

Pacifiers and Breastfeeding

A Systematic Review

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Objective: To summarize current evidence on the association between infant pacifier use and breastfeeding.

Data Sources: MEDLINE, CINAHL, the Cochrane Library, EMBASE, POPLINE, and bibliographies of identified articles.

Study Selection: A search for English-language records (from January 1950 through August 2006) containing the Medical Subject Heading terms *pacifiers* and *breastfeeding* was conducted, resulting in 1098 reports. Duplicate and irrelevant studies were excluded, yielding 29 studies that fit inclusion criteria for the review (4 randomized controlled trials, 20 cohort studies, and 5 cross-sectional studies). Two independent reviewers abstracted data and scored these studies for quality; disagreements were settled through consensus with a third investigator.

Main Exposure: Pacifier use.

Main Outcome Measures: Breastfeeding duration or exclusivity.

Results: Results from 4 randomized controlled trials revealed no difference in breastfeeding outcomes with different pacifier interventions (pacifier use during tube feeds, pacifier use at any time after delivery, an educational program for mothers emphasizing avoidance of pacifiers, and a UNICEF [United Nations Children's Fund]/World Health Organization Baby Friendly Hospital environment). Most observational studies reported an association between pacifier use and shortened duration of breastfeeding.

Conclusions: The highest level of evidence does not support an adverse relationship between pacifier use and breastfeeding duration or exclusivity. The association between shortened duration of breastfeeding and pacifier use in observational studies likely reflects a number of other complex factors, such as breastfeeding difficulties or intent to wean. Ongoing quantitative and qualitative research is needed to better understand the relationship between pacifier use and breastfeeding.

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THE BENEFITS OF BREASTFEEDING to mothers and infants are well known, and pacifiers have traditionally been thought to interfere with optimal breastfeeding. In the late 1980s, the World Health Organization and UNICEF adopted avoidance of pacifiers as one of the Ten Steps to Successful Breastfeeding.¹ These steps later formed the basis for the worldwide Baby Friendly Hospital Initiative, a program associated with increased breastfeeding initiation on the hospital level and the national level.^{2,3} Despite these policy initiatives and the vocal opposition to pacifiers from breastfeeding advocates, the evidence linking pacifiers to breastfeeding difficulties has been limited, consisting mainly of observational studies.

Concurrent with these large-scale efforts to discourage pacifier use among breastfed infants, evidence mounted that pacifiers may actually decrease the incidence of sudden infant death syndrome (SIDS). Two meta-analyses^{4,5} of 7 case-control studies have shown a protective effect for pacifier use, particularly when

used at bedtime, with a potential reduction in the risk of SIDS by as much as 61%.⁴ This growing evidence led the American Academy of Pediatrics to recommend offering a pacifier at nap time and bedtime to reduce the risk of SIDS.⁶ For breastfed infants, the guidelines recommend delaying introduction of the pacifier until 1 month of age to ensure that breastfeeding is well established.⁶

Physicians who counsel families about pacifier use must now weigh the potential protective effect against SIDS against the potential deleterious effect on breastfeeding. To assist in this decision balance, a systematic review of the literature regarding the impact of pacifier use on breastfeeding was undertaken in an attempt to summarize the current evidence.

METHODS

DATA SOURCES AND STUDY SELECTION

MEDLINE, CINAHL, the Cochrane Library, EMBASE, and POPLINE were searched for rec-

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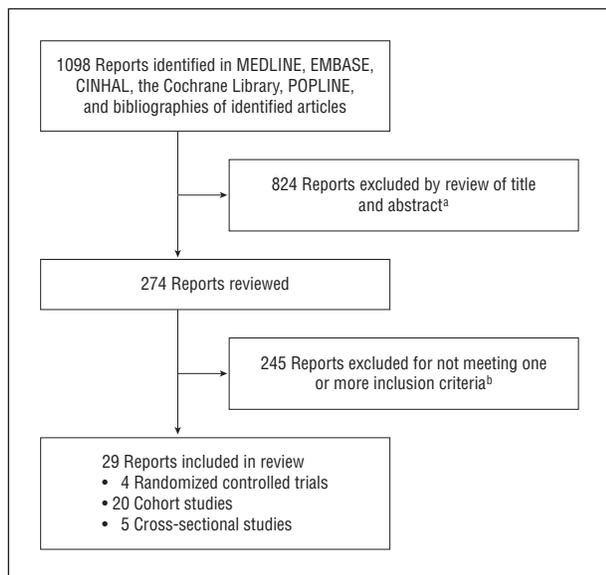


