

# Symptoms and Otoloscopic Signs in Bilateral and Unilateral Acute Otitis Media



**WHAT'S KNOWN ON THIS SUBJECT:** Bilateral acute otitis media (AOM) is considered more severe than unilateral AOM, and several guidelines recommend more active management of bilateral AOM. However, severity of symptoms and otoscopic signs of bilateral and unilateral AOM have previously not been comprehensively studied.



**WHAT THIS STUDY ADDS:** Bilateral AOM seems to be clinically only a slightly more severe illness than unilateral AOM. When assessing AOM severity, bilaterality should not be used as a determining criterion; instead, the child's symptoms together with otoscopic signs should also be acknowledged.

## abstract

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**OBJECTIVE:** Bilateral acute otitis media (AOM) is considered more severe than unilateral AOM, and several guidelines recommend more active treatment and/or follow-up of bilateral AOM. We studied whether bilateral AOM is a clinically more severe illness than unilateral AOM by comparing symptoms and otoscopic signs between bilateral and unilateral AOM.

**METHODS:** Two hundred thirty-two children aged 6 to 35 months diagnosed with AOM were eligible. We surveyed the symptoms with a structured questionnaire and recorded the otoscopic signs systematically.

**RESULTS:** Ninety-eight children had bilateral and 134 children unilateral AOM. Children with bilateral AOM were more often <24 months than children with unilateral AOM (87% vs 75%;  $P = .032$ ). Fever ( $\geq 38^{\circ}\text{C}$ ) occurred in 54% and 36% ( $P = .006$ ) and severe conjunctivitis in 16% and 44% ( $P = .047$ ) of children with bilateral and unilateral AOM, respectively. In 15 other symptoms, we found no overall differences even when adjusted with age. We observed the following severe otoscopic signs in the bilateral and unilateral AOM group, respectively: moderate/marked bulging of tympanic membrane (63% and 40%;  $P = .001$ ), purulent effusion (89% and 71%;  $P = .001$ ), bulla formation (11% and 10%;  $P = .707$ ), and hemorrhagic redness of tympanic membrane (7% and 10%;  $P = .386$ ).

**CONCLUSIONS:** Bilateral AOM seems to be a clinically only slightly more severe illness than unilateral AOM. Therefore, when assessing AOM severity, bilaterality should not be used as a determining criterion; instead, the child's symptomatic condition together with otoscopic signs should also be taken into consideration. *Pediatrics* 2013;131:e398–e405

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### KEY WORDS

acute otitis media, symptoms, otoscopic signs, unilateral, bilateral

### ABBREVIATIONS

AOM—acute otitis media

AOM-Si—acute otitis media total severity index

AOM-SOS—acute otitis media severity of symptom scale

CI—confidence interval

OR—odds ratio

OS-8 score—otoscopy score, 8 grades

Dr Uitti carried out the initial analyses and interpreted the data, drafted the manuscript, and approved the final manuscript as submitted; Drs Laine and Tähtinen took part in collecting of data, revised the manuscript critically for important intellectual content, and approved the final manuscript as submitted; Professor Ruuskanen made substantial contributions to conception and design of the study, reviewed and revised the manuscript critically for important intellectual content, and approved the final manuscript as submitted; and Dr Ruohola conceptualized and designed the study, took part in collecting of data and also coordinated and supervised data collection, interpreted the data, reviewed and revised the manuscript critically for important intellectual content, and approved the final manuscript as submitted.

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Acute otitis media (AOM) is a common disease especially in early childhood, and yet the knowledge of the symptoms of AOM remains scarce. The diagnostic definition of AOM includes acute symptoms. However, we recently showed that, in children whose parents had suspected them to have AOM, symptoms and symptom scores do not differ between children with and without AOM.<sup>1</sup> Not even ear pain is a differentiating symptom at otitis-prone age, which responds to preverbal age.

