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Associations between symptoms, clinical findings and the short-term prognosis among children with otitis media: A cohort study

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ABSTRACT

Objective: Otitis media (OM) is a common childhood disease and a frequent reason for seeking medical care in general practice. Only few studies have focused on what happens after diagnosis and initial treatment of OM. In particular, there is a lack of research on how different patient- and disease-related factors influence the course of OM. The aim of this study was to analyze to what extent symptoms at the time of initial diagnosis are associated with the short-term course of otitis media.

Methods: Cohort study in general practice comprising 747 children between 0 and 7 years with a new ear symptom. At the first consultation the GPs registered symptoms, results of otoscopy and tympanometry, together with diagnosis and treatment. The children were followed up four weeks later.

Results: Sleep problems at inclusion are statistically significant associated with having one or more symptom after four weeks in children between 0 and 2 years (OR: 2.02 (95% confidence interval (CI): 1.24–3.31)). If the result of tympanometry is a flat curve, the OR for being referred is 3.24 (CI: 1.61–6.55) in children between 0 and 2 years compared to children without a flat curve. The OR for being referred in children between 2 and 7 years with a flat curve is 8.94 (CI: 4.18–19.11) when compared to children without a flat curve.

Conclusion: Sleep problems at inclusion were the only symptom statistically significant associated with having one or more symptoms after four weeks in children between 0 and 2 years.

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1. Introduction

Otitis media (OM) is a common childhood disease and a frequent reason for seeking medical care in general practice [1]. The most prevalent types of OM in children are acute otitis media (AOM) and middle ear with effusion (MEE), also called secretory otitis media [2]. The course of OM is highly variable with respect to duration and severity of symptoms [3,4]. AOM symptoms comprises typically fever, earache and sleep problems [5]. In MEE the symptoms are not acute and less pronounced, and the reason for doctor-seeking may be suspicion of hearing loss [6].

There is an abundance of research on risk factors for development of OM, e.g. gender, lack of breastfeeding and allergy [7–10], and on treatment strategies [11]. In contrast, only few studies have focused on what happens after diagnosis and initial treatment of OM [12,13]. In particular, there is a lack of research on

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how different patient- and disease-related factors influence the short-term course of OM.

In many diseases the presence and severity of symptoms are closely associated with severity of the disease. It may be hypothesized that symptoms in children examined due to suspicion of middle ear problems may be predictors of the prognosis of otitis media.

The aim of this study was to analyze to what extent symptoms at the time of initial diagnosis was associated with the short-term course of otitis media.

2. Methods

2.1. Study design

We conducted a cohort study comprising 126 general practitioners (GPs) and 954 children from January 2010 to June 2010. All children presenting with a new ear problem (that means no contacts to the healthcare system in connection with the ears for the previous 4 weeks) were included consecutively. During the first consultation the GPs registered symptoms, results of otoscopy and tympanometry, diagnosis and treatment. Four weeks after the

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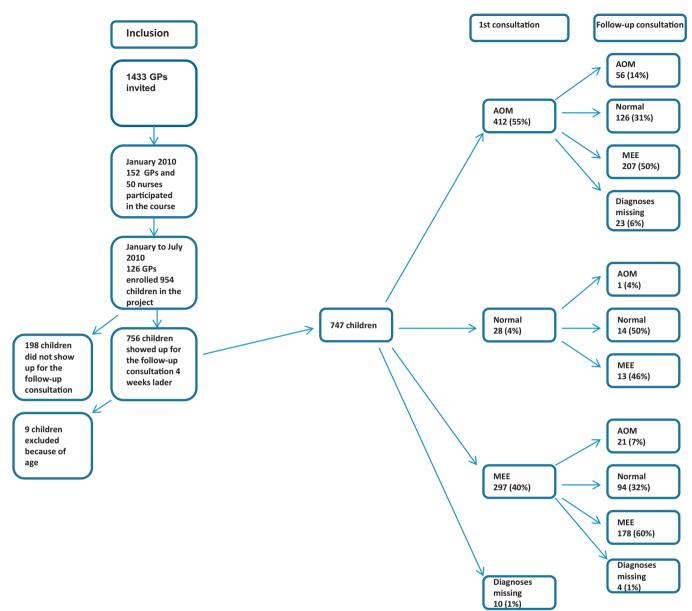


Fig. 1. Inclusion of GPs and children and distribution of diagnoses at first consultation and at the follow-up consultation.

first consultation, the children were seen again by the GP in order to monitor the disease and register symptoms, diagnosis, treatment, and referrals (Fig. 1).

