

Does This Child Have Acute Otitis Media?

Russell Rothman, MD, MPP

Thomas Owens, MD

David L. Simel, MD, MHS

ACU TE OTITIS MEDIA (AOM) IS one of the most common problems in pediatrics.

CLINICAL SCENARIO

A mother notices that her 15-month-old child has a low-grade fever and is tugging at his ears after several days of cough and runny nose. The child attends day care services and had 1 previous episode of acute otitis media (AOM) about 4 months ago. In the physician's office, he is afebrile but somewhat irritable and has clear rhinorrhea, mild posterior pharyngeal erythema, and normal chest auscultatory findings. Cerumen occludes the view of his right tympanic membrane, while the left tympanic membrane shows normal landmarks and good mobility on pneumatic otoscopy. After removal of the cerumen from his right ear, landmarks are visible on a slightly erythematous tympanic membrane. The tympanic membrane shows normal mobility on pneumatic otoscopy.

Why Is This an Important Question to Answer With the Clinical Examination?

Acute otitis media can be a difficult and controversial diagnosis to make, but studies suggest that AOM is responsible for more than 30 million clinic vis-

See also p 1608 and Patient Page.

CME available online at
www.jama.com

Context Acute otitis media (AOM) is one of the most common problems in pediatrics. An accurate diagnosis of AOM can guide proper treatment and follow-up.

Objective To systematically review the literature regarding precision and accuracy of history taking and physical examination in diagnosing AOM in children.

Data Sources We searched MEDLINE for English-language articles published from 1966 through May 2002. Bibliographies of retrieved articles and textbooks were also searched.

Study Selection We located studies with original data on the precision or accuracy of history or physical examination for AOM in children. Of 397 references initially identified, 6 met inclusion criteria for analysis.

Data Extraction Two authors independently reviewed and abstracted data to calculate likelihood ratios (LRs) for symptoms and signs.

Data Synthesis Four studies of symptoms used clinical diagnosis as the criterion standard and were limited by incorporation bias. Ear pain is the most useful symptom (positive LRs, 3.0-7.3); fever, upper respiratory tract symptoms, and irritability are less useful. One study of clinical signs used tympanocentesis as the criterion standard, and we adjusted the results to correct for verification bias. A cloudy (adjusted LR, 34; 95% confidence interval [CI], 28-42), bulging (adjusted LR, 51; 95% CI, 36-73), or distinctly immobile (adjusted LR, 31; 95% CI, 26-37) tympanic membrane on pneumatic otoscopy are the most useful signs for detecting AOM. A distinctly red tympanic membrane is also helpful (adjusted LR, 8.4; 95% CI, 6.7-11) whereas a normal color makes AOM much less likely (adjusted LR, 0.2; 95% CI, 0.19-0.21).

Conclusions Although many of the studies included in this analysis are limited by bias, a cloudy, bulging, or clearly immobile tympanic membrane is most helpful for detecting AOM. The degree of erythema may also be useful since a normal color makes otitis media unlikely whereas a distinctly red tympanic membrane increases the likelihood significantly.

JAMA. 2003;290:1633-1640

www.jama.com

its a year in the United States, at a total cost exceeding \$5 billion. This makes AOM one of the most commonly diagnosed and expensive childhood illnesses.¹⁻⁴ Studies have shown that by age 1 year, up to 60% of all children have been diagnosed as having at least 1 episode of AOM, and by age 3 years, more than 80% of children have had at least 1 episode.^{1,5} The best estimates of the prevalence of AOM are based on the National Ambulatory Medical Care Survey. In 1990, the percentage of office visits with otitis media as the principal diagnosis was 17.4% for chil-

dren aged 0 to 2 years, 18.1% for children aged 2 to 5 years, 10.5% for children aged 6 to 10 years, and

Author Affiliations: Departments of Medicine and Pediatrics, Vanderbilt University Medical Center, Nashville, Tenn (Dr Rothman); and Departments of Medicine and Pediatrics, Duke University Medical Center (Dr Owens), and Durham Veterans Affairs Medical Center and Duke University Medical Center (Dr Simel), Durham, NC.

Corresponding Author and Reprints: Russell Rothman, MD, MPP, Center for Health Services Research, Vanderbilt University Medical Center, Suite 6000, Medical Center East, Nashville, TN 37232 (e-mail: russell.rothman@vanderbilt.edu).

The Rational Clinical Examination Section Editors: David L. Simel, MD, MHS, Durham Veterans Affairs Medical Center and Duke University Medical Center, Durham, NC; Drummond Rennie, MD, Deputy Editor, JAMA.

Box. Agency for Healthcare Research and Quality Definition of Acute Otitis Media⁶

Presence of middle ear effusion, demonstrated by actual **presence of fluid** in the middle ear as diagnosed by tympanocentesis or physical presence of fluid in the external ear canal as a result of tympanic membrane perforation or indicated by limited or absent mobility of the tympanic membrane as diagnosed by pneumatic otoscopy, tympanogram, or acoustic reflectometry with or without the following:

- Opacification**, not including erythema
- Full or **bulging** tympanic membrane
- Hearing loss**

AND

Rapid onset (over a course of 48 hours) of 1 or more of the following signs or symptoms with or without anorexia, nausea, or vomiting:

- Otalgia** (or pulling of ear in an infant)
- Otorrhea**
- Irritability** in infant or toddler
- Fever**

