

Assessing Diagnostic Accuracy and Tympanocentesis Skills in the Management of Otitis Media

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Background: The distinction between acute suppurative otitis media (AOM) and otitis media with effusion (OME) is important for antibiotic treatment decisions. Tympanocentesis may be useful in the diagnosis of AOM in selected patients.

Objectives: To assess physician accuracy in diagnosing AOM and OME from physical examination findings and technical competence in performing tympanocentesis.

Design and Subjects: Five hundred fourteen pediatricians and 188 otolaryngologists viewed 9 different videotaped pneumatic otoscopic examinations of tympanic membranes during a continuing medical education course. Diagnostic differentiation of AOM, OME, and a normal tympanic membrane was ascertained. An infant mannequin model was used to assess the technical proficiency of performing tympanocentesis on artificial tympanic membranes.

Results: Overall, the average correct diagnosis by pediatricians was 50% (range, 25%-73%) and by otolaryngologists was 73% (range, 48%-88%). Pediatricians and otolaryngologists correctly recognized the absence of normality 89% to 100% and 93% to 100% of the time, respectively, but overdiagnosed AOM in 7% to 53% (mean, 27%) and in 3% to 23% (mean, 10%) of examinations. Performance of tympanocentesis was optimally performed by 89% of otolaryngologists and by 83% of pediatricians.

Conclusions: The use of video-presented examinations to assess diagnostic ability suggests that AOM and OME may be misdiagnosed often. Interactive continuing medical education courses with simulation technology may enhance skills and improve diagnostic accuracy and treatment paradigms.

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ANTIBIOTICS are indicated for acute suppurative otitis media (AOM) but may be appropriately deferred for children with acute otitis media with effusion (OME) in agreement with recommendations by the US Agency for Healthcare Policy and Research.¹ The distinction is essential for management decision making. In both AOM and OME, fluid collects in the middle ear space and the mobility of

moniae Therapeutic Working Group convened by the Centers for Disease Control and Prevention (Atlanta, Ga).² The objective of the group was to provide consensus recommendations for the management of AOM. The group stated:

... diagnostic tympanocentesis with culture and susceptibility testing of isolates, although difficult to achieve in most practice settings, may be necessary to guide the choice of therapy in difficult AOM cases ... Although logarithmic delineated choices of broad spectrum antibiotics eg multiple shots of ceftriaxone or high-dose amoxicillin/clavulanate may be as effective as a culture-directed therapy approach for most patients ... obtaining a culture may be particularly important if a child has recently received several courses of antimicrobial therapy and is therefore more likely to harbor a multiply resistant strain ... In an era of increasing antimicrobial resistance, clinicians treating children with AOM should consider developing the capacity to perform tympanocentesis themselves or establish a ready referral mechanism to a clinician with this capacity.²

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the tympanic membrane (TM) may be diminished with pneumatic otoscopy examination. The TMs of patients with AOM are under positive (full or bulging) pressure while the TMs of patients with OME are under negative pressure (retracted) or no pressure (neutral position). Patients with OME are said to have an absence of symptoms (other than reduced hearing) although some may experience mild otalgia.

In January 1999 a report was issued from the drug-resistant *Streptococcus pneu-*

