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Adverse Drug Reaction of Case Report of Cefuroxime Injection

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Abstract: *The observational, quick cross-sectional investigation was carried out at Manipal Hospital's pharmacy department. Following the collection of adverse drug reactions (ADRs) reported by MANIPAL HOSPITAL Doctors, an assessment was conducted to determine the cause, severity, and preventability of the reactions. ADRs were noted anaphylactic reaction & hypotension with flushing after injecting cefuroxime (Axifur-H). To guarantee safe medication use and patient care, the healthcare system might encourage the ADR top Pharmacovigilance Centers to report ADRs on a voluntary basis. The majority of ADRs that were recorded were likely, unquestionably avoidable, and of a minor kind. According to our research, tertiary care hospitals should monitor ADRs closely in order to discover them early.*

Keywords: Adverse drug reaction, Cefuroxime, Anaphylactic reaction, Hypotension.

I. INTRODUCTION

Any unpleasant, unexpected, and undesirable side effects of a medication that happen at dosages utilized for treatment, diagnosis, or prevention are known as adverse drug responses. The term "adverse drug reaction," or "ADR," refers to any negative effects that can arise from taking a prescribed medication at its recommended dosage and using it normally. ADRs can happen after taking a medication for an extended period of time, after a single dose, or as a result of taking two or more medications together. This expression's meaning is different from what "side effect" means because it also implies that the consequences might be advantageous. Pharmacovigilance is the field that studies adverse drug reactions. Any harm brought on by a medication is referred to as an adverse drug event, or ADE. In their daily clinical work, practically all doctors encounter several cases of suspected adverse cutaneous drug responses (ACDRs), which can take many distinct forms. Even though these cutaneous reactions are frequent, many cases go unreported, making full information about their occurrence, severity, and long-term health impacts difficult to come by. As a result of the nearly constant introduction of new drugs to the market, there is always a possibility that an unreported new drug response could occur anywhere in the world.The key to managing and preventing a more severe drug rash is early diagnosis of the problem, identification of the offending drug, and prompt omission of it, even though the presentation is frequently too mild and benign. Because of this, not only dermatologists but also all other practicing physicians thought to be knowledgeable about these illnesses in order to identify them early and be ready to treat them appropriately. Adverse effects may occur when various medications are used together.Drug interactions can result in other significant responses or a change in the drug's effects. For instance, co-administration of a medication that inhibits CYP3A4 (clarithromycin) and a medication that is processed by CYP3A4 (cyclosporine), respectively, causes delayed clearance and increased blood levels.

ADR Detection methods & Reporting:

Detection methods –

1) Premarketing studies
2) Post marketing surveillance
3) Assessing Causality
4) Communicating ADRs
5) Postal survey method

The opportunity to identify major adverse drug reactions (ADRs) leading to hospitalization and ADRs happening in hospitalized patients that is, patients with high comorbidity receiving medications that are only given in hospitals is

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provided by the detection of ADRs in hospitals. The most often used techniques include encouraging doctors and nurses to report on their own, having trained professionals gather information thoroughly, and, more recently, employing computer-assisted ways that use routine data from hospital information systems. varied medication classes are therefore accountable for varied ADR rates and types as a result of the various ADR detection techniques employed.

Spontaneous Reporting of Adverse Drug Reactions: The most popular and voluntary method used by regulatory agencies to gather adverse drug reaction (ADR) data for pharmaceuticals after they are marketed is the spontaneous reporting framework.

Individual Case Safety Report: a record that, at any given time, contains all of the information available about a specific case. A main reporter's description of a potential adverse reaction (or reactions) connected to the administration of one or more pharmaceutical items to a single patient at a specific period is called an individual case.

Objectives of ADR Monitoring

- To identify the nature and frequency of ADRs
- To assist the Drug Regulatory Authority, Public Health Programmed, Scientists and Consumer Society to minimize ADRs.
- To deliver updated Drug Safety Information to Health Care Professionals.
- To spread information by organizing proper education programmed to consumers.
- To find the risk factors which can predispose induce or influence the development, severity and incidence of ADRs.

Who Should Report

1) Healthcare Professionals -are the preferred source of information in pharmacovigilance, for example physicians, family practitioners, medical specialists, and dentists.

2) Nurses and other health workers -may also administer medicines and should report relevant adverse drug reactions experienced by the patients.

3) Pharmacists -can play an important role in the stimulation of reporting and in the provision of additional information (for example, on co-medication and previous medicine use)

4) **Patients & their relatives -**can also report their experienced adverse drug reactions directly to JPC, or through their healthcare professionals. In this case seek the patient permission to contact their healthcare professionals for additional information and data verification.

