How to Cite:
Pawar, P. A., Deshmukh, T. A., & Naik, J. B. (2022). Evaluation and assessment of adverse drug reactions at a tertiary care hospital: A prospective study. *International Journal of Health Sciences*, *6*(S2), 6938–6946. https://doi.org/10.53730/ijhs.v6nS2.6734

Evaluation and assessment of adverse drug reactions at a tertiary care hospital: A prospective study

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***Abstract*---**Background: Improvement of patient care and safety in relation to the use of medicines with medical and paramedical interventions remains to be an important parameter. Adverse drug reactions have proved a significant problem in healthcare for a decade. The main aim of ADRs monitoring is to the promoting rational use of drugs, safe use of medicines improving patient care, improving public health. Objectives: The study aimed to determine the prevalence of ADRs in a tertiary care hospital to generating data safety of medications. Materials and Methods: The Prospective, observational study was conducted in the wards of a tertiary care Hospital. All patients were monitored for ADRs during their admission period. ADRs are a common occurrence but are often not recognized. Even if recognized, they are underreported as many physicians are unaware that all ADRs should be reported to ADR monitoring centers. Results and Discussion: Over the study period of two years, a total of 325 patients reports were monitored. The ADRs observed were higher in male patients and the highest number of ADRs were reported in the case of Sacubitril/valsartan followed by Amlodipine and in most of the cases drug is withdrawn. The age group belongs to 51-60 years have reported maximum numbers of ADRs. Conclusion: Continuous monitoring by a clinical pharmacist in a hospital setup will reduce the occurrence of ADR and improve patient safety. There is an increasing need for interventions for the prevention of ADR-related health

problems. Better knowledge of preventable ADRs could help to design strategies to protect patients from being affected by ADRs.

***Keywords*---**adverse drug reaction, pharmacovigilance, causality assessment, patient safety.

Introduction

World Health Organization defines an adverse drug reaction (ADR) as “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 modification of physiological function". The science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problem is pharmacovigilance. Pharmacovigilance helps in the safety and serves as an indicator of the standards of clinical care practiced within a country. ADRs have been regarded as a major public health problem since they represent a sizable percentage of admissions and an economic burden[1]. Prevention, monitoring, and reporting of adverse drug reactions is still a challenge among healthcare professionals. Even though some adverse drug reactions are minor and can be resolved quickly some can cause permanent disability or death. It is the responsibility of the healthcare professionals to detect, investigate, manage and report adverse drug reactions.

Adverse drug reporting plays an important contribution in maintaining the drug regulation to protect public health by identifying, evaluating, and minimizing safety issues to ensure that the overall benefits of medicines outweigh the risks. That is to monitoring the post-marketing surveillance, drug safety, efficacy, and quality of drugs, as well as the accuracy and appropriateness of the drug information available to the public to reduce the adverse drug reactions. The purpose of documenting adverse drug events is to prevent future injuries for patients. New adverse drug reactions are often discovered when drugs are used in larger or in different populations than studied during initial clinical trials. Therefore, documentation and reporting become a crucial element in clarifying the side effect profile of a drug. But recent data on the incidence and clinical characteristics of ADRs which occur following hospital admission are lacking[2]. It is clear that adverse drug reactions adversely affect patient's quality of life and can also cause patients to lose confidence in the healthcare system and reduce the patient therapeutic outcome and medication adherence because of the related ADRs of each medicine that the patient experience. Apart from that, there is a significant impact through increase costs of patient care and the potential to lengthen hospital stays[3].

The main aim of the study is ADRs monitoring to promote the rational use of drugs, safe use of medicines improving patient care, improving public health, and determining the prevalence of adverse drug reactions in a tertiary care hospital. It is essential to improve the quality and quantity of ADR reports and to promote surveillance programs in health care facilities. The present study depicted an overview of the different types of ADRs encountered in a tertiary care hospital. ADRs are an important cause of morbidity and mortality all over the world and

are an important public health concern. It inflicts a negative impact on the treatment and exerts a greater economic burden on the patient if it results in prolongation of the duration of hospitalization or other comorbidities. Therefore, the practicing physicians, as well as the nursing staff, should be sensitized to the importance of ADR reporting to their respective pharmacovigilance centers. Medical science has grown in leaps and bounds since ancient times. Modern-day pharmaceutical drugs have changed the way diseases are managed and controlled. They have increased life expectancy and improved quality of life for millions of people. However, despite all the benefits, evidence continues to suggest that adverse reactions to medicines are a common, yet often preventable, cause of illness, disability, and even death.

