



COMPARISON OF CEFPODOXIME AND AMOXICILLIN CLAVULANATE IN PEDIATRIC ACUTE OTITIS MEDIA IN RURAL HEALTH CARE FACILITY

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ABSTRACT: Acute Otitis Media (AOM) is a common ear disease encountered in children below three years. Amoxicillin clavulanate is the first line drug in treatment of AOM in paediatric age group. Although Cefpodoxime has shown good antimicrobial activity against various types of pathogen that are labelled as main causative microorganisms of AOM in paediatric age group. In this study to try to compare the efficacy and safety of cefpodoxime and amoxicillin clavulanate in the treatment of AOM in children below three years of age. This study was a prospective longitudinal study which was conducted on children diagnosed with AOM who were less than three years of age. 30 children were included in our study, 15 in the Group A (amoxicillin clavulanate) and 15 in the Group B (cefpodoxime). The outcome of the study was assessed in two variants one was the clinical success rate at day 7 visit and other was any incidence of some kind of Adverse Events during the treatment period. The clinical success rates were 94.4% in Group A and 93.4 % in Group B. These rates were comparable with no statistically significant difference between the two groups. No side effects and adverse effects were observed in cefpodoxime group and the drugs were well tolerated in all patients whereas diarrhea was seen in three patients who were put on amoxicillin. The results of our study showed that a 7 day course of cefpodoxime was found to be therapeutically comparable to amoxicillin-clavulanate in terms clinical success with diarrhoea being seen in two patients who were put on amoxicillin clavulanate for the treatment of AOM in children below three years of age.

Keywords: acute otitis media (AOM), side effects, antimicrobial agents, safety.

Introduction

The protocol for treatment of AOM has continuously been changing mainly in pediatric age group. Our study is mainly focused on finding out alternative and side effect free treatment of AOM. It has been seen that due to lack of proper treatment and untreated cases of AOM may ultimately lead to various long term complications, especially in children under three years. Acute Otitis Media (AOM) is a common ear disease encountered in children below three years are treated routinely with antimicrobial agents although, there has been a different school of thoughts for the necessity of usage of antimicrobial drugs in children with uncomplicated AOM. The main factor for successful treatment in acute otitis media is the choice of antimicrobial agent. With the passage of time there has been an increase in resistance to various antimicrobials and also costs of antimicrobial therapy plays a role in need of judicious and rational use of antimicrobial drugs [1, 2].

Causative microorganism and the antibiotic susceptibility pattern to the specific bacteria guides the choice of antimicrobial agents in the treatment of AOM. The bacteria which mainly responsible for causing AOM in children are *Streptococcus pneumoniae*, *Haemophilus influenzae* and *Moraxella catarrhalis* [3]. High dose amoxicillin exceeding the Minimum Inhibitory Concentration (MIC) of *S.*

pneumoniae in middle ear fluid is required for elimination of bacteria. A total of 4 to 6 days management with high dose amoxicillin clavulanate has been found effective to eradicate *S. pneumoniae* from middle ear [4, 5]. Various studies show that 58% to 82% of *H. influenzae* are susceptible to regular and high dose amoxicillin. Data also shows that 100% of *M. catarrhalis* found in upper respiratory tract are susceptible to amoxicillin clavulanate 3-5]. Hoberman A et al., reported that 10 days treatment with amoxicillin-clavulanate potassium in children between 6 to 23 months of age with AOM showed resolution of signs and symptoms and decreased overall symptoms burden [6]. American association of paediatrics also recommends amoxicillin-clavulanate potassium as the first line drug in treatment of AOM [7]. Cefpodoxime is a wide spectrum third generation cephalosporin. It has been seen to be active against aerobic Gram-positive and Gram-negative bacteria as well as anaerobic organisms. American association guidelines of pediatrics suggests that ceftriaxone and cefuroxime can also be used as other options in treatment of AOM in under three years [7]. The present study was conducted to compare the efficacy and safety of cefpodoxime with amoxicillin-clavulanate in AOM in children below three years.

Material and Methods

This study was a prospective interventional study conducted in the Department of Health and family welfare via both ENT and Paediatrics specialist at civil hospital jwalamukhi. Data was collected from 30 children which report to either ENT or paediatrics outpatient department over a ten month period between July 2019 and April 2020. Inclusion criteria were as follow:

1. Children of either sex below three years of age who were clinically diagnosed as AOM after through ENT examination.
2. Those parents who gave consent from the children to be enrolled in study.

Exclusion criteria included

1. Children with hypersensitivity to the drugs used in study
2. Children with diagnosed hearing loss since birth.
3. Children who were with complications of AOM and were with toxic signs.

Our study was designed to find out between two treatment groups with respect to their efficacy and safety. Equivalence limit was set at 10%, True mean difference was considered zero, expected standard deviation was 10%, and power was 90%. Primer of biostatistics software (version 5.0) was used to calculate the sample size. Thirteen subjects were required in each treatment group. So 15 patients in each group were included in our study.

