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Use of Symptoms and Risk Factors to Predict Acute Otitis Media in Infants

David P. McCormick, M.D.¹, Kristofer Jennings, Ph.D.², Linda C. Ede, M.D.¹, Pedro Alvarez-Fernandez, M.D.¹, Janak Patel, M.D.¹, and Tasnee Chonmaitree, M.D.^{1,3}

¹ Department of Pediatrics, University of Texas Medical Branch at Galveston, Texas, USA.

² Department of Preventive Medicine and Community Health, University of Texas Medical Branch at Galveston, Texas, USA.

³ Department of Pathology, University of Texas Medical Branch at Galveston, Texas, USA.

Abstract

Objectives—Infants and children with upper respiratory tract infection (URI) often have concurrent acute otitis media (AOM). Young infants have less specific symptoms than older children. The purpose of this study was to evaluate the usefulness of symptoms and other risk factors in predicting the presence of AOM in infants.

Methods—Healthy infants, age four weeks, were enrolled and followed prospectively for up to age one year. Infants were scheduled for a research visit when their parents noted the onset of symptoms. At each URI visit, parents first reported the severity of symptoms. An investigator then diagnosed the presence or absence of concurrent AOM. Risk factors and symptom scores for infants with and without AOM were studied.

Results—Infants (N=193, mean age at first URI 3.9 ± 2.5 months) experienced 360 URI episodes and 63 AOM events. Symptoms consisting of fever, earache, poor feeding, restless sleep, and irritability together (ETG-5) were statistically associated with the prediction of AOM ($P=0.006$). A multiple variable statistical model (J-Score) that included day care attendance, age, severity of cough and earache best predicted AOM ($P < 0.001$), with 95% specificity. Both ETG-5 and J-score yielded relatively low sensitivity for AOM prediction.

Address correspondence to: David P. McCormick, M.D., Clinical Professor, Division of General Academic Pediatrics, University of Texas Medical Branch (UTMB), Primary Care Pavilion, Suite 2.701, 301 University Boulevard, Galveston, TX, USA 77555-1119, Office (409) 772-6283, Fax (409) 747-0784, dpmccorm@utmb.edu.

Jennings: krjennin@utmb.edu

Ede: lcede@utmb.edu

Alvarez-Fernandez: pedroenrique1971@gmail.com

Patel: jpatel@utmb.edu

Chonmaitree: tchonmai@utmb.edu

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Conclusions— In infants with URI in the first year of life, severity of symptoms was significantly associated with concurrent AOM. Daycare attendance, presence and severity of earache and cough added to better correlation. These observations may have clinical application in identification of infants at risk for AOM.

Keywords

acute otitis media; respiratory infection; child; infant; diagnosis; symptoms

Introduction

Acute otitis media (AOM) is a common illness that complicates upper respiratory tract illness (URI) in young children. During their first three years of life, children experience about 5 episodes of URI and 1.7 episodes of AOM per child-year [1]. In the past, recurrent AOM has been reported to occur in the first six months of life in up to 20% of children [2]. In recent years otitis media incidence rates have decreased, in part due to the widespread use of influenza and pneumococcal vaccines [3]. Compared to older children, infants who experience AOM before age 12 months are more likely to experience recurrent AOM, prolonged middle ear effusion, concomitant conductive hearing loss, and a greater likelihood of requiring tympanostomy tube surgery [2,4]. Also, very young infants may be susceptible to pneumococcal AOM because they may not have been fully immunized with pneumococcal vaccine [5]. Worldwide, parents consider the symptoms of AOM to be a burden [6]. Ear pain is a common complaint in older children with AOM. However, in infants with an illness, symptoms may be nonspecific and difficult to identify.

Quantitative assessment of AOM symptoms can assist in evaluating the clinical outcome of AOM treatment. [7,8]. Studies have described methods to assess AOM-specific symptoms in children, but these studies focused primarily on children aged > 12 months [9-12]. The recent guidelines on the diagnosis and treatment of AOM [13] recommend diagnosis based on the presence of a bulging tympanic membrane alone, and deemphasize the consideration of symptoms in making the diagnosis. The purpose of this study was to determine whether it is possible for caregivers to identify factors that contribute to the suspicion of AOM in very young children with URI.