Bilateral AOM is nowadays considered more severe than unilateral AOM, and more active antimicrobial treatment and/or follow-up of bilateral AOM is recommended by the guidelines of, for example, the Netherlands, England, Italy, and Sweden,<sup>2–5</sup> which are largely based on the meta-analysis of Rovers et al.<sup>6</sup> According to their results, young children with bilateral AOM benefit more from antimicrobial treatment than those with unilateral AOM. Nevertheless, the symptoms and signs of bilateral and unilateral AOM at the time of diagnosis have previously been compared by only 2 study groups. McCormick et al<sup>7</sup> observed no difference in symptoms between bilateral and unilateral AOM in the 5-item ear treatment group symptom questionnaire consisting of fever, ear pain (or tugging), irritability, feeding, and sleeping. On the other hand, they recorded erythema, opacification, and bulging of tympanic membrane more often in children with bilateral AOM. Leibovitz et al<sup>8</sup> compared temperature, irritability, bulging, and redness of tympanic membrane between the groups by using the clinical/otologic score, the bilateral AOM group having the mean score of 8.3 and the unilateral AOM group 7.8, respectively. Consequently, the occurrences, durations, and severity of individual symptoms of bilateral and unilateral AOM have previously not been studied comprehensively.

Our aim was to find out whether bilateral AOM is a clinically more severe

illness than unilateral AOM by comparing the symptoms and otoscopic signs between bilateral and unilateral AOM.

## METHODS

Children aged 6 to 35 months came for an outpatient visit when they had acute symptoms of infection and their parents suspected them of having AOM. Initially, there were 746 visits during which children were examined. We previously reported the symptoms of 237 and 232 children with and without AOM, respectively.<sup>1</sup> In this study, we have included the same children with AOM, with the exception of 5 children in whom laterality could not be determined because of obstructive cerumen in 1 ear canal. We conducted this study between 2006 and 2008, and it was part of a project examining diagnostics and treatment of AOM at the primary care level ([www.clinicaltrials.gov](http://www.clinicaltrials.gov), identifier NCT00299455).<sup>9</sup> Written informed consent was obtained from a parent of all children before any study procedures were done. All visits were free of charge, and no compensation for participation was given. The study protocol was approved by The Ethical Committee of the Hospital District of the Southwest Finland.

Before otologic examination, the study physician interviewed the parents about their assessment of the occurrence, duration, and severity of 17 symptoms listed in a standardized, structured questionnaire. Fever was defined as temperature  $\geq 38^{\circ}\text{C}$  within the preceding 24 hours. For the occurrence and duration of fever, we also accepted if parents assessed that their child had had fever without any temperature measurement. However, for the highest measured temperature within 24 hours, we recorded the highest of all actual temperature measurements either at home or at the study clinic and included in analyses those children whose highest measurement

was  $\geq 38^{\circ}\text{C}$ . We asked parents to estimate the durations of symptoms in days (with the accuracy of 0.5 days). For the following symptoms, we asked parents to assess the severity as mild, moderate, or severe: parentally reported ear pain, child's verbal expression of ear pain, ear rubbing, and irritability. For the following, we asked parents to assess the severity as mild or severe: excessive crying, restless sleep, less playful or active, poor appetite, rhinitis, nasal congestion, cough, hoarse voice, conjunctivitis, mucus vomiting (retching and throwing up swallowed mucus), vomiting (throwing up partially digested foods and drinks), and diarrhea.

After the symptom survey, the study physicians performed tympanometry, pneumatic otoscopy, and video otoscopy, as recently described in detail elsewhere.<sup>9</sup> The study physicians, who were trained otoscopists, recorded the otoscopic signs systematically. We recorded the position of tympanic membrane as normal (slight concave position); full, that is, slight bulging (convexity increased until the edges of tympanic membrane); or moderate/ marked bulging (convexity increased beyond the edges of tympanic membrane). We classified the effusion behind the tympanic membrane as clear (transparent effusion without any color), serous (transparent effusion with amber color), cloudy (nontransparent effusion), or purulent (nontransparent effusion with obvious yellow color). We recorded the redness of the tympanic membrane as the degree of tympanic membrane vascularity: not increased, increased, strongly increased, or hemorrhagic redness.

The diagnosis of AOM required the following 3 criteria. First, middle ear effusion had to be detected by pneumatic otoscopy (at least 2 of the following signs on tympanic membrane: bulging position, decreased or absent mobility, abnormal color or opacity not due to

scarring, or air–fluid interfaces). Second, at least 1 acute inflammatory sign of tympanic membrane had to be identified (distinct erythematous patches/streaks, or increased vascularity over full/bulging/yellow convexity). Third, there had to be symptoms and signs of acute infection. Unilateral AOM was diagnosed if a child had AOM on 1 side, but the contralateral side did not meet the criteria for AOM, that is, the ear was healthy or had otitis media with effusion. Bilateral AOM was diagnosed if a child had AOM on both sides. Regarding cases with bilateral AOM, the ear with worse otoscopic signs was taken into analyses.

