Otoscopic Signs of Otitis Media

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Background: Lack of agreed-upon diagnostic criteria for acute otitis media (AOM) has led to inconsistencies in clinical care, misleading research results, and misguided educational efforts. The objective of this study was to examine findings that expert otoscopists use when diagnosing AOM.

Methods: A group of experienced otoscopists examined 783 children presenting for primary care. In addition, endoscopic still images of the tympanic membranes (TMs) were obtained. A random sample of 135 of these images was sent for review to a group of 7 independent physicians who were expert otoscopists. We examined the findings that both groups of observers used to distinguish between AOM, otitis media with effusion (OME), and no effusion.

Results: Among both groups of observers, bulging of the TM was the finding judged best to differentiate AOM from OME: 96% of ears and 93% of ear image evaluations assigned a diagnosis of AOM by members of the 2 groups were reported as showing bulging of the TM, compared with 0% and 3%, respectively, of ears and ear image evaluations assigned a diagnosis of OME. Opacification of the TM was the finding that best differentiated OME from no effusion.

Conclusions: We describe findings that are used by experienced otoscopists to diagnose AOM and OME. The findings point to the advisability under most circumstances of restricting antimicrobial treatment for AOM to children who have TM bulging, and they call into question clinical trials of the treatment of AOM in which TM bulging has not been a required element for participation.

Key Words: acute otitis media, signs and symptoms, reliability, physical examination, otitis media with effusion, pneumatic otoscopy

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More than a century ago, standard textbooks of pediatrics[1] and of otology[2] described bulging of the tympanic membrane (TM) as the most characteristic diagnostic feature of acute otitis media (AOM) in infants and young children. Often since then, the prominence of TM bulging as the hallmark sign of AOM has been restated both in textbooks[3,4] and in various reports and reviews.[5–10] Nonetheless, in many clinical trials testing the efficacy of antimicrobial treatment for children with AOM, the presence of TM bulging has not been included among the criteria for trial eligibility. Therefore, among the 9 trials included in the most recent Cochrane Collaboration review of the subject,[11] 8 different sets of diagnostic criteria were used, only one of which required bulging of the TM for inclusion in the trial. This use of differing diagnostic criteria among studies has resulted in inconsistent and misleading conclusions regarding the treatment of AOM.[7,12,13] Accordingly in clinical practice, the danger exists that the use of nonstringent diagnostic criteria for AOM results in overdiagnosis, and in particular, confusion of otitis media with effusion (OME) as AOM, which may lead, in turn, to inappropriate use of antimicrobials.

Variability in the criteria used in diagnosing AOM is not a new problem. From a survey of 165 pediatricians, Hayden reported in 1981 that 147 different combinations of signs and symptoms were endorsed as criteria for diagnosis.[14] However, no ideal criterion standards exist against which diagnostic criteria for AOM can be validated. However, for this purpose, the use of findings from tympanocentesis and culture is problematic for 2 reasons. First, because tympanocentesis is invasive, ethical considerations would seem to dictate that it be performed only on children whose TMs are bulging. Under such circumstances, the procedure could provide information concerning the sensitivity and positive predictive value of TM bulging, but not concerning its specificity or negative predictive value, or concerning the test characteristics of any other individual TM finding. Second, although the presence or absence of middle-ear effusion may be confirmed by tympanocentesis, cultures of middle-ear fluid from children with AOM may not always yield middle-ear bacterial pathogens[15–19]—presumably because the etiology in at least some of the cases is viral—whereas bacterial pathogens may sometimes be recovered from children with OME.[15–18,20] The use of antibiotics before tympanocentesis or poor technique may also result in false-negative cultures. Because of these problems, only one study to date has used tympanocentesis to assess diagnostic accuracy of individual TM findings.[21] Although the authors demonstrated that cloudiness, bulging, and decreased mobility of the TM were associated with the presence of middle-ear fluid, because the middle-ear fluid was not cultured, this study cannot be used to determine which findings are helpful in the diagnosis of OME and which ones are helpful in the diagnosis of AOM.

