Comparison of Soy-Based Formulas With Lactose and With Sucrose in the Treatment of Acute Diarrhea in Infants

Ibrahim M. Fayad, MD; Mohamed Hashem, MD; Abeer Hussein, MD; Maha Abou Zikri, MD; Mona Abu Zikri, MD; Mathuram Santosham, MD, MPH

Objective: To evaluate the effect of feeding infants a soy-based formula with lactose compared with a soy-based formula with sucrose during an acute diarrheal episode.

Participants and Methods: Two hundred boys, aged 3 to 18 months, who were admitted to the hospital with acute diarrhea and signs of dehydration were randomly assigned to receive a soy-based formula with lactose or sucrose after initial rehydration. Intake and output (stool, urine, and vomit) were measured and recorded every 3 hours until diarrhea resolved.

Results: The stool output during the first 24 hours of maintenance therapy, the total stool output during maintenance therapy, and the stool output during the entire illness (measured in grams per kilograms) were significantly lower among patients who received the soy-based formula with sucrose ($P < .05$, $P < .001$, and $P < .001$, respectively) than among patients who received the soy-based formula with lactose. The duration of diarrhea was significantly shorter among patients who received the soy-based formula with sucrose ($P < .001$). The relative risk of being withdrawn from the study increased to 1.95 (95% confidence interval, 0.65-9.2) and the relative risk of recurrence of dehydration after feeding was initiated increased significantly to 3.49 (95% confidence interval, 1.1-9.6; $P < .01$) in the group receiving the soy-based formula with lactose.

Conclusion: During diarrheal episodes, feeding infants a soy-based formula with sucrose has a better outcome (lower stool output, shorter duration of diarrhea, and lower failure rates) than feeding infants a soy-based formula with lactose.


Editor’s Note: It looks like there’s no need for anyone to manufacture a soy-based formula with lactose.

Catherine D. DeAngelis, MD

RECENT DATA support feeding immediately after rehydration therapy for patients with diarrhea.1-4 The World Health Organization, Geneva, Switzerland, recommends that children continue their normal diets during diarrheal episodes.5 However, the composition of diets introduced during diarrheal episodes is controversial and has been the topic of extensive research and investigation.

Previous studies2-3 have documented that the use of soy-based, lactose-free formula during diarrheal episodes is safe and may reduce the severity of diarrhea6 (as measured by stool output and duration of diarrhea). In one study,7 infants with diarrhea were randomized to receive 1 of the 4 soy-based formulas containing different carbohydrates: lactose, sucrose, polyacose, and a sucrose-polyacose mixture. Resolution of diarrhea was similar in all 4 carbohydrate groups and infants recovered from mild gastroenteritis irrespective of the carbohydrate ingested. However, only 20 patients per group were included in that study. Brown et al8 reviewed several other studies that compared lactose-containing milk formula with lactose-free soy formula, lactose-containing milk formula with lactose-free milk formula, and undiluted cow’s milk with a lactose-free, soy-based formula or dilute cow’s milk. Several of these studies have concluded that introducing an undiluted lactose-containing formula or cow’s milk during a diarrheal episode is safe. In contrast, several studies have concluded that the introduction of undiluted lactose-containing formula or cow’s milk aggravates the diarrhea. To confirm these findings, we conducted a randomized clinical trial among 200 infants.

From the Gastroenterology Unit, Hospital Abu El-Reeche, Cairo University, Cairo, Egypt (Drs Fayad, Hussein, Zikri, and Zikri); and the Center for American Indian and Alaskan Native Health, The Johns Hopkins University, Baltimore, Md (Drs Santosham and Hashem).
PARTICIPANTS AND METHODS

