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ADR Monitoring and Reporting in General Medicine Department of Tertiary Care Hospital

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Abstract: ***Background: Anadverse drug reaction (ADR) is defined as a response to a medicinal product that is noxious and unintended. ADRs drive up healthcare expenses and significantly contribute to morbidity and mortality. Pharmacovigilance systems help regulatory agency choices made in many nations by detecting signals from data from the worldwide ADR register and preventing risks associated with drug usage, particularly for recently commercialized pharmaceuticals. Only a few medications are taken off the market, primarily because of hepatotoxicity. The biggest drawback of automatic notification of ADRs is under - reporting, which makes it the least expensive, most accessible, and most popular way to identify new drug safety issues. Increased patient, physician, government, and pharmaceutical company involvement and the application of new technology will characterize the future of pharmacovigilance and ADRs. Methods: A prospective observational study conducted in a tertiary care hospital over a period of 3 months. All patients meeting inclusion criterea were enrolled in study. Results and Discussion: Out of 50 patients 17 adr were collected and majority adr were occured in age group 31 - 45 years, according to Causality assessment 17 adrs were probable of which 8 adrs were mild and contributed to 47.8% of total ADR. Most of the patients who experienced ADR, were recovered with the treatment and management of ADR including drug withdrawal. A total of 5 drug related ADR were observed during study which were considered already as drug alerts by pharmacovigilance drug safety alert. Conclusion: Patients' safety and improvement in health care delivery system is important and one crucial step is reporting adr. By reporting adr and providing important drug information, patients quality of life can be improved***

Keywords: Adverse drug reaction, Pharmacovigilance, Drug alerts, Patients safety.

1. Introduction

An adverse drug reaction (ADR), as defined by the WHO, is an undesirable effect of taking medication. This term has a different meaning than "side effect" because side effects can be both advantageous and harmful. An adverse event (AE), whether or not it is related to the administration of the drug, is any unanticipated or inappropriate occurrence that occurs while the drug is being taken. With each additional prescription a patient accumulates, the probability of an ADR incident rises, directly increasing the length of stay. Multiple drug therapy is more typical among ADRs. [1]

They might also lead to a lower quality of life, more physician visits, hospital stays, and even results in death. Additionally, they raise the cost of health care delivery system which significantly burden health care resources as a result.

Finding solutions to the issue and ways to prevent it effectively can be aided by researching the pattern and range of ADRs. Following a product's global introduction, post - market surveillance studies can be used to evaluate the data that led to drug recalls, regulatory agency safety alerts, and changes in product labeling. ADR reports have also been shown to be practical tools for pharmacological research and for enhancing medication utilization. [2]

Less than 50% of ADRs are typically detectable during drug development, with the remaining more than 50% being discovered following global launch and during the whole product life cycle. Because of this, examining the ADRs following the introduction of new medicine is crucial. [3]

The most frequent causes of ADR are incorrect diagnosis, improper dosage, inadequate patient assessment, non - compliance, drug - drug interactions, drug interactions with food or herbal remedies, self - medication, fake drugs, and expired medications. Age, the number of medications a patient takes, and conditions that affect drug distribution or metabolism, such as renal or hepatic insufficiency, congestive heart failure, anemia, and alcoholism, are some risk factors for adverse drug responses that have been proposed to date. [4]

Type A: Dose - related Reactions, Type B: Non - dose related Reactions, Type C: Dose and Time - related Reactions, Type D: Time - Related Reactions, Type E: Withdrawal Reactions, and Type F: Unexpected Failure of Therapy are the different categories for adrs.

Patient - related factors (such as age, gender, allergies, body weight, and fat distribution) and medication - related factors (such as polypharmacy, drug dose, and frequency) are critical determinants of adverse drug reactions. [5]

Pharmacovigilance (PV) is one of the primary methods used globally to enhance patient safety and care by identifying issues related to medication use and evaluating the benefits, efficacy, dangers, and side effects to minimize injuries and maximize therapeutic results. [6]

Therefore, Monitoring drug safety is crucial to the healthcare system and providing high - quality medical care. According to the WHO, it is described as the science and actions involved in identifying, evaluating, comprehending, and preventing side effects or any other drug - related issues.