Materials and Methods

Detailed descriptions of this project have been previously published [14, 15]. Otherwise healthy, full-term infants aged < 4 weeks were recruited from the nursery or well-baby clinic at the University of Texas Medical Branch (UTMB). We excluded newborns with diagnosis of prematurity, congenital defects, cleft lip or palate, immunological deficiency, or other serious medical conditions. The parent or guardian signed an informed consent approved by the UTMB Institutional Review Board.

Parents were instructed to call the study personnel and arrange for a visit when they observed the onset of URI symptoms. Parents were compensated for time, travel and parking. At each research visit, prior to the physical examination, English/Spanish fluent research personnel obtained history of smoke exposure, children living at home, day care

attendance, and feeding status (formula, mixed formula and breast, or solo breast feeding). Day care attendance was categorized as: a) no day care, b) low < 5 children and < 20 hours per week, c) medium > 5 children and < 20 hours per week or < 5 children and > 20 hours per week, and d) high > 5 children and > 20 hours per week. Symptoms were assessed using the validated ETG-5 scoring questionnaire (Ear Treatment Group-5 items), as previously described [10, 16, 17]. ETG-5 is the total of 5 items, each measured on a 0 - 3 scale (none, mild, moderate and severe), yielding a maximum score of 15. The five items were fever (None = 0, 1 = <38.4° C or parent observed but did not measure, 2 = 38.4 –38.8, 3 = > 38.8), earache (by parent's suspicion), poor feeding, restless sleep, and irritability. Five additional URI symptoms were also assessed on the same 0-3 scale: sore throat (by parent's suspicion), cough, nasal stuffiness, runny nose, and watery eyes. An investigator then performed a physical examination, and pneumatic-video otoscopy (Digital Macroview™, Welch Allyn, Skaneateles Falls, NY). All investigators were validated in the diagnosis of AOM using sets of standard photographs and the examination of live ears of subjects with URI, with or without concomitant AOM. The diagnosis of AOM required acute (rapid) onset of symptoms [13], an abnormal, inflamed, tympanic membrane (characterized by mild, moderate, or severe bulging, loss of landmarks, and opacification), and the presence of a middle ear effusion as verified by pneumatic and/or pneumatic-video otoscopy. The investigator then provided appropriate treatment and parent education. All infants were followed for a minimum of six months. However, infants who had not experienced an episode of URI with AOM by age six months were followed until they experienced AOM, or until they reached the age of 12 months, whichever came first. Data were collected on all URI and AOM episodes.

Visit data were considered eligible for analysis only if a trained investigator evaluated the infant and if the research visit occurred < 10 days following the onset of URI symptoms. Visits were consolidated into episodes by using just the first visit's symptom scores (of that episode). Two groups were compared: 1) episodes with URI only, and 2) episodes with URI complicated by AOM. Categorical data were compared using Fisher's exact test. Mean differences were compared using Student's t-test. Since a child could experience more than one URI and AOM, mixed logistic regression models estimating the probability of AOM were fit. Variables were selected for inclusion in the model according to which model minimizes the Bayesian Information Criterion [18]. To simplify the calculation in the predictive model, estimated coefficients were rounded to values that were not significantly different from the original estimates. Regression models that were considered included potential covariates obtained at enrollment: gender, race/ethnicity, family history, birth weight, gestational age, and other children living at home. Variables obtained at the time of the visit were days of URI, symptoms at time of the visit, feeding status, tobacco smoke exposure, children living at home, and day care attendance. In the final model, daycare categories a), b) and c) were scored 0. Daycare category d) was scored 1. Results are presented as mean plus or minus standard deviation. All reported P values are two-sided. All calculations were conducted in R (The R Foundation for Statistical Computing, Vienna, Austria, Version 3.0.2).

Results

Demographic Data, URI and AOM Episodes

A total of 367 children were enrolled from October 2008 to April 2013; 56 were dropped (declined to participate following enrollment, or lost to follow up prior to the first URI). During follow up 195 subjects experienced 369 unique URI episodes, resulting in 450 research visits with URI and 87 visits with URI and AOM. Of these, 193 children contributed 360 URI episodes that were eligible for analysis (defined as the first URI visit for a given episode and the subject was examined by a trained investigator). Sixty-three of these URI episodes were complicated by AOM on at least one visit. All subjects received pneumococcal vaccine.

