

Pacifier use and the occurrence of otitis media in the first year of life

John J. Warren DDS, MS Steven M. Levy DDS, MPH H. Lester Kirchner PhD Arthur J. Nowak DMD, MA
George R. Bergus MD

Dr. Warren is an assistant professor, and Dr. Levy is a professor, Department of Preventive & Community Dentistry; Dr. Nowak is a professor emeritus, Departments of Pediatric Dentistry and Pediatrics; and Dr. Bergus is an associate professor, Department of Family Medicine, The University of Iowa. Dr. Kirchner is an instructor, Division of Clinical Epidemiology, Department of Pediatrics, Rainbow Babies and Children's Hospital Case Western Reserve University, formerly in the Department of Preventive Medicine & Environmental Health, The University of Iowa. Correspond with Dr. Warren at john-warren@uiowa.edu

Abstract

Purpose: The purpose of this study was to assess pacifier use as a risk factor for otitis media during the first year of life.

Methods: A volunteer cohort of 1,375 infants was recruited from eight hospital postpartum units in Iowa. Parents were asked to provide detailed information on their child's health at 6 weeks, 3, 6, 9 and 12 months of age. Questions were posed concerning occurrence of specific childhood illnesses, including otitis media, at each time point, as well as other factors.

Results: Over 70% of children were reported to have experienced one or more episodes of otitis media during their first year of life, with its occurrence much more common during the second six months. Multivariate analyses using Generalized Estimating Equations assessed factors associated with otitis media during the entire 12-month period. These analyses showed that pacifier use, age, male sex, greater number of childcare days, and higher family incomes were significantly associated with occurrence of otitis media.

Conclusions: Multivariate analyses found that the occurrence of otitis media was associated with pacifier use, one of few modifiable risk factors for otitis media. (*Pediatr Dent* 23:103-107, 2001)

Otitis media (OM) is one of the most common diseases in young children.^{1,2} Studies have demonstrated that most children have one or more episodes during the first five to seven years of life.³⁻⁵ OM has also been reported to be most likely to occur during the first year of life,^{4,7} with studies reporting first-year-of-life incidence ranging from 22%⁴ to 79%.⁵ Overall, it has been reported that OM is responsible for a large proportion of preschool children's physician visits in the United States,³ with enormous costs and loss of work days for parents.⁸

Several recent studies have concluded that use of a pacifier was a risk factor for OM,⁹⁻¹² supporting a suggested association between pacifier use and OM first reported in 1975.¹³ A study in Finland, which included only children who regularly attended day-care found that 30% of children who used a pacifier had 3 or more episodes of OM during the first two years of life, compared to only 21% of children who did not use a pacifier.^{9,10} While the relative risk (the ratio of occurrence of OM among those using a pacifier to OM occurrence among those

not using one) of 1.6 for developing OM between pacifier users and non-users was not statistically significant for the birth to 2 year age group, the relative risk for 2- to 3-year-olds (2.9) was significant, and the authors estimated that pacifiers were responsible for 25% of OM occurrences in children age 3 or younger.⁹

A study in the U.S. reported by Jackson and Mourino¹¹ assessed pacifier use, childcare attendance and other risk factors for otitis media. Their study found, using logistic regression, that pacifier use was a significant risk factor for otitis media (Odds Ratio =2.09, $P=0.04$), regardless of childcare attendance.¹¹ A "controlled trial" of the effects of parental counseling to restrict pacifier use on subsequent occurrence of otitis media found that greater pacifier use resulted in greater risk of OM.¹² In this study, OM occurrence was compared between a group of children whose parents had received an intervention designed to discourage pacifier use, and a group of children whose parents had received no such advice. While the intervention had modest effects on prevalence of any pacifier use, the amount of time per day using a pacifier was significantly ($P=0.0001$) reduced in the intervention group, and occurrence of OM was 29% lower in the intervention group over a six-month period.¹²

The purpose of the present investigation was to assess the risk of occurrence of otitis media with pacifier use during the first year of life utilizing a longitudinal study design among a large cohort of children.

