Effect of Formula Supplementation in the Hospital on the Duration of Breast-Feeding: A Controlled Clinical Trial

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ABSTRACT. To avoid methodologic pitfalls in previous observational studies linking formula supplementation in the hospital to early discontinuation of breastfeeding, a controlled clinical trial of restricted supplementation was conducted. In a pretrial sample of 621 newborns, a comparison of two "well-baby" nurseries found no differences in either hospital supplementation practices or the proportion of infants still being breast-fed at 4 or 9 weeks postpartum. Restriction of supplementation in one of the nurseries for the trial period (n = 781) did not result in higher breastfeeding rates at 4 or 9 weeks. There was, however, a slightly greater mean percent of birth weight lost in the restricted group (6.0% vs 5.1%; P < .001). In examining the control group for evidence of an "observational" association, it was found that infants still breast-feeding at 4 or 9 weeks were far more likely to have been unsupplemented than those no longer being breast-fed. It thus appears that formula supplementation in the hospital is a marker, rather than a cause, of breastfeeding difficulty. Pediatrics 1985;75:514-518; breastfeeding, formula supplementation, clinical trials.

The health benefits of breastfeeding are widely acknowledged.1-3 Although more striking in the developing world, evidence is accumulating that some of these benefits apply to industrialized societies as well.4-7 It is thus heartening to witness the steady increase since 1971 in the proportion of North American mothers who initiate breastfeeding.8 Unfortunately, however, the duration of breastfeeding is often short; recent studies9,10 report that up to 50% of mothers who begin breastfeeding are no longer doing so at 2 months.

In an attempt to understand and ultimately improve this trend, recent research has focused on the factors related to breastfeeding duration, and especially on those factors that might be subject to intervention. Nonmodifiable factors include maternal age and education, marital status, postpartum employment, and whether the mother was herself breast-fed as an infant.8,10-12 Potentially modifiable factors include early maternal-infant contact, rooming-in, feeding routine (scheduled vs "on demand"), support by friends and community groups, distribution of free infant formula samples, and formula supplementation in the hospital.13-17 This study addresses the last of these potentially modifiable factors.

The association between formula supplementation and breastfeeding duration is based largely on observational studies.12,15,18,19 Whether an infant receives supplementation, however, depends on characteristics of the mother and infant as well as the hospital routine. For example, mothers of unsupplemented babies tend to be older and better educated, and the clinical impression (consistent with our prestudy chart review) is that more supplementation is usually provided with cesarean deliveries and maternal or infant health problems. Thus, any observed association between supplementation and a shorter duration of breastfeeding may be caused by these confounding factors, rather than by the supplementation per se. The best way...
of reducing confounding is by using an experimental research design, ie, a controlled clinical trial. This report describes the implementation and results of such a trial.

MATERIALS AND METHODS

Any full-term, healthy infant born during the study period at Montreal's Royal Victoria Hospital and weighing at least 2,500 g was considered eligible for the trial if the infant was initially breast-fed and if the mother spoke either English or French, had her postpartum stay on an obstetric ward, and lived within 160 km (100 miles) of Montreal. Any infant who received at least two breast-feedings (according to the nursing notes in his medical record) was considered to be breast-fed.

The study hospital is a McGill University teaching hospital that serves a socioeconomically and culturally diverse population. The maternity unit has 3,500 deliveries per year and operates as both a community obstetric service and a high-risk referral center. The usual postpartum stay is four days. The hospital has two similar well-baby nurseries (henceforth designated as the East and West nurseries) and a neonatal special care unit. Mothers entering the hospital are assigned by the hospital admissions personnel to either the East or West nursery, depending on available bedspace. We chose to allocate treatment (restricted vs traditional supplementation) by nursery rather than to randomly assign individual mothers and infants. We wished to avoid the contamination that would occur if (1) mothers sharing rooms had newborns assigned to different treatments, and (2) nurses were concurrently implementing both treatments in the same nurseries. Because we did not use random assignment, however, we undertook a pretrial nursery comparison.

Pretrial Comparison

The pretrial (February to May 1982) comparison was undertaken to ensure that there were no differences between the two nurseries in either the degree of supplementation given or the subsequent duration of breast-feeding. During the 4-month pretrial period, 665 infants were enrolled; fifteen mothers refused to participate; and 29 mothers were unreachable for a follow-up interview. Thus, there was a pretrial study sample of 621 infants (305 from the East and 316 from the West nursery).

