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Research Article

# Evaluation of the Adverse Drug Reactions reported to the Adverse Drug Reaction Monitoring Centre in a Tertiary Care Hospital, Ongole, Prakasam District

**Syed Shabnam[1], Tadikonda Venkata Naresh[2*], K.Chandrakala[2]**

[1]Department of Pharmacology, A.C. Subba Reddy Government Medical College, Nellore, Andhra Pradesh, India.

[2]Department of Pharmacology, Government Medical College, Ongole, Andhra Pradesh, India.

*Corresponding author: venky.naresh96@gmail.com*

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**ABSTRACT**

According to the World Health Organization (WHO), an Adverse Drug Reaction (ADR) is defined as a "noxious and unintended response to a drug that occurs at doses normally used in humans for diagnosis, prophylaxis, treatment, or modification of physiological functions1." Periodic monitoring of ADRs in hospital settings is crucial to identifying risks associated with drug use and ensuring patient safety and efficacy. Aims of current study were to evaluate and analyze ADRs reported to the AMC, GMC, Ongole, to determine the severity of ADRs using the Modified Hartwig–Siegel Scale, and assessment of the causality of ADRs using the WHO-UMC scale. ADRs reported to the AMC, Government Medical Collage (GMC), Ongole between December 2022 and August 2024 were assessed. Parameters included patient demographics, suspected drugs, organ systems involved, and categorization of ADRs based on causality and severity. The WHO-UMC scale was used for causality assessment, and the Modified Hartwig–Siegel scale for severity classification. A total of 337 ADR cases were analyzed. The most affected group was adult males (n=174). Dermatological reactions were the most frequently reported. Antimicrobials, particularly amoxicillin, were the leading drug class involved. Based on causality assessment, 256 (75%) cases were classified as 'possible'. Most ADRs (88%) were mild in severity. Antimicrobials were the leading cause of ADRs, emphasizing the need for strict antibiotic stewardship and rational prescribing practices. There is a need for increased awareness and training in pharmacovigilance.

**Keywords:** Adverse Drug Reaction; Pharmacovigilance; WHO- UMC scale, Modified Hartwig– Siegel scale, Antimicrobials

## INTRODUCTION

Medicines are the most common medical interventions to relieve sufferings but as said rightly "drugs are double edged weapons'' possessing the ability to produce both advantages and disadvantages. According to World Health Organization (WHO) ADR's- "is defined as any noxious and unintended response to a drug which occurs at doses used for prophylaxis, diagnosis, therapy or modification of physiologic function"[1]. Adverse effects may develop immediately, after prolonged medication or even after stoppage of the drug. Incidence of 10–25% ADRs has been documented in different clinical settings[2]. According to the Centre for Health Policy Research, more than 50% of the approved drugs in the United States were associated with fairly few types of adverse effects which was overlooked prior to approval[3]. At the minimum of one ADR has been reported in 10 to 20% of patients who are hospitalized[4]. Pharmacovigilance which refers to monitor ADR was launched by WHO in 1960[5]. In India the Central Drugs Standard Control Organization under aegis of Government of India, Ministry of Health and Family welfare under Pharmacovigilance Programme of India (PvPI) established Adverse Drug Reaction Monitoring Centres from July 2010[6]. The Indian Pharmacopoeia Commission which is the National Coordinating Centre is located at Ghaziabad in Uttar Pradesh. According to WHO, Pharmacovigilance is defined as "the science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problems[7]. Its main aim is to improve reporting rate of ADR's for enhancement of patient care & safety. PvPI also support public health programs by giving reliable and balanced information for the proper assessment of the benefit-risk profile of medicines[8]. Pharmacovigilance (PV)'s information is utilized to educate doctors about adverse drug effects and to regulate their use by authorities[9]. It plays crucial role in the rational use of medicines as it forms the basis for evaluating the safety of medicines.

In India, the rate of ADR reporting is 1% whereas globally it is 5%8. In India ADR monitoring and reporting activity is in infancy stage. This is as a consequence of lack of awareness about PvPI and the importance of reporting the harmful effects of medicine. Even the Health-care professionals are not prioritizing to report drug reactions and are ignoring less severe reactions. Periodic monitoring of the harmful effects of medicines used in a hospital helps to find out the risks related with the usage of drugs sequentially ensuring patients efficacy & safety. Hence, this study is to collect the data, characterize and evaluate the ADR's received to the AMC in a Tertiary Care Hospital, in Ongole, Prakasam District.

## AIM & OBJECTIVES OF THE STUDY

To evaluate and analyze the ADR's reported to the Adverse Drug Reaction Monitoring Centre in a Tertiary Care Teaching Hospital.

To determine severity of ADRs (assessed using Modified Hartwig–Siegel Scale)

To understand the spectrum of ADRs depending on causality (assessed using WHO-UMC scale).