Other authorities have advocated tympanocentesis for the child who is

METHODS

An accredited 3½-hour continuing medical education workshop titled "Improving Outcomes in Otitis Media," organized by Outcomes Management Educational Workshops (Boynton Beach, Fla), was conducted in Rochester, NY. The course consisted of 3 components: improving diagnostic accuracy (1 hour); improving familiarity with otitis media diagnostic tests, ie, tympanometry, acoustic reflexometry, audiometry, and tympanocentesis training (1½ hours); and judicious antibiotic selection strategies (1 hour). To improve diagnosis skills, participants were shown 30-second video clips of TMs projected on a large screen. Two example examinations were shown first: (1) a normal TM (translucent, slightly gray, fully mobile on pneumatic otoscopy, no evidence of middle ear effusion) and (2) a typical TM from a patient with AOM (bulging, red, opaque, diminished mobility on pneumatic otoscopy, and middle ear effusion). The distinguishing features of a normal examination compared with AOM and OME (gray, retracted, or neutral position, diminished mobility, and middle ear effusion) were reviewed. Then, 9 sequential video clips of TMs were shown. The video footage included a 10-second interval in still frame, 10 seconds with pneumatic otoscopy, and 10 seconds in still frame. All cerumen had been removed from the external auditory canal prior to filming. The participants were instructed to record the TM findings in a structured format and to diagnose the patient with 1 of 4 possible conditions: AOM, OME, retracted but otherwise normal, and normal. (The correct diagnosis had been previously established by consensus among an expert panel based on reviewing the video plus tympanometry and tympanocentesis findings.) Participants were afforded as much time as necessary for each member in the course to reach a conclusion and record his or her answers on a digitized personal keypad that was electronically linked to a laptop computer, thereby creating a database. Active instruction and interaction between instructor and participants occurred as the correct answers were reviewed for each diagnostic test.

DESCRIPTION OF THE MANNEQUIN

To assess the skill of otolaryngologists in performing tympanocentesis and to train pediatricians, a mannequin model was developed and validated. The mannequin consists of a plastic head and shoulders with an external pinnae and auditory canal. The caliber, length, and angulation of the external auditory canal are designed to simulate

the anatomical specifications of a 2-year-old child. The ear canal material is slightly spongy, flesh colored, and moderately resistant to needle puncture.

A cartridge consisting of 4 simulated TMs is inserted into the head portion of the mannequin model. A sliding mechanism positions the artificial TM at an anatomically accurate angle. The TM is engineered to simulate the appearance and feel of a pop when a tympanocentesis needle or myringotomy knife is used for penetration. Behind the TM, artificial pus is placed in the inferior portion of the simulated middle ear space—the recommended target for tympanocentesis. The anterior inferior quadrant is suggested as the preferred location (out of concern for safety and the provision of increased depth before the posterior wall of the middle ear space is encountered during the aspiration procedure). The superior half of the simulated middle ear space contains a red dye. This is an area of designated avoidance owing to possible injury to the malleus, incus, or stapes. At a depth of approximately 5 mm, a second membrane is present, which prevents access to a second chamber containing a blue dye. The depth between the TM surface and the second chamber is anatomically correlated with the depth of the middle ear space in a 1- to 2-year-old child. Thus, the trainee is instructed to insert the tympanocentesis needle in the inferior half of the simulated TM with preference to the anterior inferior quadrant. The trainee is further advised to avoid the superior half of the TM completely. Finally the trainee is advised that if the tympanocentesis needle is advanced too far, a blue dye will appear.

HAND POSITIONING

Instruction is provided on hand positioning during the procedure. An operating head on a handheld otoscope is used. For this simulation, a 20-gauge, 3½-in spinal needle is attached to either a 1- or 3-mL syringe. The needle is bent approximately one third from the hub at a 45° to 90° angle to allow advancement of the needle via the external auditory canal to the TM without blockage of visualization through the operating scope magnifying lens. Each TM cartridge contains 4 artificial TM/middle ear effusion disks to allow 4 attempts during the training session. Each participant is allowed 15 minutes to complete the 4 tympanocentesis procedures. All participants are evaluated based on their success with each of the 4 test disks. Each trainee is also assessed for 3 additional parameters: (1) familiarity with the procedure, (2) familiarity with instruments, and (3) manual dexterity. For these parameters the trainee is assessed as below average, passing, or above average.

highly febrile, toxic-appearing, and in severe pain.³⁻⁶ The procedure can be safely performed in an office practice setting without general anesthesia.⁵⁻¹¹ With these indications, it is neither necessary nor appropriate for the insertion of tympanostomy tubes. Otolaryngologists and properly trained and certified primary care physicians can and should perform the procedure with increasing frequency in an era of rising antibiotic-resistant otitis media pathogens.

