

New Guidelines for AOM Treatment in Sweden

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Abstract

In October 2010 new recommendations were issued in Sweden concerning the treatment of acute otitis media (AOM). Watchful waiting is recommended for otherwise healthy children aged 1-12 years with uncomplicated AOM. In all patients with complicating circumstances and all patients under the age of 1 year and over the age of 12 years (including adults) antibiotic treatment of AOM is recommended. In the guidelines treatments as well as diagnostic methods are recommended.

To make guidelines for the treatment of conditions that are self-limiting in the majority of cases but might cause serious or even life-threatening complications is a challenge. Acute Otitis Media (AOM) is just that kind of entity. New guidelines for the treatment of AOM have been issued in many countries during the last years. These Guidelines are different in many aspects but it seems as though they are beginning to converge. We will present the new Swedish guidelines accepted in October 2010. The guidelines were issued after a conference where ENT, paediatricians, GPs, microbiologists and officials from the Swedish Centre for Disease Control were involved.

Background

AOM (**Figure 1**) is the most common bacterial infection in small children. Almost all children will experience at least one episode of AOM during infancy and some will experience many more¹. According to a report from 2008² more than 2 000 Swedish children have grommets (tympanostomy tubes) placed every year on account of AOM.

Figure 1. AOM caused by pneumococci.

Photo: Margaretha Foglé-Hansson



Middle ear conditions are by no means a new problem. Before the introduction of antibiotics the morbidity and mortality in AOM and its complications were high especially in small children. At this time *Streptococcus pyogenes* (group A-streptococci) and *Streptococcus pneumoniae* (pneumococci) were the two main causing agents. The infections were protracted and in as much as 17 % of the cases mastoiditis followed³.

Already before the introduction of routine treatment of AOM with penicillin during the late 1940s there was a change and the proportion of infections caused by group A streptococci was radically reduced. Since the middle of the 1950s pneumococci have been the most common bacteria isolated in AOM. The gram-negative bacteria *Haemophilus influenzae* and *Moraxella catarrhalis* have become more common perhaps partly since many less sick children are admitted but also because of a real increase in the population.

There is also an increasing interest in virus and the influence they might have on AOM. They have been isolated as sole agents in a small proportion of cases but probably have more impact as part of the bacterial infections. RS, influenza-, parainfluenza- and adenovirus are those most often found in AOM.

Serious but uncommon complications

During the last part of the 20th century almost all countries recommended antibiotic treatment of all AOM with the main goal to reduce the number of complications. The combination of a changed bacteriology and aggressive treatment have made the complication rate go down dramatically so that in the beginning of the 21st century we see a complication rate that instead of being 17 % is less than one in a thousand. Mastoiditis still is the most common complication to AOM and in Sweden with a population of nine millions there are approximately 70 cases recorded every year ^{4,5}. Several other serious complications are still seen but are very rare but potentially life-threatening. Among those meningitis (with or without mastoiditis), labyrinthitis and sinus thrombosis are most often mentioned.

We still have very little knowledge of why complications appear in certain patients. We know that certain agents are more prone to cause complications than other but far from all pneumococcal AOM will cause mastoiditis. Is it a factor in the bacteria or in the host? Or is it perhaps an unsuitable combination?

High percentage of spontaneous resolution

Worldwide bacterial strains with reduced sensitivity to antibiotics are emerging. Many studies have shown that this might be counteracted by reducing the use of antibiotics, especially in small children ^{6,7}. Since AOM is the most common cause of antibiotic treatment in small children there has been a lot of discussion lately concerning the use of routine treatment of AOM.

Many studies have shown that the spontaneous resolution of AOM is high ⁸. From the Netherlands van Buchem et al reported in several studies during the 1980s that it seemed to be without great risks to abstain from routine use of antibiotics in uncomplicated AOM ⁹. This led to new guidelines in the Netherlands where antibiotic treatment of AOM was not recommended in healthy children without signs of complications. Most other countries have revised their recommendation and very few guidelines now recommend routine treatment of AOM in otherwise healthy children.

This introduction of “watchful waiting” in the treatment of AOM seems to be associated with a very small increased risk of complications although it is hard to evaluate the effect ¹⁰.

Worldwide some studies have however been published to try to evaluate the effects of treatment with antibiotics in uncomplicated AOM. Five major studies

have been published since 2000 when the last guidelines introducing “watchful waiting” in Sweden was published ¹¹. All these studies have different designs and different criteria for inclusion and exclusion. Some uses placebo and some compare treatment to “watchful waiting”. In some of the studies as much as 25-30 % of the children in the non-treatment group is eventually treated which makes it harder still to evaluate the results

Several of the studies have very wide criteria for exclusion and all exclude children that have seriously affected general condition. In one study children with a bulging eardrum are excluded since they are thought to be too ill! These differences make it hard to compare the studies to each other but some meta-analyses have been published ^{12, 13}.

In these it is concluded that:

- antibiotic treatment reduces the pain during the first days
- antibiotics do not reduce the risk of secretory otitis media after an episode of AOM
- children of all ages with perforated AOM have a considerable benefit of antibiotics
- children under the age of two years with a bilateral AOM also have a considerable benefit of antibiotics
- whether antibiotics reduce (or perhaps increase) the risk of late recurrences is unclear

Some groups of children are less studied than others. Children below the age of one year as well as children with recurrent AOM are in most studies excluded. Children below the age of one are even when they are included in the studies very few. In all the studies together less than 200 of these children are included in the “watchful waiting” groups and almost 50 % of these actually had to be treated since the rate of complication/threatening complications was so high.