5.2% for children aged 11 to 15 years.⁶ The most common potential **risk factors** for diagnosis of AOM include age **younger than 2 years**, **male sex**, **day care attendance**, **fall or winter season**, **exposure to cigarette smoke**, **genetic factors**, and **prior history of AOM**.^{1,7} **Breastfeeding appears to be protective.**

Making a correct diagnosis of AOM is often difficult, particularly in young children. **Distinguishing between AOM and otitis media with effusion (OME) can be particularly challenging.** Several studies have suggested that **physicians are uncertain of their diagnosis of AOM as much as 40% of the time.**⁸ This uncertainty probably contributes to **overdiagnosis**, as suggested by a study that found that if a physician believes the odds that a patient has AOM are 50% or less, 3 of 4 will still prescribe antibiotics (and that 1 of 4 prescribe antibiotics if the odds of AOM are ≤25%).⁹ Varying definitions and diagnostic criteria for AOM may also contribute to overdiagnosis. In a study by Hayden,¹⁰ 18 different criteria sets were used in 26 articles, and 165 surveyed clinicians identified 147 unique criteria. Recently, an expert panel convened by the Agency for Healthcare Research and Quality (AHRQ) released a definition requiring the presence of a

middle ear effusion and rapid onset of associated symptoms (BOX).^{6,11}

Overdiagnosis of AOM is thought to be common^{7,12,13} and contributes to increased antibiotic use and bacterial resistance. Overdiagnosis may also result in unnecessary specialty referrals and increased use of tympanostomy tubes. In addition, improper diagnosis of AOM in younger children may hinder the proper diagnosis of other underlying causes of fever or illness.

Anatomical/Physiological Origins

Genetic, infectious, immunologic, and environmental factors contribute to an underlying predisposition to ear infections.² The eustachian tube, **shorter and angled much less steeply** in children than in adults, plays a critical role by more easily allowing the **reflux of organisms from the nasopharynx** into the middle ear.² When the tube becomes congested, as it may with a viral infection in the upper respiratory tract, **negative pressure within the middle ear** causes secretions to accumulate, and this leads to the proliferation of pathogenic organisms. The bacterial agents most commonly identified in AOM include *Streptococcus pneumoniae*, *Haemophilus influenzae*, and *Moraxella catarrhalis*.⁵ **Coinfection with viruses is**

also observed in at least 30% to 40% of cases and may play a role in the virulence of symptoms, but less than 10% of AOM is caused by viruses alone.^{5,14,15}

Most ear infections resolve without any specific treatment, so the exact role of bacterial or viral pathogens remains unclear.

The buildup of infectious debris behind the tympanic membrane, along with inflammatory mediators, produces the symptoms and signs of AOM. An effusion changes the tympanic membrane's appearance from transparent to opaque and can distort or bulge the membrane, making it difficult to visualize normal landmarks (FIGURE). Erythema of the tympanic membrane is related to vascular congestion of the membrane and is thought to represent a nonspecific sign related to irritation of the drum or crying.^{2,12}

How to Elicit Symptoms and Signs

Common but usually **nonspecific symptoms** associated with the diagnosis of AOM include **fever, ear pain, ear pulling, irritability, cough, and rhinitis.** In a study of 354 children younger than 15 years (mean, 3.85 years) presenting for an acute illness, **90% of children in whom AOM was diagnosed had fever, ear pain, crying, and irritability alone or in combination,** but 72% of children without AOM also presented with these symptoms.^{12,16}

To properly examine the ear for AOM, clinicians should use a **pneumatic otoscope** to visualize the landmarks and mobility of the tympanic membrane. After the patient is placed in a restrained or other safe position, the otoscope speculum is placed into the external auditory canal. The largest-sized speculum that can comfortably fit into the canal is recommended because a small speculum can limit the visual field and potentially cause pain by irritating the bony canal.^{2,17} A study by Cavanaugh¹⁸ suggested that children older than 18 months should have a soft-tipped speculum to provide an adequate seal and prevent air leakage when performing pneumatic otoscopy. It is also important that the oto-

scope have a bright light source for visualizing the tympanic membrane. Barriga et al¹⁹ tested otoscopes in clinics and emergency departments and found that 22% were inadequate due to either a worn bulb or a weak battery source.

To properly examine the tympanic membrane, one should evaluate the position, color, landmarks, degree of translucency, and mobility. The position refers to whether the drum appears to be bulging toward the examiner (suggestive of AOM), neutral (normal), or retracted away from the examiner (observed in chronic OME). The tympanic membrane can appear red, pink, yellow (with pus behind the drum), or pearly gray or translucent (normal). Landmarks that should be visible in a normal ear include the **pars flaccida**, the **malleus**, and the **light reflex** below the umbo (Figure). With a **translucent tympanic membrane**, the outline of the **incus** can sometimes be visualized as well. An opaque drum may be a sign of infection or middle ear effusion and can result in a diminished light reflex.

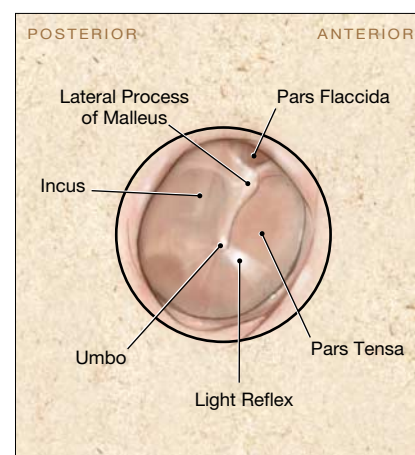
A bulb attachment can test the mobility of the drum with the slightest pressure or release. A study by Cavanaugh²⁰ suggests that **only 10 to 15 mm H₂O of positive pressure is needed to assess drum mobility**, while bulb attachments can easily create pressures of 1000 mm H₂O or more. Forceful pressing of the bulb creates excessive positive pressure that causes pain; in this instance, pain on insufflation does not diagnose infection. The correctly applied positive or negative pressure creates synchronous movement of the normal drum. An immobile drum or one with reduced mobility suggests the presence of a middle ear effusion.