2.2. Setting

All GPs from the Region of Southern Denmark and Region Zealand (N = 1433) and their practice nurses (if they were involved in the procedure with tympanometry in the practice) were invited to participate in the project [14]. A total of 152 GPs or doctors in training and 45 GP nurses participated in a one-day course. Subsequently, 126 of the GPs included children in the cohort from January 2010 to June 2010.

2.3. The Danish healthcare system

Denmark has a tax-funded healthcare system, providing free access to general practice, outpatient clinics and hospital care for all citizens. Otolaryngologists can be accessed without a referral from a GP. A total of 98% of 5.5 million Danish citizens are registered with a general practitioner and receive free medical care. Prescribed medications are partly subsidized [15].

2.4. Audit Project Odense

Data for the study were collected via an audit about ear problems in preschool children carried out by Audit Project Odense (APO). APO is a quality development concept widely used in many countries [16,17]. It includes registration of the GPs' activities, courses, follow-up and evaluation of their treatment patterns in connection with specific projects. APO data have proved to be valid for research purposes and are used in many other research projects [18,19]. During the consultation, the GP registers information about the patient's characteristics and treatment. Questionnaires used for registration are described below.

2.5. Course on ear symptoms, diagnosis and tympanometry

Prior to the inclusion the GPs participated in a one-day course about ear symptoms, diagnosis and tympanometry. The GPs were

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encouraged to let their nurses participate in the course, especially designed to improve diagnosis and treatment of OM in general practice [14].

On the course an otolaryngologist taught about diagnosing ear diseases and gave practical information about tympanometry. The more technical details regarding the use of tympanometry were presented by representatives from Interacoustics A/S, a company producing tympanometers (www.interacoustics.com).

2.6. Participants

The children included were between 0 and 7 years old. Children whose parents could not read or write Danish were not included. Furthermore, children with ongoing middle ear problems and children with tympanostomy tubes were not included.

2.7. Questionnaire

Questionnaires to the GPs were developed by the authors based on literature review and clinical experience and were subsequently pilot tested and minor changes were made. The first questionnaire comprised questions on symptoms (fever, sleep problems, earache, ear rubbing, reduced hearing, ear fluid, delayed language development, problems with the balance) reported by the parents. The GPs recorded results of otoscopy, results of tympanometry, the diagnosis, whether any drug was prescribed, and whether the child was referred to an otolaryngologist or a hospital.

During the first consultation the parents were asked to bring their child to a follow-up consultation four weeks later, regardless of the child having ear symptoms after four weeks.

The questionnaire for the follow-up consultation was quite similar to the first questionnaire, but in addition it also included questions on symptoms. Result of tympanometry and otoscopy, diagnoses, prescription of drugs, and referral were recorded at follow-up.

2.8. Statistical analyses

Proportion and mean value are presented with 95% confidence intervals (CIs). We used logistic regression to analyze the associations between referral to otolaryngologists after four weeks and symptoms at inclusion, and between symptoms after four weeks and symptoms at inclusion. The analyses were adjusted for possible cluster effects from children sharing the same GP using robust cluster estimation.

Tests for relevant interactions were conducted where interactions seemed probable. Interactions between age and each of the

Table 1Basic characteristics.

		Ν	%
Characteristic of th	e GPs		
Gender	Male	55	44
	Female	71	56
Age	27–68 years		
Mean age		49.30	
Characteristic of th	e children		
Gender	Boys	383	51
	Girls	364	49
Age	0–7 years		
Mean age		2.57	

symptoms, antibiotics and fever, and antibiotics and earache were tested. Because of interaction between age and several of the symptoms, all analyses were stratified on age groups. STATA release 11.0 was used for all statistical analyses.

