

## TRANSATLANTIC TOPIC

## Ear, ears, and more ears!

In the US this year, clinicians will write approximately 25 000 000 oral antibiotic prescriptions for acute otitis media (AOM). I thought it worthwhile to describe current management in the US, given how often clinicians diagnose AOM, the concern about appropriate use of oral antibiotics, and the European trend for not treating this condition with antibiotics.

In 1999, the Drug-Resistant *Streptococcus pneumoniae* Therapeutic Working Group, sponsored by the Centers for Disease Control, published their recommendations regarding initial antibiotic choice for AOM.<sup>1</sup> Essentially, they divide children into two categories, those who received antibiotics in the month before, and those who did not. Young age, daycare attendance, residence in certain communities, and previous treatment with oral antibiotics are major risk factors for resistant pneumococcal disease. For children who have not been on antibiotics the working group recommended high dose amoxicillin or usual dose amoxicillin. Children with clinically defined failure on day three should receive high dose amoxicillin-clavulanate, cefuroxime axetil, or intramuscular ceftriaxone. For children who have been on antibiotics in the previous month they recommended high dose amoxicillin, high dose amoxicillin-clavulanate, or cefuroxime axetil. If these children have clinical failure on day three, they should receive intramuscular ceftriaxone, clindamycin, or a tympanocentesis. Their recommendations were based upon the scientific literature and the experience of experts. Unfortunately, there was no formal review of the evidence and the quality of the evidence was not graded. It is unclear how many US clinicians are following these recommendations. At my medical centre most clinicians use either amoxicillin or amoxicillin-clavulanate. I have used intramuscular ceftriaxone in a number of younger children with AOM who have been on numerous antibiotics in the previous two to three months. Although the working group recommended three doses of ceftriaxone, we only give one dose and if the patient improves clinically, we do not give the second or third dose.

Despite the recommendations of the CDC, many US children with AOM are treated with azithromycin and other cephalosporins. The popularity of azithromycin is attributable to its ease of administration (single dose per day) and length of treatment (five days). Single dose and short course treatment are preferred by parents, and most of my colleagues report that parents are requesting/demanding this antibiotic.

Although there has been some new literature about the “no treatment” option for AOM, neither I nor most US paediatric infectious disease experts support this option, particularly for children less than 2 years of age. The recent BMJ report of a randomised controlled trial that included a placebo group in infants (6 months to 2 years) and which has been widely touted as providing evidence that no treatment is a reasonable option in young children, has a number of important limitations.<sup>2</sup> Firstly, children who received amoxicillin were less likely to have persistent symptoms at day 4 (59%) than those who received placebo (72%). Secondly,

only infants who were well with AOM and “did not require antibiotics” were included in the study, and despite this, one of 123 children in the placebo group developed bacterial meningitis. Another child in the placebo group had to be hospitalised because of “deterioration of symptoms of acute otitis media”. These data are disturbing and suggest that not treating infants with AOM may be associated with significant morbidity. In addition, families and physicians in the US do not accept even rare risk very well, as suggested by our recent change from oral polio vaccine to inactivated polio vaccine because of 6–8 cases of vaccine associated paralytic polio each year (one case per 2.4 million oral doses distributed). Certainly, US families will not accept a much more substantial risk of developing bacterial meningitis from AOM if infants are not treated with antibiotics.

I do not believe that the “no treatment” option for AOM in the US will ever win widespread acceptance, nor do I think it is critical in the campaign to reduce inappropriate antibiotic use.<sup>3</sup> We can reduce the number of children who receive antibiotics for AOM if we improve our diagnostic accuracy. Many clinicians continue to make the diagnosis without testing the mobility of the tympanic membrane. Although this is probably reasonable in older children who indicate that their ear hurts, and on physical examination have a red tympanic membrane (and the other is grey), in younger children, the diagnosis of AOM is much more complicated. In my conversations with clinicians I urge them to test if the tympanic membrane is mobile before concluding a child has AOM. They can do this with pneumatic otoscopy.

