Development of an Algorithm for the Diagnosis of Otitis Media

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ABSTRACT

BACKGROUND: The relative importance of signs and symptoms in the diagnosis of otitis media has not been adequately evaluated. This has led to a large degree of variation in the criteria used to diagnose otitis media, which has resulted in inconsistencies in clinical care and discrepant research findings.
METHODS: A group of experienced otoscopists examined children presenting for primary care. We investigated the signs and symptoms that these otoscopists used to distinguish acute otitis media (AOM), otitis media with effusion (OME), and no effusion. We used recursive partitioning to develop a diagnostic algorithm. To assess the algorithm, we validated it in an independent dataset.
RESULTS: Bulging of the tympanic membrane (TM) was the main finding that otoscopists used to discriminate AOM from OME; information regarding the presence or absence of other signs and symptoms added little to the diagnostic process. Overall, 92% of children with AOM had a bulging TM compared with 0% of children with OME. Opacification and/or an air-fluid level was the main finding that the otoscopists used to discriminate OME from no effusion; 97% of children diagnosed with OME had an opaque TM compared with 5% of children diagnosed with no effusion. An algorithm that used bulging and opacification of the TM correctly classified 99% of ears in an independent dataset.
CONCLUSIONS: Bulging of the TM was the finding that best discriminated AOM from OME. The algorithm developed here may prove to be useful in clinical care, research, and education concerning otitis media.

KEYWORDS: acute otitis media; diagnostic algorithm; otitis media; otitis media with effusion; otoscopy; physical examination; signs and symptoms

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WHAT'S NEW

We developed and validated an algorithm that describes the signs and symptoms that experienced otoscopists use when diagnosing otitis media. This algorithm promises to be useful in clinical care, research, and education concerning otitis media.

SYMPTOMS ARE CLEARLY important in the diagnosis and management of children with acute otitis media (AOM). The presence of symptoms prompts parents to seek medical care, and the subsequent course of symptoms helps guide clinical care for these children. Clinicians prescribe antimicrobials for children with AOM in part under the assumption that this results in a more rapid resolution of symptoms. In addition, symptoms (eg, otalgia) are often used to determine eligibility for clinical trials.

In several studies authors have identified symptoms that correlate with otoscopic diagnosis, but no studies to date have compared the relative importance of otoscopic signs versus symptoms in the diagnostic process. This absence of empiric data regarding the relative importance of signs and symptoms is partly responsible for that lack of consensus that exists regarding the diagnostic criteria for otitis media. For example, the 2004 American Academy of Pediatrics Guidelines for the diagnosis of AOM provided clinicians with a list of signs and symptoms associated with the diagnosis of AOM.[1] However, without information regarding the relative importance of these symptoms with respect to each other, and with respect to signs present on otoscopic examination, such a list is difficult to implement in practice. This was best illustrated by a study by Hayden, who, in a survey of 165 pediatricians, found that 147 different combinations of signs and symptoms were endorsed as criteria for diagnosis.[2] The consequences of inaccurate diagnosis are not trivial; inappropriate use of antimicrobials for AOM contributes significantly to increased resistance among respiratory-tract pathogens. Furthermore, the use of nonstringent diagnostic criteria in clinical trials has permitted the inclusion of children who did not actually have AOM but instead had otitis media with effusion (OME) in conjunction with nonspecific symptoms. This has resulted in

discrepant and misleading conclusions regarding the treatment of AOM.[3]

By empirically examining the findings used by a group of experienced otoscopists to classify otitis media, we aimed 1) to determine the relative importance of signs and symptoms in the diagnosis of AOM, and 2) to use this information to develop a diagnostic algorithm that could categorize children into the 3 diagnostic categories, that is, AOM, OME, or no effusion. We assessed the performance of the algorithm by applying it to an independent dataset. Please see a related video at http://www.academicpedsjnl.net/content/acap-videos.

