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Pediatrics 2000;106;483-488

DOI: 10.1542/peds.106.3.483

The online version of this article, along with updated information and services, is located on the World Wide Web at:

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American Academy of Pediatrics

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Pacifier as a Risk Factor for Acute Otitis Media: A Randomized, Controlled Trial of Parental Counseling

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ABSTRACT. *Objectives.* To evaluate the association between pacifier use and the increased occurrence of acute otitis media (AOM) in an intervention trial.

Methods. Fourteen well-baby clinics were selected to participate in an open, controlled cohort study. These clinics were paired according to the number of children and the social classes of the parents they served. One clinic in each pair was randomly allocated for an intervention, while the other served as a control. The nurses at the intervention clinics were trained to instruct the parents of children <18 months old to limit pacifier use during their prescheduled visits to the clinic. The intervention consisted of a leaflet explaining the harmful effects of pacifier use and instructions to restrict its use. Two hundred seventy-two children were successfully recruited from the intervention clinics and 212 from the control clinics. The data about pacifier use and the occurrence of respiratory infections and AOM were collected similarly in both groups.

Results. After the intervention, a 21% decrease was achieved in continuous pacifier use at the age of 7 to 18 months ($P = .0001$), and the occurrence of AOM per person-months at risk was 29% lower among children at the intervention clinics. The children who did not use a pacifier continuously in either of the clinics had 33% fewer AOM episodes than the children who did.

Conclusion. Pacifier use appeared to be a preventable risk factor for AOM in children. Its restriction to the moments when the child was falling asleep effectively prevented episodes of AOM. *Pediatrics* 2000;106:483–488; area under curve, ear infection, intervention, sucking habits.

ABBREVIATIONS. AOM, acute otitis media; PMR, person-months at risk; CI, 95% confidence interval.

Pacifier use has long been considered a harmless habit with only a temporary effect on dentition, and 75% to 85% of all children in western countries make a habit of using one.^{1,2} We previously demonstrated in an observational survey that pacifier use increases the occurrence of acute otitis media (AOM) by a risk ratio of 1.4² and the risk of recurrent attacks in children 2 to 3 years old attending a day care center by a risk ratio of 2.9.³ Because of the

frequent occurrence of AOM in young children, even a small increase in the effect of an environmental risk factor leads to a considerable population-attributable risk. In addition to its effect on the occurrence of AOM, a pacifier increases the risk of oral candida,^{4,5} and it has been found to be associated with a higher carriage rate of cariogenic microbes⁶ and development of dental caries.⁷

In Finland all preschool-aged children have prescheduled, free visits to a nurse in the well-baby clinic of the local municipal health center once a month during their first 6 months of life and at intervals of 3 to 12 months after that. In each well-baby clinic, 1 to 4 full-time nurses see the children living in their area. The nurses of the well-baby clinics monitor the growth and development of the child, perform the vaccinations, and give guidance and support to the parents. Over 95% of the Finnish families use this opportunity. Thus, it was possible for us to design a controlled, prospective, randomized intervention project, where counseling parents of healthy children <18 months old about the harmful effects of pacifier use was utilized as an intervention. The occurrence of AOM was compared in the children whose parents attended the counseling (intervention group) to those whose did not (control group).

METHODS

The study was a randomized, controlled, prospective, open cohort trial with intervention in the form of advice on restricting pacifier use. The children were enrolled from 14 well-baby clinics in the city of Oulu in northern Finland. The clinics were paired according to size and area served, and 1 from each pair was randomly allocated for the intervention and the other to serve as a control. The nurse informed all parents of the children 0 to 18 months old cared for at the clinics from December 1996 through February 1997 about the study. Altogether, 534 families were willing to participate and gave their informed consent. The Ethical Committee of the Health Center of the city of Oulu accepted the study protocol.

