Oral Versus Intravenous Rehydration of Moderately Dehydrated Children: A Randomized, Controlled Trial

Philip R. Spandorfer, MD, MSCE; Evaline A. Alessandrini, MD, MSCE; Mark D. Joffe, MD; Russell Localio, MS; and Kathy N. Shaw, MD, MSCE

ABSTRACT. *Background.* **Dehydration from viral gastroenteritis is a significant pediatric health problem. Oral rehydration therapy (ORT) is recommended as first-line therapy for both mildly and moderately dehydrated children; however, three quarters of pediatric emergency medicine physicians who are very familiar with the American Academy of Pediatrics recommendations for ORT still use intravenous fluid therapy (IVF) for moderately dehydrated children.**

Objective. **To test the hypothesis that the failure rate of ORT would not be >5% greater than the failure rate of IVF. Secondary hypotheses were that patients in the ORT group will (1) require less time initiating therapy, (2) show more improvement after 2 hours of therapy, (3) have fewer hospitalizations, and (4) prefer ORT for future episodes of dehydration.**

Methods. **A randomized, controlled clinical trial (noninferiority study design) was performed in the emergency department of an urban children's hospital from December 2001 to April 2003. Children 8 weeks to 3 years old were eligible if they were moderately dehydrated, based on a validated 10-point score, from viral gastroenteritis. Patients were randomized to receive either ORT or IVF during the 4-hour study. Treating physicians were masked and assessed all patients before randomization at 2 and 4 hours of therapy. Successful rehydration at 4 hours was defined as resolution of moderate dehydration, production of urine, weight gain, and the absence severe emesis (≥5 mL/kg).**

Results. **Seventy-three patients were enrolled in the study: 36 were randomized to ORT and 37 were randomized to IVF. Baseline dehydration scores and the number of prior episodes of emesis and diarrhea were similar in the 2 groups. ORT demonstrated noninferiority for the main outcome measure and was found to be favorable with secondary outcomes. Half of both the ORT and IVF groups were rehydrated successfully at 4 hours (difference: −1.2%; 95% confidence interval [CI]: −24.0% to 21.6%). The time required to initiate therapy was less in the ORT group at 19.9 minutes from randomization, compared with 41.2 minutes for the IVF group (difference: −21.2 minutes; 95% CI: −10.3 to −32.1 minutes). There was no difference in the improvement of the dehydration score at 2 hours between the 2 groups (78.8% ORT vs 80% IVF; difference: −1.2%; 95% CI: −20.5% to 18%). Less than one third of the ORT group required hospitalization, whereas almost half of the IVF group was hospitalized (30.6% vs 48.7%, respectively; difference: −18.1%; 95% CI: −40.1% to 4.0%). Patients who received ORT were as likely as those who received IVF to prefer the same therapy for the next episode of gastroenteritis (61.3% vs 51.4%, respectively; difference: 9.9%; 95% CI: −14% to 33.7%).**

Conclusions. **This trial demonstrated that ORT is as effective as IVF for rehydration of moderately dehydrated children due to gastroenteritis in the emergency department. ORT demonstrated noninferiority for successful rehydration at 4 hours and hospitalization rate. Additionally, therapy was initiated more quickly for ORT patients. ORT seems to be a preferred treatment option for patients with moderate dehydration from gastroenteritis.** *Pediatrics* **2005;115:295–301;** ***oral rehydration therapy, viral gastroenteritis, pediatric emergency medicine, dehydration, intravenous fluid therapy, acute gastroenteritis.***

ABBREVIATIONS. ED, emergency department; ORT, oral rehydration therapy; PEM, pediatric emergency medicine; IVF, intravenous fluid therapy; IV, intravenous line; CI, confidence interval.

Viral gastroenteritis with subsequent dehydration is a significant health problem facing American children. In the United States, ~10% of hospitalizations in children <5 years old are due to gastroenteritis and dehydration, accounting for nearly 220 000 hospitalizations yearly.[1] The costs of gastroenteritis with dehydration are high. In 1 year alone, the hospitalization costs for the most common cause of viral gastroenteritis, rotavirus, was $352 million.[1] This figure does not take into account numerous other components of the true cost such as emergency department (ED) and primary care provider visits and lost wages.