“Watchful waiting” must be - watchful!

During 2011 two new randomized studies comparing antibiotic treatment to placebo in small children (down to but not below the age of six months) with AOM were published ^{14, 15}. In both studies a better effect of antibiotic treatment was reported than in older studies. This might be due to the fact that the diagnostic criteria were stricter and that the outcome was treatment failure or not rather than alleviation of symptoms or not. The treatment studied was also an antibiotic with a rather broader spectrum than in earlier studies (Amoxicillin / clavulanic acid in both studies). The outcome was similar in both studies with “treatment failure” in 50 % of the placebo group compared to 15 % in the treatment group.

Thus it might be concluded that antibiotic treatment retains its value in otitis media in selected cases and that “watchful waiting” must be just that - watchful!

The age of the child is important!

The risk of complications to AOM is different at different ages. Children below the age of one year are immunologically very immature and at six months the maternal antibodies are running out. Thus these children are all vulnerable and it seems as though some children are later than others.

It has also been shown that the bacteriology differs largely between children

of different ages. Thus in the small children below the age of six months *Moraxella catarrhalis*, is the major pathogen while pneumococci are dominating in children around 12 months and *Hemophilus influenzae* is more common in children over the age of 18 months. Group A-streptococci, a rare pathogen in AOM today, is more common among older children and adults. Most complications are caused by either pneumococci or GAS.

New Guidelines 2010

In the new Swedish guidelines watchful waiting is recommended in cases of uncomplicated AOM in otherwise healthy children between one and 12 years¹⁶.

The older guidelines gave the possibility to choose between antibiotic treatment and watchful waiting in children between the age of two and sixteen years. The reason to lower the age is that most episodes of AOM occur before the age of two years! It was felt however that children below the age of one were too vulnerable to be left without treatment (see above).

In the new guidelines it is emphasized that it is of outmost importance to better the diagnostic criteria and skills! A combination of acute symptoms, inflammatory changes of the eardrum and pus in the middle ear should be present to ensure the diagnose of AOM.

Testing the mobility of the eardrum is recommended and if possible an otomicroscope should be used to visualize the eardrum. It is also recommended to try to ensure a diagnose even though this might include further procedures such as admittance to ENT department.

It is also stated that although watchful waiting is advocated in children between one and 12 years this does not mean that the children should not be examined when AOM is suspected. Suitable analgesics should be recommended and if there is any worsening of the symptoms or if the symptoms remains after two days new examination is recommended.

When antibiotics are prescribed penicillin V for five days is recommended as the drug of choice. In case of worsening of the symptoms or if the symptoms remains after two days amoxicillin is recommended. It is also recommended to obtain nasopharyngeal swabs as a further guidance if this should not work.

In cases were the children are allergic to betalactams macrolides are recommended. It is also recommended to obtain nasopharyngeal swabs as a further guidance since the choice at treatment failure might be hard.

Children with recurrent AOM (defined as three or more episodes of AOM in six months or four in a year) is not recommended watchful waiting but should be treated at all instances of AOM.

National survey of complications to AOM

At the same time as these new guidelines are implemented a survey is started in Sweden where all cases of mastoiditis are recorded and evaluated. This will make it possible to evaluate the effect of the changes in guidelines but also might give us a better understanding of the mechanisms behind the development of the rare but serious complications seen to AOM. This is very important since the rapid increase of bacterial strains with reduced sensitivity to antibiotics makes it important to chose which patients needs to be treated and which might even

benefit from a watchful waiting approach. It is also important to monitor the effects of general pneumococcal vaccination.

Since AOM is a disease with many different courses depending on the bacterial agent and the host it is important to learn more about factors deciding the outcome. Diagnostics is very important in this context and should be bettered to avoid over diagnosing. However it is also important not to forget the threat of complications.

Guidelines in Sweden 2010

- Children aged 1 -12 years with AOM is recommended watchful waiting. Antibiotic treatment should only be given if there are complicating factors.

- Children younger than one year, older than 12 years and all adults with AOM should be given antibiotics

Complicating factors

- Perforation of the drum in all patients
- Bilateral AOM in children younger than two years of age
- Pain that is not allivieted by appropriate analgetics
- Disturbed general condition
- Signs of threathening complications
- Immunodeficiency
- Cochlea implant or other earlier ear surgery (not grommets)
- Sensorineural hearing loss
- Earlier skull or facial trauma

Antibiotics

AOM in otherwise healthy children

- pcV 25 mg/kg x 3 for 5 days
- (adults pcV 1,6 g x 3 for 5 days)

rAOM (recurrent acute otitis media)

- pcV 25 mg/kg for 10 days or
- Amoxicillin 20 mg/kg x 3 for 10 days

Treatment failure

- Amoxicillin 20 mg/kg x 3 for 10 days
(adults 500 mg x 3 for 10 days)

Allergy to beta-lactams

- AOM in otherwise healthy children
- erytromycin 10 mg/kg x 4 for 7 days and sample from nph or MEE
- (adults erytromycin 250 mg x 4 for 7 days)

Treatment failure

- According to growth

Running ears with grommets (tympanostomy tubes)

- Uncomplicated cases should be treated with ear drops during 2-3 days. If not resolved antibiotics should be used as above.

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