ADR monitoring is defined as the practice of continuously observing the adverse effects brought on by the usage of any medicine. Pharmacovigilance is crucial to the role of ADR monitoring. [7]

Pharmaceutical regulators are required by law to monitor the market for their goods and keep track of any potential adverse reactions.

The WHO Causality Scales and the Naranjo Scale are the causality evaluation tools for suspected ADRs. The severity evaluation scale of ADR in use is the Hartwig scale. In Preventability, the Schumock and Thornton Criteria are applied. [8]

The Role of Regulatory authorityin Pharmacovigilance

Regulatory Authority is responsible for designing, implementing, and supervising regulations and guidelines to ensure that drugs meet safety and quality standards. Conversely, pharmacovigilance focuses on identifying, evaluating, comprehending, and preventing adverse effects and other drug - related issues. Regulatory Authority upholds the pharmaceutical industry's highest compliance and safety standards. The top priority is ensuring that all drugs are manufactured in strict adherence to the necessary regulations and guidelines. [9]

RA's key responsibility is to provide support and guidance in preparing and submitting drug approval applications to regulatory authorities. This involves a rigorous evaluation and assessment process to ensure that all requirements are met and that the drug is safe, effective, and of the highest quality. But the work continues beyond there. Even after approval, RA conducts ongoing inspections, audits, and other activities to ensure that drugs comply fully with all regulations and guidelines. This includes monitoring the manufacturing and distribution processes, verifying the accuracy of drug labelling and packaging, and ensuring that Good Manufacturing Practices (GMP) are always followed. [9]

Major Regulatory Agencies

Every country has its own regulatory authority, which is responsible to enforce the rules and regulations and issue guidelines for drug development, licensing, registration, manufacturing, marketing and labeling of pharmaceutical products. [10]

The various roles and responsibilities of regulatory authorities are as follows:

1. Regulatory authorities are responsible to review clinical trials of both nonregistered medicinal substances and new indications of registered medicinal substances. It has a statutory obligation to ensure that the drugs available in the country fulfils the necessary requirements for safety, quality and efficacy.2. Regulatory authorities has the responsibility to close down an on going trial in the case there are serious breaches of Good Clinical Practice. They are responsible to implement a regulatory system where in all clinical trials to be conducted in the country have to register with them.

Regulatory authorities

Country/Continent	Regulatory Authorities
International	• ICH • WHO • WTO
Europe	• EMEA (European Medicine Evaluation Agency)
India	• CDSCO (Central Drug Standard Control Organization)
US	• USFDA • DHHS (Department Of Health & Human Services) • NCCAM (National Center For Complementary & Alternative Medicine)
UK	• MHRA (Medicines & Healthcare Products Regulatory Authority)
Australia	• TGA (Therapeutic Goods Administration)
China	• SFDA (State Food & Drug Administration)
Brazil	• National Health Servillance Agency (NHSA)
Newzealand	• Medsafe (Medicines & Medical Devices Safety Authority)

2. Regulatory authorities will have the overall responsibility to promote, ensure and monitor compliance by approved ethics committees in a country with relevant legislation, regulations and guidelines including guidelines for Good Practice in the Conduct of Clinical Trials in Human Participants in the country. They are responsible for effectively reviewing all the documents (containing both clinical and non clinical data) before giving permission for the marketing of a new drug in any country to ensure the efficacy and safety of the drug in humans.

Drug Regulators Agencies in India

1) **CDSCO:** In India, the Central Drugs Standard Control Organization ('CDSCO') is the main regulatory body currently regulating import, sale and manufacture of medical devices which have been notified as drugs by virtue of Section 3 (b) (IV) of the D&C Act. The CDSCO lays down standards of drugs, cosmetics, diagnostics and devices and issues licenses to drug manufacturers and importers. It also lays down regulatory measures, amendments to Acts and Rules and regulates market authorization of new drugs, clinical research in India and standards of imported drugs etc. [11]

