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COMPARATIVE EVALUATION OF EFFICACY AND SAFETY OF CEFOTAXIME-SULBACTAM WITH AMOXICILLIN-CLAVULANIC ACID IN PATIENTS WITH LOWER RESPIRATORY TRACT INFECTIONS

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ABSTRACT

Nevertheless, several trials have assessed the effectiveness of other antibiotics to combat bacterial cirrhosis infections Beta Lactamase receptor Amoxicillin Clavulanic acid exhibits action against most bacteria responsible for infections in cirrhotic patients, including gram-negative bacilli, and gram-positive cocci. This research was primarily aimed at evaluating the effectiveness of the mixture cefotaxime-sulbactam compared to amoxicillin and clavulanic acid injection in paediatric IRTI patients. The second aim was to evaluate the efficacy of test medicines in paediatric patients. The child was considered LRTI when it had at least three signs and symptoms: cough, fever (right temperature = 38 °C), respiratory crepitations, wheezing and dyspnoeia or respiratory impairment (more than 50 breaths per minute in children aged 11 months or over and over 40 breathing/minute in children > 11 months) or when the child suffered from LRTI in children. In a Young sample, 2.2 percent of patients were affected by rash. In the same trial, 0.3% of paediatric patients were affected by phlebitis. We found that addition of the β-lactamase inhibitor sulbactam in the treatment of children with LRTIs is well-tolerated and effective. Anything similar to those listed in the documentation were the adverse effects recorded in the Co-amoxiclav population. Finally, cefotaxime sulbactam was seen to be as efficacious as co-amoxiclave treatment administered 3 times a day for up to 7 days. Findings need to be confirmed by additional trials for a greater number of patients with a more rigorous microbiology study.

Key words Lower respiratory tract infections, children, amoxicillin, cefotaxim, efficacy.

INTRODUCTION

Bacterial infections are common and serious complications in cirrhotic patients, particularly spontaneous bacterial peritonitis and bacteremia [1]. Felisart et al. have shown that cefotaxime is more effective than ampicillin tobramycin in the treatment of infection in cirrhotic patients and have achieved a resolution rate of 80-90% for infection, which is considered the first preference antibiotic for empirical treatment in these patients [2, 3]. Nevertheless, several trials have assessed the effectiveness of other antibiotics to combat bacterial cirrhosis infections Beta Lactamase receptor Amoxicillin Clavulanic acid exhibits action against most bacteria responsible for infections in cirrhotic patients, including gram-negative bacilli, and gram-positive cocci [4, 5].

The treatment of 27 episodes of spontaneous bacterial peritonitis with a resolution rate of 85 per cent and no major side effects was highly successful with ammoxicillin-clavulanic acid which suggests that it may be an alternative to cefotaxime in cirrhotic bacterial infection patients [6, 7]. A comparative analysis was however not

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done in these patients between cefotaxime and amoxicillin-clavulanic acid [8]. In many populations of cirrhotic patients at high risk of infection in the last ten years, norfIoxacin has increased its use to deter bacterial infections[9, 10]. The microbiology of infections has been updated however, as gram-positive cocci are the bacteria that are often isolated in cirrhotic norfioxacin infections. Grammatical cocci, in particular staphylococcus aureus and enterococci, display a higher susceptibility than cefotaxime to amoxicillin-clavulanic acid [11, 12]. Amoxicillin-clavulanic acid can also be given orally and is lower than cefotaxime [13, 14].

AIMS & OBJECTIVES:

This research was primarily aimed at evaluating the effectiveness of the mixture cefotaxime-sulbactam compared to amoxicillin and clavulanic acid injection in paediatric IRTI patients. The second aim was to evaluate the efficacy of test medicines in paediatric patients.

METHODOLOGY:

It was a prospective, randomized, active control, inpatient study conducted at multi-specialty hospital. The protocol and other study documents were approved by the Staff of Institutional ethics committee. In compliance with the Helsinki Declaration, the legal guardian of all patients consented to the registration in writing in advance. The research was conducted and monitored in line with the needs of good clinical practice.

