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Original Contribution

Comparison of ultrarapid and rapid intravenous hydration in pediatric patients with dehydration☆

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Abstract

Objective: The purpose of this study is to test the efficacy of ultrarapidly infused vs rapidly infused intravenous (IV) hydration in pediatric patients with acute gastroenteritis and moderate dehydration.

Methods: Patients 3 to 36 months, with vomiting and/or diarrhea and moderate dehydration, were eligible. Subjects were randomly assigned "ultra" (50 mL/kg normal saline for 1 hour) vs "standard" (50 mL/kg normal saline for 3 hours) after failing an oral fluid challenge. Subjects were weighed and had serum electrolyte testing, and urine was obtained before/after IV hydration. Input/output and vital signs were tabulated hourly during the study. Subjects were discharged after fulfilling specified criteria. A follow-up questionnaire was completed 24 hours after discharge. Comparison data included success and timing of rehydration, number of patients who returned and/or were admitted, output during the rehydration period, laboratory differences, and serious complications.

Results: Eighty-eight of 92 subjects completed the study: 45 ultra and 43 standard. Four patients failed treatment (1 ultra and 3 standard), were hospitalized, and excluded from the study. Groups were similar regarding sex, days of symptoms, episodes of vomiting/diarrhea before treatment, capillary refill time, tears, and vital signs and laboratory results. No subject had evidence of serious complications. Ninety-one percent of subjects completed the follow-up questionnaire. Seven ultra and 6 standard subjects returned. Six ultra subjects received oral fluid, one received IV fluid, and all were discharged. Five standard subjects received oral fluid, one received IV fluid, and all were discharged.

Conclusion: Based on this pilot study, ultrarapid hydration for 1 hour preliminarily appears to be an efficacious alternative to standard rapid hydration for 3 hours and improves emergency department throughput time.

1. Background

Dehydration resulting from acute gastroenteritis is a major cause of morbidity and mortality. In the United States, approximately 220 000 pediatric patients (9% of all pediatric hospitalizations) are admitted for the treatment of dehydration caused by gastroenteritis, and 400 deaths are reported annually

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[1]. Worldwide, 2001 data estimate that 1.5 million children younger than 5 years die of diarrheal diseases, with 80% of deaths in the first 2 years of life [2]. With emergency departments (EDs) becoming more crowded and waiting times becoming increasingly prolonged, time-consuming treatments for conditions, such as dehydration, may cause increasing delays in efficiency and patient flow. Although attempts at oral rehydration are an appropriate initial treatment of dehydration, as advocated by the American Academy of Pediatrics [3], intravenous (IV) hydration plays a necessary and vital role in expediting ED treatment and throughput of pediatric patients. Depending on the patient's interest and ability to drink, IV rehydration may be the best treatment option.

Inpatient and ED studies reflect effectiveness of IV hydration for pediatric patients with moderate or severe dehydration. If IV rehydration is performed, normal saline or lactated Ringer's solution is typically administered at 20 mL/kg for 1 hour [4], although variation exists. For example, patients may receive a variable amount of fluid for one or several hours because no standardized rate of fluid administration exists.

Because emergency physicians vary in clinical practice regarding IV fluid volume and rate, clinical studies are needed to determine IV rehydration rates appropriate for the dehydrated pediatric patient. Standardizing rapid fluid administration may enhance the timeliness and quality of patient care while improving ED throughput.

Therefore, we sought to determine if young children experiencing moderate dehydration caused by presumed acute gastroenteritis could be effectively treated with IV fluid administered more rapidly. We hypothesized that IV fluids given in the amount of 50 mL/kg for 1 hour would be comparable with 50 mL/kg for 3 hours and be equally efficacious.

2. Materials and methods

This pilot study was a single-center, randomized, controlled, convenience sample conducted in a large, urban, pediatric, tertiary care teaching hospital that serves the primary and subspecialty needs of children in Los Angeles. The annual census of the ED is 62 000 visits per year, including 60% of patients with general problems and diagnoses and 40% with problems requiring subspecialty care.

