Research Article

A prospective observational study on assessment of adverse drug reactions in the in-patients of general medicine department at a tertiary care hospital

Dhanush Bellapu*, Padmalatha Kantamneni, Sravanthi Appikonda, Priyanka Jamalapurapu, Lavanya Eli, Lavanya Kancharla

Vijaya Institute of Pharmaceutical Sciences for Women, Enikepadu, Vijayawada, Andhra Pradesh– 521108 India

Received: 7 May 2021 Revised: 14 June 2021 Accepted: 15 June 2021

Abstract

Objective: According to World Health Organisation (WHO), "an Adverse Drug Reaction (ADR) is a response to a drug which is noxious and unintended that occurs at doses which are normally used to prophylaxis, diagnosis, therapy of disease or for the modifications of physiological function". The main aim of the present study was to evaluate and assess the ADRs with prescribing rationale in the patients admitted in General Medicine Department at a tertiary care teaching hospital. **Material and Methods:** It is a Prospective Observational Study that was carried out for a period of 6 months in new Government General Hospital, Vijayawada. **Results and conclusion:** A total of 208 subjects were included in this study and assessed using WHO causality assessment scale, Naranjo's Causlity assessment scale and Hartwig's Severity assessment scale. Among the 208 subjects 54(25.96) ADRs were observed. Most of the ADRs were seen in males when compared to females between the age groups of 31-40 years and 51-60 years and affected gastrointestinal tract. Depending upon the Causality, most of the ADRs were 'Probable' as per WHO-UMC Causality Assessment Scale and 'Possible' as per Naranjo's Causality Assessment Scale.

Keywords: ADRs, drugs, tertiary care hospital, General Medicine department, observational study, causality assessment and severity assessment.

According to the World Health Organization (WHO), Adverse Drug Reaction (ADR) is defined as "a response to a dangerous and unintended drug, which occurs in doses commonly used for prophylaxis, diagnosis, treatment or physical therapy" (Shukla et al., 2017). Although India accounts for 10% of global drug use, the reported ADR of drugs is 2%. This is mainly due to the poor report of drug abuse in India (Bahri, 2016). The incidence of ADRs as a whole leads to emergency admissions ranging from 0.2% to 41.3% worldwide, while 28.9% are safe (Palanisamy, 2013). Hospital admissions for ADR ranged from 2.9% to 5.6%. About 35% of patients in hospitals receive ADR. In India, the incidence of ADR is between 5.9 to 22.3% while deaths due to ADR accounts as 1.8% (Sivasankaaran et al., 2016). Many factors can put a patient at the forefront of the diagnosis of ADR patients with one or more risk factors for ADR including the pharmacy of Poly, many diseases and current, age, drug characteristics, gender, race and genetic factors (G. Parthasarathi, Sten Olsson). The purpose of this study was to evaluate and evaluate Adverse Drug Reaction with reasonable determination in patients admitted to the General Department of Health of a tertiary education hospital.

Address for Corresponding Author:
Dhanush Bellapu
Vijaya Institute of Pharmaceutical Sciences for Women, Enikepadu, Vijayawada, Andhra Pradesh– 521108 India
Email: dhanushbellapu@gmail.com

Materials and methods

Source of data: Collection of data from the patients admitted into General Medicine

Department of New Government General Hospital, Vijayawada.

Study Procedure: All the patients admitted in the General Medicine department during the

study duration were followed from the day of admission to the day of discharge and during the follow up.

Study Site: New Government General Hospital, Vijayawada.

Study Duration: The study was carried out for a period of 6 months from 1st August 2019 to 31st January 2020.

Study Design: A Prospective Observational Study.

Study Criteria: The study was carried out by considering the

DOI: https://doi.org/10.31024/ajpp.2021.7.3.5

following criteria:

Inclusion Criteria:

- All the patients admitted with-
- Age: 21 to 60 years,
- Gender: Male and Female.

Exclusion Criteria:

- Paediatrics and Geriatrics
- Patients who were discharged without notice
- Patients transferred from other departments.

Sample size: 208 subjects

Software Used: MS Excel

Ethical Approval: Approved by Institutional Ethical Committee (IEC) of Siddhartha

Medical College and Government General Hospital, Vijayawada with IEC Ref. No. IEC/2019/096C/SMC on 19th August, 2019.

Results and discussion

The present Prospective Observational study was done at Department of General Medicine, New Government General Hospital, and Vijayawada over a period of 6 months since July 2019 to December 2019. A total number of 208 cases were collected. Among them 54 ADRs were observed.

The age and gender wise distribution of 54 ADRs reported in the study was presented in Table 1 and Figure 1. Among the reported 54 ADRs 11 ADRs were reported in the age group of 21-30 yrs. 15 ADRs were reported in the age group of 31-40 yrs, 13 ADRs were reported in the age group of 41-50 yrs and 15 ADRs were reported in the age group of 51-60 yrs.

