

Giornate di Pediatria Preventiva e Sociale

Capri 2008

10 - 11 Ottobre 2008
Hotel la Palma - Capri



**L'otite media acuta e pratica clinica:
trattare, non trattare, complicanze e
benefici**

Michele Miraglia del Giudice
Dipartimento di Pediatria "F.Fede"
Seconda Università di Napoli

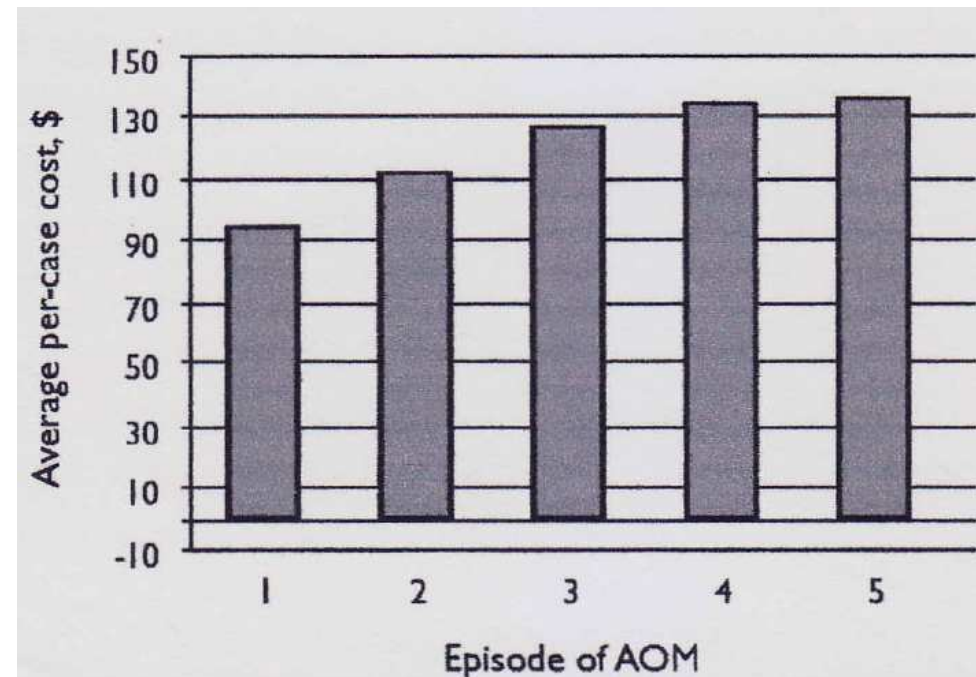


Total annual costs for AOM are estimated between \$1.4 billion and \$4.1 billion.

Cost of care is influenced not only by medication costs, but additional direct costs such as office-based provider visits and indirect costs such as caregiver/parent missed work days, which affect employers who provide health insurance to their employees.

Treatment success in AOM is largely dependent on:

- proper diagnosis
- efficacy of treatment
- adherence to therapy



Assessing Diagnostic Accuracy and Tympanocentesis Skills in the management of Otitis Media

Michael E. Pichichero et al. Arch Pediatr Adolesc Med. 2001;155:1137-1142

Table 2. Comparison of Diagnostic Accuracy Between Physician Specialties of Video-Presented Tympanic Membrane (TM) and Middle Ear Findings*

Video Examination No.	Correct Diagnosis	Percentage of Correct Diagnoses Made	
		Pediatricians (n = 524)	ENTs (n = 188)
1	OME	48	88
2	OME	45	69
3	Retracted TM, otherwise normal	56	76
4	AOM	73	76
5	OME	50	79
6	OME	25	48
7	Retracted TM, otherwise normal	46	83
8	OME	48	84
9	Retracted TM, otherwise normal	59	65
	Overall	50	73

*ENTs indicates board-eligible or board-certified otolaryngologists; OME, otitis media with effusion; and AOM, acute otitis media.

