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A Study Of The Adverse Drug Reaction Of Inj. Ferinject Given To A Pregnant Woman: A Case Report Observational Study.

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Abstract: -

An adverse drug reaction (ADR) is described by the World Health Organisation (WHO) as any reaction to a medicine "which is noxious and unintended and which occurs at doses used in man for prophylaxis, diagnosis, or therapy. This observational case were carried out in Manipal Hospital Baner, Pune. A 26-year-old pregnant woman. Her family history was not significant. She had iron iron deficiency anaemia (hemoglobin-8.7 g/dl) at the time of presentation. With the preview of anaemia, patient was started on Inj. Ferenject was planned to give with each day a dose of 500mg (one vial) intravenous over one hour. The patient developed breathlessness and myalgia half an hour after the first dose was completed. Half hour later patient had vomiting (one episode) non-projectile which was managed with an anti-emetic. A diagnosis to allergy to ferric carboxymaltose was made.

Keywords:- Breathlessness, Myalgia, ADR, Ferric carboxymaltose, IDA

1.INTRODUCTION

An adverse drug reaction (ADR) is described by the World Health Organisation (WHO) as any reaction to a medicine "which is noxious and unintended and which occurs at doses used in man for prophylaxis, diagnosis, or therapy[1].

The most common reason for this is that the clinical studies generally have limited sample size and have low statistical power. Therefore, the ADRs monitoring is an essential need for the better health care and therefore the health care centre should promote the spontaneous monitoring, reporting, documentation and prevention of ADRs[2]

Anaemia affects about 25% of people globally. Fifty percent of anaemias are caused by iron deficiency, which is also the most prevalent cause. In underdeveloped nations, the frequency of iron insufficiency is higher than in the US, where 1% of males under 50 have iron-deficiency anaemia. Ten percent of American women of childbearing age experience menstrual losses, and nine percent of children between the ages of twelve and thirty-six months are iron deficient, with one-third of these infants developing anaemia. Despite the low prevalence of iron-deficiency anaemia in the US, families with poor incomes are more vulnerable.[3]

The importance of understanding the predictability of an ADR was first reviewed in 1971. Where it was estimated that 70-80% of ADR's are predictable and may be preventable. It is true that some ADR's are unavoidable and will occur even with the most extraordinary precautions in place. However, a large proportion of ADR's may be preventable. Yet, in most hospitals today, too little is done to identify and understand preventable ADR's. This information is of utmost importance for guiding educational programs and systems to facilitate a reduction in the number of ADR's that occur. The preventability of ADR's is an appropriate data element which can be fed back into the system to facilitate the improvement process[4]

In everyday clinical practice, almost all physicians come across many instances of suspected adverse cutaneous drug reactions (ACDR) in different forms. Although such cutaneous reactions are common, comprehensive information regarding their incidence, severity and ultimate health effects are often not available as many cases go unreported. In the present world, almost every day a new drug enters market; therefore, a chance of a new drug reaction manifesting somewhere on some form in any corner of world is unknown on unreported.[4]

The study mainly focused on understanding of the adverse effects of Inj.Ferinject in therapeutic use, informs clinicians of the risks and provides a picture of the ADR.

AIMS & OBJECTIVE-

Aim -

Aim of this case report Observational study is to study adverse drug reaction of Inj. Ferinject given dose of drug to the patients.

The work was focused on studied the case report on adverse drug reaction of inj. Ferinject in pregnant woman

Objective –

Primary objective

To study the ADRs of a Inj. Ferinject in a pregnant woman.

3. MATERIALS & MATHODS-

3.1) Study Title -

To study adverse drug reaction due to FERINJECT INJECTION.

The Present study was conducted at Manipal Hospital, Baner during the period of 15.03.2023 to 17.03.2023.

3.2) Study Design -

Case report observational study

3.3) Source of study population -

IPD patient visited to Manipal Hospital, Baner.

3.4) Inclusion Criteria -

Patient's name, age, gender.

Drug Prescribed.

Dosage of Drugs Prescribed & dosage form.

Route of Administration.

3.5) Exclusion Criteria -

Incomplete information regarding patient

4) CASE STUDY PRESENTATION

4.1) PATIENTS DEMOGRAPHICS –

A pregnant woman of 26 years old, received Inj.FERENJECT 500mg OD for the treatment of iron deficiency anaemia, after 1 hour patient complaints about breathlessness, headache, nausea and to episodes of vomiting.

Hence, current treatment was stopped and antiallergic AVIL, Hydrocort were administred

Name/Initial: DL

Age: 26

Sex: Female

Hospital/Clinical: Manipal Hospital Baner – Pune

4.2) CONCOMITANTS MEDICAL PRODUCT -

Name (Brand /Generic)	Dose	Route	Frequency	Dates Started	Date Stopped	Indication
EMANZEN - D	50, 10mg	PO	TDS	15.03.23	17.03.23	Analgesic
METROGYL	400 mg	PO	TDS	15.03.23	17.03.23	Post Delivery Antibiotics Prophylaxis.
TAXIM - O	200mg	PO	BD	15.03.23	17.03.23	Post Delivery Antibiotics Prophylaxis.