The nurses of the intervention clinics were trained in 1 afternoon session to instruct the parents to limit pacifier use by their child. The aim and purpose of the project, which was to evaluate the effect of pacifier use on the occurrence of AOM, were explained to the nurses. The nurses at the intervention clinics were informed by 2 pediatricians (M.U. and M.N.) and a clinical psychologist (Marja U.) about the harmful effects of both AOM and prolonged pacifier use (Table 1) and were told to pass this information on to the parents. A leaflet that included information about the effects that pacifier sucking has on the occurrence of AOM, on the occurrence of candidiasis of the mouth, on dentition, and on the development of caries was given to the parents. They were also told that the need for sucking during the first 6 months of life is often great and reflexive⁸ and that a pacifier can be used at that

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Received for publication Mar 12, 1999; accepted Jan 19, 2000.

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TABLE 1. Aspects Presented at the Intervention Clinics in Counseling Parents About Pacifier Use*

The use of a pacifier
increases the incidence of acute otitis media ^{2,3}
increases the incidence of candidiasis of the mouth ^{4,5}
increases the incidence of caries ^{6,7}
increases the incidence of malocclusion ⁹
Thus, pacifier use
can be free until the age of 6 months
should be limited to the moments when the child is falling asleep after the age of 6 months
should be terminated after the age of 10 months

* This information was given both in a leaflet and in the discussions with the clinical nurse during the prescheduled visit to the well-baby clinics.

age as often as it is wanted. They were encouraged, however, to limit pacifier use to the moments of falling asleep once the child reaches the age of 6 months and to discontinue its use after the age of 10 months (Table 1).

A similar afternoon session was also held for the nurses working at the control clinics, but they were told about the possible harmful effects of AOM and that the epidemiology of infectious diseases in small children would be monitored in the area. The parents at the control clinics received no counseling on pacifier use.

The nurses instructed the parents to register the occurrence of AOM on a daily symptom sheet. During the follow-up period the parents of both the intervention and the control groups wrote down their child's infections on a daily symptom sheet, and if the child was taken to a physician, the parents asked the physician to write the diagnosis and the possible medication on the same sheet. The dates of possible changes in the habit of pacifier use were also recorded on the sheet. The symptom sheets were mailed to us monthly by the parents. The monitoring was to last until the end of May 1997 (ie, from 3 to 6 months depending on the date the child was recruited).

The follow-up was successful in 91% of the children. Five families moved away from the area and 45 families did not return the symptom sheets even when requested by phone. Monitoring data covering at least 1 month were available for 484 children. The mean duration of monitoring was 4.6 months (range: 1–6 months). Information on the history of AOM episodes in the index child and in his/her siblings, the mode of day care, whether adenoidectomy or tympanostomy had been performed, the signs or symptoms of allergy, and the sucking habits before the monitoring period was collected from the parents during the enrolment visit to the clinic (Table 2). The mode of day care was classified as care at home, at a family day care, or at a day care center for at least 4 hours a day. The same information was collected again by mail after the monitoring had been completed. The parents of the children in the intervention group were also asked by multiple-choice questions whether the intervention raised interest, anxiety, guilt, indignation, or some other feelings in them.

The sample size was calculated by assuming, based on our earlier observations, that about 75% of all children use a pacifier at some time, and that about one fifth stop using one at the age of 10 months. Thus, about half of the children attending well-baby clinics would benefit from counseling of the parents on pacifier use. Half of the children in the control group were expected to develop AOM during the follow-up. Our aim was to reduce this occurrence by 25% by means of the intervention. A type I error level of .05 and a power of 90% were chosen. With these assumptions, the calculated sample size was 273 children in each group. To achieve this, a total of 14 well-baby clinics were chosen and randomized.