Material and Methods

Study design

A prospective, observational study was carried out using the Spontaneous reporting method. Spontaneous reporting and intensive monitoring are the most suitable methods in clinical/hospital set up. The study was designed as a prospective, observation, voluntary reporting study. This study was based on those patients who experienced an adverse reaction to medicine use, either during their stay in hospital or outside the hospital, and visited the outpatient department and ultimately reported to clinical pharmacist[4-6]. All In-patients of both genders who experienced an ADR were enrolled for the study, with the approval of the Institutional Ethics committee and the consent of the study population. There are four elements of the ADR case:

1. An identifiable patient.
2. An identifiable reporter.
3. A suspect drug.
4. An adverse reaction

Number of Patients

Total 325 patients have reported adverse drug reactions on the administration of medicines. Adverse Drug Reaction Monitoring was carried out at Institute. For some newly approved cardiovascular drugs the pharmacovigilance study has been carried out as; Ticagrelor, Amlodipine, Telmisartan, Apixaban, Sacubitril/valsartan, Midodrine , Azilsartan, Efonidipine, Macitentan and Riociguat.

Study criteria

Inclusion criteria: Patients with ADR, of any age of either sex, have reported to the clinical pharmacist from the outpatient department in India.
Exclusion criteria: The ADR that due to Medication errors, overprescribing, overdosing/excess consumption, drug-drug interaction, drug-food interaction, drug interaction with the use of the alternative system of medicine.

Data collection

Data on the reported ADRs were evaluated to understand the pattern of the ADRs with respect to patient demographic disease, nature of the reactions, characteristics of the drugs involved, and outcome of the reactions. The collected data was analyzed using descriptive statistics, showing numbers and percentages respectively.

The data collected by the informants regarding the use of their data on adverse drug reaction for research purpose and their assurance that their identity shall not reveal at any stage without their due concurrence. The informants were also assuring their identities too shall not be disclosed while making a pharmacovigilance reporting in the research work as well as data basis. This is standard practice under the pharmacovigilance programme of India.

Analysis of ADRs

The severity of adverse drug reactions was assessed using the WHO-UMC scale (Edwards, 2012). According to the WHO-UMC scale (Edwards, 2012) causality assessment scale, ADRs were classified into certain, probable, possible, unlikely, unclassified, and unclassifiable.

Results

A total number of 325 patients have reported Adverse drug reactions. Sacubitril/valsartan has shown the highest number of adverse drug reaction reported 15.69% followed by Amlodipine 15.07%, Ticagrelor 12.61%, Riociguat 10.46%, Azilsartan 9.84%, Apixaban 8.61%, Efonidipine 8%, Telmisartan 7.07%, Midodrine 7.07%, and Macitentan 5.53% as shown in fig 1. Most of the adverse drug reaction are shown by 51-60 age group 25.53% followed by 61-70 age group**;** 23.38%, 41-50 age group; 14.46%, 71-80 age group 12.30%; 31-40 age group 11.69%; 21-30 age group 4.61%; 11-20 age group 0.30% and lowest by 01-10 age group 0% as shown in table no. 1 and fig. no. 2. Mostly male patients have reported adverse drug reaction 62.76% and female patients 37.23% as shown in table no. 2 and fig. no. 3. 60.92% of adverse drug reaction are reported by doctors, 9.23% by Public hospital doctors 11.38% by Other Healthcare worker and 18.46% by patients. Doctors have reported more adverse drug reactions maybe they are well aware of the medical field which may be difficult for patients to understand. Most of the adverse drug reactions are reported are of Type- A 57.53% and Type-B 42.46%.

The outcomes show that 26.87% of patients reported that outcomes are recovered, 9.84% recovering, 8.92% not recovered, 2.46% fatal and 52% are unknown. In 26.15% drug is withdrawn, 6.76% drug is reduced, 12% does not change, 8.61% not applicable, and 46.46% untraced. In 47.07% of cases, adverse drug reaction is mild, 45.84% moderate and 7.07% is severe. Distribution of ADRs by WHO-UMC causality assessment parameters has shown Certain is 46.46%, 12.0% Probable, Possible 16.30%, Unlikely 8.61%, Unclassified 15.69% and Unclassifiable 0.92% type of adverse drug reaction

