

# Lack of Seasonal Variability for Recurrent Otitis Media in Very Young Children

Harold A. Williamson, Jr, MD, MSPH, Joseph DePra, MD, and Leigh Ann Sulzberger

**Background.** Effective strategies are available to prevent recurrent otitis media (ROM). Because epidemiologic studies have demonstrated marked seasonal variation in acute otitis media (AOM), clinical guidelines often recommend cessation of prophylactic measures during the summer. Unfortunately, those studies did not separately assess seasonal variation in children with ROM, the group most likely to benefit from preventive measures.

**Methods.** The charts of 648 children who had at least one diagnosis of AOM were reviewed to count AOM rates by calendar month and age. Children with at least three infections in a 6-month period were assigned to a ROM group and analyzed separately. Seasonal variability was statistically assessed using the ranked-sums method of Hewitt.

**Results.** The criterion for ROM was met by 176

children (27%), who had 1096 episodes of AOM and accounted for 52% of all infections. In the ROM group, the monthly infection rate remained above 10% for the first 2 years of life. There was no seasonal variation in the ROM group under 1 year of age. The recurrence risk for those who met the ROM criterion was very high: first month, 32%; second month, 30%; third month, 22%; fourth month, 20%.

**Conclusions.** The youngest otitis-prone children show a high rate of infection in the summer months and a very high rate of recurrence. In these children, decisions about beginning or continuing preventive measures should not be influenced by the season of the year.

**Key words.** Otitis media; seasons; child.  
*J Fam Pract* 1991; 33:489-493.

Acute otitis media (AOM) and its sequelae are common in childhood and account for about one third of visits to providers of health care for children.<sup>1</sup> In a prospective study,<sup>2</sup> 62% of children in the first year of life had at least one episode of AOM, and 83% had at least one ear infection by age 3 years. The cost of AOM is high, in terms of both dollars and suffering, particularly for those who are otitis prone.<sup>3</sup>

"Otitis-prone" children are those who suffer episodes of recurrent otitis media (ROM). In an early study describing the otitis-prone condition, Howie et al<sup>4</sup> found that 12% of children under 6 years of age experienced at least six episodes of AOM. In another study,<sup>2</sup> 17% of children had three or more episodes before the age of 1 year. In yet another study of recurrent otitis media,<sup>5</sup> 12% of children had more than six episodes in 1 year. Risk factors for recurring episodes include young age at first

occurrence, male sex, sibling history of ROM, and not being breast-fed.<sup>2</sup>

Strategies for preventing ROM have centered around prophylactic use of antibiotics, tympanostomy tubes, tonsillectomy, and adenoidectomy. Although there is controversy surrounding the relative safety and effectiveness of these procedures, they are in common use and appear to have a legitimate role in the prevention of AOM.<sup>6</sup>

Of these preventive measures, prophylactic antibiotics are most frequently used, and a number of studies document their success in safely reducing ROM.<sup>7-13</sup> Unanswered questions about prophylactic antibiotics include when to institute treatment and how long to continue it. Prophylactic antibiotics are often prescribed after three or more ear infections in a 6-month period and are continued for 6 weeks to 3 months. Commonly, antibiotics are either not instituted during summer months or discontinued in the spring and summer.

These clinical decisions are based on original research protocols that used 2 to 3 months of prophylactic treatment<sup>8,10-12</sup> and limited enrollment to winter months.<sup>8,10,12</sup> In addition, published advice from experts and consensus panels has recommended prophylaxis in

Submitted, revised, July 29, 1991.

From the Department of Family and Community Medicine, University of Missouri-Columbia School of Medicine. Requests for reprints should be addressed to Harold A. Williamson, MD, MSPH, Department of Family and Community Medicine, University of Missouri Hospitals and Clinics, #1 Hospital Drive, Columbia, MO 65212.



winter and in early spring months when there is a high risk of upper respiratory tract infection.<sup>14,15</sup> Recommendations regarding the timing of tympanostomy and adenoidectomy have also suggested consideration of seasonal factors.<sup>16</sup>

These recommendations are, in turn, based on epidemiologic studies that document the relatively much lower rate of AOM in the summer and early fall months<sup>17-20</sup> and the lower rate of otitis media with effusion in summertime.<sup>21</sup> Unfortunately, these large studies describe monthly or seasonal rates for all cases of AOM and do not separate the cases of children with ROM.

Our clinical experience suggested that summertime AOM was not uncommon in otitis-prone children; the large winter-to-summer discrepancies noted above did not seem to be present in patients with recurrent infections. Therefore, a chart audit study was designed to describe the natural history of ROM and to determine the following: (1) whether seasonal variation occurs in children with ROM; (2) the likelihood of subsequent recurrence once the criteria for ROM are met; and (3) whether seasonal variation in children with ROM is the same for all ages.