The tympanic membrane can sometimes be difficult to visualize because of patient behavior or the buildup of cerumen in the ear canal. Apprehensive infants and young children can often be sufficiently restrained by having the parent seat the child in his/her lap, using his/her legs to wrap around the child's legs and arms to restrain the child's arms and head. The examiner

should hold the otoscope with part of the hand touching the child's head so that the otoscope will move with the child's head and prevent injury. In a study of 279 children with AOM, **29% required cerumen removal to make a proper diagnosis**.²¹ Studies have not adequately compared various modes for physically removing cerumen, though the most common methods cited by generalists are the use of a wire loop, a blunt cerumen curette, or gentle irrigation with room-temperature water. **One small randomized trial compared 2 ceruminolytic agents, liquid docosate sodium and triethanolamine polypeptide, applied at an emergency department visit with or without irrigation 15 minutes later. Liquid docosate sodium was highly effective compared with triethanolamine polypeptide, with successful cerumen removal in 82% of patients** (number needed to treat for benefit, 3; 95% confidence interval [CI], 2-4).²²

Other techniques used in the diagnosis of AOM include tympanocentesis, tympanometry, and acoustic reflectometry. Tympanocentesis is performed through an otoscope with a special attachment or an otomicroscope. A tuberculin syringe needle is placed into the inferior portion of the tympanic membrane to aspirate fluid.² This technique can be diagnostic and is considered the criterion standard for detecting the presence of fluid in the diagnosis of AOM. However, tympanocentesis is rarely practiced in the primary care setting, where most AOM is managed.¹² Tympanometry and acoustic reflectometry both require the use of additional medical equipment. For tympanometry, a specialized probe is inserted into the canal to form a seal and measure the amount of sound energy reflected back. The amount of energy reflected back is used to estimate tympanic membrane motility. In acoustic reflectometry, tympanic membrane motility is also estimated based on sound reflecting from the middle ear, but no seal is required. Both techniques assess tympanic membrane motility and generally have been studied only for detecting an effusion in

Figure. Tympanic Membrane Landmarks



patients with OME, not in the diagnosis of AOM.^{1,7,12,23}

METHODS

Search Strategy and Quality Review

We searched MEDLINE from January 1966 to May 2002 for English-language articles that examined the role of symptoms and signs in the diagnosis of AOM. Multiple MEDLINE search strategies were applied by a single author (T.O.) using techniques that have been used by other authors in this series.^{24,25} We also examined bibliographies of selected articles and used general and specialty textbooks.^{1,2,7,26-29} From 397 identified references, 50 complete articles were retrieved for review by 2 authors (R.R. and T.O.). Among these, we found 17 articles that specifically examined symptoms and signs that were directly relevant to the diagnosis of AOM.^{4,10,16,23,30-42} Articles on the diagnosis of persistent OME were generally excluded because most of these studies were performed by comparing detection of an effusion by pneumatic otoscopy or tympanometry with the presence of an effusion at the time of surgery for myringotomy, rather than in ambulatory settings. In addition, persistent OME is a disease with different pathophysiology and, possibly, different diagnostic characteristics than AOM.

Table 1. Studies Meeting Inclusion Criteria for Accuracy of Symptoms and Signs in Diagnosis of Acute Otitis Media

Source	Evidence Level*	No. of Patients	Age Range, y	Criterion Standard	Limitations
Symptoms					
Niemela et al, ¹⁶ 1994	4	354	1 mo-15 y	Clinical diagnosis	Majority of children examined by specialists Children had a high incidence of recurrent acute otitis media Not blinded
Heikkinen and Ruuskanen, ³⁵ 1995	4	302	0.6-4.2 y	Clinical diagnosis	Not blinded
Ingvarsson, ³⁶ 1982	4	171	0-15 y	Clinical diagnosis	Referred to otolaryngologist for otalgia Not blinded
Kontikari et al, ⁴¹ 1998	4	138	0.6-6.9 y	Clinical diagnosis	Not blinded
Signs					
Karma et al, ²³ 1989	3	2911	6 mo-2.5 y	Tympanocentesis	All examinations performed by either 1 pediatrician or 1 otolaryngologist Not blinded

*See "Methods" section of text for explanation of evidence levels.

The 17 identified articles underwent independent quality review by 2 authors (R.R. and T.O.). Quality was assessed using an established methodological filter for assessing internal validity that has been used and explained by other authors in this series.^{24,25} Each article was assigned a level of evidence (1-4) and consensus was reached by both reviewers. Tympanocentesis was considered the pathological criterion standard, but only 1 study that assessed physical examination findings used this standard.²³ We therefore also included articles that used a standardized clinical definition of AOM as a clinical criterion standard when examining articles that dealt with symptoms. Although using a clinical criterion standard was not ideal and might lead to accusations of circular reasoning, the quality of the literature for this extremely common problem left us little choice. However, we believed it was justified to examine these articles because most physicians make a diagnosis based on clinical criteria, and physicians make decisions to treat based on these criteria.