Figure. Study inclusion and exclusion flow diagram. ^aExclusion criteria: duplication, no apparent relevance, and non-English-language studies. ^bInclusion criteria: studies that report an association between pacifier use and breastfeeding initiation or duration, have a clearly identified comparison group, consist of healthy infant populations, and have at least 70% follow-up (cohort and randomized controlled trials) or 50% participation (cross-sectional study).

ords published in any language between January 1950 and August 2006. The search strategy included published articles with the Medical Subject Heading terms *pacifiers* (keywords *dummy* and *soother*) and *breastfeeding*. Any study design was eligible for consideration. Searches were limited to studies in humans. Combining searches resulted in 1098 reports, all of which were reviewed by one of us (K.O.T.) for relevance based on title and abstract alone. Duplicate studies (n=1), studies without apparent relevance (n=818), and non-English-language publications (n=5) were excluded (Figure), leaving 274 studies for complete review and further evaluation for inclusion. Only studies that reported an association between pacifier use and breastfeeding initiation or duration, had a clearly identified comparison group, consisted of healthy term or preterm infant populations, and had at least 70% follow-up (cohort studies and randomized controlled trials [RCTs]) or 50% participation (cross-sectional studies) were included in the systematic review. Studies that included infants with congenital abnormalities were excluded. If the abstract for a report was unavailable or if it was not clear from the abstract alone whether the study met inclusion criteria, the full report was obtained. Of the 274 studies, only 29 met all of the inclusion criteria (Figure). The bibliographies of these 29 reports were then reviewed to identify other potential reports missed by the database search; no additional studies of relevance were identified.

DATA EXTRACTION

Two independent reviewers (N.R.O. and K.O.T.) collected data pertaining to study design, population demographics, and results. For each study, approximately 20 quantitative characteristics were recorded as potential covariates for meta-analysis. The same 2 reviewers also independently evaluated the quality of each study using a simplified scoring system; RCTs and cohort studies were rated on a maximum scale of 9 points, while cross-sectional studies were rated on a maximum scale of 7 points (Table 1). We developed a single scale, based on the Users' Guides to the Medical Literature criteria for assessing an article about harm,⁷ to quantitatively compare the different study designs that resulted from the literature

Table 1. Scoring System for Studies Included in Systematic Review

No.	RCT/ Cohort	Cross-sectional	Criteria
1	1 Point	NA	All participants accounted for at conclusion of study
2	1 Point	1 Point	Study is prospective
3	1 Point	1 Point	RCT
4	1 Point	NA	≥95% Follow-up (censoring counts as complete follow-up)
5	1 Point	1 Point	>80% Participation (for surveys, participation refers to response rate)
6	1 Point	1 Point	Study was designed to look at the possible relationship between pacifiers and breastfeeding (as one of the main outcomes)
7	1 Point	1 Point	Study looks at the pacifier-breastfeeding relationship in a multivariable context
8	1 Point	1 Point	Exposure and/or outcomes were assessed identically for all participants
9	1 Point	1 Point	All eligible mothers (or random sample thereof) were invited to participate
Total	9 Points	7 Points	

Abbreviations: NA, not applicable; RCT, randomized controlled trial.

search in anticipation of weighting the studies for summary statistics in the meta-analysis. There was no published scoring system to our knowledge that accomplished this. The quality scores were determined solely by what was reported in each article; authors were not contacted for missing information. If additional articles using the same study population were referenced in a study's "Methods" section, however, these articles were obtained and used to supplement missing information when required.

ANALYSIS

Tests of interrater agreement were applied to the extracted data and quality scores. In cases of disagreement (≥1 point) between reviewers, a third reviewer (F.R.H.) evaluated the study, and consensus opinion was reached. The quantitative variables from each study were then incorporated into a meta-analytic model as individual covariates. We planned to use a proportional odds ratio (OR) model to calculate the pooled estimate, its confidence interval (CI), and the P value if the individual studies reported ORs as their preferred scale^{8,9}; or to use a random-effects model to calculate the pooled estimate if the included studies reported on a relative risk (RR) scale.¹⁰ We planned to use statistics Q and I² to evaluate inconsistency and statistical heterogeneity between the included studies.¹¹ Also, methods for detecting bias and heterogeneity, including funnel plot, Egger's statistic, L'Abbe plot, Mantel-Haenszel statistic, radial plot, and trim-and-fill method, were considered.^{12,13} All studies were to be included but a weighting factor for each, based on its quality score, was to be added to the models.