Trial

Two weeks before beginning the trial (June to September 1982), all nurses working in the West nursery met in small groups with the senior author (K.G.-D.) to learn about the study and the new policy of restricted supplementation. The mothers who had restricted supplementation were routinely awakened at 2 AM to feed their babies. The infants were given no formula supplements, unless a supplement was specifically requested by the mother. On the advice of the neonatology staff, formula supplements were also given to babies in the West (restricted) nursery for certain special situations, eg, during the first 24 hours after cesarean delivery, treatment with drugs contraindicating breast-feeding, or maternal infections that could be passed on to the infant. The use of glucose water feedings was not restricted. The routine nursing notes were followed closely, both to maximize compliance in restricting supplementation and to determine the reason for those supplements given despite restriction.

Traditional supplementation consisted of a routine formula feeding for all babies at 2 AM, unless the mother requested otherwise. At other four-hour feeding times, infants who had difficulty sucking or seemed hungry after a breast-feeding, as well as those whose mother had a fever or other postpartum difficulty, also received formula supplementation at the discretion of the nursing staff.

Data Collection

Both maternal and infant hospital records were abstracted to obtain medical information concerning the delivery and the number and volume of all formula and glucose water feedings. On the first day postpartum, mothers were informed by letter that a study of infant feeding practices was being undertaken. Mothers indicated their willingness to participate in the study by agreeing to a subsequent telephone interview at 9 weeks postpartum. The interview was conducted by a bilingual research assistant who was "blind" both to the nursery assignment and the inpatient supplementation history. The research assistant obtained information about sociodemographic and clinical variables, thus enabling us to compare the groups formed by our method of treatment allocation. Socioeconomic status was measured using Green's two-factor index based on maternal education and occupation of the household head. The outcome measure (breast-feeding duration) was evaluated using breast-feeding rates at 4 and 9 weeks postpartum, with breast-feeding termination defined as the age at which the infant began receiving more than one regular bottle-feeding per day. The usual number of formula feedings per day at 9 weeks was also ascertained for each infant.
RESULTS

Pretrial Comparison

During the pretrial period, supplementation was similar in the East and West nurseries, with a mean of 46.9 μL of formula per infant per day, respectively (t = .89; P = .38) (All reported P values are based on two-tailed tests of statistical significance.). The percentage of infants who were totally unsupplemented during their hospital stay was slightly higher in the East nursery (13.4% v 8.9%), but the difference was not statistically significant (χ² = 3.30; P = .07). Breast-feeding rates were virtually identical at 4 weeks (67.9% v 68.97%) and at 9 weeks (55.4% v 54.4%). This similarity reassured us that any difference in breast-feeding rates between nurseries that might subsequently be observed during the trial period could be attributed to the change in supplementation practices, rather than to any base-line differences in the two nurseries.

Trial

During the trial period, 845 infants met our eligibility criteria. Of these, we excluded four infants: two infants of mothers with psychiatric illness; one infant who subsequently was a victim of sudden infant death syndrome; and the infant of the senior author. Of the 841 mothers enrolled, 781 mothers (93%) responded to the questionnaire, eight refused, and 52 were unreachable. Nonrespondents were similar to respondents with respect to age, delivery type, parity, and length of hospital stay, but were less likely to be Canadian citizens (74.6% v 84.7%) (χ² = 3.91; P = .05) and to have requested a bed in a private or semiprivate room, rather than a ward (66.7% v 87.4%) (χ² = 19.90; P < .001).

To assess whether our available bedspace mode of nursery assignment had yielded two otherwise similar treatment groups, we compared the two groups according to prognostically important base-line characteristics of the mother, infant, and perinatal history. As shown in the Table, the groups were quite similar.

The extent of supplementation restriction is indicated by the proportion of infants receiving no supplements during their hospital stay: 63.1% in the restricted nursery v 15.0% in the traditional nursery (χ² = 190.26; P < .001). The reasons for supplementation in the 143 supplemented infants in the restricted nursery were as follows: cesarean section delivery (64 infants); admitted for less than 24 hours for observation in the special care unit (16 infants); mother insisted on a supplement (14 infants); mothers discontinued breast-feeding while in the hospital (seven infants); and miscellaneous reasons relating to maternal health problems or nursing errors (16 infants); for the remaining 26 infants, no reason was listed in the nursing notes.

To assess independently the biologic “potency” of this degree of supplementation restriction, we next compared the two groups according to the weight lost during hospitalization, expressed as a mean percentage of the birth weight. We found that infants in the restricted nursery lost significantly more weight (6.0%) than those in the traditional nursery (5.1%) (t = 5.74; P < .001). To ensure that this difference could not be attributed to unequal lengths of stay in the two nurseries, we also compared the percentage loss in birth weight at day 3 in the two nurseries. The difference was similar to that found over the entire hospital stay: 4.8% v 4.2% (t = 3.88; P < .001).