During a series of continuing medical education-accredited courses conducted in 35 cities across the United States, pediatricians and otolaryngologists were shown video footage of TMs that were either normal or from pa-

tients with AOM or OME; their diagnostic decisions are described in this report. The physicians also participated in tympanocentesis skill validation or training. Four artificial TMs in infant mannequin models were tapped by each participant and successful performance was assessed.

RESULTS

The sequence of TM video projections, descriptions of the findings, and the correct diagnoses are presented in **Table 1**.

There were 5 video examinations of patients with OME (ears 1, 2, 5, 6, and 8), 3 of patients with retracted

Table 1. Tympanic Membrane (TM) and Middle Ear (ME) Findings as Shown on the Video Presentation of 9 Patients*

	Video Examination No.								
	1	2	3	4	5	6	7	8	9
TM color									
Red	-	-	-	+	-	-	-	-	-
Yellow	+	-	-	-	-	-	-	-	-
Gray	+	+	+	-	+	-	+	-	+
White/pink	-	-	-	-	-	+	-	+	-
TM position									
Bulging/full	-	-	-	+	-	-	-	-	-
Retracted	+	+	+	-	+	+	+	-	+
Neutral	-	-	-	-	-	-	-	+	-
TM translucency/ME fluid									
Pus behind TM	-	-	-	-	-	-	-	-	-
Amber fluid behind TM	+	-	-	-	+	-	-	-	-
Opaque, cloudy fluid behind TM	-	-	-	+	-	+	-	+	-
Translucent, no fluid, or clear fluid behind TM	-	+	+	-	-	-	+	-	+
TM mobility									
Immobile	-	-	-	-	+	-	-	-	-
Diminished	+	-	-	+	-	+	-	+	-
Increased	-	-	-	-	-	-	-	-	-
Normal	-	+	+	-	-	-	+	-	+
Features									
Air fluid levels	+	-	-	-	-	-	-	-	-
Bubbles	-	+	-	-	-	+	-	+	-
Diagnosis									
AOM	-	-	-	+	-	-	-	-	-
OME	+	+	-	-	+	+	-	+	-
No effusion: retracted TM	-	-	+	-	-	-	+	-	+
No effusion: normal examination	-	-	-	-	-	-	-	-	-

*Minus sign indicates characteristic not present; plus sign, characteristic present; AOM, acute otitis media; and OME, otitis media with effusion.

TMs but no effusion (ears 3, 7, and 9), and 1 of a patient with classic AOM (ear 4). Ear 5 was a classic glue ear (thickened TM, completely immobile on pneumatic otoscopy, thick amber fluid in the middle ear space). Ear 6, from a patient with OME, had a hypermobile deep retraction pocket in the superior anterior quadrant.

The percentages of correct diagnoses by specialty and overall are presented in **Table 2**. There was remarkable consistency in the percentages of correct diagnoses within a specialty across cities where the course was conducted (data not shown). Overall the average correct diagnosis for pediatricians was 50% and for otolaryngologists it was 73%.

In **Table 3**, the diagnosis made by the pediatricians is presented for all 9 ears. None of the 9 examination ears was completely normal and pediatricians recognized the absence of normality accurately 89% to 100% of the time. For the distinction between AOM (antibiotics appropriate) and OME or a retracted TM but otherwise normal (antibiotics not necessary), pediatricians overdiagnosed AOM between 7% and 53% of the time (mean, 27%). In **Table 4**, the diagnosis made by otolaryngologists is presented for all 9 ears. Otolaryngologists recognized the absence of normality accurately 93% to 100% of the time and overdiagnosed AOM 3% to 23% of the time (mean, 10%).

Evaluations of the physicians' familiarity with the procedure and instruments and manual dexterity are presented in **Table 5**. Evaluations of the actual tympanocentesis procedure are presented in **Table 6**.