The study was conducted at the Cairo University children’s hospital, Abu El-Rechee Hospital, Cairo, Egypt. The protocol was approved by the ethical committees of the hospital and The Johns Hopkins University School of Hygiene and Public Health, Baltimore, Md. Male infants aged 3 to 18 months who were predominantly formula fed, had acute watery diarrhea (defined as 3 or more watery stools in the previous 24 hours) for less than 7 days’ duration, and had clinical signs of dehydration but no visible blood in the stool were eligible to enroll in the study after oral informed consent was obtained from the parents or guardians. We excluded children with severe malnutrition (obvious signs of kwashiorkor or weight for age lower than 70% of the National Center for Health Statistics median),9 and those who had systemic infections or other diseases requiring specific additional treatments. Only boys were included to facilitate stool collection separate from urine. The clinical assessment of dehydration was conducted by 1 of the investigators (A.H. or M.S.) using standard techniques.6 Patients who were severely dehydrated on admission were initially treated with an intravenous polyelectrolyte solution containing 90-mmol/L sodium, 15-mmol/L potassium, 40-mmol/L acetate, and 65-mmol/L chloride, given at a rate of 20 to 40 mL/kg per hour until their blood pressure and pulse rates returned to normal and they were able to tolerate oral fluids. Rehydration was then continued orally using the standard glucose-based oral rehydration solution (ORS) recommended by the World Health Organization and United Nations International Children’s Emergency Fund (Table 1). Infants with mild to moderate dehydration were given 30 to 80 mL/kg of body weight of the ORS solution within 3 hours. At the end of 3 hours, children were clinically reassessed; if signs of dehydration were still present, the newly calculated deficit was again replaced within the next 3-hour period. This procedure was repeated until signs of dehydration disappeared, or for a maximum of 12 hours.

The maintenance phase started at the end of the rehydration phase and extended until cessation of diarrhea or for a maximum of 7 days, whichever came first. Infants were randomized to receive 1 of 2 formulas: Nursoy ready-to-feed (Wyeth Nutritional International, Philadelphia, Pa) formula, which contains sucrose as the carbohydrate source (soy-based formula with sucrose); or a Nursoy powder (Wyeth Nutritional International), which was identical except for the carbohydrate source, lactose (69 g/L) instead of sucrose (soy-based formula with lactose). The randomization list was established at Wyeth Nutritional International with random permuted blocks of variable lengths (6-12 subjects per block). The soy-based formula with sucrose was reconstituted with an appropriate volume of sterile water so that each 100 mL provided 281.4 kJ. The soy-based formula with sucrose also provided 281.4 kJ per 100 mL. Each infant was fed his assigned formula at a volume of 150 mL/kg of body weight per day (420 kJ/kg of body weight daily) in 8 equal volumes until resolution of diarrhea. No other food was given during the study period. The ORS solution was given in volumes to replace the measured volume of continuing stool losses and vomiting until diarrhea stopped (defined as no watery or loose stools for a continuous 15-hour period); plain water was also provided ad libitum (with a maximum of 4 mL/kg every 3 hours).

Indications for administering supplemental intravenous fluids during the course of the trial were as follows: persistence of clinical signs of dehydration for more than 12 hours after oral rehydration therapy had been initiated despite the intake of estimated fluid requirements, and failure to maintain positive fluid balance with oral fluids because of persistent vomiting or a high stool purging rate (recurrence of signs of dehydration). These infants were given an intravenous polyelectrolyte solution and were withdrawn from the study. In addition, infants who required unscheduled treatment for a serious intercurrent illness or whose diarrhea lasted for more than 7 days were withdrawn and treated as clinically indicated.

All intakes and outputs were measured and recorded every 3 hours until cessation of diarrhea, for a maximum of 7 days, or until withdrawal from the study. Stool output was measured on preweighed diapers. Urine was separated from the stool by using urine collection bags. Clinical assessment of patients, the amount and characteristics of the stool passed, and the number of vomiting episodes were recorded continuously and summarized for 3-hour periods. Body weight was recorded at admission, after rehydration, and every 24 hours thereafter until the diarrhea resolved. Blood samples were obtained on admission and 24 hours later for measurement of serum sodium, potassium, chloride, serum urea nitrogen, and total protein levels.

The study was designed to detect a 33% difference in stool output and a 25% difference in the duration of diarrhea. On the basis of our previous studies,10 90 patients per treatment group were needed to show this difference with a power of 90% and a significance level of 5%. To allow for attrition, we recruited a total of 200 infants during the study period, 100 in each of the treatment groups.

Statistical analysis was computed on Epi-Info software (Centers for Disease Control and Prevention, Atlanta, Ga, and the World Health Organization, Geneva, Switzerland) and STATA for Windows software (Stata Corporation, College Station, Tex). A 2-tailed t test was used to compare the groups. Continuous variables with skewed distributions were normalized by log transformation.11 The Fisher exact test was used to compare qualitative variables. Relative risk ratios and their associated 95% confidence intervals (CIs) were calculated to identify variables related to treatment outcome.12,13

RESULTS

From August 15, 1994, to July 30, 1995, 200 male infants were enrolled in the study, 100 patients in each of the 2 treatment groups. There were no differences in the admission characteristics between the 2 treatment groups (Table 2). Data collected from all 200 children were included in the final analysis up to the time when diarrhea stopped or when subjects were withdrawn from the study before diarrhea had resolved or were removed from the study on day 7.

