Acute Otitis Media in Childhood - Use of Guidelines for Diagnosis and Treatment in Emergency Rooms

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Abstract: *Background:* AOM is characterized by its high prevalence and morbidity but low lethality. It is estimated that 70% of children will have had one episode prior to completing five years of age. Compliance with the guidelines for acute otitis media (AOM) may avoid complications. This study aimed at determining whether pediatricians follow the guidelines for AOM management. *Methods:* A prospective, cross-sectional study involving pediatricians working in emergency centers in Recife. A specific questionnaire was used to collect data. *Results:* Of the 71 pediatricians interviewed around 98% gave importance to crying/irritability and otalgia when diagnosing otitis and all recognized the significance of otorrhea. All the professionals gave importance to bulging tympanic membrane, 98.6% to acute tympanic membrane perforation, 97.1% to purulent effusion and 46.5% to bilateral hyperemia of the tympanic membrane. Regarding antibiotic therapy, 70.4% used standard doses of amoxicillin as first-line treatment (81.7% prescribing for 10 days). Furthermore only 47.9% double the dose in case of therapeutic failure. *Conclusion:* Pediatricians working in emergency departments need to be better informed about the guidelines to decrease inappropriate prescription of antibiotics for AOM. We believe that adoption of the “wait and see” strategy, even in emergency rooms, would be an important means of reducing the inadequate prescription of antibiotics in cases of AOM, thus contributing towards reducing bacterial resistance.

Keywords: Acute Otitis Media, Paediatrics, Guidelines, Diagnosis, Treatment

1. Introduction

Acute otitis media (AOM) is an inflammation of the middle ear mucosa. It is generally associated with the rapid onset of signs and symptoms of an acute middle ear infection, involving fever, otalgia and irritability. AOM is often secondary to an upper respiratory tract infection. [1] The World Health Organization estimates that 51,000 deaths occur annually in children under five years of age as a result of AOM complications. [2]

AOM is characterized by its high prevalence and morbidity but low lethality. It is estimated that 70% of children will have had one episode prior to completing five years of age. [3-4] In a cohort study, 71% of the children evaluated had had one or more episodes of AOM prior to completing three years of age, with the condition being more prevalent in boys. [5] In general, the disease affects infants in the first two years of life, with a major incidence peak at 6-11

months and a secondary peak at 4-5 years of age. The low incidence in children up to six months of age is explained by the presence of transplacental antibodies, less exposure to pathogens and the position used for breastfeeding. [6] Socialization in schools and day-care centres is the factor that most contributes to the occurrence of AOM, [7] particularly because the children share enclosed spaces as well as accessories such as feeding bottles and pacifiers, perpetuating a recurrent cycle of upper respiratory tract infections. The risk of recurrence appears to be associated with the age at which the first episode appears: 60% of children with a recurrence during childhood had their first episode prior to completing six months of age. [8]

The precise diagnosis of AOM in infants and small children can be difficult. Symptoms may be mild or may overlap those of an upper respiratory tract infection. [9] Visualization and analysis of alterations in the tympanic membrane may also be hampered by the presence of wax in the ear canal. [8-9]

Other factors that make an accurate diagnosis difficult include the child's lack of cooperation during evaluation, a lack of adequate equipment such as a pneumatic otoscope, a lack of training and inappropriate instruments with which to clean the ear canal. [8-9] Physicians need to be trained to make the differential diagnosis between AOM and otitis media with effusion, which is defined by the presence of fluid in the middle ear, with no signs or symptoms of acute infection. This is a relevant factor in the inappropriate prescription of antibiotics, consequently leading to an increase in the occurrence of adverse events and in the development of bacterial resistance. [10-12]

There is evidence that some physicians are resistant to complying with the diagnostic criteria proposed in standardized guidelines, suggesting that the information contained therein needs to be disseminated and its recommendations implemented to ensure the effective diagnosis and treatment of AOM, thus avoiding possible complications resulting from the infection. [13-17]

The accurate diagnosis of AOM is a controversial subject in medical practice. [9, 18-23] Laine et al. [23] evaluated children whose parents suspected that their child had AOM. The diagnosis was confirmed by tympanic-membrane examination in around half the children, while the other half actually had other problems of the upper respiratory tract. In relation to the symptoms used as criteria for a diagnosis of AOM, other studies [19-21] showed that otalgia is the symptom considered most relevant despite being present in only 50-60% of children.