PEDIATRICS®

OFFICIAL JOURNAL OF THE AMERICAN ACADEMY OF PEDIATRICS

Diagnosis and Management of Acute Otitis Media
Subcommittee on Management of Acute Otitis Media
Pediatrics 2004;113:1451-1465

A diagnosis of AOM requires

- 1) Recent, usually abrupt, onset of signs and symptoms of middle-ear inflammation and MEE**
- 2) The presence of MEE that is indicated by any of the following:**
 - a. Bulging of the tympanic membrane*
 - b. Limited or absent mobility of the tympanic membrane*
 - c. Air-fluid level behind the tympanic membrane*
 - d. Otorrhea*
- 3) Signs or symptoms of middle-ear inflammation as indicated by either**
 - a. Distinct erythema of the tympanic membrane or*
 - b. Distinct otalgia (discomfort clearly referable to the ear[s]) that results in interference with or precludes normal activity or sleep)*

PEDIATRICS®

OFFICIAL JOURNAL OF THE AMERICAN ACADEMY OF PEDIATRICS

Diagnosis and Management of Acute Otitis Media
Subcommittee on Management of Acute Otitis Media
Pediatrics 2004;113;1451-1465

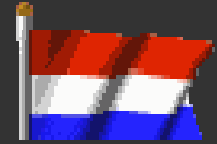
A major challenge for the practitioner is to discriminate between OME and AOM.

- **OME is more common than AOM**
- **OME may accompany viral upper respiratory infections, be a prelude to AOM, or be a sequela of AOM.**

When OME is identified mistakenly as AOM, antibacterial agents may be prescribed unnecessarily!!!

Dutch College of General Practitioners

Reasons for non-guideline-based antibiotic prescriptions for acute otitis media in The Netherlands.



Damoiseaux RAMJ et al. Family Practice 1999; 16: 50–53

The “**observation option**” for AOM refers to deferring antibacterial treatment of selected children for 48 to 72 hours and limiting management to symptomatic relief

PEDIATRICS®

OFFICIAL JOURNAL OF THE AMERICAN ACADEMY OF PEDIATRICS

Diagnosis and Management of Acute Otitis Media
Subcommittee on Management of Acute Otitis Media
Pediatrics 2004;113;1451-1465

RECOMMENDATION 3A

Observation without use of antibacterial agents in a child with uncomplicated AOM is an option for selected children based on diagnostic certainty, age, illness severity, and assurance of follow-up. (This option is based on randomized, controlled trials with limitations and a relative balance of benefit and risk.)

PEDIATRICS®

OFFICIAL JOURNAL OF THE AMERICAN ACADEMY OF PEDIATRICS

Diagnosis and Management of Acute Otitis Media
Subcommittee on Management of Acute Otitis Media
Pediatrics 2004;113;1451-1465

“is an option for **selected children**”

- 1) diagnostic certainty**
- 2) age**
- 3) illness severity**
- 4) assurance of follow-up**

PEDIATRICS®

OFFICIAL JOURNAL OF THE AMERICAN ACADEMY OF PEDIATRICS

Diagnosis and Management of Acute Otitis Media
Subcommittee on Management of Acute Otitis Media
Pediatrics 2004;113;1451-1465

TABLE 4. Criteria for Initial Antibacterial-Agent Treatment or Observation in Children With AOM

Age	Certain Diagnosis	Uncertain Diagnosis
<6 mo 6 mo to 2 y	Antibacterial therapy	Antibacterial therapy
	Antibacterial therapy	Antibacterial therapy if severe illness; <u>observation option*</u> if nonsevere illness
≥2 y	Antibacterial therapy if severe illness; <u>observation option*</u> if nonsevere illness	<u>Observation option*</u>

2) age

PEDIATRICS®

OFFICIAL JOURNAL OF THE AMERICAN ACADEMY OF PEDIATRICS

Diagnosis and Management of Acute Otitis Media
Subcommittee on Management of Acute Otitis Media
Pediatrics 2004;113;1451-1465

- **Nonsevere illness** is mild otalgia and fever $<39^{\circ}\text{C}$ in the past 24 hours.
- **Severe illness** is moderate to severe otalgia or fever $>39^{\circ}\text{C}$.

3) illness severity

PEDIATRICS®

OFFICIAL JOURNAL OF THE AMERICAN ACADEMY OF PEDIATRICS

Diagnosis and Management of Acute Otitis Media
Subcommittee on Management of Acute Otitis Media
Pediatrics 2004;113;1451-1465

Observation is an appropriate option only when follow-up can be ensured and antibacterial agents started if symptoms persist or wors

To observe a child without initial antibacterial therapy, it is important that the parent/caregiver has a ready means of communicating with the clinician. There also must be a system in place that permits reevaluation of the child. If necessary, the parent/caregiver also must be able to obtain medication conveniently.

4) assurance of follow-up

perché la vigile attesa?

