

Updated Guidelines for the Management of Acute Otitis Media in Children by the Italian Society of Pediatrics

Diagnosis

Elena Chiappini, MD, PhD,* Martina Ciarcià, MD,* Barbara Bortone, MD,* Mattia Doria, MD,† Paolo Becherucci, MD,‡ Gian Luigi Marseglia, MD,§ Marco Antonio Motisi, MD,* Maurizio de Martino, MD,* Luisa Galli, MD,* Amelia Licari, MD,§ Salvatore De Masi, MD,* Riccardo Lubrano, MD,¶ Maria Bettinelli, MD,|| Claudio Vicini, MD,** Giovanni Felisati, MD,†† Alberto Villani, MD,‡‡ Paola Marchisio, MD,§§ and the Italian Panel for the Management of Acute Otitis Media in Children

Background: In recent years, new progress has been made regarding the diagnosis, treatment and prevention of acute otitis media (AOM). The Italian Pediatric Society therefore decided to issue an update to the previous guidelines published in 2010.

Methods: Literature searches were conducted on MEDLINE by Pubmed, including studies in children, in English or Italian, published between January 1, 2010, and December 31, 2018. The quality of the included studies was assessed using the grading of recommendations, assessment, development and evaluations (GRADE) methodology. In particular, the quality of the systematic reviews was evaluated using the AMSTAR 2 appraisal tool. The guidelines were formulated using the GRADE methodology by a multidisciplinary panel of experts.

Results: The diagnosis of AOM is based on acute clinical symptoms and otoscopic evidence; alternatively, the presence of otorrhea associated with spontaneous tympanic membrane perforation allows the AOM diagnosis. The diagnosis of AOM must be certain and the use of a pneumatic otoscope is of fundamental importance. As an alternative to the pneumatic otoscope, pediatricians can use a static otoscope and a tympanometer. To objectively establish the severity of the episode for the formulation of a correct treatment program, an AOM severity scoring system taking into account clinical signs and otoscopic findings was developed.

Conclusions: The diagnosis of AOM is clinical and requires the introduction of specific medical training programs. The use of pneumatic otoscopes must be promoted, as they are not sufficiently commonly used in routine practice in Italy.

Key Words: diagnosis, acute otitis media, guidelines, otoscopy

(*Pediatr Infect Dis J* 2019;38:S3–S9)

In recent years, new progress has been made regarding the diagnosis, treatment and prevention of acute otitis media (AOM). The Italian Pediatric Society therefore decided to issue an update to the previous guidelines published in 2010.

MATERIALS AND METHODS

Guideline Group (Qualifications of Members and Processes Used)

For the drafting of these guidelines, the Italian Pediatric Society appointed a commission including experts in general pediatrics, research methodology, pneumology, clinical immunology, emergency medicine, epidemiology, pharmacology and microbiology. The members of the Guideline Group were put forward by the scientific societies of the disciplines involved. The development of the guidelines involved a number of working groups:

1. the guidelines development group, which organized and coordinated the various phases of guidelines development;
2. the multidisciplinary/multi-professional panel, which devised the clinical questions, discussed the evidence regarding efficacy and formulated the recommendations;
3. the methodology group, which performed a critical analysis of the literature available and extrapolated and summarized in tables the pertinent data;
4. a drafting group, which drew up the synopsis of the scientific literature and the final guidelines text; and
5. the drafting group, methodology group and panel attended regular meetings. The dates of the meetings and the previous versions of the guidelines were recorded.

To reach consensus regarding the topics identified for the guidelines and the strength of the recommendations, the Delphi method was adopted.¹

Guidelines Addressees and Topics

These guidelines provide recommendations concerning the diagnosis, prevention and treatment of AOM in children > 2 months of age.

They do not apply to subjects with acquired or congenital immunosuppression, chronic spontaneous perforation or grommets, chronic underlying conditions (eg, cystic fibrosis) or facial malformations.

Accepted for publication July 8, 2019.

From the *Department of Human Health Sciences, University of Florence, AOU Firenze, Florence, †Primary care paediatrician, Chioggia, Venice, ‡Primary care paediatrician, Florence, §Pediatric Clinic, Department of Pediatrics, Fondazione IRCCS Policlinico San Matteo, University of Pavia, Pavia, ¶Università degli Studi di Roma "La Sapienza" UOC di Pediatria e Neonatologia, Polo di Latina, Roma, ||Dipartimento sociosanitario di base cure primarie, ATS Città Metropolitana di Milano, Milan, **Department of Head-Neck Surgery, Otorhinolaryngology, Head-Neck and Oral Surgery Unit, Morgagni Pierantoni Hospital, Azienda USL della Romagna, Forlì, ††Otorhinolaryngology Unit, Department of Health Sciences, University of Milan, Milan, ‡‡Department of Pediatrics, Bambino Gesù Children's Hospital (IRCCS), Rome, and §§Fondazione IRCCS Ca' Granda Ospedale Maggiore Policlinico, Pediatric highly intensive care unit, Department of Pathophysiology and Transplantation, Università degli Studi di Milano, Milan, Italy.

Supported by the publication of the present supplement is funded by the University of Milan.

The authors have no conflicts of interest to disclose.

All authors approved the final version of this document.

Members of the Italian Panel for the Management of Acute Otitis Media in Children are listed in the Acknowledgments section.

Address for correspondence: Elena Chiappini, MD, PhD, Department of Pediatrics, Anna Meyer Children's University Hospital, Viale Pieraccini, 24, Florence, 50100 Italy. E-mail: elena.chiappini@unifi.it.

Copyright © 2019 Wolters Kluwer Health, Inc. All rights reserved.