Table 2. Comparison of Diagnostic Accuracy Between Physician Specialties of Video-Presented Tympanic Membrane (TM) and Middle Ear Findings*

Video Examination No.	Correct Diagnosis	Percentage of Correct Diagnoses Made	
		Pediatricians (n = 524)	ENTs (n = 188)
1	OME	48	88
2	OME	45	69
3	Retracted TM, otherwise normal	56	76
4	AOM	73	76
5	OME	50	79
6	OME	25	48
7	Retracted TM, otherwise normal	46	83
8	OME	48	84
9	Retracted TM, otherwise normal	59	65
	Overall	50	73

*ENTs indicates board-eligible or board-certified otolaryngologists; OME, otitis media with effusion; and AOM, acute otitis media.

COMMENT

To assess the ability of pediatricians and otolaryngologists to differentiate the physical findings of AOM and OME, an examination using video images was developed as a teaching tool. Among pediatricians, the average rate of misdiagnosis among 9 ear examinations was 50%. Otitis media with effusion was most frequently mis-

Table 3. Diagnoses by Pediatricians of Video-Presented TM and Middle Ear Findings*

Video Examination No.	Correct Diagnosis	Correct Diagnosis by Pediatricians, %			
		AOM	OME	Retracted TM, Otherwise Normal	Normal
1	OME	49	48	2	1
2	OME	31	45	20	4
3	Retracted TM, otherwise normal	14	18	56	11
4	AOM	73	18	5	4
5	OME	7	50	34	8
6	OME	53	25	22	0
7	Retracted TM, otherwise normal	7	31	46	0
8	OME	41	48	6	5
9	Retracted TM, otherwise normal	12	21	59	8

*AOM indicates acute otitis media; OME, otitis media with effusion; and TM, tympanic membrane.

Table 4. Diagnoses by Otolaryngologists of Video-Presented TM and Middle Ear Findings*

Video Examination No.	Correct Diagnosis	Correct Diagnosis by Otolaryngologists, %			
		AOM	OME	Retracted TM, Otherwise Normal	Normal
1	OME	12	88	0	0
2	OME	14	69	14	3
3	Retracted TM, otherwise normal	7	10	69	14
4	AOM	76	17	7	0
5	OME	3	79	15	3
6	OME	23	29	48	0
7	Retracted TM, otherwise normal	3	10	83	4
8	OME	10	84	3	3
9	Retracted TM, otherwise normal	16	12	65	7

*AOM indicates acute otitis media; OME, otitis media with effusion; and TM, tympanic membrane.

Table 5. Tympanocentesis Skills Assessment*

	Below Average		Pass		Above Average	
	ENTs	Pediatricians	ENTs	Pediatricians	ENTs	Pediatricians
Familiarity with procedure	4	15	23	70	73	15
Familiarity with instruments	0	3	40	53	60	44
Manual dexterity	4	20	9	63	87	17

*Data are given as percentage. ENTs indicates board-eligible or board-certified otolaryngologists. (n = 188). Pediatricians, n = 514.

Table 6. Tympanocentesis Performance Assessment*

	ENTs (n = 188)	Pediatricians (n = 514)
Correct taps (Yellow dye)	89	83
Correct location but too deep (Blue dye)	6	12
Incorrect taps (Red dye)	3	5

*Data are given as percentage. ENTs indicates board-eligible or board-certified otolaryngologists.

diagnosed as AOM and a retracted TM without associated middle ear effusion was often misdiagnosed as OME.

Among otolaryngologists, the average rate of misdiagnosis was 27%.

The participants in this continuing medical education course did not have the advantage of a history of symptoms relating to the physical examination findings displayed in the video images. However, symptoms predicting AOM are neither sensitive nor specific.^{12,13} The video provided a 2-dimensional image for the course participants to assess. One of the ears was particularly difficult to diagnose (ear number 6) as evidenced by the percentage of incorrect answers among both pediatricians and otolaryngologists. The lack of a better depth of field may have influenced diagnostic accuracy. On the other hand, every video image involved patients whose external auditory canal was completely cleared of cerumen and each image was shown in total for 30 seconds. Each video

What This Study Adds

The overdiagnosis of AOM occurs with unknown frequency, complicated by problems in differentiating acute OME. To address the rising bacterial resistance in AOM, the Centers for Disease Control and Prevention advocates that tympanocentesis be performed on children who fail 2 sequential antibiotic courses.

