

## Living FRIendly Summaries of the Body of Evidence using Epistemonikos (FRISBEE)

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### Antibiotics for acute otitis media in children

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#### Abstract

Acute otitis media is one of the most common infectious diseases diagnosed in children. Antibiotic treatment use remains controversial. This summary aims to evaluate the effectiveness and safety of antibiotics in children with acute otitis media. Searching in Epistemonikos database, which is maintained by screening 30 databases, we identified six systematic reviews including 18 randomized trials. We combined the evidence using meta-analysis and generated a summary of findings table following the GRADE approach. We concluded antibiotics reduce pain at 48-72 hours and reduce the risk of tympanic perforations in children with acute otitis media, but they do not reduce late recurrences and increase the risk of side effects (rash, vomiting and diarrhea).

#### Problem

Acute otitis media is defined as the presence of tympanic effusion (demonstrated by pneumatic otoscopy, fluid level or impedanciometry) associated with signs and symptoms of acute inflammation of the middle ear. Acute otitis media occurs more frequently in children at an early age and the most serious complications are mastoiditis, meningitis and tympanic perforation.

The use of antibiotics for the treatment of acute otitis media varies considerably among countries because its real efficacy and safety have not been determined. On one side, the expected benefits of antibiotics include reducing the number of complications, the duration of symptomatic stage and the risk of recurrences. On the other side, the inappropriate use of antibiotics can cause adverse effects and increases antibiotic resistance.

#### Methods

We used Epistemonikos database, which is maintained by screening more than 30 databases, to identify systematic reviews and their included primary studies. With this information, we generated a structured summary using a pre-established format, which includes key messages, a summary of the body of evidence (presented as an evidence matrix in Epistemonikos), meta-analysis of the total of studies, a summary of findings table following the GRADE approach and a table of other considerations for decision-making.

#### Key messages

- Antibiotics reduce pain at 48-72 hours and reduce the risk of tympanic perforation in children with acute otitis media. However, they do not reduce late recurrences and increase the risk of side effects (rash, vomiting and diarrhea).
- Even though the certainty of the evidence is high, the decision on the use of this intervention depends on other individual and population factors.

### About the body of evidence for this question

<p>What is the evidence. See evidence matrix in Epistemonikos later</p>	<p>We found six systematic reviews [1],[2],[3],[4],[5],[6] including 18 randomized controlled trials reported in 24 references [7],[8],[9],[10],[11],[12],[13],[14],[15],[16],[17],[18],[19],[20],[21],[22],[23],[24],[25],[26],[27],[28],[29],[30].</p>
<p>What types of patients were included</p>	<p>The eighteen studies included patients between 2 months and 15 years. Only one study [13] included patients under 6 months, five studies [10],[17],[23],[28],[30] included only patients older than 2 years and 13 studies included patients under 2 years [7],[9],[13],[14],[15],[16],[18],[19],[21],[22],[25],[26],[27].</p>
<p>What types of interventions were included</p>	<p>Thirteen studies evaluated the use of antibiotics versus placebo [7],[9],[10],[13],[14],[15],[16],[18],[22],[26],[27],[28],[30]. Five studies evaluated the use of antibiotics versus expectant management [17],[21],[22],[23],[25]. Within the antibiotics, eight studies used amoxicillin [10],[16],[18],[19],[21],[22],[23],[30], four used amoxicillin with clavulanate [7],[14],[26],[27], two used ampicillin [13],[15], two used penicillin [17],[22] and six studies used non-standardized antibiotic regimen or other antibiotic [13],[15],[22],[23],[25],[28].</p>
<p>What types of outcomes were measured</p>	<p>The main outcomes reported were:</p> <ul style="list-style-type: none"> <li>• Pain</li> <li>• Tympanic perforation</li> <li>• Late recurrences</li> <li>• Antibiotic side effects</li> </ul>

### Summary of findings

The information about the effects of antibiotic treatment for acute otitis media is based on 18 randomized studies that included 4,550 patients. Thirteen studies compared antibiotics versus placebo [7],[9],[10],[13],[14],[15],[16],[18],[22],[26],[27],[28],[30]. Seven studies reported pain [7],[13],[16],[18],[22],[26],[28], five reported tympanic perforation [10],[14],[22],[26],[27], eight reported antibiotic side effects [1],[10],[14],[18],[22],[26],[27],[28], and six studies reported the late recurrence of acute otitis media [14],[16],[18],[22],[28],[30].

