



**ORIGINAL RESEARCH PAPER**

**Pharmacology**

**A RETROSPECTIVE ANALYSIS OF ADVERSE DRUG REACTIONS IN HOSPITALIZED PATIENTS**

**KEY WORDS:**

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**ABSTRACT**

Adverse drug reactions are a major cause of morbidity and mortality in hospital. This study was conducted to create the awareness, communication and reporting of ADRs among health care professionals. This study is a retrospective analysis of total 29 reported ADR during a period of May 2016 to Dec 2018 in Apollo speciality Hospitals, Trichy. These ADRs were analysed based on Naranjo scoring, Hart wigs severity scale, type of reactions, body system involved causative drugs, outcome & management. The Majority of patients who had suffered from ADRs were between 18-44 yrs (48%) of age and male patients (59%) affected more than female (41%). In our Hospital Department of General medicine (41%) has reported highest number of ADR. Skin was the most affected system 69 % followed by CVS. Ranitidine (14%) shows the largest number followed by ceftriaxone (10%) and Cefoperazone (10%). Majority of the reactions are mild (97%) and occurred during IV use (93%) All the ADRs were possible. Most of the patients were recovered (97%) early by appropriate management. The major limitation was under-reporting of ADR. It can be overcome by creating awareness to all health care professional like discussing in Drug & therapeutic committee meeting, conducting workshop.

**INTRODUCTION:**

According to WHO an adverse drug reaction is "a response to a drug that is noxious and unintended and occurs at doses normally used in man for the prophylaxis, diagnosis or therapy of disease, or for modification of physiological function" (WHO 1972)<sup>1</sup>.

Pharmacovigilance is defined as, "The science and activities relating to the detection, assessment, Understanding and prevention of adverse effects or any other possible drug-related problems".<sup>17</sup>

Adverse drug reaction Reporting is essential to analyses drug safety in post marketing phase, Post marketing surveillance of drugs is very important in investigating and controlling the risks associated with drugs once they are accessible for the use of the general population<sup>2,3</sup>.

The Central Drugs Standard Control Organization (CDSCO), Directorate General of Health Services under the aegis of Ministry of Health and Family Welfare, Government of India in collaboration with the Indian Pharmacopeia Commission (IPC), Ghaziabad is conducting a nation-wide Pharmacovigilance Program of India (PvPI) for protecting the health of the patient by assuring drug safety. The programme is coordinated by the IPC as a National Coordinating Centre (NCC).

**METHODOLOGY**

Data was collected from all departments and ADR reporting was done on the prescribed "Suspected Adverse Drug Reaction Reporting Form". Causality Assessment was performed using Naranjo scoring

The 29 suspected ADR reports received from all departments from May 2016 to Dec 2018 were analyzed retrospectively for the following parameters

**Patient characteristics:** The patient's age and sex were considered for evaluation.

**Drug & Route characteristics:** The offending drug causing ADR were classified into drug classes and were further classified, based on their route of administration.

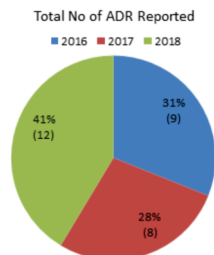
**Reaction characteristics:** The individual reactions were classified, depending on the organ system which was affected.

**Causality assessment:** Each ADR was assessed for its causality by using the Naranjo Probability scale as definite, probable and possible<sup>[4,5]</sup>.

**Severity assessment:** The ADRs were classified into mild, moderate and severe depending on their severity with the help of severity assessment criteria developed by Hart wig et al.,<sup>[4,5]</sup>.

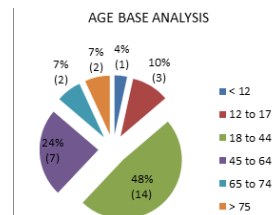
**Outcome assessment:** The patient outcomes were reported as one of the following: Fully recovered, Recovering, Unknown, and Fatal.

