Antibiotic treatment vs. watchful waiting in non severe acute otitis media: a retrospective study from an emergency department

Terapia antibiotica immediata o osservazione attenta nell’otite media acuta non grave: uno studio retrospettivo in un reparto di emergenza

SUMMARY

Objective. To evaluate the impact on antibiotic prescriptions for Acute Otitis Media (AOM) in the in Pediatric Emergency Department (PED), of the introduction of the observation option for selected patients younger than 14 years with uncomplicated AOM.

Methods. Retrospective study of those children aged younger than 14 years diagnosed with AOM, in the PED of a tertiary teaching hospital in the Basque Country, in the month of October between 2001 and 2005. Demographic data and treatments received were recorded. In the patients diagnosed with AOM in 2005, a follow-up telephone call was made 7-10 days after being discharged from the PED.

Results. During the study period we registered 1019 episodes corresponding to children with AOM, 359 (35.2%) of whom were younger than two years. One hundred children (9.9%) were already receiving antibiotics before attending the PED and were excluded, so in total, 919 children were included in the study.

Prior to implementation of the “observation option”, 514 patients were diagnosed with AOM, of which 22 (4.2%) were managed without antibacterial therapy. Following introduction of the “observation option”, 405 were diagnosed with AOM, of which 107 (26.2%) did not receive antibiotics in the PED (p < 0.00001).

In 2005, of the 221 children with AOM, follow-up was completed in 133 (60.1%). After visiting their pediatrician, 21.0% of children with AOM, sottoposti a follow-up, non ha ricevuto terapia antibiotica durante la malattia, con totale remissione dei sintomi.

Conclusions. Observation without immediate antibiotic therapy in selected patients with AOM (non severe AOM and low risk criteria) in a PED is associated with a reduction in antibiotic prescriptions of around 25%.

Key words
Children • Acute otitis media • Antibiotic • Pediatric Emergency Department

Parole chiave
Bambini • Otite media acuta • Antibiotici • Dipartimento di Emergenze Pediatriche

INTRODUCTION

Acute otitis media (AOM) is one of the most frequently occurring diseases in early infancy and childhood and remains the main cause of antibiotic prescription in childhood 1,2.
Several studies have suggested that observation without immediate antibiotic therapy (also called the “observation option” or “watchful waiting”) is possible in selected children. Antibiotics provide little benefit in treating AOM in children and, as most cases will resolve spontaneously, this benefit must be weighed against the possible adverse reactions.

The American Academy of Pediatrics (AAP) and the American College of Family Physicians have endorsed a set of guidelines for the management of AOM that includes the option for observation without immediate antibiotic therapy, in selected children with uncomplicated AOM based on diagnostic certainty, age, severity of illness, and guarantee of follow-up. Specifically, it recommends that observation be considered in children aged two years and older if symptoms are not severe. Many physicians are familiar with the AOM guidelines, but many do not follow its diagnostic and antibiotic recommendations, as it is considered a controversial issue in pediatric emergency departments (PED).

Several studies have shown that “watchful waiting” is a safe and effective practice that reduces also antibiotic use.

In 2004, the “observation option” (administration of oral analgesics-antipyretics) was introduced in our PED to treat patients aged two years and older with non severe AOM (temperature less than 39 °C and non intense pain), and low risk criteria (non attendance at a day care center, lack of previous repeated episodes of AOM, no antibiotics during the previous month, no recent hospitalization), following the recommendations of the AAP.

The aim of this study was to evaluate the impact of the introduction of the observation option on antibiotic prescriptions for AOM in the PED and the adherence of the pediatric emergency physicians to the new protocol.

**PATIENTS AND METHODS**

This was a retrospective study carried out in the PED of a tertiary teaching hospital in the Basque Country, where around 60,000 episodes per year are registered. Of these, around 4% are diagnosed with AOM. Children younger than 14 years diagnosed with AOM in our PED in the month of October between 2001 and 2005 were included.

In our PED, diagnosis of AOM is based on three criteria: 1) a history of acute onset of signs and symptoms of middle-ear inflammation and middle-ear effusion; 2) the presence of middle-ear effusion indicated by any of the following: bulging of the tympanic membrane, air-fluid level behind the tympanic membrane or otorhea; and 3) signs or symptoms of middle-ear inflammation as indicated by either distinct erythema of the tympanic membrane or distinct otalgia (discomfort clearly traceable to the ear/ears that results in interference with or precludes normal activity or sleep). We do not perform pneumatic otoscopy, tympanometry or acoustic reflectometry.