The lack of a practical criterion standard should not necessarily preclude development of sound diagnostic criteria. For example, as is the case with many other conditions for which there is no practical criterion standard, recommendations of experts can be used in the development of diagnostic criteria.[22,23] Such an approach poses problems; however, experts may not agree on the criteria that should be used, and they may disagree about the relative importance of various signs and symptoms in arriving at a diagnosis.[9,24,25] An alternate strategy might be to examine which clinical information experienced otoscopists actually use in prac-

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tice when diagnosing otitis media. In our experience, although there may be considerable disagreement on the diagnostic criteria for AOM, skilled otoscopists, when presented with the same TM image, often agree on the diagnosis. By empirically examining the diagnostic process among experts, one can determine findings that the experts use in diagnosing AOM and OME. A reasonable estimate of the validity of the diagnostic approach of one group of expert otoscopists could be arrived at by determining whether that group's diagnoses conformed to the diagnoses made by an independent panel of expert otoscopists. If results in the 2 groups proved to be the same or closely similar, one might infer that the diagnoses overall were valid. In this manuscript, we describe findings that 2 groups of experienced otoscopists used to diagnose AOM and OME.

METHODS

The study consisted of 2 parts.

Part 1

In Part 1, we analyzed data from a previously conducted cohort study at the Children's Hospital of Pittsburgh that examined the efficacy of influenza vaccination in preventing AOM.[24] A total of 783 children aged 6 to 24 months presenting for primary care were enrolled and followed for an entire respiratory season by 4 experienced otoscopists using a pneumatic otoscope. All these otoscopists had previously completed a training program in which their diagnoses had been validated against findings at myringotomy.[26] At each visit, the examining otoscopist recorded information regarding a history of otalgia, and findings concerning the following TM characteristics: color (amber, blue, gray, pink, red, white, yellow), translucency (translucent, semi-opaque, opaque), position (neutral, retracted, bulging), mobility (decreased, not decreased), and areas of marked redness, as distinct from mild or moderate redness (present, absent). In addition, endoscopic images of the TM were obtained at most visits. We examined the univariate association between individual TM findings and diagnosis using logistic regression. Analysis was based on one ear, randomly selected, from each child.

Part 2

In Part 2, we randomly selected 135 endoscopic still TM images from the influenza vaccine study in a ratio of 2:2:1 for AOM: OME: no effusion. We excluded out-of-focus images, those showing large amounts of obstructing cerumen. In 51 (38%) of the 135 images selected, hair and/or cerumen obscured a small portion of the TM. Additionally, the color of the TM as shown in the included images did not always faithfully reproduce the color as viewed otoscopically. These images were then presented for evaluation to a group of 7 physicians (2 otolaryngologists [J.H., H.H.] and 5 pediatricians [O.R., M.P., P.K., R.S., C.H.]) from various areas in the United States, who were not involved in the study in Part 1, and whom we considered expert otoscopists on the basis of their clinical and/or research experience with children with AOM. To determine whether any members of the group were color-blind, each completed an online test. To control for differences in color rendition between computers, we mailed color-calibrated laptops to each member. We used color calibration software with an external colorimeter (Spyder2 Suite, Datacolor, Lawrencville, NJ) to ensure that the color of TM images remained uniform. For each of the 135 images, we asked the members of this group to assess each of the TM characteristics, other than mobility, assessed by actual otoscopy in Part 1. The data collection forms in Part 2 differed from those in Part 1 in 2 regards: (*a*) in Part 2, physicians were asked to identify the predominant color of the TM (only one choice was allowed), whereas otoscopists in Part 1 could have selected more than one color, and (*b*) in Part 2, in addition to asking about translucency, we also asked about the presence or absence of visible air-fluid levels or bubbles. For the purpose of the analysis, the TM was also characterized as opaque if air-fluid levels or bubbles were described or if the TM was described as semi-opaque. We then asked each physician to assign a diagnosis of AOM, OME, or no effusion to each image. We conducted univariate analysis using the methods described in Part 1.

Initially, we did not disclose information regarding otalgia (present or absent) or the degree of TM mobility (normal, decreased, or absent) that had been found in each child in Part 1. After the otoscopists committed to a diagnosis; however, we provided that information and asked whether they wished to change their diagnosis. If they wished to do so, we asked whether the change was as a result of obtaining the information about either otalgia or TM mobility or both.