Methods

Data for this investigation were collected as part of the Iowa Fluoride Study (IFS), a study of fluoride exposures, biological and behavioral factors, and children's oral health.¹⁴⁻¹⁶ The IFS recruited a birth cohort of 1,882 mothers with newborns from 8 Iowa hospital postpartum wards over a 35-month period from March, 1992, to February, 1995, while 1,534 mothers declined to participate. The University of Iowa's Institutional Review Board approved the study and informed consent was obtained from participants at the time of recruitment. Among the 1,882 mothers agreeing to participate in the study, 507 (27%) mothers did not provide any data during the 12-month study period,

Table 1. Occurrence of Selected Independent Variables by Age

Variable	Occurrence by Age (%)				
	6 weeks (N=1,236)	3 months (N=1,196)	6 months (N=1,046)	9 months (N=934)	12 months (N=792)
Any Smoking in the Home	17%	18%	16%	16%	14%
Any Breastfeeding	46	37	27	18	12
Any Pacifier Use	78	68	56	42	39
Any Digit Sucking	48	80	73	48	31
Any Pacifier or Digit Sucking	85	90	87	71	60

so the total number of respondents for this analysis was 1,375. Questionnaires were sent to the parents (usually mothers) when children reached the ages of 6 weeks, and 3, 6, 9 and 12 months. They were asked to provide information regarding the preceding 6-week or 3-month period. Although retrospective, the use of frequent reporting intervals was designed to minimize errors in recall.

The survey instruments asked detailed questions about the infants' total fluoride consumption.^{14,17-20} The questionnaires also included items about breast- and bottle-feeding practices and non-nutritive sucking habits.¹⁵ Specifically, questions regarding non-nutritive sucking asked whether the child had any sucking habit, and if so, then asked the parent to identify objects on which the child sucked from a list which included thumb, other fingers, pacifier, toys, blanket, non-nutritive sucking of mother's breast, and "other". Parents were asked to estimate the frequency and duration of daily sucking of each object.

In addition to questions concerning sucking behaviors, parents were asked to report on the occurrence of selected illnesses for which antibiotics were prescribed during the previous 6-week or 3-month period. Parents were asked to select from a list, which included "ear infections (otitis media)," pneumonia, bladder infection, and skin infections. No effort at differentiation between acute otitis media and otitis media with effusion was made, and both were assumed to be included in the global term "otitis media." In addition, parents were asked to identify specific antibiotic medications that were prescribed and given to the child during the time period by selecting from a list of such drugs.¹⁶ Illnesses and antibiotic use were reported only by parents, without validation by physician interview or chart review. Parents also reported on tobacco use in the home and the number of days the child attended childcare outside the home (if any). The reliability of selected parent responses was assessed by posing repeat questions to a small sample (n=51) of respondents by telephone ap-

proximately one week after written questionnaires were returned. The percent agreement of responses to questions regarding sucking behavior was 86%. Responses regarding occurrence of otitis media and other diseases were not directly validated. Results from questionnaires were reviewed systematically by two or more study team members prior to data entry. All data were coded and double entered. Descriptive statistics, bivariate analyses (c²), and multivariate analyses were generated using SAS.²¹ Multivariate analyses were conducted using Generalized Estimating Equations (GEE)²² to relate occurrence of otitis media to changing patterns of the independent variables which included sucking behaviors, tobacco use in the home, days of childcare attendance during the reporting period, and baseline demographic variables. GEE is a method of regression for correlated data.²² In the present study, the data contain repeated measurements from the same individual that are correlated within individuals but treated independently across individuals. The GEE analysis included all 1,375 participants who had responded at one or more time points from ages 6 weeks to 12 months. The main dependent variable was the reported occurrence of at least one episode of OM during the first year of life. The GEE regression model tested potential risk factors and two-way interactions between them using the Wald χ^2 statistic.

