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Comparative Clinical Evaluation of Safety and Efficacy of Cefotaxime and Ceftriaxone in Lower Respiratory Tract Infections

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Abstract:
Background: *Lower respiratory tract infection, while often used as synonym for pneumonia, bronchitis, acute exacerbations of chronic obstructive pulmonary disease. WHO globally high burden of disease study estimated that (LRTIs) cases are around 429.2 million ,episodes of illness and accounts for 94.5 million incapacity adjusted life years. In adults aged >59 years it causes 1.6 million deaths. Betalactamase producing bacteria present a major problem in treating LRTIs. The objective of our study was to evaluate the safety ,efficacy of ceftriaxone,cefotaxime injection as an alternative therapeutic option in patients (5-65years)with LRTIs.*
Materials and Methods: *This is a Prospective comparative observational study performed for a period of six months. A total of 200 patients with LRTIs(5-65years) in govt.district head quarters hospital,Khammam were taken. Patients received cefotaxime and ceftriaxone injections intravenously during the treatment.*
Results : *Efficacy was evaluated in a total of 200 patients .Clinical success rate was 94% and 88% respectively for ceftriaxone and cefotaxime .Both the study medications were safe and well tolerated in the study population.*
Conclusion: *In conclusion , ceftriaxone administered was found to be little more effective when compared with cefotaxime therapy. However further study with large number of patients are required to confirm these findings with vigorous microbiological evaluation.*
Keywords: *LRTSs, Ceftriaxone, Cefotaxime, Pneumonia, Bronchitis.*

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I. Introduction

Respiratory tract infections are the most often reported infectious disease in human beings. Based on the part of respiratory system affected they are conventionally divided into upper respiratory tract and lower respiratory tract infections.Acute LRTIs are one of the common clinical problems in community and hospital settings. Betalactam antibiotics , macrolides and fluoroquinolones are regularly prescribed for the management of Acute LRTIs. In LRTIs lower part such as larynx, bronchi, trachea, lung parenchyma of the respiratory system is affected.LRTI is not a single disease , it includes a group of specific infection they differ from pathogenesis, clinical presentations and outcomes. The etiology and symptomology of respiratory diseases differ with age, gender, season, the type of population at risk and other factors. LRTIs are usually the first infection to occur after birth and pneumonia is too often and final illness to occur after death. The role of antibiotics in the management of larger population of patients with LRTI is less clear. The standard antibacterial treatments for LRTIs in the past have been macrolides, pencillins, cephalosporins. Adverse drug reactions lead to the number of medical and monetary consequences .eg : they extend the hospital stay , increase the cost of treatment and exposure to possible harm and death nearly two-fold. Thus there is a compelling need to create awareness among physicians and patients towards the need for ADR monitoring. Based on the anatomical region , LRTIs are classified . they are Bronchitis, Bronchiolitis and Pneumonia.

II. Material And Methods

This is prospective comparative observational study was carried out on inpatients with lower respiratory tract infections like pneumonia and bronchitis in govt. district headquartes hospital, Khammam from June 2019 to December 2019. A total 200 subjects (5-65years) were taken for the study.
Study Design: A prospective comparative , observational study.
Study Location: Govt.District Headquarters, Khammam
Study Duration: June 2019 to December 2019.
Sample size: 200 subjects

Subjects & selection method: The study population was drawn from patients with lower respiratory tract infections(pneumonia, bronchitis) presented to govt.district headquarters , Khammam. The patients were divided into two groups.100 patients were treated with cefotaxime and 100 patients were treated with ceftriaxone.
Group A(N=100) treated with cefotaxime
Group B(N=100) treated with ceftriaxone

. **Inclusion criteria:**
1. Patients from age 5 years and above
2. Patients suffering from lower respiratory tract infections and having previous history of medical, medication problems.

Exclusion criteria:
1. Pregnant women;
2. Lactating mothers
3. Cancer patients
4. Patients under other antibiotic therapy.

Source of data : Patients satisfying the inclusion criteria were selected from Acute medical care and General medicine for the study.
Procedure methodology: All the patients satisfying the inclusion criteria were selected from Acute medical care and General medicine departments in govt. headquarters, Khammam. After completely explaining the study methodology to the study population , Informed consent was taken from each patient , necessary information was collected by interviewing each patient and parents using consent form, data collection form, questionnaire etc.
After administering the intravenous doses of cefotaxime and ceftriaxone to the respective study population , Based on the time took for the patient to recover(cure of signs and symptoms) and the adverse events reported by each patient under the cefotaxime and ceftriaxone therapy, the safe and effective drug was evaluated.
Statistical analysis: Prism graphic pad and Microsoft excel were used to analyse the data.