Non severe AOM was defined as a temperature below 39 °C and no intense pain; low risk criteria were defined as not having attended a day care center, no previous repeated episodes of AOM, no antibiotics use during the previous month and no recent hospitalization. Following the AAP recommendations, the presence of otorrhea did not change the children’s classification.

Patients’ charts were reviewed and demographic data, treatments administered and, in 2005, unscheduled return visits to the emergency department were all registered.

In children diagnosed with AOM in October 2005, a telephone follow-up call was made by a pediatric emergency physician seven to ten days after discharge from the PED. Specifically, they were asked about changes in treatment, visits to their pediatrician and follow-up visits at the PED.

**INCLUSION CRITERIA**

Children younger than 14 years receiving a diagnosis of AOM in the PED.

**EXCLUSION CRITERIA**

Children younger than 14 years with a diagnosis of AOM who were taking antibiotics before attending the PED.

**IMMUNOCOMPROMISED CHILDREN**

Categorical data were examined using the chi-square test.Normally distributed continuous data were compared with the Student’s t test. Non-parametric data were compared with the Kruskal-Wallis test and the Mann-Whitney U test. SPSS 11.5 for Windows (SPSS Inc., Chicago, IL) was used for all statistical calculations. Statistical significance was defined as p < 0.05.

**RESULTS**

In the month of October, between 2001 and 2005, as many as 26,122 patients referred to our PED, 1,019 of whom with a diagnosis of AOM (3.9%). One hundred of these children (9.9%) were already receiving antibiotics before coming to the PED and were therefore excluded from the study.

During the study period, 919 children who had not taken antibiotics before attending the PED were diagnosed with AOM and were included in the study. Five hundred and eleven (55.6%) of these were male and 323 (35.2%) were younger than two years of age. Sex and age distribution were similar throughout the study period, except for a female predominance in 2003. Of the 919 children diagnosed with AOM, 129 (14.03%) did not receive antibiotics in the PED.

Prior to implementation of the “observation option” (years 2001, 2002,
In 2003, 514 patients were diagnosed with AOM, of whom 22 (4.2%) were managed without antibacterial therapy. Following the introduction of the “observation option” (years 2004 and 2005), 405 were diagnosed with AOM, of whom 107 (26.2%) did not receive antibiotics in the PED (p < 0.00001) (Tab. I).

In October 2005, 221 children not taking antibiotics prior to their arrival at the PED were diagnosed with AOM. Duration of symptoms was recorded in 205 cases, and in nearly 75% (152 cases) the duration was less than 24 hours. Of these, 161 (72.8%) received antibiotics and 60 (27.1%) only received analgesics-antipyretics (acetaminophen or ibuprofen). When antibiotic treatment was prescribed, amoxicillin was used in 90% of cases.

Management of these children in the PED is detailed in Table II. After implementation of this new protocol, 40.2% of children older than 2 years did not receive antibiotic at the PED (vs. 3.7% of children less than 2 years, p < 0.00001).

Of the 221 children with AOM, follow-up was completed in 133 (26.3% of whom were not given antibiotics in the PED). This follow-up is summarized in Table III. Of the 133 patients with AOM diagnosed in the PED and having received complete follow-up, 28 (21.0%) received no antibiotics throughout the whole process (Tab. III).

In 2005, eight patients returned to the PED because of persistence of symptoms (three of these were from the “observation option” group). Treatment of these patients was not altered.

None of the children required hospital care for any complications due to AOM, and all those who received complete follow-up made a full recovery.

**DISCUSSION**

The introduction of an “observation option” in the treatment of selected patients with AOM, following the AAP recommendations, resulted in a 20% reduction of antibiotic treatment in children aged less than 14 years with a diagnosis of AOM. Nearly 60% of children older than two years diagnosed with AOM were discharged home without antibiotic therapy.

The diagnosis of acute otitis media is the most frequent reason for prescribing antibiotics to young children and one of the most frequent diagnoses in our PED.

Classically, children with AOM were always treated with antibiotics, but over the last few decades evidence has accumulated that it may not be necessary to administer antibiotics to all children diagnosed with AOM.

**Tab. I.** Antibiotic prescriptions for acute otitis media in the emergency department. All children are aged below 14 years.