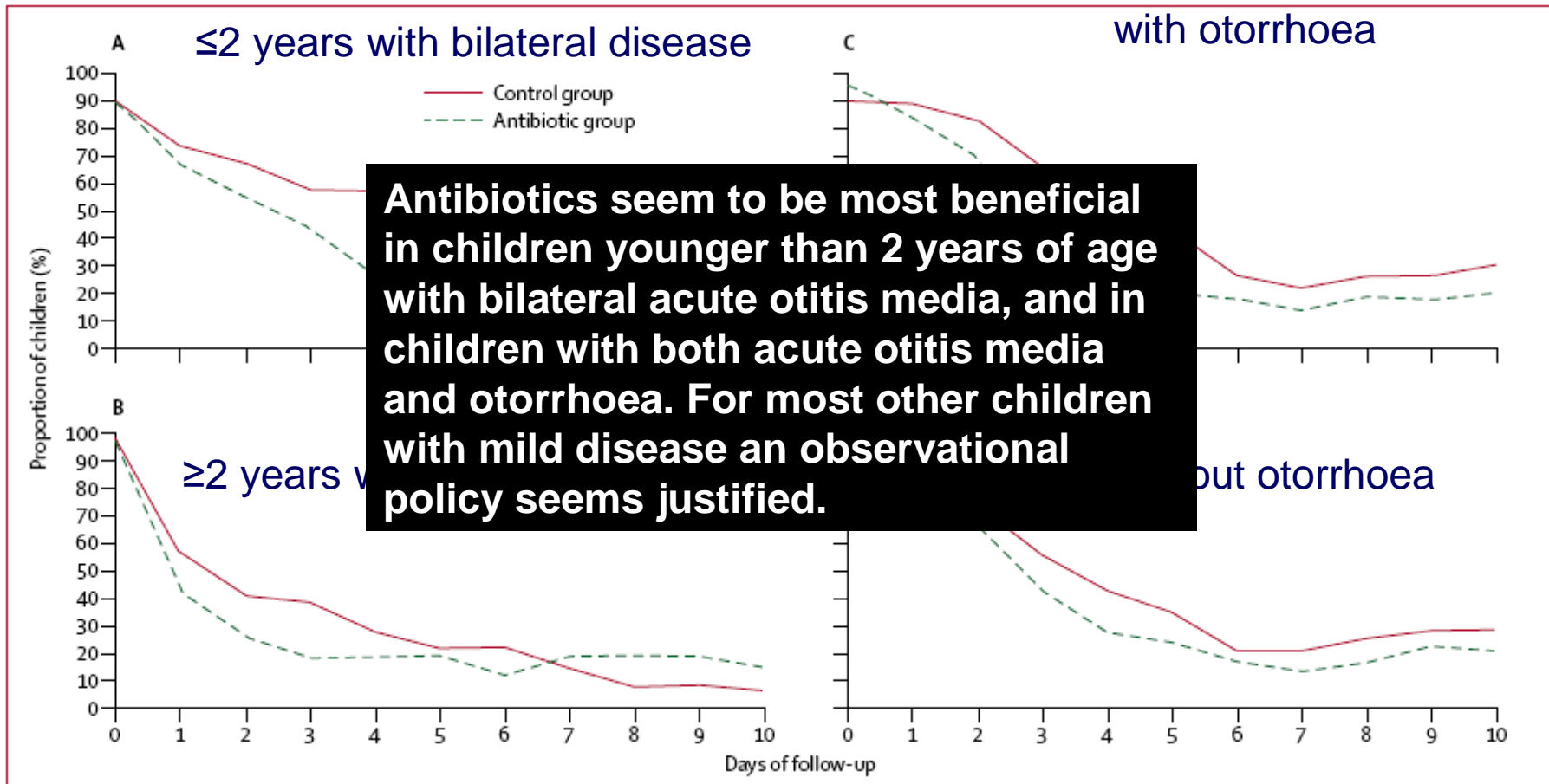


- ✓ Between 7 and 20 children must be treated with antibacterial agents for 1 child to derive benefit.
- ✓ By 24 hours, 61% of children have decreased symptoms whether they receive placebo or antibacterial agents.
- ✓ By 7 days, approximately 75% of children have resolution of symptoms.
- ✓ The AHRQ evidence-report meta-analysis showed a 12.3% **reduction in the clinical failure** rate within 2 to 7 days of diagnosis when ampicillin or amoxicillin was prescribed, compared with initial use of placebo or observation (number needed to treat: 8)

