted effort to familiarize governments and health care professionals with oral rehydration solution and to promote its implementation. In 1985, representatives from 100 countries attended ICORT II in Washington, DC. World Health Organization (WHO) Diarrheal Disease Control (CDD) Programs were multiplying and were present in countries inhabited by more than 95% of the developing world’s population. Data from ICORT II showed that with the widespread use of oral rehydration solution, some countries reported a reduction in mortality as high as 50%.13

Although the effect of diarrhea and dehydration is less significant in the United States when compared with developing countries, it remains an important public health issue and the cause of childhood morbidity and mortality. Children younger than 3 years are estimated to have from 1.3 to 2.3 episodes of diarrheal illness annually. These rates are higher among children who attend day care centers.2 Additionally, 300 to 400 children die each year of complications associated with AGE.3

Multiple studies have been published documenting the effectiveness of the use of ORT for the treatment of mild to moderate dehydration secondary to AGE. In 1996, the American Academy of Pediatrics (AAP) published a practice parameter for the treatment of children with AGE, and recommended the use of ORT for mild to moderate dehydration.2 Despite these findings, as well as additional data showing that ORT is less costly than IVT,4,5 physicians in the developed world continue to preferentially use IVT for the treatment of moderate dehydration.

In 1994, Reis et al6 surveyed general pediatricians to determine their knowledge of and attitudes toward ORT, and to identify potential barriers to the use of ORT. They found that although most respondents recognized the importance of ORT, compliance with AAP guidelines was limited. Some of the reported barriers to the use of ORT in practice included the belief that ORT administration was inconvenient, that parents would not be able to continue the rehydration regimen at home, that support staff preferred IVT and would require additional training to administer ORT, and that reimbursement for ORT would be less likely than for IVT.

More recently, Ozuah et al8 surveyed emergency department physicians to determine the relationship between the use of ORT and knowledge of the AAP practice parameters. They found that, overall, only 15.3% of emergency department physicians “almost always” or “always” use ORT for children with moderate dehydration secondary to gastroenteritis. Although physicians who reported that they were “very familiar” with AAP recommendations were more likely to use ORT as a first-line therapy for moderate dehydration than were physicians who were unfamiliar, the use of ORT was extremely limited in both groups (25% vs 0%).

Another study by Connors et al9 surveyed pediatric emergency medicine fellowship program directors to compare their use of ORT with AAP recommendations. In response to a series of 10 clinical scenarios of children with mild or moderate dehydration, 17.2% reported that they believed ORT was a better treatment, although only 6.7% said they would use ORT in all 10 scenarios. Most respondents believed that ORT would require additional staff time or a longer treatment time in the emergency department. Approximately half of the respondents believed that parents and/or primary care physicians expected the child to receive IVT.

Our data showed that when subjected to a randomized clinical trial, the barriers reported by physicians in these surveys were not upheld. In fact, our data showed that ORT performed better than IVT in terms of treatment time in the PED, in the use of staff time, and for parental satisfaction.

There were some limitations to our study. The definition of moderate dehydration was based on standard clinical criteria, some of which are subjective. Therefore, there was a possibility of misclassification of patients in terms of degree of dehydration. However, the
The use of ORT for the treatment of mild to moderate dehydration secondary to AGE is recommended by the AAP and the Centers for Disease Control and Prevention. Despite data from several studies showing that ORT is as effective as, and less costly than IVT, physicians continue to preferentially use IVT. Reported barriers to the use of ORT include the belief that parents and referring physicians expect IVT and that ORT would require additional staff time and training and a longer treatment time in the PED.

This study subjected the reported barriers to the use of ORT for moderate dehydration from AGE to a randomized controlled trial. Compared with children assigned to IVT, children randomized to ORT required less staff time and had a shorter length of PED stay, and their parents were more likely to be highly satisfied with all aspects of the visit. The barriers reported by physicians to the use of ORT were not substantiated in practice. In light of existing literature supporting the use of ORT, physicians should incorporate ORT into their practice.

mean number of clinical criteria associated with moderate dehydration was approximately the same in the 2 groups, suggesting that the groups were similar in percentage of dehydration. Documentation of PED staff time was gathered by self-report; there is a possibility that some patient encounters may not have been documented. However, there is no reason to believe that underreporting would be disproportionate between the groups. Since the satisfaction survey was not administered anonymously, parents may have been reluctant to report dissatisfaction. Again, reluctance to report dissatisfaction would be unlikely to be disproportionate, and the difference between the 2 groups was significant. Finally, it is possible that our small sample is not representative of the general population of moderately dehydrated US children. However, our PED serves a large, self-referred, heterogeneous population. Therefore, a sample from this population should reflect urban children seeking care for moderate dehydration.

Our data showed that barriers to the use of ORT as reported by physicians were not substantiated in practice. In light of the extensive literature concerning the efficacy of ORT, if further investigations confirm our findings concerning barriers to the use of ORT in the PED, physicians should consider changing their clinical practice when treating children with AGE and moderate dehydration.

Accepted for publication August 1, 2002.

We are grateful to Ellen Johnson Silver, PhD, for assistance with data analysis.

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REFERENCES