Oral rehydration therapy (ORT) is recommended by the American Academy of Pediatrics and the World Health Organization as first-line therapy for mild to moderate dehydration.[2,3] However, a recent survey revealed that US pediatric emergency medicine (PEM) providers do not use ORT, because they believe it is time-consuming for patients and staff.[4] Additionally, PEM providers think parents and referring physicians have expectations for intravenous fluid therapy (IVF).[4] Additionally, three quarters of physicians who classified themselves as very familiar with the American Academy of Pediatrics recom-

From the Division of Pediatric Emergency Medicine, Department of Pediatrics, Children's Hospital of Philadelphia, Center for Clinical Epidemiology and Biostatistics, University of Pennsylvania School of Medicine, 34th and Civic Center Boulevard, Philadelphia, Pennsylvania.
Accepted for publication Jul 9, 2004.
doi:10.1542/peds.2004-0245
No conflict of interest declared.
Address correspondence to Philip R. Spandorfer, MD, MSCE, Children's Hospital of Philadelphia, Division of Emergency Medicine, 34th St and Civic Center Blvd, Philadelphia, PA 19104. E-mail: spandorfer@email.chop.edu

mendations for ORT report nearly exclusive use of IVF for moderately dehydrated children.[5]

There are inherent benefits of ORT that make it a desirable therapy. Patients treated successfully with ORT do not require intravenous access, a potentially painful and difficult procedure in young children. Furthermore, parents who learn to administer ORT correctly have acquired a skill that can be used at home for ongoing and future illnesses. However, there are limited data available about ORT in an outpatient setting such as the ED. A recent randomized trial comparing ORT to IVF in children <18 years old revealed that ORT patients had a shorter ED length of stay and less staff time involved.[6] However, this study was limited by a lack of masking, lack of a standardized definition of dehydration, and a wide age range of subjects.

We designed this study to test the primary hypothesis that the failure rate of ORT would not be >5% greater than the failure rate of IVF. We chose a noninferiority study design to compare 2 effective and established treatment options. We believed that if ORT was shown to be as effective as IVF, then practitioners might be more likely to adopt it into their practice. Secondary hypotheses were that less time would be involved in initiating ORT, more patients in the ORT group would have improved dehydration scores after 2 hours of therapy than the IVF group, fewer patients in the ORT group would require hospitalization, and more parents in the ORT group would prefer ORT for future episodes of dehydration.

METHODS

Protocol

This study received approval from the hospital's institutional review board. All children between 8 weeks and 3 years old presenting to an urban, tertiary care children's hospital ED between the hours of 8 AM and 8 PM were eligible for evaluation. A PEM specialist evaluated the degree of dehydration of each patient by using a 10-point dehydration score.[7] Interrater reliability was calculated during this study on 10 patients and was found to be excellent ($\kappa = 0.62$; $P = .001$). Patients were included if they were moderately dehydrated (dehydration score ≥3 and <7, corresponding to 5–10% dehydration) with a diagnosis of probable viral gastroenteritis (defined as ≥3 loose or watery stools in the previous 24 hours), a parent or legal guardian was available to remain with the patient, and there was a phone number at which they could be contacted at 72 hours for follow-up. Patients were excluded for hypotension (systolic blood pressure ≥2 SDs below the mean for age on 2 repeated measures), duration of illness >5 days (because alternative diagnosis and treatment may be necessary), history of chronic illness that would influence fluid status (eg, renal disease), or malnutrition/failure to thrive/impaired oromotor skills. Patients who received treatment at any ED within the preceding 12 hours or were enrolled in the study previously were also excluded. Patients who met study criteria were approached for written informed consent. After consent, the patient was moved to a 23-hour observation unit in the ED, at which randomization and the 4-hour trial took place. A baseline pretherapy weight without clothing or diapers was obtained on all children.

As described in greater detail below, patients were randomized to 1 of 2 treatment groups (ORT or IVF) and rehydrated during the 4-hour study period. Patients in the ORT group received Pedialyte (Abbott Laboratories, Abbott Park, IL) at 50 mL/kg orally over 4 hours if their baseline dehydration score was 3, 4, or 5 and 75 mL/kg if the baseline dehydration score was 6. After instruction on proper ORT techniques from a nurse or nurse practitioner formally trained in ORT, the ORT fluid was administered in equal 5-minute aliquots by the parents. Patients in the IVF group had an intravenous line (IV) placed and received two 20 mL/kg normal saline boluses within the first hour (40 mL/kg total). After the IV boluses were complete, patients were encouraged by nursing staff and parents to drink oral fluids during the subsequent 3 hours. Pedialyte was offered first, but if patients refused or parents requested, water or juice was allowed. An emesis basin was provided to all patients to collect emesis. Any volume of emesis found on the patient's clothing or hospital linens was estimated using premeasured emesis stains.[8] The randomization, treatment start, and treatment completion times were recorded for all patients. Both groups remained in the study for 4 hours. At the end of the second and fourth hours, the child was reweighed without clothing or diapers, and the physician was brought back to perform a 10-point dehydration score. The decision to admit or discharge was made at the completion of the study.