METHODS

We developed a decision tree by using data from a previously conducted cohort study (of pneumococcal colonization) in which a convenience sample of 264 children (mean age, 12.5 months) who presented for primary care or sick visits were followed for one respiratory season via the use of serial pneumatic otoscopic examinations.[4] This dataset will be referred to as the training dataset. The study otoscopists had previously completed a training program in which their diagnoses had been validated against findings at myringotomy.[5] At each visit, and after the removal of cerumen, an otoscopist assessed the following tympanic membrane (TM) characteristics: color (amber, blue, gray, pink, white, yellow), degree of opacification (translucent, semiopaque, opaque), position (neutral, retracted, bulging), decreased mobility (yes, no), presence of air-fluid level(s) (yes, no), and presence of areas of marked redness (yes, no). At each visit, and before otoscopic examination, symptoms were recorded by the parent with a previously developed patient-reported outcome measure (Acute Otitis Media Severity of Symptoms Scale [AOM-SOS]).[4,6] The version of the AOM-SOS scale used in this study asked parents about the presence of 7 symptoms during the preceding 24 hours (ear pain, ear tugging, irritability, decreased play, decreased appetite, difficulty sleeping, and fever).

In children with AOM in one ear and OME or no effusion in the other, we selected the ear with AOM. In children with OME in one ear and no effusion in the other, we selected the ear with OME. In children with the same diagnosis in both sides, we arbitrarily chose the left ear. For each child, only the first visit with a complete set of signs and symptoms was presented. We repeated the analysis by using the right ear and using all possible visits. The results were essentially the same and thus will not be presented.

We first examined the univariate association between TM findings and the assigned diagnosis by using logistic regression. We then used recursive partitioning (CART 6.6, Salford Systems, San Diego, CA) to develop a decision tree that used signs and symptoms to classify cases into 1 of 3 diagnostic categories: AOM, OME, and no effusion. Recursive partitioning uses the predictor variables (eg, signs and symptoms) to repeatedly stratify the study group into mutually exclusive subgroups in a manner that categorizes the subjects by the outcome variable. Recursive partitioning was also used to determine the relative importance of each variable in the diagnostic process. The "importance score" from the recursive partitioning analysis represents the relative improvement in the final classification attributable to each variable (with the best variable assigned a relative value of 100). For the recursive partitioning analysis, we dichotomized predictor variables as follows: each symptom (present vs absent), position (bulging vs not bulging), air-fluid level or opacification (present vs absent), mobility (normal vs absent or decreased), color (gray or pink vs yellow or white or amber or blue), and marked redness (present vs absent). We used the default settings in CART: equal misclassification costs for false-positive and -negative results, and Gini splitting criterion in the analysis.[7]

We used the decision tree from the CART analysis and information on the interrater reliability of the signs and symptoms of otitis media and our clinical judgement to create an algorithm that describes a practical approach to the diagnosis of otitis media.

We then validated this algorithm by applying it to a different dataset from a previously-conducted, large cohort study (N = 783) that examined the efficacy of influenza vaccination in preventing AOM in a representative sample of children 6 to 24 months of age.[8] This database will be referred to as the testing database. We selected one ear at random per child. We calculated the agreement between the diagnosis that would have been assigned if the algorithm had been used in the testing dataset and the diagnosis that was actually assigned by the otoscopists at the time of examination. Of the 7 otoscopists who participated in the training dataset, 3 also participated in the testing database.

RESULTS

Of the 264 children in the study, 263 children with complete data on signs and symptoms were included in the training dataset. Table 1 describes the symptoms and TM characteristics of these 263 children according to the 3 diagnostic categories. Findings that were significantly related to diagnosis ($P < .05$) in the logistic regression model are indicated. All children with bulging TMs were diagnosed as having AOM; only 4 (8%) children diagnosed as AOM had nonbulging TMs. Marked redness of the TM was found in 30% of children diagnosed as having AOM and 0% of children diagnosed as having OME or no effusion. Opacification was found in 100% of children diagnosed with AOM, 97% of children diagnosed with OME, and 5% of children with no effusion. Normal mobility was found in 100% of children with no effusion, 32% of children with OME, and none of the children with AOM. Ear tugging was found in 44%, 24%, and 7% of children with AOM, OME, and no effusion, respectively. Children with AOM were more likely than children with OME to exhibit irritability, ear pain, ear tugging, and to have bulging TMs, TM discoloration (yellow, white, amber, or blue), decreased mobility of the TM, and TM redness. When compared with children with no effusion, children