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Original Article

## Prevalence of Otitis Media in Children and Pattern of Antibiotic Prescription at a Tertiary Hospital in Makkah

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### ABSTRACT

**Background:** Otitis media (OM) is a common inflammatory disease of the middle ear and mostly affects children less than 5 years. It is divided into several disease subcategories: acute otitis media (AOM), recurrent AOM, OM with effusion (OME), and chronic otitis media (COM). This study aims to determine the otitis media and identify the manner of prescribing antibiotics used for the treatment of OM cases in children from 3 months to 5 years old in Hera General hospital in Makkah city.

**Methods:** The samples were retrospectively conducted at a tertiary General Hospital in the western region of Saudi Arabia. 113 records met the inclusion criteria for the study. Data were analyzed using descriptive statistics (percent and frequency). For quantitative data, the chi-square test and mean were used.

**Results:** The number of OM cases was higher in patients aged 3 years old and less among age categories. The percentage of males (54.6%) was higher than females (45.4%). Amoxicillin-clavulanate was the most used treatment of OM in the inpatient ward, outpatient, emergency, and after discharge. The protocol of treatment was mostly by prescribing both antibiotics and analgesics without requesting any further samples to investigate the type of pathogen related to this infection. Cases presented to the emergency department were discharged with an antibiotic prescription without further investigation of the records for previous infection or recurrence.

**Conclusions:** Due to increasing the antibiotics resistance alert around the globe, we believe that OM recurrence could be one of the community-acquired infections that affect the pediatric population and lower the quality of life and need specific attention from a physician who prescribes antibiotics for OM without further investigation.

**Keywords:** Otitis media; antibiotic prescription; treatment protocol; children; URTI, pattern.

### INTRODUCTION

Otitis media (OM) is a common inflammation of the middle ear and it is common in children less than five years. OM is an inflammation of the middle ear caused by viral or bacterial infection. It may sometimes occur after an acute upper respiratory tract infection (URTI). Among many populations, OM has been the most frequently diagnosed illness among children less than 5 years. OM may lead to a significant complication and it is the main reason for prescribing antibiotics in childhood ages from 3

months to 5 years which remains a significant burden for clinical practice.<sup>[1]</sup> OM is subdivided into subcategories of disease which are: acute otitis media (AOM), recurrent AOM, OM with effusion (OME), and chronic suppurative OM (CSOM). AOM appears with an earache, purulent discharge (otorrhea), and fever as general symptoms. Otitis media with effusion (OME) is when fluid in the middle ear accumulated without evidence of symptoms of the ear infection. The difference between OME and AOM is that AOM is when the middle ear fluid shows a rapid onset of one or more signs or symptoms of middle ear inflammation. To treat AOM with severe symptoms in children by prescribing antibiotics, which are the main treatment available and are advised to start immediately.<sup>[2]</sup> This approach is currently questionable as some studies suggested the use of analgesics with some anti-inflammatory medication to control OM and to perform susceptibility testing before choosing antibiotic treatment. The ear infection is one cause of OM and the antibiotic prescription should be based on the presence of the bacterial infection only.

The AOM infection of the ear could be bacterial or viral which are sometimes linked to nasopharyngeal and upper respiratory tract infections (URT). Viral infections can cause AOM as a complication of upper respiratory tract infection, but bacterial infection has been reported in almost 70-90% of AOM cases.<sup>[3,4]</sup> Many studies showed that various types of bacteria can cause an ear infection. The bacterial species that are most commonly associated with AOM are *Streptococcus pneumoniae* (*S.pneumonia*), *Haemophilus influenzae*, *Moraxella catarrhalis*, *Staphylococcus aureus*, and *Streptococcus pyogenes*.<sup>[1]</sup> *S. pneumonia* and non typable *Haemophilus influenzae* (NTHi) have been indicated as the leading causes of AOM. Nontypeable *Haemophilus influenzae* is found to be the most isolated pathogen from AOM in Saudi Arabia and elsewhere in the world.<sup>[5]</sup> The susceptibility in this age group is due to the lower angle of the Eustachian tube about the nasopharynx and other environmental factors such as the increase in the use of bottle feeding which is becoming increasingly popular in many countries. It is precisely in developing countries due to overcrowding with a poor social and economic background.

