

CEFTRIAXONE RELATED ADVERSE DRUG REACTIONS IN CHILDREN IN A TERTIARY CARE HOSPITAL, KOLKATA, WEST BENGAL, INDIA

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ABSTRACT: Ceftriaxone is a third-generation cephalosporin antibiotic, which has broad-spectrum activity against Gram-positive and Gram-negative bacteria. It is a frequently used antibiotic in children worldwide. Studies revealed a number of adverse reactions related to this third generation antibiotic. A survey was done where data related with adverse drug reactions (ADRs) were collected for three months from the Department of Pediatrics of a tertiary care hospital, Kolkata, West Bengal, India and then evaluated. In the study, fifteen ADRs were detected. Ceftriaxone itself or its combinations correlated with more than thirty three percent (33.4%) adverse reaction cases in this study. Most common adverse drug reactions in the present study population were different types of rashes like urticaria and maculopapular eruptions.

Keywords: Ceftriaxone, Pediatric, Rash, Adverse drug reactions, Tertiary care hospital.

INTRODUCTION

Pharmacovigilance is the science and activities relating to the detection, assessment, understanding and prevention of adverse drugs reactions (ADRs) or any other drug related problems. ADR in hospital can occur from use of multiple drugs, drug interactions, and possible negligence etc. (Classen *et al.*, 1997). Drug eruptions are common, comprising

10–30% of all reported adverse drug reactions (Naldi *et al.*, 1999). β -Lactam antibiotics like penicillins, sulfonamides and cephalosporins develop rashes commonly. Ceftriaxone, a third-generation cephalosporin antibiotic, is a commonly used antibiotic in children. Hypersensitivity following ceftriaxone therapy are potentially life-threatening (Russellian *et al.*, 2013). Though ceftriaxone causes several adverse reactions; very few have been

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documented (Shalviri *et al.*, 2012). Present study evaluated Ceftriaxone (cephalosporins) induced adverse drug reactions in three months in the pediatric department of a tertiary care hospital, Kolkata.

MATERIALS AND METHODS

This is an observational study, carried out for a period of three months (September – November 2013) in the in-patient pediatric department of R.G. Kar Medical College and Hospital. Diagnosed cases of adverse drug reactions were selected for this report. Study protocol was approved by the Institutional Ethics Committee & verbal informed consent was taken from the parents. Only indoor patients were considered for this study.

Twenty six cases of adverse drug event was reported by the physician from paediatric

department during September-November, 2013. All the informations are spontaneous reporting, collected in the standardised form (CDSCO) and later evaluated for reporting. Causality assessment was also done and correlation was established by using Naranjo's scale.

RESULT AND DISCUSSION

The present study revealed that in three months total fifteen ADRs were diagnosed out of twenty six reported. The children suffered from different types of ADRs induced by Ceftriaxone (26.7%) and its combination (6.7%), followed by Phenytoin (20%) (Fig.1). Among all of these cases, intravenous Ceftriaxone and its combinations were responsible for most of the severe reactions (Fig.2).

Drug-induced urticaria mostly occurred due

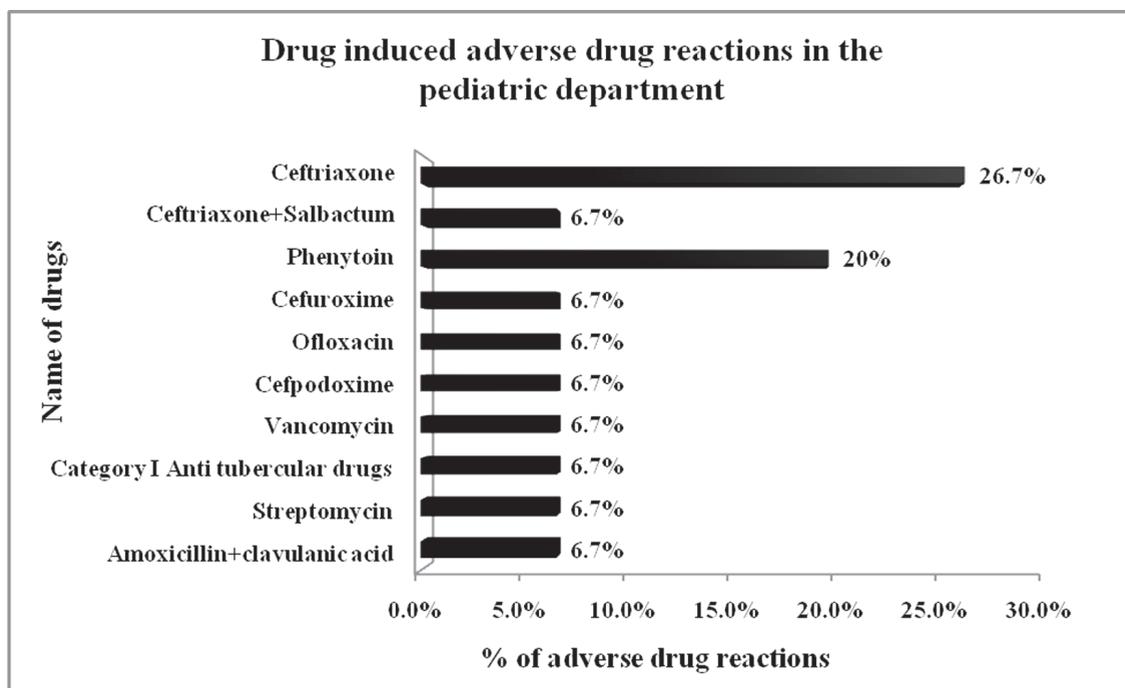


Fig. 1: Adverse drug reactions (ADRs) documented in the study [n=15]

Table 1: Detail adverse drug reactions (ADRs) profile of Ceftriaxone in the study population (n=5).