## MATERIALS AND METHODS

After taking the Institutional Ethics Committee approval from GMC/ GGH, Ongole, a retrospective observational study was conducted in Department of Pharmacology, GMC, Ongole, Andhra Pradesh. All ADRs reported to the AMC from December 2022 to August 2024 were evaluated &analysed. All ADRs uploaded in the official web-based ICSR data management portal Vigiflow, which is the National Pharmacovigilance Data base that supports the collection, processing, analysing of ADRs and AEFI was used for the collection of the data. The parameters for evaluating ADR's include patient characteristics, suspected drugs involved, bodily system wise reactions, spectrum of ADRs based on causality assessment and severity of ADR's. The WHO- UMC scale is the tool to evaluate the causality which indicates that the suspect drug is the causative for the ADR's (Table 1).

According to the Modified Hartwig– Siegel scale, ADRs are classified as mild, moderate, and severe[10] (Table 2).

Severity grades: Mild - Level 1, 2; Moderate - Level 3, 4; Severe - Level 5, 6, 7.

### Inclusion Criteria

Reported ADRs in patients irrespective of their age and sex who have developed ADR after commencement of treatment

### Exclusion Criteria

Reported ADR's among patients who took alternative medical systems such as Ayurvedic medicine, Unani, Homeopathy, and Naturopathy. Adverse events that had not met the minimum ADR reporting criteria (identifiable reporter, an identifiable patient, an adverse reaction, and a suspect product) reported in the vigiflow data base

### Statistical Analysis

The collected data was entered in MS Excel & statistical analysis was done and the results are expressed in percentages.

## RESULTS

ADRs cases reported during the study duration were 337. In these 337 reports, males were 174 (52%) and females were 163 (48%) (Figure 1) which shows some gender difference in ADR incidence. Analysis of age distribution showed that greater incidence of ADR's were reported in adults (n= 188) followed by elderly (n= 105) and least in age group less than 18 years (n= 44) of age.

The most commonly reported System Organ Classification (SOC) as per MedDRA was Skin and Subcutaneous disorders (n= 166) followed by gastrointestinal (GIT) system (n= 79) (Table 3)

Among these SOCs the highest reported Adverse events were Rash (n= 29) followed by Pyrexia (n= 22), Fixed Drug Eruptions

**Table 1:** WHO-UMC causality assessment scale

| *Causality* | *Criteria* |
|---|---|
| Certain | The ADR follows a known response pattern to the drug, and there is a high likelihood that the drug caused the ADR based on factors such as the timing of reaction, the clinical course of the ADR, and the drug's known pharmacological properties |
| Probable | The ADR follows a reasonable temporal sequence after drug exposure, and there are no other obvious causes for the reaction. The reaction may also be consistent with the known pharmacological properties of the drug |
| Possible | The ADR occurs after drug exposure, but there are other plausible explanations for the reaction, such as co-existing medical conditions or other medication. |
| Unlikely | The ADR is unlikely to be caused by the drug-based exposure and ADR onset, the clinical course of the ADR, or the known pharmacological properties of the drug |
| Conditional/ unclassified | There is insufficient information available to classify the ADR using the criteria, and more data are required to assess the ADR |
| Un assessable/ unclassifiable | Cannot be assessed because of the insufficient data. |

**Table 2:** The Modified Hartwig–Siegel Scale

| *Level* | *Description* |
|---|---|
| 1 | No treatment change |
| 2 | Suspected drug is withheld, changed. Antidote is not given and no increase in hospital stay |
| 3 | Suspected drug withheld, otherwise changed and antidote or other treatment is required. No increase in length of hospital stay |
| 4a | Any level 3 ADR increasing the length of hospital stay at least by 1 day |
| 4b | ADR is the reason for hospital admission |
| 5 | Any level 4 ADR that requires intensive medical care |
| 6 | ADR causes permanent harm to the patient |
| 7 | ADR directly or indirectly leads to death of the patient |

**Table 3:** various organ systems involved in reported Adverse Drug Reactions

| *Adverse Event (SOC)* | *Number of reports* |
|---|---|
| Skin and subcutaneous tissue disorders | 166 |
| Gastrointestinal disorders | 78 |
| Immune system disorders | 19 |
| Nervous system disorders | 17 |
| Renal and urinary disorders | 7 |
| Hepatobiliary disorders | 6 |
| Infections and infestations | 6 |
| Musculoskeletal and connective tissue disorders | 6 |
| Blood and lymphatic system disorders | 5 |
| Psychiatric disorders | 5 |
| Cardiac disorders | 4 |
| Endocrine disorders | 4 |
| Respiratory, thoracic and mediastinal disorders | 3 |
| Vascular disorders | 3 |
| Eye disorders | 2 |
| Metabolism and nutrition disorders | 2 |
| Congenital, familial and genetic disorders | 1 |
| Ear and labyrinth disorders | 1 |
| Injury, poisoning and procedural complications | 1 |
| Reproductive system and breast disorders | 1 |

**Table 4:** Causality assessment

*Causality assessment*

| Causalityparametres | Number of ADRs | percentages |
|---|---|---|
| Possible | 256 | 75 |
| Probable | 68 | 20 |
| Certain | 13 | 5 |

(n= 20), Chills (n= 18), Utricaria (n= 12). Among the various drug classes antimicrobials (n= 136) were the most common cause of ADR followed by NSAIDs (n= 30) and antidiabetic (n= 19) & Antipsychotics (n= 19) (Figure2).