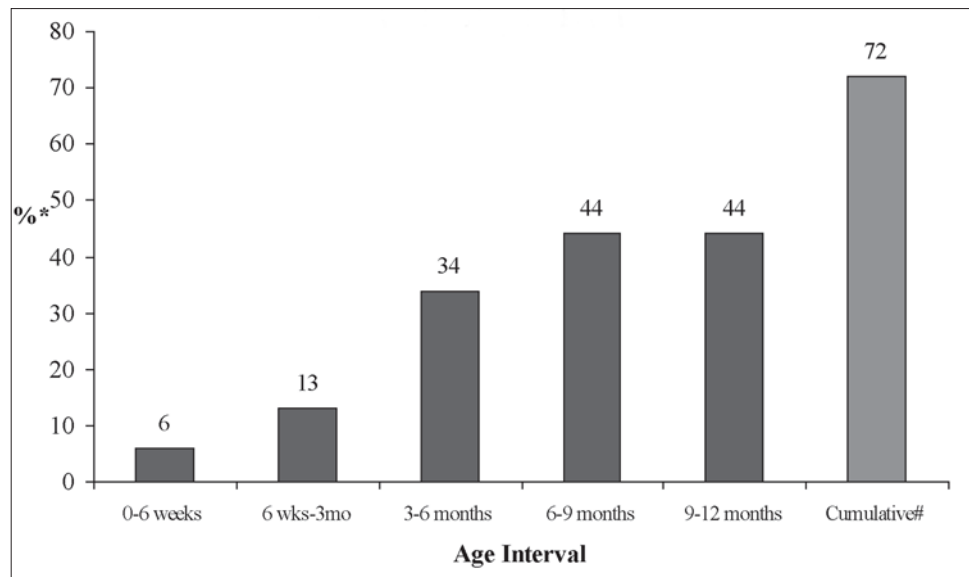


Fig 1. Reported occurrence of otitis media by age interval.

*Percentage reporting one or more episodes of otitis media during time period.

#Cumulative occurrence of otitis media among those responding at all time points (N=671).

Table 2. Reported Occurrence of Otitis Media During First Year of Life by Independent Variables

Variable	N	Otitis Media Occurrence (%)
Sex		
Male	682	57%
Female	690	53
Annual Family Income*		
< \$20,000	314	42
\$20,000 - \$40,000	472	56
> \$40,000	535	63
Mother's Education Level*		
High School or Less	418	43
Some College	442	57
College Graduate or More	511	63
Father's Education Level*		
High School or Less	423	50
Some College	340	58
College Graduate or More	464	64
Race*		
White	1305	56
Other	67	31
Childcare Attendance*		
Attended Childcare	713	64
No Childcare	659	46

* Significant differences at $P < 0.01$

Results

The sample included a near equal proportion of males (49.7%) and females (50.3%), and most (95%) children were white. The socioeconomic status of those in the study cohort was relatively high based on parental education levels, with about two-thirds of parents having attended college, and 37% of parents being college graduates. In addition, 52% of children reportedly attended some form of childcare outside the home during the first year of life. Table 1 presents independent variables related to behavior by age. Pacifier use, any breast-feeding, and any smoking in the home all generally declined with age among respondents. Digit habits were most common at 3 and 6 months of age and declined thereafter.

The occurrence of OM as reported for each time interval is presented in Fig 1. These data suggest that OM is much more common during the second six months of life than during the first six months. The overall reported occurrence of one or more episodes of OM during the first year of life among participants responding at all time points ($N = 671$) was 72%.

Table 2 presents bivariate relationships between reported occurrence of OM (cumulative) for the entire first year of life and both the baseline demographic variables and the dichotomized childcare attendance variable. These data indicate that several socioeconomic measures and childcare attendance were associated with occurrence of OM, although differences by race may not be meaningful due to the small number of non-whites in the study. As demonstrated in Table 3, pacifier sucking from 6 to 9 months ($P=0.039$) was significantly associated with OM, while pacifier sucking at 9 to 12 months approached statistical significance ($P=0.056$). No other sucking behavior/time period pair was significantly associated with OM.

As described previously, the Generalized Estimating Equation (GEE) method of longitudinal regression analysis was used as a multivariate approach to identify risk factors for OM. Using this method, the model (Table 4) identified the following significant ($P < 0.05$) risk factors for one or more episodes of OM during the first year of life: age (in months), age,² sex(male), number of childcare days during the previous time period (including full days or half days), and use of a pacifier. Other variables, including tobacco use in the home, breast-feeding and digit sucking alone (thumb or finger sucking), were not found to be related to OM occurrence in the multivariate analyses. The quadratic effect of age means that the risk for OM with increasing age was not constant during the first year of life. Instead, for each month increase in age during the first year of life the odds ratios were higher (eg, OR = 1.78 for an increase in age from 1 month to 2 months) than for monthly increases in age later during the first year of life (eg, OR = 1.15 for an increase in age from 8 months to 9 months). The odds ratio for pacifier use was 1.20 (95% CI: 1.03, 1.39) and for male sex, 1.19 (95% CI: 1.01, 1.41). As Table 4 demonstrates, there was an interaction between family income and number of childcare days.