<table>
<thead>
<tr>
<th></th>
<th>Antibiotics</th>
<th>No antibiotics</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n</td>
<td>%</td>
</tr>
<tr>
<td>2001</td>
<td>179</td>
<td>96.2</td>
</tr>
<tr>
<td>2002</td>
<td>150</td>
<td>96.7</td>
</tr>
<tr>
<td>2003</td>
<td>163</td>
<td>94.2</td>
</tr>
<tr>
<td>2004</td>
<td>137</td>
<td>74.4</td>
</tr>
<tr>
<td>2005</td>
<td>161</td>
<td>72.8</td>
</tr>
</tbody>
</table>

**Tab. II.** Management in the emergency department of children with acute otitis media in October 2005 not currently taking antibiotics.

<table>
<thead>
<tr>
<th>n = 221 children</th>
<th>Treatment in the PED</th>
</tr>
</thead>
<tbody>
<tr>
<td>Younger than 2 years, 81 ***</td>
<td>Antibiotics</td>
</tr>
<tr>
<td>No antibiotics</td>
<td>78 (96.2%)</td>
</tr>
<tr>
<td>Older than 2 years, 140 ***</td>
<td>Antibiotics</td>
</tr>
<tr>
<td>No antibiotics</td>
<td>83* (53.7%)</td>
</tr>
</tbody>
</table>

* 2 infants aged 16 months and one aged 21 months; ** 19 (22.8%) did not fulfill the criteria for receiving antibiotics according to our protocol; *** p < 0.00001

**Tab. III.** Follow-up of 133 children with acute otitis media.

<table>
<thead>
<tr>
<th>n = 133</th>
<th>Follow up in relation to the treatment administered by the PED</th>
<th>Management by the pediatrician</th>
<th>Antibiotic therapy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Antibiotics in the PED, 98</td>
<td>Continued with antibiotics</td>
<td>93 (94.8%)</td>
<td>Yes 105 (78.9%)</td>
</tr>
<tr>
<td>Antibiotics withdrawn</td>
<td>5 (5.1%)</td>
<td>No, 28 (21.0%)</td>
<td></td>
</tr>
<tr>
<td>No antibiotics in the PED, 35</td>
<td>Initiated antibiotics</td>
<td>12 (34.2%)</td>
<td>No, 28 (21.0%)</td>
</tr>
<tr>
<td>Did not prescribe antibiotics</td>
<td>23 (65.7%)</td>
<td>Yes 105 (78.9%)</td>
<td>No, 28 (21.0%)</td>
</tr>
</tbody>
</table>
Evidence of the safety and efficacy of the initial observation without immediate antibiotic therapy (also called “watchful waiting”) comes from structured reviews of randomized drug trials which, despite their flaws, suggest that immediate antibiotic treatment has only a modest effect on the course of AOM. The “observation option” for AOM defers antibacterial treatment of selected children for 48 to 72 hours and limits the management to the relief of symptoms. Around 80-90% of the patients diagnosed with AOM improve without antibiotic treatment, especially children older than two years and without severe AOM. This therapeutic option has been included in the latest AAP recommendations. Nevertheless, this is a very controversial issue in pediatrics, which may partially explain the fact that nearly one third of our patients with AOM who are initially managed without antibiotic therapy finally receive antibiotics when visiting their pediatrician. The presence of otorrhea was one of the most common reasons for initiating antibiotic therapy in the PED, which does not conform to our protocol. This issue is very controversial, so some authors who practice “watchful waiting” prefer to initiate antibiotic therapy if a tympanic perforation is detected or otorrhea is seen.

To be able to observe a child without initial antibacterial therapy, it is important that the parent/caregiver has a ready means of communicating with the clinician; in addition, parents sometimes need to be educated, as there are those who expect an antibiotic whenever their child is diagnosed with AOM. Nevertheless, some studies have shown that parents may be satisfied without a prescription, if they are provided with a clear explanation of the diagnosis and treatment plan, and if it is possible to access the physician in case the child requires further evaluation. In our PED, all patients diagnosed with AOM receive an explanatory sheet including information on what an AOM is, how to be treated at home and when they should return to the PED. Observation may be considered in children aged two years and older if symptoms are not severe. The association of age younger than two years with increased risk of failure of watchful waiting and the concern for possible severe infection among children younger than six months, influences the decision for immediate antibacterial therapy.

References