We used 5 scores described in previous literature to compare bilateral and unilateral AOM. First, we used the clinical/otologic score<sup>10</sup> primarily developed by Dagan et al<sup>11</sup> to determine the severity of AOM (temperature, irritability, redness of tympanic membrane, and bulging position were scored from 0 to 3, for a total range of 0–12). We calculated this score from our symptom questionnaire and from our systematically recorded otoscopic signs. Second, immediately after the otoscopic examination, we recorded the otoscopy score, 8 grades (OS-8 score), which McCormick et al<sup>12</sup> developed to measure the severity of tympanic membrane inflammation (range, 0–7). Third, we asked parents to assess their child's overall condition (range, 0–7) at its worst within the preceding 24 hours and at study clinic, by the AOM-faces scale, which was developed by Friedman et al.<sup>13</sup> Fourth, we used the modified AOM total severity index (AOM-Si) as suggested by McCormick et al<sup>14</sup> to determine the severity of AOM. We calculated the AOM-Si score (range, 1–14) by summing up the highest OS-8 score and the highest AOM-faces scale at its worst within 24 hours. Fifth, based on our symptom questionnaire, we calculated the AOM severity of symptom

scale (AOM-SOS; version 3.0), which Shaikh et al<sup>15</sup> created. As in their study, we included ear rubbing, excessive crying, irritability, restless sleep, less playful or active, poor appetite, and fever scored as 0 (none), 1 (a little, including our categories mild and moderate), or 2 (a lot; ie, our category severe). We classified temperature <38°C as 0 (none), 38.0 to 38.9°C as 1 (a little), and ≥39°C as 2 (a lot). A score range of 0 to 14 was the result. In addition, we assessed illness severity according to the American Academy of Pediatrics 2004 guideline of the diagnosis and management of AOM.<sup>16</sup> The child had severe illness if ear pain (parentally reported and/or child's verbal expression) was moderate/severe and/or the highest measured temperature within 24 hours was ≥39°C. Otherwise the child had nonsevere illness. We compared the proportions with  $\chi^2$  test or Fisher test as applicable. We compared the means with *t* test and the medians with the Mann-Whitney *U* test. We assessed the relationships between the scores with Spearman correlation coefficients. We used logistic regression to calculate the odds ratios (ORs). We performed statistical analyses by using SPSS 16.0 statistical

package (IBM SPSS Statistics, IBM Corporation, Armonk, NY).

## RESULTS

The study population consisted of 232 children: 98 had bilateral AOM and 134 had unilateral AOM. Age <24 months was recorded in 87% of children with bilateral AOM and in 75% of children with unilateral AOM (*P* = .032). The bilateral AOM group had siblings less often than the unilateral AOM group (45% vs 63%, *P* = .007). Otherwise, no statistically significant differences were seen in patient characteristics (Table 1).