## Materials and Methods

### *Site and Subjects*

The study sample was selected from patients seen at the Family Medical Care Center of the University of Missouri-Columbia between July 1, 1977, and June 30, 1988. The practice is affiliated with a university medical center in a city of 65,000 persons and is staffed by resident and faculty family physicians and nurse practitioners.

A roster of all children under 4 years of age who had been diagnosed with AOM was obtained from a computerized registry. During the study period, diagnoses were routinely handwritten on a registry form clipped to the patient's chart.

Because the study is not a typical case-control or clinical trial, the traditional methods of sample-size calculation could not be employed. Sample size was therefore based on the number of ROM cases needed to produce a stable seasonal curve. About 750 episodes were expected to generate a stable curve, and each child with ROM was assumed to suffer 5 episodes. We assumed that for each four children with one episode of AOM, there would be one with ROM. Therefore 150 children with ROM were expected to be adequate and were expected to come from a pool of 650 children who had had at least one episode of AOM. The first 650

names were chosen from an alphabetical list of 1440 children seen at least once during the study period for AOM.

The charts audited also included entries from other clinicians within the medical center; the likelihood of capturing visits to other outpatient clinics, the emergency room, and otologists was thus enhanced.

Each chart was audited from the earliest chart entry until the last entry before the patient was 4 years old. Episodes of AOM were recorded by year of life and month of occurrence. Also recorded were sex, race, and months during which prophylactic antibiotics were given or tympanostomy tubes were in place.

### *Definitions and Assumptions*

A record of a diagnosis of otitis media along with a prescription for an antibiotic was taken as evidence of an episode of AOM. Separate infections, as opposed to continued infection or effusion, were defined by a subsequent normal examination of the tympanic membrane, or by an interval of at least 15 days since the diagnosis of the previous infection. The chart diagnoses "serous otitis media," "effusion," "otalgia," and "chronic otitis media" were not coded as AOM unless an acute infection was also described.

Recurrent otitis media was defined as three or more episodes of AOM in any 6-month period. This definition was selected because it has commonly been used in studies of antibiotic prophylaxis.

Twenty charts were jointly audited by two investigators during a pilot period, and differences in interpretation were discussed and resolved until there was a high level of concordance.

To calculate rates of infection, a separate denominator for each year of life (1 through 4) was established. At least one visit for any reason during a year was required to include a subject in the denominator for that year of life. Rates were then calculated as AOM cases per 100 children-months of observation (ie, 10 children for 10 months = 100 children-months of observation). Hereafter this rate will be referred to as "cases/100." The presence of tympanostomy tubes or prophylactic antibiotics excluded the child for each such month from the numerator and denominator.

### *Analysis*

Aggregated monthly rates of AOM from this study were compared with other large series to provide a measure of reliability and generalizability of methods.

Monthly rates for children under 4 years of age who



had at least three episodes of AOM in any 6-month period (ROM group) were compared with rates for those who did not (non-ROM group). These monthly rates were graphed separately for each of the first 4 years of life to visually compare the ROM with non-ROM groups.

In addition, statistical evaluations for the presence of seasonal trends were performed. Hewitt et al<sup>22</sup> described a conservative, nonparametric method using a ranked-sums approach and tested the model with a Monte Carlo experiment. Hewitt's method tests for cyclic, seasonal trends by comparing rankings of months within two 6-month periods.

To ascertain the likelihood of recurrences of AOM once the conditions for ROM were met, rates of AOM for each of the subsequent 6 months were calculated for each year of life.

### Results

The charts of 648 children diagnosed as having AOM during the 11 years studied provided usable data. The numbers of subjects providing data for each year of life are: age 0 to 1 year, 542; age 1 to 2 years, 538; age 2 to 3 years, 446; age 3 to 4 years, 361. One hundred seventy-six children (27%) fit the criterion for ROM within the first 4 years of life. Of the 176 children fitting the criterion for ROM, 38% first met the criterion in the first year of life, 41% in the second, 14% in the third, and 7% in the fourth.

Boys comprised 54% of the overall group and 59% of the ROM group. Seventy-nine percent of patients in both ROM and non-ROM groups were white and 17% were black.

Tympanostomy tubes and prophylactic antibiotics were rare in this group during the study period. Tympanostomy tubes had been inserted in only 18 patients, and prophylactic antibiotics had been prescribed for 16.

There were 2103 episodes of AOM documented during the study period; 1096 episodes occurred in the ROM group and 1007 in the non-ROM group. Figure 1 demonstrates the monthly rates of AOM for all patients in this study compared with series from the British Medical Research Council<sup>17</sup> and the Finnish study of Pukander et al.<sup>18</sup> The seasonal variations are remarkably similar, suggesting the comparability of the study groups.

