Delayed prescribing of antibiotics increased duration of acute otitis media symptoms in children but reduced diarrhoea


**QUESTION:** Is a delayed (72 hour “wait and see”) prescribing strategy for antibiotics as effective as standard immediate prescribing for children with acute otitis media (AOM)?

### Design
Randomised (unclear allocation concealment), unblinded, controlled trial with about 1 week of follow up.

### Setting
General practices in south west UK.

### Patients
315 children aged 6 months to 10 years (59% > 3 y) who had acute otalgia and otoscopic evidence of acute inflammation of the ear drum. Exclusion criteria were otoscopic appearances consistent with crying or fever alone (pink ear drum only), appearances more suggestive of OM with effusion and chronic supplicative OM, serious chronic disease, use of antibiotics for ear infections in the previous 2 weeks, previous complications, or if the child was too unwell to be left to wait and see. 285 children (90%) were included in the analysis.

### Intervention
All patients were prescribed amoxicillin syrup, 125 mg in 5 ml, 4 times daily for 1 week. 164 children were allocated to delayed prescription of antibiotics. Their parents were asked to wait for 72 hours before considering using their prescription. If, after that time, their child still had substantial otalgia or fever or was not getting better, parents were instructed to then pick up the prescription from the office. Parents could, however, pick up the prescription before 72 hours. 151 children (90%) were prescribed erythromycin, 125 mg in 5 ml, 4 times daily for 1 week. 164 children were allocated to immediate prescription of antibiotics. Their parents were asked to wait for 72 hours before using the antibiotics, and adverse effects. Data were obtained from daily diaries kept by parents. Two lines of research into AOM treatment have emerged: examination of the need for any antibiotics and the feasibility of shorter courses of antibiotics. Several meta-analyses have concluded that in most children, ear pain resolves spontaneously, often within 24 hours and that 5 days of antibiotics may be a viable alternative to the traditional 7–14 day regimen.

Little et al designed an approach involving a 72 hour waiting period for antibiotic decision making. Concern over the risk of complications likely prevents primary care providers from withholding antibiotics from all patients. This design allowed for parents and/or primary care providers to identify children who were not improving spontaneously. Strengths of the study include the use of appropriate statistical methodology, a power analysis, and an adequate sample upon which to base the conclusions. The length of symptomatology before diagnosis was not mentioned in the selection criteria. If AOM is a self-limiting disorder with a predictable time course, as is implied by this and other studies, then the duration of symptoms before diagnosis should be an important criteria for treatment decision making. A disadvantage of the design is that parents and providers were not blinded to treatment. An antibiotic placebo effect could have operated in both groups and the effect of this is unknown.

The study makes a strong case for a “wait and see” approach. Duration of symptoms in the delayed antibiotic group of approximately 1 extra day, although statistically significant, could be mitigated by appropriate analgesic prescription. The difference in paracetamol (acetaminophen) use between the 2 groups is not clinically significant. The lack of difference in pain scores, episodes of distress, and absence from school support this “wait and see” approach. Also, children without antibiotics were less likely to have diarrhoea. The study provides valuable data for nurses in primary care settings. The logical conclusion for primary care providers would be to consider a “wait and see” approach in the treatment of AOM. Further research is needed to identify selection criteria that will better predict which patients are most likely to benefit from this approach.

**Conclusions**
In children with acute otitis media, a delayed prescribing strategy for antibiotics resulted in a longer duration of symptoms, more paracetamol consumption, but a lower rate of diarrhoea than an immediate prescribing strategy.

<table>
<thead>
<tr>
<th>Outcome at approximately 1 week</th>
<th>Delayed</th>
<th>Immediate</th>
<th>RRR (95% CI)</th>
<th>NNT (CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients who actually took antibiotics (%)</td>
<td>24%</td>
<td>99%</td>
<td>76% (68 to 82)</td>
<td>2 (2 to 2)</td>
</tr>
</tbody>
</table>

Abbreviations defined in glossary; RRR, CI, and NNT calculated from data in article.

**COMMENTARY**
AOM is the most frequent primary diagnosis among children < 4 years of age, and in the US it is treated with antibiotics approximately 98% of the time. Given current concern about growing antibiotic resistance, reconsideration of current treatment practices for AOM is warranted. Two lines of research into AOM treatment have emerged: examination of the need for any antibiotics and the feasibility of shorter courses of antibiotics. Several meta-analyses have concluded that in most children, ear pain resolves spontaneously, often within 24 hours and that 5 days of antibiotics may be a viable alternative to the traditional 7–14 day regimen.

Little et al designed an approach involving a 72 hour waiting period for antibiotic decision making. Concern over the risk of complications likely prevents primary care providers from withholding antibiotics from all patients. This design allowed for parents and/or primary care providers to identify children who were not improving spontaneously. Strengths of the study include the use of appropriate statistical methodology, a power analysis, and an adequate sample upon which to base the conclusions. The length of symptomatology before diagnosis was not mentioned in the selection criteria. If AOM is a self-limiting disorder with a predictable time course, as is implied by this and other studies, then the duration of symptoms before diagnosis should be an important criteria for treatment decision making. A disadvantage of the design is that parents and providers were not blinded to treatment. An antibiotic placebo effect could have operated in both groups and the effect of this is unknown.

The study makes a strong case for a “wait and see” approach. Duration of symptoms in the delayed antibiotic group of approximately 1 extra day, although statistically significant, could be mitigated by appropriate analgesic prescription. The difference in paracetamol (acetaminophen) use between the 2 groups is not clinically significant. The lack of difference in pain scores, episodes of distress, and absence from school support this “wait and see” approach. Also, children without antibiotics were less likely to have diarrhoea. The study provides valuable data for nurses in primary care settings. The logical conclusion for primary care providers would be to consider a “wait and see” approach in the treatment of AOM. Further research is needed to identify selection criteria that will better predict which patients are most likely to benefit from this approach.