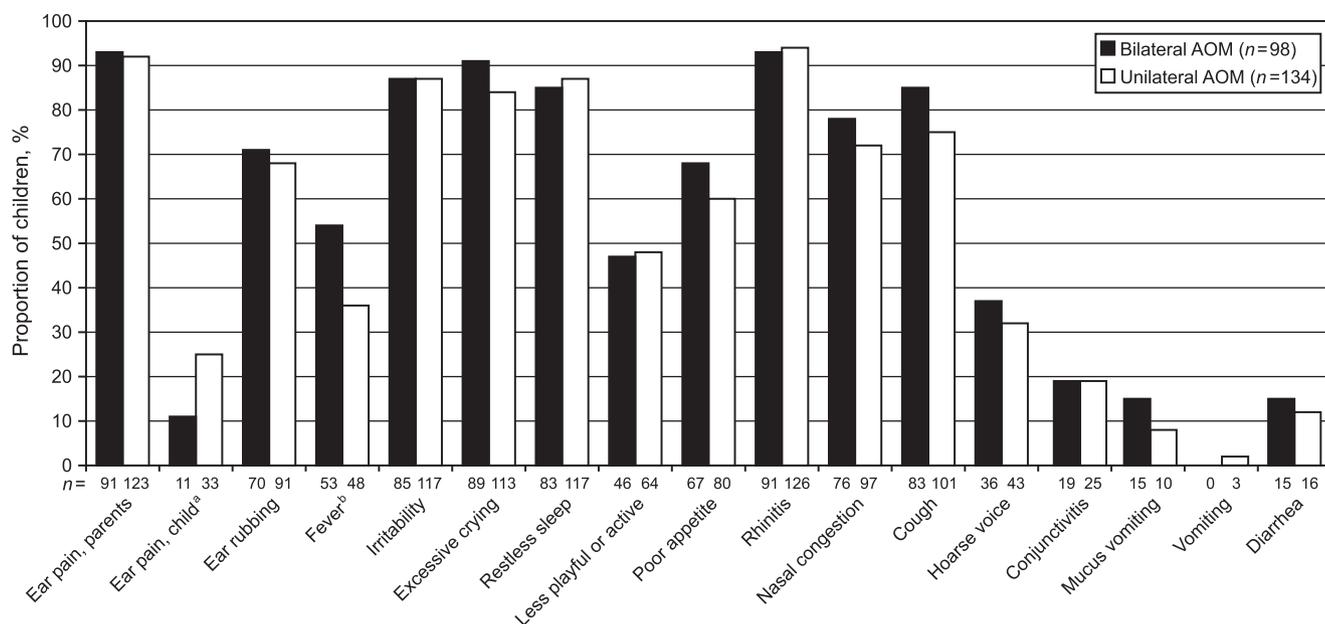
The occurrence of symptoms did not differ between children with bilateral and unilateral AOM (Fig 1), with the exception of fever and child's verbally expressed ear pain. The latter was reported in 11/98 (11%) children with bilateral and in 33/134 (25%) children with unilateral AOM (*P* = .010). However, by adjusting with age, the occurrence of a child's verbally expressed ear pain was not different between the groups (unadjusted OR for the bilateral AOM group, 0.39; 95% confidence interval [CI], 0.19–0.81; *P* = .012, adjusted OR, 0.64; 95% CI, 0.24–1.69; *P* = .368).

**TABLE 1** Characteristics of 232 Children With Bilateral and Unilateral AOM

	Bilateral AOM (n = 98)	Unilateral AOM (n = 134)	<i>P</i>
Mean (range) age, mo	15 (6–32)	18 (6–35)	.005
Age, n (%)			.056
6–11 mo	42 (43)	42 (31)	
12–23 mo	43 (44)	59 (44)	
24–35 mo	13 (13)	33 (25)	
Male gender, n (%)	52 (53)	77 (58)	.505
No. of previous AOM episodes, n (%)			.475
<3 episodes	69 (70)	100 (75)	
≥3 episodes	29 (30)	34 (25)	
Mean (range) age at first AOM episode, mo <sup>a</sup>	10 (0–27)	10 (0–26)	.875
Sibling(s) in the household, n (%)	44 (45)	84 (63)	.007
Day care attendance, n (%)	48 (49)	79 (59)	.132
Parental smoking, n (%) <sup>b</sup>	21 (22)	44 (33)	.062
Current use of pacifier, n (%)	57 (58)	65 (49)	.146
Any breastfeeding, n (%)	96 (98)	129 (96)	.702
Received ≥1 dose of pneumococcal vaccine, n (%)	3 (3)	3 (2)	.699

<sup>a</sup> Among those who had had at least 1 episode of AOM. Data were missing in 1/71 and 7/94 children with bilateral and unilateral AOM.

<sup>b</sup> Data missing for 1 child with bilateral AOM.