2) **National Institute of Health and Family Welfare (NIHFW)**
NIHFW is an Apex Technical Institute, funded by Ministry of Health and Family Welfare, for promotion ofhealth and family welfare programmers in the country through education, training, research, evaluation, consultancy and specialized services. The NIHFW was established on March 9, 1977 by a merger of the National Institute of Health Administration and Education (NIHAE) with the National Institute of Family Planning (NIFP).
3) **DRUG TECHNICAL ADVISORY BOARD (DTAB)**
The Central Government constitute a Board (to be called the Drugs Technical Advisory Board) to advise the Central Government and the State Governments on technical matters arising out of the administration of D&C, Act 1940.
4) **Indian Pharmacopoeia Commission (IPC**) is an Autonomous Institution of the Ministry of Health and Family Welfare, Govt. of India. IPC is created to set standards of drugs in the country. Its basic function is to update regularly the standards of drugs commonly required for treatment of diseases prevailing in this region. It publishes official documents for improving Quality of Medicines by way of adding new and updating existing monographs in the form of Indian Pharmacopoeia (IP). It further promotes rational use of generic medicines by publishing National Formulary of India. IP prescribes standards for identity, purity and strength of drugs essentially required from health care perspective of human beings and animals. IPC also provides IP Reference Substances (IPRS) which act as a finger print for identification of an article under test and its purity as prescribed in IP.

2. Materials and Methods

A three month prospective observational study was carried out in the general medicine department of tertiary care hospital. An appropriate data collecting form and an ADR reporting form were created to gather and record the patient medical data. Daily reviews of the general medicine department's hospitalized patient case sheets occurred during the study period. The study included patients who might experience an ADR while in the hospital and those admitted due to an ADR.

When suspected ADRs are identified, they are brought to the attention of the appropriate medical professional. The necessary information, including the patient's sociodemographic information, diagnosis, laboratory test information, information about the medications used during the hospitalization (including the name of the drug, dosage form, frequency, route of administration, and duration of treatment), as well as the reaction to the medication and its management, was recorded in the patient data collection form and the ADR monitoring and reporting form.

The patient data collection form and the ADR reporting form are used to analyze the reaction's causation, severity, and Preventability using the appropriate scales after the trial. The WHO probability scale (definite, probable, possible, unclassifiable, unlikely, conditional) and Naranjo's scale (definite, likely, likely, unlikely) were used to determine the cause of the ADRs. In addition, the ADRs were evaluated for Preventability using Modified Schumock and Thornton's Criteria (certainly preventable, probably preventable, not preventable) to determine the severity level (mild, moderate, severe).

Statistical Analysis
The patient's medication history, comorbidities, diagnoses, and medications were among the qualitative factors that were characterised using the frequency/percentage method. The classifications of age, causality, probability, severity, and preventability were given as percentages and associated frequencies. SPSS version 16.0 was used to analyse the data that was gathered.

3. Results

Age - wise distribution
The study's participants include patient between the age group of 18 - 80 years. Compared to other age groups, patients between 41 and 60 years had a higher incidence of ADR. The distribution of patients with ADR incidence by age is shown in Table 1.

Gender - wise distribution
Out of the 50 patients enrolled, there were 24 males and 26 females. When compared to men (48%), females (52%) had the highest percentage of ADRs. The specifics are shown in Table 2.

Pattern of suspected ADR among Patients
The analysis found cases of eight illnesses to be present. It was discovered that GI - related issues (41.17%), cough (17.64%), head and Hypoglycemia (11.6%), and swelling (5.88%) were the most prevalent ailments—table 3 details how diseases were distributed among these patients with or without ADRs.

Table 1: Age - wise Distribution

Age Group (years)	Total Number of Patients (n=50)	Number of Patients with ADRs (n=17)
18 - 30	10 (20%)	03 (30%)
31 - 45	17 (34%)	06 (35.29%)
45 - 60	13 (26%)	06 (46.15%)
61 - 75	08 (16%)	02 (25%)
76 - 90	02 (4%)	00 (0%)

Table 2: Gender - wise distribution

Gender	total number of patients (n=50)	Number of patients with ADR (n=17)
Male	24 (48%)	08 (33.3%)
Female	26 (52%)	09 (34.61%)