ISSN: 0891-3668/19/3812-00S3

DOI: 10.1097/INF.0000000000002429

The guidelines primarily address pediatricians, ear, nose and throat (ENT) specialists, general practitioners, nurses and pharmacists involved in the management of children with AOM.

Formulation of the Questions

The aspects and outcomes were identified by the methodology group and then shared and discussed with the rest of the panel by adopting the grading of recommendations, assessment, development and evaluations (GRADE) methodology.

The panel identified the outcomes and subsequently classified them in terms of importance, using an individual rating on a 9-point scale. Only those outcomes classified as critical and important were taken into account in the literature review and, subsequently, in the drafting of the recommendations.

Evidence Search Methodology and Formulation of Recommendations

The search was conducted on PubMed and only those studies regarding the pediatric age alone, in English or Italian, published between January 1, 2010, and December 31, 2018, were included. For each question, the keywords used for the search strategy were identified by the members of a subcommission. Relevant articles retrieved from the reference lists of the selected studies were also considered. The references were regularly updated during the drafting of the guidelines. The abstracts and articles were analyzed by a subcommission that selected those that were relevant, especially double-blind, randomized clinical studies, cohort studies, systematic reviews and all general position papers. When the reference lists included existing guidelines on the subject, they underwent methodologic assessment (using the AGREE II appraisal tool)² and a comparative analysis of their recommendations. A further literature review was performed before the final drafting phase.

Each study included in the review was summarized in summary of findings tables and assessed in terms of methodology and contents using a checklist drawn up according to the GRADE criteria.³ The quality of the systematic reviews was evaluated using the AMSTAR 2 appraisal tool.²

The results of the analysis were then discussed and approved by the entire panel involved in the drafting of the guidelines, using the Consensus Conference method.

The GRADE method is characterized by a step-by-step approach that must be scrupulously respected according to the proposed sequence:

1. definition of the clinical question for which the recommendation is to be formulated;
2. identification of all outcomes pertinent to the clinical question and assessment of their relative importance for an adequate evaluation of the specific intervention;
3. data search concerning the positive or negative effects of the various interventions considered;
4. summary of the evidence for each outcome considered to be “essential” or “important”;
5. assessment of the quality of the evidence for each outcome;
6. assessment of the overall quality of the evidence;
7. intervention risk-benefit assessment;
8. definition of the strength of the recommendation;
9. formulation of the recommendation; and
10. implementation and impact assessment.

For the formulation of the recommendations, in agreement with the GRADE methodology, the following standard expressions were used as follows:

1. must be used (“strong positive” recommendation);
2. could be used (“weak positive” recommendation);
3. should not be used (“weak negative” recommendation); and
4. must not be used (“strong negative” recommendation).

RESULT

Question No. 1. Is It Appropriate to Implement Medical Training on the Diagnosis of AOM by Means of Specific Programs?

The diagnosis of AOM is challenging.^{4,5} The circumstances in which the work-up is performed are not always ideal: the child may not be cooperative, the instrumentation used may not be adequate and the tympanic membrane may not be clearly visible. In addition, the signs and symptoms are often nonspecific.⁵

However, a correct diagnosis of AOM is fundamental for being able to devise a correct treatment program, as only an accurate and precise identification of children with certain AOM rather than those with otitis media with effusion (OME) or with other forms, can avoid unjustified treatments.⁶

International literature provides confirmation of the high number and considerable clinical relevance of diagnostic errors regarding AOM.^{7–13} Recent studies confirm that OME is still often erroneously diagnosed as AOM and is still the condition for which antibiotics are most commonly incorrectly prescribed.^{13–15}

The interpretation of the abnormalities that can be observed otoscopically varies greatly with the examiner’s level of experience, with significant differences between medical students, residents, pediatricians and expert otoscope users.^{16,17}

Training regarding the diagnosis of AOM is unsatisfactory both in Italy and internationally. In the United States, where for over 30 years significant importance has been given to the otitis media issue, only just over half of the residencies in pediatrics provides specific training on the diagnosis of AOM and OME and, consequently, a limited number of pediatrics residents are able to formulate a correct diagnosis.^{18,19} A number of recent studies conducted on medical students, pediatrics residents and specialists in pediatrics and ENT in various countries report that specific training initiatives, even those of a short duration and based on otoscopic simulations on patient simulators and web-based platforms, are associated with a significant increase in diagnostic skills. However, most authors stress that, unless they are used regularly, the skill sets acquired deteriorate within just a few months.^{13,15,20–22}

More specifically, by analyzing the literature published since 2010, 5 studies were identified, including 3 moderate-quality RCTs and 2 low-quality observational studies.^{13,15,20–23} The results report an improvement in diagnostic accuracy depending on the type of training intervention, with better results when otoscopy simulators are used, intermediate results when web-based teaching platforms are used and poorer results when conventional classroom lessons are used. No cost-effectiveness studies were identified and only 2 studies^{20,22} included a direct in vivo assessment of the diagnostic abilities on patients.

Recommendation No. 1

To improve and maintain adequate diagnostic skills, training programs are recommended; they should be conducted using appropriate tools, preferably otoscopy simulations and repeated at regular intervals—weak positive recommendation.

Question No. 2. What Are the Criteria for a Correct Diagnosis of AOM?

Symptoms

The medical history must be accurately recorded and make it possible to identify the time of onset of the symptoms and their

characteristics. These are usually very variable and nonspecific, as they often very similar to those of uncomplicated infections of the upper respiratory tract.¹⁰

Otalgia can be reported directly by older children who are able to express themselves or, before they are able to speak, can be identified by a child's tendency to touch or rub his/her ear. They may be associated with more general symptoms of sickness such as irritability, difficulties falling asleep or refusing food.

