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Clinical Spectrum of Acute Otitis Media Complicating Upper Respiratory Tract Viral Infection

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Abstract

Background—Acute otitis media (AOM) often occurs as a complication of upper respiratory tract infection (URI).

Objective—To describe otoscopic findings during URI, the full clinical spectrum of AOM, and outcome of cases managed with watchful waiting.

Methods—In a prospective study of 294 healthy children (6 mos. to 3 yrs.), characteristics of AOM complicating URI were studied. Otoscopic findings were categorized by tympanic membrane (TM) position, color, translucency, and mobility. Otoscopic score was assigned based on McCormick OS-8 scale.

Results—During days 1–7 of URI, otoscopic findings at 1114 visits were consistent with AOM in 22%; myringitis (inflamed TM, no fluid) was diagnosed in 7%. In AOM episodes diagnosed within 28 days of URI onset, TM position was described as: non-bulging (19%), mild bulging (45%), bulging (29%) and TM perforation occurred in (6%). OS-8 scale showed mild TM inflammation (OS 2–3) in 6%, moderate (OS 4–5), 59%, and severe (OS 6–8), 35%. In 54% of 126 bilateral AOM episodes, inflammation of both TMs was at different stages. Of 28 cases of non-severe AOM managed with watchful waiting, 4 progressed and 3 later required an antibiotic.

Conclusions—AOM is a spectrum of infection that may present at various stages, even in the same child with bilateral disease. During URI, otoscopic changes are observed from the first day of onset. Understanding the wide clinical spectrum of AOM is needed to help with future clinical trial design and development of a scoring system to establish treatment criteria that will minimize antibiotic use.

Keywords

upper respiratory tract infection; viral respiratory infection; acute otitis media; myringitis; clinical spectrum

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INTRODUCTION

Acute otitis media (AOM) is one of the most common diseases seen in pediatric practice and a major reason for antibiotic prescriptions in the U.S. Viral upper respiratory tract infection (URI) has been shown to precede most cases of AOM 1,2. Viral URI leads to Eustachian tube inflammation resulting in its dysfunction and negative middle ear pressure permitting secretions containing the infecting virus and pathogenic bacteria that colonize the nasopharynx to enter the middle ear 3,4. Bacteria and/or virus cause inflammation of the middle ear, which results in accumulation of the middle ear fluid (MEF) or pus. The three criteria for AOM include: acute onset of symptoms (fever, irritability, earache), signs of inflammation of the tympanic membrane (TM), and presence of MEF 5. The clinical spectrum of AOM may vary from an early stage when there are clear signs of TM inflammation and MEF accumulation, to more severe AOM when purulent MEF under pressure causes bulging of the TM, to spontaneous rupture of TM with otorrhea. Because AOM cases are seen by clinicians at various stages of disease, management of AOM may vary based on severity of signs and symptoms at the time of diagnosis. There has been no published report describing the full clinical spectrum of AOM from early TM changes during the first days of URI to more severe AOM with spontaneous rupture of TM.

We had a unique opportunity to study otologic manifestations of young children followed prospectively during URI to AOM development within 28 days of URI onset. The purpose of this report was to describe otologic findings from the onset of URI and during its course, describe the full spectrum of AOM that complicated URI and to report the outcome of cases that were managed without antibiotic.

METHODS

Study design and subjects

This study is a secondary analysis of data collected from January 2003 to March 2007 at the University of Texas Medical Branch, Galveston (UTMB) during a prospective, longitudinal study of naturally occurring URI associated with AOM⁶. The primary purpose was to capture all URI episodes occurring during a one-year period in healthy young children at the peak age incidence of AOM to study the rate and characteristics of AOM following URI. The study was approved by the UTMB Institutional Review Board; written informed consent was obtained for all children. Healthy children were enrolled at 6 mos. to 3 yrs. of age; children with chronic medical problems or anatomical or physiological defects of the ear or nasopharynx were excluded. During the year, parents were asked to notify the study office as soon as the child began to have cold or URI symptoms (nasal congestion, rhinorrhea, cough, sore throat, or fever) or if they suspected that their child had ear infection. Children were seen by a study physician as soon as possible after URI onset and followed a few days later for OM complications; parents were compensated for time and travel. Study personnel also provided 2 home visits in weeks 2 and 3 of URI for tympanometry; no otoscopic examination was performed during the home visit.

