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A Prospective Observational Study to Evaluate Adverse Drug Reactions Inpatient Ward of Tertiary Care Teaching Hospital

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ABSTRACT

Background: Most medications currently only have short-term safety and efficacy testing done on a small group of carefully chosen patients. An excessive amount of a drug has built up in the bloodstream of a person who has drug toxicity. Hence, pharmacovigilance is required, which involves ensuring the early detection of new adverse reactions or patient subgroups with extraordinary sensitivity; and establishing specific strategies to manage such risks. Clinical pharmacists' roles between doctors and patients include providing drug information, financial benefits, patient compliance, drug-related problems (DRP), and assessing how patient counselling affects the patient's quality of life. **Materials and methods:** This is a prospective observational study to find out and report adverse drug reactions in inpatient settings. The suspected or confirmed adverse medication responses were noted on the PvPI suspected adverse drug reactions form created by the Indian Pharmacopeial Commission. After gathering the forms for adverse drug responses, these adverse drug reactions were examined for causality using scales such the Naranjo algorithm scale and WHO-UMC. In order to categorise adverse medication responses and determine their preventability, a causality scale was used. **Results:** Among the departments, majorly received ADR'S from oncology (28.3%) followed by general medicine (24.05%), cardiology (16%), neurology (7.23%), paediatrics (6.6%). Mostly reported reactions belongs to Anti cancerous drugs like PACLITAXEL, DOCETAXEL, ADRIAMYCIN majorly cause alopecia, myalgia, facial puffiness, followed by antimicrobial drugs like METRONIDAZOLE leads to major reactions followed by CEFTRIAXONE, CIPROFLOXACIN and antihypertensive drugs like FUROSEMIDE, METOPROLOL, TELMISARTAN are the causes for reported adverse drug reactions. **CONCLUSION**: Incorrect administration and dose, as well as other factors including genetics, are significant causes of adverse medication reactions that are seen in hospitals. It is important to keep an eye on a patient's medicine prescription and adherence. To reduce the negative effects of the drugs. AMC-PvPI centres would receive updated information on best practises for drug safety and reporting adverse drug reactions if healthcare workers were taught about pharmacovigilance through ongoing educational interventions.

I INTRODUCTION

Drug safety and pharmacovigilance are still active fields of clinical and scientific study. The World Health Organization (WHO) defines pharmacovigilance as "the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem";[1] it is essential to this procedure because it gives doctors and patients the information they need to make an informed decision about the medication they will use to treat their condition.[2] Nonetheless, despite all of its advantages, research on drug side effects shows that they are still a significant contributor to sickness, disability, and even death. Adverse drug reactions (ADRs) are commonly cited as one of the top 10 causes of death. Mechanisms for evaluating and monitoring the safety of medicines used in clinical settings are essential to avoid or reduce patient damage and hence improve public health.

Pharmacovigilance plays a significant role in the healthcare system by keeping track of drug interactions and the impact of those interactions on the human body. This article examines the importance of good manufacturing practices (GCP) and the International Conference on Harmonization (ICH) recommendations for pharmaceuticals intended for human use as they relate to the transformation of clinical trials to the goal of pharmacovigilance. India rises to become the third-largest nation in the world for pharmaceutical output. Pharmacovigilance is presently used in India to raise awareness of adverse drug reactions (ADR), and this review provides details on how it might be put into practise to address current issues. This article outlined the goals and procedures for pharmacovigilance, along with an overview of how it is currently practised in India, its difficulties, and its prospects for the future.

Drug safety judgements are based on information that is periodically reviewed by the TGA and comes from filed ADR reports. Less than 5% of ADRs are reported, according to research conducted internationally, even in places where doing so is required. ADRs may go unnoticed for years without a reliable PV system, putting patients at risk for unanticipated health problems and harming the health care system and taxpayers. An illustration of the requirement for early detection of medication safety signals to assure global health safety is the anti-inflammatory medicine rofecoxib (Vioxx), which was taken off the market due to a significant risk of myocardial infarctions after population exposures reached millions.

Aims of Pharmacovigilance:

1. Enhance patient care and safety regarding the administration of medications and all other medical and paramedical procedures.

2. Conduct lengthy studies on the effectiveness of medications and their side effects starting in the lab and continuing all the way to the pharmacy.

3. Pharmacovigilance keeps track of any adverse drug effects.

4. Enhance public health and safety about drug use.

5. Help to the evaluation of the advantages, disadvantages, effectiveness, and risks associated with medications by promoting their safe, sane, and more efficient (including economical) use.

6. Ensure that the public is effectively informed about pharmacovigilance through education, clinical training, and advocacy.

Need for Pharmacovigilance:

Reason 1: Humanitarian concern – Insufficient evidence of safety from clinical trials animal

Experiments Phase 1-3 studies before marketing authorization.

Reason 2: Medicines are supposed to save lives. Dying from a disease is sometimes unavoidable; dying from a medicine is unacceptable.

Reason 3: Adverse drug reactions-related cost to the country exceeds the cost of the medications themselves.

Reason 4: Promoting rational use of medicines and adherence.

Reason 5: Ensuring public confidence.

Reason 6: Ethics to know of something that is harmful to another person who does not know, and not telling, is unethical.

Steps in the Pharmacovigilance Programme:

1. Finding the risk of drug.

2. Clinical trials.

3. Pharmaco-epidemiological study.

4. Case report.

Developing case series.

Analysis of case series.

Use of data mining to identify product–event combination.

Spontaneous reporting.

Steps Involved in Adverse Drug Reaction Monitoring

Identifying adverse drug reactions (adverse drug reactions).

Assessing causality between drug and suspected reaction.