Of these 200 patients, 16 left the study before the beginning of the maintenance phase. Eight patients (3 in the soy-based formula with lactose group and 5 in the...
Table 1. Composition of the Standard Oral Rehydration Solution Recommended by the World Health Organization*

<table>
<thead>
<tr>
<th>Component</th>
<th>Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glucose, mmol/L</td>
<td>111 (2000)</td>
</tr>
<tr>
<td>Sodium</td>
<td>90</td>
</tr>
<tr>
<td>Potassium</td>
<td>20</td>
</tr>
<tr>
<td>Chloride</td>
<td>80</td>
</tr>
<tr>
<td>Citrate</td>
<td>10</td>
</tr>
<tr>
<td>Osmolarity, mOsm/L</td>
<td>311</td>
</tr>
</tbody>
</table>

* All data are presented as millimoles per liter unless otherwise indicated. The following ingredients were dispensed in powdered form (all measurements in grams per liter): sodium chloride, 3.5; trisodium citrate dihydrate, 2.9; potassium chloride, 1.5; and glucose, 20.

soy-based formula with sucrose group) were withdrawn before formula feeding was initiated because their dehydration could not be corrected with the ORS solution within the initial 12 hours of rehydration and they required intravenous fluids. The other 8 patients (3 among those receiving the soy-based formula with lactose and 5 receiving the soy-based formula with sucrose) left the study protocol at the end of the rehydration period because their diarrhea stopped during the rehydration phase. Data from these 16 patients were analyzed only during the rehydration phase.

One hundred eighty-four patients (94 receiving the soy-based formula with lactose and 90 receiving the soy-based formula with sucrose) still had diarrhea when formula feeding was initiated. Of these 184 patients, 12 left the study before their diarrhea had stopped (8 among those receiving the soy-based formula with lactose and 4 receiving the soy-based formula with sucrose). Treatment was considered to have failed in 8 patients: 7 children, after completion of the rehydration phase, had recurrent dehydration secondary to high stool output and failed to maintain a positive fluid balance with oral fluid and were scheduled for supplemental intravenous fluid infusion (6 among the lactose group and 1 in the sucrose group); and 1 child in the sucrose group still had diarrhea on day 7 of the study. Treatment was not considered to have failed in the other 4 patients who were removed from the study before their diarrhea had resolved: 1 child in the sucrose group was voluntarily withdrawn by his parents before cessation of diarrhea, and 3 children (2 in the lactose group and 1 in the sucrose group) were removed from the study by the investigator before cessation of diarrhea. One of the patients had fever, tachypnea, inspiratory stridor, barking cough, and respiratory distress at the time of removal, was diagnosed as having viral croup, and was given intravenous fluids and cold humidified oxygen; another child developed a high-grade fever and sepsis at the time of removal; and the third patient developed dysentery with mucus, pus, and blood in the stools and tenesmus and a stool that tested positive for Entamoeba histolytica trophozoite.

Of the 172 children who successfully completed the study according to protocol, 21 (16 [17%] receiving the soy-based formula with lactose and 5 [6%] receiving the soy-based formula with sucrose) had recurrence of dehydration during the maintenance period after formula feeding was initiated and their deficit was corrected orally.

Table 3 summarizes the outcome variables during the rehydration phase for all 200 patients. There were no differences between the groups in any of the parameters tested. The average time of onset of feeding (duration of rehydration period) was similar.

Table 4 summarizes the outcome variables during the maintenance period (after feeding with the soy-based formula was initiated) for the 184 patients still in
the study and still having diarrhea at the end of the rehydration phase.

The mean stool output during the first 24 hours of maintenance therapy, total stool output during maintenance therapy, and total stool output during entire illness (measured in grams per kilograms) were significantly lower among patients who received the soy-based formula with sucrose (P < .001, P < .001, and P < .001, respectively). The purging rate (stool weight per kilogram of body weight per hour) from the time feeding was initiated until the time of discharge from the study and from the time of admission to the end of diarrhea (Table 5) was significantly lower among patients who received the soy-based formula with sucrose (P < .05 and P < .005, respectively). The distribution of the variable stool output and purging rate during the entire illness was significantly different between treatment groups (Kolmogorov-Smirnov Z test, P < .001 and P < .05, respectively).

