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Clinical Practice Guidelines for the diagnosis and management of acute otitis media (AOM) in children in Japan – 2013 update

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ABSTRACT

Objective: To (1) indicate methods of diagnosis and testing for childhood (<15 years) acute otitis media (AOM) and (2) recommend methods of treatment in accordance with the evidence-based consensus reached by the Subcommittee of Clinical Practice Guideline for Diagnosis and Management of AOM in Children (Subcommittee of Clinical Practice Guideline), in light of the causative bacteria and their drug sensitivity of AOM in Japan.
Methods: We investigated the most recently detected bacteria causing childhood AOM in Japan as well as antibacterial sensitivity and the worldwide distinct progress of vaccination, produced Clinical Questions concerning the diagnosis, testing methods, and treatment of AOM, searched literature published during 2000–2004, and issued the 2006 Guidelines [1–4]. In the 2009 and 2013 Guidelines, we performed the same investigation with the addition of literature, which were not included in the 2006 Guidelines and published during 2005–2008 and during 2009–2012, respectively.
Results: We categorized AOM as mild, moderate, or severe on the basis of tympanic membrane findings and clinical symptoms, and presented recommended treatment for each degree of severity.
Conclusion: Accurate assessment of tympanic membrane findings is important for judging the degree of severity and selecting a method of treatment. Some of new antimicrobial agents and pneumococcal vaccination are recommended as new treatment options.

1. Introduction

Acute otitis media (AOM) is a typical upper respiratory inflammation commonly affecting children, and is mainly treated by otolaryngologists. Its exact frequency of occurrence in Japan is unknown, however. According to reports from Europe and the US, 62% of children aged less than one year and 83% of those up to the age of three have suffered from at least one bout of AOM [1]. Faden et al. [2] have reported that it affects 75% of children up to the age of one.

Some authors in Europe and the US do not recommend the use of antimicrobial agents for AOM. In the Netherlands, it has been proposed that antimicrobial agents are unnecessary in at least 90% of cases, and that patients should be observed for 3–4 days without antimicrobial agent administration [3,4]. Rosenfeld et al. have also reported observation as a management option [5–7], and more recent studies have also found no significant difference in clinical outcome if antimicrobial agents are not given immediately but

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rather are prescribed if there is no improvement in symptoms after 48 or 72 h [8,9]. A Cochrane Review that examined randomized controlled trials of antimicrobial agent administration versus placebo also found that antimicrobial agents had little effect on childhood AOM [10]. In addition, a double-blind randomized controlled trial of amoxicillin (AMPC) and a placebo found no significant difference in therapeutic efficacy between the two [11,12]. Dagan et al. [13,14] and Toltzis et al. [15], in a review and case–control study, advised that antimicrobial agent use would be reduced because the use of a wide variety of antimicrobial agent increases the survival of resistant *Streptococcus pneumoniae* (*S. pneumoniae*) in the nasopharynx, which can cause additional infections in middle-ear (ME) fluid.

In Japan, regular nationwide surveys are performed of the causative bacteria for AOM, acute sinusitis, acute tonsillitis, and peritonsillar abscess. These surveys have reported that multi-drug-resistant bacteria are now being detected more frequently [16,17], which means that the recommendation to avoid administration of antimicrobial agents proposed in Europe and the US does not apply. In addition, the criteria and assessment levels used in conventional clinical assessment are not necessarily uniform even within Europe and the US [18]. Investigation and unified evaluation of the diagnosis and treatment of childhood AOM are therefore required, based on the actual situation in Japan. Based on this perspective, the Japan Otological Society (JOS), the Japan Society for Infectious Diseases in Otolaryngology (JSIDO), and the Japan Society for Pediatric Otorhinolaryngology (JSPO) produced 2006 Clinical Practice Guidelines consistent with evidence-based medicine (EBM) [19] with the aim of supporting the diagnosis and treatment of childhood AOM [20–23], which was revised and published in 2009 [24].