In addition to parental self report of URI, the study personnel called the parents twice monthly to document any history of current URI symptoms and occurrence of any URI or AOM episodes missed since the last contact. An extensive review of medical records was performed at the completion of each child's study. UTMB is the sole provider of pediatric healthcare in Galveston; diseases diagnosed and treated in our children are likely to be documented in our medical records. URI and AOM episodes not seen by the study group but captured from parent's interviews or from medical records were recorded as "missed episodes".

URI and AOM Visits, Signs and Symptoms

During each study visit for URI or AOM, data were collected on clinical symptoms and current medications; tympanometry was also performed. The child's ears were examined using pneumatic otoscopy by trained investigators (77% by KR, 10% by TC, 7% by JP and 6% by other study physicians). Diagnosis of URI was made based on presence of rhinitis (nasal congestion, or rhinorrhea), cough, and / or sore throat, with or without constitutional symptoms such as fever, decreased appetite, restless sleep, vomiting or diarrhea, in the absence of lower respiratory tract symptoms. Diagnosis of AOM was based on: presence of acute symptoms, signs of TM inflammation and presence of MEF as documented by pneumatic otoscopy and/or tympanometry. The day of onset of AOM in the course of URI was determined from day 1 (first day of URI symptoms) to the day of AOM diagnosis.

For acute symptom scoring, we have chosen 5 items (Ear Treatment Group-five symptoms or ETG-5), which we have found to be the most responsive measure of change in AOM symptoms before and after treatment 7–9. The ETG-5 is a parent questionnaire consisting of items assessing: fever, irritability, poor feeding, sleep disturbance, and earache/tugging; each item is scored 0–3 (no symptom, mild, moderate, severe). Reports of temperature measurement obtained during this illness were classified as follows: no fever noticed, score=0; temperature measurement converted to $<38^{\circ}\text{C}$, score=1; $38\text{--}39^{\circ}\text{C}$, score=2; $>39^{\circ}\text{C}$, score=3. Maximum total ETG-5 symptom score was 15.

Study physicians who performed ear examination recorded (by check marks) the following characteristics of the TM: 1) Position (normal, retracted, full, bulging), 2) Color (normal=grey/pearly, red, dull/white, blue/yellow/fluid), 3) Translucency (translucent, partially opaque, totally opaque) 4) Mobility (normal, decreased, immobile). Opacification was recorded when the translucent TM became inflamed and thickened and/or when pus was seen behind the TM. The physician then scored ear findings based on the otoscopy scale (OS-8), 8 scores of severity of acute TM inflammation our group has developed⁷. Otoscopic scoring is described as: score 0=normal ear, no AOM; 1=erythema only, no effusion (myringitis); 2=erythema, air-fluid level, clear fluid; 3=erythema, complete effusion, no opacification; 4=erythema, opacification with air-fluid level or air bubble(s), (mild or no bulging TM); 5=erythema, opacification, complete effusion (mild or no bulging TM); 6=erythema, bulging, rounded donut appearance of the TM, 7=erythema, bulging, complete effusion and opacification with bulla formation. Acute perforation of TM/otorrhea was given an OS score of 8. AOM was considered when OS score was 2 or higher.

In children diagnosed with AOM, acute otitis media faces scale (AOM-FS) 7 was also used for the parent to describe the child's symptoms in the previous 24 hours. The scale consisted of 7 levels of symptom severity corresponding to 1) not a problem (not present), 2) hardly a problem, 3) somewhat of a problem, 4) moderate problem, 5) quite a bit of problem, 6) very much of a problem and 7) extreme problem.