5) Marketing authorization holder (MAH) - being primarily responsible for the safety of their products, they are obligated to report serious adverse drug reactions they receive about their products to JPC. While the non-serious ADRs should be included in the periodic safety update report (PSURs). For new medicines report all the suspected reactions, including minor ones. (medicines are considered “new” up to five years after marketing authorization).

What Should be reported

For established medicines or well-known medicines report all serious or unusual suspected adverse reactions, (see definition of a serious reaction, expectedness of reactions.

Report if an increased frequency of a given reaction is suspected.

Report all suspected ADRs associated with drug-drug, drug food or drug-food supplements (including herbal and complementary products) interactions.

Report when suspected ADRs are associated with medicine withdrawals.

Report ADRs occurring from overdose or medication error.

Report ADRs in special fields of interest such as medicine abuse and medicine use in pregnancy (teratogenicity) and during lactation.

In children under the age of 18, all suspected ADRs occurring, should be reported regardless of whether the medicine is licensed for use in children. Children are often not exposed to medicines during clinical trials and many medicines are used in children even if they are not licensed for this purpose.

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Classification of ADRs:

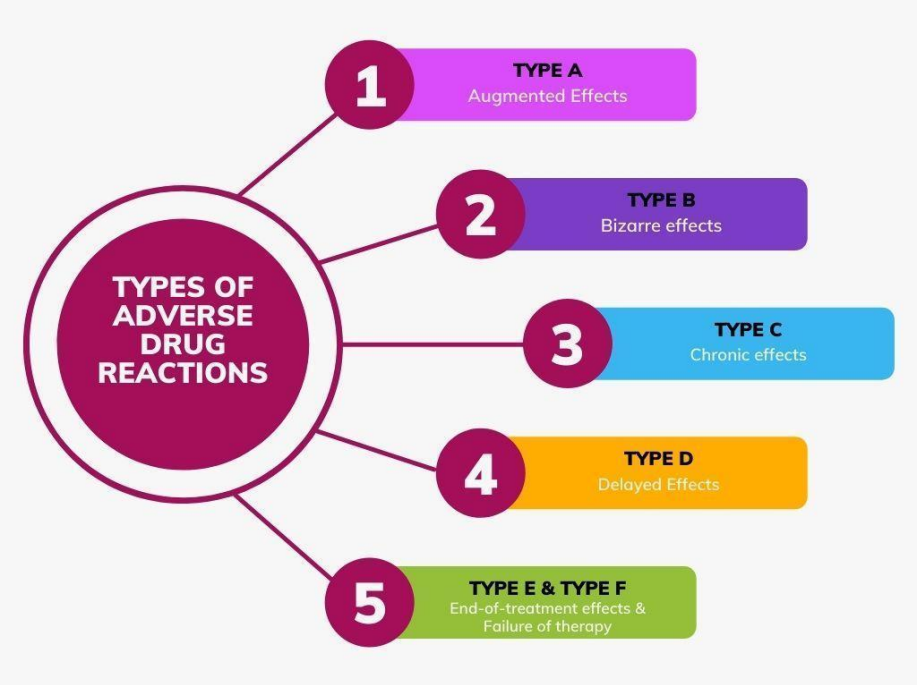

Figure – 1.1 – Types of ADR

Type A: Dose-related reactions (adverse effects at either normal dose or overdose), e.g. serotonin syndrome or anticholinergic effects of tricyclics. This can include adverse effects at either normal dose or overdose. These may include expected extensions of the therapeutic effect of the drug, e.g. bleeding in heparin. Toxic effects e.g. serotonin syndrome. Side effects are included, e.g. anticholinergic effects of tricyclics

Type B: Non-dose-related reactions (i.e. any exposure is enough to trigger such a reaction), e.g. allergic or anaphylaxis reactions. This refers to drug effects which are totally unrelated to the dose (i.e. any exposure is enough to trigger such a reaction).

Type C: Dose and time-related reactions, egg due to dose accumulation, or with prolonged use. (e.g. adrenal suppression with corticosteroids) This refers to drug effects which occur due to dose accumulation, or with prolonged use. Adrenal suppression with corticosteroids is one example.

