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 highlighting 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.
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, or to use a random-effects model to calculate the pooled estimate if the included studies reported ORs as their preferred scale, or to use a random-effects model to calculate the pooled estimate if the included studies reported ORs on a relative risk (RR) scale. We planned to use statistics Q and I² to evaluate inconsistency and statistical heterogeneity between the included studies. Also, methods for detecting bias and heterogeneity, including funnel plot, Egger’s statistic, and Mantel-Haenszel statistic, radial plot, and trim-and-fill method were considered. 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 RCTs, (Table 1), 20 cohort studies, and 5 cross-sectional studies. The research was conducted in 12

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**Table 1. Scoring System for Studies Included in Systematic Review**

<table>
<thead>
<tr>
<th>No.</th>
<th>RCT/ Cohort</th>
<th>Cross-sectional</th>
<th>Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>1 Point</td>
<td>NA</td>
<td>All participants accounted for at conclusion of study</td>
</tr>
<tr>
<td>2</td>
<td>1 Point</td>
<td>1 Point</td>
<td>Study is prospective</td>
</tr>
<tr>
<td>3</td>
<td>1 Point</td>
<td>RCT</td>
<td>≥95% Follow-up (censoring counts as complete follow-up)</td>
</tr>
<tr>
<td>4</td>
<td>1 Point</td>
<td>NA</td>
<td>&gt;80% Participation (for surveys, participation refers to response rate)</td>
</tr>
<tr>
<td>5</td>
<td>1 Point</td>
<td>1 Point</td>
<td>Study was designed to look at the possible relationship between pacifiers and breastfeeding (as one of the main outcomes)</td>
</tr>
<tr>
<td>6</td>
<td>1 Point</td>
<td>1 Point</td>
<td>Exposure and/or outcomes were assessed identically for all participants</td>
</tr>
<tr>
<td>7</td>
<td>1 Point</td>
<td>1 Point</td>
<td>All eligible mothers (or random sample thereof) were invited to participate</td>
</tr>
</tbody>
</table>

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

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**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, to quantitatively compare the different study designs that resulted from the literature 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.

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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 qualities 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 of the 4 studies, 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 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 classified infants as pacifier users based on any pacifier use, while other studies 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 pacifiers; pacifier use in the neonatal period vs pacifier introduction after 4 weeks postpartum; and a Baby Friendly Hospital environment in which pacifiers were avoided vs unrestricted use of pacifiers (Table 2). One of the studies limited enrollment to preterm infants born at 23 to 33 weeks’ gestation. 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, 18.3% of infants in the intervention group were not supposed to receive a pacifier at any time; 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 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, 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, infants in the control group were not supposed to receive a pacifier at any time; 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 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. |
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 breastfeeding 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-

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

<table>
<thead>
<tr>
<th>Source</th>
<th>No. of Cases/ Controls</th>
<th>Intervention</th>
<th>Control</th>
<th>BF Outcome(s)</th>
<th>Univariate OR, RR, or HR (95% Confidence Interval)</th>
<th>Multivariate OR, RR, or HR (95% Confidence Interval)</th>
<th>Variables Adjusted for in Multivariate Analysisa</th>
<th>Score</th>
<th>Failed Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>Collins et al, 2004, Australia14</td>
<td>151/152 Preterm infants born at 23-33 weeks gestation</td>
<td>Infants in NICU randomized to receive pacifier during tube feedings and soothing</td>
<td>No pacifier use in hospitalb</td>
<td>Exclusive BF at discharge</td>
<td>0.84 (0.51-1.39)</td>
<td>1.09 (0.94-1.27)</td>
<td>1-3</td>
<td>8</td>
<td>5</td>
</tr>
<tr>
<td>Howard et al, 2003, United States15</td>
<td>354/346 Healthy infants born at ≥36 weeks gestation</td>
<td>Infants randomized to receive pacifier any time after delivery (early use)</td>
<td>No pacifier use until after 4 wk of age (delayed use)</td>
<td>Shortened duration of exclusive BF</td>
<td>1.5 (1.0-2.0)c</td>
<td>Not significantc</td>
<td>1-14</td>
<td>8</td>
<td>6</td>
</tr>
<tr>
<td>Kramer et al, 2001, Canada16</td>
<td>140/141 Healthy infants born at &gt;37 weeks gestation</td>
<td>Infants randomized to participate in educational program emphasizing avoidance of pacifiers and alternative methods of soothingb</td>
<td>Received educational program that included pacifier use in soothing techniques</td>
<td>Shortened duration of any BF</td>
<td>1.0 (0.6-1.7)d</td>
<td>1.0 (0.5-1.9)</td>
<td>8, 15</td>
<td>6</td>
<td>4, 5, 9</td>
</tr>
<tr>
<td>Schubiger et al, 1997, Switzerland17</td>
<td>294/308 Healthy infants born at &gt;37 weeks gestation</td>
<td>Infants randomized to UNICEF/WHO Baby Friendly Hospital protocol including avoidance of pacifiersc</td>
<td>Standard protocol including unrestricted pacifier use</td>
<td>Exclusive BF at 2 mo</td>
<td>Not significantd</td>
<td>No multivariate analysis performed</td>
<td>None</td>
<td>5</td>
<td>4, 5, 7, 9</td>
</tr>
</tbody>
</table>

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.

b Of the infants, 31% received a pacifier at some point during their hospitalization.

c ORs are for pacifier use vs no use at 4 weeks’ postpartum.

d Reported for early vs delayed pacifier use.

14 Of the infants, 61.4% used a pacifier and 40.8% of the total group used a pacifier daily.

f RR is presented for intention-to-treat analysis using groups from original randomization.

g Of the infants in the UNICEF group, 24% received a pacifier.

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. However, 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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REFERENCES