Infants were male gender 103/193 (53%), ethnicity Hispanic 100/193 (52%), and race: white 144/193 (75%), African-American 46/193 (24%) and Asian 3/193 (1%). The mean age at first URI was 3.9 ± 2.5 months (range 0.5-11.5 months); the mean number of URI's per child was 1.9 ± 1.1 (range 1-6), and the mean number of URI's complicated by AOM was 0.32 ± 0.49 (range 0 - 2), per child. The mean number of days of URI symptoms prior to the research visit was 4.06 ± 1.85 (median = 4, interquartile range = 2). The ratio of URI without AOM to URI complicating AOM, was 4.7:1. Risk factors considered in the multivariate analysis are summarized in Table 1.

Symptom severity and scores

In order to develop statistical models, we first evaluated the frequency counts of parent-reported symptoms, by severity, for the subjects experiencing a URI episode, with and without AOM (Table 2). All children had URI symptoms; nasal stuffiness was the most common symptom described by the parent. Cough was also a frequent complaint. Sore throat was not a useful symptom in this very young group, being reported by parents in only 8% of subjects. Even in the infants with AOM, the parent rarely reported fever. Parents reported earache in twice as many (39.7%) children subsequently diagnosed with AOM, as compared with children not having AOM (17.6%).

Symptoms and risk factors associated with AOM

We then calculated the effect of each factor in predicting the probability of AOM in infants with URI (Table 3). These factors were first evaluated independently (univariate analysis) and then controlling for the other factors (multivariate analysis). Regarding the demographic and risk factors, in this group of infants with URI, older age increased the risk. Daycare attendance, number of children in the family, and gestational age contributed independently to the risk of AOM. Taken together, while controlling for all variables in the group, demographic and risk factors contributed significantly to the prediction of AOM ($P=0.001$). Regarding symptoms, on univariate analysis, severity of cough, runny nose, and earache, all predicted AOM. However, when controlling for all symptom variables, cough and runny nose dropped out as important contributors. Earache alone predicted AOM. All symptoms taken together, including URI symptoms and the ETG-5 symptoms in the same multivariate analysis, did not accurately predict AOM ($P=0.05$).

Development and testing of statistical models to predict AOM

Since clinical studies using ETG-5 had been previously published (10, 16, 17), the ETG-5 scoring system was used as a standard against which to compare new statistical models that might more accurately predict AOM in infants. A higher ETG-5 score did predict AOM in infants. The mean ETG-5 score for URI episodes with AOM, versus those without AOM, was 3.22 ± 2.93 (N=63) versus 2.21 ± 2.25 (N=297, $P=0.01$), respectively. Several statistical models predicting the percent likelihood of AOM during URI were developed using symptoms, demographic variables, and risk factors. The optimal model that predicted AOM ($P < 0.001$) with simple coefficients was given by the so-called, "J" equation: $J = 2 \times (\text{age in months}) + 4 \times (\text{coughing score}) + 5 \times (\text{earache score}) + 10 \times (\text{high daycare score})$. The maximum possible score for our sample would be a 12 month old with severe cough and earache, attending daycare: $J = 2 \times 12 + 4 \times 3 + 5 \times 3 + 10 = 61$ (range 0 – 61), although in our sample the maximum score was 45 and all but 17 episodes were below 30. The model classification and criterion performance was not improved by the inclusion of any other demographic or risk factor co-variables.

Table 4 compares ETG-5 score versus J-score on sensitivity, specificity, positive and negative predictive value for 360 URI visits. The J-score model, which included demographic and risk factors, provided a better specificity than the ETG, which only utilized symptom scores. That is, compared with ETG-5, the J score more accurately identified infants with URI who did not simultaneously have AOM.

In estimating the probability of AOM in infants with URI, information needed was the child's age and daycare status, plus the severity of the cough and earache, as reported by the parent. Figure 1 plots J score versus the percent likelihood of AOM in infants. A J-score < 20 predicts $< 20\%$ probability of AOM; a J-score > 43 predicts a $> 80\%$ probability of AOM. A cutoff at 27 gave maximum sensitivity and specificity for J-score. A typical example would be an 8-month-old child with URI, a moderately severe cough and earache (scores = 2 each), and exposure to a day care group of > 5 children > 20 hours per day ($J=44$). This infant would have an estimated 80% chance of having AOM.

Discussion

Our data suggested that the severity of AOM symptoms (ETG-5 score) and presence/severity of specific symptoms such as ear pain and cough, when combined with age and current day care attendance (J-score), could help caregivers suspect AOM in infants with URI. These models were best at accurately identifying infants with URI who did not have concurrent AOM because of high negative predictive values.