Figure 2 displays monthly episode rates comparing ROM and non-ROM cases partitioned by year of life. Three observations are noteworthy. First, there is a general seasonal trend for most years. Second, the ROM group in the 1st year of life does not demonstrate the

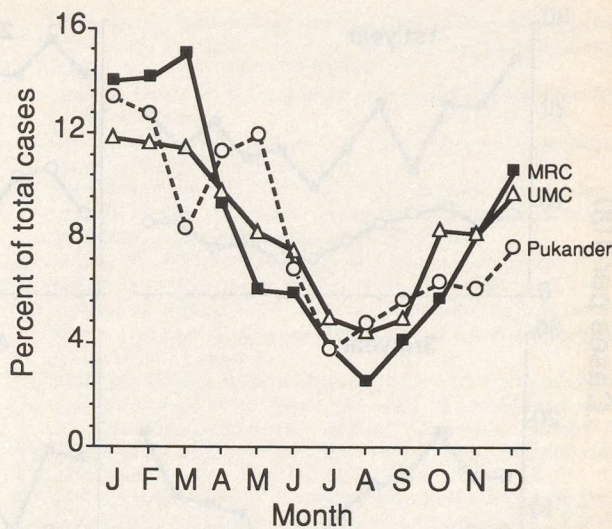


Figure 1. Monthly frequency distribution for all cases of acute otitis media (recurrent and nonrecurrent) from the British Medical Research Council<sup>17</sup> (MRC, n = 1323), the current study (UMC, n = 2103), and the Finnish study of Pukander et al<sup>18</sup> (Pukander, n = 6518). The large seasonal variability for aggregated cases has formed the basis for believing that prophylactic measures are not needed in the summer.

expected summertime decrease in AOM rates. Third, during the first 2 years of life, the prevalence for the ROM group never falls below 10 cases/100 children.

The visual phenomenon in Figure 2 was tested statistically with the nonparametric criteria for seasonality used by Hewitt et al.<sup>22</sup> This ranked-sums method demonstrated statistically significant scores ( $P < .04$ ) for all groups except the ROM group in the 1st year ( $P = .19$ ), thus confirming the lack of seasonality in the 1st year of life.

Figure 3 shows the likelihood of a patient having AOM subsequent to meeting the ROM criterion. During the first 2 years of life, the recurrence rates of otitis media remain quite high for the subsequent 3 months. In the 1st year of life, the recurrence rates remain above 20 cases/100 for 4 months.

### Discussion

Improvements in prognostic ability and clinical management strategies are often created by a better understanding of the natural history of disease. Previous clinical epidemiologic studies have shown that AOM is a very common disease<sup>2</sup> and that there is a strong seasonal variation when aggregated cases of AOM are studied.<sup>17-20</sup> Clinical trials have also demonstrated that recur-



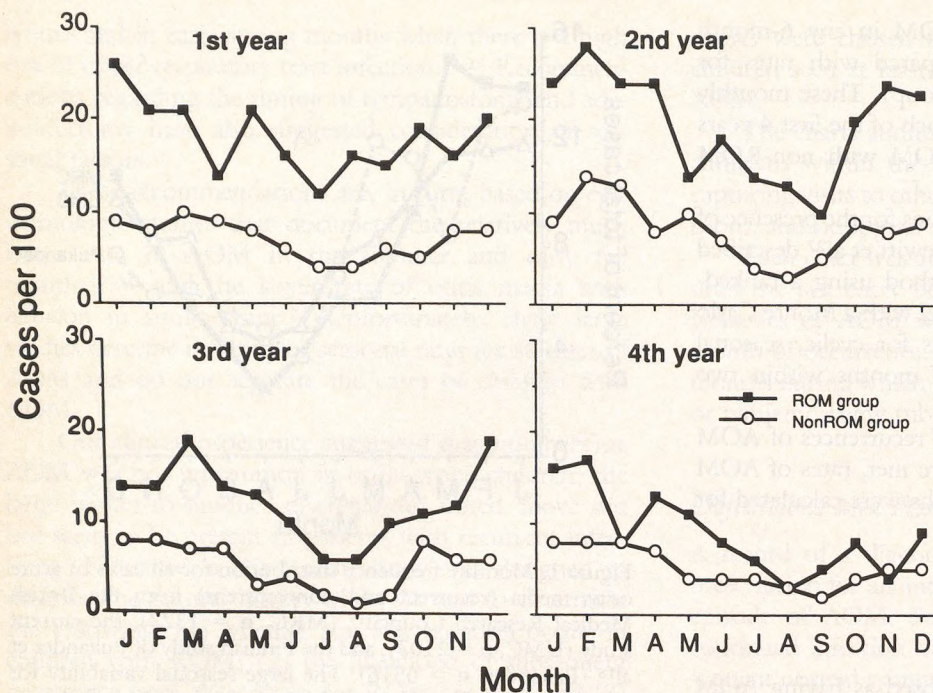


Figure 2. Monthly variation of acute otitis media rates for recurrent (ROM) and nonrecurrent (non-ROM) groups for each of the first 4 years of life. No seasonal variation is seen for children with recurrent otitis media during the 1st year of life.