The general policy for antibiotic treatment in this study was not to treat mild AOM (worse ear OS score of 2–3); antibiotic was prescribed for cases with moderate (OS score 4–5) and severe AOM (OS score 6–8). Exceptions were made based on the parent's strong preference, physician's decision based on severity of symptoms, availability for follow-up visits and other clinical diagnoses.

RESULTS

Otoscopic Findings during URI days 1–7

Of 294 children enrolled in the study, a total of 1295 URI episodes were documented; 867 (67%) of these were seen by the study group and URI symptoms and otoscopic findings

were documented during 1678 study visits. Of these, 1114 study visits occurred during days 1–7 of URI onset. Table 1 shows otoscopic diagnosis by day of URI during days 1–7. Otoscope diagnosis was categorized based on OS-8 score into: 1) AOM (meeting 3 criteria and OS score of 2 or higher), 2) acute myringitis (inflammatory changes of TM without presence of MEF; OS score =1), and 3) no AOM (normal TM, OME or previous changes such as healing TM from previous infection, no acute inflammatory changes). The proportion of children with AOM by days 1–7 ranged from 18–29% (see Table 1). Overall, 244 episodes of AOM were diagnosed during days 1–7 of URI illness. TM inflammation was mild (OS score 2–3) in 8%, moderately inflamed (OS score 4–5) in 58%, severely inflamed or perforated (OS score 6–8) in 34%. Acute myringitis proportion from URI days 1–7 ranged between 0 and 10%, with average of 7% of URI visits.

Clinical Spectrum of Acute Otitis Media Complicating URI

Altogether, 414 episodes of AOM complicating URI were documented between 1–24 days of URI onset. During 1678 study visits for which otoscopic findings were recorded, a total of 304 (73%) AOM episodes were diagnosed or confirmed by the study group. Of these, 294 AOM episodes in 130 children were seen before antibiotic treatment and data on signs and symptoms were available. There were 53% male, 43% Hispanic-Latino ethnicity, 57% Caucasian, 27% Black, 3% Asian and 12% biracial. The median age at AOM diagnosis was 16 months (range 6–35 months). The mean follow-up duration was 11.5 months (range 0.7 to 12.6 months). Number of AOM episodes diagnosed in each child during the follow-up period ranged from 1 to 10. The peak day of AOM diagnosis was day 3 of URI. The median day of AOM diagnosis after URI onset was day 5. Of the 294 AOM episodes, 168 were unilateral and 126 episodes were bilateral AOM. A total of 420 AOM ears were studied (225 right and 195 left AOM ears).

Acute Symptoms—All children presented with URI symptoms of (nasal stuffiness, rhinorrhea, sore throat, cough, red/watery eyes with or without fever). At the time of AOM diagnosis, the AOM Faces Scale⁷ were filled out by parents in 248 AOM episodes. Moderate to extreme problem was reported in 65%, somewhat of a problem or hardly a problem in 31%; 4% of parents reported ‘not a problem’ on AOM-FS. ETG-5 symptoms mean score was 4 (range, 1–11) in 259 (88%). In 29 of 35 cases with no ETG-5 symptoms, 23 parents reported that their child had symptoms based on the AOM-FS. Overall, 6 children (2%) were without acute symptoms by either ETG-5 or AOM-FS; one had a perforated TM with otorrhea and the remaining children were diagnosed AOM with full or bulging TM.

