Managing otitis media: an evidence-based approach

***Peter S Morris**, Menzies School of Health Research, and Institute of Advanced Studies, Charles Darwin University, and Northern Territory Clinical School, Flinders University; and **Amanda J Leach**, Menzies School of Health Research, and Institute of Advanced Studies, Charles Darwin University, Darwin*

Summary

Otitis media is a common illness in young children. Historically it has been associated with frequent and severe complications. These days it is usually a mild condition that often resolves without treatment. This has led us to re-evaluate many interventions that were used routinely in the past. Evidence from a large number of randomised controlled trials can help in discussing treatment options with families. In Australia, Aboriginal children have more severe disease and will benefit from effective treatment of persistent (or recurrent) bacterial infection.

Key words: antibiotics, children, ear.

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Introduction

Otitis media is a common illness in young children (and occurs much less frequently in children over six years of age).[1,2] In developed countries, otitis media is the commonest indication for antibiotic prescribing and surgery in young children. In the United States, annual costs were estimated to be US$3–5 billion in the 1990s.[1]

Diagnosis

Otitis media is best regarded as a spectrum of disease. The most important conditions are acute otitis media without perforation, acute otitis media with perforation, otitis media with effusion and chronic suppurative otitis media (see Table 1). There is currently a lack of consistency in definitions of different forms of otitis media (especially acute otitis media).

Children with middle ear infections will usually present with features related to:

- pain and/or fever (acute otitis media)
- hearing loss (otitis media with effusion)
- ear discharge (acute otitis media with perforation or chronic suppurative otitis media).

In some children, otitis media will be detected as part of a routine examination. Making an accurate diagnosis is not easy. Generally it requires a good view of the whole tympanic membrane and the use of either pneumatic otoscopy or tympanometry (to confirm the presence of a middle ear effusion). Studies of diagnostic accuracy in acute otitis media have found ear pain to be the most useful symptom, but not very reliable on its own. Bulging, opacity and immobility of the tympanic membrane are all highly predictive of acute otitis media. Normal (pearly grey) colour of the tympanic membrane makes acute otitis media unlikely.[3]

Acute otitis media

Most children will experience at least one episode of acute otitis media.[1] The peak incidence of infection occurs between 6 and 12 months. Although the pathogenesis of this condition is multifactorial, both viruses and bacteria are implicated.[1]

The pain associated with acute otitis media resolves within 24 hours in around 60% and within three days in around 80% of patients.[2] Young children (under two years of age) are less likely to experience spontaneous resolution.[4]

Complications of acute otitis media include chronic suppurative otitis media, mastoiditis, labyrinthitis, facial palsy, meningitis, intracranial abscess, and lateral sinus thrombosis.[5] Mastoiditis was the most common life-threatening complication in the pre-antibiotic era. It is now rare in developed countries. A small proportion of children with acute otitis media will experience recurrent acute otitis media (three episodes in six months, or four episodes within 12 months).[1]

Table 1

Clinical features of otitis media

Condition	Clinical features
Acute otitis media without perforation	Bulging tympanic membrane with or without ear pain
Acute otitis media with perforation	Recent discharge through perforated tympanic membrane with or without ear pain
Recurrent acute otitis media	Recurrent clinical diagnosis of acute otitis media (at least three in six months)
Otitis media with effusion	Asymptomatic persistent middle ear effusion confirmed by pneumatic otoscopy or tympanometry
Chronic suppurative otitis media	Discharge through a perforation of the tympanic membrane for more than six weeks

Otitis media with effusion

This is the commonest form of otitis media and affects all children but is usually asymptomatic. The point prevalence in screening studies is around 20% in young children.[1] It is more common in Aboriginal communities and was detected in over 40% of young children in a recent survey in the Northern Territory.[6]

Otitis media with effusion can occur spontaneously, as part of rhinosinusitis, or following an episode of acute otitis media. The same respiratory bacterial pathogens associated with acute otitis media have been implicated in its pathogenesis.