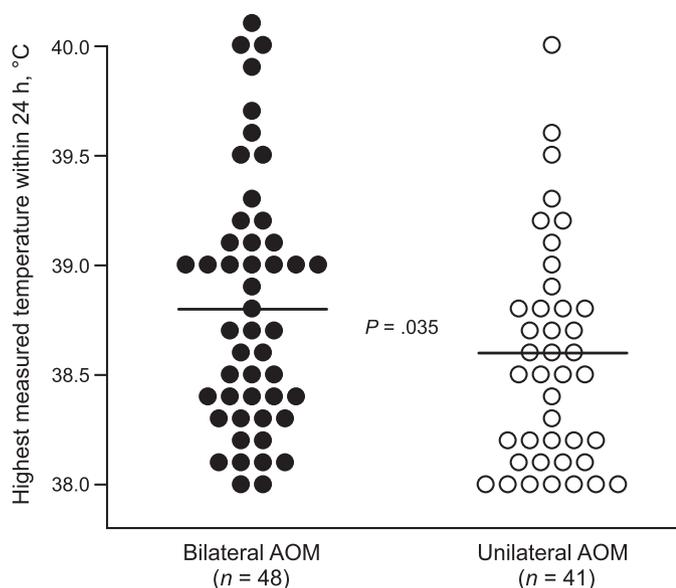
**FIGURE 1**

Occurrence of symptoms in bilateral and unilateral AOM. The numbers below the bars show the number of children with the symptom and thus indicated the numerator (n). The percentages were based on the occurrence of the symptoms versus nonoccurrence. The severity of the symptoms did not affect these calculations. Fever was defined as a measured temperature  $\geq 38^{\circ}\text{C}$  within the preceding 24 hours, but if no temperature measurement was available, the occurrence of fever was also accepted if parents assessed that their children had had fever. <sup>a</sup>Ear pain, child  $P = .010$  by  $\chi^2$ . Unadjusted OR for the bilateral AOM group, 0.39; 95% CI, 0.19–0.81;  $P = .012$ . Age adjusted OR, 0.64; 95% CI, 0.24–1.69;  $P = .368$ . <sup>b</sup>Fever,  $P = .006$  by  $\chi^2$ . Unadjusted OR for the bilateral AOM group, 2.11; 95% CI, 1.24–3.59;  $P = .006$ . Age-adjusted OR, 2.26; 95% CI, 1.31–3.91;  $P = .003$ .

Fever occurred in 54% (53/98) of the bilateral versus 36% (48/134) of the unilateral AOM group ( $P = .006$ ). Unadjusted OR for fever was 2.11 (95% CI, 1.24–3.59;  $P = .006$ ) for the bilateral AOM group and age-adjusted OR was 2.26 (95% CI, 1.31–3.91;  $P = .003$ ). The difference between the groups was not explained by the use of antipyretics before study visit (77% [41/53] vs 71% [34/48] in children with fever in the bilateral versus unilateral AOM group,  $P = .454$ , and 60% [59/98] vs 56% [75/134] in all children in the bilateral versus unilateral AOM group,  $P = .519$ ). As Fig 2 shows, the measured mean temperature was slightly higher in the bilateral than in the unilateral AOM group. Likewise, the measured temperature  $\geq 39^{\circ}\text{C}$  was recorded in 44% (21/48) and 20% (8/41) of the bilateral and unilateral AOM group, respectively ( $P = .015$ ). Regarding the rest of the symptoms studied, the age adjustment did not change the ORs (data not shown).

The duration of symptoms before the study visit was similar between the groups (Table 2). Furthermore, the severity of symptoms did not differ between the groups, with the exception

that parentally reported ear pain and conjunctivitis were more often severe in the unilateral AOM group (Table 3). However, OR for parentally reported ear pain to be moderate/severe was



**FIGURE 2**

The highest measured temperature within 24 hours in children with measured temperature  $\geq 38^{\circ}\text{C}$  in bilateral and unilateral AOM group. The horizontal lines show the highest measured mean temperature in each group (38.8°C in bilateral AOM and 38.6°C in unilateral AOM;  $P = .035$ ).

**TABLE 2** Mean Duration (days) of Symptoms in Children With Bilateral and Unilateral AOM

	Bilateral AOM	Unilateral AOM	<i>P</i>
Parentally reported ear pain	1.8	1.4	.092
Child's verbal expression of ear pain	0.9	1.1	.533
Ear rubbing	2.3	2.3	.996
Fever <sup>a</sup>	2.3	1.9	.272
Irritability	3.0	3.9	.102
Excessive crying	3.0	3.6	.174
Restless sleep	3.3	3.4	.825
Less playful or active	2.4	2.5	.789
Poor appetite	3.6	4.0	.495
Rhinitis	7.8	7.8	.985
Nasal congestion	6.8	7.0	.875
Cough	6.2	6.2	.954
Hoarse voice	4.2	4.3	.797
Conjunctivitis	4.2	2.9	.163
Mucus vomiting	2.7	2.6	.936
Vomiting	0	0.5	
Diarrhea	2.8	2.4	.571

Duration of each symptom is calculated among those children who had the symptom as shown in Fig 1.