RESULTS

Of the 29 studies identified for systematic review, there were 4 RCTs¹⁴⁻¹⁷ (Table 1), 20 cohort studies,¹⁸⁻³⁷ and 5 cross-sectional studies.³⁸⁻⁴² The research was conducted in 12

countries (Australia, Brazil, Canada, Hungary, Italy, New Zealand, Poland, Russia, Sweden, Switzerland, the United Kingdom, and the United States) involving participants from a range of demographic and socioeconomic backgrounds.

Unfortunately, significant types and quantities of heterogeneity were found among the studies. Outcomes were defined differently among the studies, and they were measured in different scales (ORs, RRs, and hazard ratios [HRs]) for different subsets of the target population (breastfed infants). These sources of heterogeneity could not be adequately addressed by existing meta-analytic methods, and hence we reverted to a systematic review of the identified articles, grouped by study design.

The RCTs were designed to study the effect of pacifier use on breastfeeding duration; in 3^{14,15,17} of the 4 studies,^{14,17} the use of supplemental feeding was also investigated. Few of the observational studies (cohort and cross-sectional) were designed to specifically investigate the relationship between pacifiers and breastfeeding duration or exclusivity; in most cases, pacifier use was one of many variables included for their potential impact on breastfeeding.

There was a great deal of variation between studies in the definition of pacifier use. Some studies^{14,17,37} examined pacifier use in the hospital only (consistent with a focus on implementation of Baby Friendly Hospital practices), while most studies looked at pacifier use at 2 weeks, 1 month, 2 months, or 6 months of age. In addition, some studies^{19-31,33,34,37,38,40-42} classified infants as pacifier users based on any pacifier use, while other studies^{18,35,36,39} attempted to differentiate between frequent and occasional users.

In addition, extensive variation was found in the breastfeeding outcomes chosen. While some studies* used overall duration of breastfeeding as the primary outcome, the remaining studies assessed breastfeeding at set time points ranging from hospital discharge to 12 months of age. Definitions of breastfeeding varied widely between studies but could be broadly classified into exclusive (breastfeeding with no other types of milk or solids except vitamins and minerals), predominant (mostly breastfeeding with some water and juices allowed), or any (not specified as exclusive or predominant breastfeeding).

Based on our quality scale criteria, the resulting scores of the RCTs were 5, 6, 8, and 8 (of a maximum of 9 points). Each of these RCTs randomized infants to a different intervention: pacifier use during tube feedings or for soothing vs no pacifiers¹⁴; pacifier use in the neonatal period vs pacifier introduction after 4 weeks postpartum¹⁵; an educational program for mothers emphasizing avoidance of pacifiers and alternative methods of soothing vs use of pacifiers for soothing¹⁶; and a Baby Friendly Hospital environment in which pacifiers were avoided vs unrestricted use of pacifiers¹⁷ (**Table 2**). One of the studies limited enrollment to preterm infants born at 23 to 33 weeks' gestation.¹⁴ Breastfeeding outcomes were then assessed. None of the studies found a significant difference in breastfeeding outcomes with the pacifier-related intervention. For example, in the study by Kramer and colleagues,¹⁶ 18.3% of infants in the intervention group (educational program for mothers emphasizing avoidance of pacifiers) were

weaned by 3 months vs 18.3% in the control group (RR, 1.0; 95% CI, 0.6-1.7).

Twelve of the observational studies† looked at more than one relationship between pacifier use and breastfeeding, including different durations of breastfeeding, breastfeeding type (exclusive, predominant, or any), age at pacifier introduction, and frequency of pacifier use. Seventeen of these studies‡ reported an OR, RR, or HR of shortened duration or exclusivity of breastfeeding with pacifier use for all the respective outcomes studied; the remaining 8 studies^{18,22,24,30,34,36,37,40} did not find statistically significant associations with either all or some of the breastfeeding outcomes studied. Most of the studies included multivariate analyses; some controlled for a large number of possible confounders while others only considered educational level and maternal age. The ORs, RRs, and HRs for multivariate analyses that were statistically significant ranged from 1.18 (95% CI, 1.04-1.34)³³ to 3.01 (1.78-5.09).²⁸ Values greater than 1 indicate that pacifiers are associated with increased risk of not breastfeeding.