Children aged 3 to 36 months were eligible if they had acute complaints of vomiting and/or diarrhea and were moderately dehydrated (Table 1) [3]. If criteria were found in more than one category, subjects were included. If most of the criteria were in the moderate dehydration category, all patients were given an oral fluid challenge, in aliquots of 5 to 10 mL doubled every 10 minutes for 30 minutes. If the patient refused oral fluid, vomited, demonstrated disinterest, or was unable to drink sufficient quantities, according to this regimen, consent for study participation was pursued from the patient's caregiver. A computer-generated random number scheme assigned patients to 1 of 2 treatment arms, 50 mL/kg of normal saline for 1 hour (ultrarapid IV hydration, or "ultra"), or 50 mL/kg normal saline IV for 3 hours (standard ED, IV fluid for moderate dehydration, or "standard"). All IVs were either 22- or 24-gauge IV catheters placed by experienced pediatric ED nurses. This study was approved and monitored by the institutional review board at the hospital.

Patients were excluded because of severe dehydration, shock, suspected intussusception, appendicitis, malrotation, recent trauma, meningitis, or congestive heart failure, or if these diagnoses appeared as the study progressed. Patients were also excluded if they had any significant chronic diseases or if patients had significant laboratory abnormalities on initial bedside laboratory testing, including sodium (Na) lower than 130 or higher than 150 mmol/L and/or potassium (K) lower than 3.2 or greater than 5.5 mmol/L. These laboratory abnormalities were determined to be an exclusion based on an institutional review board request. In addition, any patient requiring admission to the hospital was considered a study failure and excluded from analysis because all patients were required to be treated as outpatients based on the study protocol.

Table 1 Determination of dehydration

Variable	Mild (3%-5%)	Moderate (6%-9%)	Severe (>10%)
Blood pressure	Normal	Normal	Normal to reduced
Quality of pulses	Normal	Normal or slightly decreased	Moderately decreased
Heart rate	Normal	Increased	Increased *
Skin turgor	Normal	Decreased	Decreased
Fontanel	Normal	Sunken	Sunken
Mucous membranes	Slightly dry	Dry	Dry
Eyes	Normal	Sunken orbits	Deeply sunken
Extremities	Normal capillary refill	Delayed capillary refill	Cool, mottled
Mental status	Normal	Normal to listless	Lethargic or comatose
Urine output	Slightly decreased	<1 mL/kg per hour	<1 mL/kg per hour
Thirst	Slightly increased	Moderately increased	Very thirsty

Adapted from Duggan et al. found in the American Academy of Pediatrics guideline [3].

* Bradycardia may appear in severe cases.

For clarification, the following terms and definitions were used for study purposes. Vomiting and/or diarrhea were considered acute if the symptoms had been present for less than 7 days. Capillary refill time was defined as the amount of time for vascular reperfusion after application of blanching pressure to the nail bed [5]. Hypoglycemia was defined as a serum glucose level less than 60 g/dL. Fluid deficit was analyzed using pre- and posttreatment weights; however, clinical criteria were used to ascertain the degree of dehydration as a requirement of study enrollment.

Minor complications related to IV placement included multiple attempts (>3), extravasation of IV fluids, significant bleeding at the IV site, and inadvertent displacement of the IV catheter before treatment was completed. Serious complications related to fluid administration included evidence of fluid overload, swollen or edematous soft tissues, crackles, tachypnea and/or retractions on lung examination, a gallop rhythm on cardiac examination, seizures, deteriorating mental status, and laboratory abnormalities: Na lower than 130 or higher than 150 mmol/L and/or K lower than 3.2 or higher than 5.5 mmol/L.

All study subjects were weighed initially (single scale calibrated daily) and underwent blood and urine studies pre- and postintervention, including serum Na, K, chloride (Cl), bicarbonate (CO_2), blood urea nitrogen, creatinine (Cr), urine chemistry, and specific gravity. All patients were catheterized for urine samples if they did not void spontaneously. Subjects also had rapid bedside electrolyte testing performed at the beginning of the study to determine if electrolyte abnormalities existed (Na <130 or >150 mmol/L or K <3.2 or >5.5 mmol/L). Such abnormalities would result in study exclusion. In addition, all patients were tested for hypoglycemia and treated as necessary with 2 mL/kg of 10% dextrose water before commencing rehydration therapy. Stool cultures for common bacterial pathogens were obtained from all subjects presenting with diarrhea. Urine cultures were obtained by urinary catheterization for patients in diapers or by clean catch if the patient was toilet trained.