**RESULTS:**

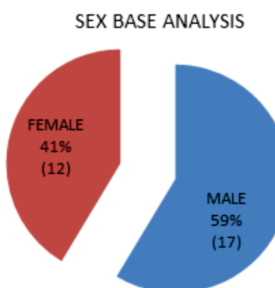


**Figure 1** Figure 1 Shows No of ADR reporting Increased from 2016 to 2018

**The patient's age and sex were considered for evaluation:**

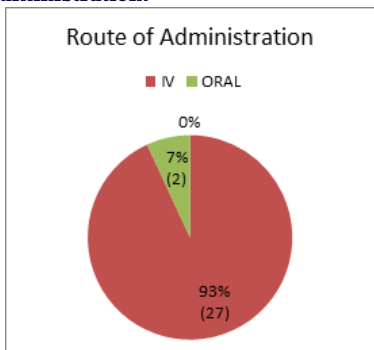


**Figure 2** Figure 2 shows 48% of ADR reported for the age group of 18 to 44 years

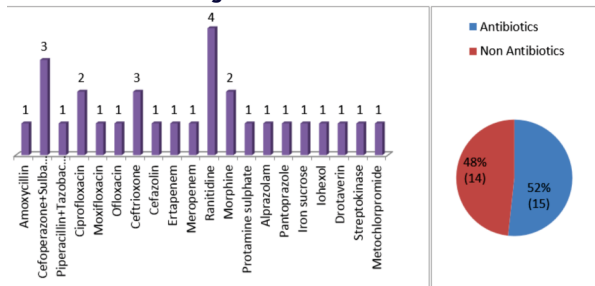


**Figure 3** Figure 3 shows male patients (59%) affected more than female (41%)

**Route of Administration:**



**Figure: 4** shows 93% of ADR occurred in I V route of Administration Drug characteristics:

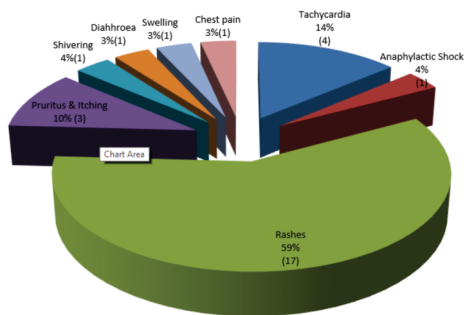


**Figure: 5**

**Figure: 5.1**

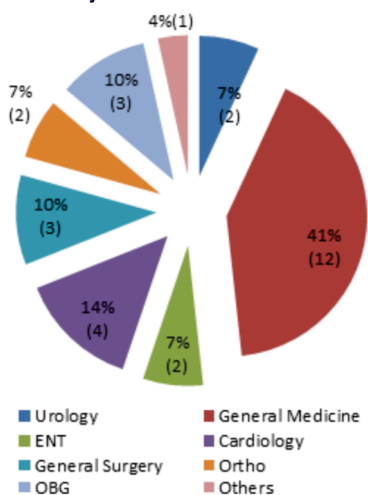
Figure 5 & 5.1 Shows 52% of the ADR Reported from Antibiotic group

**Reaction characteristics:**

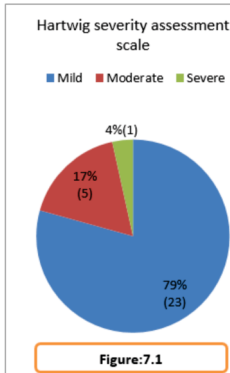


**Figure : 6** - its Shows 79% of Reported A D R from Mild Category based on the Harwigs Scale

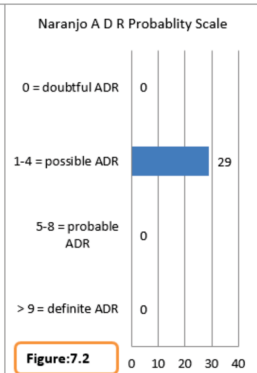
**Severity & Causality assessment:**



**Figure: 7** Figure 7 Shows General medicine (41%) has reported highest number of ADR



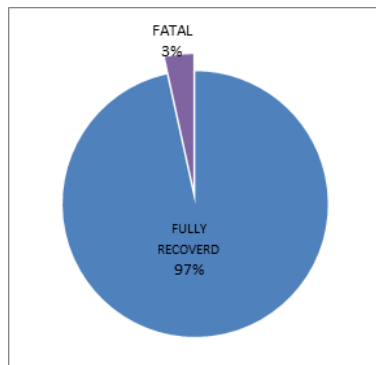
**Figure:7.1**



**Figure:7.2**

Figure 7.1 & 7.2 shows All ADR are possible ADR with 79% of Mild Severity ADR

**Outcome assessment**



**Figure: 8** Figure 8 Shows Most of the patients were recovered (97%) early by appropriate management.

**DISCUSSION:**

ADRs are a major cause of mortality and morbidity in hospitalised patients. There is under-reporting of ADR due to lack of awareness, improper communication and documentation.

Our Study results show male predominance (59%). Dutta et al., Sen M et al study results also showed similar results. Miller MA results showed Female predominance.<sup>18,19,20</sup>

The age group most commonly affected was 18 – 44yrs. Reporting of ADR less than 12 yrs. and more than 75 yrs are very less. It is very important to monitor both age groups.

Because Paediatric patients are not aware about the ADR. Geriatric patients are Susceptible for serious ADR, because of multiple drugs (drug – drug interactions), comorbidities, varying Pharmacokinetic & pharmacodynamics profile.

The organ system most commonly affected by ADRs was skin (45%) The common ADRs shown by patients were rashes, Tachycardia, pruritus& itching, diarrhoea. Similar trend was observed other studies.<sup>18,19</sup> Majority of the patients recovered (97%), but 3 % were fatal, 83 % of ADR was mild 14% was moderate & 3% was severe category.

Parenteral route was most commonly involved (93%) in ADR followed by oral (7%). For all the patients the suspected drug was stopped. Most of the Reported ADRs were categorized as possible ADR (based on Naranjo Scoring) 52% of ADR Reported in Antibiotics, 10% of the ADR was preventable. It occurred due to Wrong infusion time & wrong dilution We got approval from ethical committee. IEC APP NO: ASH/ACAD-001/03-19

**CONCLUSION**

ADR reporting is essential for drug safety evaluation in the

post marketing phase. It is an ongoing and continuous process.

By regular discussion in Drug & therapeutic committee meeting, Infectious meeting, with consultants, DMO and paramedical staff ADR reporting awareness can be created 3 ADR was occurred because of Improper dilution. So Standard dilution protocol was created. Poly pharmacy should be minimized to avoid drug – drug interaction related ADR

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