rent episodes can be markedly diminished with tympanostomy tubes and prophylactic antibiotics.<sup>6-13</sup>

This study adds to our clinical knowledge by demonstrating that seasonal variation is insignificant in the 1st year of life of otitis-prone children. Otitis-prone children, particularly young children, have very high rates of recurrence in the months subsequent to meeting

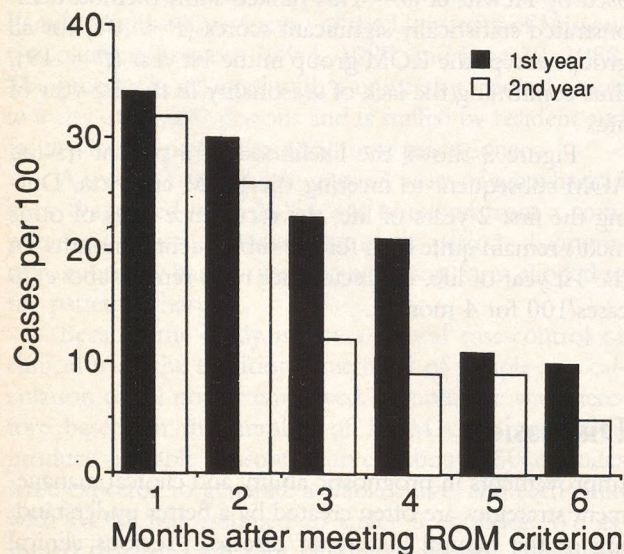


Figure 3. Risk of acute otitis media for each of 6 months subsequent to meeting the criterion for recurrent otitis media (ROM) during the 1st and 2nd years of life. The risk remains high during the first 4 months.

the criterion for ROM. These findings suggest that withholding preventive interventions in the summer months is not warranted and that interventions should last at least 4 months to minimize recurrence risk.

In addition to the clinical applications listed above, this study also has implications for our understanding of the pathophysiology of ROM. The absence of seasonal variation in only very young otitis-prone children suggests that anatomic factors, and not merely the presence of seasonal viral upper respiratory tract infections, may be the determinants of recurrence. This, in turn, suggests that plans for prophylaxis based on immunization against common respiratory viruses may not be successful in otitis-prone infants, the group most in need of protection.

Limitations to consider when interpreting these data derive from the retrospective nature of chart audits. The clinicians' diagnosis of AOM was accepted, and there were undoubtedly varying criteria used for AOM; this probably resulted in misclassification of some cases. Only a prospective study using currently accepted diagnostic criteria could avoid these problems. Such a study would be quite difficult to construct and would necessitate a long study period. To some extent, the same problems are present for prospective studies as well; the reliability of the results are dependent on the variability and unreliability of clinical diagnosis.<sup>24</sup> The variability in clinician criteria for diagnosis and for chart documentation may have influenced the absolute rates of AOM but should



not have influenced seasonal variation, which was the subject of this study. The close correlation of our data to other studies of seasonal variation for aggregated cases also suggests that the criteria used in the study practice are similar to those used in other settings. It is also important to note that the extant studies that form the basis of our beliefs about otitis media seasonality were also retrospective.<sup>17-20</sup>

It is likely that some of the children included in the study had episodes of AOM diagnosed outside the university medical center during the study period. It is also possible that our decision to include a child in the year-of-life denominator if he or she was seen at least once during the year resulted in an inflated denominator. Both of these limitations probably resulted in an underestimation of absolute rates but should not have influenced seasonal variation.

The small number of patients who were treated with prophylactic antibiotics was surprising because this was believed to be a common therapeutic intervention in our practice. Nonetheless, the relative rarity of antibiotic prophylaxis gave us an opportunity to observe a larger number of cases representing the "natural history" of ROM than we could have anticipated.

Otitis media in very young otitis-prone children does not demonstrate significant seasonal variability. The criterion used to define ROM (at least three episodes of AOM in a 6-month period) successfully predicted children at high risk of continued recurrence. Indeed, over one half of the cases of AOM in our study were in the ROM group. Recurrence rates after meeting the ROM criterion remain over 20% per month for 4 months in very young children. These findings suggest that preventive strategies for very young otitis-prone children, the group at highest risk, should not be discontinued or postponed based on seasonal factors.

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