Previously, Laine, et al. [19], in the study of an older age group, reported that parents have no better than a 50% chance of guessing the presence of AOM in infants and children with URI. Our study is not directly comparable with Laine's, who recruited subjects whose parents thought they might have AOM. We enrolled subjects whose parents observed URI symptoms, and we did not ask parents if they thought their child had an ear infection. It has been said that ear pain is a nonspecific symptom in young children and should not be counted on to assist in the diagnosis [20]. Infants under age 12 months do express pain in

facial expression, crying, restlessness, irritability and touching the painful area with a hand or finger. We have examined many children with normal ears, whose parents brought them because they had been “batting” at or touching the auricula. We have also observed, during the physical examination, a fussy infant batting unilaterally at the specific ear that was infected. We agree that ear touching or pulling, in the absence of other symptoms and risk factors, is not a good predictor of AOM in young children. However, in this study, parents were able to identify pain referable to the ear. Our data suggested that, in infants with URI, and observant parents, ear pain and cough, combined with exposure to bacteria and respiratory viruses in day care, increased the probability of AOM diagnosis.

Young infants are generally believed to have less specific symptoms during acute infection. Our data point out that even in infants, severity of symptoms and specific risk factors might be helpful in identification or elimination of the possibility of AOM. Both the symptom-based (ETG-5) and combined risk factor/symptom-based (J-score) predictors had high negative predictive values of 85-87%. Thus, when few criteria were met, the infant had a low probability of AOM. The prediction model provides a statistically significant probability of AOM given fulfillment (or non-fulfillment) of the necessary criteria. This issue has practical implications for clinicians in general practice, whose office personnel often deal with anxious parents on the telephone; such parents may express uncertainty about bringing the child to the office for an examination and possible antibiotic treatment. The decision is often based on the circumstances and the characteristics of the child's symptoms, as described by the parent.

These results were limited by the relatively small number of AOM episodes experienced by this very young group of infants, who still possess maternal antibodies. All infants received pneumococcal vaccine during follow up, and few infants were in day care. This resulted in a lower risk of URI and AOM, as compared with what would have been the case had the study group been older. A weakness is that the results were, in part, dependent on subjective data, since the infants' symptoms were obtained by parent report. In addition, in this study the parents provided information on the presence of fever, with or without having made temperature measurements. Body temperatures were not measured at the research visit. The infants, upon arrival at the research office, were not very ill; almost all infants were afebrile at the time of the research visit. During enrollment, parents had been requested to bring their children to the office at the first sign of a URI. Therefore, children in the study had less severe symptoms than children typically seen in a pediatric practice, where parents often wait until the child is more symptomatic before coming to the office. Therefore, compared to the research setting of this report, in clinical practice, symptoms in infants with URI may play a more important role in suggesting the likelihood of AOM.

Conclusions

Presence and severity of specific symptoms, as observed by parents, when combined with known risk factor data may provide clues to the presence or absence of concurrent AOM in young infants with URI. Our data suggest that an infant in day care who had URI symptoms, whose parent described moderate or severe cough and ear pain had a good chance of having

AOM. These observations might have potential application to clinical practice in identification of infants with URI who may benefit AOM evaluation.

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Abbreviations

AOM	acute otitis media
ETG-5	ear treatment group 5-item symptom questionnaire
URI	upper respiratory infection

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What's known on this subject: In older children, ear symptoms may suggest the presence of acute otitis media (AOM). Symptoms in infants were believed nonspecific and may not be helpful in AOM diagnosis. Therefore, in an infant with upper respiratory infection, it is more difficult for caregivers to predict whether AOM may concurrently be present.

What this study adds: In an infant with upper respiratory tract infection, more severe symptoms, combined with specific risk factors, can lead to the suspicion of concurrent AOM.

Figure 1. Relation between the probability of an acute otitis media episode during upper respiratory tract infection in infants, versus J-score.

Table 1

Risk factors for AOM in infants. N=193 subjects, N = 360 episodes.

