# Age of introduction of complementary foods and growth of term, low-birth-weight, breast-fed infants: a randomized intervention study in Honduras[1–4]

*Kathryn G Dewey, Roberta J Cohen, Kenneth H Brown, and Leonardo Landa Rivera*

**ABSTRACT**

**Background:** The optimal age at which to introduce complementary foods is a topic of considerable debate.

**Objective:** This study was designed to evaluate this issue in a nutritionally vulnerable population in Honduras.

**Design:** Mothers of low-birth-weight (1500–2500 g) term (ie, small-for-gestational-age) infants were recruited in the hospital and assisted with exclusive breast-feeding during the first 4 mo. At 4 mo, mothers were randomly assigned to either continue exclusive breast-feeding to 6 mo (EBF; $n = 59$) or to feed complementary solid foods (jarred rice cereal, chicken, and fruit and vegetables) twice daily from 4 to 6 mo while continuing to breast-feed at their initial frequency (SF; $n = 60$). At 4 and 6 mo, breast milk and total energy intake were measured for a nonrandom subsample (those who could stay overnight in a central unit: 32 EBF and 31 SF).

**Results:** At 4 mo, breast milk intake in the subsample was not significantly different between groups (EBF: 729 ± 135 g/d; SF: 683 ± 151 g/d; $P > 0.2$); from 4 to 6 mo it increased (by 28 g/d) in the EBF group but decreased (by 39 g/d) in the SF group ($P < 0.005$). Nonetheless, total energy intake (including solid foods) increased more from 4 to 6 mo in the SF than in the EBF group. However, there were no significant differences between groups in weight or length gain during the intervention or subsequently (6–12 mo).

**Conclusion:** There was no growth advantage of complementary feeding of small-for-gestational-age, breast-fed infants between 4 and 6 mo of age. *Am J Clin Nutr* 1999;69:679–86.

**KEY WORDS** Breast-feeding, weaning, infant nutrition, complementary foods, low birth weight, growth, age, infants, Honduras

## INTRODUCTION

Current evidence indicates that exclusive breast-feeding until ≈6 mo of age is recommended for full-term, normal-birth-weight infants (1), but it is unclear whether this recommendation also applies to low-birth-weight (<2500 g) infants. Low-birth-weight infants represent >30% of births in some developing countries (2). Because infant sucking ability is related to birth weight (3), mothers of these infants may have more difficulty establishing lactation. Low-birth-weight infants are also more vulnerable to nutritional deficiencies because they are more likely to be born to malnourished mothers and to have lower stores of several key nutrients at birth.

We reported previously results of a randomized intervention study designed to evaluate the optimal timing of introducing complementary foods to breast-fed infants in a low-income population in Honduras (4). The results indicated that infants aged 4–6 mo self-regulated their total energy intake and consumed less breast milk when other foods were introduced. As a result, there was no growth advantage to complementary feeding before 6 mo, even with hygienically prepared foods of high nutritional quality. Under circumstances in which complementary foods are often contaminated and thus increase diarrheal morbidity, their use before 6 mo of age can impair growth (5). In our previous study, only 28 of the infants had a low birth weight. Although the results for this subgroup were the same as for the larger cohort, the sample size was considered too small for definitive conclusions. Therefore, we initiated a second randomized study specifically designed to determine whether complementary feeding before 6 mo of age influences the growth of full-term, low-birth-weight (ie, small-for-gestational age) breast-fed infants.

## METHODS

### Study design

The study was designed as a prospective observational study of infants from birth to 4 mo of age, followed by a randomized

[1] From the Department of Nutrition and the Program in International Nutrition, University of California, Davis, and Medicina Infantil, San Pedro Sula, Honduras.

[2] The opinions expressed herein are those of the authors and do not necessarily reflect the views of the US Agency for International Development or of Wellstart International.

[3] Supported by UNICEF and Wellstart International (through the Health Services Division, Office of Health, Bureau of Global Programs, Field Support and Research Development, US Agency for International Development) under the terms of Cooperative Agreement no. DPE-5966-A-00-1045-00.

[4] Reprints not available. Address correspondence to KG Dewey, Department of Nutrition, University of California, One Shields Avenue, Davis, CA 95616–8669. E-mail: kgdewey@ucdavis.edu.

Received April 17, 1998.
Accepted for publication September 8, 1998.

intervention trial of complementary feeding from 4 to 6 mo. Mothers of full-term (≥37 wk gestation) infants weighing 1500–2500 g at birth, who were willing to exclusively breast-feed for 6 mo and were not planning to work outside the home, were recruited from the 2 main maternity hospitals in San Pedro Sula, Honduras. Gestational age was assessed independently by 2 physicians using the Capurro et al rating (6). Lactation guidance was provided to all subjects in the hospital and at home visits 3 d postpartum and every week thereafter. Continued exclusive breast-feeding was encouraged by having the lactation counselors use a flipchart of pretested motivating messages. Demographic and socioeconomic data were collected from the mothers at the first home visit. Anthropometric and morbidity data were collected each week. Blood samples were collected at 2, 4, and 6 mo of age. Infants with hemoglobin <100 g/L at any age were given iron supplements ($5 mg \cdot kg^{-1} \cdot d^{-1}$) for 2 mo. The study protocol was approved by the Human Subjects Review Committee of the University of California, Davis.