Inclusion criteria:

- Children both sexes between 3 months and 12 years were admitted into this study with LRTIs, such as too severe pneumonia and bronchopneumonias, requiring parenteral treatment and hospitalisation.
- The child was considered LRTI when it had at least three signs and symptoms: cough, fever (right temperature = 38 °C), respiratory crepitations, wheezing and dyspnoeia or respiratory impairment (more than 50 breaths per minute in children aged 11 months or over and over 40 breathing/minute in children > 11 months) or when the child suffered from LRTI in children.

Exclusion criteria:

- Patients with a history of hypersensitivity to cefotaxime, sulbactam, amoxicillin, clavulanic acid or related drugs were excluded from the study.
- Patients with significant renal impairment (creatinine clearance < 30 m l/min) or with hepatic impairment, patients with neutropenia, patients with other antibiotics within 72 h until enrolment (serum-glutamic oxaloaacetic transaminase/serum glutamic pyruvinase > 2.5 times the normal upper laboratory value).
- No research test was taken in patients diagnosed with an immunodeficiency condition and/or some other serious disease.

RESULTS & DISCUSSION:

There have been 50 randomised injections of cefotaxime-sulbactam and 52 injections of amoxicilline-clavulanic acid. 59 men and 43 women were enrolled in this study. The median age in the treatment group was 30 months as compared to 24 months of cefotaxime-sulbactam injections in the treatment group. Chest X ray showing consolidation of both of these cases radiologically supported the diagnosis of LRTI. None of these patients were interstitial. For all the treatment populations, the demographic and baseline features ($p > 0.05$) were similar [Table 1]. There was no difference between the two groups in either signs and symptoms of disease or disease status at baseline.

Table 1: Patient demographics and basic features with respect to clinical conditions

Signs and symptoms	Cefotaxime-sulbactam injection (n= 50)	Amoxicillin-clavulanic acid injection (n = 52)	p-Value
Presence of cough (%)	48 (96)	49(96)	0.512
Presence of dyspnoea (%)	46 (94.0)	51 (98.07)	0.535
Fever (body temperature ≥ 38 °C) (%)	45 (87.0)	46 (87.53)	0.825
Presence of crepitations (%)	37 (77)	45 (85.1)	0.391
Poor feeding (%)	25 (50)	30 (61.02)	0.332
Abnormal sucking (%)	18 (38.0)	26 (50.0)	0.310
Decreased air entry (%)	15 (25)	13 (25)	0.146
Presence of bronchial breathing (%)	5 (10)	5 (10.53)	0.802
Presence of sputum (%)	2 (5.0)	1 (2.84)	0.373

The analysis is performed by a total of 96 (94.11%) patients: 47 (94%) of cefotaxime-sulbactam injection and 49 (94.23%) of amoxicillin-clavulanic acid injection groups. The basic signs and symptoms of infection in all therapeutic classes were markedly reduced at the conclusion of the therapy visit. Thirty-five (74.46%) cefotaxime sulbactam group and 33 (67.34%) amoxicillin clavulanic acid group patients have been clinically treated. In 90.47 percent of Cefotaxime sulbactam and 81.39 percent of Co-amoxiclav Injections treated patients fever have been solved (body temperature = 37.5° C). The resolution of signs and symptoms between the two care classes was not significantly different. The resolution and baseline for clinically evaluable patients with psychiatric signs and symptoms at the conclusion of the therapy session.

In this analysis, the adverse effects recorded are of a kind commonly expected in children with LRTI. Little to moderate severity was recorded as most adverse effects. Just one patient receiving cefotaxime-sulbactam confirmed a major unwarranted case. The adverse reactions identified in the population of cefotaxime-sulbactams were close to the recipients of cefotaxime alone in the literature. In a Young sample, 2.2 percent of patients were affected by rash. In the same trial, 0.3% of paediatric patients were affected by phlebitis. We found that addition of the β-lactamase inhibitor sulbactam in the treatment of children with LRTIs is well-tolerated and effective. Anything similar to those listed in the documentation were the adverse effects recorded in the Co-amoxiclav population.

CONCLUSION:

Finally, cefotaxime sulbactam was seen to be as efficacious as co-amoxiclave treatment administered 3 times a day for up to 7 days. Findings need to be confirmed by additional trials for a greater number of patients with a more rigorous microbiology study

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