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Use of symptoms and risk factors to predict acute otitis media in infants

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ABSTRACT

Objectives: Infants and children with upper respiratory tract infection (URI) often have concurrent acute otitis media (AOM). Young infants have fewer 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 less than 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.

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.

1. 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

Abbreviations: AOM, acute otitis media; ETG-5, ear treatment group 5-item symptom questionnaire; URI, upper respiratory infection.

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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.

2. 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 h per week; c) medium, >5 children and <20 h per week or <5 children and >20 h per week; and d) high, >5 children and >20 h 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 five 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 enrolment: 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).

3. Results

3.1. 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 enrolment, 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.

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)