

Clinical Efficacy of Azithromycin versus Co-amoxiclave in Acute Otitis Media

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Abstract

Acute otitis media (AOM) is one of the most common diseases in infancy and early childhood, resulting in parents frequently seeking medical assistance for their child. Antibiotics are often prescribed. Decongestants and antihistamines have commonly been recommended by clinicians with the aim of targeting the middle ear effusion that develops in AOM. The first line antibiotic treatment, if warranted, is amoxicillin. If the bacteria is resistant, then amoxicillin-clavulanate or another penicillin derivative plus beta lactamase inhibitor is second line. Five days of treatment has been found to be as effective as ten days in otherwise healthy children. Co-amoxiclave has been found to have more clinical efficacy as compared to azithromycin.

Key words : Acute Otitis Media (AOM), Azithromycin, clinical efficacy, Co-amoxiclave,

INTRODUCTION

Otitis media is inflammation in the middle ear. Subcategories include acute otitis media, otitis media with effusion (also known as “glue ear”), recurrent acute otitis media, and chronic suppurative otitis media. Acute otitis media presents with systemic and local signs and has a rapid onset. The persistence of an effusion beyond three months without signs of infection defines otitis media with effusion, whereas chronic suppurative otitis media is characterized by continuing inflammation in the middle ear giving rise to otorrhoea and a perforated tympanic membrane [1].

Earache in children with upper respiratory tract infection is indicative of acute otitis media, but the absence of earache does not preclude acute otitis media. Therefore, even in the absence of any signs and symptoms localized to the ear, all children at risk for acute otitis media should be examined during upper respiratory tract infection, and if respiratory symptoms persist for several days after the initial visit, a reexamination should be performed. Restless sleeping and fever are of no value in distinguishing acute otitis media from an uncomplicated upper respiratory tract infection.[2]

The symptom with the strongest association with acute otitis media was earache but

sore throat night restlessness and fever also had significant associations.[3]

Antimicrobial drugs have a modest but significant impact on the primary control of acute otitis media. Treatment with β -lactamase-stable agents does not increase resolution of acute symptoms or middle ear effusion; initial therapy should be guided by considerations of safety, tolerability, and affordability, and not by the theoretical advantage of an extended antibacterial spectrum.[4]

In comparison with the original formulation of Augmentin® administered tid for 10 days in the treatment of AOM in children, the new formulation of amoxicillin/clavulanate potassium oral suspension administered bid for 10 days provides at least equivalent efficacy and causes substantially less diarrhea. Administration for 5 days appears not to provide equivalent efficacy, but the difference appears limited to younger children and the margin of difference is small.[5]

On the basis of bacteriologic outcomes it was found that high dose amoxicillin/clavulanate (90/6.4 mg/kg/day) was highly efficacious in children with AOM, including those most likely to fail treatment, namely children <24 months of age and those with infections caused by

penicillin resistant *Streptococcus pneumoniae* (PRSP).[6]

High dose (70 to 90 mg/kg/day) amoxicillin is recommended as first line therapy of acute otitis media (AOM) in geographic areas where drug-resistant *Streptococcus pneumoniae* is prevalent. Information on the bacteriologic efficacy of high dose amoxicillin treatment for AOM is limited. The predominant pathogens isolated from children with AOM failing high dose amoxicillin therapy were beta-lactamase-producing organisms. Because its overall clinical efficacy is good, high dose amoxicillin is still an appropriate choice as first line empiric therapy for AOM, followed by a beta-lactamase-stable drug in the event of failure.[7]

Amoxicillin/clavulanate was significantly more likely to eradicate all bacterial pathogens and *Haemophilus influenzae* from middle ear fluid than was azithromycin. Amoxicillin/clavulanate was also more likely to eradicate *Streptococcus pneumoniae*, but the difference was not statistically significant. On Days 12 to 14, signs and symptoms were more likely to resolve completely or improve in all culture-positive patients and in those with *H. influenzae* infections who received amoxicillin/clavulanate compared with those who received azithromycin. Otherwise there were no significant differences between groups in clinical outcomes on Days 12 to 14 or at follow-up. Amoxicillin/clavulanate has superior bacteriologic and clinical efficacy compared with azithromycin in children with AOM.[8]

Azithromycin was significantly better tolerated and caused fewer treatment-related adverse events (7.2%) than amoxicillin/clavulanate (17.1%). In response to the interview and questionnaire, parents of children treated with azithromycin noted less need for special arrangements to give medication. Children liked the taste of azithromycin (89.2%) and did not have to be forced to take the medication (2.4%).