We assessed inter-rater agreement concerning TM findings by comparing each observer's assessments with each other observer's assessments, using kappa and weighted kappa statistics.[27]

RESULTS

Part 1

Table 1 shows the TM findings according to middle-ear diagnosis in the 783 children (for one ear, randomly selected, from each child), as reported by the otoscopists in the influenza vaccine study. Table 2 shows the individual TM findings in combination with each other. Bulging, opacification, discoloration, marked redness, and decreased mobility were all most commonly described in ears diagnosed as having AOM. Bulging was reported in 96%, and marked redness in 20%, of ears diagnosed with AOM; neither finding was reported in any ears diagnosed with OME or with no effusion. In ears diagnosed with OME, opacification, discoloration, decreased mobility, and retraction were reported in 98%, 79%, 69%, and 37%, respectively; corresponding values in ears diagnosed with no effusion were 0.5%, 0%, 0.2%, and 2%,

TABLE 1. Tympanic Membrane Findings According to Middle-ear Diagnosis in 783 Children, as Reported by the Otoscopists Participating in Part 1*

Tympanic Membrane Findings	Middle-ear Diagnosis No. (%) Ears		
	AOM n = 71	OME n = 131	No Effusion n = 581
Position†			
Bulging	68 (96)	0	0
Neutral	3 (4)	82 (63)	569 (98)
Retracted	0	49 (37)	12 (2)
Opaque‡			
Yes	71 (100)	129 (98)	3 (0.5)
No	0	2 (2)	578 (99.5)
Color†‡			
Gray or pink	7 (10)	28 (21)	581 (100)
White or yellow	64 (90)	83 (63)	0
Amber or blue	0	18 (14)	0
>2 colors	0	2 (2)	0
Marked redness†			
Yes	14 (20)	0	0
No	57 (80)	131 (100)	581 (100)
Decreased mobility†‡			
Yes	70 (99)	90 (69)	1 (0.2)
No	1 (1)	41 (31)	580 (99.8)

*One TM per child selected at random.
†AOM versus OME comparison on univariate analysis; $P < 0.05$.
‡OME versus no effusion comparison on univariate analysis; $P < 0.05$.

TABLE 2. Combinations of Tympanic Membrane Findings According to Middle-ear Diagnosis in 783 Children, as Reported by the Otoscopists Participating in Part 1*

Tympanic Membrane Findings					Middle-ear Diagnosis No. (%) Ears		
Marked Redness	Bulging	Opaque	Discolored†	Decreased Mobility	AOM n = 71	OME n = 131	No Effusion n = 581
No	No	No	No	No	—	1 (1)	578 (99.5)
			Yes	Yes	—	1 (1)	—
		Yes	No	No	—	11 (8)	2 (0.3)
				Yes	2 (3)	16 (12)	1 (0.2)
			Yes	No	—	29 (22)	—
				Yes	1 (1.5)	73 (56)	—
	Yes	Yes	No	Yes	3 (4)	—	—
			Yes	No	1 (1.5)	—	—
				Yes	50 (70)	—	—
Yes	Yes	Yes	No	Yes	2 (3)	—	—
			Yes	Yes	12 (17)	—	—

*Combinations that were not found are indicated by a dash in the table.
†Not gray or pink.

TABLE 3. Inter-rater Reliability for Selected Characteristics of the Tympanic Membrane Among the Physicians Participating in Part 2

Tympanic Membrane Characteristic	Degree of Agreement (Kappa*)		
	Mean	Minimum	Maximum
Position	0.55	0.35	0.80
Opacification	0.56	0.41	0.67
Fluid level	0.50	0.14	0.70
Predominant color	0.33	0.11	0.54
Marked redness	0.32	0.10	0.53

*Kappa scores can range from −1 (perfect disagreement) to +1 (perfect agreement), with a value of 0 indicating agreement equal to chance.