Type D: Time related reactions, i.e. due to prolonged use in a drug which doesn't tend to accumulate. (e.g. tardive dyskinesia from antipsychotics) This refers to drug effects which occur due to prolonged use in a drug which doesn't tend to accumulate. An example might be tardive dyskinesia after decades of using typical antipsychotics

Type E: Withdrawal reactions, i.e. the undesired effects of ceasing the drug. (for example, opiate withdrawal) This refers to the undesired effects of ceasing the drug. Classical examples might include opiate withdrawal and rebound hypertension after stopping clonidine.

Type F: Unexpected failure of therapy, where a drug undesirably increases or decreases in efficacy for example, the decreased clearance of a drug by dialysis, or the decreased effect of antibiotics due to resistance. This category has been added to describe an undesirable reduction in the drug's efficacy (or, the undesirable increase thereof) Examples may include increased clearance by dialysis and plasmapheresis, drug interactions altering metabolism, and the effects of critical illness on protein binding and elimination.

Reactions that may occur with susceptibility:

1) Drug intolerance-A low threshold to the normal pharmacological action of a drug

2) Drug idiosyncrasy-A genetically determined, qualitatively abnormal reaction to a drug related to a metabolic or enzyme deficiency

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3) Drug allergy-An immunologically mediated reaction, characterized by specificity, transferability by antibodies or lymphocytes, and recurrence on re-exposure
4) Pseudo-allergic reaction-A reaction with the same clinical manifestations as an allergic reaction (egg - as a result of histamine release) but lacking immunological specificity.

Reactions that occur in any species:
1) Drug Overdose-Toxic reactions linked to excess dose or impaired excretion, or to both
2) Drug side effect-Undesirable pharmacological effect at recommended doses
3) Drug interaction-Action of a drug on the effectiveness or toxicity of another drug

Importance of ADR reporting in india: Adverse drug reactions account for 0.3% to 7% of all hospital admissions and are the fourth or sixth most common cause of death for hospitalized patients. Severe adverse drug reactions occur 6.7% of the time. Over the past few decades, the number of new pharmaceuticals hitting the market has increased rapidly. With over a billion potential drug users, India is the second most populous country in the world. Because pre-clinical and clinical data alone cannot determine a drug's complete safety, it is imperative that any adverse reaction to a pharmaceutical product be reported in order to evaluate its safety and efficacy and ensure the best possible patient care.

Aim & objectives:
Aim: Aim of this cross-sectional study is to analyses the adverse drug reaction of cefuroxime

Objective:
- To study the drug from which the ADR has been occur
- To study the adverse drug reaction occurs in a patient.

Naranjo Scale:
The Naranjo algorithm, Naranjo Scale, or Naranjo Nomogram is a questionnaire designed by Naranjo et al. for determining the likelihood of whether an ADR (adverse drug reaction) is actually due to the drug rather than the result of other factors. Probability is assigned via a score termed definite, probable, possible or doubtful. Values obtained from this algorithm are often used in peer reviews to verify the validity of author's conclusions regarding adverse drug reactions. It is also called the Naranjo Scale or Naranjo Score. The ADR Probability Scale consists of 10 questions that are answered as either yes, no, or "Do not know". Different point values (-1, 0, +1 or +2) are assigned to each answer. A simplified version of the 10 questions is provided below:
Are there previous conclusive reports of this reaction?
Did the adverse event appear after the drug was given?
Did the adverse reaction improve when the drug was discontinued or a specific antagonist was given?
Did the adverse reaction reappear upon readministering the drug?
Were there other possible causes for the reaction
Did the adverse reaction reappear upon administration of placebo?
Was the drug detected in the blood or other fluids in toxic concentrations?
Was the reaction worsened upon increasing the dose? Or, was the reaction lessened upon decreasing the dose?
Did the patient have a similar reaction to the drug or a related agent in the past?
10.Was the adverse event confirmed by any other objective evidence?

Adverse Drug Reaction Probability Scale:

Sr. No.	Questions	Yes	No	Do not know	Scores
1.	Are there previous conclusive reports of this reaction?	+1	0	0	
2.	Did the adverse event appear after the suspected drug was	+2	-1	0	

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	administered?				
3.	Did the adverse reaction improve when the drug was discontinued or a specific antagonist was administered?	+1	0	0	
4.	Did the adverse reaction reappear upon readministering the drug?	+2	-1	0	
5.	Are there alternative causes that could on their own have caused the reaction?	-1	+2	0	
6.	Did the reaction reappear when a placebo was given?	-1	+1	0	
7.	Was the drug detected in blood or other fluids in concentrations known to be toxic?	+1	0	0	
8.	Was the reaction more severe when the dose was increased or less severe when the dose was decreased?	+1	0	0	
9.	Did the patient have a similar reaction to the same or similar drugs in any previous exposure?	+1	0	0	
10.	Was the adverse event confirmed by any objective evidence?	+1	0	0	

