**International Journal of Pharmacy and Pharmaceutical Research (IJPPR)**
Volume 30, Issue 8, August 2024 pp 76-81. **ijppr.humanjournals.com** ISSN: 2349-7203

# Assessment of Adverse Drug Events in a Tertiary Care Teaching Hospital - A Retrospective Study

**Binu KM*, CM Mukthar Rifan, Jaya Swathi B P, Faiza Fatima, Malakari Pujari, S Sharath Kumar, Saleem Akhtar, H. Doddayya**

N.E.T Pharmacy College Raichur – 584103, Karnataka, India.

Received: 2024-08-01 Revised: 2024-08-05 Accepted: 2024-08-10

## ABSTRACT

**Background:** Adverse drug events are any untoward medical occurrence that may be present during treatment with medicine. Institutes of Medicine defined adverse drug events as an "injury resulting from medical intervention related to a drug" This includes medication errors, adverse drug reactions, allergic reactions, and overdoses. Hospital adverse events are an important source of morbidity and mortality in different countries and settings and represent an important item of expenditure for health care systems and their prevention could be associated with a relevant cost-saving. **Aim:** To assess the adverse drug events like adverse drug reactions, medications errors, drug-drug interactions encountered in a tertiary care hospital. **Materials and Methods:** A retrospective observational study was conducted in tertiary care teaching hospital. Data were collected from Medical Records Department of study hospital. ADE occurred during August 2023 to October 2023 were collected. Sample size was calculated based on a previous study which recorded the prevalence of 0.74. Taking 95% confidence Interval, the required sample size for the study was 133 cases. **Results**: We analysed 76 cases of suspected ADRs, majority of adverse drug reactions were found in skin and subcutaneous systems i.e., 35(46.05%) followed by general disorders i.e., 18 (23.68%). Causality assessment by Naranjo's Scale showed that majority of adverse drug reactions were probable i.e., 90% (69) which is followed by 6 cases of possible i.e., 7.8% (6) adverse drug reactions. Most of adverse drug events were caused due to antibiotics. Most of the medication error was caused by lack of knowledge or experience i.e., 21(58.33). We observed that most of drug-drug interactions were due to distribution mechanism i.e., 14(66.66%) cases. Moderate interactions were in higher in number i.e., 12(57.14%). **Conclusion:** Adverse drug events were commonly occurs in study hospital. Adverse drug reactions, medication errors and drug-drug interactions vary according to treatment settings and still significantly underestimated. Under reporting of ADE is an increasing and challenging problem. Further researches, using individual and contextual risk factors should be performed in order to develop a better understanding of ADEs.

**Keyword:** Adverse Drug Events, Adverse Drug Reactions, ADR reporting system, Drug-Drug Interactions, Education, Medication Error, Yellow Card

## INTRODUCTION

Adverse drug events (ADEs) are any untoward medical occurrence that may be present during treatment with medicine. Institutes of Medicine defined ADEs as an "injury resulting from medical intervention related to a drug." This includes medication errors, adverse drug reactions (ADRs), allergic reactions, and overdoses. Hospital adverse events are an important source of morbidity and mortality in different countries and settings and represent an important item of expenditure for health care systems and their prevention could be associated with a relevant cost-saving. They are among the leading causes of morbidity and hospitalization in health facilities. In a study done across low- and middle-income countries, the rate of adverse events was around 8%, of which 83% could have been prevented and 30% led to death.[1]

An adverse drug reaction (ADR) is an unwanted, undesirable effect of a medication that occurs during usual clinical use. Adverse drug reactions occur almost daily in health care institutions and can adversely affect a patient's quality of life, often causing considerable morbidity and mortality. Adverse drug reactions may cause patients to lose confidence in or have negative emotions toward their physicians and seek self-treatment options, which may consequently precipitate additional ADRs. Around 5% of all hospital admissions are the result of an ADR, and around 10%– 20% of inpatients will have at least one ADR during their hospital stay (Kongkaew 2008; Lundkvist 2004; Pirmohamed 1998). The actual incidence of ADRs may be even greater because some ADRs

mimic natural disease states and may thus go undetected and/or unreported. Although some ADRs present as minor symptoms, others are serious and cause death in as many as 0.1%–0.3% of hospitalized patients (Lazarou 1998; Pirmohamed 1998). Adverse drug reactions should be quickly identified and managed to limit their detrimental effects on the patient.[2]

