Pacifier Use, Early Weaning, and Cry/Fuss Behavior
A Randomized Controlled Trial

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PACIFIERS HAVE BEEN AROUND for a very long time. Small clay pacifiers have been found in Cypriot graves dating back to about 1000 BC, and breast-shaped pottery nipples have been recovered from Roman graves dating from around AD 100.[1,2] In the early 1900s, however, pacifiers began to be condemned by the infant welfare movement. Various reformers referred to the pacifier as a product of "perverted American ingenuity,"[3] an "instrument of torture,"[4] and a "curse of babyhood."[5] More recently, clinicians and public health practitioners have raised concerns that the pacifier causes "nipple confusion" and thereby leads to early weaning.[6] In fact, avoidance of pacifiers constitutes step 9 of the World Health Organization/United Nations Children's Fund Baby-Friendly Hospital Initiative.[7]

What is the evidence of actual benefit or harm associated with pacifier use? Several observational studies published since the Baby-Friendly Hospital Initiative was developed, including studies from Brazil,[8-10] Sweden,[11,12] England,[13,14] New Zealand,[15] and the

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Context The World Health Organization and the United Nations Children's Fund strongly discourage use of pacifiers because of their perceived interference with breastfeeding. Observational studies have reported a strong association between pacifier use and early weaning, but such studies are unable to determine whether the association is causal.

Objectives To test whether regular pacifier use is causally related to weaning by 3 months postpartum and to examine differences in results according to randomized intervention allocation vs observational use or nonuse of pacifiers.

Design Double-blind, randomized controlled trial conducted from January 1998 to August 1999.

Setting Postpartum unit of a university teaching hospital in Montreal, Quebec.

Participants A total of 281 healthy, breastfeeding women and their healthy, term singleton infants.

Interventions Participants were randomly allocated to 1 of 2 counseling interventions provided by a research nurse trained in location counseling. The experimental intervention (n=140) differed from the control (n=141) by recommending avoidance of pacifier use and suggesting alternative ways to comfort a crying or fussing infant.

Main Outcome Measures Early weaning, defined as weaning within the first 3 months, compared between groups; 24-hour infant behavior logs detailing frequency and duration of crying, fussing, and pacifier use at 4, 6, and 9 weeks.

Results A total of 258 mother-infant pairs (91.8%) completed follow-up. The experimental intervention increased total avoidance of pacifier use (38.6% vs 16.0% in the control group), reduced daily use (40.8% vs 55.7%), and decreased the mean number of pacifier insertions per day (0.8 vs 2.4 at 4 weeks [$P<.001$]; 0.8 vs 3.0 at 6 weeks [$P<.001$]; and 1.3 vs 3.0 at 9 weeks [$P=.004$]). In the analysis based on randomized intervention allocation, the experimental intervention had no discernible effect on weaning at 3 months (18.9% vs 18.3% in the experimental vs control group; relative risk [RR], 1.0; 95% confidence interval [CI], 0.6-1.7), and no effect was observed on cry/fuss behavior (in the experimental vs control groups, respectively, total daily duration, 143 vs 151 minutes at 4 weeks [$P=.49$]; 128 vs 131 minutes at 6 weeks [$P=.81$]; and 110 vs 104 minutes at 9 weeks [$P=.58$]). When randomized allocation was ignored, however, we observed a strong observational association between exposure to daily pacifier use and weaning by 3 months (25.0% vs 12.9% of the exposed vs unexposed groups; RR, 1.9; 95% CI, 1.1-3.3).

Conclusions We found a strong observational association between pacifier use and early weaning. No such association was observed, however, when our data were analyzed by randomized allocation, strongly suggesting that pacifier use is a marker of breastfeeding difficulties or reduced motivation to breastfeed, rather than a true cause of early weaning.

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United States,[16] have reported a significant association between pacifier use and early weaning. The question is whether such an association is causal, or whether pacifier use is a marker of breastfeeding difficulties or a mother's reduced motivation to continue breastfeeding. No physiological evidence has validated the concept of nipple confusion; an infant can apparently distinguish nutritive from nonnutritive sucking.[17-20] It is clear that pacifiers reduce crying in the short term[21-25] but no studies have assessed whether the regular use of pacifiers reduces the overall duration or frequency of crying and fussing. Such studies are important, because proscription of pacifier use could conceivably increase infant distress and thereby impair infant-parent relationships.

The major objectives of our study were to assess whether advice to avoid pacifier use and to use other modes of calming a crying or fussing infant reduces the risk of early weaning (before age 3 months) and increases the frequency or duration of crying and fussing. We also wished to assess the bias that occurs in using an observational vs an experimental design to study the effect of pacifier use on breastfeeding duration.