Variable	Response	No. (%)
Family history of otitis media	Parents	7 (4)
	Mother	15 (7)
	Father	7 (4)
	Siblings	19 (10)
	None	141 (73)
	Other	2 (1)
	Missing data	2 (1)
Feeding status at time of visit	Formula	248 (69)
	Breast	49 (14)
	Mixed	63 (17)
Day care	High	37 (10)
	Medium	10 (3)
	Low	9 (3)
	None	304 (84)
Tobacco smoke exposure	Yes	54 (15)
	No	305 (85)
	Missing data	1 (0.3)

Table 2

Frequency counts of parent-reported symptoms observed in subjects with URI and AOM (N=63) versus URI without AOM (N=297)

	Severity of symptoms (N, %)			
	None	Mild	Moderate	Severe
<u>URI with AOM</u>				
Sore throat	58 (92.1)	5 (7.9)	0	0
Cough	11 (17.5)	27 (42.9)	20 (31.8)	5 (7.9)
Nasal stuffiness	11 (17.5)	22 (34.9)	23 (36.5)	7 (11.1)
Runny nose	12 (19.4)	24 (38.7)	21 (33.9)	5 (8.1)
Red, watery eyes	34 (54.0)	21 (33.3)	7 (11.1)	1 (1.6)
Earache	38 (60.3)	13 (20.6)	11 (17.5)	1 (1.6)
Poor feeding	41 (65.1)	12 (19.1)	7 (11.1)	3 (4.8)
Restless sleep	31 (49.2)	20 (31.8)	8 (12.7)	4 (6.4)
Irritable	26 (41.3)	20 (31.8)	12 (19.1)	5 (7.9)
Fever	57 (90.1)	3 (4.8)	0	3 (4.8)
<u>URI without AOM</u>				
Sore throat	267 (89.9)	20 (6.7)	9 (3.0)	1 (0.3)
Cough	48 (16.2)	158 (53.2)	73 (24.6)	18 (6.1)
Nasal stuffiness	22 (7.4)	154 (51.9)	91 (30.6)	30 (10.1)
Runny nose	64 (21.6)	143 (48.2)	73 (24.6)	17 (5.7)
Red, watery eyes	171 (57.6)	97 (32.7)	24 (8.1)	5 (1.7)
Earache	245 (82.5)	37 (12.5)	10 (3.4)	5 (1.7)
Poor feeding	208 (70.0)	62 (20.9)	21 (7.1)	6 (2.0)
Restless sleep	161 (54.2)	86 (29.0)	35 (11.8)	15 (5.1)
Irritable	135 (45.5)	97 (32.7)	44 (14.8)	21 (7.1)
Fever	280 (94.3)	14 (4.7)	2 (0.7)	1 (0.3)

Table 3

The relative strength of each factor in association with AOM.

Variables	Univariate analysis		Multivariate analysis	
	Chi-square	P-value	Chi-square	P-value
<u>Demographic and risk factors</u>				
Age	20.9	<0.001	17.0	0.001
Number of children in family	2.45	0.12	6.45	0.011
Family history of OM	3.61	0.06	0.05	0.82
Gender	0.16	0.29	2.82	0.09
Birth weight	0.55	0.46	2.91	0.09
Gestational age	3.55	0.06	6.23	0.01
Ethnicity	0.83	0.36	0.77	0.38
Race	0.005	0.94	0.81	0.67
Feeding status	1.20	0.55	0.50	0.78
Tobacco smoke exposure	1.71	0.19	0.72	0.40
Day care	5.78	0.12	11.28	0.01
Demographic Variables (Total)	48.74	<0.001	36.69	0.001
<u>Symptoms</u>				
Sore throat	0.044	0.83	0.33	0.86
Cough	5.98	0.014	3.06	0.08
Nasal stuffiness	2.55	0.11	0.08	0.78
Runny nose	10.24	0.001	0.69	0.41
Watery eyes	2.93	0.087	0.27	0.60
Fever	4.14	0.042	1.92	0.17
Earache	12.02	0.001	6.37	0.01
Poor feeding	2.28	0.13	0.048	0.83
Restless sleep	2.37	0.12	1.33	0.25
Irritability	2.17	0.14	1.34	0.25
Symptom variables (Total)	30.19	<0.001	18.14	0.05

Table 4

Compares ETG-5 score versus J-score in predicting concurrent AOM in infants with URI (N=360 URI visits).

Cutoff value	ETG-5 score		J-score	
	<5	5	<27	27
URI and AOM	44	19	42	21
URI no AOM	253	44	281	16
Sensitivity	30		33	
Specificity	85		95	
Positive predictive value	30		57	
Negative predictive value	85		87	
P	0.006		0.001	