Otalgia cannot be considered the most reliable diagnostic criterion, as it may not be present in 50% of cases in children under 2 years of age and in up to 35% of older children.²⁴ It is directly reported in this age range by a limited percentage of children, whereas in the vast majority of cases it is the parent who associates the child's behavior with pain, with a high incorrect interpretation rate that also depends on subjective experiences and social and economic status.^{25,26} The physical exam and the direct observation of the tympanic membrane by the physician is therefore crucial for the diagnosis and definition of the severity of AOM.

Additionally, the severity of the reported symptoms, considering also their relatively nonspecific nature, does not correlate with an increased risk of AOM.²⁶ One large good-quality study conducted in Finland by Laine et al²⁷ including 469 children between 6 and 35 months of age, whose parents suspected AOM, showed that it cannot be diagnosed exclusively on the basis of the presence, severity or duration of the symptoms.

Furthermore, the behavior traditionally associated with the presence of a middle ear condition, such as complaints of pain, disturbed sleep or pulling at the ear were not directly correlated with the presence of AOM.

Conflicting evidence was recently reported by McCormick et al²⁸, in a study that recruited 193 healthy full-term newborns < 4 weeks old who were followed prospectively for 1 year. The children were examined whenever their parents observed signs or symptoms of an upper respiratory tract infection. During the observation period, there were 360 episodes of upper airway infections and 63 episodes of AOM. In this limited and carefully selected sample, the simultaneous presence of fever, irritability, refusal of feeds, ear rubbing and difficulties in sleeping correlated significantly with the diagnosis of AOM.

Although fever is often identified as a primary symptom of AOM, it can vary greatly and may not be present in over half of all children.²⁴ This is confirmed in 1 good-quality study that evaluated 98 children with bilateral AOM and 134 with unilateral AOM, which identified a temperature of over 38°C in 54% and 36% of subjects, respectively.²⁹

Signs

The detection of tympanic membrane inflammation with the presence of effusion in the middle ear is based on the otoscopic finding of a bulging membrane associated with at least 1 of the following characteristics: intense hyperemia or yellow color (caused by the vision in translucency of purulent material in the middle ear).

Alternatively, it should be stressed that the presence of otorrhea with a spontaneously ruptured tympanic membrane is in itself a certain objective sign of AOM.

Therefore, the presence of middle ear effusion should always be actively investigated to formulate a certain diagnosis of AOM. This clinical element is decisive for defining the subsequent therapeutic strategy: watchful waiting and/or antibiotic therapy.¹⁴

In addition to the case of acute otorrhea, the presence of effusion can only be directly detected by tympanocentesis (not practical in routine practice and to be reserved for carefully selected cases and performed by expert physicians); it can, however, be indirectly detected by observing tympanic membrane mobility with a

pneumatic otoscope and/or by tympanometry and/or reflectometry or, in selected cases, using other techniques such as otomicroscopy or video endoscopy, performed by ENT specialists.¹⁴

Clear bulging of the tympanic membrane is the sign that, alone, has the highest correlation with bacterial AOM confirmed by a culture test on the material obtained by tympanocentesis and is indicative of the positive pressure exerted by the inflammatory process inside the tympanic cavity on the membrane, which is displaced towards the outer ear canal.^{10,30,31}

The following are to be considered inadequate signs for a certain diagnosis of AOM: (1) tympanic membrane hyperemia alone (a frequent finding in young children after prolonged crying); (2) loss of the traditional landmarks (luminous triangle) alone; (3) tympanic membrane retraction; (4) evidence of air-fluid levels in the middle ear. These last 3 signs tend to guide diagnosis towards OME. More specifically, conditions characterized by hyperemia along the handle of malleus, involving the posterior-superior region alone while the remaining tympanic membrane remains normal in terms of both appearance and mobility should not be considered indicative of AOM.^{31,32}

A study by Karma et al³³ published in 1989 is still regarded one of the best regarding the correlation between otoscopic signs of AOM and diagnosis confirmed by tympanocentesis. In 2 different Finnish cities, an ENT specialist and a pediatrician followed 2911 children between 6 months and 2 and a half years. Myringotomy was performed whenever signs of membrane effusion were associated with suggestive symptoms.

The otoscopic tympanic membrane findings were classified as follows:

- 1) Color: hemorrhagic; slightly-moderately-severely red; opaque; normal
- 2) Position: bulging; retracted; normal
- 3) Mobility: slightly-clearly impaired; normal

A total of 11,804 examinations were considered in the results. A TM that is simultaneous opaque and bulging with limited mobility were found to be the signs most predictive of AOM. Impaired mobility is the sign with greatest sensitivity and specificity (95% and 85%, respectively), followed by membrane opacity (74% and 93%). Membrane bulging was observed to have a high specificity (97%) but poor sensitivity (51%). A slightly red membrane did not correlate with a diagnosis of AOM, whereas intense hyperemia was present in 68%–88% children with AOM.³³

These findings require the clinician to perform a thorough evaluation of the degree of TM mobility, to confirm the presence of effusion in the middle ear.

Similar data are also confirmed by the study conducted by Laine et al²⁷ in 2010 on 237 children with AOM, 93% of whom presented severe tympanic membrane bulging on the otoscopy.