METHODS
Design

We carried out a randomized controlled trial from January 1998 to August 1999 of women giving birth at the Royal Victoria Hospital, a McGill University–affiliated maternity hospital in Montreal, Quebec. The Royal Victoria Hospital Research Ethics Board approved the study. Women who intended to breastfeed for at least 3 months and who were delivered of (vaginally or by cesarean) healthy singleton newborns of at least 37 completed weeks' gestational age and 2500 g birth weight were eligible for inclusion. They were recruited during their postpartum stay, with enrollment of at most 1 mother per room to avoid the treatment contamination that would likely occur if mothers randomized to different interventions occupied the same hospital room.

Women were stratified by parity and, if multiparous, according to whether they had breastfed previously. Randomization within each stratum was accomplished using computer-generated random numbers in blocks of 4. Women consented to randomization to 1 of 2 different breastfeeding promotion "packages" (see below); the assigned allocation was contained in an opaque envelope opened by a research nurse after consent was obtained. Based on the literature available[8,9,11,15] at the time we planned this trial, we estimated that a reduction in daily pacifier use from 60% to 40% would reduce the risk of weaning before age 3 months from 40% to 35%. With an α level of .05 and a β of .10, approximately 140 infants were required per group.

Interventions

The basic breastfeeding promotion package included in both interventions consisted of a 45-minute interview promoting breastfeeding plus an information sheet, both provided by a nurse with specialized training in lactation counseling. This interview and information focused on positioning, the importance of frequent feeding and feeding on demand, the avoidance of formula and other liquids, the management of sore nipples and breast engorgement, and provided the telephone numbers of persons and agencies whom the mother could call for answers to questions, help with difficulties, and general support. In addition, for the experimental intervention, the mother was asked to avoid pacifiers when the infant cried or fussed and to first offer the breast instead, and failing that, to try carrying and rocking the infant. In the control intervention, all options were discussed for calming the infant, including breastfeeding, carrying, rocking, and using a pacifier. The experimental vs control intervention was reinforced by the research nurse by telephone calls at 10 days and 3 weeks postpartum.

Ascertainment of Outcomes

We asked mothers to complete a validated behavior diary[26,27] on 3 consecutive days, including 2 weekdays and 1 weekend day, when their infants were 4, 6, and 9 weeks of age. This diary provides exhaustive and mutually exclusive indicators of infant behaviors, including the frequency and duration of all crying and fussing episodes. Periods of unsoothable crying are recorded separately. An indicator for each pacifier insertion was added to a previous version of the instrument.[28] Study mothers were interviewed at 3 months by a research assistant who was blinded to the intervention status of the mother. The assistant asked whether the mother was still breastfeeding. If so, the research assistant also asked about the frequency of breastfeeding and whether the infant was receiving other foods in addition to breast milk. If the infant was no longer breastfeeding, the research assistant asked the age at which the infant was weaned (ie, when breastfeeding was permanently discontinued) and the reasons for weaning. In addition, she asked about the average frequency of pacifier use over the infant's first 3 months of life.

Statistical Analysis

The primary outcome, early weaning (weaning within the first 3 months), was compared between the 2 randomized intervention groups using the relative risk (RR) and the 95% confidence interval (CI). We also carried out a multiple logistic regression analysis to ensure that the crude RR was not confounded by observed differences in baseline characteristics. Secondary outcomes included the frequency (number of episodes per day) and total duration (minutes per day) of crying or fussing and the duration of unsoothable crying (minutes per day); these outcomes were compared using 2-tailed t tests, with $P<.05$ indicating statistical significance. All analyses were based on randomized intervention allocation in the mothers who completed the study, because no outcomes could be ascertained in those who were lost to follow-up.

To contrast the results obtained for the primary outcome based on randomized intervention allocation with those obtained if randomized allocation was

ignored, we also analyzed the data as if we had done an observational study. This analysis compared the RR and 95% CI in groups who had ever (vs never) been exposed to a pacifier and in groups who were (vs were not) exposed on a daily basis.

All statistical analyses were carried out using SAS version 6.12 (SAS Institute, Cary, NC).

RESULTS

Of the 281 mothers randomized, 258 (91.8%; 127 experimental and 131 control) completed the study (**FIGURE**). **TABLE 1** compares the baseline charac-

Figure. Flow of Study

teristics of these 258 mothers. Maternal age and education, infant birth weight, English-language interview, maternal employment outside the home, parity, and previous breastfeeding experience were very similar in the 2 groups, although a slightly lower proportion of experimental mothers were married and a slightly higher proportion smoked during pregnancy. The only differences in baseline characteristics observed among the 23 mothers originally randomized who did not complete the study were a lower proportion who were married (69.6% vs 81.4%), a higher proportion who smoked (26.1% vs 13.0%), and, paradoxically, a lower proportion who worked outside the home (43.5% vs 76.0%).