2.9. Ethics

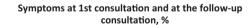
The study was approved by the Danish Data Protection Agency. The study did not need approval by the Regional Ethics Committee as it did not involve human biological material (www.dnvk.dk/ CVK/Home/English.aspx). Written informed consent was obtained from a parent of each child before inclusion.

3. Results

In total, 126 GPs included 954 children. Of the 954 children, 747 attended the follow-up consultation (Table 1). Fig. 2 shows the symptoms at first consultation and at the follow-up consultation for children aged 0–2 and 2–7 years. During the first consultation 30 children had only "other symptoms" (e.g. cough, poor appetite or other upper respiratory symptoms). At the first consultation 56% (CI: 52–60) of the children were diagnosed with AOM and 40% (CI: 36–44) with MEE (Fig. 1). After AOM 32% (CI: 27–37) and after MEE 31% (CI: 29–35) had normal tympanometry in the ears at follow-up.

Of the 747 children 266 (36%) received a prescription for antibiotics at the first consultation. Among the children 57% with a fever, 43% with earache, 39% with sleeping problems and 39% rubbing their ears received a prescription for antibiotics.

At the first consultation 30 of the 747 children were referred to an otolaryngologist or the hospital, and of those 9 had a fever, 8 had an earache, 11 were rubbing their ears and 16 had sleeping problems.



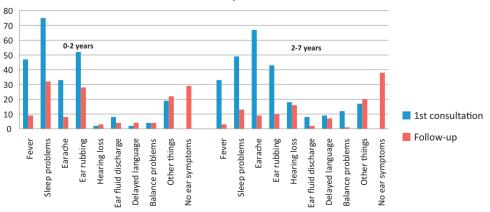


Fig. 2. Symptoms at 1st consultation and at the follow-up consultation, %.

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Table 2

Crude and adjusted odds ratio for 1 or more symptoms at the follow-up consultation.