Presence of Middle Ear Fluid—Of 420 AOM ears, TM perforation/otorrhea occurred in 19 (4.5%). Presence of MEF was documented in all AOM ears with intact TM (n=401) by either pneumatic otoscopy, tympanometry, or both. We considered Type B tympanogram an indication of presence of the MEF; based on previous studies 10· 11, > 80% of this tympanogram type was associated with presence of the MEF. Type C was considered associated with possible/probable MEF as previous studies reported presence of MEF in 15–82% 10· 11. Pneumatic otoscopy was documented in 393; 304 (77%) TMs were immobile, 83 (21%) had decreased mobility. In all 6 AOM ears with normal mobility by pneumatic otoscopy, tympanometry was abnormal - type B (n=4) and C tympanogram (n=2). The C type tympanograms were a C1 (the child also had bullous myringitis) and a C3 (TM described as full, erythematous and partially opaque). In 8 AOM ears with intact TM for which pneumatic otoscopy results were not documented, tympanometry was abnormal in all – type B (n=6) and type C (n=2).

Signs of Middle Ear/ Tympanic Membrane Inflammation—Using the otoscopic scoring (OS-8) scale, the proportion of each of OS-8 scores in the worse ear is: OS-2, 2%;

OS-3, 4%; OS-4, 23%; OS-5, 36%, OS-6, 26%, OS-7, 3%, and OS-8, 6% (see Table, Supplement Digital Content 1, <http://links.lww.com/INF/A573>). TM perforation/acute otorrhea (19 ears) occurred in 18 (6%) of the 294 AOM episodes; all but one was a unilateral perforation; intact TM's were recorded in 276 AOM episodes. TM position was described as bulging (donut shape with no visible landmark) in 31%, full (mild bulging) in 48% and non-bulging in 21% (see Table, Supplement Digital Content 1, <http://links.lww.com/INF/A573>). Although evidence of MEF was present in all cases, bulging or mild bulging (full position) of the TM was recorded in only 79% of cases with intact TM (74% of all cases). Normal TM color was described as grey and pearly; abnormal color was described as: red (significant erythema) in 25%, dull/white (41%), blue/yellow/fluid (34%). Ninety-five % of TM were described as opaque.

Early and Mild AOM—A total of 17 AOM episodes were considered early and mild; 5 were given OS score of 2 (erythema, air-fluid level, clear fluid) and 12 were given OS score of 3 (erythema, complete effusion, no opacification). All OS-2 cases were seen within 3–4 days of URI onset and there was a clear description of visible fluid layer, along with acute erythematous change of TM. One OS-2 case was bilateral; both TMs were in normal position, tympanograms were type A variants with wide gradient (≥ 150 daPa). Four OS-2 cases were unilateral AOM; TM position was retracted in 2 and normal in 2; tympanograms in these 4 cases were abnormal (type B in 2, C3 in 1 and type A variants with wide gradient in 1).

Of 12 OS-3 cases, 7 cases were diagnosed within the first 3–4 days of URI onset; the remaining were on days 6, 7, 8, 11 and 17 of URI. In all cases, TM were erythematous and effusion was documented by decreased mobility or no mobility of TM ($n=11$) or abnormal tympanometry (type B in 9, types C2, C3 in 3) or both. TM position was normal in 8 and full in 4. In 3 of these cases, TM in the contralateral 'uninfected' ear was in retracted position.

Comparison of Otoscopic Findings in Cases with Bilateral AOM—We compared both ear findings in 126 cases with bilateral AOM (see Table, Supplement Digital Content 2, <http://links.lww.com/INF/A574>); in 58 (46%) cases, both ears were in the same stage of inflammation (same OS score). In 68 (54%) cases, right and left TMs were at different stages; findings of the worse ear vs the contralateral ear by OS score and TM position are shown in SDC 2.

Antibiotic Treatment and Outcome of Cases Managed with Watchful Waiting

Of the AOM episodes with a maximum OS score ≥ 4 ($n=277$), antibiotic was prescribed in 264 (95%). Thirteen children with OS score 4–5 did not receive antibiotic (3, parent refusal; 10, decision based on mild symptoms). Of AOM episodes with OS score of ≤ 3 ($n=17$), antibiotic was prescribed in only 2 cases. One child was given antibiotic because of the concurrent diagnosis of sinusitis; in the other case, a contingency prescription was given because AOM was diagnosed prior to a long holiday weekend.