At the end of the previous century the recommendation was to prescribe antibiotics at the time of diagnosis of AOM to minimize the risk of complications. Nevertheless, since 2004 and with the update in 2013 the American Academy of Paediatrics (AAP) guidelines [24] recognize that in cases of AOM with no complications antibiotic treatment may be unnecessary and recommend monitoring these patients and prescribing only analgesics. On the other hand, Coco et al. [15] conducted a study between 2002 and 2006 in outpatient

clinics in the United States and reported that the rate of antibiotic prescription remained unchanged following publication of the clinical guideline in 2004, with the only difference being an increase in the prescription of amoxicillin and analgesics and a reduction in the prescription of amoxicillin/ clavulanate.

Considering the importance of otitis, the difficulties involved in appropriately diagnosing and treating the condition, and the few studies carried out in Brazil to evaluate the correct management of this disease, the objective of the present study was to evaluate paediatricians' compliance with the principal international and national guidelines on the management of AOM.

2. Methods

This was a cross-sectional cohort study conducted in the paediatric emergency department of the *Instituto de Medicina Integral Prof. Fernando Figueira* (IMIP), which provides healthcare to patients within the Brazilian National Health Service (*Sistema Único de Saúde – SUS*), and in the emergency rooms of two private hospitals: the *Hospital Esperança* and the *Hospital Real Português*. The convenience sample included duty doctors and medical residents. Data were collected at the study sites between November 2014 and April 2015.

The protocol of this study was approved by the internal review board of the *Faculdade Pernambucana de Saúde* under reference number 909.899. The study was conducted in accordance with the relevant ethical guidelines governing research in human beings. All participants signed an informed consent form. Participants' identity was strictly protected throughout the study and their anonymity will continue to be preserved afterwards.

The clinical variables evaluated with respect to their importance in the diagnosis of AOM were: fever, a runny nose/cough, crying/irritability, associated rhinitis, vomiting associated with fever, otalgia, and otorrhoea. The weight given to the use of conventional or pneumatic otoscopy in the examination was recorded. The otoscopic findings evaluated for their importance were: unilateral/ bilateral hyperaemia, opacity, bulging, perforation and retraction of the tympanic membrane; the presence of purulent effusion; and non-visualization of the auditory ossicles.

The variables related to treatment were: the use of antibiotics, the drug used (standard dose of amoxicillin 40-50 mg/kg/day; double dose of amoxicillin 90 mg/kg/day; standard dose of amoxicillin plus clavulanate; double dose of amoxicillin 80-100 mg/kg/day plus clavulanate; cefaclor; ceftriaxone; cephalexin; clarithromycin; clindamycin), predicted duration of antibiotic use, need for re-evaluation, and the number of days between the implementation of antibiotic therapy and the recommended clinical re-evaluation. The use of symptomatic treatment such as oral corticoids, decongestants, and analgesics was also evaluated.

When the participants returned their completed form,

they were recorded in a registration log. Next, a database was constructed, with data entry being performed in duplicate to ensure that any errors or inconsistencies would be corrected.

The STATA/SE software package, version 12.0, and Excel 2010 were used for data analysis. Significance level was established at 95%. Tables of absolute and relative frequency were constructed. For the categorical variables, Fisher's exact test was used to verify the existence of association and, when necessary, the chi-square test was used, with p -values < 0.05 being considered statistically significant.

3. Results

The sample consisted of 71 paediatricians working at public and private emergency departments in three hospitals in the city of Recife. The characteristics of the sample are shown in Table 1. Fifty-eight of the paediatricians in the sample (81.7%) were female. More than half were over 35 years of age and 44 participants (62%) had been working as a paediatrician for at least five years at the time of the study.

Table 1. Sociodemographic characterization of the paediatricians – Knowledge, Attitude and Practice in managing acute otitis media. Recife, Brazil, 2015.