Parents of children receiving amoxicillin/clavulanate noted that 61.8% liked the medication and 19.4% of children had to be forced to take it. This study demonstrated that azithromycin was comparable to amoxicillin/clavulanate in achieving satisfactory clinical response rates in children with acute otitis media attending day care or school. Azithromycin was significantly better tolerated than amoxicillin/clavulanate. Parents considered azithromycin to be significantly more convenient to administer and more acceptable to children.[9]

A total of 389 children with typical signs and symptoms of acute otitis media were randomized to treatment with either azithromycin or co-amoxiclav. The dosage schedule for azithromycin was 10 mg/kg/day, in a single daily dose, administered for three days. Co-amoxiclav was given at a dose of 13.3 mg/kg (amoxicillin equivalent) tid for ten days. Patients were evaluated 4–6 days and 12–16 days after the start of therapy. A satisfactory clinical response was reported for 93.2% of the 192 evaluable azithromycin-treated patients (144 cured, 35 improved), and for 97.3% of the 189 evaluable co-amoxiclav-treated patients (148 cured, 36 improved). Six (3.0%) relapses occurred in the azithromycin group, and four (21%) in the co-amoxiclav treatment group, respectively. Side-effects were recorded in a significantly fewer number of the azithromycin patients compared with the co-amoxiclav patients. Adverse events were mainly gastrointestinal in nature, with diarrhoea the most frequent complaint (32 cases with co-amoxiclav; five with azithromycin). One patient from each group discontinued therapy because of treatment-related adverse events. It was concluded that three-day, single-dose azithromycin and ten-day tid co-amoxiclav therapy have comparable clinical efficacy in paediatric patients with acute otitis media; however,

there was a lower incidence of side effects in the azithromycin group.[10]

In children with acute otitis media, azithromycin given once daily for 5 days and amoxicillin/clavulanate given three times daily for 10 days had similar efficacy; however, azithromycin was significantly better tolerated.[11]

MATERIALS AND METHODS

Retrospective study was carried on acute otitis media out patients. To carry out the study, Sir Ganga Ram hospital, Lahore was targeted. The hospital has a separate ENT department. The study was designed with an aim to learn about the most commonly used medications for the treatment of Acute Otitis Media, And to study the clinical efficacy of amoxicillin vs azithromycin. The study included direct interaction with 25 patients of either sex belonging to any age group suffering from acute otitis media. The patients were evaluated on the basis of questionnaire. Different parameters on sociodemographic basis including age, gender, socio-economic status , clinical signs and symptoms, family history of acute otitis media, tobacco smoke exposure, recurrent attacks of acute otitis media and

most commonly prescribed medicines were documented.

RESULTS

The study was carried out on 25 out patients of Ganga Ram Hospital, Lahore. A well designed Performa was made to collect the data and then it was evaluated.

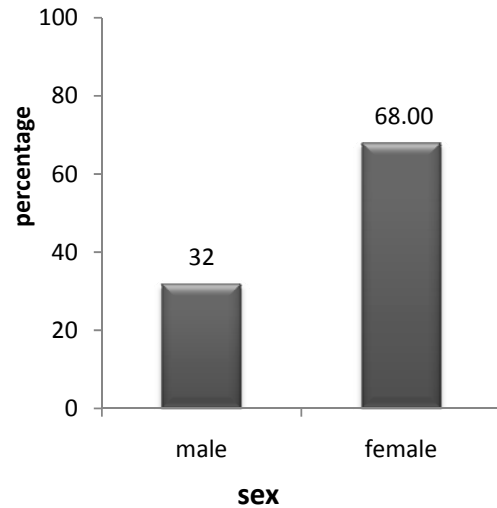


Figure 1: Gender group (n=25) Percentage of females suffering from acute otitis media was more.

Figure 2 shows that mostly patients belonged to age group 20-30 years.