The mean urine output during the first 24 hours (20 ± 19 mL/kg in the soy-based formula with lactose group vs 26 ± 25 mL/kg in the soy-based formula with sucrose group), and the rate of total urine output measured in milliliters per kilogram per hour (0.8 ± 0.7 in the soy-based formula with lactose group vs 1.0 ± 1.0 in the soy-based formula with sucrose group) were similar in both groups.

The number of children who vomited during the maintenance period was significantly greater (P < .001) among children who received the soy-based formula with lactose (55% of the children receiving the soy-based formula with lactose vs 24% receiving the soy-based formula with sucrose) (relative risk, 3.8; 95% CI, 1.8-8.1). However, during the rehydration phase and before feeding with 1 of the soy-based formulas was initiated, the number of children with vomiting was similar in the 2 groups (44% vs 37% of the soy-based formula with sucrose, respectively).

Intake of ORS during the first 24 hours of maintenance therapy, total ORS intake during maintenance therapy (Table 4), and total ORS intake from admission to the end of diarrhea (measured in milliliters per kilogram) were significantly lower among patients who received the soy-based formula with sucrose (P < .001, P < .001, and P < .001, respectively). The rate of ORS intake (measured in milliliters per kilogram body weight per hour) during the maintenance period was also significantly lower among patients who received the soy-based formula with sucrose (P < .001) (data not shown).

Diet intake during the first and second 24 hours of maintenance therapy and the mean daily diet intake (measured in milliliters per kilogram) was similar for both treatment groups (Table 4). The mean percentage of weight gain was similar after completion of the rehydration phase and at the time of discharge from the study (Table 3 and Table 5). Percentage of weight gain was calculated as:

\[
\frac{\text{weight at resolution of diarrhea} - \text{admission weight}}{\text{admission weight}} \times 100
\]

A comparison of the duration of diarrhea in the 2 treatment groups was done by the Kaplan-Meier method (Figure). The log-rank test confirmed that the duration of diarrhea was significantly shorter among patients who received the soy-based formula with sucrose (P < .001).

### Table 4. Clinical Features of Patients During the Maintenance Phase

<table>
<thead>
<tr>
<th>Variable</th>
<th>No. of Patients</th>
<th>Soy-Based Formula With Lactose</th>
<th>Soy-Based Formula With Sucrose</th>
<th>Comparative Data</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stool output during first 24 h, g/kg†</td>
<td>94</td>
<td>103 (87 to 122)</td>
<td>90</td>
<td>57 (48 to 68)</td>
<td>1.8 (1.4 to 2.3)</td>
</tr>
<tr>
<td>Total stool output, mL/kg‡</td>
<td>94</td>
<td>164 (131 to 208)</td>
<td>90</td>
<td>69 (55 to 87)</td>
<td>2.4 (1.7 to 3.3)</td>
</tr>
<tr>
<td>Stool purging rate, g/kg‡</td>
<td>86</td>
<td>6.1 (2.4)</td>
<td>86</td>
<td>5.3 (2.3)</td>
<td>0.8 (0.1 to 1.5)</td>
</tr>
<tr>
<td>ORS intake, mL/kg†</td>
<td>86</td>
<td>170 (132 to 217)</td>
<td>86</td>
<td>58 (43 to 79)</td>
<td>3.0 (2.0 to 4.0)</td>
</tr>
<tr>
<td>Mean diet consumption, mL/kg‡</td>
<td>86</td>
<td>146 (15)</td>
<td>86</td>
<td>146 (16)</td>
<td>-0.1 (-4.6 to 4.4)</td>
</tr>
</tbody>
</table>

*ORS indicates oral rehydration solution; ellipses, data not applicable.
†Arithmetic mean (95% confidence interval); comparative data = difference (95% confidence interval) in population (geometric) means (soy-based formula with lactose/soy-based formula with sucrose).
‡Mean diet consumption measured in milliliters per kilogram per hour.