Meaning	Total N	N (%)	Crude OR	Adjusted OR	Adjusted P-values
Girls	167	114 (68.3)	1	1	
Boys	179	124 (69.3)	1.05	1.03 (0.64-1.66)	0.89
•		. ,			
No fever	181	130 (71.8)	1	1	
Fever (>38.5 °C)	165	108 (65.5)	0.74	0.93 (0.56-1.54)	0.78
No	85	49 (57.7)	1	1	
Yes	261	189 (72.4)	1.93	2.02 (1.24-3.31)	<0.01
No	235	166 (70.6)	1	1	
Yes	111	72 (64.9)	0.77	0.75 (0.44-1.25)	0.27
No	169	114 (67.5)	1	1	
Yes	177	124 (70.0)	1.13	1.22 (0.76-1.97)	0.41
No	191	140 (73.3)	1	1	
Yes		. ,	0.62	0.69 (0.42-1.14)	0.15
No		· · ·		· · · ·	
					0.37
				1	0.07
Yes	34	25 (73.5)	1.30	0.95 (0.42-2.14)	0.90
Meaning	Total N	N (%)	Crude OR	Adjusted OR	Adjusted P-value
Girls	168	102 (60.7)	1	1	
		. ,	0.82	0.86 (0.56-1.30)	0.47
j-		()			
No fever	227	130 (57.3)	1	1	
					0.67
· · ·				· · · ·	
					0.16
		. ,		1	0110
		. ,		•	0.16
				· · /	0.10
			-		0.39
105	145	15 (54.5)	0.74	0.00 (0.45 1.52)	0.55
No	208	119 (57 2)	1	1	
No Ves	208 132	119 (57.2) 80 (60.6)	1 1 15	1 1 25 (0 69–2 29)	0.46
Yes	132	80 (60.6)	1.15	1.25 (0.69–2.29)	0.46
Yes No	132 245	80 (60.6) 149 (60.8)	1.15 1	1.25 (0.69–2.29) 1	
Yes	132	80 (60.6)	1.15	1.25 (0.69–2.29)	0.46 0.51
	Girls Boys No fever Fever (>38.5 °C) No Yes No Yes No Yes No Yes No Yes No Yes No Yes No Yes No Yes	Girls 167 Boys 179 No fever 181 Fever (>38.5 °C) 165 No 85 Yes 261 No 235 Yes 111 No 169 Yes 177 No 169 Yes 177 No 191 Yes 154 No 250 Yes 95 No 311 Yes 34 Meaning Total N Girls 168 Boys 175 No fever 227 Fever (>38.5 °C) 114 No 173 Yes 168 No 116 Yes 225 No 196	Girls 167 114 (68.3) Boys 179 124 (69.3) No fever 181 130 (71.8) Fever (>38.5 °C) 165 108 (65.5) No 85 49 (57.7) Yes 261 189 (72.4) No 235 166 (70.6) Yes 111 72 (64.9) No 169 114 (67.5) Yes 177 124 (70.0) No 169 114 (67.5) Yes 177 124 (70.0) No 169 114 (67.5) Yes 154 97 (63.00) No 250 165 (66.0) Yes 95 72 (75.8) No 311 212 (68.2) Yes 34 25 (73.5) Meaning Total N N (%) Girls 168 102 (60.7) Boys 175 98 (56.0) No fever 227 130 (57.3) Fever (>38.5 °C) 114	Girls 167 114 (68.3) 1 Boys 179 124 (69.3) 1.05 No fever 181 130 (71.8) 1 Fever (>38.5 °C) 165 108 (65.5) 0.74 No 85 49 (57.7) 1 Yes 261 189 (72.4) 1.93 No 235 166 (70.6) 1 Yes 111 72 (64.9) 0.77 No 169 114 (67.5) 1 Yes 177 124 (70.0) 1.13 No 191 140 (73.3) 1 Yes 154 97 (63.00) 0.62 No 250 165 (66.0) 1 Yes 95 72 (75.8) 1.61 No 311 212 (68.2) 1 Yes 34 25 (73.5) 1.30 Meaning Total N N (%) Crude OR Girls 168 102 (60.7) 1 Boys 175	Girls 167 114 (68.3) 1 1 Boys 179 124 (69.3) 1.05 1.03 (0.64-1.66) No fever 181 130 (71.8) 1 1 Fever (>38.5 °C) 165 108 (65.5) 0.74 0.93 (0.56-1.54) No 85 49 (57.7) 1 1 Yes 261 189 (72.4) 1.93 2.02 (1.24-3.31) No 235 166 (70.6) 1 1 Yes 111 72 (64.9) 0.77 0.75 (0.44-1.25) No 169 114 (67.5) 1 1 Yes 154 97 (63.00) 0.62 0.69 (0.42-1.14) No 250 165 (66.0) 1 1 Yes 95 72 (75.8) 1.61 1.29 (0.74-2.26) No 311 212 (68.2) 1 1 Yes 34 25 (73.5) 1.30 0.95 (0.42-2.14) Meaning Total N N (%) Crude OR Adjusted O

The adjusted ORs are adjusted for GPs gender and age, the result of tympanometry at first consultation and all variables included in the table.

At the follow-up consultation 123 (16%) children were prescribed antibiotics and among those 43% with a fever, 41% with an earache, 27% with sleeping problems and 22% pulling their ears received antibiotics.

At the follow-up consultation 163 (22%) were referred to an otolaryngologist or the hospital. Of those children, 15 had a fever, 69 sleeping problems, 32 earaches, and 41 were pulling their ears.

Sleep problems at inclusion was significantly associated with one or more symptoms at the follow-up consultation in the youngest age group (OR: 2.02 (CI: 1.24–3.31)) (Table 2). In children with sleep problems at the first consultation the most frequently reported symptom at the follow-up consultation was also sleep problems (52%). Tympanometry findings in children with sleep problems did not differ from the findings in children without sleep problems.

Antibiotic prescribing at the first consultation was not significantly associated with symptoms after four weeks. Neither the child's gender nor treatment or symptoms at the first consultation were associated with one or more symptoms at the follow-up consultation in the oldest children between 2 and 7 years (Table 2).

There were no significant associations between characteristics of the GPs (age and gender) and symptoms after four weeks in any of the age groups (results not shown). Further, there were no significant associations between the result of tympanometry at first consultation and one or more symptoms after four weeks in any age group (results not shown).