- Antibiotics reduce pain at 48-72 hours in children with acute otitis media. The certainty of the evidence is high.
- Antibiotics do not reduce late recurrences of acute otitis media. The certainty of the evidence is high.
- Antibiotics reduce the risk of tympanic perforation. The certainty of the evidence is high.
- Antibiotics increase the number of side effects (rash, vomiting and diarrhea). The certainty of the evidence is high.

<b>Antibiotics versus placebo for acute otitis media in children</b>				
<b>Patients</b>	Children between 2 months and 15 years old with acute otitis media			
<b>Intervention</b>	Antibiotics			
<b>Comparison</b>	Placebo			
Outcomes	Absolute effect*		Relative effect (95% CI)	Certainty of the evidence (GRADE)
	WITHOUT ANTIBIOTICS	WITH ANTIBIOTICS		
	Difference: patients per 1000			
Pain at 2-3 days	159 per 1000	111 per 1000	RR 0.70 (0.57 to 0.86)	⊕⊕⊕⊕ High
	Difference: 48 patients less per 1000 (Margin of error: 22 to 69 less)			
Side effects of antibiotics	196 per 1000	270 per 1000	RR 1.38 (1.19 to 1.59)	⊕⊕⊕⊕ High
	Difference: 74 patients more per 1000 (Margin of error: 37 to 115 more)			
Tympanic perforation	48 per 1000	17 per 1000	RR 0.36 (0.18 to 0.73)	⊕⊕⊕⊕ High
	Difference: 31 patients less per 1000 (Margin of error: 13 to 39 less)			
Late otitis media recurrence	221 per 1000	201 per 1000	RR 0.91 (0.77 to 1.07)	⊕⊕⊕⊕ High
	Difference: 20 patients less per 1000 (Margin of error: 51 less to 15 more)			
RR: Risk ratio. Margin of error = 95% confidence interval (CI). GRADE: evidence grades of the GRADE Working Group (see later in this article).  * The risk <b>WITHOUT antibiotics</b> is based on the risk in the control group of the trials. The risk <b>WITH antibiotics</b> (and its margin of error) is calculated from relative effect (and its margin of error).				

### About the certainty of the evidence (GRADE)\*

⊕⊕⊕⊕

**High:** This research provides a very good indication of the likely effect. The likelihood that the effect will be substantially different† is low.

⊕⊕⊕○

**Moderate:** This research provides a good indication of the likely effect. The likelihood that the effect will be substantially different† is moderate

⊕⊕○○

**Low:** This research provides some indication of the likely effect. However, the likelihood that it will be substantially different† is high.

⊕○○○

**Very low:** This research does not provide a reliable indication of the likely effect. The likelihood that the effect will be substantially different† is very high.

\*This concept is also called 'quality of the evidence' or 'confidence in effect estimates'.

† Substantially different = a large enough difference that it might affect a decision.

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## Other considerations for decision-making

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### To whom this evidence does and does not apply

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- This evidence can be applied to pediatric population between 2 months and 15 years old with the diagnostic of acute otitis media. The diagnosis can be based on clinical manifestations, on otoscopy findings or pneumo-otoscopy findings. This evidence can be used either in primary or secondary care.
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### About the outcomes included in this summary

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- The critical outcomes for decision-making were selected based on the opinion of the authors of this summary.
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### Balance between benefits and risks, and certainty of the evidence

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- This is an intervention for which we have high certainty evidence that shows both benefits and risks. On one hand, it can be argued the use of antibiotics is beneficial and relatively safe, but on the other hand, the natural progression is positive even without antibiotics in many cases, and overuse of antibiotics can lead to increased bacterial resistance at population level [31].
  - It may be possible that in high risk groups, as children under two years, the decision can be different. Also it will vary depending on the values and preferences of individual patients and epidemiological context.
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### What would patients and their doctors think about this intervention

