

Is pacifier use a risk factor for acute otitis media? A dynamic cohort study

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Background. Recently, the use of a pacifier has been identified as a risk factor for acute otitis media (AOM). The studies performed so far, however, suffer from methodological limitations.

Objective. To study whether pacifier use increases the risk of AOM.

Methods. Four hundred and ninety-five children between the ages of 0 and 4 years followed from 2000 to 2005 in a dynamic population study in the Leidsche Rijn residential area in Utrecht, The Netherlands. At baseline, the parents of these children filled out a questionnaire regarding pacifier use and potential confounders. AOM was diagnosed by GPs according to the International Classification of Primary Care coding system. Odds ratios (ORs) and 95% confidence intervals (CIs) were calculated.

Results. Of the 216 children that used a pacifier at baseline, 76 (35%) developed at least one episode of AOM, and of the 260 children that did not use a pacifier, 82 (32%) developed at least one AOM episode; for recurrent AOM, these figures were 33 (16%) versus 27 (11%), respectively. The adjusted ORs for pacifier use and AOM and recurrent AOM were 1.3 (95% CI 0.9–1.9) and 1.9 (95% CI 1.1–3.2), respectively.

Conclusion. Pacifier use appears to be a risk factor for recurrent AOM. Parents should be informed about the possible negative effects of using a pacifier once their child has been diagnosed with AOM to avoid recurrent episodes.

Keywords. Acute otitis media, children, pacifier, risk factor.

Introduction

Acute otitis media (AOM) is one of the most common childhood infections, the leading cause of doctors' visits by children and the most frequent reason for children to receive antibiotics or undergo surgery.^{1,2}

Several risk factors for AOM have been identified. AOM is inversely related to breastfeeding and has positive associations with upper respiratory tract infections (URTIs), number of siblings, parental smoking and day care outside the home.^{2–6} Pacifier use has also been suggested to increase the occurrence of AOM. Two causal mechanisms have been proposed for this association.^{7–10} First, sucking on a pacifier increases the reflux of nasopharyngeal secretions into the middle ear, i.e. during a common cold pathogens can enter

the middle ear more easily through this route.⁷ Second, the use of a pacifier may induce changes in dental structure and thereby dysfunction of the Eustachian tube.⁸

The studies performed so far, however, suffer from methodological limitations.^{7,8} For example, Niemelä *et al.*⁸ performed a retrospective study, which may have been subject to recall bias. They also studied self-reported AOM, which may have resulted in an overestimation of the association. Another study performed by Niemelä *et al.*⁷ was based on a selected population, i.e. children attending day care known to be at a higher risk of developing AOM. Besides, the follow-up of this study was only 10 months, and the results were not adjusted for other potential confounding factors.

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Since 75–85% of all children in western countries use a pacifier,^{9,11} which appears to be a modifiable risk factor, more research on this association is needed.

We therefore prospectively studied the risk of AOM associated with pacifier use in a large cohort study, taking into account potential confounding factors.

Methods

Study population

The present study was performed as part of the Utrecht Health Project (UHP).^{12,13} The UHP is a dynamic population study that recruits participants in the new residential area Leidsche Rijn in Utrecht, The Netherlands. All new inhabitants are invited to participate upon registering with a GP in the area. Baseline investigations include questionnaires on health status and disease history. Participants are followed up regarding medical diagnoses and treatment.

For the present study, information was used on all children aged between 0 and 4 years, recruited in the UHP between April 2000 and August 2005. These children were followed by the UHP from moment of recruitment until November 2005 or until the moment they moved out of the area, which ever came first. Children with birth defects were excluded.

Pacifier use

Pacifier use was recorded, upon inclusion, in a baseline questionnaire filled out by the parents and was defined as using a pacifier often or sometimes.

Acute otitis media

Information on the diagnosis of AOM was obtained from the electronic medical files as recorded by the GPs involved in the UHP. These diagnoses were coded according to the International Classification of Primary Care (ICPC).¹⁴

Both AOM (ICPC code H71) and recurrent AOM were studied; recurrent AOM was defined as three or more doctor's diagnosed episodes of AOM during the study period.

Confounders

Information on potential confounders such as attending day care (yes versus no), breastfeeding (>3 months versus ≤3 months), passive smoking (yes versus no), use of a feeding bottle (yes versus no), thumb sucking (yes versus no), educational level of the parents (high, moderate and low), atopy/allergies (any versus non) and ethnicity (Caucasian versus other) was also included in the baseline questionnaire. Information on URTIs was obtained from the electronic medical files; for this diagnosis, ICPC code R74 was used.

Data analysis

To determine whether pacifier use is associated with a higher risk of developing AOM, ORs with 95%

confidence intervals (CIs) were calculated. The ORs were calculated for both AOM and recurrent AOM. Logistic regression analyses were used to adjust for potential confounders and to calculate adjusted ORs. Furthermore, a sensitivity analysis with different cut-off points for pacifier use was performed. All analyses were performed in SPSS (version 12.0).