Despite near consensus about treating young infants with AOM with antibiotics, some US clinicians are offering, and some parents are demanding, the “no treatment” option in older children. This often requires more visits and closer contact with families, but is growing in popularity. Physicians are experimenting with giving parents of older children an antibiotic prescription, and instructing them to fill it in 24–48 hours if their child is not better. Although I believe that the number of children with AOM that are not being treated is small, many clinicians are shortening the course of treatment of AOM in older children to 5–7 days. As I think that most parents only give older children with AOM antibiotics for 5–7 days, our clinical treatment is now consistent with what most parents do.

Where do we stand in respect of the overall use of oral antibiotics? I believe that inappropriate use of oral antibiotics in children has peaked. Most of my colleagues report substantially less parent pressure to dispense antibiotics than in the past. Our professional societies and governmental agencies have done a good job educating physicians, and parent magazines have done a wonderful job of re-educating parents about appropriate indications for oral antibiotics. The pendulum is swinging, and many parents in the past who requested/expected antibiotics, now ask if they are really necessary. Finally, with the recent release of the new conjugate pneumococcal vaccine, additional progress will be made against this common bacterial

disease in children. How this will influence physician prescribing patterns for AOM has yet to be determined.

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- 1 Dowell SF, Butler JC, Giebink SG, *et al.* Acute otitis media: management and surveillance in an era of pneumococcal resistance: a report from the

Drug-Resistant *Streptococcus pneumoniae* Therapeutic Working Group (DRSPTWG). *Pediatr Infect Dis* 1999;18:1-9.

- 2 Damoiseaux RA, van Balen FAM, Hoes AW, *et al.* Primary care based randomised, double blind trial of amoxicillin versus placebo for acute otitis media in children aged under 2 years. *BMJ* 2000;320:350-4.
- 3 Bauchner H, Phillip B. Reducing inappropriate oral antibiotic use: a prescription for change. *Pediatrics* 1998;102:142-5.

### Problems after sedation

Findings from a US study of severe adverse events after sedation in children have been reported in two papers (Charles J Coté and colleagues. *Pediatrics* 2000;105:805-14 and *Ibid* 2000;106:633-44).

They used the US Freedom of Information Act to obtain data from the Food and Drug Administration about reports of adverse events received between 1969 and 1996 and also obtained reports of adverse events reported to the US Pharmacopoeia and from a survey of paediatric anaesthetists, intensivists, and emergency medicine specialists. Altogether, they reviewed 118 reports, 95 of which proved suitable for analysis. Fifty one of the 95 children died and nine had permanent neurological sequelae. Fourteen were normal on follow up. Death and neurological damage occurred more frequently with sedation outside hospital (93% in hospital *v* 37% outside) and were attributed to inadequate monitoring and resuscitation. The importance of pulse oximetry monitoring was stressed.

The second paper concentrates on drug use and adverse events. No single drug or class of drug or method of administration was particularly associated with poor outcome. Use of excessive dose was an important factor. Of 39 instances in which the maximum recommended dose was exceeded by between 25% and 500%, 28 resulted in death or permanent neurological damage. The use of multiple sedating drugs was also associated with adverse outcome. Twenty nine of the deaths followed sedation for dental procedures and these were particularly associated with the use of multiple drugs and of nitrous oxide. Fifteen patients died after being sedated with chloral hydrate, as the sole drug in seven (in overdose or unknown dose in six of these). Twelve of the 95 children suffered the adverse event at home (8) or in a car (4); 11 of these died or were permanently neurologically damaged. Drugs with long half lives (chloral hydrate, pentobarbitone, promazine, promethazine, and chlorpromazine) were more likely to be associated with adverse events after leaving medical supervision.

These adverse events after sedation were related not to specific drugs or modes of administration but to overdose, multiple drug use, and failures of clinical practice.

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