An interaction is said to occur when the effects of one drug are changed by the presence of another drug, herbal medicine, food, drink or by some environmental chemical agent. The outcome can be harmful if the interaction causes an increase in the toxicity of the drug. For example, there is a considerable increase in risk of severe muscle damage if patients on statins start taking azole antifungals. Patients taking monoamine oxidase inhibitor antidepressants (MAOIs) may experience an acute and potentially life-threatening hypertensive crisis if they eat tyramine-rich foods such as cheese. The more drugs a patient takes the greater the likelihood that an adverse reaction will occur. One hospital study found that the rate was 7% in those taking 6 to 10 drugs but 40% in those taking 16 to 20 drugs, which represents a disproportionate increase. A possible explanation is that the drugs were interacting.[3]

Medication error is defined as "any preventable events that may cause or lead to inappropriate medications use or patient harm while the medication is in the control of health care professionals, patients, or consumer. Such events may be related to professional practice, health care products, procedures, anion, product labelling systems including prescribing, order communication, packaging, and nomenclature, compounding, distribution, administration, education, monitoring and use". Many studies have described medication error rates in hospital settings, but data for primary care is relatively scarce. This is particularly true of low- and middle-income countries, despite the increasing use of medications. Estimating the prevalence of medication errors is difficult due to the varying definitions and classification systems employed. Rates can vary depending on the denominator used (e.g., patient, prescription or a specific medication). The challenge is compounded by variations in health care system organization and the availability and use of incident reporting systems. [4]

As adverse drug events are occurring commonly in hospital, there is a need to assess the adverse drug reactions, medication errors, and drug interactions. Majority of the hospitals have Pharmacovigilance programme, so adverse drug reactions can be monitored and reported, but drug interactions and medication errors were under reported. Minimising drug interactions and medication errors are also very important as they will cause adverse drug events. Preventing ADEs will help to provide cost effective drug therapy, thereby improves quality of life of patients. In this regard we conducted the study entitled "**Assessment of Adverse Drug Events in A Tertiary Care Teaching Hospital - A Retrospective Study"** to assess the adverse drug events encountered in a tertiary care hospital.

**MATERIALS ANE METHODS:**

A retrospective cross-sectional study was conducted in tertiary care teaching hospital. Data were collected from medical record department of study hospital. Any ADE occurred during August 2023 to October 2023 were included. Sample size was calculated based on a previous study which recorded the prevalence of 0.74. Taking 95% confidence Interval, the required sample size for the study was minimum of 133 cases. Data were collected using suitably designed data collection forms. The study was approved by IEC committee by issuing Ethical Clearance Certificate.

**Collection of Data**

The study was carried out for a period of 6 months. Project team collected patient data from Medical Records Department. Data was collected by a suitably designed patient data entry form. Patients socio-demographic characteristics were incorporated in Part A, vital signs and laboratory investigation in part B, diagnosis and plan of treatment in plan C. Additionally, ADR reporting forms issued by Indian Pharmacopeial Commission, Suspected ADR reporting forms, Naranjo's scale form, Medication Error reporting form and Drug-Drug interaction reporting forms were used in the study.

**Inclusion Criteria:** All the cases of individuals encountered with adverse drug events like adverse drug reactions, medication errors and drug-drug interactions.

**Exclusion Criteria:** Cases of individuals who had not encountered any of adverse drug events and case with incomplete information.

**Statistical Analysis:** Data were entered in to Microsoft excel sheet and results were presented using descriptive statistics like percentage, mean etc.