At 16 wk of age, infants who were still exclusively breast-fed were randomly assigned to 1 of 2 groups: 1) continued exclusive breast-feeding to 6 mo (EBF), or *2*) complementary feeding plus breast-feeding from 4 to 6 mo, with mothers encouraged to maintain baseline (16 wk) breast-feeding frequency (SF). Randomization was performed by week of birth (ie, all infants born in the same week were assigned to the same group) to facilitate provision of feeding instructions to each group. Subjects were not informed of their assignment until they had completed the first 16 wk of the study. The target sample size was 56 per group, which was based on detecting a difference between groups of ≥15% in weight or length gain between 4 and 6 mo by using SDs for these outcomes for the 28 low-birth-weight infants in our previous study (4) (233 g weight gain, 0.86 cm length gain from 4 to 6 mo), assuming a two-sided test with $\alpha = 0.05$ and $\beta \geq 0.9$.

Growth and morbidity from 16 to 26 wk were assessed for all infants in the intervention phase. Measurements of breast milk intake and composition and total energy intake at 16 and 26 wk were completed for a subsample (all who were willing to participate in this component; about half of all subjects). These latter subjects came to a central facility at each of these time points for 24-h measurement of milk volume and collection of a milk sample for determination of energy density. At 26 wk, intake of solid foods by infants in the SF group was also determined. After the intervention phase, infant growth was measured monthly until 12 mo of age.

### Complementary foods

The complementary foods were provided in jars (Beech-Nut Nutrition Corp, St Louis) and included rice cereal with applesauce (fortified with iron, ascorbic acid, thiamine, niacin, and riboflavin), chicken, fruit (banana and pear with pineapple, both fortified with ascorbic acid), and vegetables (carrots, squash, and mixed vegetables). The ingredients in these foods are all locally available and commonly used for infants. Commercially prepared foods were used instead of home-prepared foods to avoid contamination. Foods were given by spoon at 2 meals/d, each ≈1 h after breast-feeding. Rice cereal was fed at both meals; chicken, a fruit, and a vegetable were each fed once per day. Women were advised to use each jar only once, to give away or discard any excess food, and not to give the infant any other foods or liquids. To avoid dependence on the continued use of commercially prepared baby foods, all mothers were given a baby food grinder at 26 wk and taught how to prepare nutritionally adequate baby foods at home. All of the EBF mothers began complementary feeding shortly after the intervention ended at 26 wk.

### Monitoring of compliance

Before 16 wk, any evidence of use of other foods or fluids was noted at the weekly home visits and discussed with the mother. When a woman admitted to giving other liquids or foods regularly, her infant was ineligible for the randomized trial at 16–26 wk. All mothers were asked to keep daily home records of breast-feeding frequency each week from 1 to 26 wk using a simple pretested form used in our previous study (4). In addition, an observer went to the home for 12 h/d at 14–15, 18–19, and 23–24 wk postpartum to record daytime breast-feeding frequency and duration and adherence to the feeding instructions. For the SF group, the observer also measured intake of complementary foods at 18–19 and 23–24 wk.

### Anthropometry

Birth weight was measured within 30 min of birth on a scale accurate to the nearest 10 g. The scale was calibrated daily by using standard weights. Subsequently, weights were determined at 3 d, each week from 1 to 26 wk, and monthly thereafter, usually in the home with a Salter scale accurate to the nearest 100 g (ITAC Corporation, Silver Spring, MD). Infant recumbent length (to the nearest 0.1 cm) and head circumference (to the nearest mm) were measured at birth and every month thereafter. Weight-for-age and length-for-age *z* scores were calculated by using National Center for Health Statistics reference data (7). Weight and length gains were calculated by adjusting for the actual length of the interval between measurements. Maternal height (to the nearest 0.1 cm) and weight (to the nearest 0.2 kg) were measured within the first 7 d, and weight was remeasured every week thereafter.

### Infant intake

For the subsample of mother-infant pairs who came to the central facility overnight at 16 and 26 wk, breast milk intake was measured by 24-h test weighing with an electronic balance (Sartorius; Brinkmann Instruments, Westbury, NY) accurate to 1 g. The timing and duration of each breast-feeding were recorded. Breast milk intake was corrected for insensible water loss during feedings by using the methods described previously (4).

Energy intake from breast milk was calculated as milk intake times milk energy density with 2 different methods: by using measured values for milk energy density from single milk samples collected at 16 wk from mothers in the subsample and by using an assumed value for milk energy density for all mothers [2.89 kJ/g, the average of the 24-h pooled milk samples at 4 and 6 mo from our previous study in the same population (4)]. For the first method, a breast milk sample was collected in the morning (between 0800 and 1200) after the 24-h test-weighing period by expressing the complete contents of one breast with an electric breast pump (Egnell Inc, Cary, IL). This sampling was conducted after an interval equivalent to the mother's average feed interval (average: 140 min/breast) calculated from the previous 24 h. This procedure was used to obtain a sample that was reasonably representative of 24-h milk energy density because previous studies have shown that the interfeed interval is the most important determinant of milk lipid (and hence, milk energy) concentrations (8). Milk samples were analyzed for lipid concentration by using the modified Folch procedure (9), and energy density was calculated by using the prediction equation developed in our previous study in the same population (4). Each mother's milk energy density at 16 wk was also used for the 26-wk calculations, on the basis of the observation that there is little change in milk energy density during this interval (10).