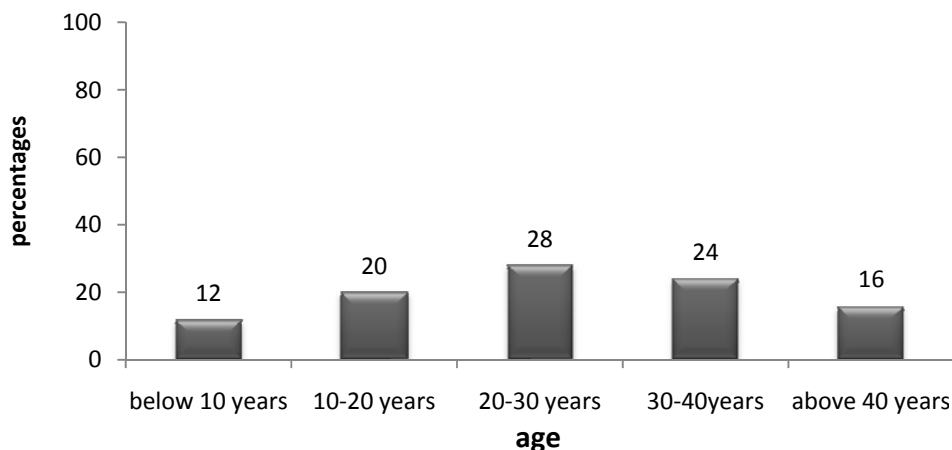


Figure 2: Ager group (n=25)

Figure 3 depicts that most of the patients had a poor social back-ground.

Figure 4 shows which ear of the patients was involved in the disease.

Figure 5 88% of patients were suffering from ear ache

56% patients were suffering from fever/cough in conjunction with acute otitis media .There was temporary hearing loss in 72% of patients. There was drainage of pus from the ears of 80% patients.

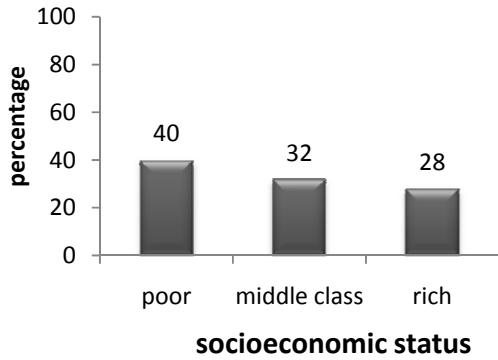


Figure 3: Socio-economic status (n=25)

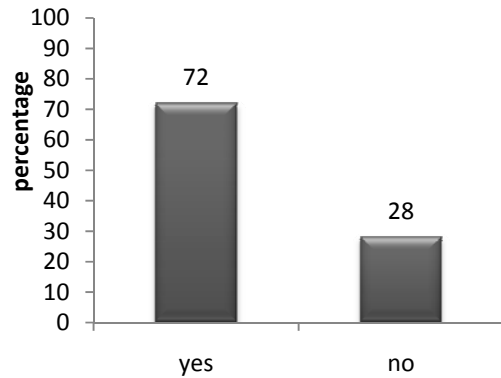


Figure 6: Temporary hearing loss (n=25)

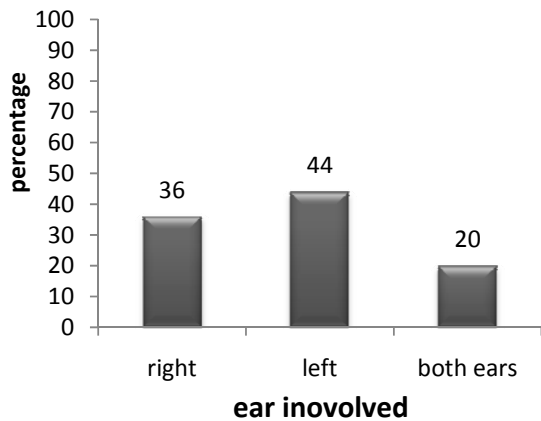


Figure 4: Ear involved (n=25)

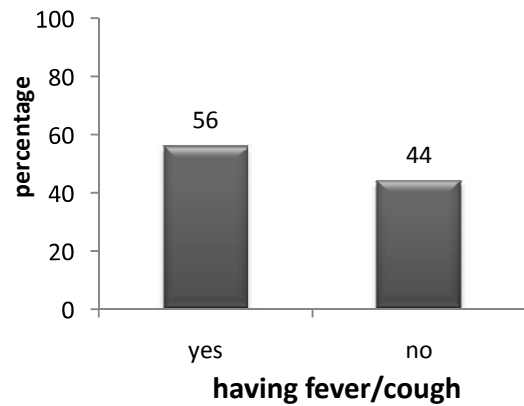


Figure 7: Fever/cough (n=25)

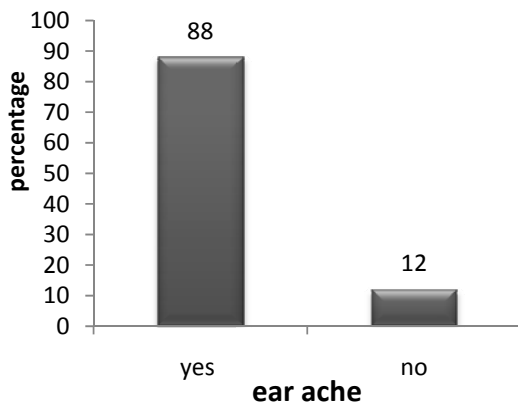


Figure 5: Ear ache (n=25)