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- Pediatric practice requires the consideration of parental apprehensions. Physicians should not exclude parents from decision-making. In those patients that receive expectant management it is reasonable to consider an early follow-up.
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### Resource considerations

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- Antibiotics for the treatment of acute otitis media have low cost and are highly available.
  - Expectant management requires a health system that allows follow-up at 48 hours and availability for early control if needed.
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### Differences between this summary and other sources

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- Our summary is consistent with the systematic reviews that were analyzed.
  - The clinical practice guidelines of the American Academy of Pediatrics were reviewed [31] and they are consistent with the conclusions of our summary.
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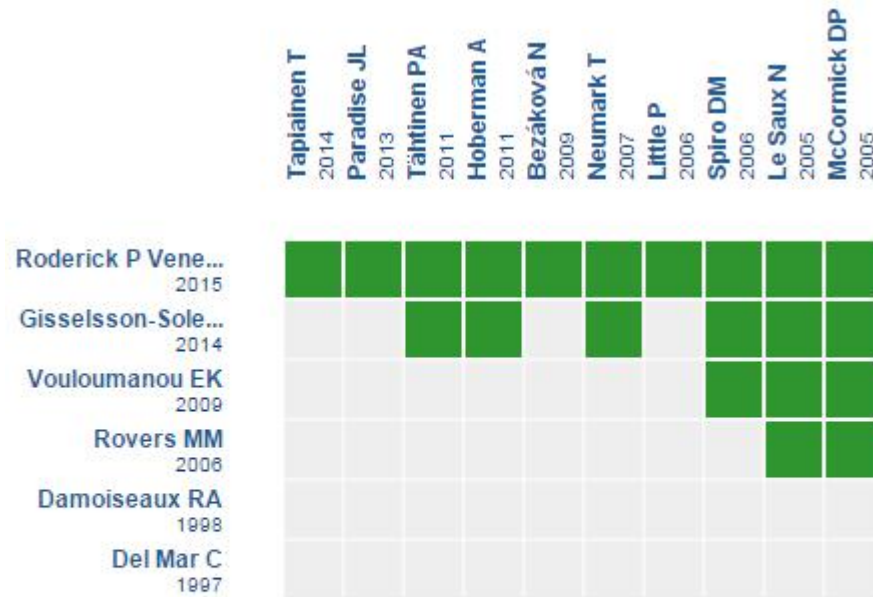
### Could this evidence change in the future?

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- The likelihood that future evidence can change the key findings of this summary is very low due to the high certainty of this evidence.
  - We are not aware of ongoing studies that could provide new information.
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## How we conducted this summary

Using automated and collaborative means, we compiled all the relevant evidence for the question of interest and we present it as a matrix of evidence.



Starting from any systematic review, Epistemonikos builds a matrix based on existing connections in the database.

The author of the matrix can select relevant information for a specific health question (typically in PICO format) in order to display the information set for the question.

The rows represent systematic reviews that share at least one primary study, and columns display the studies.

The boxes in green correspond to studies included in the respective reviews.

Follow the link to access the **interactive version**: [Antibiotics for acute otitis media in children](#)

## Notes

The upper portion of the matrix of evidence will display a warning of “new evidence” if new systematic reviews are published after the publication of this summary. Even though the project considers the periodical update of these summaries, users are invited to comment in *Medwave* or to contact the authors through email if they find new evidence and the summary should be updated earlier. After creating an account in Epistemonikos, users will be able to save the matrixes and to receive automated notifications any time new evidence potentially relevant for the question appears.

The details about the methods used to produce these summaries are described here <http://dx.doi.org/10.5867/medwave.2014.06.5997>.

Epistemonikos foundation is a non-for-profit organization aiming to bring information closer to health decision-makers with technology. Its main development is Epistemonikos database ([www.epistemonikos.org](http://www.epistemonikos.org)).

These summaries follow a rigorous process of internal peer review.

### Conflicts of interest

The authors do not have relevant interests to declare.

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