For the SF group, solid food intake was measured in the home at 18–19 and 23–24 wk (total sample) and in the central facility at 26 wk (subsample) by weighing the baby food jars before and after each feeding. Nutrient intake from solid foods was calculated by using the manufacturer's values.

### Morbidity

Infant morbidity data were collected by maternal recall of illness symptoms (eg, nasal discharge, cough, and fever) at each weekly home visit. Mothers kept a daily record of the infants' stool frequency and consistency. Diarrhea was defined as >3 liquid stools in 24 h. For each symptom, prevalence was calculated as the percentage of days ill from 16 to 26 wk.

### Data analysis

Data were analyzed by using SAS-PC software (11). Group comparisons were performed with Student's *t* test and chi-square tests. Analysis of variance was used to determine the effect of the intervention on breast-feeding frequency and duration, breast milk, total energy intake, and growth from 16 to 26 wk.

## RESULTS

### Sample size and characteristics

During the 24 wk of recruitment there were 8218 infants born, 575 (7%) of whom had a low birth weight. Of these 575 low-birth-weight infants, 222 qualified initially for the study and their mothers agreed to participate. Reasons for not qualifying were maternal employment that would prevent exclusive breast-feeding (39%); residence outside of the recruitment zone (28%); prematurity (16%); maternal or infant illness, death, congenital defect, or adoption (7%); inability of fieldworkers to find the subject's home (4%); refusal by spouse or family to participate (3%); refusal to exclusively breast-feed (1%); refusal to participate (1%); mother aged <15 y (1%); and twin birth (1%).

Of the 222 subjects who were enrolled at birth, 128 were eligible to enter the intervention phase at 16 wk postpartum. The remaining 94 subjects were ineligible for the following reasons: *1*) moved or could no longer be located (31%); *2*) did not maintain exclusive breast-feeding, either because of employment (23%) or for other reasons (28%); *3*) spouse or family refused permission to continue (9%); and *4*) infant or mother died or was very ill (3%). There were no significant differences between the 128 subjects who remained eligible and the 94 subjects who were not eligible with regard to age, education, socioeconomic status, marital status, parity, or prenatal care of the mothers; anthropometric indexes of the mothers and infants; or the sex, gestational age, Apgar score, or birth measurements (weight, length, head circumference, and ponderal index) of the infants.

Of the 28 subjects who did not exclusively breast-feed for the first 16 wk for reasons other than employment, the following reasons were given for introducing other fluids or foods: *1*) insufficient milk (25%); *2*) baby cried too much and disturbed husband (18%); *3*) mother never intended to exclusively breast-feed that long (despite saying so at recruitment) (14%); *4*) mother was too busy, had to leave the house often, or family pressure (14%); *5*) infant sucking problems (11%); *6*) breast-feeding problems, or baby had to be hospitalized and mother did not want to persevere or relactate (11%); and *7*) mother intended to go back to work (7%).

Of the 128 subjects who entered the intervention phase at 16 wk, 119 completed measurements to 26 wk. There were 8 dropouts in the EBF group and 1 in the SF group ($P = 0.02$). Mothers in the EBF group dropped out for the following reasons: they moved away ($n = 3$), they went back to work ($n = 2$), they never intended to exclusively breast-feed ($n = 1$), they felt they were losing too much weight ($n = 1$), and they experienced a decrease in their milk supply as a result of taking medication for tuberculosis ($n = 1$). The one subject who dropped out of the SF group did so because she did not want to continue.

There were no significant differences between the 119 participants and the 9 dropouts in infant sex, gestational age, ponderal index, or weight and length gains from birth to 16 wk, nor in maternal height, body mass index, income, or prenatal care. However, the dropouts had significantly lower birth weights (2204 ± 173 compared with 2346 ± 162 g, $P = 0.01$), head circumferences (31.1 ± 0.9 compared with 31.7 ± 0.9 cm, $P = 0.02$), Apgar scores at 5 min (8.3 ± 1.0 compared with 8.9 ± 0.7, $P = 0.04$), and maternal ages (19.6 ± 2.3 compared with 23.9 ± 6.1 y, $P = 0.03$). Except for birth weight, none of these variables was significantly associated with the primary outcome variables (weight and length gains from 16 to 26 wk); birth weight was negatively correlated with length gain from 16 to 26 wk ($r = -0.19$, $P = 0.04$), although weight gain was not.

Characteristics of subjects who completed the intervention phase are shown in **Table 1**. There were no significant differences between the EBF and SF groups in any of the maternal or infant characteristics. The subsample of subjects who completed the intake measurements did not differ significantly from the total sample in any characteristic. Within the subsample, the EBF mothers had a significantly lower level of education (5.3 ± 2.6 compared with 6.8 ± 2.6 y, $P = 0.03$) and had more children (2.5 ± 1.9 compared with 1.6 ± 1.0, $P = 0.04$) than the SF mothers, but there were no other significant differences between groups.

