

# What Is the Natural History of Recurrent Acute Otitis Media in Infancy?

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**BACKGROUND.** Chemoprophylaxis or tympanostomy tubes are often recommended for recurrent acute otitis media because of the associated morbidity, temporary hearing loss, financial costs, and risks of middle-ear sequelae. The aim of this study was to study the natural course of recurrent acute otitis media in infancy without such prophylactic treatment.

**METHODS.** Two hundred twenty-two children who had recurrent acute otitis media and received no prophylaxis were monitored for subsequent acute otitis media and the development of chronic otitis media with effusion.

**RESULTS.** Only 4% of the 222 infants with recurrent acute otitis media developed chronic otitis media with effusion and an additional 12% continued having recurrent episodes. The most significant factor predicting an increased risk of recurrence was young age (<16 months of age). Attending day care and having siblings had a less pronounced effect.

**CONCLUSIONS.** Spontaneous recovery from recurrent acute otitis media is common with increasing age. Thus, until reliable causal evidence between recurrent otitis media and developmental disability is presented, chemoprophylaxis or tympanostomy tubes seem superfluous for most infants after the age of 16 months.

**KEY WORDS.** Otitis media with effusion; prophylaxis; otitis media; infant; child; recurrent otitis media. (*J Fam Pract* 1996; 43:258-264)

Children suffering from recurrent acute otitis media are familiar to general practitioners, pediatricians, and otolaryngologists. Special prophylaxis, primarily chemoprophylaxis or tympanostomy tubes, is recommended for recurrent acute otitis media because of the associated morbidity, temporary hearing loss, financial costs, and risks of middle-ear sequelae, primarily chronic otitis media with effusion.<sup>1-5</sup> All of these are short-term indications, as no causal link has yet been found between middle-ear effusion and severe developmental disability.<sup>6-9</sup> Moreover, even if a causal link exists, little is known about whether it can be influenced by prophylactic measures.<sup>10</sup>

Only a small proportion of children with recurrent acute otitis media in northern Finland received special prophylaxis at the time when the

present data were acquired.<sup>11</sup> The aim of this study was to investigate more closely the natural course of the condition in infants who fulfilled the criterion for recurrent acute otitis media but did not receive special prophylaxis.

## METHODS

All pregnant women in the two northernmost provinces of Finland whose estimated date of delivery was between July 1, 1985, and June 30, 1986, were enrolled in a research project that concerned both the fetal period and the later development and morbidity of the newborn.<sup>12</sup> Altogether, 9478 children were born to these women (99% of whom were born in the designated time frame). A sample of 2512 children from 10 local government districts was drawn by a two-stage random cluster method from this birth cohort to form a study population for a special investigation into the epidemiological aspects of acute otitis media.<sup>11</sup>

Under the pediatric health care system in Finland, all the children were expected to attend their local health center for regular examinations, performed free of charge, at 3, 6, 12, 18, and 24

Submitted, revised, June 6, 1996.

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months of age, at which time their ears and hearing would be checked. At each illness-related visit to a health center, hospital, or private practitioner, the ears were routinely examined by pneumatic otoscopy, and myringotomy was often performed to relieve symptoms. The universal practice was to prescribe a 10-day course of antibiotics for acute otitis media and to arrange standard checkup visits at 2- to 3-week intervals until the ears were deemed to have healed.

The first author retrospectively collected data on infections and treatment for 2512 infants by means of reviewing all possible medical records of 1987 and 1988 in the sample area, including 10 primary health care centers, three central hospitals, one university hospital, and three private practices. An observation time for each child was calculated by subtracting the date of birth from either the date of moving away from the area or the time of data collection, whichever occurred earlier. The mean observation time was 22 months (range, 0 to 36 months).

#### DEFINITION OF THE VARIOUS FORMS OF OTITIS MEDIA

We classified a child as representing a case of recurrent acute otitis media if at any time during the observation period he or she fulfilled the most commonly used criterion: three acute episodes diagnosed in primary care during the previous 6 months or four episodes in a period of 1 year.<sup>2</sup> The diagnosis of acute otitis media required both acute symptoms and pneumo-otoscopic signs suggestive of inflammation of the tympanic membrane, ie, distinct redness and outward bulging or reduced mobility.