Overall, 28 AOM episodes were managed without antibiotic; their follow-up otoscopic exam and outcomes are shown in Table 2. Of 15 episodes with mild AOM, 13 had follow-up otoscopic exam by the study physician 1–7 days later. Two cases of unilateral AOM had worsening of OS score in the contralateral ear, one of whom was given antibiotic 5 days later. Two cases with no follow-up otoscopic exam were clinically improved as reported by parents at home visit 14 and 23 days later. All but one of 15 cases with mild AOM had an abnormal follow-up tympanogram consistent with presence of MEF 2–29 days after AOM diagnosis. One case with the same OS score in the follow-up exam (2 days later) developed

a new episode of URI during the following 12 days; AOM was diagnosed during the subsequent URI episode. Therefore, we were not able to determine the final outcome of mild AOM in this case. Similarly, follow-up outcome was not available in 2 cases of moderate AOM; one received tympanostomy tube placement 7 days after AOM was diagnosed, another case was lost to follow-up. Overall, spontaneous recovery occurred in 12 of 14 (86%) of mild AOM and 9 of 11 (82%) of moderate AOM cases. Two cases in each group progressed and 3 of these 4 later received antibiotic.

DISCUSSION

URI and AOM are common reasons for children's visits to healthcare providers. We report here a detailed study of TM appearance in a large number of children with URI; these children were at the peak age incidence of AOM (6 mos. to 3 yrs). There had been no previously published description of otoscopic findings during URI in large number of young children. We observed otologic changes from the first day of URI symptoms; during days 1–7 of URI illness, approximately 22% of children developed AOM, another 7% had myringitis. Our data are novel and informative to clinicians who often see children with URI symptoms and must decide on a management plan mainly based on presence or absence of AOM.

Myringitis is an inflammation of the TM, by definition 12. We defined myringitis in this study as TM inflammation without MEF, an early stage of infection before MEF accumulation; therefore, these cases did not meet AOM definition. Our myringitis definition agrees with previously reported definition. Casselbrant and Mandel 13 defined myringitis as an inflammation of the TM without MEF. Bluestone 14 regarded myringitis as an early stage of AOM. Because TM inflammation also occurs in AOM, some investigators reported specific forms of myringitis such as bullous and hemorrhagic myringitis that occurred during AOM as manifestations of true AOM and suggested clinical management as such 15. Studies have shown that bullous and hemorrhagic myringitis specifically, can be of bacterial or viral etiology 16–17. In our study, 7% of children with URI had acute myringitis without MEF, another 3% of our AOM cases had bullous myringitis.

Most otitis studies began enrolling children at the time of AOM diagnosis. We enrolled children and followed them prospectively in a one-year, longitudinal study, which provided us a unique opportunity to collect data from URI onset before AOM development. This allowed us to capture a wide spectrum of AOM, especially early stages of development after eustachian tube dysfunction resulted in negative middle ear pressure (retraction of TM, type C tympanogram), MEF accumulation and TM inflammatory changes. We are aware that diagnostic criteria for AOM may vary 18–19; a review of the diagnostic criteria used in AOM clinical trials showed that only 20% of 88 studies met all three American Academy of Pediatrics (AAP) criteria for diagnosis of AOM 19. We used strict AOM definition based on acute symptoms, presence of MEF and signs of TM inflammation; these criteria agree with the 2004 AAP guidelines 5 and our study physicians were well-trained otoscopists. Because of our ability to capture mild and early AOM (OS score ≤ 3), the proportion of these cases was slightly higher than that reported in previous AOM studies by us and others (see Table 3) 9–20. McCormick et al. 9, enrolled non-severe AOM in a clinical trial comparing outcomes of watchful waiting vs. immediate antibiotic treatment. The criteria for non-severe AOM in that study included symptoms, OS-8 and tympanometric scores; non-severe AOM was considered when total severity index fell below the 50th percentile. In a Finnish study, Laine et al. 20 (see Table 3), used OS-8 scale in children with parental suspicion of AOM to compare those who were diagnosed as having AOM or no AOM. There was no report of cases with OS score of 3 in that study and the investigators categorized 3 cases with OS score of 2 (erythema, air-fluid level, clear fluid) in the non-AOM category. It was unclear if