Total Score=

Table No-4.1 Adverse Drug Reaction Probability Scale

Naranjo Algorithm - ADR Probability Scale:

Score	**Interpretation of Scores**	
Total Score ≥ 9	**Definite**	**The reaction** 1)followed a reasonable sequence after a drug or in which a toxic drug level had been established in body fluids or tissues, 2)followed a recognized response to the suspected drug, and 3)was confirmed by improvement on withdrawing the drug and reappeared on preexposure.
Total Score 5 to 8	**Probable**	**The reaction** 1)followed a reasonable temporal sequence after a drug, 2)followed a recognized response to the suspected drug, 3)was confirmed by withdrawal but not by exposure to the drug, and 4)could not be reasonably explained by the known characteristics of the patient's clinical state.
Total Score 1 to 4	**Possible**	**The reaction** 1)followed a temporal sequence after a drug, 2)possibly followed a recognized pattern to the suspected drug, and 3)could be explained by characteristics of the patient's disease.
Total Score ≤ 0	**Doubtful**	The reaction was likely related to factors other than a drug.

Table No.-4.2 Naranjo Algorithm - ADR Probability Scale

The Scale is classified as:

1. Mild: A reaction that does not required treatment or hospital stay.

2. Moderate: A reaction that requires treatment and or prolongs hospitalization by at least one day.

3. Severe: A reaction that is potentially life threatening or contributes to the death of patient is permanently disabling requires intensive medical care or results in a congenital anomaly cancer or unintentional overdose.

To study the onset of ADRs:

1. Acute: Acute events are those which are observed within 60 minutes after the administration of medication.

2. Sub-Acute: These occur within 1-24 hours from the time f administration of medication.

3. Latent: These reactions take 2 more days to become apparent.

Preventability of ADRs:

Completepreventability of ADR is not possible, but some of the ADR can be preventable if that ADR can give at least

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one answer of Schmick and Thornton Scale.

Predictability of ADRs:

Patients who have had the drug on previous occasion(s): If the drug was previously well-tolerated at the same dose and route of administration, the ADR is NOT PREDICTABLE; there was a history of allergy or previous reaction to the drug, the ADR is PREDICTABLE.

Indications

Cefuroxime is categorized as a β-lactam agent and is a member of the second generation of cephalosporin antibiotics. Following its approval by the U.S. Food and Drug Administration (FDA) in December 1987, cefuroxime shows promise in treating a variety of bacterial illnesses due to its broad-spectrum efficacy against both gram-positive and gram-negative organisms. When treating community-acquired diseases such as upper and lower respiratory tract infections, genitourinary tract infections, skin and soft tissue infections (SSTIs), and Lyme disease, cefuroxime is commonly used as an empirical treatment.

Pharmacology

Mechanism of Action

Binds to penicillin-binding proteins, inhibiting the last transpeptidation step of peptidoglycan synthesis and causing cell-wall death; resists beta-lactamase degradation; the patient's condition, the severity of the infection, and the microorganism's susceptibility all play a role in determining the proper dosage and mode of administration.

Pharmacokinetics

Comprehending the cefuroxime pharmacokinetic profile is essential for administering medication in the right dose, keeping track of progress, and maximizing therapeutic effects. The following lists the essential elements of cefuroxime's pharmacokinetics.

Absorption:

Cefuroxime can be given intravenously or orally. Following oral treatment, the parent molecule, cefuroxime, shows limited absorption. The ester prodrug version of cefuroxime, cefuroxime acetyl, is efficiently absorbed from the intestines and rapidly hydrolyzed to cefuroxime by esterase's in the gastrointestinal tract's mucosal cells. It is then released into the bloodstream, which greatly improves absorption when food is present. Cefuroxime acetyl pills have a bioavailability of roughly 37% when taken empty and 52% when taken with meals. Adults usually attain peak serum concentration of cefuroxime in 2 to 3 hours after oral administration; in children, it takes about 3 to 4 hours. Following intramuscular (IM) or intravenous (IV) injection, cefuroxime is quickly absorbed into the bloodstream; the peak serum concentration is reached in two to three minutes.