<sup>a</sup> Data missing in 1 child in the unilateral AOM group.

0.87 (95% CI, 0.49–1.54; *P* = .624) for the bilateral AOM group and age-adjusted OR was 0.86 (95% CI, 0.48–1.55; *P* = .616).

Of the otoscopic signs, we recorded moderate/marked bulging of tympanic membrane in 63% and 40% and purulent effusion in 89% and 71% of the bilateral and unilateral AOM group, respectively (for both comparisons, *P* = .001). We observed bulla formation on tympanic membrane in 11% of the children with bilateral AOM and in 10% of the children with unilateral AOM (*P* =

.707). We observed hemorrhagic redness of tympanic membrane in 7% and 10% of the bilateral and unilateral AOM group, respectively (*P* = .386). Moreover, the OS-8 scores ranged from 4 to 7, and we recorded score 6 or 7 in 59% and 37% of the children with bilateral and unilateral AOM, respectively (*P* = .001). Adjustment with the age did not change the results of any of the otoscopic signs listed above (data not shown).

The median clinical/otologic score was 4.5 and 4.0 in children with bilateral and

unilateral AOM, respectively (*P* = .003) (Fig 3). However, the AOM-Si score, which also consists of symptomatic and otoscopic assessment, did not differ between the bilateral and unilateral AOM groups (11.0 vs 11.0; *P* = .387). The scores solely based on symptoms, namely AOM-faces scale and AOM-SOS, did not diverge between bilateral and unilateral AOM, as Fig 3 indicates. According to the American Academy of Pediatrics 2004 guideline definition for illness severity classification, 69 (70%) children with bilateral AOM and 90 (67%) children with unilateral AOM had severe illness (*P* = .599).

## DISCUSSION

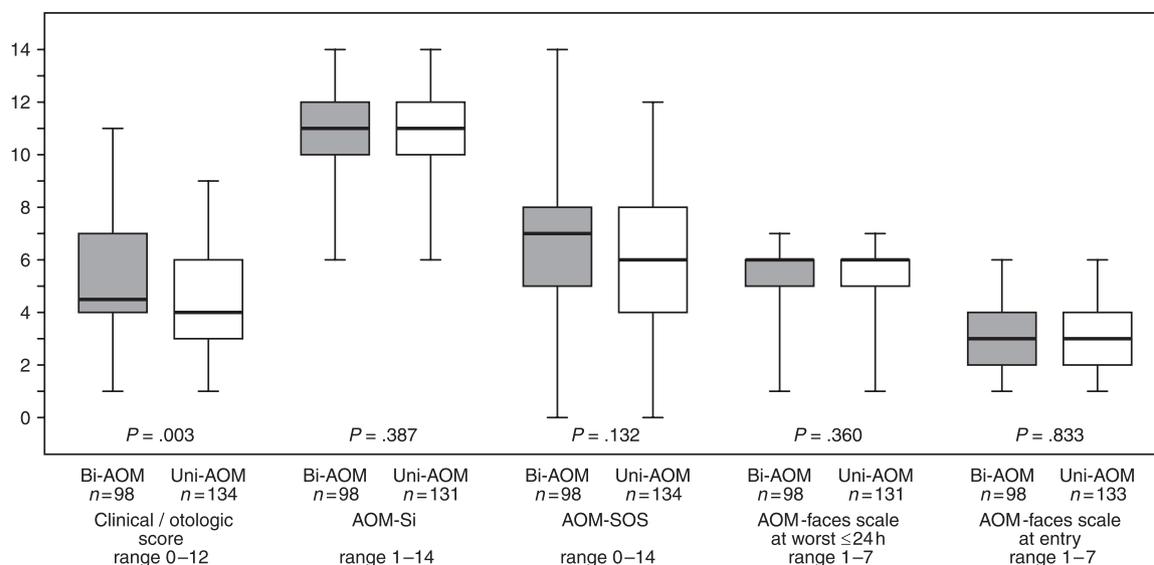
Our main finding was that the occurrence, duration, and severity of symptoms did not differ between bilateral and unilateral AOM. Only fever was an exception, because children with bilateral AOM had fevers more often and fevers that were slightly higher. This was a new finding. On the other hand, Leibovitz et al<sup>8</sup> did not investigate fever at all, because all their patients had fever according to their diagnostic criteria for AOM. Then again, McCormick