International Journal of Pharmacy and Pharmaceutical Research (IJPPR)
Volume 30, Issue 8, August 2024 pp 76-81. ijppr.humanjournals.com ISSN: 2349-7203

**RESULTS:**

**System commonly affected by ADRs**

Majority of ADRs were found in skin and subcutaneous systems i.e., 35(46.05%) followed by general disorders i.e., 18 (23.68%), Respiratory systems 10 (13.15%), Cardiovascular and GI systems 2(2.36%) respectively as shown in Table.No.01.

**Table.No. 01: System commonly affected by ADRs (n=76)**

| Sl.No | System effected | Number of cases (%) |
|---|---|---|
| 1 | CNS | 9 (11.84) |
| 2 | Skin snd subcutaneous systems | 35 (46.05) |
| 3 | Respiratory systems | 10 (13.15) |
| 4 | Cardio vascular systems | 2 (2.63) |
| 5 | GI systems | 2 (2.63) |
| 6 | General disorders(Facial edema, periorbital edema, fatigue, malaise, fever etc) | 18 (23.68) |

**Types of ADRs**

Most commonly occurred ADR were found to be Pruritus, erythema i.e, 35(46.05) followed by miscellaneous i.e, 18(23.68), wheezing and cough i.e, 10(13.15), head ache and light headedness i.e, 9(11.84), prolongation of QT interval, nausea and vomiting i.e, 2(2.63) as shown in Table.No.02.

**Table.No.02: Types of ADRs (n=76)**

| Sl.No | Types of ADRs | Number of cases (%) |
|---|---|---|
| 1 | Head ache, light headedness | 9 (11.84) |
| 2 | Pruritus, erythema | 35 (46.05) |
| 3 | Wheezing, cough | 10 (13.15) |
| 4 | Prolongation of QT interval | 2 (2.63) |
| 5 | Nausea, vomiting | 2 (2.63) |
| 6 | Miscellaneous | 18 (23.68) |

**Department Distribution of ADRs**

Majority of participants were admitted in general medicine i.e., 56 (73.6%), followed by dermatology i.e., 11 (14.4%), orthopaedics 4(5.3%) Surgery and OBG i.e., 2(2.6%) respectively. Least number of cases was found in Paediatrics department i.e., 1(1.3%) participant as shown in Table.No.03.

**Table.No.03: Department wise Distribution of ADRs (n=76)**

| Sl.No | Department | Number of cases (%) |
|---|---|---|
| 1 | General medicine | 56 (73.61) |
| 2 | Orthopedics | 4 (5.3) |
| 3 | Surgery | 2 (2.6) |
| 4 | OBG | 2 (2.6) |
| 5 | Paediatric | 1 (1.3) |
| 6 | Dermatology | 11 (14.4) |

International Journal of Pharmacy and Pharmaceutical Research (IJPPR)
Volume 30, Issue 8, August 2024 pp 76-81. ijppr.humanjournals.com ISSN: 2349-7203

**Causality assessment of suspected ADRs by Naranjo's scale**

Causality assessment of suspected ADRs were done using Naranjo's Scale. It was found that majority of ADRs were probable i.e., 69(90%) is followed by 6 cases of possible i.ie, 6(7.8% ) and one case of definite 1(1.2%) ADR as show in Table. No. 04.

**Table.No.04: Causality assessment of suspected ADRs by Narango's scale**

| Sl.No | Causality assessment (Naranj's scale) | Number of cases (%) |
|---|---|---|
| 1 | Definite | 1 (1.2) |
| 2 | Probable | 69 (90) |
| 3 | Possible | 6 (7.8) |

**Common drug category causing ADEs**

Table 5 shows that majority of ADEs were caused due to Antibiotics i.e., 37 (48.6%), blood products 19 (14.4%) cases of ADEs followed by 6(7.84%) by NSAIDS. The least ADEs were caused due to Multi-vitamins and Anti-Tubercular Drugs and Antidepressants i.e., 1(1.31%).