Most children will improve spontaneously within three months and complications from this illness are uncommon.[1] A small proportion of children who have persistent otitis media with effusion have associated hearing loss. The average hearing loss associated with otitis media with effusion is around 25 decibels.[1] Despite large numbers of studies, a causal relationship between otitis media with effusion and speech and language delay has not been proven.[5,7]

Chronic suppurative otitis media

Occasionally, children with acute otitis media with perforation will go on to develop chronic suppurative otitis media. In developed countries, chronic suppurative otitis media is now very uncommon and most often occurs as a complication of tympanostomy tube insertion. However, in impoverished populations including those in developed countries, chronic suppurative otitis media occurs as a complication of acute otitis media with perforation. In rural and remote communities in northern Australia, more than 20% of young children are affected.[8]

Chronic suppurative otitis media is the most disabling form of otitis media.[5,9] Although there is a lack of well-designed longitudinal studies, this type of otitis media is most likely to persist without treatment.

The range of bacterial pathogens associated with chronic suppurative otitis media is considerably broader than that seen in acute otitis media. The associated hearing loss is usually more than that seen in otitis media with effusion. Chronic suppurative otitis media represents the most important cause of moderate conductive hearing loss (greater than 40 decibels) in many developing countries.[9]

Interventions

A range of different interventions has been recommended for middle ear infections. Fortunately, many of these have been assessed in randomised controlled trials (see Table 2). This evidence can help with decision making, particularly when discussing options with families.

Acute otitis media

Most children with acute otitis media will improve spontaneously within 14 days and complications from this illness are uncommon. There are data from randomised controlled trials on antibiotics, antihistamines, decongestants, myringotomy and analgesics (see Table 2).[2] Antihistamines, decongestants and myringotomy showed no benefit.

The options at this stage are symptomatic relief with analgesics and either watchful waiting or antibiotics. Antibiotics are most appropriate in the following children:

- aged less than two years with bilateral acute otitis media
- with acute otitis media with perforation
- at risk of complications like chronic suppurative otitis media or mastoiditis (e.g. Aboriginal children living in remote communities, children with immunodeficiency syndromes)
- those who have already had 48 hours of watchful waiting.[4]

Aboriginal children in many communities have a relatively high risk of complications and so you would expect this group to be prescribed antibiotic treatment more often. Current national guidelines recommend amoxycillin 50 mg/kg/day in 2–3 daily doses.[10]

'Wait and see' prescribing

If the child is not in a high risk group but the family prefers antibiotic treatment, the clinician should discuss 'wait and see' prescribing. Provision of a script for an antibiotic along with advice only to use it if the pain persists for 48 hours will reduce antibiotic use by two-thirds (with no negative impact on family satisfaction).[11] If antibiotics are to be used, there is evidence that a longer course of treatment (at least seven days) is more effective, but the beneficial effects are modest (persistent acute otitis media reduced from 22% to 15%). Amoxycillin is the most often prescribed antibiotic for this indication in Australia. Although some clinicians have strong preferences for other antibiotics, there is no evidence that any one of the commonly used antibiotics is more effective than the others.

Recurrent acute otitis media

Prophylactic antibiotics, adenoidectomy and tympanostomy tube insertion have been assessed in randomised controlled trials (Table 2).[2] Antibiotics given for 3–6 months are effective but the benefits are modest. A Cochrane review did not find any evidence that alternative antibiotics were more effective than amoxycillin.[12] The rates of acute otitis media also reduce spontaneously without treatment so that absolute benefits are less impressive than anticipated. Insertion of tympanostomy tubes also appears to reduce acute otitis media and the effect is similar to antibiotics. Either of these options could be considered in those children with very frequent severe infections (especially if occurring before the peak of respiratory illness in winter). However, children with tympanostomy tubes may develop a discharging ear, so this is not a good option in children at increased risk of suppurative infections (including those with

Table 2

Evidence from randomised controlled trials to assist discussion about managing otitis media*