Sl No.	Name of drug	Age	Adverse drug reaction	Route	Dosing details
1.	Ceftriaxone	7 years	Diarrhoea	Intravenous	1gm, twice daily
2.	Ceftriaxone	11months	Maculopapular rash	Intravenous	375mg, twice daily
3.	Ceftriaxone	7 years	Urticaria	Intravenous	800mg, twice daily
4.	Ceftriaxone +Sulbactam	3 years	Urticaria	Intravenous	750mg, twice daily
5.	Ceftriaxone	9 years	Swelling of body	Intravenous	1.5gm, twice daily

to antibiotics of which cephalosporins were the most common causative drugs (Rutnin *et al.*, 2011). Cephalosporin induced reactions may be immediate or non-immediate. Immediate reactions are IgE mediated like urticaria, angioedema, bronchospasm, and/or anaphylaxis, which usually occurs within an hour of drug exposure (Pichichero 2005, Romano *et al.*, 2008). Non-immediate reactions are maculopapular or morbilliform rashes and delayed appearance of urticaria. Rashes or urticaria was the most commonly occurring adverse reaction of intravenous Ceftriaxone in children, supported from the present study.

Another study from Puducherry showed the same results (Russelian *et al.*, 2013). A study from Malaysia showed that most of the antibiotics-induced reactions were indeed maculopapular eruptions and Ceftriaxone is one of the responsible inducer (Wen *et al.*, 2010). Present study was also in agreement of this. Microbiological evaluation was also done in the study.

Another adverse reaction documented was Diarrhoea. Similar data was found in a study from Ohio State University, Columbus that diarrhoea is associated with Ceftriaxone in pediatric patients (Nahata and Miller 1989). A study from Virginia also detected multiple potential adverse events of frequently used antibiotic ceftriaxone including elevation of liver enzyme levels in 3% of patients, diarrhea in 2.7%, leukopenia in 2.1%, and hypersensitivity reactions in 1.7% (Boggs *et al.*, 2011).

CONCLUSION

Ceftriaxone is a frequently used antibiotic in both inpatient and outpatient department for its wide dose range and broad coverage of common infections, but have multiple potential adverse events. Potential adverse drug reactions due to Ceftriaxone are confirmed in the present study. Therefore children under antibiotic therapy, treatment must be done cautiously. Further in depth long term study is required for

proving more information aimed to safer therapeutics, specially for antibiotics.

REFERENCES

Boggs SR, Cunnion KM, Raafat RH (2011) Ceftriaxone-Induced Hemolysis in a Child With Lyme Arthritis: A Case for Antimicrobial Stewardship. *Pediatrics* 128: e1-e4.

Classen DC, Pestonik SL, Evans RS, Lioyd JF, Burke JP (1997) Adverse drug events in hospitalized patients excess length of stay, extra cost and attributable mortality. *J Am Med Assoc* 277: 301–306.

Nahata MC, Miller MA (1989) Diarrhoea associated with ceftriaxone and its implications in paediatric patients. *J Clin Pharm Ther* 14: 305-307.

Naldi L, Conforti A, Venegoni M (1999) Cutaneous reactions to drug: an analysis of spontaneous reports in four Italian regions. *British J Clin Pharmacol* 48: 839–846.

Pichichero ME (2005) A review of evidence supporting the American Academy of Pediatrics

recommendation for prescribing cephalosporin antibiotics for penicillin-allergic patients. *Pediatrics* 115: 1048-57.

Romano A, Gaeta F, Valluzzi RL, Alonzi C, Viola M, et al. (2008) Diagnosing hypersensitivity reactions to cephalosporins in children. *Pediatrics* 122: 521-524.

Russelian A, Chandrasekaran V, Nanda C, Palanisamy S (2013) Hypersensitivity due to ceftriaxone mimicking measles in a child. *Ind J Pharmacol* 45: 528-529.

Rutnin NO, Kulthanan K, Tuchinda P, Jongjarearnprasert K (2011) Drug-induced urticaria: causes and clinical courses. *J Drugs Dermatol* 10: 1019-1024.

Shalviri G, Yousefian S, Gholami K (2012) Adverse events induced by ceftriaxone: a 10-year review of reported cases to Iranian Pharmacovigilance Centre. *J Clin Pharma Ther* 37: 448–451.

Wen YD, Chew KL, Siew EC (2010) Cutaneous adverse drug reactions seen in a tertiary hospital in Johor, Malaysia. *Int J Dermatol* 49: 834–841.

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