III. Result

A total 200 patients were taken and 100 were treated with cefotaxime and 100 were treated with ceftriaxone . The study enrolled 123 males and 77 female subjects. The diagnosis of LRTI was confirmed radiologically by chest X- ray showing consolidation in all these patients.
Sample size N= 200

Table 1: Demographic details of the patient

Gender	Number	Percentage
Male	123	61.5%
Female	77	38.5%

Table 2: Distribution of study population according to age

Age	Distribution	Percentage
Below 15(5-15)	49	24.5%
15-25	29	14.5%
25-35	22	11%
35-45	26	13%
45-55	31	15.5%
55-65	43	21.5%

Table 3: Number of patients suffering from the disease

Disease	Number	Percentage
Pneumonia	137	68.5%
Bronchitis	63	31.5%

Table 4: Comparision of signs and symptoms of patients under cefotaxime and ceftriaxone therapy

Signs and symptoms	Ceftriaxone	Percentage	Cefotaxime	Percentage
Cough	100	100%	100	100%
Dyspnea	98	98%	98	98%
Temperature>99F	93	93%	87	87%
Crepitations	86	86%	84	84%
Sputum	90	90%	86	86%

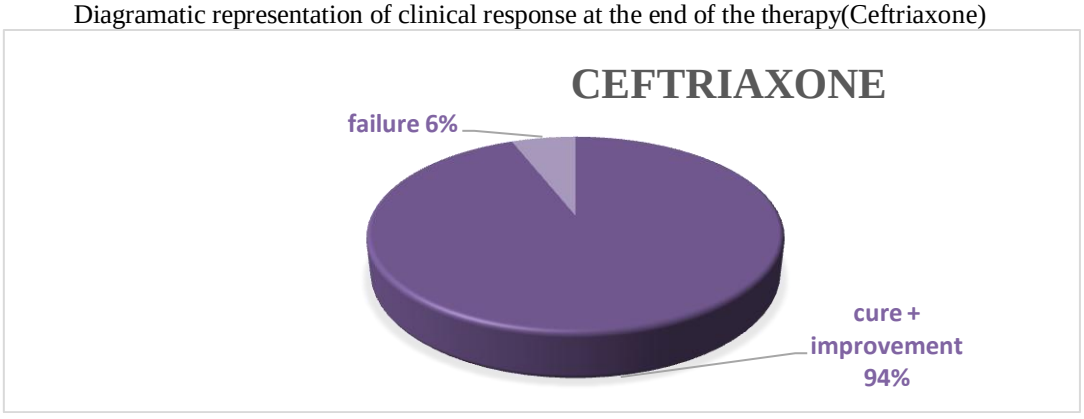
Table 5: Adverse events reported in the treatment groups under cefotaxime and ceftriaxone therapy

Adverse events	Ceftriaxone	Cefotaxime
Injectionsite reactions	15%	22%
Skin rashes	09%	13%
Nausea	08%	08%
Vomiting	13%	15%
Diarrhea	11%	14%
Dizziness	07%	15%
Headache	10%	09%

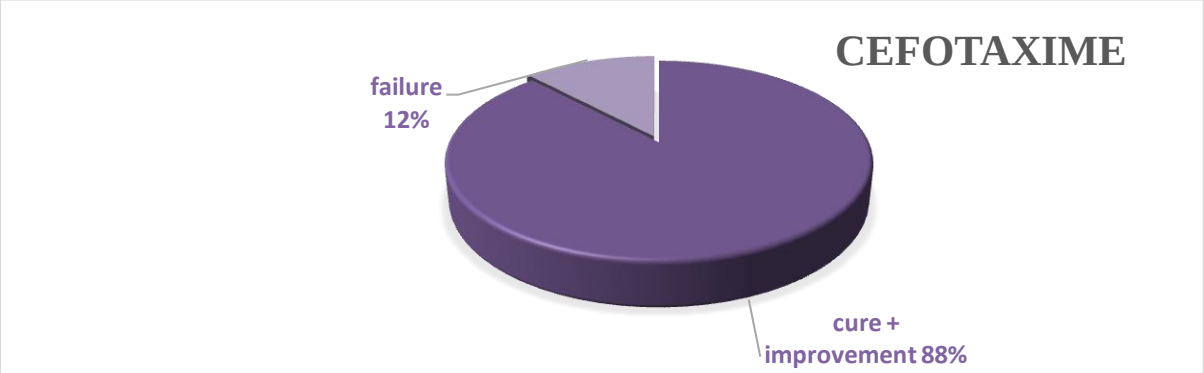
Table 6: Clinical response and results of equivalence comparisions at the end of the therapy

Treatment group	Cure+improvement	Failure
Ceftriaxone (n=100)	94(94%)	6(6%)
Cefotaxime(n=100)	88(88%)	12(12%)

Diagramatic representation of clinical response at the end of the therapy(Ceftriaxone)



Diagramatic representation of clinical response at the end of the therapy(Cefotaxime)



IV. Discussion

The reported adverse events were of mild to moderate intensity and possibly seen in the study drugs. The incidence of adverse events with cefotaxime was slightly more to that reported in ceftriaxone (table 5).

In the present study , ceftriaxone injection was slightly more effective than cefotaxime therapy in patients with LRTIs . Both the study treatments were effective with good clinical response rates. Although the response rates for both the drugs were statistically similar , more patients under ceftriaxone therapy were clinically cured than patients under cefotaxime therapy(94%,88%) respectively. More adverse events reported were mild to moderate intensity. The adverse events reported in the study of ceftriaxone as well as cefotaxime are injection site reactions, skin rashes, nausea, vomiting, diarrhea, headache, dizziness. The adverse events reported in ceftriaxone group were similar to those reported in the patients receiving cefotaxime.

V. Conclusion

In conclusion Ceftriaxone administered was found to be safe and effective than Cefotaxime. However , further studies with large number of patients are required to confirm these findings with more robust microbiological evaluation. Understanding the profile of lower respiratory tract infections is very important. Steps should be taken to combat various modifiable risk factors of malnutrition and prevention of further complication.

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