No article examined met evidence level 1 or 2, which required using an independent blind comparison of signs or symptoms against a criterion standard among consecutive patients. All articles reviewed were graded as evidence level 3 to 5, but we only retained the level 3 and 4 articles. Level 3 studies used an independent, blind comparison of symptoms to the criterion stan-

dard and nonconsecutive patients suspected to have the targeted condition. Level 4 studies had a nonindependent comparison of symptoms to the criterion standard and "grabbed" a sample of patients with the target condition and, perhaps, some healthy individuals. The excluded level 5 studies used a nonindependent comparison of symptoms to a standard of uncertain validity.

When possible, we used published raw data from the identified articles to calculate sensitivity, specificity, likelihood ratios, and 95% CIs using conventional definitions.⁴³ Likelihood ratios (LRs) indicate how much a given diagnostic test result will raise or lower the pretest probability of AOM. An LR of greater than 1.0 increases the probability that AOM is present, while an LR of less than 1.0 indicates that AOM is less probable. In general, LRs of more than 10.0 or less than 0.1 generate large and often conclusive changes in the likelihood of AOM, while LRs of 5.0 to 10.0 or 0.1 to 0.2 are less conclusive but may still be clinically useful.

For articles in which data were presented stratified by multiple age groups, we present data for all age groups combined unless otherwise noted. Pooled analyses of multiple studies were not performed because of the small number and heterogeneity of studies available. In 1 study, published data were presented of the utility of physical examination findings compared with tympanocentesis for 2 individual clini-

cians who were examining 2 separate groups of children.²³ In that study, 64.4% of children presenting with acute symptoms (such as ear pain, fever, respiratory symptoms, vomiting, or diarrhea) underwent tympanocentesis, while 38.3% of patients without acute symptoms underwent tympanocentesis. Tympanocentesis was performed in any child suspected to have a middle ear effusion on pneumatic otoscopy.

In our analysis of that study, we calculated LRs excluding patients with perforation because these patients did not undergo tympanocentesis. To correct for verification bias, we made the conservative assumption that children who did not undergo tympanocentesis had normal-appearing ears (normal color, position, or mobility).⁴⁴ Likelihood ratios were adjusted by the calculated verification fraction for each clinical sign subset (color, position, and mobility). The correction for verification bias protects against overly optimistic estimates of the examiner's ability to rule out AOM and overly pessimistic estimates of the ability to rule in AOM. Because the color of the tympanic membrane appeared to have ordinal properties (eg, normal, slightly red, distinctly red, cloudy), we described the overall accuracy of this finding by the area under the receiver operating characteristic curve.

RESULTS

From the 397 references initially identified, we found 6 articles that satisfied

inclusion criteria. This included 1 article concerning precision, 4 articles on accuracy of symptoms, and 1 article on accuracy of signs (TABLE 1).^{4,16,23,35,36,41}

Precision of Symptoms and Signs

To our knowledge, no studies concerning precision of symptoms have been published, and there are only a few studies on precision of signs. A comparison of diagnoses among practitioners would be important, especially during training, when medical students and house staff learn to interpret otoscopic findings from their instructors. Recently, Steinbach et al⁴ compared diagnoses of AOM among pediatric residents with diagnoses made by otolaryngologists. Complete examinations were only available for 43 children, but the study found only fair agreement between the residents and the otolaryngologists. Overall agreement on diagnosis of AOM between the 2 types of practitioners had a κ statistic of 0.30 (fair). κ Statistics on tympanic membrane features such as erythema, color, effusion, mobility, and position were also fair to slight ($\kappa=0.40, 0.40, 0.31, 0.21$, and 0.16 , respectively). Correlations between pediatric residents and otolaryngologists comparing tympanometry in the detection of an effusion were also fair ($\kappa=0.25$ and 0.30 , respectively).

Accuracy of Symptoms and Signs

Symptoms. Sensitivity, specificity, and positive and negative LRs derived from articles that examined the role of symptoms in the diagnosis of AOM are included in TABLE 2.^{16,35,36,41} The presence of ear pain appears to be the only symptom that may be useful in making the diagnosis of AOM. Ear pain has positive LRs of 3.0 to 7.3 but is only present in 50% to 60% of children with AOM. Using a baseline prevalence for AOM of 20% among children up to 5 years old making an acute pediatric office visit (estimated from the National Ambulatory Medical Care Survey), the presence of ear pain increases the probability of AOM to approximately 43% to 65%.

Fever is often cited as a primary symptom of AOM^{27,28} but shows variability in