Children between 0 and 2 years with the diagnosis AOM at the first consultation had a higher risk (OR: 2.30 (CI: 1.32–4.00)), of being referred to an otolaryngologist at the follow-up consultation compared to children diagnosed with MEE at the first consultation (Table 3). Of the 59 referred children between 0 and 2 years with AOM at the first consultation 22 (37% (CI: 25–49)) were diagnosed with AOM at the follow-up consultation, and 28 (47% (CI: 34–60)) of the referred children with AOM at the first consultation were diagnosed with MEE at the follow-up consultation (results not shown). Children between 0 and 2 years with a fever at the first consultation are less likely to be referred to an otolaryngologists at the follow-up consultation compared to children without fever (OR: 0.54 (CI: 0.31–0.95)).

Female GPs referred children between 0 and 2 years to otolaryngologists more often than male GP. OR was 2.47 (CI: 1.16–5.29). No other associations between characteristics of the GPs and referral to otolaryngologists after four weeks were significant in any of the age groups (results not shown).

If the result of tympanometry is a flat curve the OR of being referred is 3.24 (1.61–6.55) in children between 0 and 2 years compared to children without a flat curve. The OR of being referred in children between 2 and 7 years with a flat curve is 8.94 (CI: 4.18–19.11) compared to children without a flat curve.

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Table 3

Crude and adjusted odds ratio for being referred to an ENT physician at the follow-up consultation.

Variable	Meaning	Total N	N (%)	Crude OR	Adjusted OR	Adjusted P-values
Children 0-2 years (N=3	357)					
Gender	Girls	173	44 (25.4)	1	1	
	Boys	184	43 (23.4)	0.89	1.03 (0.58-1.83)	0.91
Symptoms at 1st cons	ultation					
Fever	No fever	188	47 (25.0)	1	1	
	Fever (>38.5 °C)	169	40 (24.7)	0.93	0.54 (0.31-0.95)	0.03
Sleep problems	No	88	17 (19.3)	1	1	
	Yes	269	70 (26.0)	1.47	1.50 (0.72-3.14)	0.28
Ear ache	No	242	59 (24.4)	1	1	
	Yes	115	28 (24.4)	1.00	0.93 (0.54-1.62)	0.81
Ear rubbing	No	175	42 (24.0)	1	1	
0	Yes	182	45 (24.7)	1.04	1.10 (0.60-2.00)	0.77
Diagnoses at 1st consu	ıltation					
Diagnosis	MEE	137	27 (19.7)	1	1	
0	AOM	201	59 (29.4)	1.69	2.30 (1.32-4.00)	<0.01
Result of tympanomet	ry at follow-up consultation					
Tympanometry	Other types	109	13 (11.9)	1	1	
	Type B (flat curve)	240	72 (30.0)	3.16	3.24 (1.61-6.55)	<0.01
Children 2–7 years (N=3	51 ()		(, , , , , , , , , , , , , , , , , , ,			
Gender	Girls	184	43 (23.4)	1	1	
	Boys	191	33 (17.3)	0.68	0.64 (0.34-1.22)	0.18
Symptoms at 1st cons	5					
Fever	No fever	250	49 (19.6)	1	1	
	Fever (>38.5 °C)	123	26 (21.1)	1.10	1.44 (0.64–3.25)	0.38
Sleep problems	No	189	44 (23.3)	1	1	
	Yes	184	31 (16.9)	0.67	0.79 (0.41-1.55)	0.50
Ear ache	No	123	37 (30.1)	1	1	
	Yes	250	38 (15.2)	0.42	0.65 (0.31-1.35)	0.25
Ear rubbing	No	211	48 (22.8)	1	1	
	Yes	162	27 (16.7)	0.68	0.80 (0.39–1.65)	0.55
Diagnoses at 1st consu		102	27 (1017)	0.00		0100
Diagnosis	MEE	156	39 (25.0)	1	1	
	AOM	200	33 (16.5)	0.59	0.62 (0.30–1.26)	0.19
Result of tympanomet	ry at follow-up consultation		(,		()	
Tympanometry	Other types	180	10 (5.6)	1	1	
	Type B (flat curve)	190	62 (32.6)	8.23	8.94 (4.18–19.11)	<0.01

The adjusted ORs are adjusted for GPs gender and age and for all variables included in the table.