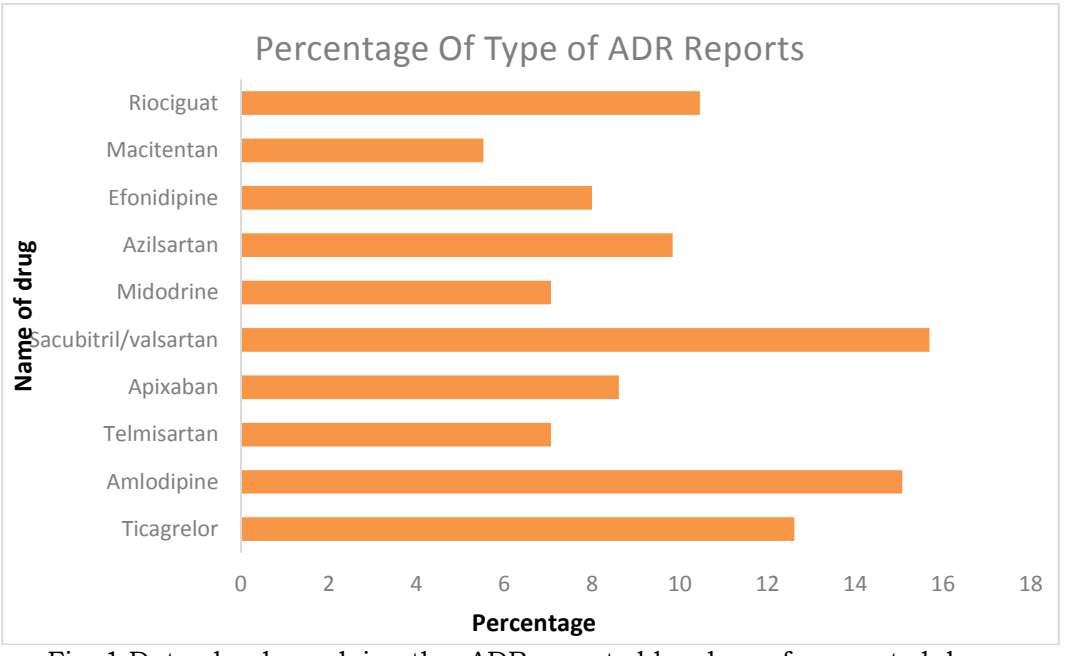

Fig. 1 Data clearly explains the ADR reported by class of suspected drugs

Table no. 1- Distribution of ADRs by Age

S.No.	Age group(year)	No. of Reports	Percentage of ADRs Report
1.	01-10	0	0.00%
2.	11-20	1	0.30%
3.	21-30	15	4.61%
4.	31-40	38	11.69%
5.	41-50	47	14.46%
6.	51-60	83	25.53%
7.	61-70	76	23.38%
8.	71-80	40	12.30%
9.	81-90	25	7.69%
10.	91-100	0	0.00%