Table 1. Demographics of ADRs reported in Study Population

Age Groups (yrs)	No. of ADRs reported	No. of males	No. of females
21-30	11	6	5
31-40	15	10	5
41-50	13	9	4
51-60	15	9	6

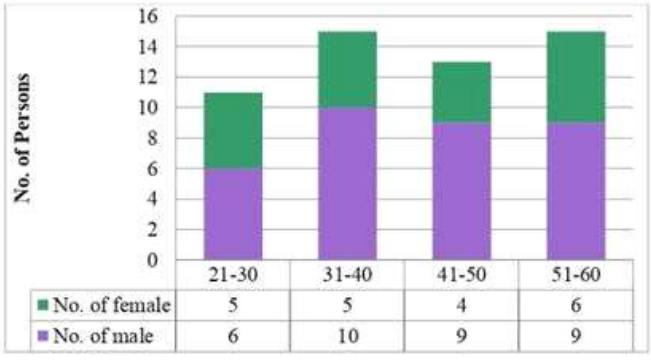

Figure 1. Demographics of ADRs reported in Study Population

The number and percentage of population reported with ADR's and population without any ADR was presented in Table 2 and Figure 2. In the study population 25.96% of ADRs were reported during the study.

The distribution of the reported ADRs was presented in Table 3 and Figure 3. One ADR was reported in 44 cases, two ADRs were reported in 2 cases and three ADRs were reported in 2 cases.

The number and percentages of causality of 54 ADRs reported among the sample size of depending upon the WHO-UMC Causality Assessment scale (Parida S, 2013) (Table 4 and Figure 4). Certain were 8, probable were 13,

Table 2. Percentage of ADRs in the study population

Population	Percentage (%)
Population with ADRs	25.96
Population without ADRs	74.04

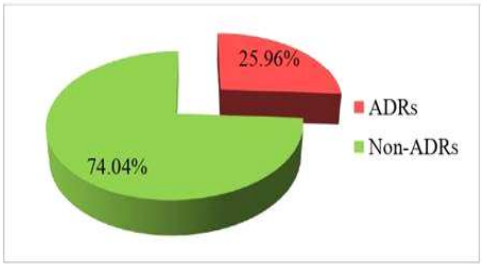

Figure 2. Percentage of ADRs in the study population

Table 3. Distribution of reported ADRs among the Study Population

No. of ADRs in a case	No. of cases	Percentage (%)
One	44	81.48
Two	2	3.7
Three	2	3.7

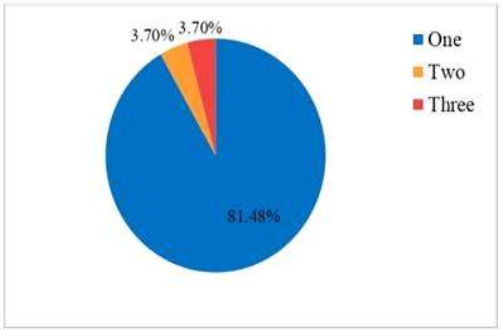

Figure 3. Distribution of reported ADRs among the Study Population

possible were 41, unlikely were 1, unclassified were 0 and unclassifiable were 0.

The number and percentages of causality of 54 ADRs reported among the sample depending on Naranjo's Causality Assessment scale (Naranjo's et al., 1981) was presented in Table 5 and Figure 5. Unlikely were 0, possible were 29, probable were 22 and definite were 3.

Table 4. ADRs based on WHO-UMC Causality Assessment Scale

Causality	No. of ADRs	Percentage (%)
Certain	8	14.81
Probable	31	57.42
Possible	14	25.92
Unlikely	1	1.85

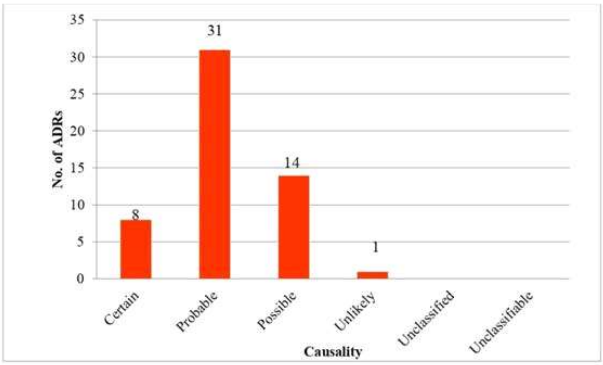

Figure 4. ADRs based on WHO-UMC Causality Assessment Scale

Table 5. ADRs based on Naranjo Causality Assessment Scale

Causality	No. of ADRs	Percentage (%)
Unlikely	0	0
Possible	29	53.70
Probable	22	40.75
Definite	3	5.55