As our trial was an open cohort study, different children contributed different lengths of time to the trial. These times were summed up as person-months at risk (PMR). The shortest period accepted was 1 month. Because age is an important confounding variable when evaluating the occurrence of AOM, we stratified the time for which the children had had different sucking habits (ie, used a pacifier continuously, only when falling asleep, or not at all) into 3-month periods as PMR. The occurrence of AOM attacks was calculated per PMR according to pacifier use and according to

TABLE 2. Background Information on the 484 Children Enrolled in the Intervention Study, by Group

	Intervention (272) n (%)	Control (212) n (%)
Mean age at the beginning of monitoring	8.2 mo (range: 1.8–20.8)	8.1 mo (range: 1.3–23.7)
Sex (boys)	134 (49.3)	117 (55.2)
Day care		
At home	252 (93.0)	187 (93.0)
Family day care	10 (3.7)	4 (2.0)
Day care center	9 (3.3)	10 (5.0)
History of AOM		
None	186 (68.6)	135 (68.2)
1–2	62 (22.5)	55 (20.7)
>2	24 (8.9)	22 (11.1)
Adenoidectomy performed	3 (1.1)	3 (1.5)
Tympanostomy performed	4 (1.5)	5 (2.5)
Number of siblings		
None	132 (48.5)	100 (47.9)
1–2	126 (46.4)	96 (44.6)
>2	14 (5.1)	16 (7.5)
Pacifier use		
None	54 (20.0)	51 (25.2)
When falling asleep	98 (36.3)	59 (29.2)
Continuously	118 (43.7)	92 (45.5)
Parental smoking		
Mother smokes	49 (18.8)	30 (15.1)
Father smokes	78 (29.5)	58 (29.9)
Atopic eczema	52 (19.1)	38 (18.1)
History of wheezing	7 (2.8)	5 (2.7)
Breastfed now	110 (41.7)	85 (42.1)
Snores	33 (12.1)	28 (13.9)

membership in the intervention or control group. The effect of the intervention on pacifier use was evaluated by calculating the time for which children >6 months old used a pacifier continuously, only when falling asleep, or not at all during the monitoring period and the proportion differences were then calculated and their significance tested by Fisher's exact test.

Linear regression modeling was used to evaluate which variables had an effect on pacifier use. Here, the time of using a pacifier (dependent variable) was summed by multiplying the time for which the child was monitored by 0 if no pacifier was in use, by 1/3 if a pacifier was used only when falling asleep, and by 1 if a pacifier was used when awake as well. The explanatory variables entered were age, sex, intervention group, nursing, and mode of day care. Similar linear regression modeling was used to evaluate the effect of the intervention on the occurrence of AOM. To present the effect of the counseling on the occurrences/PMR of AOM, these occurrences were expressed graphically and the areas under the curve were calculated and compared between the groups.

RESULTS

Of the 484 children for whom monitoring data covering at least 1 month were available, 272 were enrolled at the intervention clinics and 212 at the control clinics (Table 3). Their mean age at the beginning of the study was 8.1 months, and 251 (51.9%) of them were boys. Most of the children monitored were 7 to 18 months old (Table 4). Before the monitoring, 31.6% of the children had already had attacks of AOM, and 79.0% of the intervention children and 74.7% of the controls had been using a pacifier (Table 2). There were no clinically significant differences between the children in the intervention or control clinics (Table 2).

At the end of the study, 68% of the children in the intervention group and 66.5% in the control group were still using a pacifier. However, after the inter-

TABLE 3. Number of Nurses Working, Number of Children Recruited, and Sum of Follow-Up Times as PMR for Each Clinic Participating in the Intervention Trial

No. of Pair	Control Clinic			Intervention Clinic		
	Nurses	Children	PMR	Nurses	Children	PMR
1	2	38	183.6	3	32	154.8
2	4	18	74.4	3	47	219.6
3	2	33	134.4	2	42	196.8
4	2	21	91.2	1	11	48.0
5	3	34	129.6	4	36	144.0
6	1	25	112.8	1	20	98.4
7	6	43	219.6	3	84	403.2
Sum	20	212	945.6	17	272	1264.8

vention the children 6 to 10 months old in the intervention group spend 35% of their monitoring time using a pacifier continuously as compared with 48% in the control group, and a 27% decrease was thus achieved in this age group with the intervention on continuous pacifier use (95% confidence interval [CI]: 13%–41%; $P = .0001$; Fig 1). Of the children >10 months old in the intervention group 33% used a pacifier continuously versus 36% in the control group, a 10%, statistically not significant decrease (CI: -4%–25%; $P = .2$). When considering children 7 to 18 months old, a 21% decrease (CI: 11–32) was achieved in the continuous pacifier use ($P = .0001$; Table 4). The proportion of children not using a pacifier at all did not differ significantly between the 2 groups at any age.