TABLE 4. Tympanic Membrane Findings According to Middle-ear Diagnosis in 945 Image Evaluations, as Reported by the Physicians Participating in Part 2*

Tympanic Membrane Findings	Middle-ear Diagnosis No. (%) Image Evaluations		
	AOM n = 328	OME n = 406	No Effusion n = 211
Position†			
Bulging	306 (93)	13 (3)	1 (0.5)
Neutral	11 (3)	158 (39)	162 (77)
Retracted	11 (3)	235 (58)	48 (23)
Opaque or air-fluid level(s)‡			
Yes	328 (100)	392 (97)	33 (16)
No	0 (0)	14 (3)	178 (84)
Predominant color†‡			
Gray or pink	71 (22)	168 (41)	161(76)
White or yellow	211 (64)	115 (28)	2 (1)
Amber or blue	15 (5)	116 (29)	46 (22)
Red	31 (9)	7 (2)	2 (1)
Marked redness†			
Yes	192 (58)	89 (22)	27 (13)
No	136 (42)	317 (78)	184 (87)

*135 images were viewed independently by each of 7 otoscopists; thus 945 assessments were made.
†AOM versus OME comparison on univariate analysis; $P < 0.05$.
‡OME versus no effusion comparison on univariate analysis; $P < 0.05$.

respectively. Marked redness was a very uncommon finding being noted in only 2% (14 of 783) of children. Marked redness in the absence of bulging was not observed in these children.

Part 2

The 7 physicians participating in Part 2 of the study had been in practice for a mean of 32 years; none was functionally colorblind. Each reported using pneumatic otoscopy "all the time," 3 performed tympanocentesis regularly, and 5 reported having used otoendoscopes.

Table 3 shows inter-rater reliability values for each finding as measured by the kappa statistic. Inter-rater reliability was moderate regarding position (mean kappa, 0.55) and opacification (mean kappa, 0.56), but poor regarding color and marked redness.

Table 4 shows the TM findings according to middle-ear diagnosis in the 945 image evaluations (135 images, each viewed by 7 physicians) as reported by these physicians. Table 5 shows the individual TM findings in combination with each other. Findings were generally similar to those in Part 1, with 2 exceptions: overlap in findings between middle-ear conditions was slightly greater than in Part 1; and marked redness, which in Part 1 had been described only in ears diagnosed otoscopically as having AOM, was described in Part 2 in appreciable numbers of image evaluations resulting in diagnoses of either OME or no effusion. As in Part 1, bulging, opacification, discoloration, marked redness, and decreased mobility were all most commonly described in image evaluations resulting in a diagnosis of AOM. Bulging was reported in 93% of image evaluations resulting in a diagnosis of AOM, in 3% of image evaluations resulting in a diagnosis of OME, and in 0.5% of image evaluations resulting in a diagnosis of no effusion. Among image evaluations resulting in a diagnosis of OME, opacification, discoloration, retraction, and marked redness were reported in 97%, 57%, 58%, and 22%, respectively. Corresponding values among image evaluations resulting in a diagnosis of no effusion were 16%, 23%, 23%, and 13%, respectively. Marked redness as an isolated finding, in the absence of other abnormalities, was reported in only 13 image evaluations; each of these resulted in a diagnosis of no effusion. In 114 additional image evaluations, in which marked redness was reported in association with other abnormalities, but not with bulging, resulted in diagnoses of either OME or no effusion in 87%.

For 120 of the 135 images used in Part 2 (88.9%; 95% confidence interval, 84%–94%), the diagnosis made by the majority of physicians agreed with the diagnosis that had been made by

TABLE 5. Combinations of Tympanic Membrane Findings According to Middle-ear Diagnosis in 945 Image Evaluations, as Reported by the Physicians Participating in Part 2[*†]

Tympanic Membrane Findings				Middle-ear Diagnosis No. (%) Image Evaluations		
Marked Redness	Bulging	Opaque	Discolored[‡]	AOM n = 328	OME n = 406	No Effusion n = 211
No	No	No	No	—	7 (1.7)	126 (59.7)
			Yes	—	6 (1.5)	33 (15.6)
		Yes	No	1 (0.3)	116 (28.6)	17 (8.1)
			Yes	6 (1.8)	178 (43.8)	8 (3.8)
	Yes	Yes	No	31 (9.5)	1 (0.2)	—
			Yes	98 (29.9)	9 (2.2)	—
Yes	No	No	No	—	—	13 (6.2)
			Yes	—	1 (0.2)	6 (2.8)
		Yes	No	4 (1.2)	43 (10.6)	4 (1.9)
			Yes	11 (3.3)	42 (10.3)	3 (1.4)
	Yes	Yes	No	35 (10.7)	1 (0.2)	1 (0.5)
			Yes	142 (43.3)	2 (0.5)	—