Table 3: Pattern of ADR among Patients

Symptoms	With ADRs (n=17)	Without ADRs (n=30)
GI Related	41.17%	4 (8.00%)
Cough	17.64%	6 (35.29%)
Headache	11.76%	7 (47.06%)
Hypoglycemia	11.76%	5 (29.41%
Swelling	5.88%	7 (41.18%)

Drugs Responsible for ADRS

Amoxicillin + Clavulanic (11.7%), Sulfamethoxazole + Trimethoprim (8.8%), antihypertensive (34.64%), antibiotic, Telmisartan, and proton pump inhibitor each anticoagulant, followed by antiemetics and antifungal medicines, were the drug classes that most frequently produced ADRs.

Table 4: provides information on the medications that cause ADRs.

Table 4: Drugs responsible for ADRS

Drug Class	Drug Name	Frequency
Antibiotics	Amikacin	1 (2.9%)
	Amoxicillin + Clavulanic acid	4 (11.7%)
	Ceftriaxone	1 (2.9%)
	Sulfamethoxazole + Trimethoprim	3 (8.8%)
	Vancomycin	1 (2.9%)
	Azithromycin	1 (2.9%)
	Doxycycline	1 (2.9%)
Anti - Diabetic	Insulin	2 (5.8%)
Antihypertensive drugs	Telmisartan	1 (2.9%)
	Amlodipine	1 (2.9%)
	Antihypertensive	(34.64%)

Symptoms associated with ADRS

Hypoglycaemia (11.76%), Hyperuricemia (5.88%) and Cough (5.88%) were the most frequently symptoms seen with suspected drugs, Table 5 lists the suspected medications as well as ADRs.

Table 5: Suspected Drugs with ADR

Drug	Pattern of ADR	Frequency (n=17)
Insulin	Hypoglycemia	2 (11.76%)
Telmisartan, levitiracetam	Cough	1 (5.88%)
Amlodipine	Swelling	1 (5.88%)
Furosemide	Hypereurecimia	1 (5.88%)
Hydrochlorothiazide	Hyperuricemia	1 (5.88%)
Metoprolol, Enoxaparin sodium	headache	2 (11.76%)
Hydrocortisone	Increase Appetite	1 (5.88%)
Cefixime	Diarrhea	1 (5.88%)
Tramadol	Constipation	2 (11.76%)
Pantoprazole	Abdominal pain	2 (11.76%)
Ondansetron	Constipation	1 (5.88%)
Fluticasone	Dry cough	1 (5.88%)

Assessment of ADRS

Naranjo's causality assessment of ADRs: Given that 4 (23.5%) reactions were definite, and 3 (17.64%) responses were possible, the Naranjo causality scale reveals that 10 (58.82%) were probable ADRs accounted for the majority of the ADRs. Fig.1 shows how the Naranjo scale was used to evaluate ADR.

Severity	Number of ADRs (n=17)	Percentage
Definite	4	23.53%
Probable	10	58.82%
Possible	3	17.65%

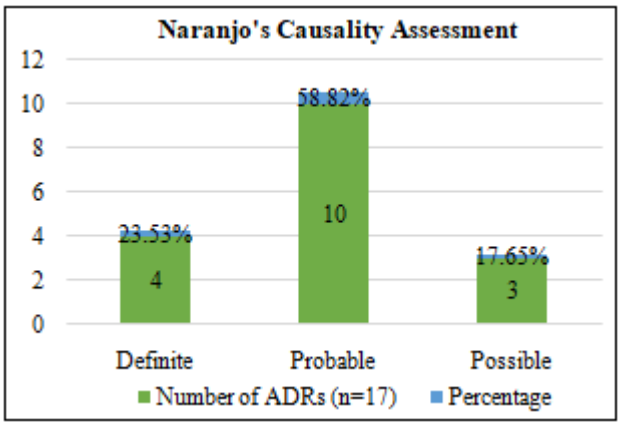


Figure 1: Naranjo Causality Assessment of ADRs

Severity	Number of ADRs (n=17)	Percentage
Mild	8	47.05%
Moderate	6	35.29%
Severe	3	17.64%

WHO probability

The majority of reactions were determined to be probable 8 (47.06%) by the WHO's causality evaluation, while 4 (23.52%) were certain, 3 (17.64%) were possible, and 2 (11.76%) were conditional. The ADRs are depicted in Fig.2 and are included in the table below according to the WHO's causation scale.