Children who were complaint with the selection criteria, were randomly divided into two treatment groups. Children with AOM in Group A received amoxicillin clavulanate 30 mg/kg/ day in three divided doses for 7 days. Children with AOM Group B received cefpodoxime 10 mg/kg/day in two divided doses for 7 days. A part from the study drugs, concomitant medication Montelukast + Levoceterizine was administered to the children. Safety monitoring was done throughout the study. All Adverse Effects (AE) and side effects reported by the parents or elicited by the treating Pediatrician and ENT specialist were made note of. The efficacy of drug was assessed by the number of children who achieved total relief from signs and symptoms in each treatment group. Treatment success was assessed on basis of the AOM-SOS scores [9, 10] [Table/Fig-1] at day 7 visit

The response was divided into two categories one with full clinical cure if the AOM-SOS score was 0 or 1 at 7th day of treatment and two as clinical improvement if score was between 2 and 4 on day 7. Treatment failure was defined as in cases which required a modification in therapy or presented with complications of AOM.

TABLE 1 DEPICTING AOM-SOS SCORE.

Symptoms / Scores	Ear Tugging	Crying	Irritability	Difficulty In Sleeping	Diminished Activity	Diminished Appetite	Fever
Score 0	none	none	none	none	none	none	none
Score 1	little	little	little	little	little	little	little
Score 2	Too much	Too much	Too much	Too much	Too much	Too much	Too much

Every child was given treatment for 7 days and was evaluated clinically on day zero i.e. day of presentation and at subsequent follow-up visits on Day four and seven. Friedman's test was used for intra-group comparison with in group and Mann-Whitney U test was used for

inter group comparison in between groups. Chi-square test was used for categorical data. A p-value < 0.05 was considered to be statistically significant.

RESULTS

All 30 children included in study which fulfilled the selection criteria, were given adequate treatment according to their respective groups. 15 children were given amoxicillin-clavulanate and included in Group A. Remaining 15 children were given cefpodoxime and included in Group B. The mean age of children was 2 years 1 month and 2 years in the Group A and B respectively. Gender percentage was 69.3% boys in Group A and 72.4% boys in Group B.

AOM-SOS score (mean± SD) in Group A are 12.6±0.4, 5.1 ±0.4, 0.3±0.1 at days 0, 5 and 10 respectively and in Group B are 12.8±0.5, 4.5±0.3, 0.4±0.1 at days 0, 5 and 10 respectively. While comparing the scores in the same group p value of significance was <0.05* when 4, 8, 12 week were compared with baseline scores at day 0 in Group A as well as group B. When comparing the scores of both group A and B at day 4 p value was 0.9 and at day 7 p value was 0.3. Statistical test used was Mann-Whitney U test. Within the group the AOM-SOS score at baseline (day 0) against day 4 and day 7 scores showed a highly significant decrease in both groups A and B and clinically significant improvement in the signs and symptoms of the AOM were seen in both groups. Thus, it was concluded that both cefpodoxime and amoxicillin clavulanate are highly effective and safe in treatment of AOM in children less than 3 years of age. Inter group analysis of the AOM-SOS scores between group A and group B showed no statistically significant difference in the baseline, day 4 and day 7 AOM-SOS scores. So, it can be concluded that cefpodoxime as well as amoxicillin-clavulanate are also equally effective in treatment of AOM in children with similar results almost. Two adverse effect were reported during the study period. Two male children in group A reported to have mild diarrhoea. None of the children in group B reported any adverse effect. These were mild adverse effects and did not required any modification of drug therapy during the treatment.

DISCUSSION

In our study it was found that cefpodoxime as well as amoxicillin clavulanate are both equally effective in AOM in children, both in terms of efficacy and safety and the treatment with a 7 day course in the cefpodoxime lead to 93.4 % curable rate and it was 94.4% in the amoxicillin clavulanate so the clinical success rates were comparable. The incidence of adverse effects was also minimal with two in the amoxicillin clavulanate group and none in cefpodoxime group. A study which was conducted by Hoberman A et al., showed that children between 6 to 23 months of age with clinically proved AOM showed fast recovery with decreased signs on otoscopic examination when treated with amoxicillin-clavulanate potassium for 10 days [6]. Number of studies has tried to evaluate efficacy of oral cephalosporins in treatment of AOM in children [11-14]. But, till date there is no such guideline available in India and till date to use which drug in AOM in children so our study tried to compare the effectiveness of third generation cephalosporin with amoxicillin clavulanate and found out that both cefpodoxime and amoxicillin clavulanate are equally effective in treatment of clinically diagnosed cases of AOM in children, both in terms of their effectiveness and safety in children below three years of age.

Some limitations of our study were that a randomized double blind clinical trial was not conducted due to lack of resources and the sample size in our study was relatively small as to prove the exact efficacy of treatment a larger sample size would have been more reliable.

CONCLUSION

Our study shows that efficacy and safety of 7 days therapy with cefpodoxime is almost comparable to that of amoxicillin clavulanate in AOM in children below three years of age. But Future trials will be required to assess the relapse rates and bacteriological cure to provide more scientific insight into our study.

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