### Feeding patterns

Data on daytime breast-feeding frequency and time spent breast-feeding from the home observations are shown in **Table 2** and both daytime and nighttime data from the central unit are shown in **Table 3**; data from the mothers' records (not shown) were similar to the results in these tables. At baseline, breast-feeding frequency averaged 16 feeds/24 h and breast-feeding time averaged 216 min/24 h; breast-feeding frequency did not differ significantly between the groups. In the total sample, SF mothers had a slightly but significantly lower daytime breast-feeding frequency at baseline, but there was no significant difference between the EBF and SF groups in the change in daytime, nighttime, or total breast-feeding frequency during the intervention in either the total sample or the subsample for whom breast milk intake was measured; both the EBF and SF groups maintained their breast-feeding frequency. However, time spent breast-feeding declined by 38 min/24 d in the SF group, whereas it increased by 11 min/d in the EBF group during the intervention period (subsample: $P < 0.01$).

Within the subsample, daytime breast-feeding frequency in the central unit did not differ significantly from that in the home at either 14–16 or 23–26 wk, nor did daytime time spent breast-

**TABLE 1**
Characteristics of subjects who completed the intervention trial[1]

| | EBF (*n* = 59) | SF (*n* = 60) |
|---|---|---|
| Mother | | |
| Age (y) | 24.3 ± 6.4[2] | 23.4 ± 5.7 |
| Education (y) | 5.7 ± 2.7 | 6.2 ± 3.0 |
| Weight, 1–2 wk (kg) | 52.5 ± 8.7 | 52.0 ± 8.6 |
| BMI (kg/m$^2$) | 23.3 ± 3.3 | 23.0 ± 3.3 |
| Marital status (% married) | 85 | 88 |
| Parity | 2.3 ± 1.6 | 2.0 ± 1.4 |
| Prenatal care (number of visits) | 3.3 ± 2.9 | 3.6 ± 2.8 |
| Infant | | |
| Birth weight (g) | 2364 ± 137 | 2327 ± 183 |
| Median | 2400 | 2390 |
| Birth length (cm) | 46.1 ± 1.2 | 45.8 ± 1.5 |
| Ponderal index (wt/length$^3$) | 2.42 ± 0.17 | 2.41 ± 0.19 |
| Head circumference (cm) | 31.7 ± 0.7 | 31.7 ± 1.0 |
| Sex (% boys) | 46 | 42 |
| Gestational age (wk) | 38.9 ± 1.0 | 38.8 ± 1.1 |
| Apgar score (5 min) | 8.8 ± 0.6 | 8.9 ± 0.8 |
| Weight, 4 mo (g) | 5761 ± 739 | 5653 ± 576 |
| Length, 4 mo (cm) | 59.3 ± 2.3 | 59.3 ± 2.2 |
| Socioeconomic status | | |
| Income ($/mo) | 125 ± 64 | 131 ± 80 |
| Floor type (scale 1–3) | 1.9 ± 0.5 | 2.0 ± 0.4 |
| Number of rooms | 2.0 ± 1.5 | 2.2 ± 1.3 |

[1] There were no significant differences between groups.
[2] $\bar{x}$ ± SD.

feeding at 14–16 wk. However, in both of the intervention groups, daytime time spent breast-feeding was significantly greater in the central unit at 26 wk than in the home at 23–24 wk (99 ± 42 compared with 81 ± 40 min/12 h, respectively, for the EBF and SF groups combined; $P$ <0.05).

### Breast milk, solid food, and total energy intake

At baseline (16 wk), breast milk intake (based on data for the subsample) was slightly but not significantly lower in the SF group than in the EBF group (**Figure 1**). During the intervention, breast milk intake declined by 39 g/d in the SF group but increased by 28 g/d in the EBF group ($P$ = 0.10); when adjusted for initial breast milk intake, the difference was significant at $P$ = 0.006. Breast milk intake was significantly different between groups at 26 wk ($P$ = 0.003). In the SF group (total sample), solid food intake (based on home observations) averaged 0.40 ± 0.26 MJ/d at 19 wk and 0.51 ± 0.29 MJ/d at 24 wk. At 24 wk, the percentage of energy from each type of food was 45% for rice cereal, 15% for chicken, 29% for fruit, and 11% for vegetables.

Energy intakes of the subsample determined from the measured values for breast milk energy density ($\bar{x}$ ± SD: 3.06 ± 0.50 kJ/g), by food source, are shown in **Table 4**. There were no significant differences in initial energy intake between groups (all from breast milk), although it tended to be lower in the SF group. At 26 wk, energy intake from breast milk was significantly lower in the SF group than in the EBF group. In the SF group, energy intake from solid foods at 26 wk was greater at the central unit than at home (at 23–24 wk), by 0.08 ± 0.25 MJ/d ($P$ = 0.09). This difference likely resulted because the mothers had more time to encourage their infants to eat while in the central unit than they did at home. The data in Table 4 are shown with and without adjustment for this difference. With or without this adjustment, total energy intake did not differ significantly between intervention groups at 26 wk, but the change in total energy intake between 16 and 26 wk was significantly greater in the SF group than in the EBF group. These results did not change when maternal education, number of children, or initial energy intake at 16 wk were controlled for, or when breast milk energy density was based on an assumed value (2.89 kJ/g) rather than on measured values.