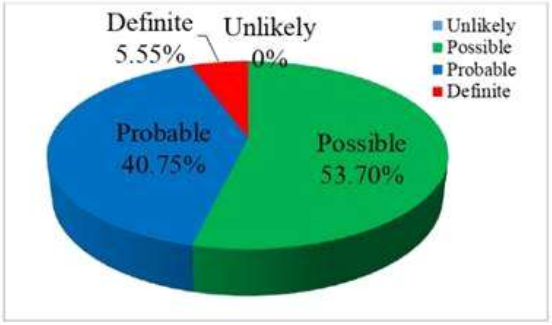

Figure 5. ADRs based on Naranjo Causality Assessment Scale

Table 6. Organ systems affected by ADRs

System	No. of ADRs	Percentage (%)
Gastrointestinal tract	20	37.03
CNS	13	24.07
Skin and appendages	08	14.81
ENT	4	7.04
others	3	5.56
CVS	2	3.71
Respiratory	2	3.71
Musculoskeletal	2	3.71

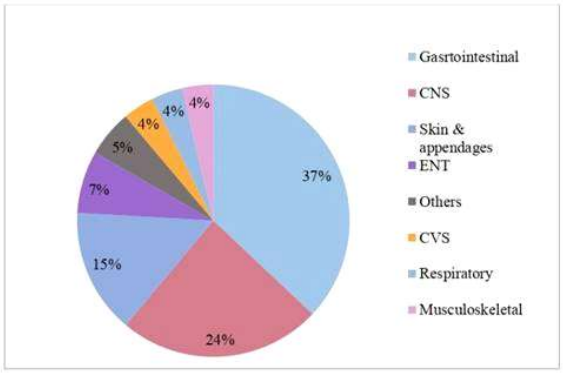

Figure 6. Organ systems affected by ADRs

The number and percentage of organ systems that were mostly affected due to the ADRs was presented in Table 6 and Figure 6. The most commonly affected organ system was gastrointestinal tract followed by CNS, Skin and appendages, ENT, others (fever), CVS, Respiratory system and Musculoskeletal system.

The number and percentage of ADRs reported in 54 cases due to different category of drugs was presented in Table 7 and Figure 7. The category of drugs that were mostly causing ADRs were Antibiotics, Anti-hypertensives, Anti-platelets, Corticosteroids, Statins, Analgesics, Anti-emetics, Anti-epileptics, Anti-malarials, Proton pump inhibitors, Supplements, Antispasmodics, Anxiolytics, Benzodiazepines, Bronchodilators, Laxatives and Psycho-stimulants.

Conclusion

From this study we conclude that 25.96% (54) of ADRs occurred in the population of 208, mostly seen in the age group of 31-40 years and 51-60 years. Male were mostly affected by ADRs when compared to female population. Depending upon the Causality, most of the ADRs were 'Probable' as per WHO-UMC Causality Assessment Scale and 'Possible' as per Naranjo's Causality Assessment Scale. The organ system which was vulnerable to ADRs was

Table 7. Drugs that caused ADRs

Category of drugs	No. of ADRs	Percentage (%)
Antibiotics	18	33.34
Antihypertensives	5	9.26
Anti-platelets	5	9.26
Corticosteroids	4	7.42
HMG CoA reductase inhibitors	4	7.42
Analgesic	2	3.7
Anti-emetics	2	3.7
Anti-epileptics	2	3.7
Anti-malarials	2	3.7
Proton pump inhibitors	2	3.7
Supplements	2	3.7
Antispasmodics	1	1.85
Anxiolytics	1	1.85
Benzodiazepines	1	1.85
Bronchodilators	1	1.85
Laxative	1	1.85
Psycho stimulants	1	1.85

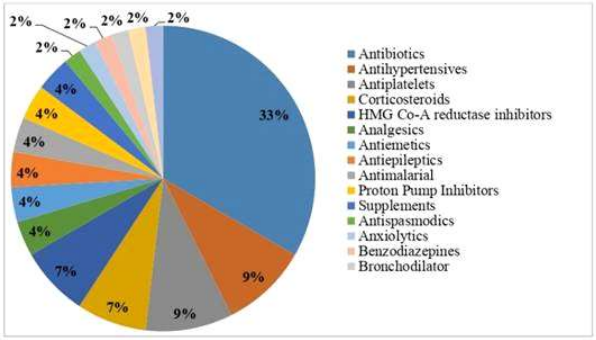

Figure 7. Drugs that caused ADRs

gastrointestinal tract followed by cardiovascular system. The drugs which caused more ADRs were Antibiotics followed by Anti-hypertensive.

Acknowledgement

The authors are thankful to Vijaya Institute of Pharmaceutical Sciences for Women, Enikepadu, Vijayawada and Government General Hospital, Vijayawada for their constant support and help.