Characteristics	n	%
Sex		
Female	58	81.7
Male	13	18.3
Age *		
24-29 years	19	26.7
30-35 years	13	18.3
> 35 years	37	52.1
Time in the specialty		
≤ 5 years	27	38.0
> 5 years	44	62.0
Specialist degree		
Yes	31	43.6
No	35	49.3
Place of employment		
Public service	35	49.3
Private service	36	50.7

* data missing in two cases

Table 2 describes the signs, symptoms and otoscopic findings used by the paediatricians in the emergency rooms to diagnose otitis. When diagnosing otitis, the vast majority gave importance to the presence of crying/irritability (98.6%) and otalgia (97.2%), and all gave weight to the presence of otorrhoea. With respect to the otoscopic findings, 71 professionals (100%) gave importance to tympanic membrane bulging, while 70 (98.6%) gave importance to acute tympanic membrane perforation and 69 (97.1%) took the presence of a purulent effusion into consideration. Nevertheless, only 33 professionals (46.5%) gave importance to bilateral hyperaemia of the tympanic membrane, while 40 (56.3%) took unilateral hyperaemia into consideration.

Table 2. Importance given by the paediatricians to the signs, symptoms and otoscopic findings for a diagnosis of acute otitis media. Recife, Brazil, 2015.

Factors considered important	n	%
Clinical data		
Otorrhoea	71	100.0
Crying/irritability	70	98.6
Otalgia	69	97.2
Fever	55	77.5
Associated rhinitis	51	71.8
Runny nose/cough	49	69.0
Vomiting associated with fever	41	57.7
Otoscope Findings		
Tympanic membrane bulging	71	100.0
Acute tympanic membrane perforation	70	98.6
Purulent effusion	69	97.2
Opacity of the tympanic membrane	61	85.9
Auditory ossicles not visualized	54	76.0
Tympanic membrane retraction	53	77.9
Unilateral hyperaemia of the tympanic membrane	40	56.3
Bilateral hyperaemia of the tympanic membrane	33	46.5

These professionals' first choice of antibiotic for the management of otitis is shown in Table 3.

Table 3. Therapeutic management of acute otitis media as reported by the paediatricians. Recife, Brazil, 2015.

Condition management	n	%
Drug initially used for the treatment of otitis		
Amoxicillin - standard dose	50	70.4
Amoxicillin - standard dose plus clavulanate	15	21.1
Amoxicillin – double the standard dose	6	8.5
Period of use of the first drug		
≤ 5 days	3	4.2
6-8 days	6	8.5
9-10 days	58	81.7
> 10 days	4	5.6
Recommends re-evaluation		
Yes	64	90.1
No	7	9.9
Re-evaluation (days)		
2 days	14	19.7
3-5 days	36	50.7
6-10 days	9	12.6
> 10 days	5	7.0
Did not answer	7	9.8
Drug used as second option for the treatment of otitis		
Amoxicillin – double the standard dose	34	47.9
Amoxicillin – standard dose plus clavulanate	16	22.5
Amoxicillin – double the standard dose plus clavulanate	9	12.7
Amoxicillin – standard dose	4	5.6
Cefaclor	1	1.4
Did not answer	7	9.8
Drug most commonly used in cases of no response to first-line therapy		
Amoxicillin – double the standard dose	29	40.8
Amoxicillin – double the standard dose plus clavulanate	17	23.9
Amoxicillin – standard dose plus clavulanate	12	16.9
Did not answer	13	18.3
Recommends use of oral corticoids		
Yes	9	12.6
No	59	83.0
Did not answer	3	4.2
Recommends use of systemic decongestant		
Yes	5	7.0
No	66	93.0
Recommends use of analgesic		

Condition management	n	%
Yes	69	97.2
No	1	1.4
Did not answer	1	1.4

Around 70% of the paediatricians ($n = 50$) reported that they used amoxicillin at the standard dose as first-line treatment. In relation to the duration of treatment, 58 paediatricians (81.7%) prescribed a 10-day course of antibiotics, with only 3 professionals (4.2%) routinely prescribing a 5-day course. Sixty-four paediatricians (around 90%) recommended clinical re-evaluation after treatment had been instituted, with 50.7% of physicians stating that re-evaluation should take place after 3-5 days.

Regarding the antibiotic prescribed in cases of treatment failure, the answers given were: amoxicillin at double the standard dose (34 professionals; 47.9%), amoxicillin at double the standard dose plus clavulanate (16 paediatricians; 22.5%) and amoxicillin at the standard dose plus clavulanate (9 professionals; 12.7%).

Only 9 doctors (12.6%) prescribed symptomatic treatment with corticoids, while 5 (7%) prescribed systemic decongestants. The vast majority (69 physicians; 97.2%) routinely prescribed analgesics.