### Table 5. Clinical Features of Patients for Variables Calculated Over the Entire Course of the Study

<table>
<thead>
<tr>
<th>Variable</th>
<th>No. of Patients</th>
<th>Soy-Based Formula With Lactose</th>
<th>Soy-Based Formula With Sucrose</th>
<th>Comparative Data</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stool purging rate, g/kg per hour*</td>
<td>86</td>
<td>6.2 (2.3)</td>
<td>86</td>
<td>5.2 (2.1)</td>
<td>1.0 (0.3 to 1.7)</td>
</tr>
<tr>
<td>Duration of diarrhea, h*</td>
<td>86</td>
<td>39 (26)</td>
<td>86</td>
<td>23 (21)</td>
<td>17 (9 to 24)</td>
</tr>
<tr>
<td>Mean weight gain (% of admission weight)*</td>
<td>86</td>
<td>4.3 (2.5)</td>
<td>86</td>
<td>4.2 (2.3)</td>
<td>0.1 (-0.6 to 1.4)</td>
</tr>
<tr>
<td>No. (%) of treatment failures†‡</td>
<td>94</td>
<td>6 (6)</td>
<td>90</td>
<td>2 (2)</td>
<td>3.0 (0.9 to 11.3)</td>
</tr>
<tr>
<td>No. (%) with recurrence of dehydration‡</td>
<td>94</td>
<td>16 (17)</td>
<td>90</td>
<td>5 (6)</td>
<td>3.5 (1.1 to 9.6)</td>
</tr>
</tbody>
</table>

*Arithmetic mean (SD); comparative data = difference (95% confidence interval) in means (soy-based formula with lactose/soy-based formula with sucrose).
†Ellipses indicate not applicable.
‡After feeding with 1 of the soy-based formulas was initiated.
The relative risk of treatment failure requiring unscheduled intravenous fluid therapy after feeding was initiated was substantially increased to 3.0 among children in the lactose group (95% CI, 0.9-11.3); 6 infants in the lactose group vs 2 in the sucrose group. The relative risk of the recurrence of dehydration after feeding was initiated was significantly increased to 3.49 in children receiving the soy-based formula with lactose; 16 (17%) in the soy-based formula with lactose and 5 (6%) in the soy-based formula with sucrose (95% CI, 1.1-9.6; P < .01).

Because the recurrence of dehydration was 10% higher in infants after feeding was initiated, the outcome variables may have been affected. Therefore, we performed another set of analyses excluding the 21 children in whom a recurrence of dehydration occurred during the maintenance period after feeding with the soy-based formula was initiated and their deficit was corrected orally (16 patients receiving the soy-based formula with lactose and 5 patients receiving the soy-based formula with sucrose). The stool output during the maintenance therapy and after feeding with soy-based formula was initiated (measured in grams per kilograms) remained significantly lower among patients who received the soy-based formula with sucrose (P < .001). The distribution of the variable stool output during maintenance therapy remained significantly different between treatment groups (Kolmogorov-Smirnov Z test, P < .001). The duration of diarrhea also remained significantly shorter among patients who received the soy-based formula with sucrose (P < .001). A comparison of the duration of diarrhea in the 2 treatment groups was done by the Kaplan-Meier method excluding the 21 children. Again, the log-rank test confirmed that the duration of diarrhea was significantly shorter among patients who received the soy-based formula with sucrose (P < .001). However, the differences in the purging rate (measured in grams per kilograms of body weight per hour) and the stool output during the first 24 hours were no longer significant after excluding the 21 children.

The mean serum sodium concentration at 24 hours was significantly lower in children who received the soy-based formula with sucrose (135 ± 6 mmol/L for the sucrose group vs 140 ± 7 mmol/L for the lactose group; P < .001), as were the mean serum chloride concentrations at 24 hours (107 ± 9 mmol/L for the sucrose group and 112 ± 10 mmol/L for the lactose group; P < .001). The mean serum total protein concentrations at 24 hours were lower in children who received the soy-based formula with sucrose (5.3 ± 0.8 mmol/L for the sucrose group vs 5.6 ± 0.9 mmol/L for the lactose group; P < .001) (data not shown).

These data indicate that when a soy-based formula is used during a diarrheal episode, the duration of diarrhea and the stool output are reduced considerably (40% and 50%, respectively) in infants who were given the soy-based formula with sucrose compared with infants who were given the soy-based formula with lactose.