Table 2. Accuracy of Symptoms

Source and Symptoms	Sensitivity, %	Specificity, %	Positive LR (95% CI)	Negative LR (95% CI)
Niemela et al, ¹⁶ 1994				
Ear pain	54	82	3.0 (2.1-4.3)	0.6 (0.5-0.7)
Ear rubbing	42	87	3.3 (2.1-5.1)	0.7 (0.6-0.8)
Fever	40	48	0.8 (0.6-1.0)	1.2 (1.0-1.5)
Cough	47	45	0.9 (0.7-1.1)	1.2 (0.9-1.4)
Rhinitis	75	43	1.3 (1.1-1.5)	0.6 (0.4-0.8)
Excessive crying	55	69	1.8 (1.4-2.3)	0.7 (0.5-0.8)
Poor appetite	36	66	1.1 (0.8-1.4)	1.0 (0.8-1.1)
Vomiting	11	89	1.0 (0.6-1.8)	1.0 (0.9-1.1)
Sore throat	13	74	0.5 (0.3-0.8)	1.2 (1.1-1.3)
Headache	9	76	0.4 (0.2-0.7)	1.2 (1.1-1.3)
Heikkinen and Ruuskanen, ³⁵ 1995				
Ear pain	60	92	7.3 (4.4-12.1)	0.4 (0.4-0.5)
Fever	69	23	0.9 (0.8-1.0)	1.4 (0.9-2.0)
Cough	84	17	1.0 (0.9-1.1)	1.0 (0.6-1.6)
Rhinitis	96	8	1.0 (1-1.1)	0.5 (0.2-1.4)
Restless sleep	64	51	1.3 (1.1-1.6)	0.7 (0.5-0.9)
Ingvarsson, ³⁶ 1982				
Ear pain	100	NA	NA	NA
Fever	79	70	2.6 (1.9-3.6)	0.3 (0.2-0.5)
Upper respiratory tract infection	96	29	1.4 (1.2-1.6)	0.3 (0.2-0.5)
Kontiohari et al, ⁴¹ 1998				
Parental suspicion of acute otitis media	70	80	3.4 (2.8-4.2)	0.4 (0.3-0.5)

Abbreviations: CI, confidence interval; LR, likelihood ratio; NA, not applicable.

usefulness. One study shows that the likelihood slightly increases with a fever, but 2 studies found no effect, with the positive LR approaching 1.0. The absence of fever seems to confer little change in the likelihood of AOM.

Kontiohari et al⁴¹ examined the ability of parents to predict whether their child had AOM. Parents were fairly accurate and showed similar ability to predict that their child did have AOM (positive LR, 3.4) and that their child did not have AOM (negative LR, 0.4). These findings are partially tempered by the fact that the physicians were not blinded to parental predictions, and this may have biased their ultimate diagnoses. We suspect that parents learn from their children's symptoms with each febrile or upper respiratory tract illness, so that more experienced parents may have better diagnostic acumen, but the impact of parental experience on their accuracy and LR of diagnosing otitis media has not been evaluated. Thus, we do not know if parents of children with frequent infections of any type are more or less able

to accurately assess ear involvement with each childhood illness episode.

A final symptom that deserves mention is ear pulling. Ear pulling has long been debated as a possible sign of AOM because parents and primary caregivers frequently observe this phenomenon.⁵ Many physicians have been taught that ear pulling is not a useful sign because children pull at their ears because "they are there." In the study by Niemela et al,¹⁶ "ear rubbing" appeared to have some predictive ability for the diagnosis of AOM (positive LR, 3.3; 95% CI, 2.1-5.1). The only other study that we know of that has addressed this symptom is a small, poorly designed but often referenced study by Baker,³⁰ who examined 100 consecutive children with a chief complaint of ear pulling and found that 20 children had ear pulling as their sole complaint while 80 children had other symptoms. Of the 20 children with ear pulling as the sole complaint, none met Baker's unspecified criteria for AOM compared with 12 of the other 80 children.

Table 3. Accuracy of Signs²³

Signs	Unadjusted Positive LR	Adjusted Positive LR (95% CI)*
Color		
Cloudy	11	34 (28-42)
Distinctly red†	2.6	8.4 (6.7-11)
Slightly red	0.4	1.4 (1.1-1.8)
Normal	0.1	0.2 (0.19-0.21)
Position		
Bulging	20	51 (36-73)
Retracted	1.3	3.5 (2.9-4.2)
Normal	0.4	0.5 (0.49-0.51)
Mobility		
Distinctly impaired	8.4	31 (26-37)
Slightly impaired	1.1	4.0 (3.4-4.7)
Normal	0.04	0.2 (0.19-0.21)

Abbreviations: CI, confidence interval; LR, likelihood ratio.

*Results reported by Karma et al²³ (1989) were calculated by combining data reported from 2 groups. Results are rounded so that precision is not overstated and results remain clinically meaningful with estimates not beyond 1 decimal point.

†Distinctly red was described qualitatively as "hemorrhagic, strongly red, or moderately red."

Any conclusions about symptoms that can be drawn from the studies in Table 2 are limited by the study designs. Two of the 4 studies^{16,36} involve "spectrum bias," in which a spectrum of patients are used who are not representative of the population as a whole. Failure to incorporate an appropriate spectrum of patients can affect the sensitivity and specificity of findings.⁴⁵⁻⁴⁷ In the 2 studies identified in this analysis, patients were often seen by specialists and had a higher incidence of recurrent AOM or chronic OME. These patients may differ from those in primary care clinics, and this can potentially impact the generalizability of the results.

Another significant design limitation in all 4 included studies is their use of a clinical diagnosis of AOM, rather than tympanocentesis, as the criterion standard. Because the diagnosis of AOM potentially requires the presence of the symptoms that are being examined, an "incorporation bias" can occur when tympanocentesis is not performed as a confirmatory test. Incorporation bias typically overestimates sensitivity and specificity (William C. Miller, MD, PhD, MPH, written communication, 2001).⁴⁶ This bias may be further exaggerated because examiners who make the di-

agnosis of AOM also elicit the history in a nonblinded fashion. The bias created by using a clinical diagnosis as the criterion standard should improve the LRs for the symptoms; if that is the case, then it is possible that very few symptoms would prove themselves independently useful in methodologically stronger studies.