Children with the following findings were designated as having chronic otitis media with effusion: asymptomatic middle-ear effusion behind an intact tympanic membrane of at least 2 months' duration, either prevailing after an acute episode or found at a regular checkup together with specific otomicroscopic findings in the operating room (thick tympanic membrane and middle-ear mucosa or mucous middle-ear effusion). Middle-ear effusion was diagnosed in primary care if pneumatic otoscopic examination revealed an opaque, creamy or yellow retracted or concave tympanic membrane in which mobility was impaired. In 90% of cases, this finding was confirmed by myringotomy.

When the children in the sample were 2 years

old, the parents were sent a self-administered questionnaire concerning various background factors.<sup>11</sup> The response rate for this survey was 87%. The questionnaire items used in this study included (1) atopic manifestations (atopic dermatitis, food allergy, asthma, allergic rhinitis, wheezy bronchitis), (2) type of day care during each month of the observation period (home, family day care, day nursery), (3) smoking habits of both parents (number of cigarettes per day and whether smoking took place inside the home or out of doors), and (4) number of siblings.

The cumulative incidence of chronic otitis media with effusion and the number of acute otitis media episodes and the incidence rate (per child year) for those who did not have chronic otitis media with effusion were calculated during the 6 months subsequent to meeting the criterion for recurrent acute otitis media. The calculations were performed both overall and in various categories of the risk factor values at the time of fulfillment of the criterion. In addition, the observation times for all infants who had a follow-up time of at least 24 months were divided into four 6-months age groups (1 to 6, 7 to 12, 13 to 18, and 19 to 24 months) and the incidence of chronic otitis media with effusion and numbers of new episodes in successive periods were calculated and cross-tabulated by period.

The research protocol was accepted by the Ministry of Health and Social Welfare and the Ethical Committee of the Faculty of Medicine, University of Oulu, Finland.