Although childcare days varied from 0 to about 65 days per reporting period in half-day or full-day increments, Table 5 presents three examples of childcare attendance levels to demonstrate the interaction effects of childcare attendance and family income levels on OM. Specifically, Table 5 presents the odds ratios and 95% confidence intervals for OM occurrence with childcare attendance of 0, 25, and 60 days for the three income groups. As this table demonstrates, regardless of the

Table 3. Occurrence of Otitis Media by Independent Variables by Age

Variable	Occurrence of Otitis Media (%)				
	6 weeks (N=1,236)	3 months (N=1,196)	6 months (N=1,046)	9 months (N=934)	12 months (N=792)
Pacifier Use					
Yes	7%	14%	36%	48%*	48%**
No	6	12	32	42	41
Digit Sucking					
Yes	6	14	33	45	43
No	6	10	37	44	44
Pacifier or Digit Sucking					
Yes	6	14	34	46	47
No (neither)	6	8	34	40	40

* $P = 0.039$ ** $P = 0.056$

Table 4. Results of Regression Analysis Using Generalized Estimating Equations(GEE) for Predictors of Otitis Media During the First Year of Life

Variable	Parameter Estimate (S.E.)	P-value	Adjusted Odds Ratio (95% CI)
Age (months)	0.290 (0.016)	<0.001	1.34 (1.30, 1.38)
Age ²	-0.032 (0.003)	<0.001	0.97 (0.96, 0.97)
Pacifier Use (yes/no)	0.181 (0.077)	0.019	1.20 (1.03, 1.39)
Male	0.177 (0.085)	0.038	1.19 (1.01, 1.41)
Childcare Days	-0.005 (0.008)	0.510	0.99 (0.98, 1.01)
Income Category	0.034 (0.068)	0.620	1.03 (0.91, 1.18)
Childcare * Income	0.009 (0.003)	0.009	1.01 (1.01, 1.02)

income level, an increase in childcare days resulted in an increased odds ratio of OM; however, this increase is not constant across income levels (as indicated by a significant interaction term).

Discussion

The study found that use of a pacifier was a risk factor for the occurrence of otitis media during the first year of life, while controlling for other factors. This finding was consistent with previous studies in Finland and the United States.⁹⁻¹² In addition, age, male sex, and childcare attendance/ family income were also significant risk factors for the occurrence of OM. As described previously, the interaction of the family income and childcare attendance variables means that with increasing level of family income, there was an increase in the effect of the number of days of childcare attendance on OM occurrence.

While it appears, based on the present study and other recent studies, that pacifier use is associated with increased risk for OM, the mechanism by which pacifiers may contribute to otitis media is unknown. The authors of previous studies have speculated that the most important mechanism may be that non-nutritive sucking alters the normal function of the Eustachian tubes, resulting in a reflux of organisms from the nasopharynx to the middle ear.⁹⁻¹² However, the present study, along with previous studies,^{9,11} found that digit sucking alone was not associated with increased occurrence of OM, suggesting that the physical sucking of an object may not explain the relationship between pacifier use and OM. Clearly, more research is needed to establish a mechanism to explain the association between pacifier use and OM.

In addition to the present study's findings concerning pacifier use, other risk factors identified were also generally consistent with previous studies.^{3,5-7,23-27} For example, the findings of overall high OM prevalence during the first year of life, and higher occurrence of OM during the second six months

of life are consistent with two large studies of OM in the Boston³ and Pittsburgh⁵ areas, which used otoscopic and tympanometric assessments. The study of OM in the Boston area, which was conducted beginning in 1975,³ found first year of life prevalence for acute OM to be 62%, with much higher prevalence during the second six months of life. The more recent study of OM in the Pittsburgh area found first year of life prevalence of OM to be 79%, and also demonstrated a general trend toward highest prevalence of OM between 6 and 11 months of age.⁵

While the present study confirms the findings of previous studies regarding the association between pacifier use and OM, and generally agrees with other studies regarding OM occurrence and its risk factors, the study had several limitations. First, the self-reported data upon which this study was based cannot be expected to be as accurate or definitive as physician-based diagnosis and classification of OM. In addition, the estimated overall first year of life occurrence of OM (72%) includes only those subjects with responses at each time period. Since not all subjects responded at all time points, the occurrence of OM among all subjects may have been higher or lower than found for those reporting at all time points.