Antibiotics are one of the major developments in history to fight infectious diseases. Inappropriate use by individuals may rapidly develop the risk of antibiotic resistance, which often fails therapy for various infections including OM. Unsuitable use of antibiotics can also be associated with significant adverse events. The treatment regimens for AOM are varied due to the increased prevalence of resistant organisms.<sup>[6]</sup> The recommendation for treating AOM as first-line from Saudi pediatricians differs but the most prescribed antibiotics have a place with the  $\beta$ -lactam class. Recommendations for the management and diagnosis of children with AOM from the American Academy of Pediatrics Subcommittee on Management of Acute Otitis Media are: high-dose Amoxicillin (80–90 mg/ kg per day in 2 divided doses) is prescribed as the first-line treatment in most.<sup>[7]</sup> For uncomplicated AOM, the duration of treatment is 5-7 days. The first-line treatment of OM is using Amoxicillin and Augmentin is the choice as a second-line antibiotic if a child has antibiotic resistance. The antibiotic treatment also can be used as a combination of oral erythromycin and sulfonamides as another option if the patient has allergic to penicillin.<sup>[8]</sup> If a highly resistant pathogen such as *Streptococcus pneumonia* is the cause of the OM infection, the use of clindamycin or intramuscular ceftriaxone as third-line agents are advisable.<sup>[8]</sup> Many cases of AOM would not need antibiotics like children with non-severe symptoms or sometimes the middle ear exudate having discharge may drain via the Eustachian.<sup>[9]</sup>

The importance of identifying pathogen causing agent of AOM is to define the type of antibiotic that will be used to eradicate the infection.<sup>[6]</sup> *Streptococcus pneumoniae* isolates were gathered from laboratories of various hospitals in Saudi Arabia. In isolates from otitis media 55.4% were penicillin-resistant, and 44.6% were susceptible to penicillin.<sup>[6]</sup> OM with *S. pneumonia* is a major cause in Saudi Arabia and more than half of the cases have become more resistant to penicillin.<sup>[9]</sup>

The most clinically relevant symptom in patients with AOM is ear pain. Pain management is the first step in treatment.<sup>[10]</sup> It is recommended if the ear pain is related to the fever: The systemic administration analgesics (oral paracetamol or ibuprofen) at appropriate doses are the main and sufficient treatment to relieve pain. Local anesthetics systematically can be used with systemic analgesic therapy just in children older than three years old without perforation.<sup>[11]</sup> It is not recommended to use other treatments (decongestants, steroids, or antihistamines) except analgesics as adjunctive therapy in association with antibiotics for the treatment.<sup>[12]</sup>

Several AOM cases resolve spontaneously, which is advised against the universal antibiotic treatment of all children influenced by AOM. Several studies exhibited that watchful waiting appears to be able to reduce the requirement for a prescription antibiotic. Consequently, it reduces therapy and treatment costs, limits symptoms of treatment, and lowers the danger of new medication-resistant strains.<sup>[13]</sup>

On the other hand, the studies indicate that immediate pain-relieving analgesics have a significant impact in terms of duration of pain and intensity-dependent on systematic reviews.<sup>[14]</sup> The studies agree on the advantage of using immediate antibiotic treatment in a short duration on patients with AOM younger than 2 years of age and on those with a bilateral episode, spontaneous otorrhea, and in the case of spontaneous perforation.<sup>[15,16]</sup> For uncomplicated AOM, it is possible to wait watchfully with a parental agreement and all other cases and prescribe antibiotics only if the symptoms worsen or do not improve within 48-72 hours.<sup>[12]</sup> Children who show no improvement or get worse after 72 hours of using an appropriate antibiotic are considered a treatment failure. They should receive clavulanic acid, or cefpodoxime, or cefuroxime if not treated effectively with amoxicillin.<sup>[12]</sup>

If the AOM is known to be caused by a bacterial infection, then the choice of the optimal treatment decision should be based on the examination of the most frequent causative bacterial pathogens and their susceptibility to the most broadly used medications.<sup>[11]</sup> The duration of antimicrobial use may vary depending on the patients age and other factors.

This study aims to determine the otitis media and identify the manner of prescribing antibiotics used for the treatment of OM cases in children from 3 months to 5 years old in Hera General hospital in Makkah city.

## **MATERIALS AND METHODS**

Data were conducted retrospectively from Hera General Hospital (HGH) by attaining patient files throughout the period from 2013 to 2018. The data were grouped into three categories: (1) the emergency (ER) for patients aged from 3 months to 5 years old who visited the ER, (2) outpatient with otitis media (OM) alone or OM accompanied by upper respiratory tract infection (URTI). Data for this category also searched for the treatment protocols (antibiotics, analgesic with the treatment dose. (3) The third category was investigated from the inpatient files with OM cases, recurrent cases, and inpatient after discharge.

