Close Follow-up in Children With Acute Otitis Media Initially Managed Without Antimicrobials

According to several national guidelines, close follow-up is required if initial observation without antimicrobial agents is chosen for the management of acute otitis media (AOM) in children.1–4 The aim of this study was to examine whether close follow-up with reexamination is needed for children with AOM initially managed without antimicrobial agents who have symptomatic improvement during the first week after diagnosis, as assessed by their parents.

Methods | This study is part of a project examining diagnostics and treatment of AOM (Clinicaltrials.gov identified NCT00299455).5 Children aged 6 to 35 months with acute symptoms and parental suspicion of AOM were eligible. Acute otitis media was diagnosed from March 16, 2006, to December 5, 2008, excluding June and July of each year, with the use of stringent criteria and children were randomized in a double-blind fashion to receive either a combination of amoxicillin, 40 mg/kg per day, and clavulanate potassium, 5.7 mg/kg per day, divided into 2 daily doses, or placebo for 7 days. The scheduled visits were 48 to 72 hours and 1 week after the day of the diagnosis of AOM; additional visits were arranged on any other day by parental request. At each visit, the physician examined the child and recorded signs as seen on pneumatic otoscopy as completely resolved, better, no improvement, worse, or perforation of the tympanic membrane. Correspondingly, at each visit, parents assessed their child’s overall condition as healthy, better, no improvement, or worse.

In our analysis, we included 158 patients who received placebo and divided them into 2 groups. The group with symptomatic improvement (n = 104) included children whose overall condition improved within 48 to 72 hours and did not deteriorate within 1 week of diagnosis, according to assessment by their parents. The group with symptomatic failure (n = 54) included children whose overall condition did not improve within 48 to 72 hours or deteriorated within 1 week of diagnosis, according to assessment by their parents.

Data analysis was conducted from January 29 to February 12, 2016. We used a χ2 test to compare the signs seen on otoscopy recorded for the 2 groups after 1 week or earlier if the study drug was stopped and an open-label antimicrobial treatment was initiated owing to symptomatic treatment failure. The odds ratio for the worsening (including perforation of the tympanic membrane) of signs as seen on otoscopy in children with symptomatic improvement was calculated by using a binary logistic regression model.

The study protocol was approved by the ethics committee of the Hospital District of Southwest Finland. Written informed consent was obtained from parents of all children before any study procedures were performed.

Results | Of the 104 children with symptomatic improvement, 3 (2.9%) developed worse signs or perforation of the tympanic membrane as seen on otoscopy, 15 (14.4%) showed no improvement, and 86 (82.7%) showed improvement or complete resolution of signs as seen on otoscopy (Table). Of the 54 children with symptomatic failure, 16 (29.6%) developed worse signs or perforation of the tympanic membrane as seen on otoscopy, 26 (48.6%) showed no improvement, and 12 (22.2%) showed improvement or complete resolution of signs as seen on otoscopy. Perforation of the tympanic membrane was seen in 2 children with symptomatic improvement and in 3 children with symptomatic failure. In children with symptomatic improvement, the odds ratio for the worsening of signs as seen on otoscopy during the 1-week follow-up was 0.07 (95% CI, 0.02-0.26).

Discussion | Our results indicate that the resolution of signs of AOM as seen on otoscopy seems to be related to the child’s overall symptomatic condition. When parents assessed their child’s symptomatic condition as improving, otoscopic signs worsened in only 3 children (2.9%), including 2 children with perforation of the tympanic membrane. Thus, it appears that in children with symptomatic improvement, a routine follow-up visit may not be needed and a telephone call between the physician and parents would be sufficient to ensure the child’s well-being. Even the telephone call might be unnecessary if the physician considers the parents to be independently reliable to assess their child’s overall condition. However, when a child has symptomatic failure, parents should contact the physician, who will reexamine the child if there is any suspicion of toxic effects. Alternatively, parents of a child

![Table. Development of Signs Seen on Otoscopy During Follow-up at 1 Week](https://www.jamapediatrics.com/letters/1107/1107_table.png)

<table>
<thead>
<tr>
<th>Signs as Seen on Otoscopy</th>
<th>No. (%)</th>
<th>Children With Symptomatic Improvement (n = 104)</th>
<th>Children With Symptomatic Failure (n = 54)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Worse or perforation of the tympanic membrane</td>
<td>3 (2.9)</td>
<td>16 (29.6)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>No improvement</td>
<td>15 (14.4)</td>
<td>26 (48.1)</td>
<td>&lt;.001</td>
<td></td>
</tr>
<tr>
<td>Completely resolved or better</td>
<td>86 (82.7)</td>
<td>12 (22.2)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Signs seen on otoscopy were recorded before the 1-week visit in 4 children with symptomatic improvement and in 36 children with symptomatic failure owing to the cessation of the study drug.

*Perforation occurred in 2 children (aged 16 and 22 mo) with symptomatic improvement and in 3 children (aged 10, 16, and 25 mo) with symptomatic failure. In children with symptomatic improvement, the perforation was diagnosed on a scheduled follow-up visit 48 h after the day of diagnosis with acute otitis media. The parents had not noticed any ear discharge and they assessed their child’s overall condition as better than it had been at the time of diagnosis.
with symptomatic failure may fill the prescription written by the physician when AOM was diagnosed either independently or after a telephone consultation with the physician. Nevertheless, regardless of the child’s overall condition, parents should be advised to contact the physician for the initiation of antimicrobial treatment in the case of purulent otitis media.

In conclusion, our results give evidence that if initial observation without antimicrobial agents is chosen for children with AOM, close follow-up with reexamination may not be needed for children with symptomatic improvement. This finding could ease the burden of families and physicians, as symptomatic failure is encountered by only a minority of children with AOM who actually need reassessment.

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Critical revision of the manuscript for important intellectual content: Tähtinen, Laine, Ruohola.

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Obtained funding: All authors.

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Results | Thirty-four patients were enrolled a median of 6 days after injury (interquartile range, 3–10) (Table). Most patients (n = 28; 82%) responded to more than 80% of prompts. Levels of physical and cognitive activity and symptoms during follow-up are reported in the Figure. Higher cognitive activity on a given day corresponded to a higher symptom score that day and on the following 2 days (correlation, approximately 0.35), especially in patients with high initial symptoms (≥15).