

Table, Supplemental Digital Content 1.

Baseline characteristics, according to study group.

	Delayed antimicrobial treatment group (n=53)	Immediate antimicrobial treatment group (n=161)	Absolute difference (95% CI)
Demographics			
Male gender, n (%)	27 (51)	92 (57)	-6 (-21 to 9)
Age, mean (SD), mo	16 (7)	16 (7)	
Age, n (%)			
6–11 mo	18 (34)	57 (35)	-1 (-16 to 13)
12–23 mo	27 (51)	78 (48)	3 (-13 to 18)
24–35 mo	8 (15)	26 (16)	-1 (-12 to 10)
Otitis media risk factors			
Recurrent acute otitis media in 1 st degree relatives, n (%)	32 (60)	90 (56)	5 (-11 to 20)
Day care attendance, n (%)	36 (68)	87 (54)	14 (-2 to 29)
Parental smoking, n (%) ^a	13 (25)	57 (36)	-11 (-26 to 4)
Current use of pacifier, n (%)	29 (55)	80 (50)	5 (-11 to 21)
No breastfeeding, n (%) ^a	2 (4)	6 (4)	0 (-6 to 6)
Total number of previous episodes of acute otitis media, n (%)			
0	16 (30)	43 (27)	4 (-10 to 17)
1–3	27 (51)	88 (55)	-4 (-19 to 12)
4–6	8 (15)	22 (14)	1 (-9 to 12)
>6	2 (4)	8 (5)	-1 (-8 to 5)
Vaccinations			
≥1 dose of pneumococcal conjugate vaccine, n (%)	3 (6)	3 (2)	4 (-1 to 9)
≥1 dose of influenza vaccine, n (%)	8 (15)	17 (11)	5 (-5 to 15)
≥1 dose of <i>Haemophilus influenzae</i> type b vaccine, n (%)	53 (100)	161 (100)	0
Preceding symptoms			
Fever ≥38 °C within 24 h, n (%)	19 (36)	64 (40)	-4 (-19 to 11)
Ear pain reported by parents, n (%)	41 (77)	123 (76)	1 (-12 to 14)
Ear pain reported by child, n (%)	9 (17)	24 (15)	2 (-9 to 13)
Ear rubbing, n (%)	31 (59)	104 (65)	-6 (-21 to 9)
Poor appetite, n (%)	32 (60)	99 (62)	-1 (-16 to 14)
Decreased activity, n (%)	20 (38)	76 (47)	-10 (-25 to 6)
Irritability, n (%)	43 (81)	127 (79)	2 (-10 to 15)
Restless sleep, n (%)	44 (83)	136 (85)	-2 (-13 to 10)
Excessive crying, n (%) ^b	44 (88)	113 (82)	6 (-6 to 18)
Respiratory symptoms, n (%)	52 (98)	156 (97)	1 (-4 to 6)
Vomiting, n (%)	2 (4)	2 (1)	3 (-2 to 7)
Diarrhea, n (%)	6 (11)	17 (11)	1 (-9 to 10)
Severe illness, n (%) ^c	33 (62)	98 (61)	1 (-14 to 17)
Otoscopic signs at enrollment			
Bilateral acute otitis media, n (%) ^d	26 (50)	60 (38)	12 (-3 to 28)
Moderate/marked bulging of the tympanic membrane in worse ear, n (%)	34 (64)	77 (48)	16 (8 to 32)

^a Data were missing for one patient in the immediate antimicrobial treatment group.^b Data were missing for three patients in the delayed antimicrobial treatment group and 23 patients in the immediate antimicrobial treatment group.^c Severe illness was defined as moderate to severe otalgia or fever ≥ 39 °C according to the American Academy of Pediatrics 2004 guidelines for the diagnosis and management of acute otitis media.³^d Data were missing for one patient in the delayed antimicrobial treatment group and two patients in the immediate antimicrobial treatment group, in whom an adequate view of the contralateral tympanic membrane was not possible owing to thick cerumen.