Signs. TABLE 3 presents the results from the only study that has examined signs in the diagnosis of AOM.²³ The selective performance of tympanocentesis in this study created verification bias, which overestimates sensitivity and underestimates specificity and positive LRs.^{45,48} Fortunately, the investigators provided clinical examination findings for all patients, allowing us to correct for verification bias. This study suggests that a tympanic membrane that is cloudy (adjusted positive LR, 34), bulging (adjusted positive LR, 51), or distinctly immobile (adjusted positive LR, 31) is highly suggestive of AOM. In contradiction to what is often taught to physicians in training, a tympanic membrane that is distinctly red, defined as "hemorrhagic, strongly red, or moderately red" also suggests otitis media (adjusted positive LR, 8.4), while a drum that is only slightly red (adjusted positive LR, 1.4) is not very helpful. These data suggest that color of the tympanic membrane can be treated as an ordinal variable ranging from normal through redness to cloudy (Table 3), with the likelihood of AOM increasing with the intensity of redness (the area under the receiver operating characteristic curve as a measure of accuracy of tympanic membrane color is 0.88 [SE, 0.003]).

After correction for verification bias, normal color or normal mobility make otitis media much less likely (LR=0.2 for both). Given a baseline prevalence of 20% among children at an acute office visit, the probability of AOM decreases to less than 5% when the tympanic membrane is normal in either color or mobility. The independence of the findings of color, position, and mobility has not been assessed. Although it would seem that abnormalities in 2

or all 3 of these components would be more important than the finding of just 1 abnormality, we cannot quantify the impact of increasing numbers of abnormal findings.

Means of Improvement

Since AOM is so prevalent in the pediatric population, and more accurate diagnosis of AOM can potentially lead to a decrease in antibiotic use and other costs, the improvement of diagnostic skills for AOM is clearly important. This improvement can be achieved by using more standardized diagnostic criteria and by improving diagnostic skills. A survey by Rosenfeld⁸ suggested that application of the AHRQ recommended criteria for AOM could reduce the rate of diagnosis of AOM by more than 20% by excluding cases that do not have evidence of a middle ear effusion.

Tools to improve diagnostic skills include teaching otoscopes that have 2 viewing areas,⁴⁹ videotapes, mannequin models, computer- and Web-based applications, and the use of more controlled settings, such as children undergoing myringotomy procedures. The American Academy of Pediatrics, for example, supports a multimedia "virtual classroom" Web site designed to help clinicians improve their skills in the diagnosis and treatment of otitis media (<http://www.aap.org/otitismedia/www/>).

Several studies have documented that clinicians can improve their diagnostic accuracy by practicing pneumatic otoscopy in children who are scheduled to undergo myringotomy.^{37,50} In this setting, clinicians perform ear examinations prior to anesthetization and in the operating room and compare their findings with the results of myringotomy. In addition, clinicians receive feedback from skilled, previously validated otoscopists. Pichichero and Poole⁵¹ have demonstrated that videotaped pneumatoscopic examinations and infant mannequin models may be used to assess and potentially improve accuracy in the diagnosis of AOM and the performance of tympanocentesis.

Despite studies suggesting that diagnostic accuracy in AOM can be improved, current training remains poor. A recent survey by Steinbach and Sectish³ revealed that only 59% of pediatric residency programs currently provide a formal curriculum (defined as a “structured and consistent part of the residency program, not an occasional occurrence”) for training residents in the diagnosis and treatment of AOM. The formal curriculum that is provided usually consists of less than 3 didactic lectures per year, with limited assessment of resident performance.

SCENARIO RESOLUTION

This child is certainly at risk of AOM because he is in the age group in which AOM is common, he has a history of previous AOM, and he has had a preceding upper respiratory tract infection. None of his presenting symptoms are predictive of AOM. On examination, the left ear appears normal. Cerumen is correctly removed from the right ear to better visualize the drum. This drum was described by the physician as “slightly” red but with normal motility. The precision of diagnosing an ear as “slightly” red as opposed to “distinctly” red is not known; however, based on the work of Karma et al,²³ a “slightly” red tympanic membrane does not have a high enough LR to independently confirm AOM, nor does it meet standardized criteria for AOM (such as from the AHRQ). The slightly red drum may be related to irritation from the cerumen removal and is not very suggestive of AOM (probability is only 26% given a baseline prevalence of 20% and an LR of 1.4 for a slightly erythematous membrane). The normal mobility more definitively suggests that AOM is not likely in this scenario (probability would be only 5% with a baseline prevalence of 20% and an LR of 0.2).

CLINICAL BOTTOM LINE

The diagnosis of AOM can be very difficult, and studies examining this condition are somewhat limited. The studies we reviewed suggest that ear pain may be an important symptom but that

other symptoms are not reliable. Although physical examination results are limited by the existence of only 1 well-performed study, a tympanic membrane that is cloudy, bulging, or distinctly immobile is highly suggestive of AOM. The presence of a distinctly red tympanic membrane also appears useful, although not as important as cloudiness of the tympanic membrane. Children with normal color and mobility of their tympanic membranes are much less likely to have otitis media than those with abnormalities. The discovery that erythema may be useful contradicts the instruction many clinicians receive and, therefore, deserves further study.