Nursing staff monitored all patients during rehydration with hourly assessments of vital signs, intake and output (including emesis, urine, and stool volumes), general clinical state, capillary refill time, and the development of any complications. In addition, all fluid infusions were monitored per standard nursing protocol to verify that all fluid administered was performed as ordered by the physician. At the end of respective 1- or 3-hour rehydration periods, patients in both study groups were immediately given an oral fluid challenge (5-20 mL) and had postintervention studies (electrolytes and urinalysis) performed 30 minutes later. Patients were discharged home if they tolerated an oral fluid challenge, had normal vital signs (based on age-specific norms measured in a uniform standardized fashion), and demonstrated presence of streaming tears, moist oral mucosa, normal capillary refill time, and adequate urine output, considered any urine produced during the rehydration period. Approximately 24 hours after discharge, one of the investigators (ALN) contacted all caregivers by telephone using a standardized questionnaire. Although blinded to the study arm, questions were asked to determine the patients' ability to drink, the number of episodes of vomiting and/or diarrhea, the amount of urination, the presence of tear production, and the evidence of saliva or drooling, and whether care was sought elsewhere. The investigator encouraged caregivers of patients to return to the ED if signs and symptoms of dehydration appeared to recur or persist, or otherwise, at the discretion of the caregiver.

This pilot study was undertaken to provide some evidence for our belief that the ultra protocol could be performed effectively with similar results as the standard hydrating method. Efficacy, in this regard, would include an analysis of success in rehydration between groups based on standardized discharge criteria, an evaluation of study failures, that is, those patients that required admission, output (urine, emesis, stool) during the treatment phase, pre- and posttreatment laboratory abnormalities, number of return visits, and whether serious complications occurred.

Comparisons between groups were analyzed regarding rehydration effectiveness based on standardized discharge criteria, an evaluation of study failures, that is, those patients who required admission, output (urine, emesis, stool) during the treatment phase, pre- and posttreatment laboratory abnormalities, number of return visits, and whether serious complications occurred. Upon successful completion, we would expect a multicenter clinical trial to be carried out to verify our expected results. Although this was only a pilot study, the results of an equivalence power analysis showed that an expected sample size of 45 in each group would have provided more than 60% power for detecting if the ultra approach had more than 10% or greater protocol failures over the standard hydrating method. Summary statistics comparing the 2 randomized groups were made using means, SDs, and proportions. Statistical comparisons of the 2 groups were performed using the χ^2 test for categorical variables and the 2-sample t test or the rank sum tests for continuous and ordinal variables, respectively. Statistical analysis was performed separately on initial and final laboratory results, and the change from initial to final. Because there were few comparisons between the groups that resulted in significant differences, more extensive multivariate comparisons were not done. Data were entered using a Microsoft Excel spread sheet and then validated and analyzed using Stata, Version 10 (StataCorp, College Station, Tex) [6].

3. Results

From September 2003 until April 2007, the ED evaluated 386 potential eligible dehydrated subjects. Of potential eligible study subjects, we enrolled 92 subjects that had acute gastroenteritis and were determined to have moderate dehydration by one of the study investigators. Of the 92 subjects enrolled, 4 subjects failed treatment and were admitted; 1 of 46 ultra was secondary to profuse diarrhea,

leaving 45 ultra who completed the study; and 3 of 46 standard were secondary to substantial vomiting and diarrhea, leaving 43 standard who completed the study. Therefore, 45 (97.8%) ultra (95% confidence interval [CI], 0.06%-11.5%) and 43 (93.5%) standard (95% CI, 1.4%-17.9%) completed the study, $P = .617$.

Table 2 illustrates baseline characteristics between ultra and standard groups. There were no statistically significant differences between the ultra and standard subjects regarding sex, ethnicity, days of symptoms, episodes of vomiting, and/or diarrhea before treatment, capillary refill time, tear production, and heart rate. All study subjects in both groups failed their oral fluid challenge as a requirement of study enrollment. Because of postintervention study requirements (weight, oral fluid challenge, laboratory, and urine testing), all ultra subjects were discharged 2 hours from the onset of study intervention, and standard subjects were discharged 4 hours from the onset of study intervention. All subjects were diagnosed with acute gastroenteritis. No patient had a culture proven urinary tract infection or a bacterial enteritis. The mean age among ultra subjects was 18.7 months, and the mean age of standard subjects was 16.7 months.