**TABLE 3** Severity of Symptoms in Children With Bilateral and Unilateral AOM

Symptom	Bilateral AOM			Unilateral AOM			<i>P</i>
	Mild	Moderate	Severe	Mild	Moderate	Severe	
Parentally reported ear pain	31/91 (34)	47/91 (52)	13/91 (14)	38/123 (31)	46/123 (37)	39/123 (32)	.010
Child's verbal expression of ear pain	4/11 (36)	6/11 (55)	1/11 (9)	8/33 (24)	10/33 (30)	15/33 (46)	.092
Ear rubbing	43/70 (61)	22/70 (31)	5/70 (7)	46/91 (51)	33/91 (36)	12/91 (13)	.288
Irritability	24/85 (28)	49/85 (58)	12/85 (14)	41/117 (35)	56/117 (48)	20/117 (17)	.388
Excessive crying	56/89 (63)		33/89 (37)	69/113 (61)		44/113 (39)	.787
Restless sleep	29/83 (35)		54/83 (65)	41/117 (35)		76/117 (65)	.988
Less playful or active	37/46 (80)		9/46 (20)	54/64 (84)		10/64 (16)	.590
Poor appetite	45/67 (67)		22/67 (33)	52/80 (65)		28/80 (35)	.783
Rhinitis	43/91 (47)		48/91 (53)	55/126 (44)		71/126 (56)	.599
Nasal congestion	43/76 (57)		33/76 (43)	57/97 (59)		40/97 (41)	.773
Cough <sup>a</sup>	53/82 (65)		29/82 (35)	65/101 (64)		36/101 (36)	.969
Hoarse voice	29/36 (81)		7/36 (19)	36/43 (84)		7/43 (16)	.714
Conjunctivitis	16/19 (84)		3/19 (16)	14/25 (56)		11/25 (44)	.047
Mucus vomiting	15/15 (100)		0/15 (0)	8/10 (80)		2/10 (20)	.150
Vomiting	0		0	3/3 (100)		0/3 (0)	
Diarrhea	13/15 (87)		2/15 (13)	14/16 (88)		2/16 (13)	1.000

The values shown are n/N (%). n, numerator; N, denominator.

<sup>a</sup> Data missing in 1 child in the bilateral AOM group.



**FIGURE 3**

Distributions of the score values in bilateral (Bi-AOM) and unilateral (Uni-AOM) AOM. The box plots show the 25th, 50th (median), and 75th quartiles together with the minimum and maximum values of each score. The Spearman correlation coefficient between the clinical/otologic and the AOM-Si scores was positive within the bilateral AOM ( $r = 0.414$ ;  $P < .001$ ) and within unilateral AOM ( $r = 0.483$ ;  $P < .001$ ), and also positive between AOM-SOS and the AOM-faces scale (at worst  $\leq 24$  hours) within bilateral AOM ( $r = 0.373$ ;  $P < .001$ ) and within unilateral AOM ( $r = 0.183$ ;  $P = .037$ ).

and his study group measured the temperature at study clinic after many subjects had received antipyretic medication as they mentioned themselves.<sup>7</sup> On the contrary, we initially surveyed the occurrence of fever and then analyzed the highest measured temperature within 24 hours. Although we observed statistically significant differences in both, these differences were clinically modest, and only half of the children with bilateral AOM had fever. In addition, laterality was not related to moderate/severe ear pain, which is the other criterion for severe illness according to the American Academy of Pediatrics 2004 guideline.<sup>16</sup> All in all, our data suggest that children with bilateral AOM might carry only slightly greater symptomatic burden than those with unilateral AOM.