The greater weight loss in the restricted supplementation group did not appear to increase the risk of clinically important hyperbilirubinemia. The percentage of infants with a peak indirect serum bilirubin value ≥15 mg/dL was similar in the restricted and traditional nurseries: 3.9% v 4.5%, respectively (χ² = .18; P = .67). Glucose water was given to the same degree in restricted and traditional nurseries: 45.4 μL 44.7 mL per infant per day (t = .40; P = .69).

We next examined whether the restriction had an impact on the major outcome of study interest: breast-feeding duration. The percentage of mothers still breast-feeding (≥1 supplement per day) was virtually identical in the traditional and restricted groups at both 4 weeks (70.7% v 67.8%) (χ² = .80; P = .37) and 9 weeks (54.7% v 54.1%) (χ² = .03; P = .87). Furthermore, the statistical power to detect a 5% difference (improvement) in breast-feeding rates with this sample size is .99 at 4 weeks and .94 at 9 weeks.

Because the term “breast-feeding” can encompass a range of feeding practices, from exclusive (unsupplemented) to only occasional feedings at the breast, we compared mothers’ supplementation

| TABLE. Base-Line Comparison of Trial Groups* |
|-----------------------------|-----------------------------|
| Variables (units)           | Traditional (n = 393)       | Restricted (n = 398)   |
| Maternal age (yr)           | 29.0                       | 28.9                   |
| Maternal education (% high school) | 30.5                       | 26.2                   |
| Socioeconomic status score  | 63.8                       | 63.5                   |
| Parity (% primiparas)       | 48.1                       | 51.6                   |
| Cesarean delivery (%)       | 16.0                       | 19.3                   |
| Birth weight (g)            | 3486                       | 3459                   |

* None of the differences is statistically significant at P ≤ .05.
practices at 9 weeks postpartum using five different “cut-off” points to define feeding groups (see Figure). No statistically significant differences were observed between treatment groups using any of these five definitions.

We next examined the results in three potentially vulnerable subgroups of mothers: primiparas, those delivering by cesarean section, and those with a high school education or less. We wished to determine whether restricted supplementation in these subgroups had an effect that might have been obscured by our analysis of the entire study sample. Although the overall breast-feeding rates were lower within these groups, we found no differences at 9 weeks between the traditional and restricted nurseries for primiparas (47.1% v 48.5%) (χ² = .08; P = .78), cesarean section delivery (47.6% v 53.3%) (χ² = .45; P = .50), or lower level of education (45.8% v 40.4%) (χ² = .67; P = .41). Similarly, no effect of restricted supplementation was observed in these subgroups at 4 weeks.

Finally, in an attempt to reconcile our negative experimental findings with previous observational reports of a significant association between supplementation and breast-feeding duration, we examined the evidence for such an association within our own control (traditional) group. We thus analyzed our data in the same manner as previous observational studies, ie, by comparing in-hospital supplementation histories in mothers still breast-feeding at 4 weeks (n = 278) and 9 weeks (n = 215) with those having discontinued breast-feeding by these times. Babies who were still breast-feeding were far more likely to have been unsupplemented: 19.4% v 4.4% (χ² = 14.49; P < .001) at 4 weeks and 20.9% v 7.9% (χ² = 13.03; P < .001) at 9 weeks.

DISCUSSION

The findings from this trial suggest that restricting supplementation has no effect on subsequent breast-feeding duration. These negative results at first appear to contradict reports of a significant association in previous observational studies. Confirmation of the observational association in our own data, however, clarifies this apparent contradiction and dramatically illustrates the epidemiologic maxim that association does not prove causation. The observational approach creates the false impression that supplementation leads to shorter breast-feeding duration. Our negative experimental results, however, clearly demonstrate that supplementation is not the cause of breast-feeding discontinuation and suggest that it may be merely an associated finding in mothers who are less strongly committed to breast-feeding or those in whom postpartum problems interfere with the successful establishment of breast-feeding. Thus, supplementation appears to be a marker, rather than a cause, of breast-feeding difficulty.

This study compared two nursery supplementation practices: traditional (one formula feeding each night and occasional extra feedings during the day) and restricted (supplementation provided only for specified reasons). The degree of supplementation in our restricted nursery was similar to that reported by others studying the effect of restricting supplementation and may represent an irreducible minimum, given current neonatology practice. We caution, however, that our results should not be generalized to greater degrees of supplementation or restriction (including glucose water), nor to other geographic or socioeconomic settings (eg, developing countries). Nonetheless, until evidence to the contrary is forthcoming from well-designed clinical trials, we believe that public health efforts to restrict supplementation will probably not be effective in prolonging the duration of breast-feeding.

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REFERENCES


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