ADRs among antimicrobials were most commonly linked to amoxicillin (n= 24), ceftriaxone (n= 23), ofloxacin (n= 12), cefixime (n= 10) and metronidazole (n= 7)

Based on the WHO- UMC scale, causality assessment was performed in which possible related was assessed for 256 (75%) of cases (Table 4).

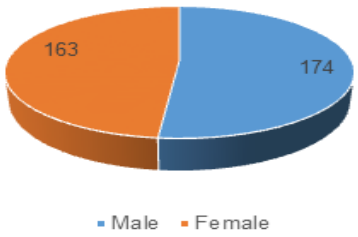


**Figure 1:** Gender distribution

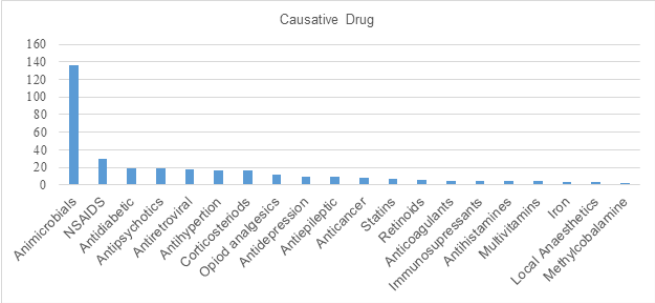


**Figure 2:** Causative Class of Drugs

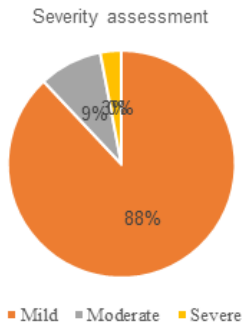


**Figure 3:** Severity assessment

Assessment of severity as per Modified Hartwig- Siegel Scale resulted in 298 (88%) mild cases, 29 (9%) moderate cases, and 10 (3%) severe cases (Figure 3).

## DISCUSSION

In this retrospective study, 337 ADRs were analysed. Demographic analysis showed that ADRs reported in male patients 174 (52%) compared to female patients was higher which is similar to the study done by Shamna et al., in which male patients were (53%) and female patients were (47%)[11]. A previous similar study done by Rani et al.,[12] showed more number of ADRs in adults followed by pediatric& elderly, which is in contrast with the present study were more number of ADRs in adults followed by elderly and least to be in pediatric age group. Among all the reported ADRs rash is the most commonly reported ADR which is homogenous to the study done by Bharathi et al.,[13]

In the present study maximum number of ADRs were reported with Antimicrobials. Among the antimicrobials penicillins (amoxicillin) was commonly reported drug, which is similar to the study done by Jung et al.,[14]. Causality assessment of ADRs were possible (75%) followed by probable (20%), which is similar to the study done by Rani et al.,[12] which resulted possible (67%), followed by probable (33%). The majority of Adverse Drug Reactions (ADRs) were graded as mild (88%), followed by moderate (9%) and severe (3%), which is similar to the study done by Shamna et al.,[11].

This study highlights the importance of reporting ADRs as it provides valuable insights in to their pattern of occurance. The underreporting of ADRs can have significant implications for patient safety, as it may lead to delayed recognition and management of potentially life-threatening adverse events. Furthermore, underreporting can also hinder the development of effective

strategies for preventing and mitigating ADRs. The reasons for underreporting of ADRs are multifactorial and may include inadequate awareness among healthcare professionals, inadequate training on pharmacovigilance, and insufficient infrastructure for reporting ADRs

Steps must be taken at the national level to promote spontaneous ADRs reporting in our country by encouraging patients to self-report any suspected ADRs, regular training programs for health-care professionals, mandatory provision of ADR reporting forms in every hospital, timely updates on the safety of drugs to the general population, exposing medical students to ADR reporting during clinical postings, and involving them in PV program

## LIMITATIONS

The number of cases reported in this study was constrained by the brief study period. The data was collected from single institution, hence findings of the study might not accurately reflect ADR trends in larger populations or in various healthcare environments. Assessment of outcome of the reactions which adds credibility to the reported ADRs were not done in the study due to loss of follow up of many mild to moderate cases which constitutes more than 95 % of reported ADRs.

## CONCLUSION

This study was conducted to evaluate & analyze the ADRs reported to ADR monitoring center in a tertiary care hospital. Among the reported ADRs antimicrobials constitute the highest reported which alarm to check the implementation of strict antibiotic guideline policies and promote the rational and safe use of them. With the reported number of ADRs in the study period, we think that there is under reporting of ADRs due to the factor that number of patients receiving treatment from our tertiary care hospital and number of drugs available. Conclusions drawn from the study can help to raise awareness among health care professionals about the importance of considering the possibility of ADRs when managing any medical condition as ADRs can significantly influence the treatment course.

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## CONFLICTS OF INTEREST

Nil

## ETHICAL APPROVAL

The study was approved by the Institutional Ethics Committee of Government Medical College, Ongole Approval No.IEC/GMC-OGL/227/2024

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None

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