We considered that some patients would not be able to perform ORT and defined inability to perform ORT a priori as vomit ≥25% of the hourly oral requirement or 6 consecutive oral refusals. These children were considered an ORT failure for the main outcome of successful rehydration at 4 hours and for the criteria for discharge at 2 hours. These children remained in the ORT group for all statistical analyses. An IV was placed, and they were rehydrated with intravenous fluids.

Outcome Measures

The primary outcome was success of treatment in the ED at 4 hours, which was defined as resolution of moderate dehydration (a 4-hour dehydration score ≤2, which would indicate mild to no dehydration), weight gain, production of urine output during the trial, and absence of severe emesis (≥5 mL/kg) during the fourth hour of the trial. The criteria for the primary outcome were chosen to reflect objective reasons that a moderately dehydrated child <3 years old would need additional treatment.

Predefined secondary outcome measures included time to initiate therapy, improvement in the dehydration score after 2 hours of therapy, hospitalization rate, parental therapy preference at 4 hours, and 72-hour ED revisits. The time to initiate therapy was defined as the interval between the randomization time and the treatment start time. After 2 hours of therapy, a PEM-trained physician masked to the treatment assignment performed an evaluation on all patients including a repeat dehydration score. The disposition decision was made after the treatment assignment had been revealed to the treating physician at the completion of the study and was an unmasked secondary outcome measure. Parental preference was assessed after the 4-hour rehydration period by using a survey administered to parents about their therapy preferences. Seventy-two-hour ED-revisit information was obtained through a follow-up phone call to all subjects. If the patient was admitted to the hospital and still an inpatient at 72 hours, they were excluded from this particular analysis, because they were not eligible for a 72-hour ED revisit. All patients remained in the study for a 4-hour period.

Sample Size

Although there were no published data on rehydration in an outpatient setting during the planning of this trial, the published ORT failure rate is 3.4% in an inpatient setting with nasogastric tube use if the patient was unable to take ORT fluid orally.[9] Because we did not use nasogastric tubes for patients who were unable to tolerate ORT, we assumed there would be a 20% failure rate of ORT in the ED. Before the start of the study we estimated a need for 50 patients in each group to have 80% power to demonstrate that the failure rate of ORT was lower than or at most no more than 5% greater than the corresponding rate for IVF using a 1-sided α of .05.

Statistical Analysis

Descriptive analysis techniques were used to compare demographics and historical information of the 2 study groups. Risk differences with 95% confidence intervals (CIs) were used to compare binomial outcomes such as successful treatment at 4 hours and hospitalization rate. *t* tests were used to evaluate differences in continuous outcomes such as time to initiate therapy. The primary statistical analyses were conducted on an intention-to-treat basis.

Assignment

The subjects were randomized to the treatment groups by using block randomization of variable block sizes. Blocks of 6, 8, and 10 were determined by using a table of random numbers, and randomization within the blocks was also determined by using a table of random numbers. The assignments were kept in a sealed packet with all study-related materials in an area of the ED to which only the nurse practitioners had access. After written informed consent was obtained, the nurse practitioner acquired a packet, the patient was brought to the 24-hour unit, and the sealed treatment assignment was opened.

Masking

The study was single-masked. The subject and family were aware of the treatment assignment; the treating physician was masked. Masking was accomplished for the ORT group by placing a sham IV with a heparin lock taped to the outside of the subject's hand, a sham IV board, a sham protective covering over the heparin-locked IV, and occasionally a sham bandage on the other hand to give the appearance of 2 IV attempts. For the IVF group, patients had the same equipment, except the IV was actually placed intravenously. To maintain masking, both groups of subjects were taken to a separate treatment room away from all study materials to obtain 2- and 4-hour dehydration scores and weights. No rehydration supplies were visible to the physician making the assessment. The nurses and families were reminded not to disclose the treatment assignment to the physician. To determine the effectiveness of masking, the physicians were asked at the 2- and 4-hour dehydration assessment whether they thought the patient was receiving ORT or IVF or if they were uncertain of the treatment assignment.