Distribution:

At 0.25 to 0.3 L/kg, cefuroxime has a comparatively narrow volume of distribution, with between 33% and 50% of the drug binding to plasma proteins. The lungs, tonsils, sinus tissues, bronchial mucosa, aqueous fluid of the eye, and middle ear effusion are among the tissues that cefuroxime efficiently penetrates. Cefuroxime stands out for its notable ability to penetrate bone tissue, which makes it a useful tool for treating odontogenic infections.

Metabolism:

From its ester prodrug, cefuroxime, the active parent molecule, is created.

Elimination:

The kidneys eliminate cefuroxime in its unaltered form, which leads to a high quantity in the urine.[32] In a 12-hour period, the urine will recover around half of the dosage. Cefuroxime has an elimination half-life of 1.4 to 1.9 hours in children and 1 to 2 hours in adults. Cefuroxime's renal excretion affects its pharmacokinetics; a decrease in renal function lengthens its half-life.

Administration:

Cefuroxime comes in a number of forms, including as oral pills, oral solution, and injectable powder. There are two strengths of cefuroxime acetyl oral tablets: 250 mg and 500 mg. There are two strengths of the oral suspensions available: 125 mg/5 mL and 250 mg/5 mile The injection-grade powder is provided in vials containing cefuroxime sodium in amounts of 750 mg, 1.5 g, and 7.5 g. The powder for injection can be given intramuscularly (IM) or intravenous (IV).

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Common side effects

- Rash
- Itching
- Fever
- Wheezing
- Seizures
- Hearing loss
- Diarrhea
- Colitis
- Upset stomach
- Allergy

II. MATERIAL & METHODS

Study location:
The study will be carried out in the Manipal Hospital including both outpatient and inpatient departments.

Study design:
The study will be an observational type, prospective and descriptive type.

Study setting:
Study will be based only on those patients who experience an adverse reaction to medicine used either during their stay in hospital (IPD) or visiting the outpatient departments (OPD).

Study criteria:

Inclusions:

• Patient's name, age, gender.
• Drug Prescribed.
• Dosage of Drugs Prescribed & dosage form.
• Route of Administration.

Exclusions:

• Incomplete information regarding patient.

Data collection
Data on the Reported ADRs will be evaluated to understand the pattern of the ADRs with respect to patient demographic disease, Nature of the reactions, characteristics of the drugs involved, and outcome of the reactions.

Criteria for identifying ADRs:
ADR identified by physicians will be considered and will be included in the study.

Analysis of ADRs:
Nature and description of ADDRs reported.

Casualityassesmentof ADR basedonalgorithm:
The degree of association of an adverse of an adverse reaction with a drug is done with the help of Naranjo's algorithm.

Severity of ADRs:
After the causality assessment has been done, the severity of the ADR is analyzed

Observation:
A female patient of 33 years age having pacemaker explanation & replacement therapy during that she had anaphylactic reaction of hypotension with flushing due to Cefuroxime Injection.

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manipalhospitals
LIFE'S ON

SUSPECTED ADVERSE DRUG REACTION REPORTING FORM Version 1.4

For VOLUNTARY reporting of ADRs by Healthcare Professionals
INDIAN PHARMACOPOEIA COMMISSION (National Coordination Centre-Pharmacovigilance Programme of India) Ministry of Health & Family Welfare, Government of India, Sector-23, Raj Nagar, Ghaziabad-201002
PvPI Helpline (Toll Free) :1800-180-3024 (9:00 AM to 5:30 PM, Monday-Friday)

Initial Case ☐ Follow-up Case ☐

FOR AMC / NCC USE ONLY
Reg. No. / IPD No. / OPD No. / CR No. :
AMC Report No. :
Worldwide Unique No. :

A. PATIENT INFORMATION *
1. Patient Initials: JR
2. Age or date of birth: 33Yr.
3. Gender: M ☐ F ☐ Other ☐
4. Weight (in Kg.)

B. SUSPECTED ADVERSE REACTION *
5. Event / Reaction start date (dd/mm/yyyy): 27/09/2023
6. Event / Reaction stop date (dd/mm/yyyy): 27/09/2023
7. Describe Event/Reaction management with details , if any
During Pacemaker explantation and Replacement Patient faced anaphylactic reaction after the usage of INJ. CEFUROXIME I.SG (AXIFUR H), Hypotension with flushing developed which was treated with Inj.Neosynephrine, AVIL and HYDROCORT.