Groothuis et al7 observed that replacement of lactose with either sucrose or glucose polymer in a soy-based formula offered no advantage and that infants recovered from gastroenteritis irrespective of the carbohydrate ingested. However, the sample size for the study was relatively small. Thus, drawing firm conclusions from that study is not possible. Margolis et al14 showed that the clinical outcome was no different in a group of 36 infants with mild diarrhea whether they received oral rehydration therapy followed by diluted soy, full-strength soy, or diluted cow’s-milk formula or their usual formula without any alteration.

The routine elimination of lactose from the diet of infants and children during the acute stage of diarrhea remains controversial, in part because previous studies have included patients with varying degrees of illness and have employed a variety of study diets and research designs. Furthermore, individual studies have often been inconclusive because of the relatively small numbers of patients enrolled.8

Recently a meta-analysis was performed on 29 clinical trials that evaluated the use of undiluted lactose-containing formula or cow’s milk during an episode of diarrhea.9 Nine of the studies reported data on the duration of the diarrhea following the initiation of either lactose-containing or lactose-free diets. In accordance with our results, the pooled data indicated that there was a small but statistically significant increase in the mean diarrheal duration when a lactose-containing diet was consumed (P < .001). The combined meta-analysis also indicated that there was significantly greater stool output among children in the lactose group (P < .005). The authors concluded that lactose-containing milks or formulas caused marginally greater stool output compared with lactose-free formulas, and that these differences are unlikely to be of clinical importance except among children with severe underlying malnutrition or for whom treatment had failed. They also concluded that although the duration of diarrhea may be slightly prolonged in children who receive lactose-containing regimens, the magnitude of this difference is of little clinical importance.9

Our results show that treatment with a soy-based formula with lactose was associated with a substantially higher rate of treatment failure, and a clinically and statistically significant increase in recurrence of dehydration after feeding with a lactose diet was initiated (the percentage of infants receiving the soy-based formula...
with lactose who had a recurrence of dehydration was 10% higher than in the other group). Similar risks of failure were observed in the meta-analysis. However, the studies that reported increased failure rates among patients who received lactose-containing diets included patients whose initial degree of dehydration was severe. Among those studies that included patients with apparently severe dehydration initially, 38% (95% CI, 31%-44%) of the children did not respond to treatment in the lactose group compared with 16% in the sucrose group (95% CI, 12%-20%). The relative risk of treatment failure with lactose-containing diets was 2.4% (95% CI, 1.8%-3.3%). By contrast, when studies that included only patients with less severe dehydration were examined, failure rates were no longer significant. Our findings demonstrate a statistically significant increase in adverse clinical outcomes in mildly to moderately dehydrated infants who are fed soy-based formula with lactose compared with infants who are fed soy-based formula with sucrose.

In a recently published review, the authors concluded that undiluted nonhuman milk is well tolerated in most children with acute diarrhea, but that continuing a lactose-containing diet may result in an increase in the stool output, duration of illness, and treatment failure rates in some children, and that these outcomes are even more obvious in severely dehydrated children. In contrast to other studies, our findings demonstrate a statistically significant increase in adverse clinical outcomes in mildly to moderately dehydrated infants who are fed a soy-based, lactose-containing formula compared with infants who are fed a soy-based, lactose-free formula. We would like to emphasize that the findings of the current study are not relevant to most infants in developing countries. These data are relevant for treatment of diarrhea in a hospital setting or in regions of the world where soy-based formulas are available and are within the economic means of the population.

We conclude that both the soy-based formula with lactose and the soy-based formula with sucrose were well tolerated among infants with diarrhea. However, the infants who received soy-based formula with sucrose had a substantially lower stool output (50%) and a shorter duration of diarrhea (40%) compared with the infants who received the soy-based formula with lactose. The relative risk for requiring intravenous therapy was also increased to 1.95% in the group that received the soy-based formula with lactose. The percentage of infants who had a recurrence of dehydration was 10% higher in the group that received the soy-based formula with lactose; their deficit was corrected orally (relative risk, 3.49; 95% CI, 1.1-9.6; P<.01). Additionally, 25% more infants receiving the lactose-containing formula experienced vomiting during the maintenance period (relative risk, 3.2; 95% CI, 1.7-6.3; P<.001). Therefore, if a soy-based formula is used during a diarrheal episode, a lactose-free formula is preferred.

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Corresponding author: Mathuram Santosham, MD, MPH, The Johns Hopkins University, 621 N Washington St, Room 5505, Baltimore, MD 21205 (e-mail: msantosh@jhsphs.edu).

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