RESULTS

Over a 17-month period from December 2001 to April 2003, 355 patients were assessed for eligibility, and 73 patients were enrolled in the trial: 36 in the ORT group and 37 in the IVF group (Fig 1). The patients who refused to participate (n = 36) were similar to the group of patients who participated with respect to age, gender, and baseline dehydration score. Three subjects in each group who did not receive their assigned treatment were included in the analysis to maintain the intention-to-treat approach. In the ORT group, these 3 subjects were withdrawn at parental request after randomization to ORT and before starting treatment. In the IVF group, 1 subject underwent multiple unsuccessful attempts at IV ac-

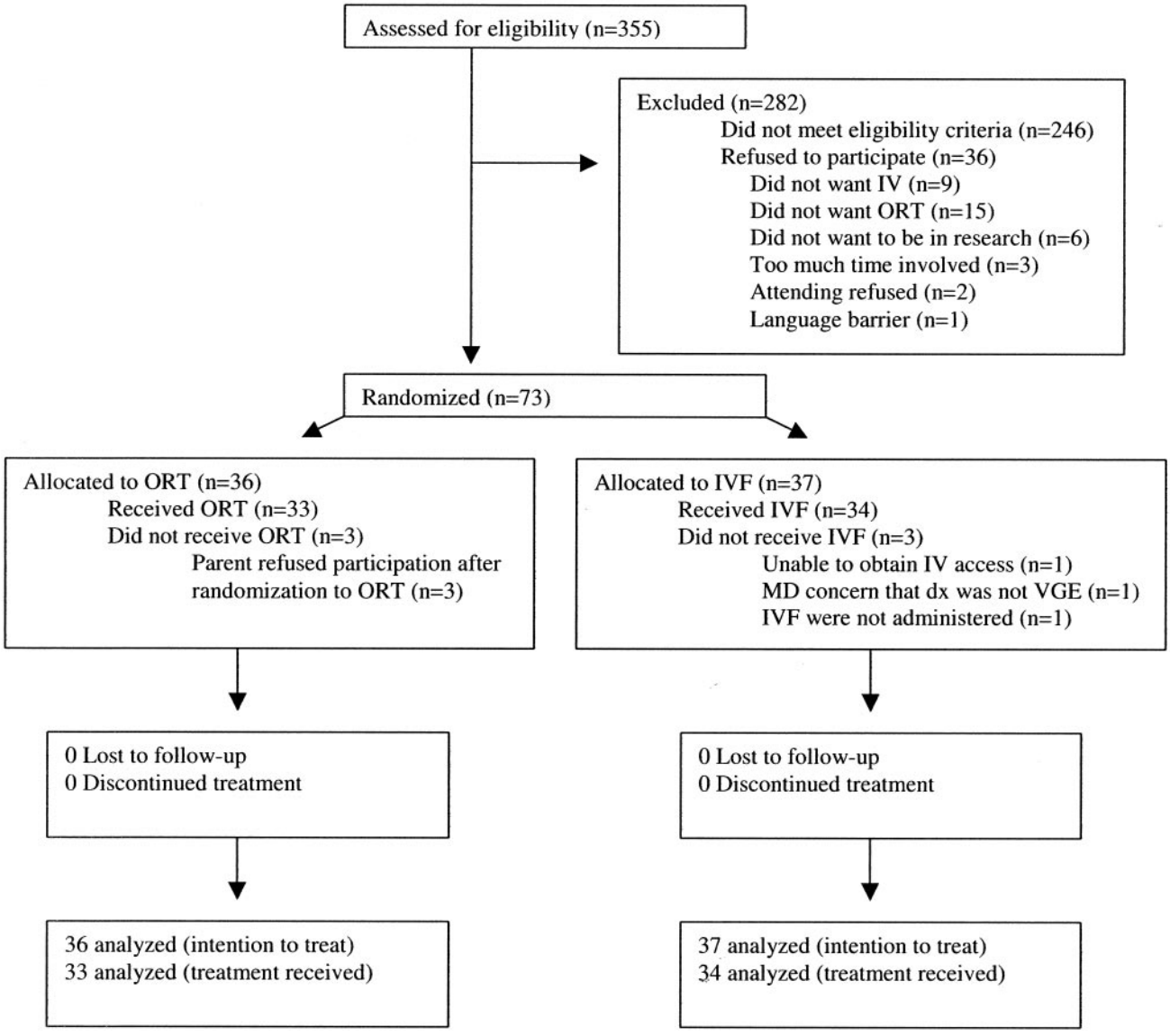

Fig 1. Numbers of patients assessed, enrolled, and completing follow-up.

cess and was subsequently treated successfully with ORT and discharged from the hospital; 1 subject was withdrawn by the attending physician for concerns of a diagnosis other than gastroenteritis; and 1 subject was excluded for protocol violation (the patient did not receive the intravenous fluids ordered). Baseline characteristics of subjects in both groups are presented in Table 1. The baseline dehydration score was similar between the 2 study groups. The original sample size was calculated to be 100 subjects (50 per group). The study was stopped early when enrollment rates declined after the second gastroenteritis season. At that time, ORT had been adopted into practice by the ED staff. As a result, many families were started on ORT before evaluation by research staff and subsequently declined participation in the study.