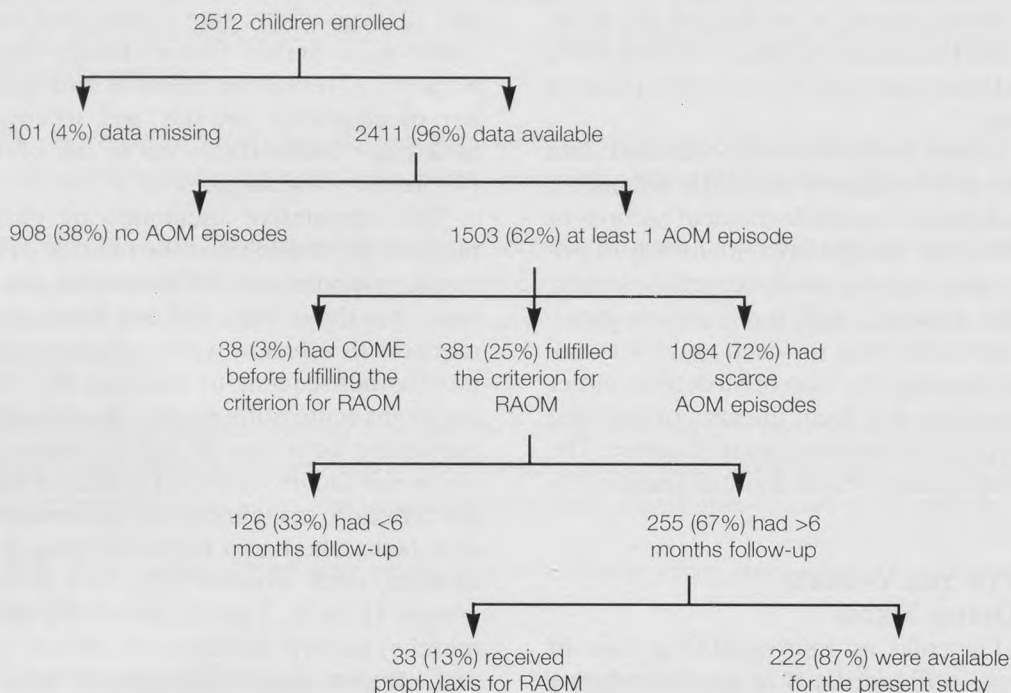
## RESULTS

The observation time was known for 2411 infants, 1503 (62%) of whom experienced a total of 4170 acute otitis media episodes. Myringotomy yielding effusion was performed in 1681 (40%) of the episodes. Of the 381 children who fulfilled the criterion for recurrent acute otitis media at least once during the observation period, 126 had a follow-up time of less than 6 months after meeting the criterion, and 33 underwent surgery or received chemoprophylaxis for recurrent acute otitis media. Excluding these, 222 children with recurrent acute otitis media were available for the present analysis (Figure 1).

The mode age for meeting the criterion for the first time was 12 months (Figure 2). During the 6

**FIGURE 1**

A schematic tree of the selection of the study population of 222 infants with recurrent acute otitis media from a random sample of 2512 children. AOM denotes acute otitis media; COME, chronic otitis media with effusion; RAOM, recurrent acute otitis media.



subsequent months, 8 infants of the 222 (4%) developed chronic otitis media with effusion and the remaining 214 infants had 227 episodes of acute otitis media, for an overall incidence rate of 2.1 episodes per child year. Tympanocentesis yielding effusion was performed in 100 (44%) of the episodes. Eighty-five infants (38%) did not have any episodes, 103 (46%) had one or two, and only 26 infants (12%) continued to have recurrent episodes without chronic otitis media with effusion (Table). The most significant factor predicting an increased risk of recurrence was young age (<16 months of age). Attending day care and having siblings had a modest effect.

Figure 3 shows that among the 937 infants observed for 24 months, nearly all new cases of both recurrent acute otitis media and chronic otitis media with effusion in each successive 6-month age period originated from a group of infants who had had no acute episodes or only a few during the previous period (79/82 of the cases of recurrent

acute otitis media and 41/45 of the cases of chronic otitis media with effusion).

## DISCUSSION

Spontaneous recovery from recurrent acute otitis media without any special prophylaxis was common with increasing age in our population-based child cohort. Only 4% of the 222 infants with recurrent acute otitis media developed chronic otitis media with effusion, and another 12% continued having recurrent acute episodes during the 6 months subsequent to meeting the most often-used criterion. The majority faced only one acute episode or none at all.

Moreover, most of the new cases of recurrent acute otitis media occurred in infants who had had relatively few episodes previously. Thus, it is difficult to predict a specific time at which children will be at a high risk for recurrent episodes in the near future, and therefore difficult to identify children

who would actually need special prophylaxis, such as tympanostomy tubes or chemoprophylaxis. The idea of using the criterion for recurrent acute otitis media in prevention is based on the assumption that the majority of children who have had numerous episodes in the past will continue to have them. This was not the case in the current study. To the contrary, fulfillment of the criterion was a poor predictor of future proneness to otitis.

Targeting for prophylaxis is those infants who are under 12 months of age, have siblings, and attend day care outside the home would increase the probability that an infant with future recurrent acute otitis media would need be treated, but a large number of infants would still be treated unnecessarily and a notable proportion of future cases would escape appropriate prophylaxis. For example, in the current study, nine of the 26 cases with continuing recurrent acute otitis media were over 12 months of age when first fulfilling the criterion, nine were in home care, and two had no siblings. At least for infants over 16 months of age special prophylaxis seems superfluous.

