

The Effect of Amoxicillin-Clavulanate and Actifed Versus Actifed Only in treatment of Otitis Media with Effusion

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J Fac Med Baghdad
Vol. 50, No. 3, 2008
Received: Feb 2008
Accepted: July 2008

Summary:

Background: Otitis media with effusion(OME)is a common cause of deafness in children with subsequent impairment of speech development and scholastic difficulties.Treatment remains controversial.

Aim: To study the effect of amoxicillin-clavulanate in treatment of OME

Patients and methods: A prospective study of a target sample consisting of sixty children under the age of 12 years presented with chief complaints duration for at least 6 weeks and on examination there were bilateral red and retracted tympanic membranes without oversized adenoids and no underlying causes require surgical correction e.g cleft palate.The patients were divided into two groups;group A which received Actifed for 4 weeks and group B which received Actifed +Amoxicillin-clavulanate for 4 weeks treatment course.After complete history and otolaryngological examination,all the patients were sent to x-ray of postnasal space(to exclude oversized adenoids),audiometry and tympanometry.Assessment was repeated at the end of 2 and 4 weeks of treatment course including audiometry and tympanometry.The response to treatment in group B was compared to that in group A at the end of 4 weeks treatment course.In this study,we referred to improvement in otoscopic findings and tympanometry results to show the response to 4 weeks treatment course.

Results: Eight patients(25.81%)in group A have shown response to treatment at the end of 4 weeks treatment course,while the response in group B was seen in 15 patients(51.72%).

Conclusion: Amoxicillin-clavulanate has statistically significant effect in treatment of otitis media with effusion(OME)in short term follow-up and the clearance of middle ear efussion in response to amoxicillin-clavulanate indicates that bacterial infection may play a role in the aetiology of OME.

Keywords: Otitis media with effusion,Amoxicillin-clavulanate,Tympanometry.

Introduction :

Otitis media with effusion(OME)is characterized by an accumulation of fluid in the middle ear,in the absence of acute inflammation.⁽¹⁾OME is the most common cause of aquired hearing loss in childhood and may negatively affect language development.^(2,3)The reason why the condition develop is uncertain,but a low-grade infection,poor Eustachian tube function,and adenoidal infection or hypertrophy have all been implicated.⁽⁴⁾The prevalence of recurrent OME may be increasing.⁽⁵⁾Positive bacterial cultures have been demonstrated in up to 50% of middle ear effusions,bacteria found are similar to those cultured in cases of acute suppurative otitis media.⁽⁶⁾The surface endotoxin of *Haemophilus influenzae* may be responsible for the induction of OME.⁽⁷⁾Stenfor and Raisanen have shown positive middle ear cultures for *Haemophilus influenzae*,*Streptococcus pneumoniae* and *Moxarella catarrhalis* in 30% of cases.⁽⁸⁾

Studies have shown a relationship between viral infection and the incidence of OME.⁽⁹⁾The newer models describe the primary event as inflammation of the middle ear mucosa caused by a reaction to bacteria already present in the middle ear.⁽¹⁰⁾Bluestone and others have shown that reflux up the Eustachian tube is demonstrable in children prone to otitis media.⁽¹¹⁾Crapko et al demonstrated the presence of pepsin in the middle ear space of 60% of children with OME.⁽¹²⁾Yilmas et al documented significant changes in oxidative stress in patients with OME.⁽¹³⁾

Patients and methods

This is a prospective study of 60 patients under the age of 12 years attending the outpatient clinic,department of otolaryngology at Al-yarmuk Teaching Hospital during the period from February 2007 to March 2008 complaining of hearing impairment,speech delay and learning difficulties for at least 6 weeks duration.Complete history including:age,sex,chief complaint and its duration,nasal obstruction,snoring,rhinorrhoea and history of recent upper respiratory tract infection

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was taken. Complete otolaryngological examination was done. All the patients were sent to X-ray of postnasal space. Patients with oversized adenoids and those with underlying causes require surgical correction like cleft palate were excluded from the study. Tympanograms were done for all patients, pure tone audiograms were performed for children aged 4 years and over; those under 4 years were assessed by free field test to confirm the presence of deafness. All the patients were diagnosed as bilateral OME.