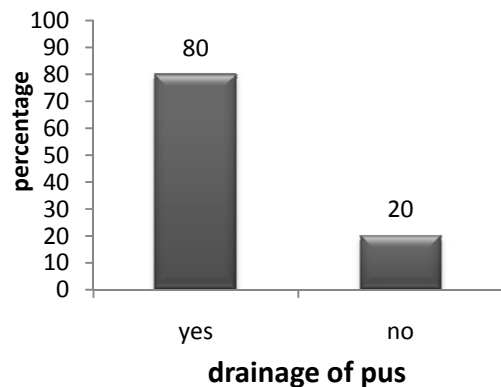


Figure 8 : Drainage of pus (n=25)

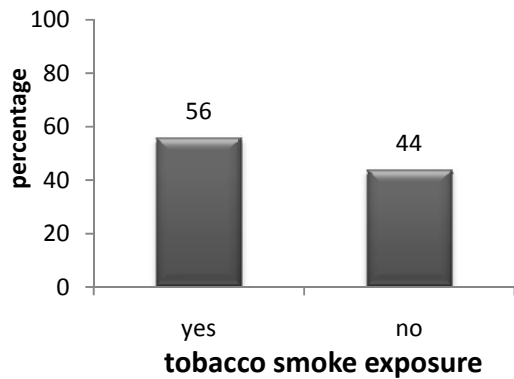


Figure 9: Tobacco smoke exposure (n=25)

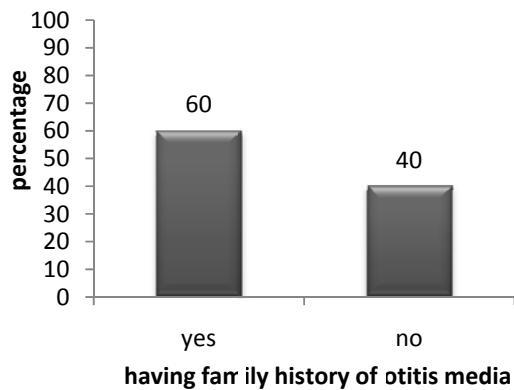


Figure 10: Family history of AOM (n=25)
The patients who were exposed to tobacco smoke exposure were more at risk of developing AOM. 60% patients were with family history acute otitis media. There were recurrent attacks of AOM in majority of patients.

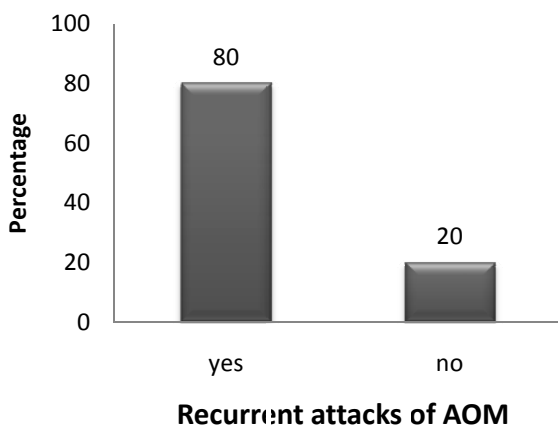


Figure 11: Recurrent attacks of AOM (n=25)

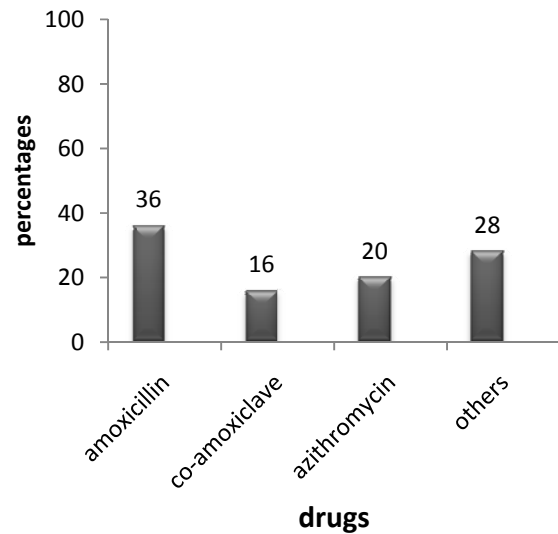


Figure 12: Drugs used in treatment of acute otitis media (n=25)
Amoxicillin was the most commonly prescribed antibiotic in acute otitis media.