Question	Clinical evidence	Source
Prevention		
Why didn't the conjugate pneumococcal vaccine prevent all these infections?	In 3 studies (39 749 participants), acute otitis media episodes were reduced by 6% (e.g. from 1 to 0.94 episodes per year). Insertion of tympanostomy tubes was reduced from 3.8% to 2.9%.	Systematic review[15]
Should children have influenza vaccine?	In 11 studies (11 349 participants), there were inconsistent results. There was a modest protection against acute otitis media during influenza season in some studies.	Systematic review[16], meta-analysis[17]
Treatment of initial acute otitis media		
Do you recommend antihistamines and/or decongestants?	In 12 studies (2300 participants), there was no significant difference in persistent acute otitis media at 2 weeks.	Systematic review[18]
What about antibiotics?	In 8 studies (2287 participants), persistent pain on days 2–7 was reduced from 22% to 16%.	Systematic review[19]
	Analysis of individual patient data from 6 studies (1643 participants) found that persistent pain was reduced from 55% to 30% in children under 2 years with bilateral acute otitis media, and from 53% to 19% in children with acute otitis media with perforation.	Meta-analysis of individual patient data[20]
Is myringotomy worth considering?	In 3 studies (812 participants), early treatment failure actually increased from 5% to 20%.	Meta-analysis[5]
Do analgesics like paracetamol or ibuprofen help?	In 1 study (219 participants), persistent pain on day 2 was reduced from 25% to 9%.	Randomised controlled trial[21]
Treatment of recurrent acute otitis media		
Is there a role for prophylactic antibiotics?	In 16 studies (1483 participants), acute otitis media episodes were reduced from 3 to 1.5 episodes per year.	Systematic review[12]
What about adenoidectomy?	In 6 studies (1060 participants), there was no significant reduction in rates of acute otitis media.	Meta-analysis[5], randomised controlled trials[22–24]
Do tympanostomy tubes help?	In 5 studies (424 participants), acute otitis media episodes were reduced from 2 to 1 episode per year.	Meta-analyses[5,25], randomised controlled trial[24]
Treatment of persistent otitis media with effusion		
Do antibiotics work?	In 9 studies (1534 participants), persistent otitis media with effusion at around 4 weeks was reduced from 81% to 68% (antibiotic courses for 14–30 days).	Meta-analysis[5]
Do tympanostomy tubes help?	In 11 studies (about 1300 participants), there was a modest improvement in hearing; 9 decibels at 6 months and 6 decibels at 12 months. There was no improvement in language or cognitive assessment.	Systematic review[26], meta-analysis of individual patient data[27]
What about antihistamines and decongestants?	In 7 studies (1177 participants), there was no difference in persistent otitis media with effusion at 4 weeks (75%).	Meta-analysis of individual patient data[27], systematic review[28]
Should we try one of those autoinflation devices?	In 6 studies (602 participants), there were inconsistent results. There was a modest improvement in tympanometry at 4 weeks in some studies.	Systematic review[29]
What about using antibiotics plus oral steroids?	In 5 studies (418 participants), persistent otitis media with effusion at 2 weeks was reduced from 75% to 52%.	Systematic review[30]
Treatment of chronic suppurative otitis media		
Do topical antibiotics work?	In 7 studies (1074 participants), persistent chronic suppurative otitis media at 2–16 weeks reduced from around 75% to 20–50%.	Systematic review[31,32]
Can we use ear cleaning alone?	In 2 studies (658 participants), there were inconsistent results. There was no reduction in persistent chronic suppurative otitis media at 12–16 weeks (78%) in a large African study.[33]	Systematic review[31,32]

* See online publication for references 15–33

immunodeficiency or persistent bacterial rhinosinusitis). For these children, prophylactic antibiotics or prompt antibiotic treatment of infections are probably the more appropriate choices. Consistent with this, the benefits of long-term antibiotics in reducing perforation of the tympanic membrane have been demonstrated in a randomised trial of Aboriginal infants living in a remote community.[13] In this study, infants with otitis media with effusion were randomised to twice-daily amoxycillin or placebo for up to six months. Episodes of acute otitis media continued to be treated with antibiotics, so benefits were presumably due to the fact that many episodes go unrecognised.

Otitis media with effusion

There is evidence from randomised controlled trials on treatment effects of antibiotics, insertion of tympanostomy tubes, autoinflation devices, antihistamines and decongestants, and antibiotics plus steroids (see Table 2).[14]

A course of watchful waiting may be appropriate initially. For those children who have persistent otitis media with effusion in both ears associated with hearing loss, a trial of antibiotics is reasonable. Insertion of tympanostomy tubes is most appropriate in children where the primary concern is the conductive hearing loss and communication difficulties. In randomised controlled trials of early versus late insertion of ventilation tubes, watchful waiting for 6–12 months did not adversely affect speech and language development. Children with the most severe conductive hearing loss or established speech and language problems are more likely to benefit.