A subsequent good-quality study conducted in the United States and including 263 children showed that severe tympanic membrane bulging was present in 92% of children with AOM, versus 0% in children with OME.³⁴ In the absence of membrane bulging, an opaque membrane was observed in 97% of children with OME.³²

In the most recent study by Uitti et al²⁹ including 98 children with bilateral AOM and 134 children with unilateral AOM, tympanic membrane bulging was present in 63% and 40% of cases; purulent effusion was present in 89% and 71% of cases; and a hyperemic tympanic membrane was observed in 7% and 10% of cases, respectively. One recent good-quality systematic literature review,⁵ included a concise assessment of existing international guidelines on the diagnosis and management of pediatric AOM. All the guidelines considered agree on the criteria to be included for a correct diagnosis (Table 1).^{5,14}

TABLE 1. Diagnostic Criteria for AOM

All of the following elements must be present for a certain diagnosis
Acute (in the previous 48 hours) onset of symptoms associated with a middle ear inflammation (otalgia, touching at the ear, irritability, fever, disturbed sleep and loss of appetite)
Signs of inflammation, including intense hyperemia or yellow color of the tympanic membrane
Presence of middle ear effusion, as indicated by bulging of the tympanic membrane or, in its absence, by greatly reduced/absence of mobility or by otorrhea secondary to spontaneous perforation. The sole presence of otorrhea, not secondary to external otitis, associated with a spontaneously perforated tympanic membrane must be considered in itself a certain objective sign of AOM

Recommendation 2

AOM must only be diagnosed in the presence of a simultaneous finding of

1. acute onset of symptoms;
2. signs of inflammation of the tympanic membrane; and
3. presence of middle ear effusion.

The sole presence of otorrhea, not secondary to external otitis, associated with a spontaneous perforation of the tympanic membrane should also be considered in itself a certain objective sign of AOM—strong positive recommendation.

Question No. 3. Is It Useful to Use a Clinical Scoring System to Define the Severity of AOM?

The concept of AOM symptom severity is still controversial, as the reported definitions of severity are diverse and do not always coincide.^{5,14,35–38} Nevertheless, the definition adopted to indicate the severity of AOM is particularly important as it is one of the criteria used to define the therapeutic approach.

In an attempt to standardize the definition of severity, a number of studies have proposed the use of “clinical scoring systems.”^{25,28,30,36,38}

Although the use of a clinical scoring system is not always easy, it is nevertheless a useful way of identifying and standardizing the rating of the clinical elements needed for diagnosis.

Scoring systems based exclusively on symptoms (subjective and/or parent-reported) are unreliable, as they are not able to make a distinction between upper airway infections with and without AOM.²⁷ The scoring system must therefore include an assessment of the tympanic membrane.

The severity scoring system proposed by Le Saux et al³⁶ identifies 5 clinical criteria (level of fever, irritability, ear pulling, TM hyperemia and TM bulging) and 3 severity levels (AOM scores: 0–2 mild, 3–7 moderate and 8–15 severe). This scoring system has the limitation that it assigns the same score weight to both symptoms and signs.

McCormick et al²⁸ devised the Ear Treatment Group-5 items score that identifies 5 clinical criteria [fever, earache (by parent's suspicion), poor feeding, restless sleep and irritability] measured on a severity score of 0–3. This score, however, does not take into consideration the clinical examination of the TM. It was seen to be useful not particularly for diagnosing severity at AOM onset but for evaluating clinical evolution during treatment or watchful waiting.³⁰

Casey et al³⁹ proposed a clinical scoring system based on 10 signs and symptoms in 330 children with AOM assessed at the onset of the clinical presentations and after 3 weeks. Once again, these authors did not calculate the sensitivity and specificity of the score for

diagnosing the severity of AOM in itself, but for rating clinical evolution. A sensitivity of 87% and a specificity of 98% (PPV 91%; NPV 97%) was reported in making a distinction between cure and therapeutic failure, using assessments by expert otoscope users as a standard.

Shaikh et al^{34,40,41} devised the AOM Severity of Symptom Scale for children under 2 years of age and based on the symptoms reported by parents. It includes 7 clinical criteria [ear pain, ear tugging, irritability (ie, fussiness or increased crying), decreased play, decreased appetite and difficulty sleeping and fever] showing that it correlated with otoscopic diagnosis and that it could be used to monitor the evolution of clinical response to a treatment strategy.¹⁶

Lastly, the Japanese guideline proposes a severity scoring system that assigns a diversified score on the basis of the following parameters: child's age, intensity of otalgia, level of fever, intensity of crying/irritability, degree of TM hyperemia, presence of TM bulging, presence of otorrhea (AOM score: ≤ 5 mild, 6–11 moderate and ≥ 12 severe). However, no studies have been conducted to validate its sensitivity and specificity for the diagnosis of AOM.³⁸

International literature does not therefore agree on which scoring system should be privileged and the various severity scores have been used for study purposes without finding widespread application and validation in clinical practice.

Furthermore, certain scoring systems, such as that proposed by Shaikh et al¹⁶, which is mentioned in the US guidelines, are based exclusively on the symptoms, as rated by the parents, whereas others, such as the OS-8 scoring system proposed by McCormick et al²⁸, are based exclusively on otoscopic signs.¹⁴

As the diagnosis of AOM is based on the confirmation of the simultaneous presence of characteristic elements (clinical symptoms and otoscopic signs), the panel suggests a easy to use scoring system that takes into account these aspects. An episode of AOM is defined as severe for scores same or higher than or equal to 4 (Table 2).

Recommendation 3

The severity of the episode can be established on the basis of a clinical score.

In any case, the presence and degree of signs and symptoms (such as fever, pain, irritability, TM hyperemia, bulging, mobility and otorrhea) should be assessed—weak positive recommendation.

Question No. 4. How Can a Satisfactory Visibility of the Tympanic Membrane Be Obtained?

The definition of tympanic membrane inflammation with the presence of middle ear effusion is based on the otoscopic finding of a bulging membrane associated with intense hyperemia or a yellow color (caused by the vision in translucency of purulent effusion in the middle ear).