The patients were divided into two groups: group A consisting of 31 patients received Actifed syrup (pseudoephedrine-HCl 30mg, triprolidine-HCl 1.25 mg/5ml), 5ml t.d.s. for children under 6 years and 7.5ml t.d.s. for children 6-12 years for 4 weeks, and group B consisting of 29 patients received Actifed syrup (same previous doses) + Amoxicillin-clavulanate syrup (250/62 mg/5ml), 2.5ml t.d.s. for children under 6 years and 5ml t.d.s. for children 6-12 years for 4 weeks. All the patients were re-examined clinically and by audiometry and tympanometry at 2 and 4 weeks of treatment course.

In this study, we referred to otoscopic findings and tympanometry results before and after the completion of 4 weeks treatment course in both groups to demonstrate whether the patients were responded to treatment or not. Improvement in otoscopic findings and change in tympanograms from flat type B before treatment course to type A after 4 weeks treatment course indicate that the patients were responded to treatment. The response in group B were compared to that in group A and statistical study were done to show whether amoxicillin-clavulanate is effective in treatment of OME or not.

Results

Pretherapy assessment

All the patients included in this study were under 12 years, 63.3% of patients were between 3-6 years. Thirty four patients were male and 26 patients were female with male to female ratio 1.3:1.

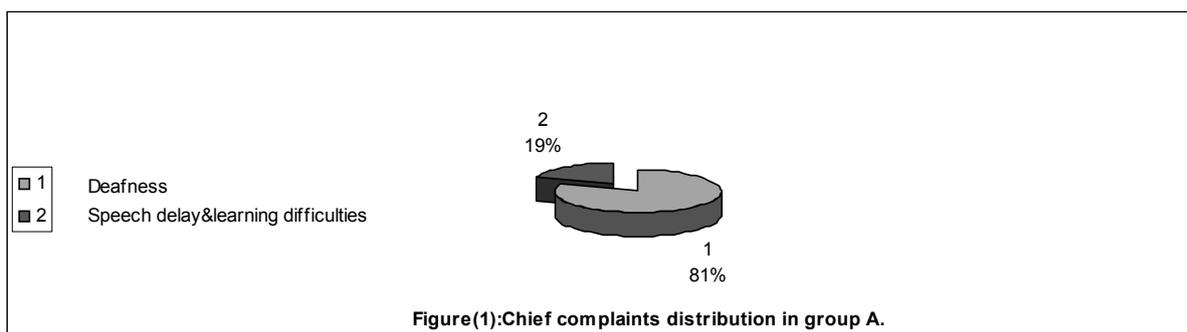
Deafness was the most common chief complaint in both groups. Fig.(1) and Fig.(2) show the chief complaints distribution in group A and group B respectively.

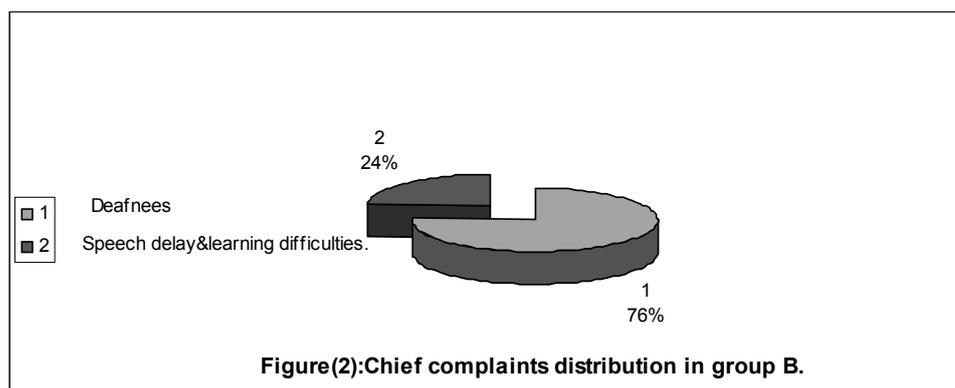
Otoscopic examination had shown bilateral red and retracted tympanic membranes in 100% of patients. Table(1) shows pretherapy otoscopic findings.

Pure tone audiometry was done for all children 4 years & over (21 children in group A, and 23 children in group B), the remaining patients less than 4 years were subjected to free field test. Table(2) shows pretherapy pure tone audiometric results in patients 4 years & over.

Post-therapy assessment

In this study, there was gradual improvement in the presenting chief complaints, otoscopic findings, audiometric and tympanometric results during the treatment course. We referred to otoscopic findings and tympanograms to assess patient's response to treatment course. At 2 weeks of treatment course, the improvement was seen in 3 patients (9.68%) in group A and in 6 patients (20.69%) in group B. At the end of 4 weeks treatment course, the response was seen in 8 patients (25.81%) in group A, while 15 patients (51.72%) in group B had been improved.