Moreover, the present study may underestimate its true prevalence for several reasons. In the present study, only OM cases where antibiotics were prescribed were reported; OM was reported only when treatment was sought, so that some cases of OM may have occurred but went undiagnosed, (which may explain why OM was more prevalent among higher income families who may be more likely to seek care); the present study utilized parents' reports of illness, so that diagnoses of OM were not standardized, and there was undoubtedly some misclassification of disease occurrence on an individual basis. A further limitation was that the primary focus of the study was to assess fluoride intake patterns and oral health on a large cohort of children, so that it was not feasible to contact individual physicians or conduct chart reviews. Lastly, in some instances, it is possible that some cases of OM occurred before exposure to pacifier within a specific time period. However, given that pacifier use was nearly universal and OM occurrence relatively rare during the first two reporting periods, in most cases, at least some exposure to pacifier occurred prior to OM occurrence.

Despite the limitations of the study, we did find significant associations between the use of pacifiers and the occurrence of OM. While our odds ratios suggest that the risk of OM from pacifier use is relatively small, our findings—coupled with the findings of the Finnish studies,^{17,18} along with the U.S. study by Jackson and Mourino¹¹—suggest that pacifier use is an important risk factor for OM both for those attending and not attending childcare. Based solely on the odds ratios and the reported relative risk in this and other studies (2.1, 1.4 and 1.6),⁹⁻¹¹ it may be difficult to justify any general recommendation to eliminate pacifier use during the first year of life due to increased risk of OM. However, the magnitude of the OM problem in terms of prevalence, treatment costs, and so

Table 5. Adjusted Odds Ratios and 95% Confidence Intervals for Occurrence of Otitis Media and Specific Childcare / Annual Income Categories

Childcare \ Income	<\$20,000	\$20,000 – \$39,999	\$40,000+
0 Days	1.00*	1.03 (0.91, 1.18)	1.07 (0.82, 1.40)
25 Days	1.13 (0.83, 1.55)	1.46 (1.09, 1.97)	1.89 (1.33, 2.68)
60 Days	1.28 (0.68, 2.43)	2.26 (1.49, 3.44)	3.98 (2.58, 6.15)

*Reference cell

forth, suggests that even modest reductions in OM prevalence brought about by restricting pacifier use may be warranted, particularly since other risk factors such as age, sex, and socioeconomic status cannot be readily modified. Clearly, more study is needed to further characterize the relationship between the use of pacifiers and the occurrence of OM, including investigation of the specific mechanism of how pacifiers may facilitate pathogenesis of infectious organisms, and ways that pacifier use may be modified to reduce the risk of OM.

Conclusions

Although the adjusted odds ratios were relatively modest, multivariate analyses found that the occurrence of otitis media was significantly associated with pacifier use.

This study was supported by NIH grants R01-DE09551 and P30-DE10126.