The screening process includes susceptibility testing for resistance and treatment protocol antibiotics for inpatients in addition to the pattern of prescribing other treatments for OM such as analgesics. Male and female patients that are less than five years who were admitted to an emergency room, inpatient and outpatient in Hera Hospital with URTI or OM in (HGH) patients filed were included in this study while those who had another condition were excluded. Ethical approval was granted by the Ethics Committee of the Ministry of Health in Makkah with the number: H-02-K-076-1812 dated 19/01/ 2019.

Data were analyzed using descriptive statistics (percent and frequency). For quantitative data, the t-test and mean and all graphs were produced by using the software Prism 8 GraphPad®.

## RESULTS

### 1. Prevalence of OM in Makkah reagon

#### 1.1 Differences in cases about age and gender

The percentage of females was (44.3%) while it was (55.8%) for males, which is slightly higher than the females' percentage. The number of cases admitted to the emergency department was higher regarding acute otitis media AOM cases for males more than females (Table 1). However, more females with AOM were recorded in the inpatient department. The records obtained from the patients' files documented different stages of OM: Acute OM, Chronic OM, OME, and one OM with ear perforation. The cases of COM were only 2 patients, ages 3 and 5 years old. One patient was documented as OM with ear perforation (age 1 year).

**Table 1:** The number of male and female children diagnosed with Otitis Media in Hera General Hospital from the period 2013-2018.

	Total cases of OM (n=113)	OM in Emergency				OM in inpatient			
		AOM	OM with ear perforation	OM with effusion	COM	AOM	OM with ear perforation	OM with effusion	COM
<b>Male</b>	63 (55.8%)	48 (76.2%)	0	3 (4.8%)	0	7(11.1%)	0	4 (6.3%)	1 (1.6%)
<b>Female</b>	50 (44.3%)	32 (64%)	1 (2%)	2 (4%)	1 (2%)	11 (2.2%)	0	3 (6%)	0
<b>Age group</b>									
<1	19	13 (68.4%)	0	0	0	6 (31.6%)	0	0	0
1	19	16 (84.2%)	1 (5.3%)	1(5.3%)	0	3 (15.8%)	0	1(5.3%)	0
2	19	10 (52.6%)	0	1 (5.2%)	0	6 (31.6%)	0	2 (10.5%)	0
3	23	17 (73.9%)	0	2 (8.7%)	1 (4.3%)	2 (8.7%)	0	1 (4.3%)	0
4	19	14 (73.7%)	0	1 (5.2%)	0	1 (5.2%)	0	3 (15.8%)	0
5	14	12 (85.7%)	0	0	0	1 (7.1%)	0	0	1 (7.1%)

Abbreviations: OM (otitis media); AOM (acute otitis media); COM (chronic otitis media)

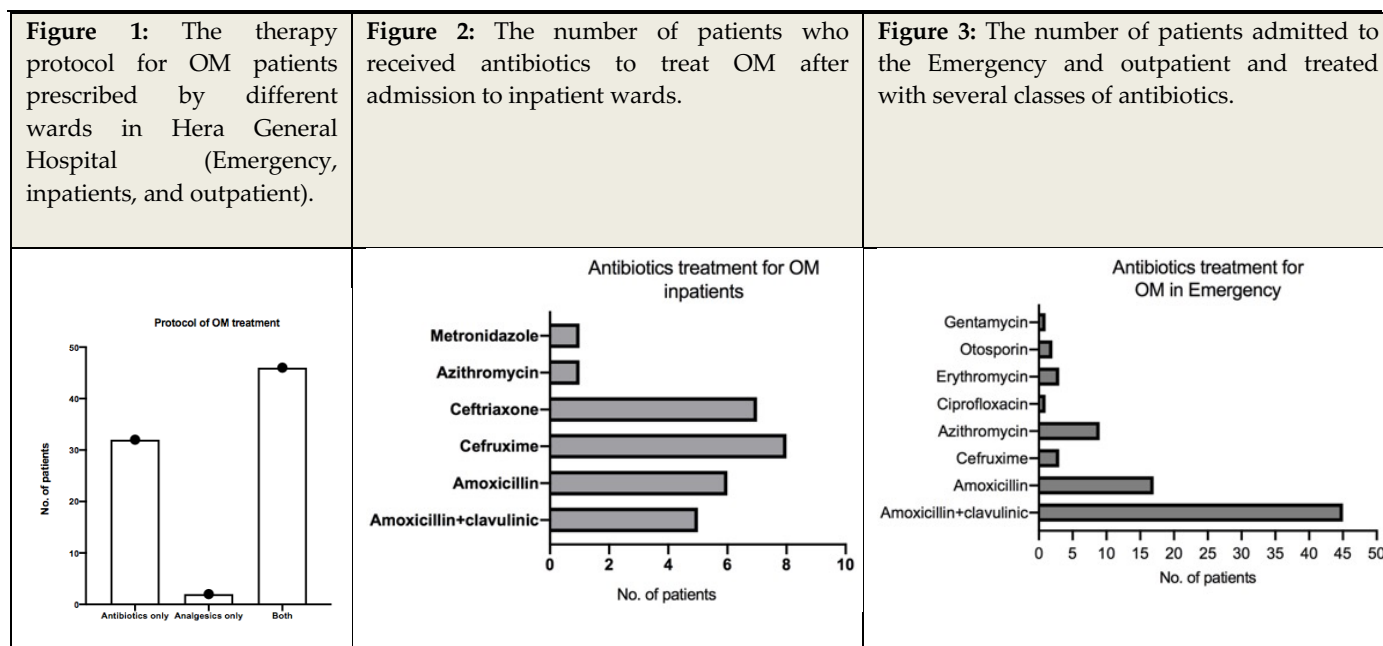
#### 1.2 Number of cases about the stage of OM