Primary Outcome

There was no difference between the 2 groups in terms of overall successful rehydration at 4 hours (55.6% of ORT patients and 56.8% of IVF patients; risk difference: −1.2%; 95% CI: −24.0% to 21.6%). ORT-treated patients demonstrated noninferiority in individual measures such as resolution of moderate dehydration, the production of urine, and the absence of severe emesis, and these measures were neither clinically nor statistically different (Table 2). More patients treated with IVF had weight gain by the end of the 4-hour study.

Secondary Outcomes

Time to initiate therapy was substantially shorter in the ORT group (Table 3). The median time was similar to the mean time for each respective group as well: 36 minutes in the IVF group and 15 minutes in the ORT group. Both groups showed comparable improvement in the 2-hour dehydration (2.0 for the ORT group and 2.3 for the IVF group). Fewer patients in the ORT group were hospitalized (30.1% ORT compared with 48.7% IVF); however, this finding was not statistically significant. There were no differences in the other secondary outcomes, ie, parental preference for therapy if the child should become dehydrated again and 72-hour ED-revisit rate.

Fluid parameters of study subjects are presented in Table 4. As expected, in the intention-to-treat analysis, IVF patients received more intravenous fluids

TABLE 1. Baseline Characteristics of the Study Sample

Variable	ORT (n = 36)	IVF (n = 37)
Age, mo		
Mean	15.8	15.7
Median	12.8	14.4
Range	3.1 to 33.4	2.2 to 32.6
Gender, % male	52.8 (n = 19)	75.7 (n = 28)
Race		
Non-Hispanic white	19.4% (n = 7)	16.2% (n = 6)
Black	72.2% (n = 26)	81.1% (n = 30)
Other	8.3% (n = 3)	2.7% (n = 1)
Number of emesis episodes in previous 24 h*		
Mean	7.3	7.8
Median	5	6
Range	0–28	0–25
Number of diarrhea episodes in previous 24 h*		
Mean	6.8	8.9
Median	5	8
Range	0–28	0–24
Baseline dehydration score		
Mean	4.3	4.1
Median	4	4
Range	3–7	3–6
Referred by primary medical doctor	36.1% (n = 13)	48.7% (n = 18)
Triage heart rate, beats per min		
Mean	142	148
Median	139	148
Range	102–180	108–197
Triage temperature, °C		
Mean	37.7	37.6
Median	37.5	37.7
Range	36.2–39.9	35.6–40.1
Saw primary medical doctor prior to coming to ED	30.6% (n = 11)	32.4% (n = 12)
Accompanied by		
Mother only	63.9% (n = 23)	70.3% (n = 26)
Father only	0% (n = 0)	8.1% (n = 3)
Both parents	36.1% (n = 13)	21.6% (n = 8)
First-born child	38.9% (n = 14)	40.5% (n = 15)
Mother employed	45.5% (n = 15)	62.2% (n = 23)
Maternal education, y		
Mean	12.9	12.6
Median	12	12
Range	7–20	7–20

The data are shown for the intention-to-treat population.
* Some values are missing; the range of missing values was 0 to 2 per cell.

TABLE 2. Successful Rehydration at 4 Hours, Including Individual Components of Successful Rehydration

Variable	ORT	IVF	Difference (95% CI)*
Successful rehydration	55.6% (20/36)	56.8% (21/37)	−1.2% (−24.0% to 21.6%)
Resolution of moderate dehydration (score <2)	90.6% (29/32)	82.9% (29/35)	7.8% (−8.3% to 23.8%)
Production of urine	88.2% (30/34)	85.7% (30/35)	2.5% (−13.3% to 18.4%)
Weight gain	82.8% (24/29)	100% (31/31)	−17.2% (−31.0 to −3.5%)
Absence of severe emesis (<5 mL/kg)	100% (33/33)	100% (33/33)	0%

To provide the most conservative estimate of treatment differences, any subject with even a single data element missing from the main outcome measure of "successful rehydration" was considered unsuccessful. However, for the 4 individual subcomponents of the main outcome, the analysis excluded missing data points as reflected in the denominator of each individual cell in the table.
* Differences that do not cross zero are statistically significant.

