

Acute otitis media

Summary

- Acute otitis media is a common self-limiting illness in children. 80% recover in around three days without antibiotics. Complications are rare.
- Antibiotics should not be prescribed routinely for acute otitis media in children. They reduce pain to a small degree but this should be balanced against the risk of causing adverse effects such as vomiting, diarrhoea or rashes.
- Antibiotics may be beneficial in sub-groups of patients. For example, children:
 - under two years with bilateral infection **or**
 - with discharge from the ear **or**
 - who are systemically unwell (e.g. fever or vomiting) **or**
 - with recurrent infections.
- A strategy of watchful waiting and use of delayed prescriptions may be appropriate for many.
- Paracetamol and ibuprofen have been shown to reduce earache.
- There is insufficient evidence to support the use of decongestants or antihistamines.



Background — what is otitis media?

Otitis media is inflammation of the middle ear and is generally divided into acute otitis media (AOM) and otitis media with effusion (OME) or glue ear. These conditions are part of the same disease continuum and differentiating between them can be difficult. However, AOM has a rapid onset and usually presents with local signs and symptoms (see **Table**) including earache, rubbing or tugging of the ear, fever, irritability and poor sleep. It is often preceded by upper respiratory symptoms such as cough and rhinorrhoea. By contrast, OME is often asymptomatic, with earache being rare. Children may present with hearing impairment and speech problems following chronic inflammation and fluid accumulation in the middle ear.¹ This document focuses on the management of AOM.

AOM is one of the most common complaints seen in children in primary care. Age is the most important risk factor, with three quarters of cases of AOM occurring in those aged less than 10 years. At least one in four children has an episode of AOM before they are ten years old with the peak incidence occurring between the age of three and six years. The other main risk factor is contact with other children, for example at nursery.²

Diagnosis should not be based on history alone, and the eardrum should be examined using otoscopy.¹ A systematic review (six studies, n=3,919) found that a cloudy, bulging or distinctly immobile eardrum is most useful to predict AOM. A distinctly red eardrum is also helpful, whereas a normal colour means AOM is unlikely (see **Table**).³

Table: Signs and symptoms associated with an increase in the likelihood of AOM³

Ear pain
Ear rubbing
Cloudy eardrum
Bulging eardrum
Distinctly immobile eardrum
Distinctly red eardrum

AOM may be due to viral or bacterial infection. It is a self-limiting illness that will resolve without antibiotics in around three days in 80% of children. Complications include mastoiditis, labyrinthitis and meningitis, but these are rare in otherwise healthy children from developed countries. OME is also a common complication of AOM, but should not

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be diagnosed until the effusion has been present for at least three months.²

Management options

There is limited evidence to support the use of analgesics for AOM.⁴ One randomised controlled trial (RCT) in 219 children aged one to six years who were also receiving antibiotic treatment, found that ibuprofen or paracetamol reduced earache after two days, as assessed by parental observation, compared with placebo (ibuprofen relative risk [RR] 0.28, 95%CI 0.11 to 0.71, number needed to treat [NNT] 5; paracetamol RR 0.38, 95% CI 0.17 to 0.85, NNT 6).⁴

A Cochrane review (15 trials, n=2,695) found that there was insufficient evidence to support the use of decongestants or antihistamines in children with AOM, and both medications have undesirable side effects.⁵

Who needs an antibiotic?

A Cochrane review (8 RCTs, n=2,287) has assessed the effects of antibiotics versus placebo in children with AOM.⁶ It found that two thirds of children had no pain 24 hours after treatment started, irrespective of whether they received antibiotics or not, and 80% of children receiving placebo had spontaneously recovered from pain at two to seven days. Antibiotics achieved a further 7% absolute reduction in the risk of pain, or put another way, 15 children needed to be treated with antibiotics to prevent one extra child from having pain after two to seven days.⁶ Also, for every 17 children treated with antibiotics, one suffered an adverse effect (e.g. vomiting, diarrhoea, rash).⁴ Few serious complications occurred in either the antibiotic or placebo group, with only one child (who was treated with penicillin) developing mastoiditis. The review concludes that the role of antibiotics in AOM is limited because most cases resolve spontaneously without complications, and antibiotics have adverse effects. However, it also suggests that antibiotics may be beneficial in subgroups of patients, e.g. children under two years and those with fever or vomiting (see below).⁶

What about children under two years?