COMMENT

Given current American Academy of Pediatrics guidelines to consider offering a pacifier to all infants at bedtime to reduce the risk of SIDS, the potential impact of pacifiers on breastfeeding is increasingly important to understand. Even small deleterious effects on breastfeeding duration or exclusivity could have significant public health implications. At the same time, the potential reduction in SIDS with pacifier use at the initiation of sleep is compelling. This systematic review demonstrates that the relationship between pacifier use and breastfeeding is complex and poses challenges for study.

Randomized controlled trials provide stronger evidence than cohort or cross-sectional studies. Thus, the failure of the RCTs in this review to demonstrate any deleterious effect of pacifiers on breastfeeding duration or exclusivity is significant and important.

Two of the RCTs showed that pacifier use is high even among those who were instructed not to use them. In the study by Kramer and colleagues,¹⁶ 61.4% of infants in the intervention group (nonuser group) used pacifiers (vs 84.0% in the control group); 40.8% of infants in the intervention group used pacifiers daily (vs 55.7% in the control group). In the study by Collins and co-authors,¹⁴ infants in the control group were not supposed to receive a pacifier in the hospital, but 31% received a pacifier at some point before discharge. Data on actual pacifier use were not reported in the remaining 2 RCTs.

Two of the 4 RCTs^{14,17} controlled for pacifier use in the hospital only. We do not know whether the intervention and control groups differed in pacifier use at later times; it may be that mothers offer pacifiers to their infants after discharge independent of hospital practices or educational interventions.

Conversely, most observational studies demonstrated a negative association between pacifiers and breastfeeding

*References 15, 18, 25, 27, 33, 36, 38, 39, 41.

†References 18, 22, 23, 27, 28, 30, 33-37, 39.

‡References 19-21, 23, 25-29, 31-33, 35, 38, 39, 41, 42.

Table 2. Summary of Randomized Controlled Trials on Pacifier Use and Breastfeeding

Source	No. of Cases/Controls	Intervention	Control	BF Outcome(s)	Univariate OR, RR, or HR (95% Confidence Interval)	Multivariate OR, RR, or HR (95% Confidence Interval)	Variables Adjusted for in Multivariate Analysis ^a	Score	Failed Criteria
Collins et al, 2004, Australia ¹⁴	151/152 Preterm infants born at 23-33 weeks' gestation	Infants in NICU randomized to receive pacifier during tube feedings and soothing	No pacifier use in hospital ^b	Exclusive BF at discharge Any BF at discharge Any BF at 3 mo Any BF at 6 mo	NR NR NR NR	0.84 (0.51-1.39) 0.83 (0.45-1.05) 0.99 (0.56-1.77) 1.23 (0.66-2.30)	1-3	8	5
Howard et al, 2003, United States ¹⁵	354/346 Healthy infants born at ≥36 weeks' gestation	Infants randomized to receive pacifier any time after delivery (early use)	No pacifier use until after 4 wk of age (delayed use)	Shortened duration of exclusive BF Shortened duration of full BF (infrequent use of water or juice) Shortened duration of any BF	1.5 (1.0-2.0) ^c Not significant ^c Not significant ^c	1.09 (0.94-1.27) ^d 1.04 (0.89-1.21) ^d 1.22 (1.03-1.44) ^d	1-14	8	6
Kramer et al, 2001, Canada ¹⁶	140/141 Healthy infants born at >37 weeks' gestation	Infants randomized to participate in educational program emphasizing avoidance of pacifiers and alternative methods of soothing ^e	Received educational program that included pacifier use in soothing techniques	Weaned before 3 mo	1.0 (0.6-1.7) ^f	1.0 (0.6-1.9)	8, 15	6	4, 5, 9
Schubiger et al, 1997, Switzerland ¹⁷	294/308 Healthy infants born at >37 weeks' gestation	Infants randomized to UNICEF/WHO Baby Friendly Hospital protocol including avoidance of pacifiers ^g	Standard protocol including unrestricted pacifier use	Exclusive BF at 2 mo Any BF at 2 mo Exclusive BF at 6 mo Any BF at 6 mo	Not significant ^d Not significant ^d Not significant ^d Not significant ^d	No multivariate analysis performed	None	5	4, 5, 7, 9

Abbreviations: BF, breastfeeding; HR, hazard ratio; NICU, neonatal intensive care unit; NR, not reported; OR, odds ratio; RR, relative risk; UNICEF/WHO, United Nations Children's Fund/World Health Organization.

