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Early Otitis Media Among Minnesota American Indians: The Little Ears Study

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Abstract

Objectives—We examined relationships between otitis media risk factors, sociodemographic characteristics, and maternal knowledge and attitudes and early onset of otitis media.

Methods—Pregnant women from Minnesota American Indian reservations and an urban clinic were enrolled in our study between 1998 and 2001. Follow-up was performed on enrollees′ infants until the children were aged 2 years. Research nurses collected data by ear examination, from interviews and questionnaires given to enrolled mothers, and otitis media episodes that were abstracted from medical records.

Results—Sixty-three percent of infants had experienced an otitis media episode by 6 months of age. Logistic regression analyses showed that maternal otitis media history, infant history of upper respiratory infection, and compliance with study visits were significantly related to early otitis media onset. Although high percentages of infants were exposed to cigarette smoke and other children and were formula fed, these factors were not related to otitis media. Mothers′ prenatal awareness of otitis media risks associated with environmental tobacco smoke exposure and formula feeding did not predict their postpartum behaviors.

Conclusions—We found that infant history of upper respiratory infection and maternal otitis media history are risk factors for early otitis media in American Indian infants. Mothers′ prepartum knowledge and attitudes regarding otitis media did not predict their postpartum avoidance of risk behaviors.

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Contributors

K. A. Daly originated and supervised the study, participated in developing the algorithm to diagnose otitis media, and wrote the article. P. L. Pirie trained research nurses in interview techniques, designed many of the questions, and reviewed and commented on the article. K. L. Rhodes coordinated the study and reviewed and commented on the article. L. L. Hunter trained the research nurses in tympanometry and hearing screenings, oversaw the interpretation of these tests, and participated in developing the algorithm to diagnose otitis media. C. S. Davey performed the analysis, participated in developing the algorithm to diagnose otitis media, and reviewed and commented on the article.

Human Participant Protection

This study was approved by the institutional review boards of the University of Minnesota and the Indian Health Service. A certificate of confidentiality was also obtained from the National Institutes of Health to protect the confidentiality of sensitive data collected as part of the study. Women or their legal guardians provided written informed consent.

Otitis media (OM) affects nearly all preschool children, and onset in the first few months of life predicts later chronic and recurrent OM.[1-4] Data from the Indian Health Service (IHS) and the National Center for Health Statistics revealed that, during the 1990s, OM-associated outpatient visit and hospitalization rates among American Indian and Alaska Native children aged younger than 5 years were 2.3- and 2.9-times higher, respectively, than among US children in the same age group.[5] Also in the 1990s, Northern Plains American Indians, including residents of the Bemidji Area IHS in Minnesota, had the second highest rates of IHS outpatient visits and hospitalizations for OM.[5]

Although OM rates are higher among American Indians/Alaska Natives than among other groups, little is known about specific factors that could affect their OM risk. Potentially modifiable risk factors for early OM identified in other populations include upper respiratory infections (URIs),[6,7] early colonization with OM pathogens,[8] day care attendance or sibling day care attendance,[2,7,9] short breast-feeding duration,[6,10] prone sleeping,[11] and heavy maternal smoking.[12] Family history is also an important risk factor,[1,7,13] one that may be attributed to shared environmental or genetic factors. A substantial heritable component has been demonstrated in twin studies,[14-16] and evidence for links between chronic and recurrent OM and regions on chromosomes 10q and 19q was recently demonstrated in a group of Minnesota families.[17]

Racial and ethnic differences in OM incidence may arise from disparities in socioeconomic status, access to and use of health care, and variations in the prevalence of environmental and genetic risk factors. For example, in a study of Black and White children, Paradise et al. showed that race was no longer predictive of time with middle ear effusion after control for socioeconomic status.[18] The aim of the Little Ears Study, described here, was to investigate OM epidemiology in American Indian children from birth to age 2 years, including OM incidence in the first 6 months of life (hereafter, “early OM”), as well as relationships between early OM onset and sociodemographic characteristics, OM risk factors, and maternal knowledge and attitudes.

METHODS

Enrollment and Data Collection

Participants were recruited from 3 Ojibwe reservations and an urban clinic in Minnesota. The process of gaining community support for the study involved several meetings with tribal health directors, IHS medical and service unit directors, and the medical director of the urban clinic. The grant proposal was reviewed and discussed with each health director and approved through a tribal resolution before submission. Approval was also obtained from the medical director and board of directors of the urban clinic. Health directors appointed advisory committee representatives who provided guidance in developing culturally appropriate recruitment methods, materials, and data forms; offered insights about recruitment and retention; and were given updates on the study’s progress.