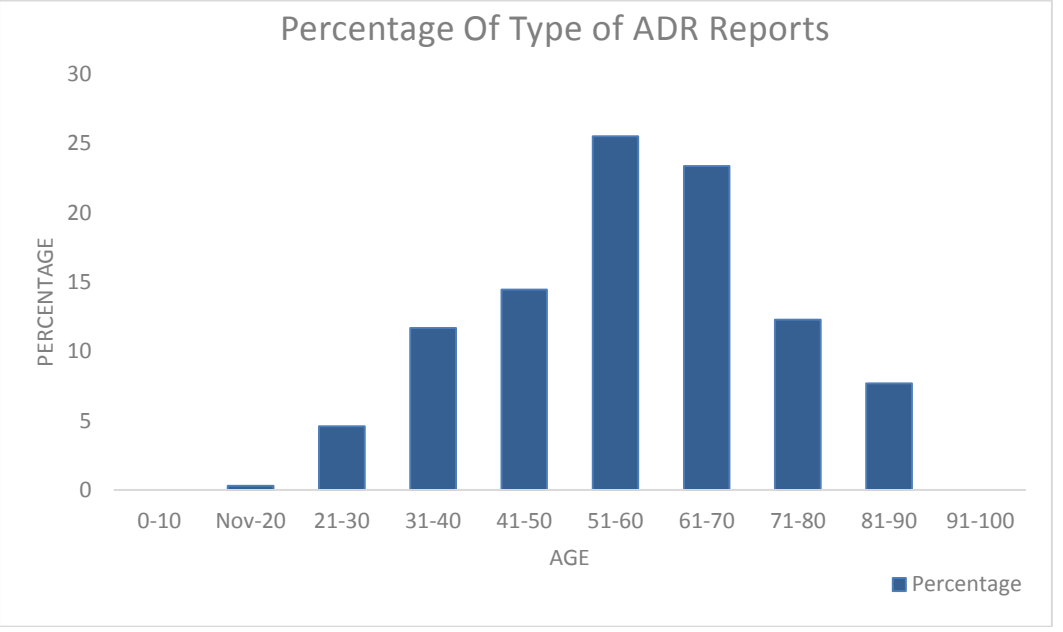

Fig. No.2 Age distribution of the patients who had encountered ADRs

Table No. 2- Distribution of ADRs by Sex

S. No.	Sex	No. of Patients Reports	Percentage
1.	Male	204	62.76%
2	Female	121	37.23%
3.	Others	0	0%

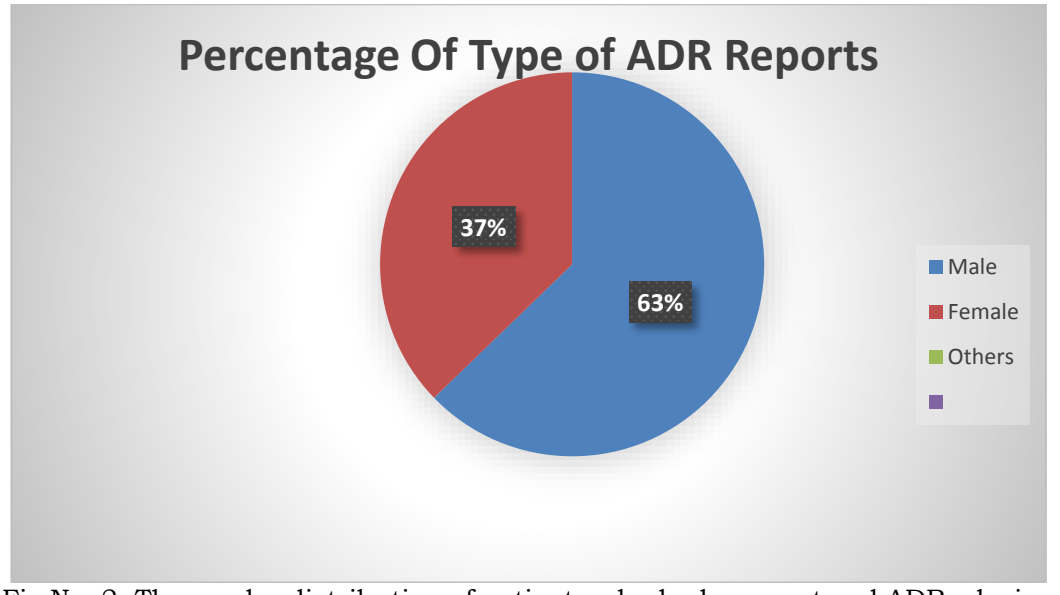

Fig.No. 2: The gender distribution of patients who had encountered ADRs during the study period

Table No. 3 Distribution of ADRs by WHO-UMC causality assessment parameters

S. No.	WHO-UMC causality assessment parameters	No. of Patients Reports	Percentage
1.	Certain	151	46.46%
2	Probable	39	12.0%
3.	Possible	53	16.30%
4.	Unlikely	28	8.61%
5.	Unclassified	51	15.69%
6.	Unclassifiable	3	0.92%