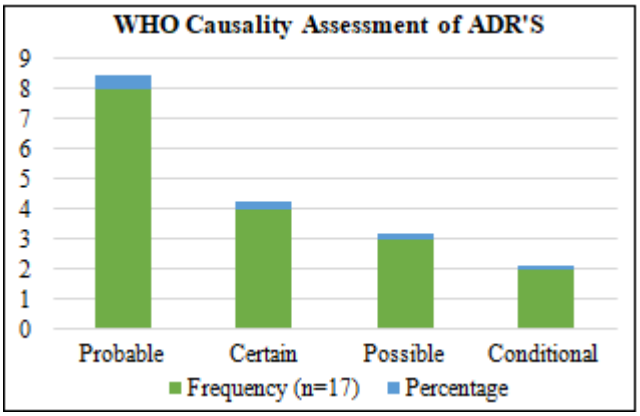


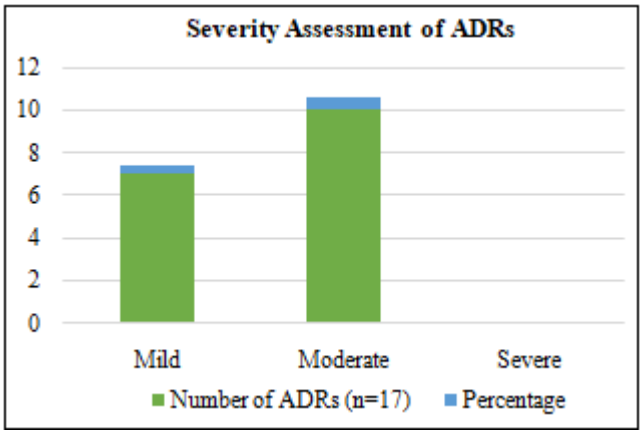
Figure 2: WHO probability Scale of ADRs

Severity assessment of ADRs:

The severity of the probable ADRs was evaluated using the Hartwig severity scale, and it was discovered that 7 (41%) reactions were mild and 10 (59%) reactions were moderate. Table 7 provides a summary of the severity levels.

Table 6: Severity Assessment of ADRs

	Number of ADRs (n=17)	Percentage
Mild	7	41%
Moderate	10	59%
Severe	0	0.00%



Preventability of ADR:
The Preventability of Suspected ADR was assessed using modified Schumock and Thornton criteria.11 (64.7%) reactions were possibly avoidable compared to 6 (35.3%) reactions that are definitely preventable. Information on the assessment of ADRs' preventability is shown in Fig.3.

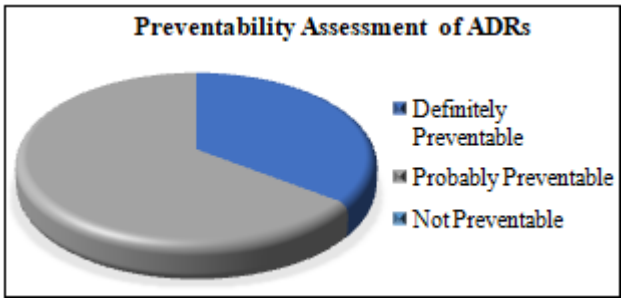


Figure 3: Preventability Assessment of ADRs:

Management of ADRS: Five cases (29.41%) out of the 17 ADRs that were found were managed by stopping the medicine. In 3 (17.64%) of the suspected drug cases, there was no change, whereas, in 4 (23.52%) of the cases, the dose was changed. In Fig.3, the specifics of ADR administration are schematically depicted.

Treatment of ADRS
In 8 (47.05%) cases, no treatment was required. In contrast, 6 (35.2%) cases required specific treatment, and 3 (17.6%) patients required symptomatic care.

The outcome of the Management of ADRS
According to this study, 3 (17.6%) patients had symptoms that persisted, whereas 14 (82.4%) reactions recovered. The outcome's specifics are illustrated.