Children who experience frequent suppurative infections (including those with immunodeficiency or persistent bacterial rhinosinusitis) are at greatest risk of developing chronic suppurative otitis media as a complication of tympanostomy tubes. Families should be informed that a small proportion of children will suffer recurrent persistent otitis media with effusion when the tympanostomy tubes are extruded, and may need a second operation. In these children, tympanostomy tubes plus adenoidectomy is a reasonable option.[5]

Chronic suppurative otitis media

Topical antibiotics, topical antiseptics, systemic antibiotics, and ear cleaning have been investigated in randomised clinical trials (see Table 2).[9] After a discussion with their doctor, most parents would choose topical antibiotic treatment initially. However, even though this is an effective treatment, prolonged or repeated courses of treatment are often required. If this is the case, topical quinolones will provide a slight benefit in terms of reduced risk of ototoxicity. Under the Pharmaceutical Benefits Scheme, ciprofloxacin ear drops are subsidised for Aboriginal and Torres Strait Islander people (aged one month or older).

Conclusion

Otitis media is a common illness that will usually resolve completely without specific treatment. Many interventions have been assessed in randomised controlled trials but none have had substantial absolute benefits for the populations studied. For most children, symptomatic relief and watchful waiting (including education of the parents about likely clinical course) is the most appropriate treatment option. Antibiotics have a role in children with (or at risk of) persistent bacterial infection and in children with discharge through a perforated tympanic membrane.

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For references 15–33 see www.australianprescriber.com/magazine/32/6/155/9/

Conflict of interest: none declared

Self-test questions

The following statements are either true or false (answers on page 171)

3. Antibiotics are not appropriate for bilateral acute otitis media in children less than two years old.
4. Topical antibiotics are an effective treatment for chronic suppurative otitis media.

Top 10 drugs

These tables show the top 10 subsidised drugs in 2008–09.

Table 1

Top 10 drugs by DDD/1000 pop/day *†

Constituent drug	PBS/RPBS ‡
1. atorvastatin	77.71
2. irbesartan	36.63
3. ramipril	28.62
4. perindopril	27.46
5. simvastatin	27.31
6. paracetamol	21.77
7. candesartan	21.44
8. esomeprazole	21.34
9. aspirin	17.79
10. frusemide	17.49

Table 2

Top 10 drugs by prescription counts †

PBS drug name	PBS/RPBS ‡
1. atorvastatin	10 950 483
2. esomeprazole	5 888 347
3. simvastatin	5 164 548
4. paracetamol	3 912 494
5. perindopril	3 891 971
6. pantoprazole	3 491 231
7. atenolol	3 224 057
8. metformin hydrochloride	3 201 944
9. rosuvastatin	3 165 641
10. irbesartan	3 134 403

Table 3

Top 10 drugs by cost to Government †

PBS drug name	Cost to Government ($A)
1. atorvastatin	621 164 182
2. clopidogrel	210 600 588
3. esomeprazole	205 083 299
4. rosuvastatin	201 708 668
5. simvastatin	170 511 054
6. salmeterol and fluticasone	164 181 553
7. olanzapine	158 870 974
8. ranibizumab	154 941 222
9. rituximab	112 256 755
10. venlafaxine	111 236 036

* The defined daily dose (DDD)/thousand population/day is a more useful measure of drug utilisation than prescription counts. It shows how many people, in every thousand Australians, are taking the standard dose of a drug every day. The DDDs now include not only the use of the drug alone, but also its use in combination products.[1]

† Based on date of supply. Does not include private prescriptions or prescriptions under PBS co-payment.

‡ PBS Pharmaceutical Benefits Scheme, RPBS Repatriation Pharmaceutical Benefits Scheme

Source: Drug Utilisation Sub-Committee (DUSC) Database as at 28 September 2009. © Commonwealth of Australia.

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