Many of the studies on the accurate diagnosis of AOM are limited by spectrum bias that affects generalizability and by lack of an acceptable criterion standard. These limitations are difficult to overcome. For example, it would be difficult to design a study in which tympanocentesis can be performed in children with a low suspicion for AOM. On the other hand, including data on all patients, as in the study by Karma et al²³ (Table 1), allows investigators to conduct practical studies with correction for verification bias that improves their validity. Future studies can be improved by using a general population of at-risk children, more standardized diagnostic criteria, and independent examinations by blinded examiners. Studies also need to assess the precision and accuracy of characterizing physical findings, as Karma et al have done, in an ordinal rather than dichotomous manner (eg, describing color as normal, slightly red, or distinctly red rather than just normal vs red). Because we do not know the relative importance of multiple abnormal findings vs 1 abnormal finding, an assessment of the independent importance of color, position, and mobility would allow clinicians to properly weigh the relative importance of these findings and, perhaps, lead to the development of a grading scheme that permits more accurate estimates of the likelihood of otitis media.

Despite the limitations of the current studies, we recommend that pneu-

matic otoscopy should be performed when considering otitis media to assess not just drum color and appearance but also mobility. Clinicians need to appreciate the amount of uncertainty in the diagnosis of AOM and how this may contribute to their decision to treat or not treat with antibiotics. Standard criteria for AOM, such as the AHRQ guidelines, which include the detection of a middle ear effusion, should also be considered, since these can result in more uniform diagnoses and hopefully decrease the rate of overdiagnosis. The use of training videos and other techniques may improve physical examination performance, but this will be more helpful after more studies have established the relationship between signs and the diagnosis of AOM.

Author Contributions: Study concept and design: Rothman, Owens, Simel.

Acquisition of data: Rothman, Owens.

Analysis and interpretation of data: Rothman, Owens, Simel.

Drafting of the manuscript: Rothman, Simel.

Critical revision of the manuscript for important intellectual content: Rothman, Owens, Simel.

Statistical expertise: Rothman, Simel.

Administrative, technical, or material support: Owens.

Study supervision: Simel.

Disclaimer: Dr Simel was not involved in the editorial review or decision to publish this article.

Acknowledgment: We thank Peter Blomgren, MD, Amelia Drake, MD, David Witsell, MD, MHS, and Michael Steiner, MD, for their helpful reviews of an early version of the manuscript.

REFERENCES

1. Rosenfeld R, Bluestone C. *Evidence Based Otitis Media*. St Louis, Mo: BC Decker Inc; 1999.
2. Bluestone C, Klein J. *Otitis Media in Infants and Children*. 3rd ed. New York, NY: WB Saunders; 2001.
3. Steinbach WJ, Sectish TC. Pediatric resident training in the diagnosis and treatment of acute otitis media. *Pediatrics*. 2002;109:404-408.
4. Steinbach WJ, Sectish TC, Benjamin DK Jr, Chang KW, Messner AH. Pediatric residents' clinical diagnostic accuracy of otitis media. *Pediatrics*. 2002;109:993-998.
5. Ruuskanen O, Heikkinen T. Otitis media: etiology and diagnosis. *Pediatr Infect Dis J*. 1994;13(1 suppl 1):S23-S26.
6. Marcy M. *Management of Acute Otitis Media*. Rockville, Md: Agency for Healthcare Research and Quality; May 2001:1-159.
7. Klein JO. Epidemiology; pathogenesis; diagnosis and clinical course of acute otitis media. Available at: <http://www.uptodate.com>. Subscription required. Accessed June 14, 2002.
8. Rosenfeld RM. Diagnostic certainty for acute otitis media. *Int J Pediatr Otorhinolaryngol*. 2002;64:89-95.
9. Gonzalez-Vallejo C, Sorum PC, Stewart TR, Chessare JB, Mumpower JL. Physicians' diagnostic judgments and treatment decisions for acute otitis