*Combinations that were not found are indicated by a dash in the table.
†135 images were viewed independently by each of 7 otoscopists; thus 945 evaluations were made.
‡Not gray or pink.

the examining otoscopist in Part 1, despite the facts that physicians in Part 2 had no information about the patient's symptoms or TM mobility, and that in a some images as noted above, hair and/or cerumen obscured parts of the TM.

Providing the physicians in Part 2 with information about otalgia and TM mobility led to the following changes in their diagnoses: Learning of the presence of otalgia led to a change in diagnosis from OME to AOM in 7 instances (involving 3 images and 5 physicians, 10% of all cases with otalgia) and of the absence of otalgia, to a change in diagnosis from AOM to OME in 7 instances (involving 7 images and 2 physicians, 0.8% of cases with no otalgia). In no instance did the information about otalgia alone led to a change in diagnosis from no effusion to AOM or vice versa. Learning that TM mobility was decreased or absent led to a change in diagnosis in 29 instances (4.9% of cases with decreased or absent mobility): from no effusion to OME in 27 instances (involving 19 images and 6 physicians) and from no effusion to AOM in one instance and from AOM to OME in one instance. Learning that TM mobility was normal led to a change in diagnosis in 14 instances (3.9% of cases with normal TM mobility): from OME to no effusion in 13 instances (involving 13 images and 4 physicians), and from AOM to no effusion in one instance.

DISCUSSION

We have shown that a large number of experienced clinicians from disparate regions of the United States, representing both pediatric and otolaryngologic practice, and all generally considered expert otoscopists, independently adhere to classic descriptions of the requisite criteria for diagnosing AOM. This has been observed despite widespread departure from those criteria as manifested in much of the relevant research literature during recent decades.[28] Specifically, the clinicians whose diagnoses we examined, rely on the presence of bulging of the TM as pathognomonic of AOM, and rarely diagnose AOM in its absence, even when other TM abnormalities such as discoloration, opacification, and impaired mobility are present. The presence of moderate agreement between experts on the position of the TM is encouraging. Again in conformance with classic teaching, the clinicians more or less uniformly considered these latter abnormalities, when they occur (usually together) in the absence of bulging, as indicative of the presence of OME. In a few instances, however, when these abnormalities suggested the presence of OME, either the additional presence of marked redness or learning of a history of otalgia occasioned a change in diagnosis from OME to AOM.

Although the appearance of intense redness before the appearance bulging has been described,[3,6] our findings suggest that this is an unreliable indicator of AOM for several reasons. First, this finding was very uncommon in this study. In Part 1, marked redness of the TM in the absence of bulging was not observed. In Part 2, perceived redness of some of the images may have been a product of the photographic process rather than a reflection of TM color as observed otoscopically. Nevertheless, marked redness in the absence of bulging was noted in only 15 images diagnosed as AOM (5% of all AOM cases). Most images (87%) with marked redness reported in association with other abnormalities, but not with bulging, were diagnosed as OME or no effusion. Finally, the relatively low inter-rater reliability of this finding limits its use as a diagnostic sign.

Previous reports have called attention to the importance of differentiating between AOM and OME in clinical decision-making for individual children, where the question is whether antimicrobial treatment is appropriate, and in interpreting the results of clinical trials, where the question is the degree of effectiveness of antimicrobial treatment.[7,12,13] In reaffirming long-established diagnostic verities, the present findings underscore the importance of TM bulging as a telltale and virtually invariable finding in children with AOM. Two conclusions follow: that in acutely ill children with TM abnormalities, antimicrobial treatment should generally be reserved for children who have demonstrable TM bulging; and that clinical trials of antimicrobial treatment of AOM must be considered suspect if TM bulging has not been a required element for participation.

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