The occurrence of AOM/PMR was 29% lower in the intervention group (Fig 2). The variables with a significant effect on the occurrence of AOM/PMR during the monitoring period according to linear regression analysis were the mode of day care ($P < .001$) and counseling ($P = .047$). In the total series the occurrence of AOM/PMR was 33% higher in the group of children who used a pacifier continuously than in those not using one or using it only when falling asleep.

Seventy-one percent of the parents in the interven-

tion group regarded the intervention as interesting and important, 11% were worried, partly because they had not been aware of the effects of a pacifier earlier, 9% felt guilty because they were not able to restrict pacifier use, and 7% felt indignant about the intervention.

DISCUSSION

We observed significantly fewer AOM episodes among the children whose parents received counseling about pacifier use. The 2 groups were similar in their background, and counseling was the only difference between the 2 groups during their prescheduled visits to the well-baby clinics. Our counseling was effective in reducing daytime pacifier use, although the parents were not able to stop its use entirely. We were already aware when planning our intervention of the possibility to cause anxiety and guilt in the parents, and to avoid this, we advised the nurses at the clinics to be as supportive as possible and not to accuse the parents at any point, even if they were not able to restrict pacifier use. Because restricting pacifier use to moments when the infant was falling asleep reduced the occurrence of AOM, we believe that this advice suffices for parents. The efficacy of our counseling in reducing the occurrence

Fig 1. Proportions of children using a pacifier continuously, only when falling asleep, or not at all during the monitoring period, by age, among those whose parents received counseling on the pacifier use (intervention, $n = 272$) and those whose parents received no counseling (control, $n = 212$).

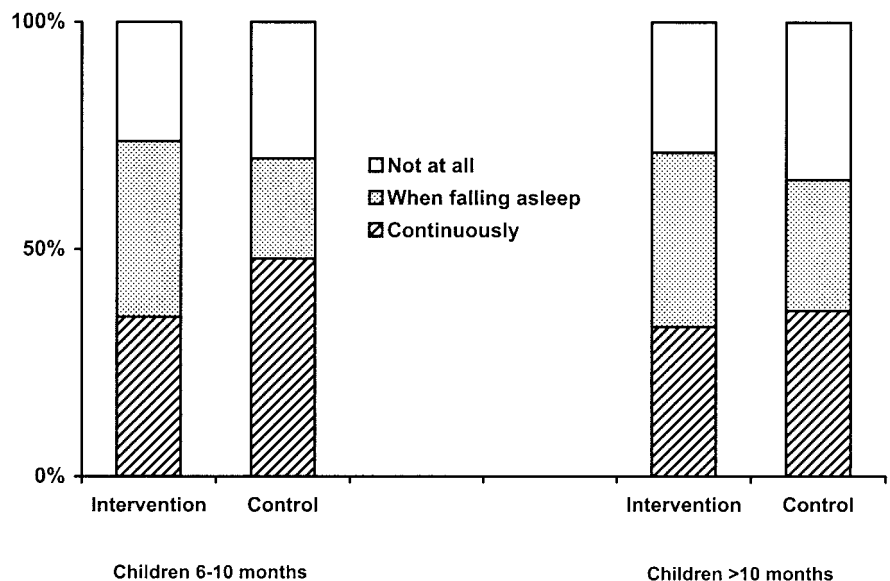


TABLE 4. Total Follow-Up Time as PMR and the Proportion (%) of PMR With Different Pacifier-Using Habits in 484 Children According to Intervention and Age Groups