As a means of evaluating efficacy between groups, this pilot study demonstrated that during the respective hydration periods, the mean emesis volume for ultra subjects was 69 mL/h as compared with 63 mL for 3 hours for standard subjects or 21 mL/h. The mean urine volume for ultra subjects was 93 mL/h vs 71 mL for 3 hours for standard subjects or approximately 24 mL/h, and stool output was 45 mL/h for ultra subjects vs 75 mL for 3 hours for standard subjects or 25 mL/h, $P = .042$. Although these results suggest that ultra subjects stooled less and urinated more, these results must take into account the differences in the hydrating periods.

For ultra subjects, the average participant weighed 11.3 kg and gained 474 g (4.2%) after treatment. This was not a statistically significant difference from the standard group in

Table 3 Mean laboratory values

Test		Ultra	Standard	*P*
Na (mmol/L)	Initials	140 ± 4.4	141 ± 4.1	.044
	Final	141 ± 3.7	142 ± 3.9	NS
K (mmol/L)	Initial	4.3 ± 0.53	4.4 ± 0.64	NS
	Final	4.0 ± 0.56	4.1 ± 0.57	NS
CO_2 (mmol/L)	Initial	16.8 ± 3.5	16.5 ± 2.6	NS
	Final	15.1 ± 2.7	16.0 ± 3.1	NS
Blood urea nitrogen (mmol/L)	Initial	13.2 ±5.8	15.0 ± 7.4	NS
	Final	10.9 ± 4.8	11.7 ± 6.2	NS
Cr (mg/dL)	Initial	0.4 ± 0.11	0.4 ± 0.11	NS
	Final	0.3 ± 0.08	0.3 ± 0.10	NS
Glucose (g %)	Initial	96 ± 22.9	97 ± 19.6	NS
	Final	79 ± 18.1	79 ± 12.6	NS
Urine specific gravity	Initial	1025 ± 6.7	1025 ± 7.7	NS
	Final	1016 ± 7.5	1020 ± 8.3	.028

NS indicates not significant.

Table 2 Baseline characteristics

Characteristic	Ultra, n = 45	Standard, n = 43	*P*
Sex	18 female (40%), 27 male (60%)	16 female (37%), 27 male (63%)	.788
Predominant ethnicity	40 Latino (89%)	41 Latino (95%)	.367
Days of symptoms (by history)			
1-2	25 (55%)	25 (58%)	.633
3-4	14 (31%)	15 (35%)	
5-6	3 (7%)	2 (5%)	
>7	3 (7%)	1 (2%)	
Occurrence of vomiting (by history)			
0	1 (2%)	1 (2%)	.367
1-4	3 (7%)	2 (5%)	
5-10	13 (29%)	17 (39%)	
11-15	12 (27%)	9 (21%)	
16-20	6 (13%)	11 (26%)	
>20	10 (22%)	3 (7%)	
Occurrence of diarrhea (by history)			
0	9 (20%)	5 (12%)	.789
1-4	6 (13%)	7 (16%)	
5-10	10 (22%)	10 (23%)	
11-15	4 (9%)	7 (16%)	
16-20	5 (11%)	3 (7%)	
>20	11 (25%)	11 (26%)	
Cap refill time (s)	13 (30%) >2, 31 (70%) <2	11 (26%) >2, 32 (74%) <2	.679
Tears (none)	36 (80%)	34 (79%)	.914
Heart rate (mean)	147 (SD, 25.9)	154 (SD, 21.3)	.163
Age (mo)	18.7 (SD, 9.7)	16.7 (SD, 7.5)	.288

which the average subject weighed 10.8 kg and gained 408 g (3.8%), $P = .343$.

The mean initial heart rate for ultra subjects before treatment was 147 vs 154 for standard subjects. The mean final heart rate for ultra subjects was 122 compared with 123 for standard subjects. The heart rate decrease noted in the ultra and standard groups was not statistically different from each other, $P = .163$.