DISCUSSION

Otitis media is a bacterial or viral infection of the middle ear. Middle ear infections often occurs as a complication of a cold, allergies, nose and throat infection, or enlarged adenoids. Middle ear infections usually clear up without complication or long-term effects. Infection is caused when bacteria and/or viruses enter the Eustachian tube from the nose or throat and become trapped in the middle ear, producing inflammation, collection of pus, and pressure. This results in pain and, since it keeps the eardrum from vibrating freely, diminished hearing. Infection usually occurs when the Eustachian tube is not functioning properly, often as a result of inflammation and swelling caused by a cold or allergy attack. Bacteria are responsible for about 90-95% of cases of otitis media. The most common bacterial offenders are *Streptococcus pneumoniae*, *Haemophilus influenzae* and *Moraxella catarrhalis*.

The most prominent symptom of acute otitis media is earache, often found together with the following signs and symptoms: Runny or stuffy nose, cough, fever, drainage of pus from the ear, temporary

hearing loss, dizziness, fussiness, irritability and difficulty sleeping in infants and younger children. Factors that increase the risk for acute otitis media include: Multiple upper respiratory infections, certain medical conditions e.g cleft palate, Down's syndrome, allergies.

A physician can diagnose acute otitis media by careful examination of the ear with an otoscope, looking for redness and fluid or pus behind the eardrum and seeing how well the eardrum moves in response to air pressure. Physicians have several tests they can perform to help them determine the severity of the problem and decide on a course of treatment: An audiogram determines hearing acuity by sounding tones at various pitch levels. Hearing is usually diminished in infected ears. Acoustic reflectometry determines the presence of fluid in the middle ear by measuring how sound waves are reflected off the eardrum. Tympanometry also utilizes sound waves to measure eardrum position and stiffness as well as the presence of fluid in the middle ear.

Treatment of otitis media is the most frequent reason for administering antibiotics. The major problems encountered in the antibiotic therapy of acute otitis media (AOM) are the tremendous increase in the resistance to antibiotics of its main pathogens and the lack of tight criteria in the selection of the appropriate antibiotic drugs for the treatment of this disease. Amoxicillin remains the antibiotic of choice for initial empiric treatment of AOM, although the traditional dosage should be increased in patients at risk for drug-resistant *S. pneumoniae*. 5 days of short-acting antibiotic use is effective treatment for uncomplicated acute otitis media.

Most of the affected patients were females. And the most commonly affected age group was 20-30 years. About 40% of people belonged to the poor family background showing that poor sanitary conditions are a risk factor for the development of acute otitis media. 44% patients had their left ear

affected, 36% right ear and 20% their both ears affected by the disease. Among the all patients, 88% complained about the ear-ache. 72% said that they suffer from a temporary hearing loss. 56% said that they also have fever or cough. Majority of the patients about 80% had complains of drainage of pus from the affected ear. 56% patients upon asking said that they were being exposed to tobacco smoke exposure either by smoking themselves or by a family member. Tobacco smoke exposure is considered a risk factor for the occurrence of AOM. About 60% of the patients had a family history of AOM which is also a risk factor for the patients. Apart from family history, one major risk factor is allergy which may lead to AOM. 80% of the patients suffered from the recurrent attacks of AOM which is a common complain of the concerned disease. Sometimes AOM is seen more often in the cold season due to the frequent upper respiratory tract infections. The upper respiratory tract infections like common cold worsen the disease condition.

CONCLUSION

From the results it was concluded that AOM is a very common disease condition in young adults. It was more commonly present in females as compared to males. As poverty brings so much other problems AOM also prevails in such population. The common complains include severe ear ache, temporary hearing loss, drainage of pus and fever. And the most important risk factors are tobacco smoke exposure, cold weather and allergy. AOM usually runs in the families and it may be recurrent. Adverse events were mainly gastrointestinal in nature, with diarrhea the most frequent complaint. It was concluded that three-day, single-dose azithromycin and ten-day tid co-amoxiclav therapy have comparable clinical efficacy in patients with acute otitis media; however, there was a lower incidence of side effects in the

azithromycin group. In children with acute otitis media, azithromycin was given once daily for 5 days and azithromycin was significantly better tolerated. Amoxicillin/clavulanate given three times daily for 10 days had similar efficacy; however, azithromycin was significantly better tolerated.

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