References

Bahri C. 2016. How India tackles adverse drug reactions – by ignoring data. India Spend Feb 8. Available from: URL:http://www.indiaspend.com/ cover-story/how- india-tackles-adverse-drug-reactions-by-ignoring-data-45036

Budnitz DS, Lovegrove MC, Shehab N, Richards CL. 2011. Emergency Hospitalizations For Adverse Drug Events in Older Americans, New England Journal of Medicine, 365, 2002-2012.

Chung W. 1942. Teratogens and their effects, Journal of Nutrition, 24:321- 333.

Claudia G, Paola MC, Elenora M, Giuseppina TR, Giuseppe M, Giorgio B, Franco R, Rosarita F, Edoardo S, Vincenzo A. 2018. Adverse Drug Reactions in Hospitalized Patients: Results of the FORWARD (Facilitation of Reporting in Hospital Ward) Study to improve ADRs monitoring in hospital wards, Frontiers in Pharmacology, 9:350- 373.

Davies EC, Green CF, Taylor S, Paula R. Williamson D, Mottram R, Pirmohamed M. 2009. Adverse drug reaction in hospital In patients: A prospective analysis of 3695 patients – episodes, Plos ONE, 4(2), e4439.

Faviel F, Gonz´alez-Galarza L, Takeshiti YC, Eduardo JM, Santos FK, Helena M Thomaz M, Luciana A, Silva Sd, Luiz A, Silva Te, Gurpreet S, Ghattaoraya, Alfirevic A, Jones AR, Middleton D. 2014. Allele frequency net 2015 update: new features for HLA epitopes, KIR and disease and HLA adverse drug reaction associations, Nucleic Acids Research, 43:784-788.

Parthasarathi G, Olsson S. 2012. Adverse Drug Reactions and Pharmacovigilence. G. Parthasarathi, Karin Nyfort-Hansen, Milap C Nahata(Ed.), A Textbook of Clinical Pharmacy Practice Essential concepts and skills, Universities Press, 104-116.

Gor AP, Desai SV. 2008. Adverse Drug Reactions (ADR) in the in Patients of Medicine Department of a Rural Tertiary Care Teaching Hospital and Influence of Pharmacovigilance in Reporting ADR, Indian Journal of Pharmacology, 40(1):37- 40.

Jayanthi CR, Bhavya Darshini M. 2018. A study to analyze the pattern, causality, severity, predictability and preventability of adverse drug reactions among patients attending department of obstetrics and gynecology at a tertiary care hospital, National Journal of Physiology, Pharmacy and Pharmacology, 9(2):172-177.

Kamala K, Vinutha S, Suresh N. 2019. A study of patterns of Adverse Drug Reactions in a tertiary care hospital of Andhra Pradesh, India, International Journal of Basic Clinical Pharmacology, 8(5):860-864.

Mohan H. 2015. "Immunopathology Including Amyloidosis" Praveen Mohan, Tanya Mohan, Sugandha Mohan (Ed.), Textbook of Pathology, Jaypee, 57-61.

Naranjo CA, Busto U, Sellers EM, Sandor P, Ruiz I, Roberts EA. 1981. A method for estimating the probability of adverse drug reactions. Clinical Pharmacology and Therapeutics, 30:239-45. https://doi.org/10.1038/clpt.1981.154 ; PMid:7249508.

Palanisamy S, Arul Kumaran KSG, Rajassekaran A. 2013. A Prospective Studyon Adverse Drug Reactions in a Tertiary Care South Indian Hospital, Indian Journal of Pharmacy Practice, 6(2):49-60.

Parida S. 2013. Clinical causality assessment for adverse drug reactions. Indian Journal of Anaesthiology,

57:325

Patel TK, Prakash H, Vohora BP, Patel B, Desai N. 2014. Adverse Drug Reactions in a tertiary care teaching hospital in India: Analysis of spontaneously reported cases, International Journal of Basic Clinical Pharmacology, 3(6):1078-1085.

Ponnusankar S, Gupta M, Basutkar Satyanarayana R, Dural R. 2016. Pattern of Adverse Drug Reactions in a Govt. District Headquartes Hospital in Tamilnadu, India, Indian Journal of Pharmacy Practice, 9(1):32-36.

Sharma S, Tandon VR, Khajuria V, Mahajan V, Gillani Z. 2014. Adverse drug reactions profile of antimicrobials: A 3-year experience, from a tertiary care teaching hospital of India, Indian Journal of Medicine, 33(3):393-400.

Shukla P, Gupta A, Kaur A, Chhabra H. 2017. Adverse Drug Reactions pattern in a tertiary level teaching hospital: A retrospective study, Indian Journal of Pharmacy Practice, 10 (1):27-31.