The main problem in the diagnosis of AOM is constituted by the difficulties encountered in viewing the tympanic membrane correctly, to examine its characteristics.

Earwax plugs, epidermal plugs, foreign bodies in the EAC or any other hindrance that fully or partly conceals the tympanic membrane can make otoscopic assessment difficult or impossible. This has been reported in up to one-third of children, with a trend that is inversely proportionate to age (greater frequency in the first year of life).^{25,42,43} Obviously in all these cases the ear canal must be cleaned.

Marchisio et al⁴⁴ demonstrated in an observational study including 819 children that cerumen was present in 72% of cases. It was observed that in clinical practice, only one-third of pediatricians remove cerumen properly to examine the tympanic membrane correctly and compared with almost all ENT specialists. This demonstrates the importance of training programs on how to

TABLE 2. Proposed Score for the Severity of AOM

Axillary body temperature	
< 38.0°C	0
38.0°C–38.9°C	1
≥ 39.0°C	2
Impairment of general conditions	
Absent	0
Present	4
Otalgia	
Mild-moderate	0
Severe otalgia and/or inconsolable crying	2
MT hyperemia	
Mild-moderate	0
Severe	2
MT bulging	
Mild-moderate	1
Severe	4

An episode of AOM is defined severe if the score is equal to or higher than 4.

remove cerumen.⁴⁴ Cerumen can be removed using different techniques (Table 3). A Cochrane review published in 2018⁴⁵ including both adult and pediatric studies (10 studies, with 623 participants) evaluated the efficacy of various types of ear drops used to remove cerumen (compounds based on oil, water or other substances, such as glycerol or hydrogen peroxide). Any treatment was reported to be more efficacious than no intervention, with a 5-day complete clearance rate of 22% versus 5% [RR: 4.09; 95% confidence interval (CI): 1.00–16.80], according to the results of only one poor-quality study. However, the available data were inadequate for clarifying whether an oil- or a water-based treatment was better than the other cerumenolytic products on the market. Although the available safety data were limited, no difference was observed in the different incidence of adverse events for the use of various cerumenolytic products. The events reported included dizziness, unpleasant odor and tinnitus. However, no severe adverse events were reported in 10 studies.

One study analyzing the possibility of external otitis in the 2 weeks following mechanical wax removal in over 1200 children did not observe any episode.^{46,47}

Recommendation 4

When performing diagnostic otoscopy, clear vision of the entire tympanic membrane is recommended, with the EAC free of cerumen and foreign bodies—strong positive recommendation.

Recommendation 5

The removal of cerumen from the EAC can be performed by an appropriately trained pediatrician or by an ENT specialist with various operational and organizational methods depending on the care setting, the level of the practitioner’s expertise and the instruments available—weak positive recommendation.

TABLE 3. Cerumen Removal Methods

Option	Lavage	Cerumenolytic Drops	Manual Removal
Advantages	Effective	Effective Easy application	Effective
Disadvantages and complications	Perforation of tympanic membrane Pain, vertigo EAC damage	External otitis Allergic reactions Pain or vertigo if tympanic membrane is not intact Transient hearing loss	Requires training Skin laceration Pain Cooperation required

Modified from Roland et al⁴⁸.

Question No. 5. Which Instruments Should Be Used to Diagnose AOM?

Other than the case of acute otorrhea, the presence of middle ear effusion can only be directly detected by tympanocentesis (to be performed in carefully selected cases only); or indirectly, by observing tympanic membrane mobility with a pneumatic otoscope and/or by tympanometry and/or reflectometry or, by ENT specialists, using other techniques such as otomicroscopy or video endoscopy.¹⁴ Video endoscopy is a technique used by ENT specialists.

The pneumatic otoscope is the most appropriate instrument for the diagnosis of AOM.^{14,49} Given the possibility of performing a dynamic examination, use of this instrument makes it possible to identify the presence of middle ear effusion [94% sensitivity (95% CI: 92%–96%) and 80% specificity (95% CI: 75%–86%)].^{14,50,51}

The otoscope must have an appropriate light source and a series of specula with varying diameters, to suit different EAC diameters; these specula should be colorless, to avoid diffusing the light, which must be directed towards the tympanic membrane.⁵² Provided the operator has been appropriately trained, use of the pneumatic otoscope is not painful for the child and does not entail substantial risks. Use of the pneumatic phase is superfluous in the event of obvious, complete bulging of the tympanic membrane or in cases of spontaneous otorrhea.⁵³

Pneumatic otoscope use is still extremely limited in routine practice in Italy.⁷ In this sense, it is important to highlight that, if it is not used, a certain diagnosis of AOM can only be formulated in the presence of otorrhea, or acute-onset severe tympanic membrane bulging and swelling.⁵

The examination of the tympanic membrane must include the assessment of 6 characteristics: integrity, position, color, translucency, lighting and mobility. To describe these characteristics properly, the membrane must be divided into 4 quadrants (anterior-superior, anterior-inferior, posterior-superior, posterior-inferior) that are obtained by imagining the prolongation of the handle of malleus to the lower wall of the external auditory meatus and tracing a line perpendicular to it that passes through the inferior tip of the handle of malleus.

The acronym “COMPLETES” facilitates the memorization of the aspects to be analyzed.⁵⁴ The description must be provided for both tympanic membranes and the episode must be described as bilateral or unilateral.³⁰

Tympanometry makes it possible to identify the presence of middle ear effusion. This study is based on pressure changes that are induced artificially by a graduated pump positioned outside the EAC.