- Rosenfeld RM et al. Clinical efficacy of antimicrobial drugs for acute otitis media: metaanalysis of 5400 children from thirty-three randomized trials. *J Pediatr.* 1994;124:355–367
- Del Mar C, et. al Are antibiotics indicated as initial treatment for children with acute otitis media? A meta-analysis. *BMJ.* 1997;314:1526–1529
- Glasziou PP et. Al. Antibiotics for acute otitis media in children. *Cochrane Database Syst Rev.* 2000;4:CD000219
- Rosenfeld RM, et.al. Natural history of untreated otitis media. In: *Evidence-Based Otitis Media.*

Antibiotics for acute otitis media: a meta-analysis with individual patient data *Rovers MM. Lancet 2006; 368: 1429–35*

Individual patient data from 1643 children aged from 6 months to 12 years were validated and re-analysed.



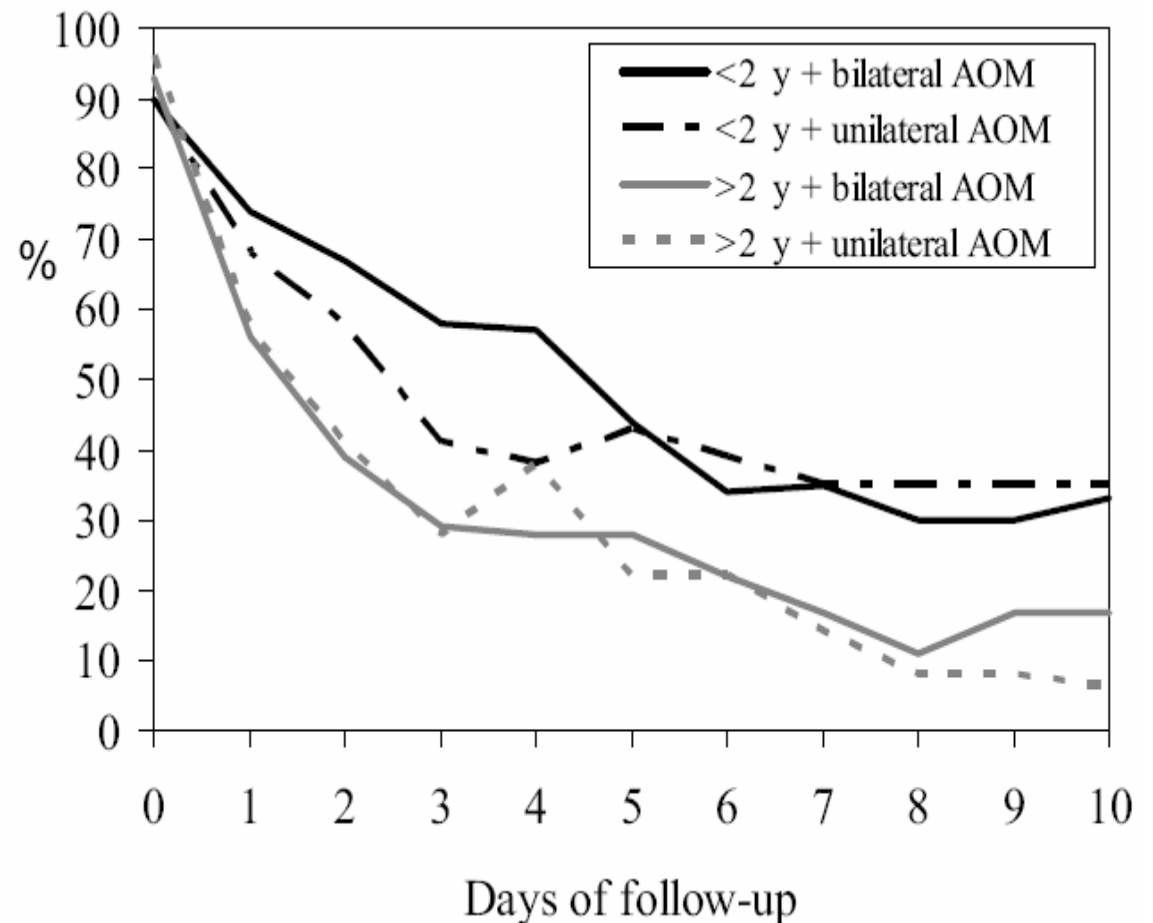
PEDIATRICS®

OFFICIAL JOURNAL OF THE AMERICAN ACADEMY OF PEDIATRICS

Predictors of Pain and/or Fever at 3 to 7 Days for Children With Acute Otitis Media Not Treated Initially With Antibiotics: A Meta-analysis of Individual Patient Data *Rovers MM. Pediatrics 2007;119:579-585*

Of the 824 included children, 303 had pain and/or fever at 3 to 7 days.