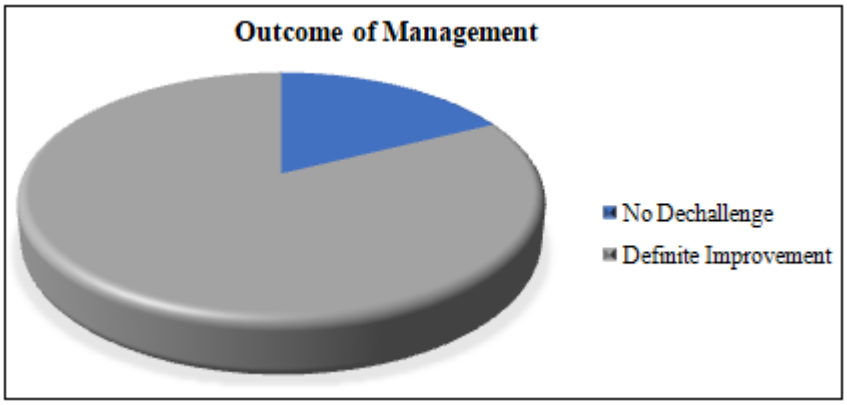
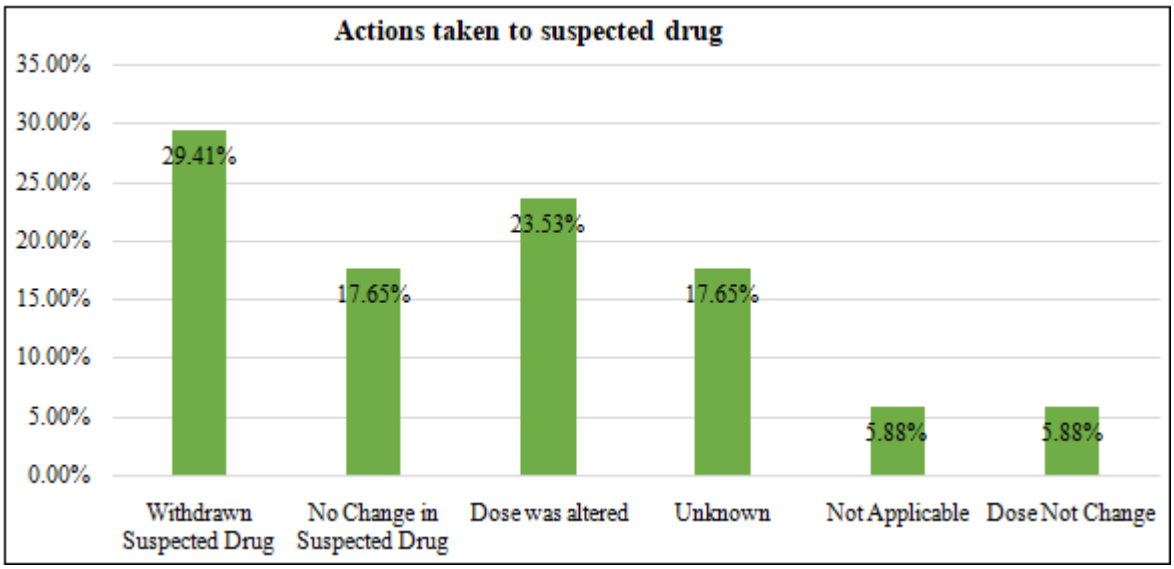


Table 7: Targeted Disease Process

	Number of ADRs (n=17)	Percentage
Withdrawn Suspected Drug	5	29.41%
No Change in Suspected Drug	3	17.65%
Dose was altered	4	23.53%
Unknown	3	17.65%
Not Applicable	1	5.88%
Does Not Change	1	5.88%