Our findings show different stages of OM: Acute OM, Chronic OM, OME, and OM with ear perforation. The recurrence of OM could be measured by observing the number of patients' admission several times from their records. This is maybe an indication of failure of the first-line antibiotic treatment and may show resistance to a specific class of antibiotics. This is difficult to assess in our study as we do not have any record in the patients' files admitted to the emergency room. It was also difficult to record the susceptibility testing and whether the pathogen was specifically susceptible or resistant to a specific antibiotic as it was not routine for emergency admission or outpatient in this hospital. Chronic cases of OM were not high in the current study. There were only two patients who had COM and one patient with OM had ear perforation. Most physicians recorded the diagnosis as OM without determining the stage of the OM condition. This made it difficult for the researcher to know the exact stage of OM and to determine whether it would be better for management to select the first line of treatment. No information

was found about the diagnostic tools used to diagnose cases of OM in inpatient, outpatient, and emergency profiles. This lack of information on diagnostic methods restrained this study as it is essential to select the best therapeutic management based on good diagnostic methods and the exact stage of OM.

## 2. The antibiotics prescription pattern

Requesting a susceptibility test is not applied to identify pathogens causing OM and to identify sensitivity/resistance to this pathogen in the microbiological diagnosis of all inpatients similar to the emergency cases in our study. This finding made it irrational to assess the antibiotic resistance, recurrence, and chronicity of OM in Makkah. This was another limitation in the current study which we could not able to confirm which bacterial pathogen is the major for OM infection for children in Makkah. Some physicians were only prescribing antibiotics and only two cases had prescribed analgesics. Most of the cases (40.7%) were treated with both antibiotics and analgesics as a protocol for therapy (figure 1). The patient with OM is divided into three groups: inpatient and treatment after discharge, emergency, and outpatient. The antibiotics prescribed to the inpatient were amoxicillin-clavulanate followed by ceftriaxone, amoxicillin, and others (figure 2). The result is statistically insignificant as the p-value was 0.240 for the two factors; age and antibiotics prescribed at inpatient wards. After discharge from the inpatient or emergency department, the most antibiotic used was also amoxicillin-clavulanate followed by amoxicillin, cefuroxime, and others (figure 3).



The result was statistically insignificant as the p-value was 0.498 for the two factors: age and antibiotics prescribed after the discharge of the patient or in an emergency. Most physicians prescribed analgesics with antibiotics as a protocol of therapy to treat the infection and symptoms. The Antibiotic prescribed at inpatient was Amoxicillin-clavulanate or ceftriaxone then amoxicillin. After discharge of the patient or in the Emergency department, amoxicillin-clavulanate or amoxicillin then cefuroxime respectively were the most prescribed antibiotics for OM.