Of the otoscopic signs, moderate/ marked bulging of tympanic membrane and purulent effusion were significantly more common in children with bilateral than with unilateral AOM. Higher OS-8 scores in the bilateral AOM group in our study, as well as in the study of McCormick et al,<sup>7</sup> mainly reflect the degree of tympanic membrane

bulging. However, degree of tympanic membrane bulging might be a clinical sign of severe illness, because Hoberman et al<sup>17</sup> showed antimicrobial treatment to be most beneficial in children with marked bulging of tympanic membrane. According to Palmu et al,<sup>18</sup> purulent effusion increases the probability of positive bacterial culture. The same study group has also shown that bulla formation and hemorrhagic redness should be regarded as signs of severity because these otoscopic signs are more often related to positive bacterial culture and severe symptoms than AOM without these signs.<sup>19,20</sup> In our study, these otoscopic signs were as common in bilateral as in unilateral AOM. Consequently, severe otoscopic signs do not seem to be entirely related to bilateral AOM. Moreover, it must be noted as McCormick et al<sup>7</sup> stated previously that bilateral AOM has greater probability of having more severe otoscopic signs, because the ear with the worse otoscopic signs is used for comparison.

The 2 scores including both symptomatic and otoscopic assessments, namely the clinical/otologic score and AOM-Si, had similar ranges among children with

bilateral and unilateral AOM. Although the clinical/otologic score was statistically significantly higher in children with bilateral AOM in our study, as well as in the study of Leibovitz et al,<sup>8</sup> the difference was clinically modest. Leibovitz et al<sup>8,21</sup> themselves have stated that this score has only limited clinical use. In our study, solely symptom-based scores, namely the AOM-faces scale and AOM-SOS, showed no difference between bilateral and unilateral AOM. The same applied to the definition of severe illness according to the American Academy of Pediatrics 2004 guideline. Previously, we reported similar score comparisons between children with AOM and without AOM and showed no differences among these children whose parents had suspected them of having AOM.<sup>1</sup> It remains to be determined whether our current score results reflect equal clinical severity of bilateral and unilateral AOM or inability of these scores to detect differences.

Our results seem to give some support to the concept that bilateral AOM is a clinically more severe illness than unilateral AOM. It is, however, important

to notice that severity assessment on a single visit can provide only a narrow window to such a dynamic disease as AOM. All clinicians know that the symptoms not only vary between individuals, but also within individuals. A child may be afebrile on 1 day and febrile on the next day, and vice versa. Furthermore, the otoscopic signs change on a daily basis,<sup>22,23</sup> and children with unilateral AOM may develop bilateral AOM.<sup>9,24</sup> Thus, not even laterality is a stable status. Our study differs from that of Rovers et al,<sup>6</sup> because their conclusions were based on outcomes 3 to 7 days after diagnosis and treatment. Recently, Hoberman et al<sup>17</sup> showed that the degree of tympanic membrane bulging was a stronger predictor of treatment failure than laterality. Moreover, laterality was not a stronger predictor than symptomatic burden or exposure to other children. We suggest that laterality should not be used alone as a determining factor to assess the severity of AOM and to decide the treatment options. We would rather suggest that clinicians would take into consideration the severity of child's symptomatic condition together with

otoscopic signs, keeping in mind the dynamic nature of AOM.

The main strength of our study is the standardized, structured symptom questionnaire, which allowed us to study the symptoms thoroughly. We also recorded the otoscopic signs systematically. In addition, we recruited the children from primary care level, where the diagnosis of AOM is mainly made in clinical practice. Nevertheless, our study has limitations. Temperature was not only measured at the study clinic, but also with variable techniques by the parents. This may under- or overestimate the occurrence of fever, but probably in similar manner in both groups. The fact that we compared the highest measured temperatures only among children with measured temperature  $\geq 38^{\circ}\text{C}$  can be seen as a limitation. However, we think that temperature differences among febrile children are clinically more significant than those among afebrile children. Even if we had included all children in this analysis, our conclusions would not have been changed. A limitation could also be that

the symptoms were surveyed via interview instead of parents having filled in the questionnaires. Nonetheless, this allowed parents to ask clarifications and thus possibly minimized misinterpretations by parents. Finally, the pneumatic otoscopy is always a subjective interpretation of the signs of tympanic membrane. Especially the assessment of the color of effusion is hampered by the opacity of the tympanic membrane, which may have led to overestimation of cloudy instead of purulent effusion. We tried to minimize the subjectivity by use of video-otoscopy which allowed us to assess the findings together.

## CONCLUSIONS

We conclude that bilateral AOM seems to be a clinically only slightly more severe illness than unilateral AOM in children 6 to 35 months of age. Therefore, we suggest that bilaterality should not be used alone as a determining criterion when assessing AOM severity; instead, child's symptomatic condition together with otoscopic signs should also be taken into consideration.

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