**Table.No.05: Common Drug category causing ADEs (n=76)**

| Sl.No | Drugs | Number of cases (%) |
|---|---|---|
| 1 | Antibiotics | 37(48.6) |
| 2 | Blood products | 19(14.4) |
| 3 | Antiepileptics | 2(2.63) |
| 4 | Anti-emitics | 2(2.63) |
| 5 | Emitics | 2(2.63) |
| 6 | Anti-deppressants | 1(1.31) |
| 7 | Anti-diabetics | 2(2.63) |
| 8 | NSAID's | 6(7.84) |
| 9 | Multi-vitamins | 1(1.31) |
| 10 | Anti-tuberculosis | 1(1.31) |

**Type of Medication Error**

The study found that majority of medication errors were due to Prescribing patterns of Prescriptions i.ie, 32 (88.9%) followed by 6(16.6%) administration errors. The least type of medication error was dispensing error i.e., 1(2.7%) as shown in Table.No. 06.

**Table.No. 06: Type of Medication Error (n=36)**

| Sl. No | Types of medication error | Number of cases (%) |
|---|---|---|
| 1 | Prescribing Error | 27(75) |
| 2 | Dispensing Error | 1(2.7) |
| 3 | Administration Error | 6(16.6) |
| 4 | Miscellaneous* | 2(5.56) |

*include compliance error, monitoring errors etc.

International Journal of Pharmacy and Pharmaceutical Research (IJPPR)
Volume 30, Issue 8, August 2024 pp 76-81. ijppr.humanjournals.com ISSN: 2349-7203

**Possible cause of Medication error**

Most of the medication error was caused by lack of knowledge or experience i.e., 21(58.33). The next leading cause of medication error was use of abbreviations i.e., 8(22.22%) which was followed by 7(19.44%) cases of negligence of peak hour as depicted in Table.No.07.

**Table.No.07: Possible cause of Medication error (n=36)**

| Sl.No | Possible cause of Medication error | Number of cases (%) |
|---|---|---|
| 1 | Lack of knowledge / Communication | 21(58.33) |
| 2 | Negligence of Peak hour | 7(19.44) |
| 3 | Use of Abbreviations | 8(22.22) |

**Categorization of drug-drug interaction based on severity**

Categorization of drug-drug interactions based on severity were done. The data showed highest number of interactions were moderate i.e., 12(57.14%). The second highest number was of Major 7(33.33%) which is followed by 2(9.52%) minor interactions as shown in Table.No. 08.

**Table.No. 08: Categorization of drug-drug interaction based on severity (n=21)**

| Sl.No | Severity | Number of cases (%) |
|---|---|---|
| 1 | Major | 7(33.33) |
| 2 | Moderate | 12(57.14) |
| 3 | Minor | 2(9.52) |

**DISCUSSION**

A retrospective observational study was carried out by collecting the data from 133 case records using a predesigned data collection form and forms issued by CDSCO for Adverse Drug Reaction Reporting to assess the Adverse Drug Events reported in a tertiary care hospital.

Majority of ADRs were found in skin and subcutaneous systems i.e., 35(46.05%) followed by general disorders i.e., 18 (23.68%), Respiratory systems (10 (13.15%), Cardiovascular and GI systems (2(2.36%) respectively. The results were similar to reports published by **Mhaidat et.al [5].** More cases of anaphylactic and cutaneous adverse reactions were recorded.

Out of 76 participants majority of participants were admitted in general medicine i.e., 56 (73.6%), followed by dermatology i.e., 11 (14.4%), orthopedics department 4(5.3%) participants, Surgery and OBG departments i.e., 2(2.6%) respectively. Least number of cases was found in Paediatrics department i.e., 1(1.3%) participant.Data evidenced that paediatric and OBG department had few drugs per prescription. So ADRs due to polypharmacy and drug interactions were minimized.