The few children with no ear diagnosis at inclusion are not included in Table 3 because none of the children between 0 and 2 years without an ear diagnosis were referred.

4. Discussion

4.1. Principal findings

Sleep problems at inclusion were statistically significantly associated with having one or more symptoms after four weeks in the youngest age group.

4.2. Strengths and weaknesses

Using a data collection tool, with which the GPs are familiar, is a strength of the study [16,17,20–22]. This optimized the consistency in the GPs' registration of the patients' data. The study was part of a quality development project for the individual practitioner; hence the GP used data gathered from their own patients for learning purposes. They were encouraged to include all children with ear symptoms consecutively, and we have no reason to believe that the GPs deviated from the consecutive procedure.

The GPs participated on a voluntary basis and may be particularly interested in ear diseases and quality development compared to other GPs. However, according to yearly practice records of the Danish College for General Practitioners, the GP population in our study was similar to GPs in the rest of Denmark with respect to age, gender and types of practice [20–22].

The accuracy of the diagnoses given by the GPs can be questioned as AOM and MEE are often difficult to distinguish [2].

However, the use of tympanometry may have enhanced the chance of establishing correct diagnoses [23]. Furthermore, a combination of tympanometry and otoscopy reduces the number of AOM diagnoses significantly [24]. A Danish study found that tympanometry can be performed successfully in general practice after appropriate instruction [25].

When children with all kinds of ear symptoms addressed in general practice are included and followed we get a cohort where the only selection is the patients' doctor-seeking. This enhances the generalisability of the study, and the results may be used in similar situations in related settings, where children present with ear symptoms in primary care.

It is likely that some of the children, who did not attend the follow-up consultation, are a selected group with few and little symptoms. If we had results from the follow-up consultation from these children, it is possible that the odds ratios for referral and symptoms at the follow-up consultation would be smaller. However, preliminary analyses showed that the distribution of age, sex and symptoms in children not attending the follow-up consultation was quite similar to that in children attending the follow-up consultation. In contrast, children not attending the follow-up consultation may have visited an otolaryngologist because of worsening symptoms.

Inclusion of children with recurrent otitis media might have increased the associations between referral to an otolaryngologist after four weeks and symptoms at inclusion, and symptoms after four weeks and symptoms at inclusion as those children might have longer or different courses of otitis media. We have tried to overcome this bias by not including children with any contact related to the ears for the last four weeks.

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4.3. Explanations and comparison with other studies

Previous studies with recurrent AOM or MEE as outcomes have identified different variables with impact on the diseases, e.g. type of day care [7,26] parental smoking [11,27], duration of breastfeeding [8,9,28] and socioeconomic factors [7,8]. To our knowledge no other studies have analyzed the extent to which symptoms at inclusion are associated with the short-term course of OM.

Sleep problems at inclusion are the only symptoms statistically significantly associated with one or more symptoms after four weeks in small children between 0 and 2 years. The most prevalent symptoms after four weeks in children with sleep problems at inclusion remained sleep problems. This indicates that sleep problems are persistent. Although sleep problems can be caused by other things [29–31], it is important that the GPs pay attention to this problem in children with ear diseases.

Children with sleep problems might be more prone to AOM or the recovery might be delayed because of large tonsils, adenoids or untreated allergic rhinitis. Since the parents do not necessarily seek medical attentions for their child's sleep problems, the ear consultations offer a chance to identify these children.

As a consequence of the association between sleep problems at inclusion and one or more symptom after four weeks it is recommended that GPs actively ask about sleep problems when they perform physical examinations of children with ear diseases. If a child with ear disease has sleep problems it might need a close follow-up, as the problem does not seem to disappear by itself.

4.4. Implications for practice and further research

Otitis media is one of the most common childhood infections. The only symptoms at the first consultation significantly associated with symptoms after four weeks are sleep problems. We recommend that GPs specifically ask about sleep problems when they perform physical examinations of children with ear diseases.

Future studies are needed to identify other factors that may have an impact on the long-term course of otitis media.

5. Conclusion

Sleep problems at inclusion are the only symptoms statistically significantly associated with having one or more symptoms after four weeks in children between 0 and 2 years.

Acknowledgements

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