Mean initial and final laboratory values for the 2 study groups are presented in Table 3. For several laboratory tests studied, there were statistically significant but clinically insignificant differences, for example, initial Na in standard subjects was 141 and initial Na in ultra subjects was 140, $P = .044$. In the ultra group, the CO_2 level decreased from 16.8 mmol/L initially to 15.1 mmol/L after treatment, whereas in the standard subjects, the mean initial CO_2 level was 16.5 mmol/L, dropping to 16.0 mmol/L after hydration, $P = .011$. The mean initial urine specific gravity was 1.025 in ultra and standard subjects; however, the decline after hydration was greater for ultra subjects (mean, 1.016) than in standard subjects (mean, 1.020), $P = .028$. Regarding glucose determination, one standard subject initially and one standard subject on final measurement were hypoglycemic. In comparison, one ultra subject was hypoglycemic on final measurement.

Approximately 98% of ultra patients had their IV placed within the first or second attempt, whereas 91% of standard patients had their IV placed within the first or second attempt. No subjects in either group had consequences or complications related to fluid administration, and no study subject developed complications related to an electrolyte abnormality.

Ninety-one percent of all study subjects (89% ultra and 93% standard) completed a standardized questionnaire approximately 24 hours after discharge. There were no statistically significant differences on any of the post-discharge telephone questions. In addition, hospital records were reviewed to determine if study subjects returned for additional treatment. Return rates for ultra and standard subjects were similar. Overall, 13 (14.8%) of 88 subjects returned: 7 (15.6%) ultra (CI, 6.5%-29.5%) and 6 (14.0%) standard (CI, 5.3%-28.0%), $P = .999$. Of ultra subjects returning, 6 received an oral fluid challenge, one received IV fluids, and all were discharged home. Of the standard subjects returning, 5 received an oral fluid challenge, one received IV fluids, and all were discharged home. There were no statistically significant differences between ultra or standard patients who returned to the ED for reevaluation. As per the standard in our ED, all returning study subjects attempted an oral fluid challenge and received IV hydration, if necessary, at the discretion of the on duty attending physician.

4. Discussion

Intravenous hydration therapy has been a treatment modality throughout modern medicine. After oral rehydration therapy fails, either because of patient disinterest, insufficient quantities consumed, persistent symptoms, or lack of clinician use, IV hydration may be a necessary alternative for dehydrated patients. No previous study has investigated the use of ultrarapid IV hydration with 50 mL/kg for 1 hour compared with another hydrating method. In our pilot study, we showed that ultrarapid IV hydration for 1 hour is comparable with standard hydration for 3 hours.

Traditionally, the decision to treat and/or admit dehydrated patients have been based on a preset notion regarding how much fluid to give, the period for administration, or predetermined criteria based on clinical or hospital protocols. This may result in undertreatment, overuse of time and resources, and, for some patients, hospitalization in lieu of being discharged home. Intravenous hydration studies have shown that IV fluid therapy is effective, changes clinical outcome, and/or prevents hospitalization. Several smaller studies have shown effective rehydration with fluid administered in amounts of 20 to 40 mL/kg over varying periods [7], and one descriptive study showed effectiveness in administering 50 mg/kg IV fluid in 30 dehydrated patients with diarrhea [8]. The largest of these IV studies included 58 patients [9]; however, none of these studies prospectively compared different hydration groups, as this study did. A survey of pediatric nephrologists indicated that most believed that prolonged deficit therapy is outdated and that high-volume fluid resuscitation, 20 to 40 mL/kg, should be implemented [10].

Despite multiple studies showing the use and effectiveness of IV hydration, amounts and rates of fluid administration differ, and therefore, the optimal administration rate for IV hydration has not been defined. The American Academy of Pediatrics, in their practice parameter, has defined mild dehydration as a patient who requires 50 mL/kg and moderate dehydration as a patient who requires 100 mL/kg given either orally or intravenously [3], but no period or rate is described.

In our pilot study, it appears that young children experiencing moderate dehydration, caused by acute gastroenteritis, may be effectively treated with ultrarapid IV hydration. We found that ultrarapid IV hydration for 1 hour was well tolerated and comparable with standard rapid IV hydration for 3 hours. No patients had complications related to fluid administration, overhydration, seizures, or deteriorating mental status, although our study was not powered to definitively determine this. Our findings indicated that ultra and standard subjects were similar in their respective group results. Both ultra and standard subjects had a worsening metabolic acidosis, which could be related to the amount of Cl in the rehydrating fluid and/or expansion acidosis. However, all subjects had a positive fluid balance, a mean weight gain, and clinical improvement in all other hydration parameters.