4. Discussion

Adverse drug reaction is any noxious and unwanted problems that occur at a dose which that is used in patients for prophylaxis. According to the study conducted, most of the adrs were attributed from the department of general medicine by Akhideno PE et al. [12, 13] We received a total of 17 ADRs during 4 months' study. From this study we found out that, females 9 (34.61%) reported more number of ADRs compared to males 8 (33.3%). However, the study conducted by Venkatasubbaiah M et al. antibiotics, are the most common class of drugs that causes ADR followed by anti - diabetic and antihypertensive [14, 15] This may be due to fact that compared tomales, females have a tendency to use more number of drugs than the males. [16, 17]. Predictability of ADRs was assessed based on the incidence of the reactions and literature reports. Results revealed that most of adrs were predictable 13 (76.47%) while, 4 (23.52 %) were not predictable [17]. The class of drugs which commonly caused ADRs were insulin (11.76%), antihypertensive (34.64%), antibiotic, anticoagulant, Proton pump inhibitor each (5.88%), anticoagulants (11.6%), followed by antiemetic (5.88%) and Antifungal drugs (5.88%). Most number of the adrs were seen in the GIT system (41.47%) and others are cough (17.64 %), head and hypoglycemia (11.6%) and swelling (5.88%). According to Morales - Rios O et al., Alayed N et al., Watson S et al., Lihite RJ et al [18, 19, 20]. According to Naranjo scale, 10 (58.82%) were probable, 3 (17.65%) were possible, 4 (23.53%) were definite and 0%were unlikely. The severities of the reactions were done using hart wig scale. Study reveals majority of adrs were moderate reactions 10 (59%) followed by mild reactions 7 (41%) and none of the reactions was severe. Withdrawal of the drug 5 (29.41%) was the main line of management of ADRs, while no change was made with the suspected drug in 3 (17.64%) and the dose was altered in 4 (23.52%) cases. Reported adrs were assessed for their preventability by using modified Shumock and Thornton method. We concluded that 6 (35%) of the adrs were definitely preventable, while 11 (65%) were probably preventable. This result is similar to that the reports of the study conducted by Khalil H et al. and Morales - Rios O et al., Ray Lees NM et al. [21, 22]. The withdrawal of the medicine, which occurred in 29.41% of cases, was used to manage the majority of ADRs. In 17.65% of cases, there was no change in the suspected drug. In 23.53% of cases, doses were changed. These results were in accordance with the study conducted by Kumar A et al., and The reports are comparable to those from the study by Guner MD et al., in which 82.4% of patients reported improvements in their health. [23, 24]

Drug safety alerts: The National Coordination Centre - Pharmacovigilance Programme of India (NCC - PvPI), Indian Pharmacopoeia Commission works under the aegis of Ministry of Health and Family Welfare, Government of India. It promotes patient safety in India and also supports post marketing surveillance programs. These drug alerts are circulated to all associated partners of the NCC - PvPI, and the AMCs follow all the patients receiving the drugs - ADR combination given as alerts at their respective sites. Any ADR among the drug alerts of PvPI are notified, especially on the follow - up of the drug therapy to improve patient quality of life. In our study, a total of 5 frequent drug related ADRs occurred which are already listed by NCC PvpI

S. No	Suspected Drug	ADR	Year of Issue
1	AMLODOPINE	Psoriasis	2017
2	METRONIDAZOLE	Vasculitis	2018
3	CEFIXIME	Skin hyperpigmentation	2018
4	TELMISARTAN	Lichenoid Keratosis	2019
5	CETRIZINE	Acute generalised exanthematous pustulosis	2019

5. Conclusion

During the study 50 patients were enrolled. Out of which the incidence of adverse drug reactions was 17 in 50 patients. Predominance of reactions were seen in females than males. Antibiotics, Antidiabetic and antihypertensive drugs are the common classes of drugs responsible for the ADRs. The major system involved in manifesting ADR was gastrointestinal system. The severity assessment of suspected ADRs was done by Hartwig severity scale which showed that most of them were moderate. Causality assessment were carried out by using Naranjo's and WHO scale gives that majority of reactions were probable. In most

case, suspected drug were withdrawn so treatment was not required to manage the ADRs. Proper monitoring of adverse reactions is useful to minimize the incidence of ADRs and to prevent further occurrence of the same. Continuing reporting system of ADRs that helps to improve the patient safety. This information may be effective in classifying and reducing the avoidable ADRs.

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