### Infant growth

There were no significant differences in weight or length gain from 16 to 26 wk between intervention groups, either for the total sample or the subsample (**Table 5**). Similarly, there was no significant difference in change in head circumference between groups. Results were nearly identical when an "intent to treat" approach was taken, ie, inclusion of subjects who did not comply with the feeding instructions after randomization (5 in the EBF group and 1 in the SF group). Average weight-for-age and length-for-age $z$ scores were similar between groups throughout the first 12 mo of life (**Figures 2** and **3**, respectively). Average $z$ scores for the normal-birth-weight (≥2500 g) cohort in our previous study are also shown in Figures 2 and 3. The low-birth-weight cohort exhibited a similar pattern of weight gain, although their average $z$ scores were significantly lower than those of their normal-birth-weight counterparts at

**TABLE 2**
Daytime (0600–1800) breast-feeding frequency and time spent breast-feeding by infant age and intervention group, from home observations[1]

| | Total completed sample | | | | Subsample[2] | | | |
|---|---|---|---|---|---|---|---|---|
| | | Infant age | | | | Infant age | | |
| | *n* | 14–15 wk | 18–19 wk | 23–24 wk | *n* | 14–15 wk | 18–19 wk | 23–24 wk |
| Breast-feeding frequency | | | | | | | | |
| EBF | 59 | 11.2 ± 3.0[3] | 11.0 ± 2.5 | 10.9 ± 2.3 | 32 | 11.0 ± 3.4 | 10.2 ± 2.1 | 10.5 ± 2.5 |
| SF | 60 | 9.9 ± 2.5[4] | 8.3 ± 2.1[4] | 9.0 ± 2.5[4] | 31 | 9.9 ± 2.6 | 8.1 ± 1.8[4] | 9.4 ± 2.8 |
| Time spent breast-feeding (min/12 h) | | | | | | | | |
| EBF | 59 | 118 ± 40 | 99 ± 42 | 90 ± 35 | 32 | 119 ± 38 | 97 ± 35 | 95 ± 38 |
| SF | 60 | 105 ± 38 | 72 ± 32[4] | 71 ± 36[4] | 31 | 104 ± 37 | 69 ± 31[4] | 68 ± 37[4] |

[1] EBF, exclusive breast-feeding; SF, breast-feeding plus solid food.
[2] Those for whom measurements of milk volume were complete.
[3] $\bar{x}$ ± SD.
[4] Significantly different from EBF, $P$ < 0.05.

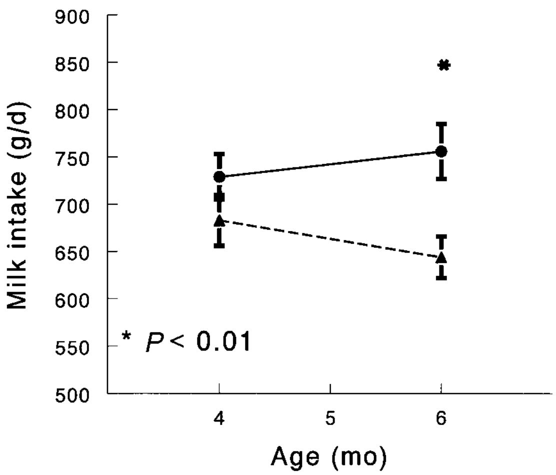


**FIGURE 1.** Mean (±SE) breast milk intake of low-birth-weight infants in the subsample who were exclusively breast-fed for 6 mo (●, EBF; *n* = 32) or given solid foods from 4 to 6 mo (▲, SF; *n* = 31).

all ages. Infant weight and length gains during the intervention were also examined in the subgroup of mothers with a relatively low body mass index (in $kg/m^2$, <21). There were no significant differences between the EBF and SF groups within this subgroup (Table 5).

## Morbidity

Morbidity data from 16 to 26 wk for the 2 intervention groups are shown in **Table 6**. There were no significant differences between groups in the percentage of days with fever or symptoms of respiratory illness, but diarrhea (>3 liquid stools/d) was significantly more common in the EBF group. The difference was marginally significant (2.9 ± 5.0% compared with 1.4 ± 3.0%, $P = 0.07$) when diarrhea was defined as >5 liquid stools/d. The difference in proportion of days with diarrhea was due to a difference in the number of episodes (data not shown), not to the duration of episodes.

## DISCUSSION

These results indicate no effect of feeding hygienically prepared, nutritious complementary foods from 4 to 6 mo of age on growth of full-term, low-birth-weight, breast-fed infants in this population. Despite the greater nutritional vulnerability of low-birth-weight infants, the results were the same as in the general population of infants in our previous study (4). It is important to assess whether the present study had sufficient statistical power to detect a difference among groups if it had occurred. Assuming that an effect size of 0.6 (ratio of the difference to the SD) is biologically meaningful, the power to detect a difference of that magnitude (weight gain of ≈215 g and length gain of 0.6 cm from 4 to 6 mo) with our sample size was 95% (assuming an $\alpha$ of 0.10). This means that there is only a 5% probability that if such a difference had occurred, it would not have been detected.

Although the SF group was able to comply with our request to maintain breast-feeding frequency after the introduction of solid foods, breast-feeding duration (min/d) and breast milk intake of their infants were lower than those of the EBF group. This confirms the findings of our previous study (4) and indicates that solid foods partially displace breast milk even when breast-feeding frequency does not decrease. Average breast-feeding frequency and duration for the low-birth-weight infants in the present study were generally higher than those for the cohort of infants in our previous study, in both the EBF and SF groups. This implies that full-term, low-birth-weight infants require more time to breast-feed than do their normal-birth-weight counterparts.