4. Discussion

The AAP published its guidelines for the diagnosis and treatment of AOM with the objective of helping primary care physicians manage the disease. [24] The aim of the present study was to determine whether the clinical data taken into consideration by physicians when attending their patients and the treatment they prescribe are indeed in compliance with those guidelines.

The number of women in medicine today and particularly in paediatrics has already been reported in other studies, [25-28] and was confirmed in the sample of participants in the present study in which 81.7% of the 71 participants were female. The fact that 62% of the participants had been working as paediatricians for at least five years suggests that the interviewees in this study were experienced in managing the principal emergencies. AOM is the principal reason for prescribing antibiotics to outpatients, [29] and it is very probable that these emergency room doctors had already had to deal with various cases of AOM. Nevertheless, in the emergency department at IMIP, data were collected not only from duty doctors but also from medical residents, and this may explain the percentage of participants with less than five years' experience in the specialty.

Nonspecific clinical data such as crying, irritability and otalgia continue to be considered highly important by paediatricians. These data are also referred to in the AAP guidelines, which address the presence of earache or a child's nonverbal act of holding, pulling or rubbing his/her ear as part of the diagnosis. This finding partially contradicts other reports, [21-23] which have shown that earache is present in only 50-60% of children with AOM.

Otorrhoea is the final stage in the evolution of AOM and

its presence was taken into consideration by all the paediatricians, emphasizing the significance of this symptom. This is in agreement with the AAP guidelines that a diagnosis of AOM should not be made without a finding of middle ear effusion at pneumatic otoscopy. Nevertheless, in the present study, only one physician mentioned the importance of pneumatic otoscopy. All the guidelines emphasize the importance of well conducted otoscopy in the diagnosis of AOM. [10, 24] In the present study, tympanic membrane bulging and the presence of a purulent effusion in the ear canal were the factors given most importance by the participants in diagnosing otitis. One of the principal diagnostic criteria proposed in the guidelines is that only the presence of otorrhoea or bilateral hyperaemia should be taken into consideration. [30-36]

The lesser importance placed on a finding of bilateral hyperaemia (46.5% of the paediatricians) compared to unilateral hyperaemia (56.3%) merits particular attention. This was an unexpected finding, since it has been reported that antibiotics are more beneficial in children under two years of age and in those in whom AOM is bilateral. [33, 37] This suggests that paediatricians in this region need more information on current recommendations regarding the importance of bilateral hyperaemia when diagnosing AOM.

The justification for prescribing antibiotics to children with AOM is based on a high prevalence of bacteria in middle ear effusion. [38] Bacterial culture and viral isolation from middle ear fluid specimens obtained by tympanocentesis in children with AOM revealed the presence of bacteria in 55% and a bacterial/viral co-infection in 15%. In recent years, the importance of correctly diagnosing and managing otitis has been emphasized in view of increasing resistance to the principal bacteria involved in its aetiology and of the favourable progression of patients not treated with antibiotics, even in cases of bacterial otitis. [22]

In the present study, the drug of choice for the treatment of otitis was amoxicillin at the standard dose, as indicated by 70.4% of these paediatricians. This therapy is considered relevant and correct in clinical practice for the treatment of AOM. Justification for the use of amoxicillin is related to its effectiveness against the common pathogens associated with AOM, as well as its safety, low cost, acceptable taste and narrow antimicrobial spectrum. [8-39] According to studies published in the United States, cephalosporins, and even amoxicillin at double the standard dose, are currently the most commonly prescribed drugs; however, the majority of guidelines emphasize this as inappropriate management. [24, 40]

In children with persistent and severe symptoms of AOM and in cases in which there is no improvement following initial treatment, the clinician may consider changing the antibiotic. [10] Thus, if the child is initially treated with amoxicillin and fails to improve, amoxicillin plus clavulanate may be an option. Another option would be to increase the dose of amoxicillin and to use a second-generation cephalosporin such as cefuroxime or a third-generation cephalosporin such as ceftriaxone (50 mg/kg intramuscularly) in a 1- to 3-day treatment course. [10, 41] In

cases in which the patient fails to respond to the first-line treatment, the options used by the paediatricians in the present study were amoxicillin at double the standard dose (40.8%), amoxicillin at double the standard dose plus clavulanate (23.9%), and amoxicillin at the standard dose plus clavulanate (16.9%). The options used were considered adequate in the majority of cases and are in accordance with the guidelines. In the great majority of cases (81.7%) the antibiotic treatment was continued for 8-10 days. Nevertheless, several studies have recommended shorter courses for children, particularly for infants under two years of age, with 5-7 day courses being recommended. [42-47]