Research nurses were trained in human participant protection, recruitment and enrollment, the informed consent process, interviewing techniques, completion of study forms, ear examinations and OM diagnoses, tympanometry, and distortion product otoacoustic emission screening for hearing loss. They recruited eligible pregnant women between June 1998 and April 2001 (women were eligible if they were aged 16 years or older, identified themselves or the infant’s father as American Indian, were willing to provide interview information during and after their pregnancy, and were available for follow-up). Interested, eligible women (or, if they were aged younger than 18 years, their parent) provided written consent before being

enrolled into the study. Infants with a craniofacial anomaly that increased their likelihood of experiencing OM episodes (Down syndrome, cleft palate, microencephaly) were excluded.

The study visit schedule included ear examinations and tympanograms at 2 weeks; 2, 4, and 6 months; and then every 3 months until the age of 2 years. Hearing screenings were performed at least 4 times during follow-up. Compliance with study criteria was defined as mothers and infants completing 2 or more study visits by the age of 6 months. Research nurses conducted interviews (prepartum and 2 weeks and 6 months postpartum) designed to gather information on sociodemographic characteristics, OM risk factors, and mothers' attitudes and knowledge regarding OM. At each study visit, research nurses inquired about illnesses experienced by infants since the previous study examination. Participants completed a questionnaire on prepartum alcohol and marijuana use and sent it to the study center in a stamped, addressed envelope.

Study visit OM diagnoses were based on an algorithm that combined results from ear examinations, tympanograms, and hearing screenings. Ear examination findings were classified as abnormal if they showed middle ear effusion or otorrhea or 2 or more abnormalities of the tympanic membrane (i.e., color, position, mobility, or appearance). If static admittance was less than 0.2 mmho (unit for Volume/Pressure; 1 mho=1000cc or 1L) or tympanometric width was more than 300 daPa (dekaPascals), the tympanogram was considered abnormal.

Infants were classified as having failed a hearing screening if they failed 2 or more of 5 frequency tests in the same ear. Most diagnoses were based on concordance of 2 or more of the tests conducted. OM diagnoses made by the child's health care provider were abstracted from medical records obtained via parental release. Clinic ear examinations accounted for 51% of OM diagnoses, and study visit examinations accounted for 49%. An episode was considered new if it had occurred at least 21 days after the preceding OM diagnosis or after a normal ear examination.

Statistical Analysis

We summarized distributions using frequency tables for categorical variables and means and standard deviations for quantitative variables. We used χ^2 and *t* tests to evaluate relationships between early OM onset and sociodemographic variables, OM risk factors, and maternal attitudes and knowledge. Characteristics of study dropouts were also explored. Variables with a significant or marginally significant relationship with early OM (at $P<.1$) were included in logistic regression models along with terms for 2-way interactions. Interaction terms that were not significant were removed from the regression models in order of decreasing significance until only main effects and significant interactions remained.

RESULTS

Enrollment

Of those contacted, 408 eligible women agreed to take part in the study (about 20% of contacts) and gave birth to 408 infants (including 4 fetal deaths and 4 sets of twins). Fifteen women also enrolled during a subsequent pregnancy, but we included only the first pregnancy or a single twin in our analyses. One infant was ineligible because of cleft palate, and one twin died during the neonatal period, leaving 406 infants. Data from 383 prepartum interviews and 373 self-completed questionnaires were collected; 344 infants underwent ear examinations, and 2-week risk factor data were available for 330 (96%) of these infants.

Women's average age at delivery was 24.1 years (SD=5.6). Most of the women were Ojibwe (Table 1), the most populous Minnesota tribe (Ojibwe is the sixth most commonly reported tribal affiliation in the United States[19]). Known OM risk factors were common in the sample

(Table 2), and women who smoked reported an average of 7.2 cigarettes per day (SD=4.6). Those who completed only the prepartum interview were similar in terms of age, marital status, and employment status to those who completed both the prepartum and 2-week interviews but were more likely to be urban residents (54% vs 24%; *P*<.01) and smokers (57% vs 43%; *P*=.06).

Risk Factors and OM Onset by 6 Months of Age

Among the 344 infants with ear examination findings for the first 6 months of life, 215 (63%) had experienced at least 1 OM episode, and 116 (34%) had experienced 2 or more episodes. OM onset occurred before age 2 months among 25% of infants, between ages 2 and 4 months among 40%, and between ages 4 and 6 months among 35%. The average number of visits (study combined with clinic) in the first 6 months was 7.2 (SD=4.6).