Table 2: Concomitants Medical Product

4.3) SUSPECTED MEDICATION -

1) Brand Name: FERENJECT

2)Manufacturer: LUPIN

3)Batch No: 1072122EA

4)Expiry Date: 30.09.24

5)Dose: 500mg

6)Route: Intravenous

7) Frequency: STAT

8) Therapy Dates:

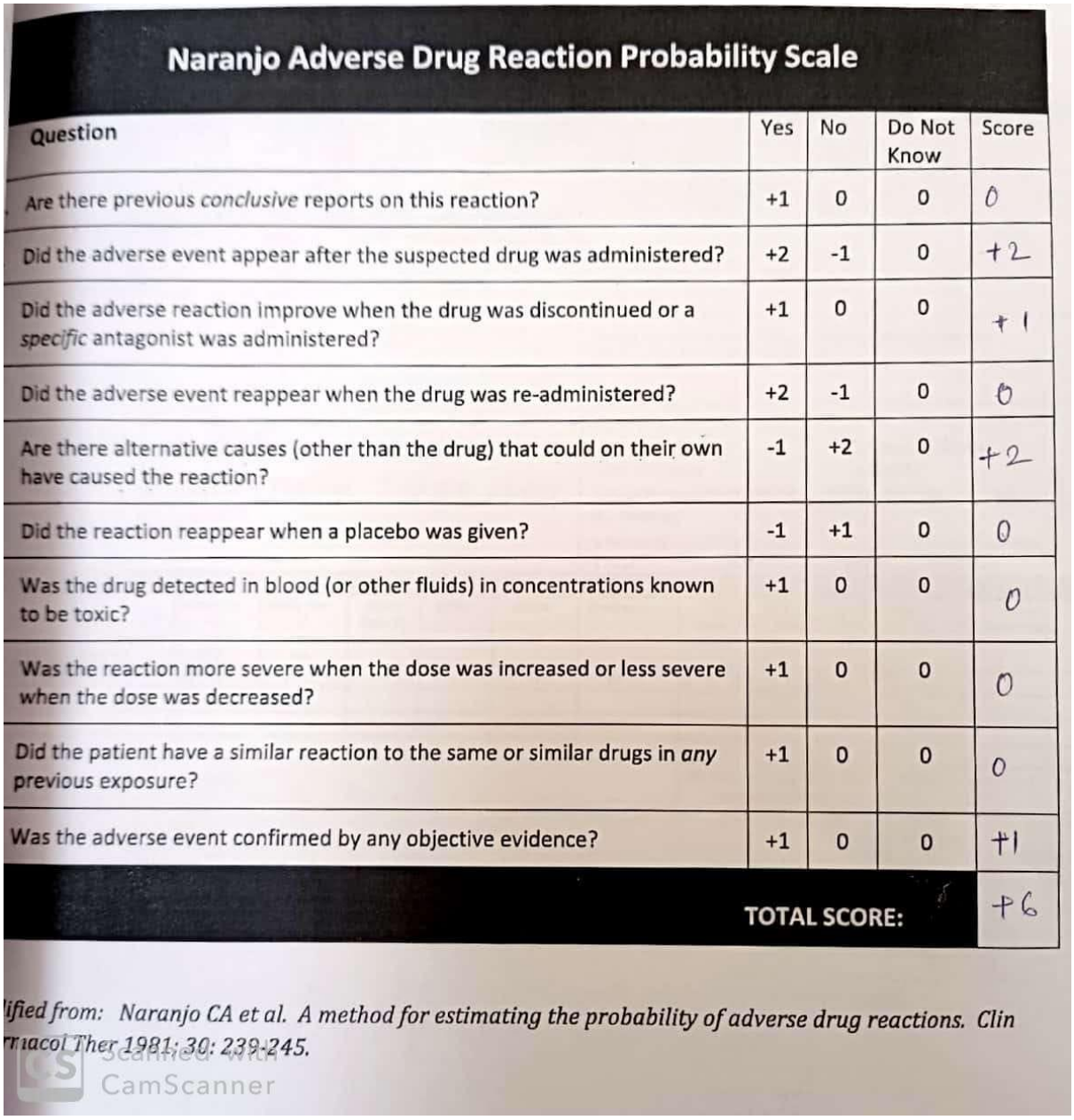
Dates Started – 16.03.23

Date Stopped – 16.03.23

9) Indication: Iron Deficiency Anaemia Hb (8.7)

CASE STUDY PRESENTATION

A 26-year-old pregnant woman. Her family history was not significant. She had iron iron deficiency anaemia (hemoglobin-8.7 g/dl) at the time of presentation. With the preview of anaemia, patient was started on Inj. Ferenject was planned to give with each day a dose of 500mg (one vial) intravenous over one hour. The patient developed breathlessness and myalgia half an hour after the first dose was completed. Half hour later patient had vomiting (one episode) non-projectile which was managed with an anti-emetic. A diagnosis to allergy to ferric carboxymaltose was made.