Tympanometry can be used as an additional resource for making a distinction between AOM and an upper airway infection. However, this method does not allow a differential diagnosis between AOM and OME, as, with the exception of a flat B-type

curve, it does not provide any information regarding the characteristics of any TM inflammation.⁵⁵

In their comparison of the diagnostic accuracy of tympanometry and pneumatic otoscopy, Rogers et al⁵⁶ confirmed that the latter has greater specificity in detecting exudate in the middle ear than tympanometry: sensitivity: 67.9% (95% CI: 57.6–78.3) and specificity 81.4% (95% CI: 73.8–88.9) versus 90.9% (95% CI: 73.9–100) and 28.6% (95% CI: 00.0–62.0).

Furthermore, it is superfluous in the presence of severe tympanic membrane bulging, as was reported also for pneumatic otoscopy.⁵⁷

An Australian study by Abbott et al⁵⁸ suggested that in clinical practice, the use of tympanometry is preferable to pneumatic otoscopy because it is considered as being a technique that is easier to perform and interpret.⁷

In recent years, video endoscopy has become increasingly used by ENT specialists, due to its ability to improve the physician's diagnostic capabilities^{59,60} the same can be said of otomicroscopy, which has shown great accuracy in identifying the presence of intratympanic effusion.⁶¹

An acoustic reflectometer is a device that makes it possible to confirm the presence of effusion in the tympanic cavity and analyze its degree of severity on a scale of 1–5, by measuring the angle at which the tympanic membrane reflects the acoustic signal.^{49,62,63}

Otoscopy using a smartphone by both physicians⁶⁴ and parents has not yet been confirmed as a valid way to diagnose otitis.^{65,66} Some low-quality preliminary studies suggest a good correlation between the images acquired using a smartphone and otoscopic findings.^{65,67} These results must be confirmed by larger, better-quality studies.

Recommendation 6

To diagnose of AOM, it is recommended to identify the presence of middle ear effusion. The recommended instrument is the pneumatic otoscope, fitted with an appropriate light source and a colorless speculum with a diameter suited to the anatomic characteristics of the child's EAC—strong positive recommendation.

Recommendation 7

The description of the episode must include all the characteristics of the tympanic membrane (integrity, position, color, translucency, lighting and mobility) and indicate whether it is bilateral or unilateral—strong positive recommendation.

Recommendation 8

In the absence of a pneumatic otoscope, pediatricians should make combined use of a static otoscope and a tympanometer, or, in the presence of diagnostic doubt, should reexamine the patient within 48 hours to define the diagnosis—weak positive recommendation.

DISCUSSION

The diagnosis of AOM is clinical and requires the introduction of specific medical training programs or the upgrading of those already present in routine practice. The use of pneumatic otoscopes must be promoted, as they are not sufficiently commonly used in routine practice in Italy.

APPENDIX: RESEARCH STRATEGY

((((acute otitis media OR middle ear effusion OR otorrhea) AND children AND diagnosis)) OR ((acute otitis media OR middle ear effusion OR otorrhea) AND children AND (otoscopy OR

tympanometry OR impedenzometry))) OR ((acute otitis media OR middle ear effusion OR otorrhea) AND children AND (clinical score OR fever OR pain OR otalgia)).

Publication date from January 1, 2010, to December 31, 2018; English; Field: Title/Abstract.

ACKNOWLEDGMENTS

Members of the Italian Panel for the Management of Acute Otitis Media in Children include Sergio Bottero (Roma), Guido Castelli Gattinara (Roma), Fabio Cardinale (Bari), Grazia Fenu (Firenze), Giorgio Piacentini (Verona), Renato Cutrera (Roma), Lorenzo Pignataro (Milano), Attilio Varricchio (Napoli), Alfonso Varricchio (Napoli), Sara Torretta (Milano), Nicola Mansi (Napoli), Bottero Sergio (Roma), Paolo Biasci (Livorno), Marina Picca (Milano), Giuseppe Di Mauro (Caserta), Maria Carmen Verga (Salerno), Roberto Mattina (Milano), Andrea Novelli (Firenze), Luciano Pinto (Napoli), Maria Enrica Bettinelli (Milano) and Marisa Bonino (Novara).

REFERENCES

1. Boulkedid R, Abdoul H, Loustau M, et al. Using and reporting the Delphi method for selecting healthcare quality indicators: a systematic review. *PLoS One*. 2011;6:e20476.
2. Brouwers MC, Kho ME, Browman GP, et al; AGREE Next Steps Consortium. AGREE II: advancing guideline development, reporting and evaluation in health care. *CMAJ*. 2010;182:E839–E842.
3. Schünemann HJ, Schünemann AH, Oxman AD, et al; GRADE Working Group. Grading quality of evidence and strength of recommendations for diagnostic tests and strategies. *BMJ*. 2008;336:1106–1110.
4. Rosenfeld RM. Diagnostic certainty for acute otitis media. *Int J Pediatr Otorhinolaryngol*. 2002;64:89–95.
5. Ovnat Tamir S, Shemesh S, Oron Y, et al. Acute otitis media guidelines in selected developed and developing countries: uniformity and diversity. *Arch Dis Child*. 2017;102:450–457.
6. Gisselsson-Solen M. The importance of being specific—a meta-analysis evaluating the effect of antibiotics in acute otitis media. *Int J Pediatr Otorhinolaryngol*. 2014;78:1221–1227.
7. Marchisio P, Mira E, Klersy C, et al. Medical education and attitudes about acute otitis media guidelines: a survey of Italian pediatricians and otolaryngologists. *Pediatr Infect Dis J*. 2009;28:1–4.
8. Pichichero ME, Poole MD. Assessing diagnostic accuracy and tympanocentesis skills in the management of otitis media. *Arch Pediatr Adolesc Med*. 2001;155:1137–1142.
9. Wald ER. Acute otitis media: more trouble with the evidence. *Pediatr Infect Dis J*. 2003;22:103–104.
10. Rothman R, Owens T, Simel DL. Does this child have acute otitis media? *JAMA*. 2003;290:1633–1640.
11. Garbutt J, Jeffe DB, Shackelford P. Diagnosis and treatment of acute otitis media: an assessment. *Pediatrics*. 2003;112(1, pt 1):143–149.
12. Blomgren K, Pohjivuori S, Poussa T, et al. Effect of accurate diagnostic criteria on incidence of acute otitis media in otitis-prone children. *Scand J Infect Dis*. 2004;36:6–9.
13. Stepniak C, Wickens B, Husein M, et al. Blinded randomized controlled study of a web-based otoscopy simulator in undergraduate medical education. *Laryngoscope*. 2017;127:1306–1311.
14. Lieberthal AS, Carroll AE, Chonmaitree T, et al. The diagnosis and management of acute otitis media. *Pediatrics*. 2013;131:e964–e999.
15. Oyewumi M, Brandt MG, Carrillo B, et al. Objective evaluation of otoscopy skills among family and community medicine, pediatric, and otolaryngology residents. *J Surg Educ*. 2016;73:129–135.
16. Shaikh N, Rockette HE, Hoberman A, et al. Determination of the minimal important difference for the acute otitis media severity of symptom scale. *Pediatr Infect Dis J*. 2015;34:e41–e43.
17. Pichichero ME. Diagnostic accuracy of otitis media and tympanocentesis skills assessment among pediatricians. *Eur J Clin Microbiol Infect Dis*. 2003;22:519–524.