Despite the fact that there was some displacement of breast

**TABLE 3**
Daytime (0600–1800) and nighttime (1800–0600) breast-feeding frequency and time spent breast-feeding by infant age and intervention group, for the subsample at the central unit[1]

| | Infant age | | |
|---|---|---|---|
| | 16 wk | 26 wk | Change from 16 to 26 wk |
| Breast-feeding frequency | | | |
| EBF (*n* = 32) | | | |
| Daytime | 10.2 ± 2.2 | 10.1 ± 2.2 | −0.1 ± 2.3 |
| Nighttime | 6.1 ± 1.8 | 6.2 ± 1.6 | +0.1 ± 1.6 |
| Total | 16.3 ± 3.1 | 16.3 ± 3.1 | +0.0 ± 2.7 |
| SF (*n* = 31) | | | |
| Daytime | 9.5 ± 2.4 | 8.8 ± 2.1[2] | −0.7 ± 2.8 |
| Nighttime | 5.9 ± 1.8 | 6.3 ± 1.9 | +0.3 ± 2.5 |
| Total | 15.4 ± 2.8 | 15.1 ± 3.2 | −0.4 ± 3.7 |
| Time spent breast-feeding (min) | | | |
| EBF (*n* = 32) | | | |
| Daytime | 123 ± 47 | 115 ± 46 | −8 ± 46 |
| Nighttime | 101 ± 43 | 120 ± 54 | +19 ± 47 |
| Total | 223 ± 78 | 234 ± 86 | +11 ± 59 |
| SF (*n* = 31) | | | |
| Daytime | 115 ± 48 | 84 ± 30 | −31 ± 44[2] |
| Nighttime | 93 ± 48 | 87 ± 44[2] | −6 ± 41[2] |
| Total | 208 ± 77 | 170 ± 64[2] | −38 ± 65[2] |

[1] $\bar{x}$ ± SD. EBF, exclusive breast-feeding; SF, breast-feeding plus solid food.
[2] Significantly different from EBF, $P < 0.05$.

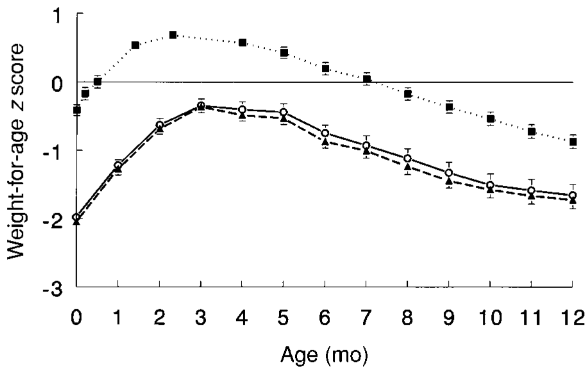


**FIGURE 2.** Mean (±SE) weight-for-age *z* scores of the low-birth-weight infants who were exclusively breast-fed for 6 mo (○, EBF; *n* = 59) or given solid foods from 4 to 6 mo (▲, SF; *n* = 60), and of the normal-birth-weight infants (■; *n* = 108) from a previous study in the same population (4).

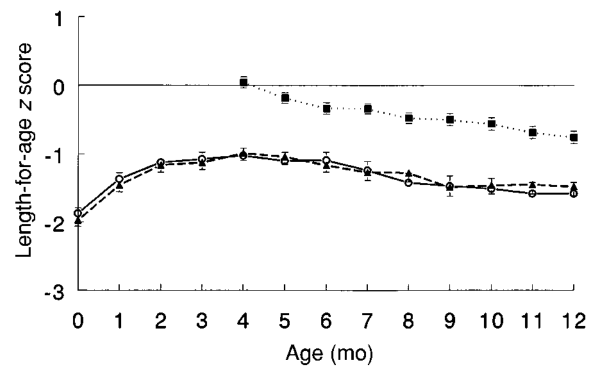


**FIGURE 3.** Mean (±SE) length-for-age *z* scores of the low-birth-weight infants who were exclusively breast-fed for 6 mo (○, EBF; *n* = 59) or given solid foods from 4 to 6 mo (▲, SF; *n* = 60), and of the normal-birth-weight infants (■; *n* = 108) from a previous study in the same population (4). Length was not measured until 4 mo in the latter study.

milk by solid foods, there was a significantly greater increase in total energy intake during the intervention in the SF group than in the EBF group (within the subsample). This was partly because the SF group had a somewhat lower energy intake initially. Absolute energy intake at 26 wk did not differ significantly between groups, which is consistent with the results of our previous study (4). There are several possible explanations for the apparent discrepancy between energy intake and growth data. First, intake by the subsample may not be representative of intake by the total sample. Second, it is possible that absolute energy intake is more important with regard to growth than is the change in energy intake between baseline and the end of the intervention. Finally, the magnitude of the difference in the change in energy intake between groups may not have been large enough to affect growth. In general, we have more confidence in the growth outcomes than in the intake measures, given the methodologic difficulties in obtaining dietary data that reflect the entire intervention period. We conclude that even if there is a real increase in energy intake from 4 to 6 mo after introduction of complementary foods, it apparently has no effect on growth (even after 6 mo of age).