Independent predictors of a prolonged course were age of 2 < years and bilateral acute otitis media.



PEDIATRICS®

OFFICIAL JOURNAL OF THE AMERICAN ACADEMY OF PEDIATRICS

*Age Inconsistency in the American Academy of Pediatrics Guidelines for Acute
Otitis Media*

S. B. Meropol 2008;121;657-668

- **Implementation of the AAP guidelines under age 2 reduces antibiotic use but at a relatively heavy cost of increased sick days and parental missed work days.**
- **In addition, the guidelines are inconsistent in their clinical and economic outcomes across age groups.**

OTITE MEDIA ACUTA

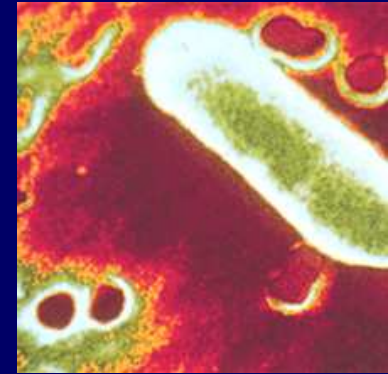
Quale antibiotico?

Patogeni in OMA

"The Infernal Quartetto"

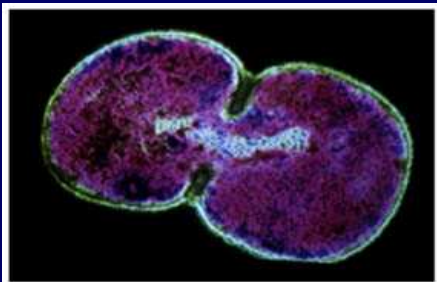
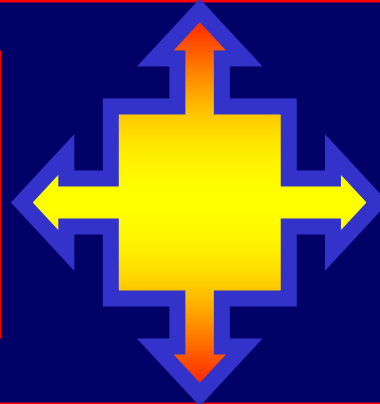


**Streptococco
Pneumoniae**



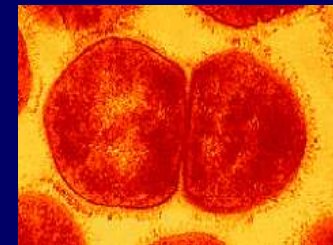
**Moraxella
Catarrhalis**

**Haemophilus
Influenzae**



Moraxella catarrhalis

**Streptococco
Pyogenes**



Therapy of acute otitis media - 2008

Temperature =39°C and/or Severe Otalgia	At Diagnosis for Patients Being Treated Initially With Antibacterial Agents	
	Recommended	Alternative
No	Amoxicillin 80–90 mg/kg/day	Non-Type I: cefdinir, cefuroxime, cefpodoxime Type I: azithromycin, clarithromycin
Yes	Amoxicillin- clavulanate (90 mg/kg/day of amoxicillin with 6.4 mg/kg/day of clavulanate	Ceftriaxone— 1 or 3 days

USA 2004 - www.aap.org

Middle ear pathogens (%) recovered from AOM pre-PCV7 (1992-1998) vs post –PCV7 (2000-2003) in vaccinees 7-24 m (> 3 doses PCV7)

Bacteria	Pre PCV 7	Post PCV7
S. pneumoniae	48	31
•Penicillin S	23	12
•Intermediate	16	13
•Resistant	9	6
H. Influenzae	41	56
•Beta lactamases +	23	36
•Beta lactamases –	18	20
M. Catarrhalis	9	11
GABS	2	2

Empiric First-line Antibiotic Treatment of Acute Otitis in the Era of the Heptavalent Pneumococcal Conjugate Vaccine