Univariate relationships between risk factors and early OM are shown in Table 3. Mothers and infants who had completed 2 or more study visits by the age of 6 months (i.e., who complied with the study criteria) were also more likely to have completed more than 3 clinic visits by the age of 6 months than were mothers and infants without at least 2 visits (64% vs 47%; *P*<.01). Compliance with study visits was not associated with OM-related variables in the univariate analyses. However, after stratification according to study visit compliance, infant history of URI was significantly related to OM among infants with noncompliant mothers but not among infants with compliant mothers (*P*s<.01 and .99, respectively).

The interaction between compliance and URI history was significant (*P*=.01). Including this interaction term in the logistic regression model resulted in nearly identical study compliance odds ratios (ORs) of 5.47 and 5.45 in the presence and absence of a history of URI, respectively (Table 4). This finding illustrates that URI history conferred no additional OMrisk among infants whose mothers had complied with the study visit criteria. The odds ratio for occurrence of a URI before occurrence of first OM among infants whose mothers did not complete the required number of visits was 4.32. The only other significant risk factor in the model was maternal history of chronic or recurrent OM (OR=1.77).

Relationships Between Attitudes and Behaviors

Prepartum interview responses showed that more than 90% of women knew the signs and symptoms of OM, and 73% believed that “smoking cigarettes around children increases their chances of getting ear infections.” However, only 15% and 24% of women associated formula feeding and day care, respectively, with increased OM risk, and 46% believed that ear infections were a normal part of life for children. Only 7% agreed that OM was nothing to worry about; these women and their infants attended fewer study visits than did women who did not have this belief (*P*=.04). Although 90% of women agreed that there were steps one could take to prevent OM, this attitude did not affect breast-feeding or smoking behaviors as reported at the 2-week interview (*P*=.86 and 0.98, respectively). Similarly, 80% agreed that cigarette smoke exposure increased an infant’s chances of experiencing OM episodes, but this belief did not influence smoking behaviors according to 2-week-interview responses (*P*=.27).

DISCUSSION

Our data illustrate that OM incidence in infants at or before the age of 6 months was higher in the Little Ears cohort than in a predominantly White cohort followed in the Minnesota Twin Cities area in the mid-1990s (63% vs 48%).[7] Diagnostic criteria for OM and mean number of study or clinic visits by the age of 6 months were similar in Little Ears and an earlier cohort[7] (7 and 6 visits, respectively).

We investigated compliance with study visits because of the obvious dependence of OM diagnoses on completion of ear examinations. Women and infants who complied with the study visit criteria completed more clinic visits as well, increasing the likelihood of OM being diagnosed. The difference in OM rates between infants whose mothers were compliant and those whose mothers were noncompliant suggests that OM may actually have been underdiagnosed in the study population. Study visit compliance was not a risk factor for OM but was related to likelihood of OM detection. Infants whose mothers were noncompliant may have been as likely as infants whose mothers were compliant to experience an OM episode but less likely to have it detected because they underwent fewer examinations.

Regular ear examinations would allow detection of asymptomatic episodes of OM, which occur frequently in the first year of life.[4] Prospective studies involving more frequent examinations have reported higher OM rates than have studies involving fewer examinations,[1,2,20] and 1 study reported that rates of acute OM were higher among American Indian children living within 5 miles (8 km) of an IHS health facility than among those living farther away, suggesting that access to care increases OM ascertainment.[21]

Maternal OM history was significantly related to early OM in this study and in an earlier study.[7] This relationship suggests a possible role for genetic factors in early OM or greater awareness of OM leading to increased care seeking and more frequent diagnoses (i.e., detection bias). A study conducted on an Apache reservation reported a significantly greater-than-expected concordance of tympanic membrane scarring in first-degree relative pairs, a finding consistent with a genetic hypothesis.[22]

We did not find that compliance with study visits was related to maternal OM history. However, infant OM would be diagnosed more frequently if mothers with a history were more likely to seek medical care for a symptomatic child. Reported maternal OM history was not validated against medical records, but women were queried about their own history of chronic and recurrent OM. In a study of college students, κ agreement values between self-report and medical record data were 0.53 for number of physician visits related to ear problems and 0.78 for tympanostomy tube placement.[23]