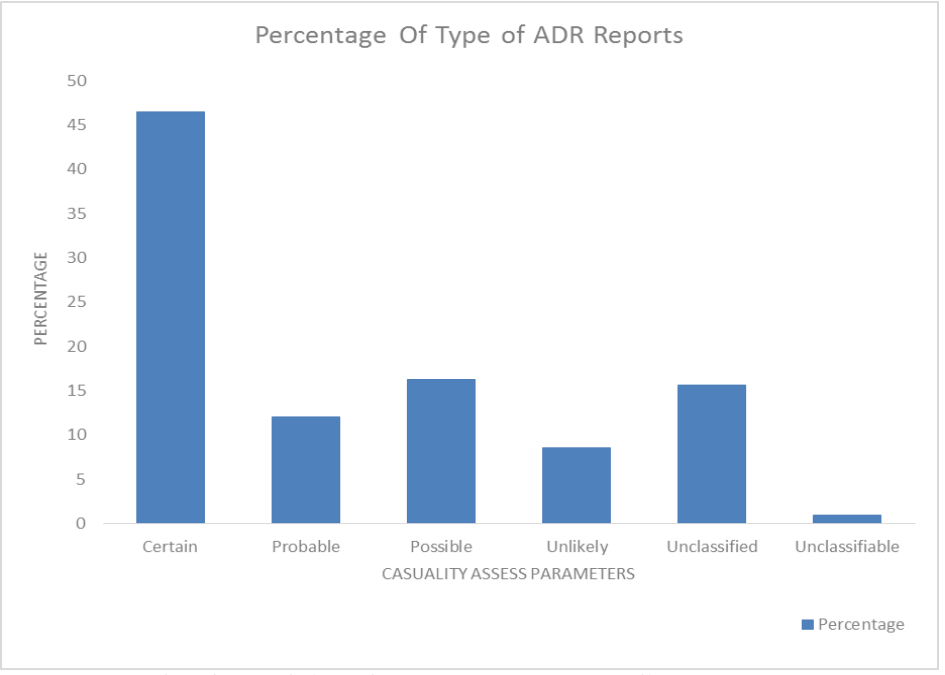

Fig.No. 4: Data clearly explains the WHO-UMC causality assessment parameters

Discussion

To prevent or reduce harm to patients and thus improve public health, mechanisms for evaluating and monitoring the safety of medicines in clinical use are vital. In order to prevent adverse drug reactions continuous monitoring of medications by a clinical pharmacist in a hospital setup will reduce the occurrence of ADR and improve patient safety. The rational use of medicines by prescribing lower doses and prefer not to use multiple therapies in the very first stage of medication should be encouraged. Health professionals such as nurses or pharmacists play a major role in monitoring drug therapy prescribed by the medical practitioners as they provide information to patients about medications and their rational use and also monitor the health and progress of patients in response to medications to ensure their safety and efficacy. Hence, health professionals should periodically be educated about adverse reactions and should be encouraged for spontaneous reporting. Over the study period of 2 years, a total

number of 325 ADRs were reported. ADRs were higher in male patients in comparison to females. A predominance of dizziness, Nausea, Headache were observed. In some cases, skin and urinary tract related problems were also observed. Most of the ADR reported by patients having Sacubitril/valsartan, Amlodipine, Ticagrelor, and Riociguat. However, Telmisartan, Apixaban, Midodrine, Azilsartan, Efonidipine, and Macitentan have reported a lesser number of ADRs.

The majority of the ADRs were managed by withdrawing the suspected drug. In 26.87% of patients reported that outcomes are recovered. The causality assessment of the ADRs has been carried out shows that the majority of the ADRs were found to be certain. Adverse drug reaction is a significant limitation to the success of therapeutics. It is essential to improve the quality and quantity of ADR reports and to promote surveillance programs in health care facilities. The present study depicted an overview of the different types of ADRs encountered in a tertiary care hospital. It highlighted that ADR is mostly prevalent among elder individuals. Detection, prevention, and treatment of ADR will not only improve the quality of life of the patient but will also reduce the cost. Thus, the implementation of pharmacovigilance programs in the hospitals is essential to ensure safe pharmacotherapy and improve patient compliance.

Conclusion

The study relates to the pattern and incidence of ADRs in the cardiac clinic of a tertiary care hospital. Pharmacovigilance plays a role in the scientific understanding of the safety profile of drugs and the issuance of advisory to the regulatory authorities. The spontaneous reporting system of ADRs is one of the commonest methods of detecting a signal in pharmacovigilance. According to the WHO, pharmacovigilance signal is "reported information on a possible causal association between an adverse event and a drug, the relationship being unclear or incompletely documented previously."

Pharmaceutical industries have also started taking part in pharmacovigilance program and have taken initiative by setting up a separate cell and self-online reporting system to counteract any adverse effects of their products[7]. Even the safety information of pharmaceutical products is communicated to doctors by pharmaceutical companies in the form of “dear doctor letters.”[8] This study aims to emphasize the awareness of the health-care providers on vigilant monitoring of ADRs and to encourage prompt reporting of the same to prevent the occurrence of ADRs. The present study had some limitations as it is an observational study of short duration; still, this would give an insight into the current situation and of trends in ADRs in tertiary health-care centers and will help to increase awareness.

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