12. Relevant investigations with dates :
13. Relevant medical / medication history (e.g. allergies,pregnancy, addiction, hepatic, renal dysfunction etc.)
14. Seriousness of the reaction : No ☐ If Yes ☐ (please tick anyone)
☐ Death (dd/mm/yyyy) ☐ Congenital-anomaly
☐ Life threatening ☐ Disability
☐ Hospitalization-Initial/Prolonged ☐ Other Medically important
15. Outcome:
☐ Recovered ☐ Recovering ☐ Not Recovered
☐ Fatal ☐ Recovered with sequelae ☐ Unknown

C. SUSPECTED MEDICATION(S) *

S. No.	8. Name (Brand/ Generic)	Manufacturer (if known)	Batch No. / Lot No.	Expiry Date (if known)	Dose	Route	Frequency	Therapy Dates: Date Started	Therapy Dates: Date Stopped	Indication	Causality Assessment
i	INJ. AXIFURH	Vexiture Healthcare	AHDA 23002 #292	02/2025	1.5GM	IV	OD	27/09/2023	27/09/2023	Prophylaxis	Probable (Nasrugo)
ii											
iii											
iv#											

9. Action taken after reaction (please tick)

S. No. as per C	Drug withdrawn	Dose increased	Dose reduced	Dose not changed	Not applicable	Unknown
i	✓					
ii						
iii						
iv						

10. Reaction reappeared after reintroduction ofsuspected medication (please tick)

Yes	No	Effect unknown	Dose (if re-introduced)

11. Concomitant medical product including self-medication and herbal remedies with therapy dates (Exclude those used to treat reaction)

S. No.	Name (Brand / Generic)	Dose	Route	Frequency (OD,BD, etc.)	Therapy Dates: Date Started	Therapy Dates: Date Stopped	Indication
i	ACENUMEROL	2 mg	PO	OD	Before 4 months		
ii	AIDALTONE	12.5mg	PO	OD			
iii#							

Additional Information :

D. REPORTER DETAILS *
16. Name & Address : Dr. Vishal Aundhe
Manipal Hospital, Baner Pin : 411045
Email : Clinical Pharmacologist Amrapali Hospital Contact No- :
Occupation : Clinical Pharmacist Signature :
17. Date of this report (dd/mm/yyyy) : 30/9/2023

Signature and Name of Receiving Personnel :

Confidentiality : The patient's identity is held in strict confidence and protected to the fullest extent. Submission of a report does not constitute an admission that medical personnel or manufacturer or the product caused or contributed to the reaction. Submission of an ADR report does not have any legal implication on the reporter.

Use separate page for more information
* Mandatory Fields for suspected ADR Reporting Form

Manipal Hospital, Baner - Pune
Survey No 111/11/1, Baner-Mhalunge Main Road, Baner, Pune 411 045, Maharashtra
P 020 681 38888www.manipalhospitals.com

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Naranjo Adverse Drug Reaction Probability Scale				
Question	Yes	No	Do Not Know	Score
1. Are there previous *conclusive* reports on this reaction?	+1	0	0	0
2. Did the adverse event appear after the suspected drug was administered?	+2	-1	0	+2
3. Did the adverse reaction improve when the drug was discontinued or a *specific* antagonist was administered?	+1	0	0	0
4. Did the adverse event reappear when the drug was re-administered?	+2	-1	0	0
5. Are there alternative causes (other than the drug) that could on their own have caused the reaction?	-1	+2	0	+2
6. Did the reaction reappear when a placebo was given?	-1	+1	0	0
7. Was the drug detected in blood (or other fluids) in concentrations known to be toxic?	+1	0	0	0
8. Was the reaction more severe when the dose was increased or less severe when the dose was decreased?	+1	0	0	0
9. Did the patient have a similar reaction to the same or similar drugs in *any* previous exposure?	+1	0	0	0
10. Was the adverse event confirmed by any objective evidence?	+1	0	0	+1
			TOTAL SCORE:	5

Modified from: Naranjo CA et al. A method for estimating the probability of adverse drug reactions. Clin Pharmacol Ther 1981; 30: 239-245.

The patient reported measure Naranjo scale and the total score of Naranjo scale was 5, that show patient reported with probable adverse drug reaction.

Patient Demographics:

A female patient of 33 years comes to hospital for peacemaker explanation & replacement therapy.She was advised to take Acenumerol 2 mg & Aldactone 12.5 mg by OD. During therapy patient had anaphylactic reaction to the

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Cefuroxime injection 1.5 g (Axifur-H) hence antibiotic was stopped then supplied adrenaline , Inj. Avil to prevent hypotension with flushing and hydrochort .