18. Steinbach WJ, Sectish TC. Pediatric resident training in the diagnosis and treatment of acute otitis media. *Pediatrics*. 2002;109:404–408.
19. Varrasso DA. Otitis media: the need for a new paradigm in medical education. *Pediatrics*. 2006;118:1731–1733.
20. Paul CR, Gjerde CL, McIntosh G, et al. Teaching the pediatric ear exam and diagnosis of Acute Otitis Media: a teaching and assessment model in three groups. *BMC Med Educ*. 2017;17:146.
21. Wu V, Beyea JA. Evaluation of a web-based module and an otoscopy simulator in teaching ear disease. *Otolaryngol Head Neck Surg*. 2017;156:272–277.
22. Wu V, Sattar J, Cheon S, et al. Ear disease knowledge and otoscopy skills transfer to real patients: a randomized controlled trial. *J Surg Educ*. 2018;75:1062–1069.
23. You P, Husein MJ. Improving learning and confidence through small group, structured otoscopy teaching: a prospective interventional study. *Otolaryngol Head Neck Surg*. 2017;28:46–68.
24. Kontiokari T, Koivunen P, Niemelä M, et al. Symptoms of acute otitis media. *Pediatr Infect Dis J*. 1998;17:676–679.
25. Shaikh N, Kearney DH, Colborn DK, et al. How do parents of preverbal children with acute otitis media determine how much ear pain their child is having? *J Pain*. 2010;11:1291–1294.
26. Uitti JM, Salanterä S, Laine MK, et al. Adaptation of pain scales for parent observation: are pain scales and symptoms useful in detecting pain of young children with the suspicion of acute otitis media? *BMC Pediatr*. 2018;18:392.
27. Laine MK, Tähtinen PA, Ruuskanen O, et al. Symptoms or symptom-based scores cannot predict acute otitis media at otitis-prone age. *Pediatrics*. 2010;127:1306–1311.
28. McCormick DP, Jennings K, Ede LC, et al. Use of symptoms and risk factors to predict acute otitis media in infants. *Int J Pediatr Otorhinolaryngol*. 2016;81:55–59.
29. Uitti JM, Laine MK, Tähtinen PA, et al. Symptoms and otoscopic signs in bilateral and unilateral acute otitis media. *Pediatrics*. 2013;131:e398–e405.
30. McCormick DP, Chandler SM, Chonmaitree T. Laterality of acute otitis media: different clinical and microbiologic characteristics. *Pediatr Infect Dis J*. 2007;26:583–588.
31. Schilder AG, Chonmaitree T, Cripps AW, et al. Otitis media. *Nat Rev Dis Primers*. 2016;2:16063.
32. Shaikh N, Hoberman A, Rockette HE, et al. Development of an algorithm for the diagnosis of otitis media. *Acad Pediatr*. 2012;12:214–218.
33. Karma PH, Penttilä MA, Sipilä MM, et al. Otic 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.
34. Shaikh N, Wang EE, Arguedas A, et al. Acute otitis media severity of symptom score in a tympanocentesis study. *Pediatr Infect Dis J*. 2011;30:253–255.
35. Hotomi M, Yamanaka N, Samukawa T, et al. Treatment and outcome of severe and non-severe acute otitis media. *Eur J Pediatr*. 2005;164:3–8.
36. Le Saux N, Gaboury I, Baird M, et al. A randomized, double-blind, placebo-controlled noninferiority trial of amoxicillin for clinically diagnosed acute otitis media in children 6 months to 5 years of age. *CMAJ*. 2005;172:335–341.
37. Heidemann CH, Lous J, Berg J, et al. Danish guidelines on management of otitis media in preschool children. *Int J Pediatr Otorhinolaryngol*. 2016;87:154–163.
38. Kitamura K, Iino Y, Kamide Y, et al. Clinical practice guidelines for the diagnosis and management of acute otitis media (AOM) in children in Japan - 2013 update. *Auris Nasus Larynx*. 2015;42:99–106.
39. Casey JR, Block S, Puthoor P, et al. A simple scoring system to improve clinical assessment of acute otitis media. *Clin Pediatr (Phila)*. 2011;50:623–629.
40. Shaikh N, Hoberman A, Paradise JL, et al. Responsiveness and construct validity of a symptom scale for acute otitis media. *Pediatr Infect Dis J*. 2009;28:9–12.
41. Shaikh N, Hoberman A, Kaleida PH, et al. Otic signs of otitis media. *Pediatr Infect Dis J*. 2011;30:822–826.
42. Ahmad N, Wacogne I. Question 3. Does the clinical finding of ear wax exclude the finding of otitis media? *Arch Dis Child*. 2009;94:912–913.