References

- Schappert SM. Office visits for otitis media: United States, 1975-1990. Advance data from vital and health statistics of the Centers for Disease Control/National Center for Health Statistics. Washington, DC: U.S. Department of Health and Human Services, 1992 (Pub. No. 214).
- Schappert SM. National ambulatory medical care survey: 1994 summary. Advance data from vital and health statistics of the Centers for Disease Control and Prevention/National Center for Health Statistics. Washington, DC: U.S. Department of Health and Human Services, 1996 (Pub. No. 273).
- Klein JO, Teele DW, Pelton SI. New concepts in otitis media: results of investigations of the greater Boston otitis media study group. *Adv Pediatr* 39:127-156, 1992.
- Stangerup SE, Tos M. Epidemiology of acute suppurative otitis media. *Am J Otolaryngol* 7:47-54, 1986.
- Paradise JL, Rockette HE, Colborn DK, et al. Otitis media in 2253 Pittsburgh-area infants: Prevalence and risk factors during the first two years of life. *Pediatrics* 99:315-333, 1997.
- Sipila M, Pukander J, Karma P. Incidence of acute otitis media up to the age of 1 _ years in urban infants. *Acta Otolaryngol* 104:138-145, 1987.
- Daly KA. Epidemiology of otitis media. *Otolaryn Clin N Amer* 24:775-786, 1991.
- Yawn BP, Yawn RA, Lydick E. The relative community burden of otitis media and varicella. *Clin Ther* 18:877-886, 1996.
- Niemela M, Uhari M, Mottonen M. A pacifier increases the risk of recurrent acute otitis media in children in day care centers. *Pediatrics* 96:884-888, 1995.
- Niemela M, Uhari M, Hannuksela A. Pacifiers and dental structure as risk factors for otitis media. *Int J Pediatr Otorhinolaryngol* 29:121-127, 1994.
- Jackson JM, Mourino AP. Pacifier use and otitis media in infants twelve months of age or younger. *Pediatr Dent* 21:255-260, 1999.
- Niemela M, Pihakari O, Pokka T, Uhari M, Uhari M. Pacifier as a risk factor for acute otitis media: a randomized, controlled trial of parental counseling. *Pediatrics* 106:483-488, 2000.
- Larsson E. Dummy- and finger-sucking habits in 4-year-olds. *Swed Dent J* 68:219-224, 1975.
- Levy SM, Kiritsy MC, Slager SL, Warren JJ, Kohout FJ. Patterns of fluoride dentifrice use among infants. *Pediatr Dent* 19:50-54, 1997.
- Warren JJ, Levy SM, Nowak AJ, Tang S. Non-nutritive sucking behaviors in pre-school children: A longitudinal study. *Pediatr Dent* 22:187-190, 2000.
- Bergus GR, Levy BT, Levy SM, Slager SL, Kiritsy MC. A longitudinal study of the exposure of infants to antibiotics during the first 200 days of life. *Arch Fam Med* 5:523-526, 1996.
- Van Winkle S, Levy SM, Kiritsy MC, Heilman JR, Wefel JS, Marshall T. Water and formula fluoride concentrations: significance for infants fed formula. *Pediatr Dent* 17:305-310, 1995.
- Levy SM, Kohout FJ, Guha-Chowdhury N, Kiritsy MC, Heilman JR, Wefel JS. Infants' fluoride intake from drinking water alone, and from water added to formula, beverages, and food. *J Dent Res* 74:1399-1407, 1995.
- Levy SM, Kohout FJ, Kiritsy MC, Heilman JR, Wefel JS. Infants' fluoride ingestion from water, supplements, and dentifrice. *JADA* 126:1625-1632, 1995.
- Kiritsy MC, Levy SM, Warren JJ, Guha-Chowdhury N, Heilman JR, Marshall T. Fluoride levels of juices and juice drinks. *JADA* 127:895-902, 1996.
- SAS User's Guide. Statistics, version 6. Cary, NC: SAS Institute Inc., 1988.
- Liang KY, Zeger SL. Longitudinal data analysis for discrete and continuous outcomes. *Biometrics* 42:121-30, 1986.
- Hardy AM, Fowler MG. Child care arrangements and repeated ear infections in young children. *Am J Public Health* 83:1321-1325, 1993.
- Alho OP, Laara E, Oja H. Public health impact of various risk factors for acute otitis media in northern Finland. *Am J Epidemiol* 143:1149-1156, 1996.
- Louhiala PJ, Jaakkola N, Routsalainen R, Jaakkola JJ. Form of day care and respiratory infections among Finnish children. *Am J Public Health* 85:1109-1112, 1995.
- Owen MJ, Baldwin CD, Swank PR, Pannu AK, Johnson DL, Howie VM. Relation of infant feeding practices, cigarette smoke exposure, and group child care to the onset and duration of otitis media with effusion in the first two years of life. *J Pediatr* 123:702-711, 1993.
- Kero P, Piekkala P. Factors affecting the occurrence of acute otitis media during the first year of life. *Acta Paediatr Scand* 76:618-623, 1987.