TABLE 3. Secondary Outcome Measures

Variable	ORT (n = 36)	IVF (n = 37)	Difference (95% CI)*
Mean time to initiate therapy, min†	19.9 + 13.4 (n = 35)	41.2 + 29.4 (n = 35)	21.2 (10.3 to 32.1)
Improved dehydration score at 2 h	78.8% (26/33)	80% (28/35)	−1.2% (−20.5% to 18%)
Hospitalization rate (24-h observation unit)	30.6% (11/36)	48.7% (18/37)	−18.1% (−40.1% to 4.0%)
Parental preference for same therapy next time	61.3% (19/31)	51.4% (18/35)	9.9% (−14 to 33.7)
72-h ED revisits‡	9.1% (3/33)	8.3% (3/36)	0.8% (−12.6% to 14.1%)

Missing data were excluded from individual analyses as indicated by the denominator in each cell.
* Differences that do not cross zero are statistically significant.
† Plus/minus values are mean ± SD.
‡ Excludes patients who were admitted and still inpatient at 72 hours after the original ED visit.

TABLE 4. Fluid Parameters at 4 Hours

Parameter	ORT (n = 36)	IVF (n = 37)	Difference (95% CI)*
Mean oral fluid intake, mL/kg	36.3	21.1	15.2 (6.3 to 24.1)
Mean IV fluid input, mL/kg	6.8	40.0	32.9 (26.9 to 38.9)
Mean total input, mL/kg	43	61.1	18.1 (9.8 to 26.3)
Mean urine output, mL/kg per h	2.3	2.1	−0.16 (−1.6 to 1.3)
Mean no. emesis	1.2	0.4	−0.8 (−1.5 to 0)
Mean no. diarrhea	1.4	1.4	0.1 (−0.7 to 0.8)
Mean weight gain, g	154	441.9	288 (197.9 to 378)

Results are representative of the intention-to-treat analysis. Each subjects' physiologic parameters are reported in the treatment group to which they were assigned originally regardless of success.
* Differences that do not cross zero are statistically significant.

and less oral fluids than the ORT group. They also had an overall higher mean fluid intake and weight gain. However, urine output was similar in the 2 groups.

Of the 36 subjects in the ORT group, 5 were unable to perform ORT and subsequently required an IV placement and intravenous rehydration, yielding a 15.2% inability-to-perform-ORT rate (95% CI: 2.7% to 27.6%). These patients remained in the ORT group for all comparisons of the 2 treatment groups. Of the 37 subjects in the IVF group, 51.4% (n = 19) had a successful intravenous placement on the first attempt. Additionally, 18.9% (n = 7) of the IVF group required 2 attempts, and 27% (n = 10) required 3 to 8 attempts for intravenous access. The quality of masking was excellent. When asked the patient's treatment assignment, 64% of physicians were uncertain, 23% chose ORT, and 13% chose IVF. Most physicians were unable to detect the correct treatment assignment (23.4% correct for the ORT group [95% CI: 13.8% to 35.7%] and 15.9% correct for the IVF group [95% CI: 8.2% to 26.7%]).

Treatment Received

When analyzed according to the treatment received, ORT still demonstrated noninferiority compared with IVF for the main outcome of successful rehydration at 4 hours. Specifically, 60.6% of ORT patients and 61.8% of IVF patients were rehydrated successfully (risk difference: −1.2%; 95% CI: −24.5% to 22.2%). Only 22.7% of subjects in the ORT group required hospitalization, as contrasted with 50% in the IVF group (risk difference: −22.7%; 95% CI: −45.4% to −0.1%). The other secondary outcomes were not different from the intention-to-treat analysis and are not presented.