Our study suggests that pediatricians correctly distinguish AOM, OME, and variations of normal TMs about 50% of the time and otolaryngologists, 73% of the time, based on a simulated video examination. Tympanocentesis training on an infant mannequin model taught the skill successfully to 83% of pediatricians and was optimally performed by 89% of otolaryngologists.

examination included pneumatic otoscopy, which has been recommended as an important tool to assist diagnostic accuracy of AOM and OME.^{3,14-18} However, not all pediatricians were familiar with pneumatic otoscopy at the outset of the teaching sessions, although they became familiar with its use and interpretation as the examinations proceeded through the 9 test ears. Given the clarity of the videos and the viewing time allowed, it seems likely that the rate of accuracy in diagnosing real patients, especially infants and toddlers, would be less than seen in this training scenario. This further underscores the magnitude of the problem in diagnosing these conditions.

In 1992, Kaleida and Stool¹⁹ described a validation program to assess accuracy regarding the diagnosis of middle ear effusion, wherein the otoscopist's examination was validated by middle ear findings with tympanocentesis. Using this approach, the investigators found that participants became more accurate in diagnosing the presence or absence of middle ear effusion. The mean sensitivity and specificity for the group as a whole were 87% and 74%, respectively. This program produced an improvement in diagnostic skills but was limited by the large amount of time required.

There is now an increasingly recognized need for both otolaryngologists and properly trained/certified primary care physicians to perform tympanocentesis in office-based settings. The mannequin model was designed to validate competency among otolaryngologists and to facilitate training among pediatricians. Training is integrated into an overall educational course. During 1999-2000, more than 3000 participants completed tympanocentesis training.

The American Medical Association level 3 certificate awarded to those successfully completing training in the course indicates readiness to perform the procedure on patients under supervision by a proctor. As such, the certificate is not sufficient qualification for a primary care physician trainee to perform the procedure. Further instruction should be provided by otolaryngologists, preferably in the operating room suite during a session of tympanostomy tube insertions. On a typical morning, if a trainee can perform the procedure on several patients to the satisfaction of the otolaryngologist, then a letter of competency could be issued to the trainee.

Performance of tympanocentesis in an office setting can be facilitated by the use of an otomicroscope. This was not used during the mannequin training session. The dexterity challenge of the syringe evacuation method of middle ear effusion can be overcome by attachment of a tympanocentesis needle to an appropriate collection device (eg, Alden-trap; Storz Instruments, Kansas City, Mo; or Tymp-Tap; Xomed Surgical, Jacksonville, Fla) hooked to suction.^{9,10} In the nonanesthetized patient a papoose board is recommended for immobilization and a nurse assistant should be present to stabilize the head firmly and pull back on the pinnae if necessary. Sedation can be helpful. The use of midazolam hydrochloride has been advocated,⁶ although in some settings its use mandates direct nurse observation, pulse oximetry monitoring, and postprocedure observation. The hypothetical problems of tympanocentesis in an office setting²⁰ are all possible consequences of inadequate full visualization of the TM and/or inadequate immobilization of the child.^{6,9,11}

Simulation technology for health care professional skills training and assessment has been recommended as the most effective in producing acquisition and retention of knowledge in the continuing medical education arena. Clearly, simulation technology is superior to traditional lectures.²¹ Davis et al²² showed that interactive continuing medical education sessions that enhanced participant activity and provided the opportunity to practice skills could affect change in professional practice and, on occasion, health care outcomes. Didactic sessions do not seem to be effective in changing physician performance.²³ The reasons physicians attend traditional continuing medical education programs have not been studied extensively. Satisfying inner standards of achievement and a need to validate knowledge and practices seem to be important reasons. Post-program application occurs if participants see the "need to do your job differently."²³ Our program most likely attracted participants who wanted to confirm that what they were doing was correct²³ and 85% responded in a postcourse evaluation that attendance would very likely change their diagnostic approach to this common malady.

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