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Original Article

COMPARATIVE STUDY OF SAFETY AND EFFICACY OF AZITHROMYCIN AND AMOXICILLIN IN TREATING CHILDREN WITH LOWER RESPIRATORY TRACT INFECTION

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ABSTRACT

Objectives: Lower respiratory infections are common among school going children. Frequent infections are troublesome children and to their parents and may lead to respiratory complication such as Chronic Bronchitis, bronchiolitis and bronchial asthma. Frequent dropouts in schools and may affect the studies of the children. So there is a need of an effective and safe drug for the infection.

Methods: The study was with 40 patients of the age group between 1 to 12 years, who were diagnosed with the lower respiratory infection. The patients were divided in to two groups. Group A Amoxicillin group (n=40) was treated Amoxicillin with 40 mg/day. Group B Amoxicillin group (n=40) was treated 10 mg/day. Both the drugs were orally. Clinical evaluation of symptoms was assessed before and after treatment (3rd and 7th days). Patient's White Blood cell Counts, Lymphocytes counts were analyzed accordingly.

Results: At the end of the treatment (3rd and 7th days) the clinical evaluation, WBC and Lymphocytes count in Azithromycin group showed significant reduction of WBCs (12.1%) and Lymphocyte counts (8.2%) than amoxicillin group. Minimal adverse drug reactions were noted in Azithromycin group.

Conclusion: There is clear evidence that Azithromycin is superior to amoxicillin in treating lower respiratory infections in children.

Keywords: Amoxicillin, Azithromycin, Lower respiratory tract infection.

INTRODUCTION

Azithromycin is an azilide antibiotic. It is chemically derived from the Macrolide erythromycin but differs by the insertion of nitrogen in 9a position of the lactone ring this chemical modification has significantly improved the pharmacokinetic profile of Azithromycin. In comparison with amoxicillin, Azithromycin has been shown to achieve good stability within the acidic environment of stomach has reliable oral bioavailability [1] The dibasic character of of the azilide structure has also enhanced uptake of Azithromycin into cells. This reflected systemically Azithromycin rapid distribution in to the tissues. Azithromycin has achieved high sustained tissue concentration and low serum concentrations [2]. Azithromycin above the Minimum Inhibitory Concentration (MIC) for the key respiratory pathogens were maintained in pulmonary tissue for several days single 10/mg/g/day oral dose.

The concentrations in the pulmonary tissue at sites are thought to be augmented by phagocyte uptake. Very high concentrations of alveolar macrophages have also been found [3]. *In vitro*, evidences indicate that high intra cellular concentration of Azithromycin may play a role in augmenting the activity of macrophages, which are an important component of host immune defense against intracellular pathogens. Studies in patients with bronchitis have revealed a mean concentration of Azithromycin in sputum of 3.8 mg/kg 24 h after a single dose of 500 mg with individual patients having concentrations up to 9.5 mg/kg these value greatly exceed the MIC of Azithromycin against the principle pathogens in bronchitis [4]. The classical spectrum of activity against Gram-positive (Staph. aureus, strep. pneumoniae, strep. pyogenes) and atypical respiratory pathogens (mycoplasma pneumoniae, legionella pneumophila and Chlamydia species.) has been retained [5]. Azithromycin also demonstrated significant activity against Haemophilus influenza and Branhamella catarrhalis has been shown to greater significantly than that of Amoxicillin. The activity of Azithromycin was not diminished against β–Lactamase or penicillinase producing strains [6]. Amoxicillin extended spectrum penicillin. It is used for the eradication of Multidrug resistant Helicobacter Pylori infection causing gastric ulcer and it is also effective against Streptococcus viridians and enterococci (SABE). Amoxicillin also used for Gonococcal urithritis with probencid [7].

MATERIALS AND METHODS

Prospective randomized double blind interventional study was conducted in Patients with lower respiratory tract infection in pediatric outpatient department of Rajah Muthaiah medical college, hospital, Chidambaram, Tamilnadu, India. Inclusion criteria 1. Patients aged between 1 to 12 Years2. Patient's guardian who has read and signed the informed consent form.3. Patients diagnosed with Lower respiratory tract infection. Exclusion criteria 1. Patients allergic to Amoxicillin or Azithromycin 2. Patients with history of Renal failure.3 Patients with any congenital abnormality. The study was approved by the institutional ethics committee and carried out in accordance with international pediatric clinical study guidelines. Informed consent was obtained from all patients' Legal Guardians. Eligible patients were made into two groups Group A Amoxicillin group (n=40) was treated Amoxicillin with 40 mg/kg/day in three divided doses. Group B Amoxicillin group (n=40) were treated 10 mg/kg\day in single dose. It was a 12 days study with 40 patients in each group. All patients who were diagnosed with LRTI were treated with either Amoxicillin or Azithromycin and their blood samples were taken on 3rd and 7th day of the treatment and analyzed in a laboratory. All patients were evaluated for blood cell counts before and after the treatment.