Experiences in clinical trials support our findings. Williams et al<sup>13</sup> recently compiled data on nine clinical trials for a meta-analysis to estimate the efficacy of antibiotics in prophylaxis for recurrent acute otitis media. They noted that the high incidence of acute otitis media episodes before the start of the trials, usually 6.0 episodes per child year, was reduced on average by one half during the trials among children not receiving active treatment. Moreover, the corresponding rate in the trial that most closely resembled our data with respect to age, preexisting acute otitis media rate, and the exclusion of chronic otitis media with effusion was 1.1 episodes per child year.<sup>14</sup>

Although the meta-analysis showed that the

**FIGURE 2**

**Age distribution of the 222 infants who received no prophylaxis upon meeting the criterion for recurrent acute otitis media for the first time.**



group receiving antibiotic treatment typically had about 50% fewer acute episodes than that receiving nonactive treatment,<sup>13</sup> the present results clearly indicate that this theoretical effect of prophylaxis remains insignificant at the population level, ie, only a tiny fraction of the total number of acute otitis media episodes would be avoided. By contrast, the effect on the individual child and family would be utterly different if one-half the episodes were avoided.

Our exclusion of 126 infants who did not have a 6-month observation period lowered the mode age of meeting the criterion for recurrent acute otitis media, but as this concurrently increased the risk of continuing recurrent acute otitis media, our results regarding the proportion of infants needing prophylaxis is an overestimate rather than an underestimate. Moreover, the excluded cases did not differ significantly from the rest of the sample with respect to the distribution of the risk factors. Only 33 infants were excluded because they had received prophylaxis for recurrent acute otitis media, and these did not differ from the rest of the infants with recurrent episodes with respect to the risk factors.<sup>11</sup> In any case, this number is so small

TABLE

**Occurrence of Acute Otitis Media (AOM) and Chronic Otitis Media with Effusion (COME) Among 222 Infants Who Received No Prophylaxis During the 6 Months After Meeting the Criterion for Recurrent Acute Otitis Media**

Characteristics	No. of Children	Distribution (%) of Children According to the Occurrence of Otitis Media					Incidence Rate*
		Chronic Otitis Media with Effusion	No COME				
			No. of AOM Episodes				
			0	1	2	≥3	
Overall	222	4	38	28	18	12	2.1
Age							
≤9 mo	48	8	23	25	23	21	3.1
10-12 mo	63	5	37	30	17	11	2.1
13-15 mo	55	2	45	20	20	13	2.0
≥16 mo	56	0	46	37	13	4	1.5
Allergy†	40	5	48	32	10	5	1.5
No allergy	145	3	35	28	21	13	2.3
Boys	130	6	33	33	16	12	2.2
Girls	92	0	46	23	20	11	2.0
In day care†							
Age ≤12 mo	14	0	14	43	14	29	3.1
Age >12 mo	53	2	51	26	11	10	1.6
In home care†							
Age ≤12 mo	79	8	32	29	20	11	2.4
Age >12 mo	35	0	46	34	20	0	1.5
Parents							
smoke†	35	3	49	20	14	14	2.1
Parents do not smoke	151	4	36	32	18	10	2.1
Winter†	59	2	34	34	17	13	2.3
Spring	78	4	40	25	18	13	2.1
Summer	27	7	32	29	21	11	2.3
Autumn	57	3	44	26	18	9	1.8
Siblings†	130	6	44	38	26	16	2.3
No siblings	45	1	21	13	6	4	1.7

\*Episodes per child year.

†Values do not total 222 because of missing information on questionnaires.

that even if all 33 infants had continuing recurrent acute otitis media, it would not have markedly altered the results.

Because of the widespread use of the national health care system both for illness and for pediatric checkup visits, we believe that the detection of cases of otitis media during the follow-up period was close to complete. The general health insurance scheme in the area provides equal access to medical and hospital services for everyone. A prospective follow-up was not necessary, in our opinion, as symptomatic outcomes related to the medical visits (short-term reasons for prophylaxis, eg, morbidity and financial costs) were being evaluated rather than developmental endpoints, which could have been affected by nonsymptomatic effusions.