Concomitant Medications:
Acenomerol 2 mg OD
Aldactone 12.5 mg OD
Suspected Medications:
Brand Name – Inj. Cefuroxime (Axifur - H)
Manufacturer- Veritaz healthcare
Batch No. / Lot No. – AHDA23CO2#292
Expiry Date – 02/02/2025
Dose – 1.5gm
Route – Intravenous (IV)
Frequency – OD
Date Started – 27/09/2023
Date Stopped – 27/09/2023
Indication – Prophylaxis
Causality Assessment: Probable
Suspected Medicament:- Inj. Cefuroxime [Axifur-H]

Figure – 8.1-Inj Cefuroxime

Adverse Drug Reactions:
For Healthcare Professionals applies to cefuroxime: injectable powder for injection, intravenous solution, oral powder for reconstitution, oral tablet. General This drug was generally well tolerated. The side effects most commonly reported with the parenteral formulation have included neutropenia, eosinophilia, transient liver enzyme/bilirubin elevations, and injection site reactions .The side effects most commonly reported with the oral formulations have included Candida overgrowth, eosinophilia, headache, dizziness, gastrointestinal disturbances, and transient liver enzyme elevations.

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Gastrointestinal

Common (1% to 10%): Diarrhea/loose stools, nausea/vomiting, abdominal pain, nausea .Uncommon (0.1% to 1%): Abdominal cramps, flatulence, indigestion, mouth ulcers, swollen tongue, dyspepsia, gastrointestinal (GI) infection, ptyalism/excess salivation, GI disturbance, vomiting .Frequency not reported: Abdominal discomfort, dry mouth, Chloridoids difficile-associated diarrhea Post marketing reports: GI disturbances (including diarrhea, nausea, vomiting, abdominal pain), pseudomembranous colitis .Cephalosporin-class: -Frequency not reported: Vomiting, abdominal pain, colitis .The onset of pseudomembranous colitis symptoms has been reported during or after antibacterial therapy.

Hepatic

Common (1% to 10%): Transient increase in AST, transient increase in ALT, transient increase in liver enzyme levels. Uncommon (0.1% to 1%): Transient increase in bilirubin. Post marketing reports: Hepatic dysfunction, hepatitis, cholestasis, jaundice (mainly cholestatic).Cephalosporin-class: -Frequency not reported: Hepatic dysfunction (including cholestasis)

Nervous system

Common (1% to 10%): Headache, dizzinesss. Uncommon (0.1% to 1%): Sleepiness, somnolence, hyperactivity. Post marketing reports: Seizures, encephalopathy .Cephalosporin-class antibiotics (including this drug) have been associated with seizures, especially in patients with renal dysfunction when the dose was not reduced.

Hypersensitivity

Common (1% to 10%): Delayed hypersensitivity reaction. Uncommon (0.1% to 1%): Hypersensitivity reactions (including rash, pruritus, urticaria) .Rare (0.01% to 0.1%): Severe hypersensitivity reactions. Frequency not reported: Serum sickness .Post marketing reports: Anaphylaxis, serum sickness-like reaction .Delayed hypersensitivity reaction to this drug has been reported in 2.9% of patients with history of delayed hypersensitivity to penicillin (but not a cephalosporin). Rare cases of severe hypersensitivity reactions (including erythema multiforme, toxic epidermal necrolysis [exanthema tic necrolysis], drug fever, serum sickness-like reaction, anaphylaxis, Stevens-Johnson syndrome) have been reported.

Hematologic

Common (1% to 10%): Eosinophilia, decreased hemoglobin and hematocrit, neutropenia, decreased hemoglobin concentration .Uncommon (0.1% to 1%): Positive Coombs test, leukopenia, thrombocytopenia .Frequency not reported: Autoimmune granulocytopenia, increased coagulation time .Post marketing reports: Hemolytic anemia, pancytopenia, increased prothrombin time .Cephalosporin-class: -Frequency not reported: Aplastic anemia, hemolytic anemia, hemorrhage, prolonged prothrombin time, pancytopenia, agranulocytosis, positive Coombs test .Profound leukopenia has sometimes been profound with oral therapy.

Renal

Frequency not reported: Increased BUN, increased creatinine, decreased Circle, acute renal failure .Post marketing reports: Renal dysfunction, interstitial nephritis (including reversible fever, azotemia, pyuria, eosinophilia) .Cephalosporin-class: -Frequency not reported: Toxic nephropathy .Acute renal failure has been reported. Renal function improved after this drug was stopped, and deteriorated upon rechallenge.