Previous studies have shown that URIs increase OM risk.[6,7] The interaction between URI and study visit compliance observed here suggests that OM was diagnosed independent of previous URIs among infants with more clinic visits. OM episodes not associated with previous URIs may have been milder and therefore not brought to the attention of physicians by noncompliant mothers. Mild episodes would have been more likely to be detected in compliant families who used health services more frequently. Viral respiratory infections promote the development of OM by releasing inflammatory mediators, increasing nasopharyngeal colonization, and suppressing immune defenses; exposure to other children increases the likelihood of colonization and infection with the viruses associated with OM.[8,24]

Although often observed and potentially modifiable OM risk factors such as short breast-feeding duration and exposure to cigarette smoke were common in this study, they did not influence early OM incidence. The reason that there was not a significant relationship between OM and smoke exposure may have been the relatively small number of cigarettes per day smoked by study mothers or the lack of a truly unexposed group, given that infant exposure to environmental tobacco smoke was common.

Some studies have shown that longer breast-feeding durations and exclusive breastfeeding decrease OM risk,[10,25,26] but others have shown that short breast-feeding duration has no effect on OM in early life.[27] Early OM rates were similar among infants with and without these 2 are protective factors and 1 is a risk factor, so inadequate power is an unlikely explanation for the lack of association between these factors and early OM. However, if infants

of women who smoked and did not breast-feed had fewer clinic visits, OM may have been underascertained, resulting in a lack of association between these risk factors and early OM.

Women's levels of knowledge about modifiable OM risk factors varied. Their prenatal belief that steps could be taken to prevent infant OM did not predict their postnatal breastfeeding and smoking behaviors. Lawlor et al. suggested that members of disadvantaged groups consider smoking to be an acceptable risk because they are more concerned about addressing immediate dangers (poor housing conditions, environmental and occupational hazards) they view as more proximate threats than smoking.[28] Discrepancies between knowledge about healthy behaviors and actual healthy behaviors has long been acknowledged by health educators and has given rise to the concept that knowledge alone is not sufficient for behavior change. Strategies intended to change health behaviors must incorporate intrapersonal, interpersonal, institutional, community, and policy factors.[29]

Data collected prospectively in 2 Minnesota studies involving similar methods revealed higher OM rates in Little Ears than in a sample derived from a health maintenance organization.[7] The present findings are also consistent with higher rates of OM-associated outpatient visits and hospitalizations reported among American Indian/Alaska Native children than among other US children.[5]

The majority of OM studies involving American Indian samples has been conducted in Navajo and Apache communities. To our knowledge, this is the first study of OM in a predominantly Ojibwe sample, and our findings may not be generalizable to other tribes.

In addition, women who took part in the Little Ears Study may not have been representative of all eligible women at the study sites. Nevertheless, results from Little Ears are similar to data reported by the Minnesota Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) and the Bemidji Area IHS on Minnesota rates of breast-feeding and smoking during pregnancy.[30,31] Breast-feeding initiation rates among mothers served by WIC in Minnesota were 60% to 68% between 1998 and 2001, as compared with 58% among participants in Little Ears.[30] In the Bemidji IHS service area, 41% of women smoked during pregnancy during 1996 through 1998, in comparison with 45% in the Little Ears Study.[31]

Participants lost to follow-up were more likely to be smokers and to be urban residents. Because OM rates did not vary according to level of environmental tobacco smoke exposure, the overrepresentation of smokers in the group lost to follow-up should not have affected rates of early OM.

In conclusion, OM onset occurred before 6 months of age in nearly two thirds of infants in the Little Ears cohort, but OM may actually have been underdiagnosed in this study, particularly among infants whose mothers did not comply with study visit criteria. URI was the only potentially modifiable risk factor identified. The significant relationship observed between maternal OM history and infant OM may have been due to genetic predisposition or to increased likelihood of detection resulting from maternal awareness of OM and its symptoms.

Although smoke exposure and short duration of breast-feeding were not related to early OM in this study, they have been reported as OM risk factors in other epidemiological studies. Women's prenatal knowledge and attitudes regarding OM risk were not concordant with their postnatal behaviors. Interventions designed to reduce OM risk factors should focus on barriers to change as well as community, cultural, and policy influences (e.g., health insurance coverage providing regular access to preventive and health care visits).

