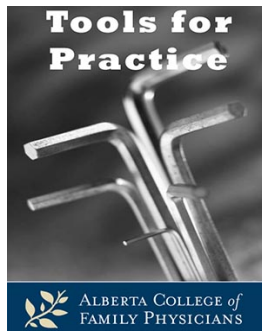


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Reviewed: March 10, 2015
Evidence Updated: Added two meta-analyses, one RCT
Bottom line: No change
First Published: February 22, 2011



Children with Acute Otitis Media: Benefits and Risks of Antibiotics

Clinical Question: In children with acute otitis media (AOM) what are benefits and risks of antibiotics?

Bottom-line: Although most children will recover from acute otitis media without complications, antibiotics will improve outcomes for 1 in 3 to 1 in 10, depending on outcome and complicating factors. Antibiotics will cause adverse events, particularly diarrhea, in up to 1 in every 5.

Evidence:

- Randomized Controlled Trial (RCT):¹ 319 patients, age 6-35 months.
 - Amoxicillin/clavulanate (40/5.7 mg/kg/day) versus placebo, divided BID x7 days
 - Treatment failure day eight: 19% (antibiotic) versus 45% (placebo), Number Needed to Treat (NNT)=4.
 - Reduced absenteeism for child (day-care) and parent (work), more fever resolution, less contra-lateral AOM, fewer rescue treatments, etc.
 - Antibiotics increased adverse events: Eczema Number Needed to Harm (NNH)=19, any diarrhea NNH=5 and for "a lot" of diarrhea NNH=12.
- RCT:² 291 patients, age 6-23 months.
 - Amoxicillin/clavulanate (90/6.4 mg/kg/day) versus placebo, divided BID x10 days.
 - Clinical failure day 4-5: 4% versus 23%, NNT=6.
 - Day 10-12: 16% versus 51%, NNT=3.
 - Antibiotics increased adverse events: Diarrhea NNH=10, diaper rash NNH=7.
- RCT:³ 84 patients, 85% ≤5 years old.
 - Amoxicillin/clavulanate (40 mg/kg/day) versus placebo, divided BID x7 days.
 - Resolution of middle ear effusion: 18.9 versus 32.6 days.
 - Ear ache five days after initiation: 0% versus 17%, NNT=6.
- Three systematic reviews:⁴⁻⁶ 7-15 RCTs (2,079-4,500 patients), antibiotic versus placebo, similar results.

- Persistent pain:⁶ At 24 hours no difference; At 2-3 days NNT=24; At 4-7 days NNT=17.
- Treatment success at 14 days:⁴ NNT=9.
- Less perforation and contralateral infection.⁶
- Vomiting, diarrhea, or rash:⁶ NNH=14.

Context:

- Natural history: 70% of untreated children have resolution at 7-14 days.^{1,2,4}
- Poor Prognostic Indicators: Bilateral Otitis Media,^{2,7} age <24 months,⁷ exposure to more children (day-care),² and more severe symptom scores.²
- Types of antibiotics: No reliable difference in the efficacy of antibiotics studied.⁴
 - Amoxicillin is the most commonly studied and recommended.^{4,8}
- Delayed versus immediate prescriptions:
 - Four studies, two found no difference and two found immediate prescriptions superior (NNT=6-7).⁴
 - Delayed prescriptions may increase patient dissatisfaction.⁹

Original Authors:

G Michael Allan MD CCFP, Christina Korownyk MD CCFP

Updated:

Braiden Hellec BSc. Pharm

Reviewed:

G Michael Allan MD CCFP

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