Naranjo Adverse Drug Reaction Probability Scale

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

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

NARANJO SACLE

8) DISCUSSION

The FDA just authorised ferric carboxymaltose as a medication in July 2013. Combination with carboxymaltose, a carbohydrate polymer that releases iron, ferric carboxymaltose is a colloidal iron hydroxide. This solution is administered intravenously. [5]

A deficiency in the erythrocytes' ability to carry oxygen in the blood is known as anaemia. Anaemia can be categorised according to lack of production, functional insufficiency (which results in blood loss), and nutritional inadequacy. Iron, vitamin B12, and folate are the nutrients that erythrocytes require to function. Anaemia may result from a deficiency in one of the components. Multiple transfusions can be used to treat anaemias caused by functional deficiencies, such as sickle cell anaemia, thalassemia, and others, which result in accelerated RBC destruction.[6]

One iron formulation that can be utilised at high doses and administered quickly is called ferric carboxymaltose (FCM). A single dose of up to 1000 mg can be injected in 15 minutes. FCM does not react with dextran antibodies because it is free of dextran and its derivatives.[7]

Breathlessness and myalgia were also seen in the population who were involved in the clinical trial phases but these adverse reaction were rare (<1%).The proposed reason for nausea and breathlessness is hypersensitivity reaction (anaphylactic type) which is also known as type 1 Hypersensitivity reactions[8]

The reported spontaneous case describes a 26-year-old pregnant Female patient who came to the hospital suffering from anemia. The patient was prescribed with a medication including Inj. Ferinject (500mg), IV. Emanzen – D 9 10mg), IV. Metrogyl(400mg),IV. Taxim(200mg). After 1 hr on the dose of intravenous Inj.ferinject the patient developed breathlessness, nausea, vomiting & headache. The score on the Naranjo scale for the case report of adverse drug reactions (ADRs) of Inj. Ferinject (500mg) is 6, it suggests a probable type of adverse reaction. It showed that there is causal relationship between the medications and the observed ADRs.

As a result, the administration of the iron replacement therapy was stopped i.e(Dechallenge). Inj. Avil & hydrocort was given to prevent the adverse drug reaction.

This case raises concerns about a potential adverse drug reaction (ADR) to INJ. Ferinject in this particular patient. Adverse drug reactions refer to undesirable and unintended effects of medications. In this case, the development of breathlessness, headache, nausea & vomiting after the injection of Ferinject. It is important to note that ADRs can manifest differently in different individuals, and the specific reaction observed in this patient may not be typical for everyone. The decision to stop inj Ferinject and administered inj. Avil & hydrocort indicates the attempt to manage the allergic reaction.

Further investigations and monitoring would be necessary to confirm the link between Ferinject and the observed adverse drug reaction. It is crucial to document and report such cases of adverse drug reactions to ensure patient safety and improve understanding of medication-related risks.

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.

CONCLISION-

As per case report mainly focused on adverse drug reaction of Inj. Ferinject in a anaemic pregnant woman. The report show dechallenge case study and in replacement of it antiallergic Inj. Avil and Inj. Hydrocort were administered. The study suggests a probable type of adverse reaction. It showed that there is causal relationship between the medications and the observed ADRs It suggests that the reaction followed a reasonable temporal sequence after a drug prescribed and it followed a recognized response to the suspected drug and it was confirmed by withdrawal but not by exposure to the drug.

Healthcare professionals should be aware of the potential for ADRs and be prepared to manage them appropriately, including promptly recognizing and discontinuing the offending medication if necessary. Overall, this case report highlights the importance of pharmacovigilance in monitoring patients for adverse drug reactions, spontaneous reporting particularly when introducing new medications or observing unexpected symptoms. It also emphasizes the need for further research and investigation to better understand the specific risk factors and mechanisms underlying adverse reactions to medications like Inj. Ferinject.

Further investigation, such as iron deficiency testing or consultation with a gynaecologist. may be warranted to confirm the specific drug allergy and determine whether Inj. Ferinject should be avoided in the future. Healthcare professionals should also consider documenting and reporting this adverse drug reaction to relevant pharmacovigilance systems, contributing to the overall understanding and monitoring of drug safety profiles.

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 higher scores indicating a higher probability of the ADR being drug-related.[9,10,11]

The score on the Naranjo scale for the case report of adverse drug reactions (ADRs) of Inj. Ferinject (500mg) IPD (Inpatient Department) patients is 6, it suggests a possible causal relationship between the medications and the observed ADRs.

A score of 6 on the Naranjo scale indicates a "probable" likelihood of the ADR being drug-related. The scale ranges from 5 to 8.[9,10,11]

The adverse drug reaction (ADR) in the patient with a Naranjo scale score of 6 suggests a possible causal relationship between the medications (Inj. Ferinject) and the observed reaction. The factors supporting this possibility are as follows:

1. 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.
2. 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 expected side effects or known adverse reactions of Inj. ferinject
3. Characteristics of the patient's disease: The reaction could be explained by features or characteristics of the patient's underlying disease. Certain conditions or patient factors can make individuals more susceptible to experiencing adverse reactions to medications.[9,10,11]

LIMITATION

The limitation of a case report is First the past information of patient was not given and. Second is past medication history and allergy and family history was not available.

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