- media in children. *Med Decis Making*. 1998;18:149-162.
10. Hayden GF. Acute suppurative otitis media in children: diversity of clinical diagnostic criteria. *Clin Pediatr (Phila)*. 1981;20:99-104.
 11. Chan LS, Takata GS, Shekelle P, Morton SC, Mason W, Marcy SM. Evidence assessment of management of acute otitis media, II: research gaps and priorities for future research. *Pediatrics*. 2001;108:248-254.
 12. Pichichero ME. Acute otitis media, I: improving diagnostic accuracy. *Am Fam Physician*. 2000;61:2051-2056.
 13. Weiss JC, Yates GR, Quinn LD. Acute otitis media: making an accurate diagnosis. *Am Fam Physician*. 1996;53:1200-1206.
 14. Arola M, Ruuskanen O, Ziegler T, et al. Clinical role of respiratory virus infection in acute otitis media. *Pediatrics*. 1990;86:848-855.
 15. Pichichero ME. Acute otitis media, II: treatment in an era of increasing antibiotic resistance. *Am Fam Physician*. 2000;61:2410-2416.
 16. Niemela M, Uhari M, Jounio-Ervasti K, Luotonen J, Alho OP, Vierimaa E. Lack of specific symptomatology in children with acute otitis media. *Pediatr Infect Dis J*. 1994;13:765-768.
 17. Pelton SI. Otoscopy for the diagnosis of otitis media. *Pediatr Infect Dis J*. 1998;17:540-543.
 18. Cavanaugh RM Jr. Obtaining a seal with otic specula: must we rely on an air of uncertainty? *Pediatrics*. 1991;87:114-116.
 19. Barriga F, Schwartz RH, Hayden GF. Adequate illumination for otoscopy: variations due to power source, bulb, and head and speculum design. *AJDC*. 1986;140:1237-1240.
 20. Cavanaugh RM Jr. Pediatricians and the pneumatic otoscope: are we playing it by ear? *Pediatrics*. 1989;84:362-364.
 21. Schwartz RH, Rodriguez WJ, McAvaney W, Grundfast KM. Cerumen removal: how necessary is it to diagnose acute otitis media? *AJDC*. 1983;137:1064-1065.
 22. Singer AJ, Sauris E, Viccellio AW. Ceruminolytic effects of docusate sodium: a randomized, controlled trial. *Ann Emerg Med*. 2000;36:228-232.
 23. Karma PH, Penttila MA, Sipila MM, Kataja MJ. Otoscopic diagnosis of middle ear effusion in acute and non-acute otitis media, I: the value of different otoscopic findings. *Int J Pediatr Otorhinolaryngol*. 1989;17:37-49.
 24. Whited JD, Grichnik JM. Does this patient have a mole or a melanoma? *JAMA*. 1998;279:696-701.
 25. Metlay JP, Kapoor WN, Fine MJ. Does this patient have community-acquired pneumonia? diagnosing pneumonia by history and physical examination. *JAMA*. 1997;278:1440-1445.
 26. Zitelli BJ, Davis HW. *Atlas of Pediatric Physical Diagnosis*. 3rd ed. St Louis, Mo: Mosby-Wolfe; 1997.
 27. Behrman RE, Kliegman R, Jenson HB, Nelson WE. *Nelson Textbook of Pediatrics*. 16th ed. Philadelphia, Pa: WB Saunders Co; 2000.
 28. Goroll AH, Mulley AG. *Primary Care Medicine: Office Evaluation and Management of the Adult Patient*. 4th ed. Philadelphia, Pa: Lippincott Williams & Wilkins; 2000.
 29. Noble J, Greene HL. *Textbook of Primary Care Medicine*. 3rd ed. St Louis, Mo: Mosby; 2001.
 30. Baker RB. Is ear pulling associated with ear infection? *Pediatrics*. 1992;90:1006-1007.
 31. Bluestone CD, Cantekin EI. Design factors in the characterization and identification of otitis media and certain related conditions. *Ann Otol Rhinol Laryngol Suppl*. 1979;88(5 pt 2 suppl 60):13-28.
 32. Cantekin EI, Bluestone CD, Fria TJ, Stool SE, Beery QC, Sabo DL. Identification of otitis media with effusion in children. *Ann Otol Rhinol Laryngol Suppl*. 1980;89(3 pt 2):190-195.
 33. Finitzo T, Friel-Patti S, Chinn K, Brown O. Tympanometry and otoscopy prior to myringotomy: issues in diagnosis of otitis media. *Int J Pediatr Otorhinolaryngol*. 1992;24:101-110.
 34. Hayden GF, Schwartz RH. Characteristics of earache among children with acute otitis media. *AJDC*. 1985;139:721-723.
 35. Heikkinen T, Ruuskanen O. Signs and symptoms predicting acute otitis media. *Arch Pediatr Adolesc Med*. 1995;149:26-29.
 36. Ingvarsson L. Acute otalgia in children—findings and diagnosis. *Acta Paediatr Scand*. 1982;71:705-710.
 37. Kaleida PH, Stool SE. Assessment of otoscopists' accuracy regarding middle-ear effusion: otoscopic validation. *AJDC*. 1992;146:433-435.
 38. Mains BT, Toner JG. Pneumatic otoscopy: study of inter-observer variability. *J Laryngol Otol*. 1989;103:1134-1135.
 39. Pukander J. Clinical features of acute otitis media among children. *Acta Otolaryngol*. 1983;95:117-122.
 40. Toner JG, Mains B. Pneumatic otoscopy and tympanometry in the detection of middle ear effusion. *Clin Otolaryngol*. 1990;15:121-123.
 41. Kontiokari T, Koivunen P, Niemela M, Pokka T, Uhari M. Symptoms of acute otitis media. *Pediatr Infect Dis J*. 1998;17:676-679.
 42. Gimsing S, Bergholtz LM. Otoscopy compared with tympanometry. *J Laryngol Otol*. 1983;97:587-591.
 43. Simel DL, Samsa GP, Matchar DB. Likelihood ratios with confidence: sample size estimation for diagnostic test studies. *J Clin Epidemiol*. 1991;44:763-770.
 44. Simel DL, Halvorsen RA Jr, Feussner JR. Quantitating bedside diagnosis: clinical evaluation of ascites. *J Gen Intern Med*. 1988;3:423-428.
 45. Begg CB. Biases in the assessment of diagnostic tests. *Stat Med*. 1987;6:411-423.
 46. Ransohoff DF, Feinstein AR. Problems of spectrum and bias in evaluating the efficacy of diagnostic tests. *N Engl J Med*. 1978;299:926-930.
 47. Mulherin SA, Miller WC. Spectrum bias or spectrum effect? subgroup variation in diagnostic test evaluation. *Ann Intern Med*. 2002;137:598-602.
 48. Begg CB, Greenes RA. Assessment of diagnostic tests when disease verification is subject to selection bias. *Biometrics*. 1983;39:207-215.
 49. Teele DW, Klein JO. Use of a teaching pneumatic otoscope. *JAMA*. 1979;242:2664-2665.
 50. Silva AB, Hotelling AJ. A protocol for otolaryngology-head and neck resident training in pneumatic otoscopy. *Int J Pediatr Otorhinolaryngol*. 1997;40:125-131.
 51. Pichichero ME, Poole MD. Assessing diagnostic accuracy and tympanocentesis skills in the management of otitis media. *Arch Pediatr Adolesc Med*. 2001;155:1137-1142.