Differences, although minor, included the observation that ultra subjects had a mean lower urine specific gravity over standard subjects, and ultra subjects had more urine production during the hydrating period. The difference in urine production existed even though the time of measurement was

different. Other differences between groups included those parameters inherent to the study design, namely, that patients were effectively treated for 1 vs 3 hours. Even with postintervention testing, ultra subjects were discharged 2 hours earlier than standard subjects, an advantage that improves ED throughput and the overall management of patients in the ED.

In addition, despite the fact that the data show that 7 ultra and 6 standard patients returned, only one ultra and one standard subject received IV fluid during their follow-up visit. More importantly, both of these patients, and 11 other patients (6 ultra and 5 standard), simply received an oral fluid challenge and were discharged home. Thus, all ultra and standard patients were successfully treated as outpatients.

It has been published that the best clinical estimate of acute dehydration is the actual percentage weight loss based on premorbid and illness weight determinations [5,11,12]. However, in the ED, preillness weight data are almost never available, thus, forcing the clinician to rely on his/her best estimate based on clinical findings. We attempted to standardize our estimate of dehydration based on Table 1, outlining clinical criteria for levels and percentages of dehydration. In addition, both groups uniformly appeared moderately dehydrated based on the established criteria, on specific laboratory determinations, and on clinical improvement. Although the amount of weight gain may suggest mild dehydration, based on Table 1, the enrolled subjects clinically matched moderate dehydration criteria. Ultimately, our goal was to hydrate patients in the ED with 50 mL/kg and then safely discharge them home to continue the rehydration process orally. We also carried out a careful assessment and recording of intake and output and vital signs, with change in weight, which may be a more accurate means of estimating a child's fluid deficit than the overall change in body weight solely.

In addition, as depicted in Table 3, laboratory results changed minimally from initial to final testing between standard and ultra subjects, thus, demonstrating that laboratory testing is of limited usefulness. This is consistent with the American Academy of Pediatric guidelines, which state that laboratory testing is not needed for pediatric patients with mild or moderate dehydration.

Our study had several limitations. This pilot study was not powered to detect serious complications or safety considerations, given the rare occurrence of serious complications, and the large number of patients needed to show statistically significant differences. In addition, although not apparent in our study, a longer period of observation (especially for those patients treated for 1 hour) may allow the clinician greater time to observe for the occasional patient who may present with diarrhea but who may have a more complicated medical condition or a surgical emergency. An analysis of serious complications, efficacy, and safety would require a large multicenter randomized controlled trial. This study was performed to demonstrate preliminary effectiveness of a new hydrating regimen.

Bedside electrolyte testing exists in our ED and allows for rapid laboratory turnaround time, but some general hospital EDs may not have this laboratory capability, and therefore, extending the hydration period to accommodate laboratory turnaround time may be necessary.

Although this study was designed as a convenience sample, the study took longer than expected to complete. We enrolled most of the patients in the first year of the study. After this year, it became more common for the ED attending physicians to use ondansetron with an oral fluid challenge, thus, decreasing the number of patients eligible for enrollment.

Because fluid administration was 1 vs 3 hours, patient and investigator blinding was not possible. It is for this reason that objective measures of fluid tolerance, such as complications, input and output, vital signs, and so on, were examined. And lastly, telephone follow-up with a standardized questionnaire was not complete. We could not contact approximately 10% of patients, and therefore, it is possible that caregivers of subjects brought their child to another treatment center for additional care, thus, possibly affecting reevaluation data.

Our pilot study demonstrated that ultrarapid IV hydration for 1 hour appears to be a comparable alternative to standard rapid IV hydration for 3 hours for pediatric patients experiencing moderate dehydration in the ED setting. Our study did not result in complications, such as overhydration, seizures, deteriorating mental status, or laboratory abnormalities. Ultrarapid IV hydration saves time and allows for patients to be discharged home 2 hours earlier than standard IV hydration subjects. In addition, electrolyte differences after hydration are inconsequential, and thus, electrolyte testing can be avoided.

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