The prescription of analgesics was shown to be practically routine, with 97.1% of doctors prescribing analgesics in addition to antibiotics for the management of otalgia and other symptoms. This concern with treating pain is in agreement with the AAP recommendations. [24] Indeed, the use of antibiotics does not provide relief from symptoms in the first 24 hours; [32, 42] on the other hand, the use of analgesics effectively provides immediate relief from symptoms.

Children with AOM should be re-evaluated, and 90.1% of the paediatricians follow this recommendation; however, this practice is often unfeasible in emergency rooms, since the child may not return to the same healthcare service or may not be seen by the same doctor who provided the initial care. This practice is more effective in outpatient visits. Since the present study was conducted exclusively with paediatricians working in emergency rooms, this may have introduced a bias to the study in the sense that the prescription of antibiotics under these circumstances may be greater.

Current guidelines recommend the “wait and see” strategy (watchful waiting) in an attempt to reduce the use of antibiotics. This attitude is supported by evidence on the safety of watchful waiting and delayed prescription of antibiotics to children. [29, 49-53] Furthermore, in a Cochrane review, Venekamp *et al.* [37] identified studies in which the majority of cases resolved spontaneously, with no complications. In several studies, only around one-third of children initially seen with AOM had to be given rescue antibiotics because their symptoms persisted or became worse, [30, 50, 52-55] suggesting that antibiotic use could be reduced by 65% in eligible children. Given the high incidence of AOM, this reduction could contribute substantially towards decreasing the adverse events associated with antibiotic use.

The “wait and see” strategy has been emphasized as the best option for these patients [52, 55] with parents/caregivers receiving a prescription for antibiotics at the consultation but being instructed to only begin treatment if the child’s condition fails to improve within 2-3 days or to initiate treatment at any moment if symptoms worsen. Nevertheless, this was not a subject of the present study due to the difficulty in implementing “wait-and-see” management in emergency rooms, a setting in which the physician seldom has the opportunity to see the patient again.

Even when antibiotics were prescribed, half the paediatricians in this study recommended that their patients

should be re-evaluated 3-5 days after the initial consultation. There is little scientific evidence on the impact of routine re-evaluation of children with a diagnosis of AOM. Therefore, re-evaluation should be at the physician’s discretion, taking into account the child’s age, the intensity of symptoms, recurrence, or a request by the parents/caregivers. [10] Ideally, after commencing treatment with antibiotics, all children should be assessed with regards to clinical response, which is another area in which there is room for improvement in the management of otitis in Brazil.

5. Conclusions

The results of the present study underline the importance of the correct management of AOM in childhood, the principal cause of outpatient antibiotic prescriptions in the United States. [29] Although the principal guidelines on the subject were first published more than ten years ago, the results of the present study show that paediatricians working in emergency rooms still need to be provided with more information on the fact that antibiotics should only be prescribed in cases of bilateral hyperaemia or otorrhoea. In addition, we believe that adoption of the “wait and see” strategy, even in emergency rooms, would be an important means of reducing the inadequate prescription of antibiotics in cases of AOM, thus contributing towards reducing bacterial resistance.

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Declaration of Conflicting Interests

The authors declare that there is no conflict of interest.

Authorship Attribution

Prof. Eduardo Fonseca Lima contributed to the concept and design of the study, analysis and interpretation of data. He drafted the article and revised it critically for important intellectual content he approved the final version to be published.

Prof. Patricia Bezerra contributed to the concept and design of the study, analysis and interpretation of data. She drafted the article and revised it critically for important intellectual content She approved the final version to be published.

Ms. Cazzetta contributed to the concept and design of the study, acquisition of data, analysis and interpretation of data. She drafted the article.

Ms. Cabral contributed to the concept and design of the study, acquisition of data, analysis and interpretation of data. She drafted the article.

Ms. Andrade contributed to the concept and design of the study, acquisition of data, analysis and interpretation of data.

She drafted the article.

Mr. Pedro Fonseca Lima collaborated on the final review and updating of bibliographic references

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