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TABLE 1

Demographic and Risk Factor Data Collected During Prepartum Interview, by Parent: Little Ears Study, Minnesota, 1997-2003

	Maternal Parent, No. (%)	Paternal Parent,[a] No. (%)
Education		
More than high school	110 (30)	56 (25)
High school or less	258 (70)	168 (75)
Employment status		
Work, school, or both	198 (54)	174 (76)
Neither	170 (46)	54 (24)
Race/tribe		
American Indian	355 (96)	267 (81)
Ojibwe	312 (87)	241 (73)
More than 1 race	30 (8)	27 (8)
Marital status		
Married/living together	229 (62)	...
Other	139 (38)	...
Alcohol use status		
Use in early pregnancy	195 (52)	...
Use in final trimester	50 (14)	...

Note. Of the 383 interviews, 15 were excluded because responses appeared to be unreliable (e.g., all true/false questions answered true).

[a] Paternal data were reported by participants.

TABLE 2

Demographic and Risk Factor Data for Infants, Collected at Age of 2 Weeks: Little Ears Study, Minnesota, 1997-2003

	Infants, No. (%)
Gender	
Male	174 (53)
Female	157 (47)
Race	
American Indian[a]	328 (99)
More than 1 race	82 (25)
WIC participant	
Yes	321 (97)
No	10 (3)
Breast-feeding	
Birth	193 (58)
2 weeks	126 (38)
Regular exposure to children[b]	
Any exposure	287 (87)
Exposure to more than 2 children	181 (55)
Living arrangements	
2 or more adults	299 (91)
More than 2 other children	87 (26)
Sleeping arrangements	
1 or more adults in same room	318 (99)
1 or more children in same room	98 (31)
Smoke exposure	
Smoker in household[c]	266 (80)
Mother smokes	174 (53)
Otitis media history	
Mother	97 (30)
Father[d]	33 (11)
Full or half sibling[e]	122 (57)

Note. WIC = Special Supplemental Nutrition Program for Women, Infants, and Children.

[a] 3 infants had 1 White and 1 American Indian parent; mother described child's race as White.

[b] Home, day care, regular visitors, or regular visits to other homes.

[c] Parent or other adult smoker in the home.

[d] 39% answered "don't know."

[e] If history was known.

TABLE 3

Percentage of Early Otitis Media (OM) in Infants, by Maternal and Infant Sociodemographic Characteristics and Risk Variables: Little Ears Study, Minnesota, 1997-2003

	No. of Infants (% With Early OM)	*P*
Maternal characteristics/beliefs		
Education		.99
More than high school	62 (63)	
High school or less	143 (63)	
Employment status		.93
Work, school, or both	93 (62)	
Neither	112 (63)	
Marital status		.72
Married/living with partner	127 (62)	
Other	78 (64)	
Age at delivery, y		.71
<19	35 (60)	
≥19	180 (63)	
Alcohol use in early pregnancy		.38
Yes	110 (65)	
No	93 (60)	
OM nothing to worry about		.01
True	10 (40)	
False/don't know	195 (65)	
OM gets better by itself		.01
True	11 (41)	
False/don't know	194 (65)	
I can take steps to prevent OM		.54
Disagree/don't know	21 (68)	
Agree	184 (62)	
Infant characteristics		
Gender		.56
Male	104 (61)	
Female	96 (64)	
Breast-feeding at 2 weeks		.81
No	123 (62)	
Yes	77(63)	
Regular exposure to children		.07
Exposure to more than 2 children	117 (67)	
Exposure to 0-2 children	83 (57)	
OM preceded by upper respiratory infection		.02
Yes	108 (69)	
No	107 (57)	
Mother smokes		.50
Yes	103 (61)	
No	97 (64)	
Any smoker in household		.69
Yes	160 (62)	
No	40 (65)	
Maternal OM history		.04
Yes	66 (69)	
No	104 (56)	
Paternal OM history		.06
Yes	26 (81)	
No	88 (59)	
Don't know	72 (61)	
Full or half sibling OM history		.14
Yes	82 (69)	
No	37 (60)	
Don't know	15 (52)	
Study visit compliance		<.001
2 or more visits	167 (70)	
Less than 2 visits	48 (45)	

TABLE 4

Results of Logistic Regression Analyses Assessing Early Otitis Media (OM) Onset: Little Ears Study, Minnesota, 1997-2003

	Odds Ratio (95% Confidence Interval)
Maternal OM history	1.77 (1.02, 3.08)
Compliance with number of study visits and URI before first OM[a]	5.47 (2.66, 11.26)
Compliance with number of study visits and no URI before first OM[a]	5.45 (2.62, 11.36)
Noncompliance with number of study visits and URI before first OM[a]	4.32 (1.62, 11.56)

Note. URI = upper respiratory infection.

[a]Reference category: noncompliance with number of study visits and no URI before first OM.