Pacifier Use (Proportion of PMR in %)	Age Group*											
	0-6 Months			7-12 Months			13-18 Months			19-24 Months		
	Control	Study	D% (CI)	Control	Study	D% (CI)	Control	Study	D% (CI)	Control	Study	D% (CI)
Continuously	45	48	-5 (-28-17)	42	33	22 (9-35)	42	34	20 (0-40)	24	31	-22 (-66-25)
Not at all or when falling asleep	54	52		58	67		58	66		76	69	
Total PMR (mo)	166	150		688	529		326	199		88	66	

* D% (CI) decrease in percentages in favor of study clinics (95% confidence interval).

of AOM confirms our earlier observation that pacifier use is a significant risk factor for AOM.^{2,3}

The method by which pacifier use increases susceptibility to AOM is not known. Pacifier use does not increase the occurrence of respiratory infections.³ Thus, the fact that the frequency of its use affected the occurrence of AOM makes it reasonable to assume that the effect may lie in an alteration in the pressure equilibrium between the middle ear cavity and the nasopharynx, which apparently impairs the functioning of the Eustachian tube.

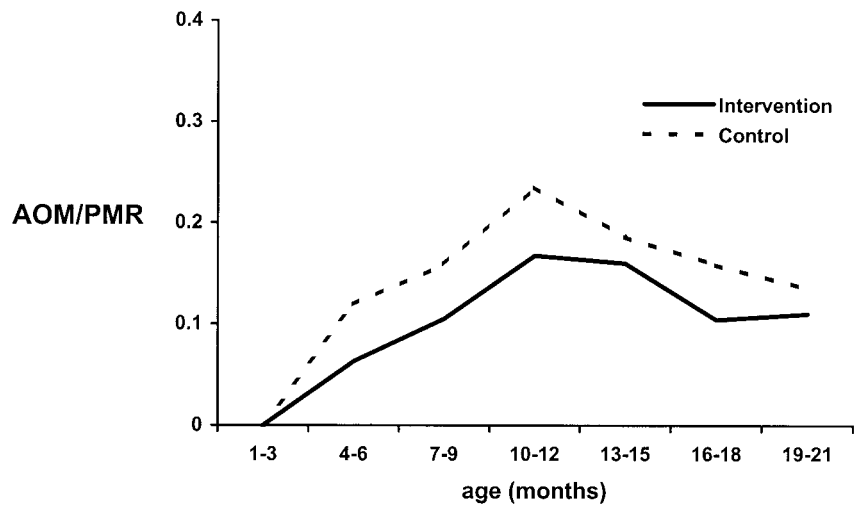
The counseling used in this intervention would be recommended not only to prevent AOM, but also to alleviate the other adverse effects of pacifier use. In addition to increasing oral candida,^{4,5} prolonged pacifier use has been shown to be associated with colonization of the oral cavity by cariogenic microbes and caries,^{6,7} and also to cause malocclusion, open bite, which usually regresses spontaneously if the habit ceases, and cross bite, which may require active orthodontic treatment.⁹ Pacifiers have been thought to reduce the risk of the sudden infant death syndrome¹⁰; pacifier use is encouraged in small children when falling asleep.

The numbers of visits made to office-based physicians in the United States at which the principal diagnosis is otitis media has increased significantly in recent years, and was estimated in 1990 to be about 24.5 million, ie, about 2.5 times more than in 1975.¹¹ Otitis media places a significant economic burden on both parents and the health care system,^{12,13} and recurrent AOM may even lead to long-term sequelae in the form of learning difficulties, especially in reading and mathematics.^{14,15} Otitis media is the most important indication for antimicrobial treatment in children, and bacterial resistance to antimicrobial agents, connected with their excessive use is a rapidly growing problem worldwide.^{16,17} Young children attending day care centers, in particular, contribute to the spread of these resistant bacteria.¹⁸ Thus, the risk factors for AOM should be carefully identified, and procedures that effectively prevent its occurrence are urgently needed.