Table(1):Pretherapy otoscopic findings.

Otosopic findings	Number of patients(groupA)	Side affected	Number of patients(groupB)	Side affected	%
Red&retracted tympanic membrane	31	Bilateral	29	Bilateral	100
Air bubbles	0	—	2	Bilateral	3.6
Hair sign	1	Right ear	0	—	1.8

Table(2):Pretherapy pure tone audiometric results in patients 4 years&over.

Air-bone gap	Number of patients(groupA)	Percentage	Number of patients(groupB)	Percentage
20-25dB	10	47.6%	9	39.1%
25-30dB	8	38.1%	10	43.5%
30-35dB	3	14.3%	4	17.4%
Total	21	100%	23	100%

All the sixty patients (100%)had shown flat type B tympanograms.

Discussion

In this study, the most common age group seen was between 3-6 years (63.3%). Zielhuis et al.,⁽¹⁴⁾ have shown two points of peak prevalence of OME, initially at about two years when approximately 20% of children are affected, and later at five years of age.

The most common presentation of OME is hearing loss.⁽¹⁵⁾ In this study, hearing impairment was the most common presenting chief complaint (81% in group A, and 76% in group B).

Repeated otoscopic examinations and serial tympanometry were used in this study to confirm improvement in effusions in response to treatment. Most studies now rely on tympanometry and, in some, this is supplemented by otoscopy to diagnose OME.⁽¹⁵⁾ Zielhuis et al.,⁽¹⁶⁾ used serial tympanometry to demonstrate improvement in effusions.

In the current study, 25.81% of patients in group A had shown resolution of effusions at the end of 4 weeks treatment course, while resolution was seen in 51.72% of patients in group B. By comparison of response to treatment in group B to that in group A, a conclusion that Amoxicillin-clavulanate which was used to treat patients in group B is statistically has significant effect in treatment of OME ($0.05 < P < 0.02$). Antibiotics produce short-term improvement of OME, but do not affect the long-term course.⁽¹⁷⁾

Thomsen et al.,⁽¹⁸⁾ in their study of children with OME, were prescribed Amoxicillin-clavulanate for a month, they found that there was resolution of effusions in 61% of cases. Chan et al.,⁽¹⁹⁾ mentioned that there was a favourable result following treatment for 10 days with Amoxicillin-clavulanate. Mandel et al.,⁽²⁰⁾ in their study of Amoxicillin in combination with decongestant and antihistamine have shown twice the resolution in the treatment group than with placebo to a 4 weeks end point. Mandel et al.,⁽²¹⁾ noted a slight benefit following Amoxicillin for 2 weeks and no benefit from Erythromycin-sulfisoxazole and Cefaclor.

Rosenfeld and Post,⁽²²⁾ have presented a meta-analysis that combined ten independent for a pooled analysis of 1325 children, ages 12 years and under, who were randomized in controlled trials of antimicrobial treatment and placebo for OME. Children treated for 10-30 days with antimicrobial therapy were two to four times more likely to have complete resolution of refractory OME than were control patients.

Because OME demonstrates viable pathogenic bacteria, treatment with appropriate antibiotics is reasonable, studies of erythromycin, sulfisoxazole, amoxicillin, amoxicillin-clavulanate, and trimethoprim-sulfamethoxazole have demonstrated clearance rates faster than those of a placebo.⁽¹⁰⁾

Thomas et al., in their study of children with hearing loss associated with OME, found that oral or topical

steroid in combination with antibiotic resulted in quicker resolution of OME in the short-term, and there was no evidence of long-term benefit.⁽²³⁾

In the current study, the response in group A which received Actifed only was seen in (25.81%), this response could be attributed to Actifed and/or spontaneous resolution. Fraser,⁽²⁴⁾ in their study found that there was no statistically significant improvement following treatment of OME with sympathomimetic amine mixture. Cantekin et al.,⁽²⁵⁾ in their study of 553 children with OME, treated by antihistamine/decongestant or placebo, found that clearance rates of the effusion did not differ.

Conclusion

Amoxicillin-clavulanate is statistically useful drug in treatment of OME in short term follow-up. Further studies are recommended to evaluate the long term effect of Amoxicillin-clavulanate in treatment of OME. The significant effect of amoxicillin-clavulanate in treatment of OME indicates that bacterial infection may play a role in the aetiology of OME.

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