In causality assessment scale of suspected ADRs using Naranjo's Scale. It was found that majority of ADRs were probable i.e., 90% (69) which is followed by 6 cases of possible i.ie, 7.8% and one case of Definite (1.2%) ADR. The results show very close similarity to study published by **Joshi DB et.al [6].**

The data showed that majority of ADEs are caused due to Antibiotics i.e., 48.6% (37) which closely similar to the study published by Sahilu T et.al. Blood products caused 14.4% (19) cases of ADEs followed by 7.84% (6) ADEs of NSAIDS. The least ADEs were caused due to Multi-vitamins and Anti-Tubercular Drugs and Anti0depressants i.e., 1.31% (1) which showed slight contradiction from the study published by **Sahilu T et.al.[1]**

The data depicted majority of medication errors was from prescribing patterns of prescriptions i.ie, 32 (88.9%) which is followed by 6(16.6%) administration errors. These results are similar to **Patel N et.al.[7]** The least type of medication error found was dispensing error i.e., 1(2.7%).

While analysing possible causes of medication errors, most of the medication errors were caused by lack of knowledge or experience i.e., 21(58.33) which is similar to the data from study published by **Branch J et.al.**[8] The next leading cause of medication errors was use of abbreviations i.e., 8(22.22%) which is followed by 7 (19.44%) cases of negligence of peak hour.

We found that highest number of drug interactions were moderately severe i.e., 12(57.14%) which is similar to study published by **Kulkarni V et.al.**[9] The second highest number was of major 7(33.33%) which is followed by 2(9.52%) minor interactions which is contrary to research article published by **Kulkarni V et.al.**

## CONCLUSION

The adverse drug events that occur in a tertiary care hospital setting were retrospectively investigated. We found that different factors that can lead to adverse drug reactions, medication errors and drug-drug interactions vary according to hospital and treatment settings and this is becoming more prevalent and challenging. To gain a better understanding of variability and the appropriate strategies to combat adverse drug events, further studies should be conducted, incorporating individual and contextual risk factors. There is a need for continues educational interventions to healthcare professionals to minimize the occurrence of ADEs.

## References

1. Sahilu, T., Getachew, M., Melaku, T., Sheleme, T. Adverse Drug Events And Contributing Factors Among Hospitalized Adult Patients At Jimma Medical Center, Southwest Ethiopia: A Prospective Observational Study. Curr. Ter. Res. 2020;93
2. Schatz SN, Weber R J.American Society Of Health-System Pharmacists. ASHP Guidelines On Adverse Drug Reaction Monitoring And Reporting. Am J Health Syst Pharm 1995;52:417-9.
3. Baxter K. Stockley's General Considerations And An Outline Survey Of Some Basic Interaction Mechanisms. In: A Textbook Of Stockley's Drug Interactions. 8th Ed. Great Britain 2008:1-8.
4. Medication Errors: Technical Series On Safer Primary Care. Geneva: World Health Organization; 2016.4-8.
5. Mhaidat NM, et al; Reporting antimicrobial related adverse Drug events in Jordan : an analysis from the vigibase Database.Antibiotics.2023;12(624):1-16.
6. Joshi BD, Mahajan R. Ninama K, Shukla F, Panchal C. A Study Of Cutaneous Adverse Drug Reaction Patterns With Causality And Severity Assessment At A Tertiary Care Centre. Int J Of Clinical And Experimental Dermatology.2018; 4 (3):185-193.
7. Patel N, Desai M, Shah S, Patel P, Gandhi A. A study of medication errors in a tertiary care hospital. Perspect Clin Res.2016;7:168-73.
8. Branch J, Hiner D, Jackson V, The impact of communication on medication error.2021:1-13.
9. Kulkarni V, Bora S S, Sirisha S, Saji M, Sundaran S. A study on drug–drug interactions through prescription analysis in a South Indian teaching hospital. Ther Adv Drug Safe. 2013; 4(4): 141–46.

How to cite this article:
Binu KM et al. Ijppr.Human, 2024; Vol. 30 (8): 76-81.

Conflict of Interest Statement: All authors have nothing else to disclose.