The greater prevalence of diarrhea in the EBF group is puzzling, given that other studies have shown the opposite to be true (12, 13). We considered whether a certain degree of noncompliance in the EBF group might have been responsible for these findings, but we found no change in the results when we excluded EBF mothers who were suspected of occasionally feeding their infants small amounts of foods or liquids other than breast milk during the intervention (*n* = 25 of 59). There was also no evidence that differences in average stool frequency or consistency (even in those without diarrhea) could explain the results. Note that diarrhea prevalence in general was quite low (3–6%) and that the foods given to the SF group were sealed in jars, which greatly reduced the chances of contamination. Had we not used preprepared baby food, the outcome probably would have been much different.

It is worthwhile to consider whether attrition either before or during the intervention may have biased some of the results. In studies of this nature, it is extremely difficult to avoid loss of subjects because the population is highly mobile and economically insecure, and the mothers are often pressured by family and neighbors to introduce other foods and fluids to their infants at an early age. Thus, despite their initial intentions and the efforts of the research team, many subjects became ineligible to participate in

**TABLE 4**

Energy intake by food source, infant age, and intervention group in the subsample[1]

| Group | Infant age: 16 wk | Infant age: 26 wk | Change from 16 to 26 wk |
|---|---|---|---|
| EBF (*n* = 32) | | | |
| Breast milk | 2.19 ± 0.50 | 2.27 ± 0.59 | 0.09 ± 0.44 |
| SF (*n* = 31) | | | |
| Breast milk | 2.02 ± 0.39 | 1.92 ± 0.39[2] | 0.10 ± 0.51 |
| Solid food | | | |
| Unadjusted | 0 | 0.60 ± 0.33 | 0.60 ± 0.33 |
| Adjusted[3] | 0 | 0.53 ± 0.33 | 0.53 ± 0.33 |
| Total | | | |
| Unadjusted | 2.02 ± 0.39 | 2.52 ± 0.43 | 0.50 ± 0.58[2] |
| Adjusted[3] | 2.02 ± 0.39 | 2.45 ± 0.44 | 0.43 ± 0.58[2] |

[1] $\bar{x}$ ± SD. EBF, exclusive breast-feeding; SF, breast-feeding plus solid food.

[2] Significantly different from EBF, *P* = 0.01.

[3] Adjusted for the difference between solid food intake in the home and that at the central unit.

**TABLE 5**
Weight and length gains from 16 to 26 wk[1]

| | Total sample | Subsample[2] | Infants of mothers with a low BMI[3] |
|---|---|---|---|
| Weight gain (g) | | | |
| EBF | 1017 ± 350 [59] | 1045 ± 362 [32] | 984 ± 322 [13] |
| SF | 1004 ± 366 [60] | 1139 ± 392 [31] | 953 ± 286 [17] |
| Length gain (cm) | | | |
| EBF | 4.5 ± 1.2 [59] | 4.5 ± 1.3 [32] | 4.7 ± 1.4 [13] |
| SF | 4.3 ± 0.9 [60] | 4.5 ± 1.0 [31] | 4.0 ± 0.9 [17] |

[1] $\bar{x}$ ± SD; *n* in brackets. EBF, exclusive breast-feeding; SF, breast-feeding plus solid food. There were no significant differences between the EBF and SF groups.
[2] Those for whom measurements of milk volume were completed.
[3] BMI (kg/m$^2$) <21.

the intervention phase. However, there were no significant differences in maternal or infant characteristics between those who remained eligible and those who did not, which makes this sort of bias unlikely. Relatively few subjects dropped out after entering the intervention ($n$ = 9, or 7%); however, all except one of these dropouts were in the EBF group, which could be of concern. There may have been less incentive for EBF mothers to remain in the study because they did not receive the free complementary foods provided to the SF group, but the reasons given for dropping out (3 moved away and 2 went back to work) suggest that this was not a factor for most of the dropouts. Greater attrition in the EBF group would be of most concern if those who dropped out were less able to sustain exclusive breast-feeding than those who remained in the study. However, this was highly unlikely considering that infant weight gain before 16 wk (a good indicator of lactation performance) by the 8 dropouts in the EBF group (3304 ± 519 g) was not significantly different from that of the remaining 59 EBF infants (3399 ± 708 g). Furthermore, the reasons for dropping out were unrelated to perceived lactational adequacy for 7 of the 8 dropouts in the EBF group. Although the dropouts differed from participants in several characteristics, only one of these variables (infant birth weight, which was lower among dropouts) was significantly related to growth outcome. The association between birth weight and length gain from 16 to 26 wk was negative, which means that if there had been any bias due to this difference, it would have worked against the EBF participants. In other words, if the dropouts had been included, length gain of the EBF group would likely have been higher than it was. Thus, it is safe to conclude that there was no growth advantage from complementary feeding between 4 and 6 mo of age.

These results are supported by data from observational studies in both developing and developed countries. When growth rates of exclusively or fully breast-fed infants from 4 to 6 mo were compared with those of their breast-fed counterparts who were given complementary foods, there was either no significant difference between groups or a significant advantage for the exclusively breast-fed group (1). Most other studies have examined the effect of nutritional supplementation of infants who were not exclusively breast-fed. Even under those circumstances, a recent intervention study in 4 countries showed little or no effect of such a program (14).