## DISCUSSION

OM is widespread in children, especially in males which is corresponding to previous studies. In the current study, the percentage of AOM was high at the age of 3 years, which corresponded to a previous study that shows 10% of children will have almost an episode of AOM at the age of 3 months and 3 years old.<sup>[17]</sup> Another study shows similar results in the USA and worldwide.<sup>[18]</sup> The OM affected all ages, the *p*-value was 0.306 for age and diagnosis was statistically insignificant (table 1). In general, OM affected all ages, but the highest percentage was (84.2%) in patients with 3 years old. Previous studies aimed to determine the epidemiology of acute otitis media (AOM) showed that the risk increased with males more than with females.<sup>[5,16]</sup> They also found that OM was common in children less than 5 years old. Most of the age groups infected by OM were patients aged 3 years or less, and the mean was 2.9 years, which is within the less than 5 years old age group. The result of the current study shows that there is no association between age and the prescribed antibiotics. This is in contrast to the previous study, which documented the occurrence of acute otitis media peaks in younger children, from six to eight respiratory infections per year, and dropping after the age of 2 to 3 years.<sup>[23]</sup>

Recurrent cases of AOM were not documented in patients profiles as the emergency cases were produced for each case without linking to the patient file then cases were treated without any connection to previous episodes. The investigators in the current study considered that all OM records were acute otitis media unless the patient was admitted several times with OM. The diagnosis of OM with multiple episodes is deliberated as a recurrence. However, four cases of recurrence were found, and more than one episode of OM was registered for ages less than 5 years in the inpatient data.

The effect of recurrent AOM (rAOM) in children is between 10% to 20% among most cases of AOM.<sup>[19,20]</sup> Recurrent AOM resulted from resistance to bacteria that colonized the middle ear causing treatment failure and disease recurrence.<sup>[13]</sup> Previous studies showed that pneumatic otoscopy remains the standard technique of examination in a patient who may have OM.<sup>[21]</sup> In the present study, there were no documented data in detail regarding the clinical diagnosis of OM which results from the lack of determination of OM stages of infection and thus selecting better management.

A previous study showed that the most common antibiotic dispensed in the same case is amoxicillin/clavulanate.<sup>[9]</sup> In the current study, most cases have some information was absent such as antibiotics prescribed to treat OM and OM subcategories, the route of administration, the dose of the drug, duration, and frequency. Amoxicillin–clavulanate has been afforded to treat AOM in children for 10 days and it has a measurable short-term benefit.<sup>[22]</sup> Alternative treatments such as cefuroxime and ceftriaxone are used in children with a penicillin allergy.

Some studies have revealed that acute otitis media resolves without the therapy of antibiotics.<sup>[20]</sup> The American Academy of Pediatrics established guidelines for acute otitis media treatment.<sup>[24]</sup> The guideline shows observations for patients older than the age of 6 months who defer antibiotic treatment for 2 days to 3 days. Conversely, the use of immediate antibiotics in children up to 35 months was the most effective.<sup>[22,24]</sup> The initiation of immediate antibiotics is recommended in children up to 2 years of age with bilateral acute otitis media.<sup>[25]</sup> The first-line treatment for AOM varies, but the most frequently prescribed antibiotics belong to the  $\beta$ -lactam class.<sup>[26]</sup>

The importance of identifying the pathogen-causing agent of AOM is to select the type of antibiotic that should be used to eradicate the infection and to avoid unnecessary antibiotic prescriptions. During the preparation of this study, a similar study published by Addas *et al.* (2019) stated that the most common causative pathogen for ear infections were *P. aeruginosa*, *S. aureus*, and yeast.<sup>[27]</sup> The study conducted a retrospective analysis of the ear infection including adults and children from the period 2010 to 2016 from medical records of patients admitted to inpatients and outpatients at King Abdulaziz University

hospital.<sup>[27]</sup> The inclusion and exclusion criteria of the study involve a different population than our study, therefore, it is expected to find different causative pathogens. These factors need more investigation to involve multi-center health institutions and include a comparison between these different population.

## CONCLUSION

In conclusion, this study shows that OM cases are higher in male compared to female children. AOM was the most reported case of OM which affects children of 3 years of age and less. Most physicians have prescribed analgesics with antibiotics as a protocol of therapy to treat the infection and symptoms. However, this treatment protocol is subject to the effect of some factors that may contribute to developing more occurrences of OM infections in the Makkah region. One of these factors may increase the resistant pathogens for upper respiratory tract infection which this retrospective study was not able to achieve. Amoxicillin-clavulanate has been prescribed as the first line of antibiotic therapy either in inpatients or emergency cases. The accurate diagnosis of OM is as important as much as the treatment prescribed. This study provides us with better knowledge about the pattern of OM in children and the manner of prescribing antibiotics and treatment of OM in the city of Makkah, Saudi Arabia.

## Conflict of Interest

The author declares that there are no conflicts of interest relevant to this article.

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