those cases were acute otologic changes occurring with new onset of URI. In both McCormick and Laine studies 9, 20, children with TM perforation/otorrhea were not included; however, our 6% perforation rate compares well with that in other studies 21, 22. The findings reviewed and presented here, including our data on differing degrees of inflammation in ears of children with bilateral AOM strongly suggest that AOM is a spectrum of middle ear infection, which may present at various stages.

Although a bulging TM is more widely accepted as a hallmark of AOM 18, 22, the position of the intact TM is known to vary in AOM 20, 22. AOM with a bulging TM represented 74% of all cases and 79% of cases with intact TM in this report but more than half of our bulging TM cases were mild bulging (full). Even if we were to exclude the 13 cases of mild AOM ($OS \leq 3$), AOM with bulging TM would still account only for 83% (217 of 263) in our series. Laine et al. 20, reported full or bulging TM in 93% of their AOM cases. On the other hand, Karma et al. 22, reported otoscopic findings from a large number children with AOM for whom MEF was obtained by tympanocentesis; bulging TM was documented in only 53% of 4563 AOM cases; in 35% of AOM cases the TM position was normal; in 12% it was retracted. These findings clearly suggest that the AOM spectrum spans beyond AOM with bulging TM. Whether AOM cases with non-bulging TM (presumably milder cases) require antibiotic treatment is a different issue that still deserves further investigation.

The 2004 AAP clinical practice guideline on diagnosis and management of AOM recommended antibiotic treatment vs. observation based on the age of the child and the severity of illness⁵. The guideline defined severe AOM in children with temperature $\geq 39^{\circ}\text{C}$ and/or severe otalgia. We and others have found it difficult to assess otalgia in young children. Ear pain and ear tugging are often mentioned by parents; these may reflect only eustachian tube dysfunction during URI before AOM developed or during OME 20, 23. Laine et al 20, have recently shown that neither ear pain nor ear rubbing predicted the presence of AOM in children with parental suspicion of AOM; interestingly, ear rubbing tended to be more common in children with no AOM. There is still a continued need to find better ways to differentiate cases that will benefit from antibiotic treatment from cases that will resolve spontaneously.

Our antibiotic treatment policy in this study was conservative and based on OS score; cases of mild AOM ($OS \leq 3$) were managed with watchful waiting and follow-up examination while moderate to severe AOM cases ($OS \geq 4$) were treated with antibiotic. Exceptions were made in some cases based on the study physician's decision when incorporating symptom severity, parental preference, and follow-up availability. Overall, antibiotics were prescribed in 90% of the AOM episodes; therefore, the number of cases managed with watchful waiting was small. In the majority of these cases, resolution occurred without antibiotic treatment; only a few cases progressed and later required antibiotic.

It is important for clinicians and investigators to understand that AOM, like any infection/abscess, may present at various stages. This understanding has two major implications. First, management of AOM likely depends on stages of the infection; for example, most mild AOM may not require antibiotic treatment while most severe cases do and moderately severe AOM cases may fall in between. While further investigations are needed to find better ways to differentiate cases that require antibiotic from those that do not, use of a clinical severity scoring systems may help in this regard. Knowledge on clinical stages of AOM will help with the development of useful scoring system. Secondly, in clinical trials of AOM treatment, in order to assess the outcome from a uniform pool of cases, it is important that enrollment criteria include AOM in the same stage (e.g. AOM with bulging TM) or categorize outcomes by the pre-treatment AOM stages. Many previous AOM clinical trials have flaws in design, including lack of strict and rigorous enrollment criteria 24.