According to a local survey using a questionnaire in Ishikawa Prefecture, Japan, 85% of otolaryngologists and 52% of pediatricians acknowledged 2006 Guidelines, and among them, 56% of otolaryngologists and 49% of pediatricians have actually put it to practical use [25]. Other reports indicated that treatment outcome of AOM based on the 2006 Guidelines was good [26,27]. Therefore, JOS, JSIDO and JSPO issued 2009 Guidelines revised from 2006 Guidelines.

Thereafter, AOM guidelines were published from Canada [28] and from Italy [29]. In Italian Guidelines, it was noted that, as in our guidelines, identification and description of detailed tympanic membrane findings were highly appreciated, and that they also indicated as one of the choices for pediatricians to transfer the patient to otolaryngologist who can examine the tympanic membrane precisely by using microscope and/or endoscope, when pediatricians cannot identify or describe the tympanic membrane findings. That principle seems to agree well with our Guidelines, which appreciate the management of AOM based on the detailed observations of tympanic membrane findings. In 2013 AOM Guidelines published from the United States by revising their 2004 Guidelines, the necessity of detailed observation of the tympanic membrane findings was emphasized [30].

In our present 2013 Guidelines, changes of pathogens and their drug sensitivity and the grading system of AOM including signs and symptoms determining the grade were revised. Also descriptions were added based on new data as for rapid test for the detection of pneumococcal antigen, vaccinations for *S. pneumoniae*, new antimicrobial agents, and Japanese herbal medicine, and so on. Although no remarkable change has been made on the other parts of the 2009 guidelines, items described in 2006 and 2009 guidelines were included in the 2013 Guidelines.

This paper introduces extracts of the important parts of our 2013 edition of Clinical Practice Guideline for Diagnosis and Management of AOM in Children.

2. Users

The main users of these Guidelines will be otolaryngologists who perform otological procedures including the accurate evaluation of otoscopic findings and myringotomy.

3. Subjects

The subjects of these Guidelines are AOM patients aged <15 years who were free from AOM or otitis media with effusion (OME) within one month prior to onset, who do not have a tympanostomy tube inserted, who have no craniofacial abnormality, and who do not suffer from immunodeficiency. Patients with the following conditions are excluded as subjects: AOM with complications including facial palsy and inner ear disorder, elevated pinna with acute mastoiditis, and AOM with Gradenigo's syndrome or similar findings. It can be difficult to distinguish between AOM and bullous myringitis, but the latter is not covered by these Guidelines.

4. Gathering evidence

For the 2006 and 2009 Guidelines, PubMed, Japan Centra Revuo Medicina Web version 3 and 4, were used, and for the 2013 Guidelines, PubMed, the Cochrane library, and Japan Centra Revuo Medicina Web version 5 were used.

5. Criteria for deciding recommendation grades

The method proposed by the Japan Stroke Society to indicate the level of evidence, which was established on the basis of National Clinical Guidelines for Stroke (Royal College of Physicians, http://www.ebook3000.com/National-Clinical-Guidelines-for-Stroke_9350.html) modified by the Classification of Oxford Centre for Evidence-based Medicine (http://www.cebm.net/oxford-centre-evidence-based-medicine-levels-evidence-march-2009/), was used in the preparation of these Guidelines, as shown below.

Level of evidence

Ia: Meta-analysis (with homogeneity) of randomized controlled trials
Ib: At least one randomized controlled trial
IIa: At least one well-designed, controlled study but without randomization
IIb: At least one well-designed, quasi-experimental study
III: At least one well-designed, non-experimental descriptive study (e.g., comparative studies, correlation studies, case studies)
IV: Expert committee reports, opinions and/or experience of respected authorities

Recommendation grades were determined based on the evidence obtained by the search policies described above and the anticipated degree of benefit or harm. During this process, reference was made to items according to the proposed grades outlined below. In 2006 and 2009 Guidelines, five levels of recommendation grades were established, based on the US Preventive Services Task Force report (http://www.uspreventiveservicestaskforce.org/uspstf08/methods/proctab4.htm). In the 2013 Guidelines, considering the consistency with the previous two editions, the same five levels as described below were used as well.

A: strongly recommended: strong evidence is available, benefits substantially outweigh harms