DISCUSSION

This ED clinical trial demonstrated that ORT was as effective as IVF in rehydration of moderately dehydrated children due to gastroenteritis. Some measures indicated that ORT was superior. For example, initiating treatment with ORT was quicker than with IVF, a particularly important finding for busy EDs often faced with overcrowding and long waits. ORT obviates the need for potentially painful, often difficult intravenous catheter placement. This study improves on prior work in evaluation of treatment of moderately dehydrated children in the ED by masking the treatment assignment, using a validated assessment of the degree of dehydration, and limiting the age of our study population. We chose patients <3 years old, because they are at a greater risk for

significant dehydration and require a more conservative approach to determining disposition.[10,11]

Dehydration scores after rehydration therapy showed comparable improvements, with >90% of patients in the ORT group and >82% of patients in the IVF group having a 4-hour dehydration score that demonstrated resolution of their moderate dehydration. The majority of patients had made urine by 4 hours, and neither group had severe episodes of emesis during the final hour of the rehydration period. Although the other components of successful rehydration were similar between groups, the IVF group did demonstrate better weight gain than the ORT group, and this difference was statistically significant. It should be mentioned that patients are not routinely reweighed in the ED before discharge. In fact, common clinical features used alone or in combination to determine if a child is ready for discharge include an improved clinical assessment, the production of urine, and the absence of severe emesis, which are reflected in our outcome measure. We do feel, however, that the outcome measure we chose accurately describes the success of rehydration in the ED, because our success rates are comparable to our discharge rates.

Although the individual components of our definition of successful rehydration were met in >80% of cases, the overall success rate was lower, which is likely due to our conservative definition of success as well as the contribution of missing data that placed these patients in the failure category. Additionally, the mean oral intake in the intention-to-treat ORT group was 36 mL/kg. When the patients who were unable to tolerate ORT were excluded from analysis, oral intake increased to 42.8 mL/kg, very close to our 50 mL/kg goal. The results from this study support the concept that there is an inherent benefit to using the gastrointestinal tract for rehydration given the fact that the ORT patients had less fluid intake yet did just as well as the IVF patients.

Furthermore, 2 systematic reviews of rehydration therapy for dehydration from gastroenteritis also found enteral therapy to be as effective as intravenous therapy.[9,12] However, most of the clinical trials included in these reviews occurred in inpatient settings, and many took place in developing countries. The trials also lacked masking of treatment assignments, intention-to-treat analyses, and adequate description of randomization. Our trial overcomes many of these prior trial limitations.

Our original definition of success included an oral-intake parameter. However, posthoc, the oral intake was removed from the definition of success, because its presence influenced the study results such that there was a statistical and clinical benefit of ORT over IVF. It was our feeling that the benefit from the oral intake could reflect a bias in that there was a systematic offering of oral fluids to the ORT group but not the IVF group. Although, the IVF group was strongly encouraged to take oral fluids, there was not a requirement for them to do so. We feel that the definition of success as presented in this article is a more objective definition free of bias.

Some limitations of our trial should be noted. The 23-hour observation unit, the site of this study, may be different from the contiguous ED. IV-insertion time was optimized in that randomization occurred in the treatment room with a nurse ready to place an IV if the child was randomized to the IVF group. As a result, there would undoubtedly be an even greater time differential favoring ORT under nonstudy circumstances. However, the underlying aim of the study was to test the 2 treatment options as an efficacy study. The next step would be to conduct an effectiveness study in a more generalizable ED setting. Furthermore, because moist mucous membranes are a component of the dehydration score, oral intake could moisten the mucous membranes and influence measured dehydration scores. However, because both groups were allowed oral intake, minimal bias should have been introduced due to this fact.

Certain factors may affect the generalizability of this trial. Because the study was conducted between 8 AM and midnight, while research personnel were available, patients and parents were more likely to be awake and able to perform ORT. ORT may be less successful in the middle of the night. In addition, the trial was conducted in a pediatric ED in which nurses are extremely skilled in placing IVs even in dehydrated children. Subsequently, IVF may be more difficult to administer in other settings simply due to the difficulty in obtaining intravenous access.

Our study was stopped before reaching the 100-subject goal. The study occurred over 2 gastroenteritis seasons, and after the second season, there was a decline in the number of patients presenting to the ED with probable viral gastroenteritis. Furthermore, with time, the ED staff became more familiar with proper ORT administration, and many children were started on ORT before evaluation for the trial. Family satisfaction with ORT early in the ED course decreased trial participation–consent rates. The loss of clinical equipoise and declining accrual rate led to the early termination of the study. No interim analysis was performed. Still, we were able to demonstrate that ORT is not inferior to IVF in rehydrating moderately dehydrated young children. Although our study refusal rate approached 30%, less than half were due to families refusing ORT, with a similar number not desiring IVF. This result suggests that a therapeutic alliance can be made with families to initiate ORT for dehydration.