As shown in **TABLE 2**, the intervention succeeded in substantially changing pacifier use; 38.6% of mothers in the experimental group totally avoided pacifier use, compared with 16.0% in the control group, for a statistically significant RR of 2.4. Daily use of pacifiers was substantially reduced in the experimental group (40.8%) vs the control group (55.7%), for a statistically significant 30% relative reduction. The diary data indicated a large and highly sig-

nificant reduction in the mean number of pacifier insertions per day in the experimental group at 4, 6, and 9 weeks of age.

We first analyzed the results for early weaning based on randomized allocation. Among the 258 infants whose mothers completed the study, 18.9% of those in the experimental group were weaned prior to age 3 months vs 18.3% of those in the control group (RR, 1.0; 95% CI, 0.6-1.7). The results for exclusive breastfeeding were similar: 63.8% of infants in the experimental group had discontinued exclusive breastfeeding by age 3 months vs 66.4% of those in the control group (RR, 1.0; 95% CI, 0.8-1.1). To ensure that these negative experimental results were not confounded by small baseline differences in marital status or smoking, we carried out a logistic regression analysis to control for these differences. The adjusted odds ratio and 95% CI for weaning by age 3 months (1.0 [0.5-1.9]) was virtually unchanged from the crude odds ratio (1.0 [0.6-1.9]).

In contrast, the observational analysis of early weaning yielded very different results. When exposure was based on daily pacifier use, 25.0% of exposed infants were weaned prior to age 3 months vs 12.9% of unexposed infants (RR, 1.9; 95% CI, 1.1-3.3). When exposure was based on whether the infants had ever used a pacifier, the corresponding proportions weaned before age 3 months were 21.3% vs 11.4% (RR, 1.9; 95% CI, 0.9-3.8). Observational associations with exclusive breastfeeding were weaker but statistically significant. For exposure based on daily pacifier use, 72.6% of exposed infants vs 58.3% of unexposed infants had discontinued exclusive breastfeeding before age 3 months (RR, 1.2; 95% CI, 1.04-1.5). For exposure based on ever using pacifiers, the corresponding values were 69.1% vs 54.3% (RR, 1.3; 95% CI, 1.01-1.6).

Only 183 (70.9%), 156 (60.5%), and 148 (57.4%) of the mothers returned the infant behavior diaries at 4, 6, and 9 weeks, respectively, with no differences between experimental
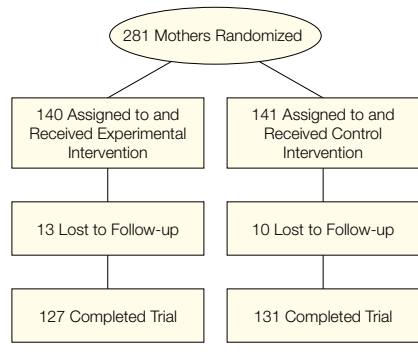
Table 1. Baseline Comparison of Experimental and Control Groups

Variable	Experimental (n = 127)	Control (n = 131)
Age, mean (SD), y	31.6 (4.5)	31.5 (4.9)
Education, mean (SD), y	16.1 (3.0)	16.0 (3.2)
Birth weight, mean (SD), g	3457 (427)	3524 (415)
English-language interview, %	66.1	66.2
Married, %	78.7	84.0
Employed outside home, %	77.2	74.8
Smoked during pregnancy, %	15.3	10.8
Primiparous, %	47.2	47.3
Previous breastfeeding (multips), %	97.0	95.6

Table 2. Effect of Intervention on Pacifier Use*

Pacifier Use	Experimental	Control	RR (95% CI) or P Value†
Total avoidance, %	38.6	16.0	2.4 (1.5-3.8)
Daily use, %	40.8	55.7	0.7 (0.6-0.95)
Mean uses per day			
4 wk	0.8	2.4	P<.001
6 wk	0.8	3.0	P<.001
9 wk	1.3	3.0	P = .004

*RR indicates relative risk; CI, confidence interval.
†P values based on 2-tailed t tests.

and control groups. TABLE 3 shows the results (analyzed by randomized intervention allocation) for cry/fuss behavior, including daily frequency, ie, the number of episodes of crying (including unsoothable crying) or fussing per day, total daily duration of all crying and fussing, and total daily duration of unsoothable crying. Cry/fuss frequency was slightly lower in the experimental group at 4 and 6 weeks, but almost identical in the 2 groups at 9 weeks. The total duration of crying and fussing was similar in the 2 groups at all 3 ages, as was the total duration of unsoothable crying.

Because of the substantial nonresponse rate to the diary completion, we compared baseline characteristics of those who did not complete diaries in the experimental and control groups at 4, 6, and 9 weeks postpartum. The results (TABLE 4) indicate that nonresponders at all 3 time periods were younger, less educated, and less likely to be married. As shown in Table 1, however, these characteristics were similar between the experimental and control groups (which was also true when stratified by diary response at all 3 time periods), and thus the differences between responders and nonresponders are highly unlikely to have biased the effects of intervention on cry/fuss behavior.

