

Case Reports: Otitis media Treatment with Sulbactomax

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Running Title: Treatment of Otitis Media with Ceftriaxone + Sulbactum + EDTA
(Ethylene - diamine tetra acetic acid)

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Summary

Acute otitis media (AOM) is most commonly a disease of childhood. Chronic suppurative otitis media is also a common infection found in developed as well as developing countries. It is difficult to accurately diagnose the disease hence there is a huge opportunity for irrational use of antibiotics hence antibiotic resistance to these disease becomes vulnerable to treat. Here we present two successful case reports following treatment of acute otitis media and suppurative otitis media with sulbactomax which is a combination of Ceftriaxone+Sulbactum+EDTA . This new combination of drug holds promising future for the treatment of infectious disease like otitis media.

Key words: Sulbactomax-(Ceftriaxone+Sulbactum+EDTA), Acute otitis media (AOM),Resistance, Chronic suppurative otitis media, Infection

Introduction

Otitis media is the generic term for middle ear inflammation which can exist in an acute and chronic state and can occur with or without symptoms 1. Otitis media is an infection or inflammation of the middle ear which is one of the most common infection in children usually a benign self limited disease, it may however progress to potentially life threatening conditions. Acute otitis media (AOM) is defined

as the presence of inflammation in the middle ear accompanied by the rapid onset of signs and symptoms of an ear infection 2. Chronic suppurative otitis media (CSOM) is the result of an initial episode of acute otitis media and is characterized by a persistent discharge from the middle ear through a tympanic perforation 3. The drugs used in the treatment of otitis media are Amoxicillin, Amoxicillin + Clavulanic acid, Azithromycin, Cephalosporins, Clarithromycin, Clindamycin, orally/IM/IV and topically ciprofloxacin, or ofloxacin is insisted 4. There is wide variation in the use of antibiotics between doctors in different countries. The purpose of this article is to present two cases, one is of acute otitis media and the other is of a Chronic suppurative otitis media, for their clinical presentation and the empirical treatment and organism specific treatment in the view to support the research scientists, clinicians and pharmacist to plan and develop new drug regimen inspite of the usual therapy, those which most of them have become resistant and have lost their clinical efficacy due to resistance.

Case Report

Case 1

A five - year - and - a half old, boy had a history of , acute otitis media one month prior and he was treated with antibiotic: Amoxicillin 80 mg/Kg. He presented to our hospital with symptoms of right ear pain and irritation surrounding the right ear and he was not able to sleep properly. The otologic examination revealed a right middle ear effusion as it was indicated by erythema of tympanic membrane. Hence he was symptomatically treated with acetaminophen (15mg/kg every six hours). The pain did not reduce even after two days. Since it was a relapse case he was treated with IV Sulbactam for 5 days. He was continuously observed for signs of serious illness, but there was no such events occurred during the treatment days. The patient was declared clinically cured and was discharged from our hospital and followed up till 6 months, there was no recurrence noted.

Case 2

A one year old baby girl presented to the out patient clinic after a three week history of left otorrhea and progressive postauricular swelling and erythema. The otologic examination of the left ear revealed, thickened granular mucosa, perforation of tympanic membrane, swelling and inflammation of the middle ear and discharge. The patient was previously treated elsewhere with Clindamycin 30mg/day given orally in four divided doses for 5 days with no improvement. Ear cultures were taken from a sterile swab from the external auditory canal showed a heavy growth of *Paeruginosa* highly sensitive to Sulbactam, and it was found resistant to clindamycin. The patient was treated with Sulbactam I.M. for 5 days and was free from swelling, inflammation and discharge, perforation of the tympanic membrane also healed completely. The patient was followed up for 6 months. There was no recurrence occurred.

Discussion

Acute otitis media (AOM) is the most commonly diagnosed disease in childhood and a primary factor in increased antibiotic resistance 5 due to variations in diagnostic criteria 6 ,and antibiotic therapy 7. Despite the great prevalence of this disease, accurate diagnosis remains difficult. Chronic suppurative otitis media is also a common infectious disease in both developing and industrialized 1,2,3 countries. In this case report a 5 yr old boy was suffering from acute otitis media and a one yr old girl baby was suffering from chronic suppurative otitis media. Both the disease can cause considerable morbidity and is a major global cause of hearing impairment in children, moreover it may lead to serious extracranial

and intracranial complications like mastoiditis and meningitis 8,9. In order to avoid serious complications a prompt approach in the management of this disease is mandatory. The case 1 represents an acute otitis media and he was treated with antibiotics elsewhere but there was recurrence observed due to resistance reported to an unknown microbe. In case 2 chronic suppurative otitis media the patient was treated with clindamycin but there was no improvement observed. However the patient was found to be infected with *P.aeruginosa*. Empirical therapy of Sulbactomax in case 1 proved to be beneficial in cure and avoidance of recurrence even after 6 months. The case 2 was also treated with Sulbactomax, and the patient has been cured and prevented recurrence even after 6 months follow up. The existing drugs used in the treatment of otitis media with infection with *P. aeruginosa* has shown resistance for amoxicillin 74% ampicillin 68% in one study 10. Amoxicillin or ampicillin are being used for acute and chronic middle ear infections in our set up keeping in view the low cost of the antibiotics as compared to other antibiotics. Kenna et al. (1986) reported that in chronic suppurative otitis media the most common causative organism was *Pseudomonas aeruginosa* 11. The case 2 patient was initially treated with Clindamycin but there was no improvement even after 5 days this is a critical stage where a higher antibiotic like Clindamycin has shown clinical failure due to resistance as it was evident from the culture sensitivity report, moreover Clindamycin resistance to *P.aeruginosa* has been reported earlier by (K. Schaffer et al.,) 12. There was nothing wrong by the outside physician in diagnosing and treatment as for the acute otitis media the choice of drug is Amoxicillin and it was used in the case 1 by the physician earlier and for suppurative otitis media for case 2 the use of clindamycin is a good choice of drug, but in both the cases a treatment failure has been observed. Though we are not sure of the cause of treatment failure in case 1 we could clearly say that the treatment failure in case 2 was because of clindamycin resistance to *P.aeruginosa*. But in both the cases Sulbactomax IV was efficient in treating the otitis media infections, hence selection of drug for a case with previously treated antibiotics should be considered with the local resistance pattern of the drug.

Conclusion

The antimicrobial agents are losing their efficacy because of the spread of resistant organism due to indiscriminate use of antibiotic, The solution can be planned by continuous efforts of clinician, microbiologist, pharmacist and community to promote greater understanding of antimicrobial resistance. The emergence and spread of antimicrobial resistance are complex and driven by numerous interconnected factors. The use of antimicrobials must be restricted and monitored in order to decline the resistance. Keeping in view the chronicity of ear infections and the preference of health given in our society, it is not all the unexpected that most of these isolates were resistant to commonly used antibiotics. In the two case reports described one important evolution has been observed is that both the acute otitis media and as well as suppurative otitis media infection has been cured completely by Sulbactomax without any relapse hence it is possible that empirical treatment as well as organism specific treatment of otitis media with Sulbactomax could be the first choice of drug in the treatment of otitis media in the present scenario of resistance but it has to be substantiated with a controlled randomized study of Sulbactomax in the treatment of otitis media.

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