CONCLUSIONS

We demonstrated in this clinical trial that ORT is as good as IVF in rehydration of moderately dehydrated children due to gastroenteritis. In addition, we found that less time was required to initiate ORT when compared with IVF in the ED. In our treatment-received analysis, patients treated with ORT had fewer hospitalizations. The results of this study suggest that ORT be the initial treatment of choice for moderately dehydrated children <3 years old with gastroenteritis.

ACKNOWLEDGMENTS

We thank the nurses, nurse practitioners, and residents in the Children's Hospital of Philadelphia's emergency department and extended care unit for all their assistance. Noreen McDaniel-Yaksco, CRNP, and Antoinette Silvestri, CRNP, were especially instrumental in the conduct of this trial.

REFERENCES

1. McConnochie KM, Conners GP, Lu E, Wilson C. How commonly are children hospitalized for dehydration eligible for care in alternative settings? *Arch Pediatr Adolesc Med.* 1999;153:1233–1241
2. American Academy of Pediatrics, Provisional Committee on Quality Improvement, Subcommittee on Acute Gastroenteritis. Practice parameter: the management of acute gastroenteritis in young children. *Pediatrics.* 1996;97:424–436
3. World Health Organization. *The Treatment of Diarrhea: A Manual for Physicians and Other Senior Health Workers*. Geneva, Switzerland: World Health Organization; 1995. WHO/CDD/SER/80.2 Rev. 3
4. Conners GP, Barker WH, Mushlin AI, Goepp JG. Oral versus intravenous: rehydration preferences of pediatric emergency medicine fellowship directors. *Pediatr Emerg Care.* 2000;16:335–338
5. Ozuah PO, Avner JR, Stein REK. Oral rehydration, emergency physicians, and practice parameters: a national survey. *Pediatrics.* 2002;109:259–261
6. Atherly-John YC, Cunningham SJ, Crain EF. A randomized trial of oral vs intravenous rehydration in a pediatric emergency department. *Arch Pediatr Adolesc Med.* 2002;156:1240–1243
7. Gorelick MH, Shaw KN, Murphy KO. Validity and reliability of clinical signs in the diagnosis of dehydration in children. *Pediatrics.* 1997;99(5). Available at: www.pediatrics.org/cgi/content/full/99/5/e6
8. Spandorfer PR, Alessandrini EA, Ruggierio G, Curry P, Bilker WB. The accuracy of estimation of emesis volume [abstract]. *Pediatr Res.* 2003;53:106A
9. Gavin N, Merrick N, Davidson B. Efficacy of glucose-based oral rehydration therapy. *Pediatrics.* 1996;98:45–51
10. Goepp JG, Santosham M. Oral rehydration therapy. In: Oski FA, DeAngelis CD, Feigin RD, McMillan JA, Warshaw JB, eds. *Principles and Practice of Pediatrics*. 2nd ed. Philadelphia, PA: J. B. Lippincott Co. 1994;849–859
11. Shaw KN. Dehydration. In: Fleisher GR, Ludwig S, Henretig FM, Ruddy RM, Silverman BK, eds. *Textbook of Pediatric Emergency Medicine*. 4th ed. Philadelphia, PA: Lippincott Williams & Wilkins 2000;197–201
12. Fonseca BK, Holdgate A, Craig JC. Enteral vs intravenous rehydration therapy for children with gastroenteritis: a meta-analysis of randomized controlled trials. *Arch Pediatr Adolesc Med.* 2004;158:483–490

CONGRESS TRIMS MONEY FOR SCIENCE AGENCY

"Congress has cut the budget for the National Science Foundation, an engine for research in science and technology, just 2 years after endorsing a plan to double the amount given to the agency. Supporters of scientific research in government and at universities noted that the cut came as lawmakers earmarked more money for local projects like the Rock and Roll Hall of Fame in Cleveland and the Punxsutawney Weather Museum in Pennsylvania. David M. Stonner, director of Congressional affairs at the science foundation, said on Monday that the reduction might be just the beginning of a period of austerity. Congress, Mr. Stonner said, told the agency to expect 'a series of flat or slightly declining budgets for the next several years.' In renewing the legal authority for science programs in late 2002, Congress voted to double the budget of the science foundation by 2007. The agency finances the work and training of many mathematicians, physicists, chemists, engineers, computer scientists, biologists, and environmental experts. The $388 billion spending bill for the current fiscal year, approved by both houses of Congress on November 20, provides $5.473 billion for the National Science Foundation, which is $105 million less than it got last year and $272 million less than requested."

Pear R. *New York Times*. November 30, 2004

Noted by JFL, MD