We conclude that, from the perspective of infant growth, exclusive breast-feeding for ≈6 mo can be recommended even among full-term, low-birth-weight infants in a developing country such as Honduras. Infant growth did not differ significantly between treatment groups even in the subgroup of infants whose mothers had a relatively low body mass index. Nonetheless, there is still a need to replicate these findings in other populations, particularly in those with more severe maternal malnutrition. It is also important to consider the micronutrient status of exclusively breast-fed infants. In low-birth-weight infants, whose iron reserves at birth are low, medicinal iron drops are recommended beginning at 2–3 mo of age (15). For prevention of iron deficiency anemia, iron drops are likely to be more effective than provision of complementary foods before 6 mo, even if the foods are iron fortified (16). Similarly, if vitamin deficiencies are of concern, supplements given directly to the lactating mother are likely to be safer than complementary foods given to young infants in environments in which contamination and diarrheal morbidity are prevalent (1). Further research is needed to identify the most effective strategies for promoting exclusive breast-feeding during the first 6 mo of life.

**TABLE 6**
Morbidity prevalence from 16 to 26 wk[1]

| | EBF ($n$ = 59) | SF ($n$ = 60) |
|---|---|---|
| | *% of days* | |
| Fever | 8.0 ± 7.2 | 7.3 ± 7.8 |
| Cough | 26.1 ± 20.3 | 29.2 ± 22.1 |
| Congestion | 15.4 ± 15.0 | 19.0 ± 23.2 |
| Nasal discharge | 12.0 ± 12.2 | 16.2 ± 17.1 |
| Hoarseness | 2.5 ± 4.3 | 2.6 ± 6.3 |
| Diarrhea | 5.4 ± 8.5 | 2.8 ± 5.4[2] |

[1] $\bar{x}$ ± SD. EBF, exclusive breast-feeding; SF, breast-feeding plus solid food.
[2] Significantly different from EBF, $P$ <0.05 (nonparametric tests for nonnormally distributed data).

We are grateful to the Honduran research team for their dedication and to the mothers of San Pedro Sula for their willingness to participate in the study. We acknowledge the collaboration of Liga de la Lactancia Materna, Honduras–the local institution involved in the study–and the Ministry of Health, Honduras, for assistance with the project. We especially thank Adolfo Hernandez and Nancy Powers for training the research team in lactation management, Jody Krantz for her assistance with the assessment of newborns, and Janet Peerson for her statistical expertise.

## REFERENCES

1. Brown KH, Dewey KG, Allen LH. Complementary feeding of young children in developing countries: a review of current scientific knowledge. Geneva: WHO/NUT/98.1, 1998.
2. UNICEF. The state of the world's children, 1997. New York: Oxford University Press, 1997.

3. Pollitt E, Gilmore M, Volcarcel M. The stability of sucking behavior and its relationship to intake during the first month of life. Infant Behav Dev 1978;1:347–57.
4. Cohen RJ, Brown KH, Canahuati J, Rivera LL, Dewey KG. Effects of age of introduction of complementary foods on infant breast milk intake, total energy intake, and growth: a randomised intervention study in Honduras. Lancet 1994;344:288–93.
5. Adair L, Popkin BM, VanDerslice J, et al. Growth dynamics during the first two years of life: a prospective study in the Philippines. Eur J Clin Nutr 1993;47:42–51.
6. Capurro H, Konichezky S, Fonseca D, Caldeyro-Barcia R. A simplified method for diagnosis of gestational age in the newborn infant. J Pediatr 1978;93:120–2.
7. National Center for Health Statistics. NCHS growth curves for children: birth–18 years. Washington, DC: US Department of Health, Education and Welfare, 1977.
8. Ruel MT, Dewey KG, Martinez C, Flores R, Brown KH. Validation of single daytime samples of human milk to estimate the 24-hour concentration of lipids in urban Guatemalan mothers. Am J Clin Nutr 1997;65:439–44.
9. Folch J, Lees M, Sloan SGH. A simple method for the isolation and purification of total lipids from animal tissue. J Biol Chem 1957;226:497–509.
10. Pérez-Escamilla R, Cohen RJ, Brown KH, Rivera LL, Canahuati J, Dewey KG. Maternal anthropometric status and lactation performance in a low-income Honduran population: evidence for the role of infants. Am J Clin Nutr 1995;61:528–34.
11. SAS Institute Inc. SAS-PC software, version 6.03. Cary, NC: SAS Institute, 1987.
12. Brown KH, Black RE, Lopez de Romana G, Creed de Kanashiro H. Infant feeding practices and their relationship with diarrheal and other diseases. Pediatrics 1989;83:31–40.
13. Popkin BM, Adair L, Adin JS, Black R, Briscoe J, Flieger W. Breast-feeding and diarrheal morbidity. Pediatrics 1990;86:874–82.
14. Simondon KB, Gartner A, Berger J, et al. Effect of early, short-term supplementation on weight and linear growth of 4–7-mo-old infants in developing countries: a four-country randomized trial. Am J Clin Nutr 1996;64:537–45.
15. UNICEF/WHO, Joint Committee on Health Policy. Strategic approach to operationalizing selected end-decade goals: reduction of iron deficiency anemia. New York: UNICEF, 1995. (JCHP 30/95/4.5.)
16. Dewey KG, Cohen RJ, Rivera LL, Brown KH. Effects of age of introduction of complementary foods on iron status of breastfed