Most of the risk factors that promote the occurrence of AOM are inherited, eg, the structure of the nasopharynx, or the occurrence of the disease in siblings, or else difficult to change, such as the form of day care.¹⁹ Pacifier sucking is an acquired habit that can be altered by parents. Thus, we believe that our finding of a decrease in the occurrence of AOM on reduced pacifier use has important practical implications. The physiologic need for sucking is most prominent during the first 6 months of life, after which pacifier use only tends to be a habit that brings a feeling of security.^{8,20} In this intervention, our advice encouraged a limitation of pacifier use after the age of 6 months to the moments the child was falling asleep and to a termination of pacifier use around the age of 10 months.

The habit of pacifier use is associated with breastfeeding, which is known to reduce the risk of AOM.²¹ The children who are weaned from breastfeeding early use a pacifier more often than those who are breastfed longer.^{1,22} Thus breastfeeding

Fig 2. Occurrence of AOM episodes per PMR among the children of the parents who received counseling on pacifier use (intervention, $n = 272$) and those whose parents received no counseling (control, $n = 212$).



might be a possible confounding variable in our analysis. However, the proportions of children breastfed at the beginning of the trial were similar in the intervention and control groups, and even when we included breastfeeding in the linear regression model when analyzing the effect of counseling, the results did not change. The mode of day care did not show any association with pacifier use, but because <10% of the children in our trial attended day care outside the home, even a fairly strong association would not have been statistically significant because of the low power in our analyses.

The intervention was given during a routine visit to the clinic and no extra time was scheduled for it. The nurses were trained in 1 afternoon session and the information the parents finally received was very much dependent on the attitude of the nurse, which might have lessened the effect of the intervention. Furthermore, the results of earlier studies concerning pacifier use as a risk factor for AOM have been published in many newspapers and magazines in Finland, which might have contaminated the control group. The diagnoses of AOM were not made according to any predefined criteria by validated otoscopists but during routine visits in local health centers or in private practice. Yet, it is reasonable to assume that similar inaccuracies in the diagnoses of AOM would have occurred in both groups. All these confounders would dilute the efficacy of our intervention, and we were, nevertheless, able to achieve a notable decrease in the occurrence of AOM. An intervention of this kind cannot be blinded between the groups, but we did allocate the clinics to the intervention and control functions on a random basis.

The information given to parents concerning the habits of their children should be positive and encouraging. At the end of the monitoring period, we asked parents how they felt about the information they had received, and most of them had been interested and were grateful for it. Only a few had problems in believing the information, and some parents experienced stress mainly because of their practices with their older children. We think that if information on the right way of using a pacifier is given early

enough, most parents can identify the time when their child's real need for sucking is over. Our results strongly suggest that even the restriction of pacifier use to the moments when the infant is falling asleep will reduce the occurrence of AOM. This restriction is easier to apply and gives rise to less anxiety than a flat denial of pacifier use. As AOM is such a common disease during childhood, even small changes in children's everyday habits may have major effects on its occurrence.

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MASS INJECTIONS AGAINST PARASITE SPREAD HEPATITIS ACROSS EGYPT

Paris, March 9, 2000 (Agence France–Presse)—A 30-year campaign in Egypt to eradicate a blood parasite went disastrously wrong, causing an epidemic of hepatitis C that now infects up to a fifth of the country's population, according to research being made public.

American and Egyptian epidemiologists, in a report to be published in the *Lancet*, the British medical weekly, said the hepatitis had been transmitted across the Egyptian population through unsterilized needles and syringes reused in a fight against a blood parasite.

As an instance of a medical campaign spreading blood-borne virus, they said, the case is the world's most extensive.

The campaign against the parasite illness, schistosomiasis, which is widespread in Africa, was conducted across Egypt from the 1950s to the 1980s. Each patient was given 12 to 16 injections of a tartar emetic, the report said. But the injections were often administered unsafely, with needles either improperly sterilized or used for multiple doses.

New York Times. March 10, 2000

Noted by JFL, MD

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