Does pacifier use cause ear infections in young children?

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Authors' objectives
To identify whether, in children under 2 years of age, pacifier (dummy) use results in a higher incidence of acute otitis media (AOM), ear infection or earache compared with children who do not use a pacifier.

Searching
The Cochrane Library, MEDLINE (from 1966 to 2001), CINAHL (from 1984 to 2001) and EMBASE (from 1980 to 2001) were searched using terms such as: 'Child$' or 'Infan$' or 'Bab$' or 'Toddle$' or 'Age$ adj4 two year$' or 'Age two year$' and 'Pacif$' or 'Sooth$' or 'Non?nutritive suck$' or 'Pacifier adj4 suck$' and 'Otitis?media' or 'Ear?infect$' or 'Ear adj3 infections'. MeSH terms, where available, were used. Manual searches of books and documents on childcare available in the Boole Library (University College Cork), and the journals 'Health Visitor' (from 1996 to 1997) and 'Community Practitioner' (from 1998 to 2001), were conducted. In addition, an Internet search was carried out using Google. Studies were excluded if they were written in a language other than English, and only studies published in journals available to the authors (i.e. held in the Boole Library, University College Cork, or King's College Library, Waterloo Campus, London) were included. There were no other restrictions.

Study selection
Study designs of evaluations included in the review
Studies that employed either a cohort or RCT design were eligible for inclusion in the review.

Specific interventions included in the review
Studies that examined the use of pacifiers in young children were eligible for inclusion in the review. These included interventions that attempted to change the extent of pacifier use in a group of children in a defined direction, compared with a control group where change was not attempted. The studies may have included parental reports and/or professional observation of non-nutritive sucking using a pacifier in children. The control interventions were defined as the non-use of pacifiers. The active interventions identified in one study (randomised controlled trial, RCT) included afternoon training sessions for nurses on the harmful effects of pacifier use on AOM, and leaflet or verbal advice for parents, where the main problems were identified.

Participants included in the review
Infants and children under two years of age were eligible for inclusion in the review. The mean ages of the participants in the included studies ranged from 3.29 to 18 months.

Outcomes assessed in the review
The outcomes assessed were AOM, earache or ear infection, as reported by either a parent or by a medical professional.

How were decisions on the relevance of primary studies made?
The authors do not state how the papers were selected for the review, or how many of the reviewers performed the selection.

Assessment of study quality
Validity was assessed on the basis of the questions posed by Sackett et al. (see Other Publications of Related Interest). These related to the following: whether there were clearly defined groups of patients, similar in all important ways other than exposure to treatment or other cause; the objectiveness of the assessment of clinical outcomes; the completion of a suitably long follow-up period for assessment of the outcome(s); and the results should satisfy some 'diagnostic tests for causation', including temporal association, dose response, positive dechallenge-rechallenge evidence, consistency of the findings with other studies, and biological sense. The authors do not state who performed
the validity assessment.

**Data extraction**
The authors do not state how the data were extracted for the review, or how many of the reviewers performed the data extraction.

Data were extracted on: study design; the number of study participants; the number of participants included in the analysis; the length of follow-up; the mean age of the participants; the type of intervention (where applicable); the nature of the data collected; analysis; and results.

**Methods of synthesis**

*How were the studies combined?*
The studies were combined narratively so no statistical pooling of the data was undertaken.

*How were differences between studies investigated?*
No formal test of heterogeneity was undertaken.

**Results of the review**

Three studies (n=10,619) were included in the review: one RCT (n=484), one prospective cohort (n=129) and one cohort study (n=10,006).

The RCT found a 29% lower occurrence of AOM per month in the active intervention group. A dose-response relationship was found in that children who did not use a pacifier had 33% fewer AOM episodes, and children who did not suck continuously had 27% fewer episodes. The prospective cohort study found a mean annual incidence of AOM of 1.9 episodes in children under 3 years who did not use pacifiers versus 2.7 in pacifier users (p=0.09; relative risk 2.9, 95% confidence interval, CI: 1.2, 7.3).

The cohort study found that 34.5% of the pacifier users had 'ear-ache since 6 months of age' versus 33.5% of the infants who neither sucked their thumb nor a pacifier. The adjusted odds ratio was 1.07 (95% CI: 0.97, 1.19).

**Authors’ conclusions**

In the context of the available evidence, there is probably a cause and effect relationship between pacifier use and AOM, although this relationship may be confounded by sociodemographic factors and, therefore, may not be a strong one.

**CRD commentary**

The review question and the study selection criteria were stated clearly. The literature search was reasonably comprehensive in terms of the sources searched and search terms used. However, the restriction to publications in English, and only those from journals readily available in the named libraries, means that key publications may have been missed or excluded. In addition, there does not appear to have been any manual searches of the reference lists from identified articles.

The authors provided no information on the literature selection, validation and data extraction processes. The results of the validity assessment were reported in two different sections, which made it confusing to follow. The decision not to pool the data in a statistical meta-analysis seems appropriate given the heterogeneity of the studies included. The statistical outcomes of the one included RCT were not reported as odds ratios or relative risks, along with 95% CIs, which would have been useful; however, it is possible that insufficient information was provided in the primary study.

The authors’ conclusions, which refer to the likelihood of a causal relationship between pacifier use and risk of ear infection, seem insufficiently cautious considering that only three studies were included in the review. One of the studies had statistically non-significant findings. There was also a possibility of sociodemographic confounding factors...
which the authors refer to.

Implications of the review for practice and research
Practice: The authors state that rather than advising parents not to use a pacifier for fear of causing AOM, advice in relation to this issue might best be restricted to pacifier users suffering from the problem in order to reduce the chances of recurrence. In particular, this applies to infants under 6 months of age when the need for sucking is greatest while the risk of AOM is relatively low, reducing the potential benefit of stopping the habit at this time. The identification of a dose-response relationship by one study suggests that benefit may be derived from reducing the use of the pacifier. Advice should be given about the cleanliness of the pacifier, particularly during the early months, and about limiting pacifier use.

Research: The authors did not state any implications for further research.

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This is a critical abstract of a systematic review that meets the criteria for inclusion on DARE. Each critical abstract contains a brief summary of the review methods, results and conclusions followed by a detailed critical assessment on the reliability of the review and the conclusions drawn.