COMMENT

Our experimental intervention succeeded in substantially reducing pacifier use, yet it had no significant effect on cry/fuss behavior at ages 4, 6, or 9 weeks. Similarly, our intervention had no effect on the risk of weaning before age 3 months. Despite these negative results, however, pacifier use was strongly associated with the risk of early weaning in observational analyses, similar to results reported in previous observational studies.[8-16] This combination of findings leads us to conclude that pacifier use is a marker of breastfeeding difficulties or reduced motivation to breastfeed, rather than a true cause of early weaning. We reported an identical contrast between experimental and observational results in an earlier trial of in-hospital formula supplementation of breastfed infants.[29,30]

Although we found no evidence that pacifier use is harmful for breastfeeding, we also detected no beneficial effects on infant crying and fussing. Thus the nonpacifier soothing methods (breastfeeding, carrying, and rocking)

advocated in our experimental intervention appear adequate. Nonetheless, the absence of a causal link between pacifier use and early weaning should lead breastfeeding promotion programs and international agencies to reexamine their staunch opposition to pacifiers.

Like any study, ours has limitations. A larger sample size would be required to exclude a small increased risk of early weaning, as shown by the width of our confidence interval for that outcome. We deliberately chose an experimental intervention that could be feasibly implemented on a large scale if it was successful in reducing the risk of early weaning, but our results cannot be generalized to more potent interventions to avoid pacifier use. Data on pacifier use were based on maternal self-report, but the recording of use from the written behavior diaries at 4, 6, and 9 weeks and the telephone interview at 3 months were consistent in showing

Table 3. Effect of Intervention on Cry/Fuss Behavior

Outcome	Experimental	Control	P Value*
4 Weeks (n = 183)			
Frequency, episodes per day	6.3	7.7	.03
Total duration, min/d	143	151	.49
Unsoothable crying, min/d	8.4	9.1	.77
6 Weeks (n = 156)			
Frequency, episodes per day	6.7	7.7	.19
Total duration, min/d	128	131	.81
Unsoothable crying, min/d	6.1	5.2	.66
9 Weeks (n = 148)			
Frequency, episodes per day	6.7	6.8	.88
Total duration, min/d	110	104	.58
Unsoothable crying, min/d	3.1	3.6	.78

*P values based on 2-tailed t tests.

Table 4. Comparison of Baseline Characteristics Between Responders and Nonresponders for Diary Completion at 4, 6, and 9 Weeks

	4 Weeks		6 Weeks		9 Weeks	
Variable	Responders (n = 183)	Nonresponders (n = 98)	Responders (n = 156)	Nonresponders (n = 125)	Responders (n = 148)	Nonresponders (n = 133)
Age, mean (SD), y	31.9 (4.3)	30.3 (5.2)	32.2 (4.1)	30.3 (5.2)	32.1 (4.0)	30.5 (5.3)
Education, mean (SD), y	16.3 (2.9)	15.2 (3.3)	16.3 (3.0)	15.4 (3.1)	16.3 (2.9)	15.5 (3.3)
Birth weight, mean (SD), g	3523 (416)	3421 (413)	3506 (406)	3465 (431)	3493 (414)	3482 (422)
English-language interview, %	64.8	70.4	65.8	68.0	66.0	67.7
Married, %	84.7	72.4	83.3	76.8	85.1	74.4
Employed outside home, %	72.7	74.5	73.1	73.6	70.9	75.9
Smoked during pregnancy, %	16.8	12.6	12.9	15.6	14.3	13.8
Primiparous, %	46.4	51.0	46.8	49.6	48.6	47.4
Previous breastfeeding (multips), %	95.9	97.9	96.4	96.8	96.1	97.1

large differences between the 2 intervention groups. Maternal self-report has been the basis of data on pacifier use in all previous studies; like ours, these studies have resulted in strong and statistically significant observational associations between pacifier use and early weaning. Finally, we had an approximately 40% nonresponse rate to the diary completion, with a potential for selection bias in our analyses of cry/fuss behavior. The characteristics of responders and nonresponders were virtually identical in the experimental and control groups, however, and thus such a bias seems unlikely.

Breastfeeding, pacifier use, and infant cry/fuss behavior are complex behaviors heavily influenced by cultural, motivational, and psychological factors that are extremely difficult to measure, and hence to control for, in an observational study. As we have previously discussed,[30] these potent factors are likely to lead to residual confounding and reverse causality bias in observational studies of the pacifier-weaning association. Unlike recent results suggesting that observational studies of pharmacological and surgical treatments can yield valid results,[31,32] valid assessment of the effects of be-

havioral interventions on behavioral outcomes appears to require the bias reduction provided by randomized trials.

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