^aVariables for multivariate analysis: 1, educational level; 2, previous BF experience; 3, gestational age; 4, maternal age; 5, birth weight; 6, race; 7, infant sex; 8, maternal smoking; 9, previous live births; 10, mother plans to return to work or school; 11, mode of delivery; 12, any smoker in the household; 13, father lives in household; 14, socioeconomic factors; and 15, marital status.

^bOf the infants, 31% received a pacifier at some point during their hospitalization.

^cORs are for pacifier use vs no use at 4 weeks' postpartum.

^dReported for early vs delayed pacifier use.

^eOf the infants, 61.4% used a pacifier and 40.8% of the total group used a pacifier daily.

^fRR is presented for intention-to-treat analysis using groups from original randomization.

^gOf the infants in the UNICEF group, 24% received a pacifier.

duration or exclusivity. However, unlike randomized trials, observational studies cannot prove the direction of causality and it is not known in these studies whether pacifier use led to decreased breastfeeding or if decreased breastfeeding (eg, during weaning) led to increased pacifier use. As a case in point, when Kramer and colleagues¹⁶ analyzed the results of their RCT ignoring randomization, they found a strong observational association between 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). They argue that breastfeeding and pacifier use are complex behaviors influenced by factors that are difficult to measure and therefore difficult to control for in observational studies.¹⁶ These factors are likely to lead to residual confounding and reverse causality bias, suggesting that valid assessment of the effects of behavioral interventions on behavioral outcomes require randomized trials. In addition, the same child-rearing beliefs that motivate women to breastfeed exclusively may discourage pacifier use for infant soothing.

Pacifier use may be a marker for breastfeeding problems; mothers might resort to pacifiers for fussy infants when breastfeeding is going poorly. In support of this, one of the cohort studies³⁵ selected a subsample of Bra-

zilian women for an ethnographic study consisting of in-depth interviews and observation. These researchers found that pacifier use is widely regarded by mothers as a positive behavior. Furthermore, mothers reported using pacifiers to take their infants off of their breasts and to lengthen the interval between feedings. Pacifiers may represent an implicit form of weaning when mothers are ambivalent about breastfeeding. Further research is needed to understand the social and cultural factors that influence a mother's decision to use a pacifier.

Despite the comprehensive nature of the literature search performed, this systematic review may be limited by its inclusion of English-language reports only. This inclusion criterion could have restricted the type of reports included and is a potential source of bias.

The American Academy of Pediatrics guideline on SIDS suggests an important paradigm that our systematic review was unable to address. None of the studies looked at pacifier use only at nap time or bedtime, which would more directly assess the impact of the American Academy of Pediatrics recommendation that pacifiers be offered at the initiation of sleep. This recommendation was based on the results of case-control studies that found stronger evidence for SIDS risk reduction when pacifi-

ers were used at “last sleep” than at other times.⁶ Future research should examine if pacifiers have an effect on breastfeeding when used in this specific capacity.

In conclusion, the strongest current evidence on pacifiers and breastfeeding indicates that pacifier use is not detrimental to breastfeeding outcomes. Ongoing quantitative and qualitative research is needed to confirm these findings and more fully understand the complex relationships between pacifier use, breastfeeding, and SIDS, including the optimal timing for pacifier introduction.

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Author Contributions: Drs O'Connor and Hauck had full access to all of the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis. Study concept and design: Hauck. Acquisition of data: O'Connor and Tanabe. Analysis and interpretation of data: O'Connor, Tanabe, Siadaty, and Hauck. Drafting of the manuscript: O'Connor, Tanabe, and Hauck. Critical revision of the manuscript for important intellectual content: O'Connor, Siadaty, and Hauck. Statistical analysis: Siadaty and Hauck. Obtained funding: Hauck. Administrative, technical, and material support: O'Connor, Tanabe, and Hauck. Study supervision: Hauck.

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