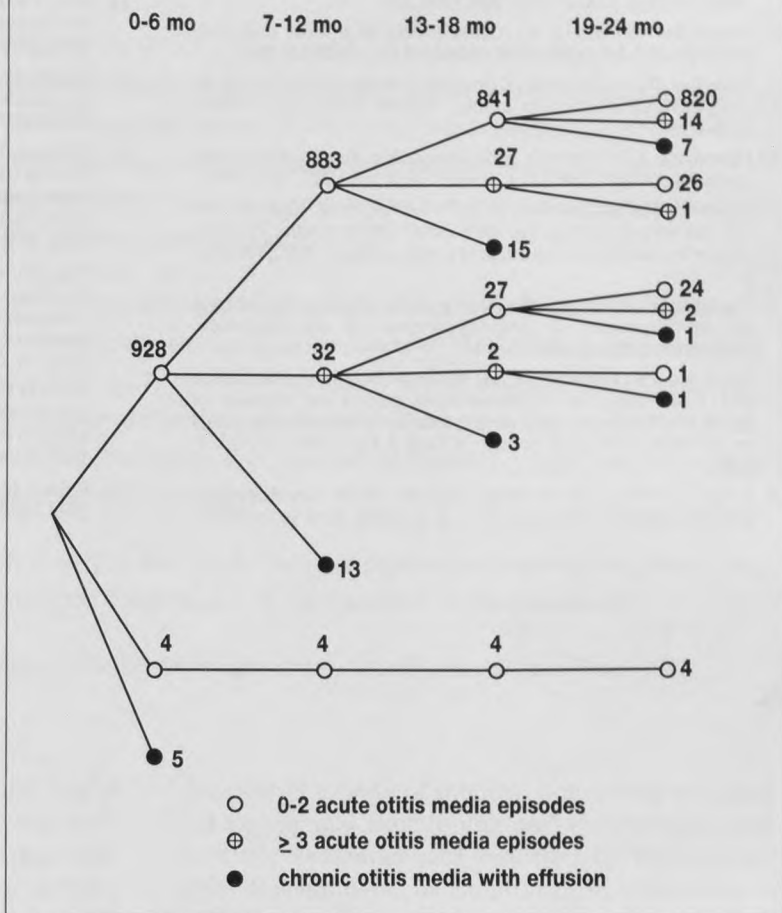
Some might criticize the diagnoses of acute otitis media, which were made in primary care and based on the otoscopic skills of numerous physicians. The physicians in the area are all uniformly trained to use a pneumatic otoscope and to perform myringotomies actively, which would tend to increase both the validity and the reproducibility of the diagnoses. In contrast to many other countries, myringotomy was used fairly often to relieve the symptoms. It has not, however, been found to affect the course of acute otitis media,<sup>15</sup> and thus, in our opinion, does not affect the generalizability of the present results.

Diagnosis is always to some degree subjective at present, and overdiagnosis probably occurred to some extent to account for the prescribing of antibiotics.<sup>16</sup> Thus, some of the cases with recurrent acute otitis media were probably not as ill as their medical records might indicate. When deciding on prophylaxis in actual clinical situations, one must rely on the standard diagnoses made in general practice.

Because children who had both recurrent acute infections and chronic otitis media with effusion were excluded, the present results do not apply to such cases. These infants may need more aggres-

FIGURE 3

Cross-classification of 937 infants with a minimum observation time of 24 months into various otitis media categories (rare or no acute episodes [0-2], recurrent acute episodes [ $\geq 3$ ], chronic otitis media with effusion) in successive 6-month age periods.



sive treatment and an intensive follow-up, which lends further emphasis to the importance of check-up visits after each acute episode to rule out long-standing effusion.

Our results show that spontaneous recovery from recurrent acute otitis media without any special prophylaxis is common with increasing age, and that it is difficult to predict a specific time at which children will be prone to otitis media in the near future. Until reliable causal evidence between recurrent otitis media and developmental disability is presented, special prophylaxis for recurrent acute otitis media seems superfluous for most infants who are older than 16 months and for whom chronic otitis media with effusion has been ruled out.

## ACKNOWLEDGMENT

We thank Jari Pääkkilä, MSc, of the Department of Mathematical Sciences and Statistics, University of Oulu, for assistance with the computing.

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