Jane Garbutt, Isabel Rosenbloom, Jenny Wu and Gregory A. Storch

Pediatrics 2006;117;1087-1094

CONCLUSIONS. In our community, widespread use of heptavalent pneumococcal vaccine has reduced the prevalence of *S pneumoniae* nonsusceptible to penicillin, and the prevalence of *S pneumoniae* nonsusceptible to amoxicillin remains low (<5%). If antibiotic treatment is elected for children with uncomplicated acute otitis media, we recommend treatment with standard-dose amoxicillin (40–45 mg/kg per day) for children with ≥3 doses of heptavalent pneumococcal vaccine, regardless of age and child care status. High-dose amoxicillin should be used for children with <3 doses of heptavalent pneumococcal vaccine and those treated recently with an antibiotic.

Rethinking the Total Cost of Care
in AOM and ABS:

The Impact of Improved Diagnostic Accuracy
and Antibiotic Treatment Where
High Efficacy and Adherence Are Achievable

Because amoxicillin does not adequately eradicate β -lactamase-producing organisms and would not be effective therapy, a focus on agents with superior clinical cure and eradication rates for nontypable H influenzae, including the β -lactamase-producing type becomes important.

un percorso terapeutico modulato - ottobre 2008

Temperature \geq
39°C and/or
Severe
Ootalgia

At Diagnosis for Patients Being Treated
Initially With Antibacterial Agents

Recommended

Alternative

No

Amoxicillin, 80–90 mg/
kg per day
o 50 mg/kg/die in vaccinati

cefaclor
cefuroxime,
cefepodoxime,

Yes +

**età < 3 anni
frequenza day-care
fratelli in day care
recente terapia AB**

Amoxicillin-clavulanate,
90 mg/kg per day of
amoxicillin, with 6.4
mg/kg per day of
clavulanate

Ceftriaxone, 1 or 3
days

Palmer DA, Bauchner H. Parents' and physicians' views on antibiotics. *Pediatrics*. 1997

In a survey of 400 parents and 100 pediatricians that asked parents to comment on their knowledge and concerns about antibiotic therapy, 41% of parents ranked the effectiveness of the antibiotic as their primary concern, 37% chose taste as their primary concern, and 33% chose dosing schedule.

Efficacy alone cannot predict treatment outcomes if adherence to therapy is lacking



OTITE MEDIA ACUTA LG AAP

It is not recommended that
other therapies be used
in the treatment
of acute otitis media

A RANDOMIZED, PLACEBO-CONTROLLED TRIAL OF THE EFFECT OF ANTIHISTAMINE OR CORTICOSTEROID TREATMENT IN ACUTE OTITIS MEDIA

TASNEE CHONMAITREE, MD, KOKAB SAEED, MD, TATSUO UCHIDA, MS, TERHO HEIKKINEN, MD, CONSTANCE D. BALDWIN, PHD, DANIEL H. FREEMAN, JR, PHD, AND DAVID P. MCCORMICK, MD

Objectives To determine whether the adjunctive drugs antihistamine and corticosteroid improve immediate and long-term outcomes of acute otitis media (AOM).

Study design Children with AOM (3 mos-6 y) were enrolled in a randomized, double-blind, placebo-controlled trial. All 179 children received one dose of intramuscular ceftriaxone and were assigned to receive either chlorpheniramine maleate (0.35 mg/kg/d) and/or prednisolone (2 mg/kg/day) or placebo for 5 days. Main outcome measures were rate of treatment failure during the first 2 weeks, duration of middle ear effusion, and rate of recurrences of AOM to 6 months.

Results Clinical outcomes and recurrence rates did not differ significantly with treatment. Children who received antihistamine alone had significantly longer duration of middle ear effusion (median, 73 days) than subjects in other treatment groups (median, 23 to 36 days, $P = .04$). Temporary normalization of tympanometric findings on day 5 occurred more frequently in the corticosteroid-treated group ($P = .04$).

Conclusions Five-day treatment with antihistamine or corticosteroid, in addition to antibiotic, did not improve AOM outcomes. Antihistamine use during an acute episode of OM should be avoided, since the drug may prolong the duration of middle ear effusion. The efficacy of 7- to 10-day treatment of AOM with corticosteroid, in addition to antibiotic, deserves further investigation. (*J Pediatr* 2003;143:377-85)

Grazie