Genitourinary

Common (1% to 10%): Vaginitis. Uncommon (0.1% to 1%): Vulvar itch, dysuria, vaginal candidiasis, vaginal discharge, vaginal itch, urethral pain/bleeding, kidney pain, urinary tract infection, vaginal irritation .Cephalosporin-class: -Frequency not reported: Vaginitis (including vaginal candidiasis)

Dermatologic

Common (1% to 10%): Diaper/nappy rash .Uncommon (0.1% to 1%): Rash, urticaria/hives, pruritus, erythema . Rare (0.01% to 0.1%): Erythema multiforme, toxic epidermal necrol

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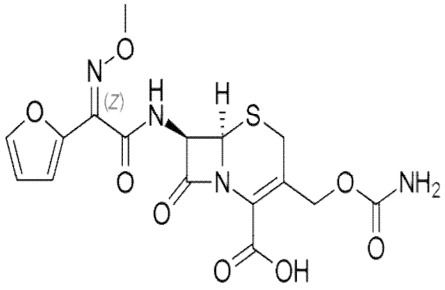

Figure-8.2-Structure of Cefuroxime

III. RESULT

The Naranjo Adverse Drug Reaction Probability Scale is a tool used to assess the likelihood that a given adverse drug reaction (ADR) is caused by a particular medication. The scale consists of ten questions, and each question is assigned a score of -1, 0, or +1, depending on the response. The total score can range from -4 to +13, with medium scores indicating a medium probability of the ADR being drug-related. The score on the Naranjo scale for the case report of adverse drug reactions (ADRs) of Inj. Cefuroxime (1.5 g) [AXIFUR-H] IPD (Inpatient Department) patients, it suggests a possible causal relationship between the medications and the observed ADRs.

A score of 5 on the Naranjo scale indicates a "Probable" likelihood of the ADR being drug-related. The scale ranges from 5 to 8 .The adverse drug reaction (ADR) in the patient with a Naranjo scale score of 5 suggests a probable causal relationship between the medications (Inj. Cefuroxime) and the observed reaction. Causality Assessment: The reaction occurred after the administration of the drugs, indicating a causality assessment between the drug exposure and the onset of the adverse event. Recognized pattern: The reaction possibly followed a known or recognized pattern associated with the suspected drugs. This could mean that the adverse event is consistent with the probably expected side effects or known adverse reactions of Inj. Cefuroxime.

IV. DISCUSSION

Any unpleasant, unexpected, and undesirable side effects of a medication that happen at dosages utilized for treatment, diagnosis, or prevention are known as adverse drug responses. An adverse drug reaction, often known as an ADR, is a term used to characterize the side effects of taking prescribed drugs at recommended dosages as directed. Pharmacovigilance is the field that studies adverse drug reactions. Any injury brought on by a drug (at a recommended dosage and/or as a result of an overdose) as well as any harm resulting from drug use (such as stopping a medication regimen) are referred to as adverse drug events, or ADEs for short. ADEs have a unique kind known as ADRs. Both the inpatient and outpatient departments of the Manipal Hospital will be involved in the study. A female patient of 33 years comes to hospital for peacemaker explantation& replacement therapy.She was advised to take Acenumerol 2 mg & Aldactone 12.5 mg by OD . During therapy patient had anaphylactic reaction to the Cefuroxime injection 1.5 g (Axifur-H). Hence, antibiotic was stopped then supplied adrenaline, Inj. Avil to prevent hypotension and hydrochort to prevent flushing .

V. CONCLUSION

ADRs are potentially avoidable causes for seeking medical attention. They increase the burden of work and can be fatal at times adding to the common person's negative perception of allopathy. With the number of drugs being marketed increasing every year, it is of paramount importance to have an in-depth knowledge of their possible adverse reactions and this is possible only when the physician is trained adequately and have knowledge on incidence of various adverse drug reactions. Among different medications antibiotic-Cefuroxime Injection [Axifur-H] were commonly responsible drugs.Causality assessment also resulted in medium score of probable categories. A robust mechanism for reporting of ADRs is required while the clinician is to be always on the lookout for ADRs. So, anticipating, preventing, recognizing and responding to ADRs should be the prime concern of the clinicians so as to minimize the incidence of ADRs. Results of this study emphasized the need of ADR reporting in tertiary care hospitals to help in assessing the benefit

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risk ratio of drugs. From this study, it had been concluded that incidence of ADR occurs due to the antibiotic-Cefuroxime Injection but exact reason behind ADR was unknown. Further investigation is needed.

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