Results

Of the 495 children aged 0–4 years in the UHP, 19 had birth defects and were excluded. Of the remaining 476 children, 216 used a pacifier at baseline. The majority of children was aged between 1 and 2 years (43%). The distribution between boys and girls was more or less equal. Seventy-six per cent of children was Caucasian, and 69% attended day care (Table 1). In this dynamic population, the mean follow-up time in the children using a pacifier and in those not using a pacifier was 2.8 and 2.9 years, respectively [overall mean follow-up time was 2.9 years (range 0.2–5.6 years)].

Of the 216 children who used a pacifier at baseline, 76 (35%) developed at least one episode of AOM during follow-up; in the 260 children who did not use a pacifier at this time, 82 (32%) developed at least one AOM episode; 33 (16%) versus 27 (11%) had recurrent AOM, respectively.

The univariate analyses showed no statistically significant association between pacifier use and AOM, OR 1.2 (95% CI 0.8–1.7), or recurrent AOM, OR 1.6 (95% CI 0.9–2.7). The adjusted ORs were 1.3 (95% CI 0.9–1.9) for AOM and 1.9 (95% CI 1.1–3.2) for recurrent AOM (Table 2). Sensitivity analyses with different cut-off points for pacifier use showed similar results.

Discussion

In this dynamic population study among 476 children with a mean age of 2.2 years, pacifier use was associated with a 1.8 times higher risk of recurrent AOM. No significant increased risk was observed for AOM. Although the causal mechanism of this finding should be studied further, the findings are compatible with the view that the first middle ear infection causes damage to the mucosa of the middle ear and thereby predisposes to further infection.¹⁵ Under these circumstances, use of a pacifier inducing reflux of nasopharyngeal secretions into the middle ear may increase susceptibility to AOM.³

The positive association between pacifier use and recurrent AOM is consistent with previous studies.^{3,9} The lack of association with a first AOM episode, however, differs from the findings by Jackson *et al.*¹¹ This might be attributed to the retrospective design of Jackson's study, in which recall bias, i.e. parents of children with frequent episodes of AOM may have

TABLE 1 Baseline characteristics of 476 children participating in the UHP

	Pacifier+	Pacifier-
	n (%)	n (%)
Age at inclusion		
0–1 years	2 (1)	0 (0)
1–2 years	108 (50)	99 (38)
2–3 years	75 (35)	65 (25)
3–4 years	31 (14)	98 (37)
Boys	105 (49)	132 (51)
Caucasian	181 (84)	181 (69)
Day-care centre	143 (67)	184 (71)
Breastfeeding (>3 months)	82 (38)	111 (43)
Passive smoking	25 (12)	24 (9)
Bottle use	123 (57)	110 (43)
Thumb sucking	4 (2)	68 (27)
Atopy	23 (15)	27 (15)
Educational level parents		
Low	29 (9)	50 (12)
Moderate	135 (42)	158 (40)
High	161 (49)	190 (48)
URTI	105 (49)	127 (49)

TABLE 2 Unadjusted and adjusted ORs regarding the association between pacifier use and otitis media

	OR (95% CI)	Adjusted OR (95% CI) ^a
AOM (yes versus no)	1.2 (0.8–1.7)	1.3 (0.9–1.9)
Recurrent (>3) AOM	1.6 (0.9–2.7)	1.9 (1.1–3.2)

^aAdjusted for all potential confounders, i.e. age, attending day care, breastfeeding, passive smoking, educational level parents, use of a feeding bottle, thumb sucking and ethnicity.

been more aware of pacifier use, cannot be ruled out. Since a prospective cohort design as used in our study minimizes the risk of biased results, it is the best way of studying the association between pacifier use and AOM.

To appreciate the results of our study, some possible limitations should be discussed. First, our study was based on patients with AOM, diagnosed by their GP. That is, probably only the more severely affected children were included, which may have resulted in an underestimation of the association. The alternative, however, self-reported AOM is also known to be imprecise and therefore could also have resulted in biased results.^{16–18}

Second, pacifier use was only documented at baseline. Over the follow-up period, pacifier use may have varied; therefore, we cannot be certain whether the children actually used a pacifier at the time of an AOM episode. Pacifier use can, however, only be a risk factor if it precedes the AOM. We therefore assessed the usage of a pacifier only at baseline. Furthermore,

our data show that pacifiers are used by 50% of the children aged 1 and 2 years and by 25% of the children aged 3 and 4 years. The association between pacifier use and otitis media was similar in both age groups.

Third, we did not calculate the relative risks based on the incidence densities, i.e. with person years follow-up time, since these person years were equally distributed in the children using a pacifier and those not using a pacifier.

Finally, given the percentages of children with otitis media in each group and the sample size of about 500 children, we calculated the power belonging to both an alpha of 0.05 and 0.1. The corresponding powers were 60% and 70%, i.e. in case of a larger sample size, the other findings might become significant as well.

In conclusion, pacifier use appears to be a risk factor for recurrent AOM. Paediatricians and GPs can use this information in their daily practice, i.e. they can dissuade parents from using a pacifier once their child has been diagnosed with AOM to avoid recurrent episodes.

Declaration

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Ethical approval: The UHP was approved by the Medical Ethics Committee of the University Medical Center Utrecht.

Conflicts of interest: None.

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