43. Schwartz SR, Magit AE, Rosenfeld RM, et al. Clinical practice guideline (update): earwax (cerumen impaction). *Otolaryngol Head Neck Surg*. 2017;156(suppl 1):S1–S29.
44. Marchisio P, Pipolo C, Landi M, et al; Italian Earwax Study Group. Cerumen: a fundamental but neglected problem by pediatricians. *Int J Pediatr Otorhinolaryngol*. 2016;87:55–60.
45. Aaron K, Cooper TE, Warner L, et al. Ear drops for the removal of ear wax. *Cochrane Database Syst Rev*. 2018;25:7.
46. Guidi JL, Wetmore RF, Sobol SE. Risk of otitis externa following manual cerumen removal. *Ann Otol Rhinol Laryngol*. 2014;123:482–484.
47. Burton MJ, Doree C. Ear drops for the removal of ear wax. *Cochrane Database Syst Rev*. 2009;1:CD004326.
48. Roland PS, Smith TL, Schwartz SR, et al. Clinical practice guideline: cerumen impaction. *Otolaryngol Head Neck Surg*. 2008;139(3 suppl 2):S1–S21.
49. Erkkola-Anttinen N, Laine MK, Tähtinen PA, et al. Can changes in parentally measured acoustic reflectometry levels predict the middle ear status? *Int J Pediatr Otorhinolaryngol*. 2017;95:72–74.
50. Takata GS, Chan LS, Morphew T, et al. Evidence assessment of the accuracy of methods of diagnosing middle ear effusion in children with otitis media with effusion. *Pediatrics*. 2003;112(6, pt 1):1379–1387.
51. Jones WS, Kaleida PH. How helpful is pneumatic otoscopy in improving diagnostic accuracy? *Pediatrics*. 2003;112(3, pt 1):510–513.
52. Block SL. Acute otitis media: bunnies, disposables, and bacterial original sin! *Pediatrics*. 2003;111:217–218; author reply 217–218.
53. Marchisio P, Lambertini L, Ghisalberti E, et al. L'otoscopio. *Area Pediatrica*. 2005;6:34–36.
54. Kaleida PH. The COMPLETES exam for otitis. *Contemporary Pediatrics*. 1997;4:93–101.
55. Helenius KK, Laine MK, Tähtinen PA, et al. Tympanometry in discrimination of otoscopic diagnoses in young ambulatory children. *Pediatr Infect Dis J*. 2012;31:1003–1006.
56. Rogers DJ, Boseley ME, Adams MT, et al. Prospective comparison of handheld pneumatic otoscopy, binocular microscopy, and tympanometry in identifying middle ear effusions in children. *Int J Pediatr Otorhinolaryngol*. 2010;74:1140–1143.
57. Spiro DM, King WD, Arnold DH, et al. A randomized clinical trial to assess the effects of tympanometry on the diagnosis and treatment of acute otitis media. *Pediatrics*. 2004;114:177–181.
58. Abbott P, Rosenkranz S, Hu W, et al. The effect and acceptability of tympanometry and pneumatic otoscopy in general practitioner diagnosis and management of childhood ear disease. *BMC Fam Pract*. 2014;15:181.
59. Jaisinghani VJ, Hunter LL, Li Y, et al. Quantitative analysis of tympanic membrane disease using video-otoscopy. *Laryngoscope*. 2000;110(10, pt 1):1726–1730.
60. Jones WS. Video otoscopy: bringing otoscopy out of the “black box.” *Int J Pediatr Otorhinolaryngol*. 2006;70:1875–1883.
61. Young DE, Ten Cate WJ, Ahmad Z, et al. The accuracy of otomicroscopy for the diagnosis of paediatric middle ear effusions. *Int J Pediatr Otorhinolaryngol*. 2009;73:825–828.
62. Laine MK, Tähtinen PA, Helenius KK, et al. Acoustic reflectometry in discrimination of otoscopic diagnoses in young ambulatory children. *Pediatr Infect Dis J*. 2012;31:1007–1011.
63. Erkkola-Anttinen N, Laine MK, Tähtinen PA, et al. Parental role in the diagnosis of otitis media: can layman parents use spectral gradient acoustic reflectometry reliably? *Int J Pediatr Otorhinolaryngol*. 2015;79:1516–1521.
64. Chan KN, Silverstein A, Bryan LN, et al. Comparison of a smartphone otoscope and conventional otoscope in the diagnosis and management of acute otitis media. *Clin Pediatr (Phila)*. 2018 21:9922818812480.
65. Shah MU, Sohal M, Valdez TA, et al. iPhone otoscopes: currently available, but reliable for tele-otoscopy in the hands of parents? *Int J Pediatr Otorhinolaryngol*. 2018;106:59–63.
66. Erkkola-Anttinen N, Irjala H, Laine MK, et al. Smartphone otoscopy performed by parents. *Telemed J E Health*. 2019;25:477–484.
67. Mousseau S, Lapointe A, Gravel J. Diagnosing acute otitis media using a smartphone otoscope; a randomized controlled trial. *Am J Emerg Med*. 2018;36:1796–1801.