The limitation of our study is that the AOM cases diagnosed was not confirmed by tympanocentesis and bacterial and viral studies of the MEF. Some children with existing OME when developed URI and acute symptoms, with signs of TM inflammation such as myringitis may have been called AOM as they fulfilled the criteria. It is difficult to differentiate AOM from viral myringitis in children with existing OME. Knowledge of presence or absence of the MEF before the URI episode is not generally available. Even with tympanocentesis and microbiologic studies of the MEF, these 2 conditions may not be differentiated with certainty. First, a dry tap has been reported in early AOM even when otoscopic and tympanometric findings suggested presence of MEF 25. Secondly, OME is also associated with positive bacterial cultures in 40–70% of cases 26, 27.

We would encourage clinicians and investigators to carefully observe and reliably describe the full spectrum of TM findings when assessing the patient with URI and suspected AOM. Further research is needed to determine the level of AOM severity that requires antibiotic treatment. A clinical scoring system that can help identify children who will benefit from treatment will lead to reduction of antibiotic use in AOM.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Table 1

Otoscope diagnosis at 1114 study visits during URI from days 1–7 of onset

Day of URI	No. of visits	AOM ^a %	Myringitis ^b %	No AOM ^c %
1	17	5 (29)	0 (0)	12 (71)
2	135	27 (20)	8 (6)	100 (74)
3	285	72 (25)	29 (10)	184 (65)
4	195	42 (22)	16 (8)	137 (70)
5	212	48 (23)	14 (7)	150 (71)
6	158	29 (18)	7 (4)	122 (77)
7	112	21 (19)	6 (5)	85 (76)
Total	1114	244 (22)	80 (7)	790 (71)

^a AOM (meeting 3 cardinal criteria and OS score of 2 or higher)^b Acute myringitis (inflammatory changes of TM without presence of MEF; OS score =1)^c No AOM (normal TM, OME or previous changes such as healing TM from previous infection, no acute inflammatory changes).

Table 2

Outcome of 28 AOM cases that were managed with watchful waiting

AOM ^a	n	Outcome at follow up exam	n	Median day between exams	Remarks
Mild (OS 2–3)	15	Improved	10	3 ^b	Evidence of MEF by follow up tympanogram 2–29 days later
		Same	1	2	New URI episode with AOM 14 days later
		Progressed	2	5	Worsening of the contralateral ear, one later received antibiotic treatment
		No exam	2		Clinically improved per home visit & parent's report
Moderate (OS 4–5)	13	Improved	7	4 ^c	Evidence of MEF by follow-up tympanogram in 5 cases, 12–24 days later
		Progressed	2	6 ^d	Received antibiotic 5 and 7 days later
		No exam	4		Two clinically improved per parents, one received tympanostomy tubes 7 days later, one lost to follow-up

^a AOM severity: OS score 0–1=no AOM, 2–3=mild AOM, 4–5=moderate AOM, ≥6=severe AOM.

^b Range 1–7 days

^c Range 2–12 days

^d Range 5–7 days

Table 3

Comparison of OS score in AOM cases from this study with cases in previous studies

OS score	Current Study (n=294)	McCormick 2005 ^a (n=223)	Laine 2010 ^b (n=237)
2	5 (2) ^c	0 (0)	0 (0)
3	12 (4)	6 (3)	0 (0)
4	68 (23)	72 (32)	49 (21)
5	105 (36)	87 (39)	81 ^d (34)
6	76 (26)	53 (24)	84 (35)
7	10 (3)	5 (2)	23 (10)
8	18 (6)	0 (0)	0 (0)

^a. McCormick DP et al., Pediatrics. 2005;115(6):1455-65 (reference 9).

^b. Laine MK et al., Pediatrics. 2010; 125(5):e1154-61 (reference 20).

^c. Numbers in parentheses are % of cases.

^d. All TM in OS-5 had 'full' position