RESULTS

Of 80 evaluable patients, clinical success at study days 7 to 10 was 94.7% in the Azithromycin and at treatment group and 70.6% in the Amoxicillin treatment group (P =0.735). Treatment related adverse events occurred in 11.2 % of the Azithromycin group and 30.9% in the Amoxicillin group (P<0.05).

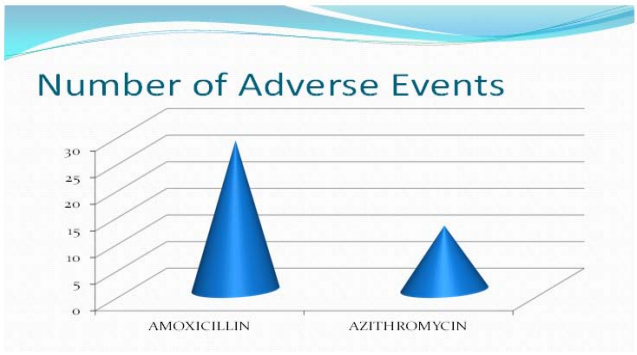

Chart 1: Shows the prevalence of group A and group B

Chart 2: Shows the wbc count and neutrophil count in A and group B before and after treatment

DISCUSSION

In the present study, a 3 day course of azithromycin suspension or tablets (10 mg/kg/24 h) in one dose per day was superior in efficacy with less incidence of side effects as compared to 7-10 day course of amoxicillin suspension (40 mg/kg/24 h) in three divided doses per day in the treatment of acute Lower Respiratory Tract Infection (LRTI). The patients treated with Azithromycin had significantly fewer adverse events than the patients treated with Amoxicillin. This was mainly attributable to a significant difference in gastrointestinal complaints. The clinical outcome in our study is comparable with those reported in previous studies.[8]In this, the first double-blind study, a 3 day course of Azithromycin showed efficacy superior to a longer, more complex regimen of Amoxicillin,7 day course in children with LRTIs. Previous studies showed that Azithromycin is well tolerated in children, with adverse events rates of 6–27% [9]. Children in the Azithromycin group in this study experienced adverse events related to the medication in 24% of cases. It is not clear why the Amoxicillin group reported such a high percentage (47%) of medication-related adverse events, as in previous studies this ranged from 11 to 31%.

It is still difficult to detect rapidly the causative pathogen in children with acute LRTI and antibiotic treatment in children with LRTI is almost always empirical. Azithromycin is one of the newer macrolides, and provides a good choice for the treatment of LRTI in children. Furthermore, administration of Azithromycin is convenient because of once-daily dosing and the short duration of therapy and the compliance is also better in the Azithromycin group.[10] In the study Azithromycin with the dose of 10 mg/kg/once daily is better tolerated and more efficient than Amoxicillin with the dose of 40 mg/kg/day divided in three doses.

CONLUSION

Azithromycin used once daily for 5 days produced a satisfactory therapeutic outcome similar to those of amoxicillin given three times for 10 days for treatment of lower respiratory infections

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CONFLICT OF INTERESTS

Declared None

REFERENCES

1. Dunn JC, Barradell L. B Azithromycin: a review of its pharmacological properties and use as 3-day therapy in respiratory tract infections. Drugs 1996;51:483–505.
2. Langtry HD, Balfour JA. Azithromycin: a review of its use in pediatric infectious diseases. Drugs 1998;56:273–97.
3. Peters DH, Friedel HA, McTavish D. Azithromycin: a review of its antimicrobial activity, pharmacokinetic properties and clinical efficacy. Drugs 1992;44:750–9.
4. Neu HC. Clinical microbiology of azithromycin. Am J Med 1991;91, Suppl 3A:12–8.
5. Lauvau DV, Verbist L. An open, multicentre, comparative study of the efficacy and safety of azithromycin and co-amoxiclav in the treatment of upper and lower respiratory tract infections in children. The Paediatric Azithromycin Study Group. J Int Med Res 1997;25:285–95.
6. Sclar DA, Tartaglione TA, Fine MJ. Overview of issues related to medical compliance with implications for the outpatient management of infectious diseases. Infect Agents Dis 1994;3:266–73.
7. Behre U, Burow HM, Quinn P, Cree F, Harrison H. E Efficacy of twice-daily dosing of amoxicillin/clavulanate in acute otitis media in children. Infection 1997;25:163–6.
8. Machin D, Campbell M. Statistical tables for the design of clinical trials. Blackwell Scientific Publications, Oxford; 1987. p. 53.
9. Roord JJ, Wolf BHM, Goossens MMHT, Kimpen JLL. Prospective, open, randomized study comparing efficacies and safeties of a 3-day course of Azithromycin and a 10-day course of erythromycin in children with community-acquired acute lower respiratory tract infections. Antimicrob. Agents Chemother 1996;40:2765–8.
10. Treadway G, Pontani D. Paediatric safety of azithromycin: worldwide experience. J Antimicrob Chemother 1996;37 Suppl:143–9.