A meta-analysis (six RCTs, n=1,643) looked at the effects of antibiotics on pain, fever, or both, at three to seven days in children aged from 6 months to 12 years with otitis media to try to find which subgroups of children were most likely to benefit from treatment.⁷ It found that, in children aged less than two years of age with bilateral AOM, 30% who were taking antibiotics had pain, fever or both at three to seven days, compared to 55% of controls (RR 0.64, 95%CI 0.52 to 0.80, NNT=4). In children with otorrhoea (discharge from the ear), 60% of the control group had pain, fever or both at three to seven days, compared with 24% of

those given antibiotics (RR 0.52, 95%CI 0.37 to 0.73, NNT=3). The effects of antibiotic treatment were not significantly affected by age alone.⁷

A RCT conducted in 53 practices (n=240) in the Netherlands looked at the effect of antibiotic treatment for AOM in children aged six months to two years.⁸ The proportion of patients with earache, fever, crying, or irritability at day four was 59% with amoxicillin and 72% with placebo (absolute risk reduction [ARR] 13%, 95%CI 1 to 25, NNT=8). These figures are much higher than those in the Cochrane review,⁶ where only 20% of the children's symptoms had not resolved at two to seven days on placebo. In the Dutch study, only eight children aged six months to two years needed to be treated with antibiotics for one to obtain symptomatic benefit at day four. In the Cochrane review, 15 children needed to be treated with antibiotics to prevent one extra child from having pain after two to seven days.⁶ This may mean that children under two years obtain more benefit from antibiotics than older children. However, the study authors concluded that this benefit is still modest, and antibiotics should not routinely be prescribed to all in this age group.⁸

What about children with systemic symptoms?

A secondary analysis of patients in a RCT studied predictors of poor outcome in 315 children with AOM aged six months to ten years.⁹ It found that antibiotics had little benefit in those without a high temperature or vomiting. In children with these symptoms, distress (ARR 21%, NNT=5, 95% CI 2 to 83) and disturbed nights (ARR 33%, NNT=3, 95% CI 2 to 8) were reduced at day three when immediate antibiotic treatment was given compared with delayed treatment (after 72 hours if required). The authors concluded that children with systemic features (e.g. fever or vomiting) are more likely to benefit from antibiotics, although it is still reasonable to wait 24–48 hours, as many children will improve spontaneously, in this time.⁹

What about delayed prescriptions?

The RCT discussed above, with 315 children aged six months to ten years, was originally designed to compare immediate and delayed prescribing of antibiotics for AOM.^{9,10} It found that immediate antibiotic prescribing provided limited symptomatic benefits. For example, immediate antibiotics reduced the duration of earache (-1.1 days, 95%CI -0.54 to -1.48) and ear discharge (-0.66 days, 95%CI -0.19 to -1.13) compared to delayed prescribing. These modest benefits of antibiotics must be balanced against the risks: immediate antibiotic treatment increased the incidence of diarrhoea by 10% (19% vs. 9% with a delayed prescription) and reinforced parents' belief in antibiotics.¹⁰ Children in this study were

Although they may be beneficial in subgroups of patients, antibiotics should not be offered routinely in children with AOM

subsequently followed up at three months and one year, and it was found that delayed antibiotic treatment was unlikely to have longer-term consequences, although children with recurrent infection may have poorer outcomes.¹¹

Recently, a study in an American emergency department randomised children aged six months to 12 years (n=283) who were diagnosed with AOM to an immediate or delayed prescription (after 48 hours if required) for antibiotics.¹² It found that 62% of delayed prescriptions were not used compared with 13% of immediate prescriptions (P<0.001). At four to six days, an immediate prescription reduced the mean number of days of earache by just 0.4 days compared with the delayed prescription group (2.0 days vs. 2.4 days, RR 0.43, 95% CI 0.07 to 0.80). There was no statistically significant difference between the groups in the number of days of fever.¹²

In summary, antibiotic treatment should not be offered routinely in children with AOM. Parents can be reassured that AOM is a self-limiting illness and serious complications are rare. Antibiotics may be useful for some patients where the benefits may outweigh the risks of adverse effects (e.g. children under two years of age, those who are systemically unwell, or those who have recurrent infections). A

strategy of watchful waiting and use of delayed prescriptions may be appropriate for many children. Paracetamol or ibuprofen can be used for symptomatic relief of pain and fever.

PRODIGY information leaflets for parents are available from www.prodigy.nhs.uk. Dr. Chris Cates has also developed a useful handout that has been tested alongside a delayed antibiotic prescription. This is available from www.nntonline.net together with the graphical displays that Dr. Cates uses to explain the likely outcomes for a theoretical group of 100 patients who are given a particular treatment.

Antibiotic treatment — which drug, dose and duration?

Amoxicillin is the recommended first-line antibiotic for AOM where antibiotics are indicated. Five days treatment at the following doses is sufficient for uncomplicated ear infections in children:^{1,13}

- under 2 years, 125mg three times daily
- 2–10 years, 250 mg three times daily
- over 10 years, 500 mg three times daily.

Erythromycin is an alternative for penicillin-allergic patients,¹³ although it is less effective against *Haemophilus influenzae*, which is the cause of AOM in around 25% of people. Azithromycin and clarithromycin are alternatives that are effective against all the main pathogens that cause AOM.²

A strategy of watchful waiting and use of delayed prescriptions may be appropriate for many children

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