Documentation of adverse drug reactions in patient's medical records.

Reporting serious adverse drug reactions to Pharmacovigilance centres /adverse drug reactions regulating authorities.

II. AIM & OBJECTIVE:

AIM:

To identify the frequency of adverse drug reactions in both inpatient and out patient departments, steps to increase awareness on reporting ADR's and the role of pharmacists in promoting adherence in patients who are seen in medical wards at Government General Hospital, Guntur, from AUGUST 2022 to DECEMBER 2022.

OBJECTIVES:

To assess adverse drug reactions by using the WHO-UMC causality scale.

To promote education, understanding and clinical training in pharmacovigilance, encourage the public and health care professionals to report adverse drug reactions in Govt. General Hospital through workshops and seminars.

To establish the underlying reasons of adverse drug reactions such as hypersensitivity, idiosyncrasy overdosing, etc.

Development of ADR ALERT CARD (YELLOW CARD SYSTEM) with the help of physicians and clinical pharmacists and promoting its use.

III.METHODOLOGY:

Study Design:

An observational prospective study. Study Period: august 2022 to December 2022 (5 Months). Study Site: Government General Hospital (GGH), a 1800 bedded tertiary care teaching hospital, Guntur. Study Materials: Suspected adverse drug reaction from patient data collection form, informed consent form (Annexure-II), ADR reporting form (IPC form) (Annexure-III), assessment scales for adverse drug reactions (Annexure-IV-VIII), and adverse drug reactions leaflet (Annexure-X).

Inclusion Criteria:

All the patients who are hospitalized and follow-up patients have suspected adverse drug reactions in the in-patient department(s).

Patients only on allopathic treatment, irrespective of age and gender.

Healthcare members i.e, medical interns, and nurses, were included in the study.

Out- patient department is also included.

Exclusion Criteria:

Patients who are on alternative system(s) of medicine.

Patients who are unable to explain the adverse drug reactions.

Study Procedure:

Patients admitted in respective departments were assessed for adverse reactions caused by drug and patient-specific information was collected. An informed consent was taken from the patients for participating in the study. The suspected or identified adverse drug reactions were recorded in IPC- PvPI suspected adverse drug reactions form. After collecting, the adverse drug reactions were analysed for causality with the help of causality assessment scales such as the WHO-UMC causality scale.

IV.RESULTS:

A Total of 636 adverse drug reactions were identified in a study period of five months i.e from August 2022 to December 2022. Out of 636 adverse drug reactions majority of adverse

drug reactions were reported from Oncology (28.30%) followed by General medicine (24.05%), Cardiology (16%), Neurology (7.23%), paediatric (6.60%), psychiatry (5.18%), ART (4.08%), Nephrology (4.08%), OBG (3.77%).

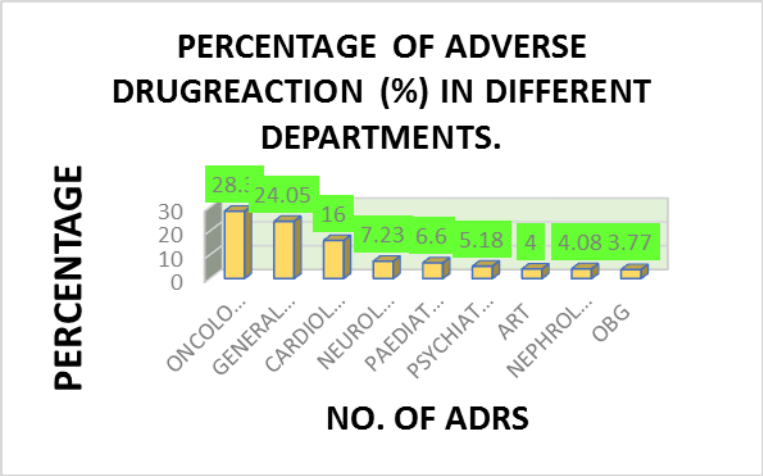

Fig:1 A graphical representation between percentage of Adverse drug reactions Vs no. of Adverse drug reactions.

The gastro-intestinal system was found to be the most commonly affected organ system (23.42%) followed by Skin &appendages (16.35%), Neurologic (15.88%) and least affected was Reproductive (0.62%), liver and biliary (0.15%).

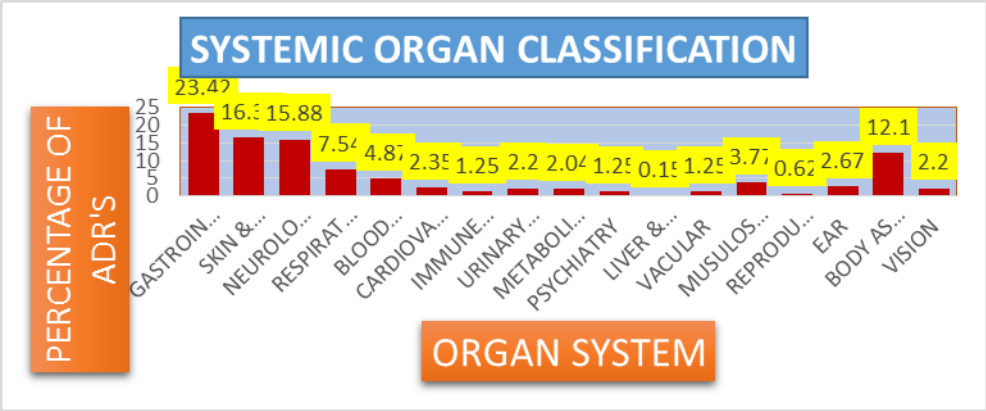

Fig 2: A graphical representation of percentage of ADR'S vs organ system.

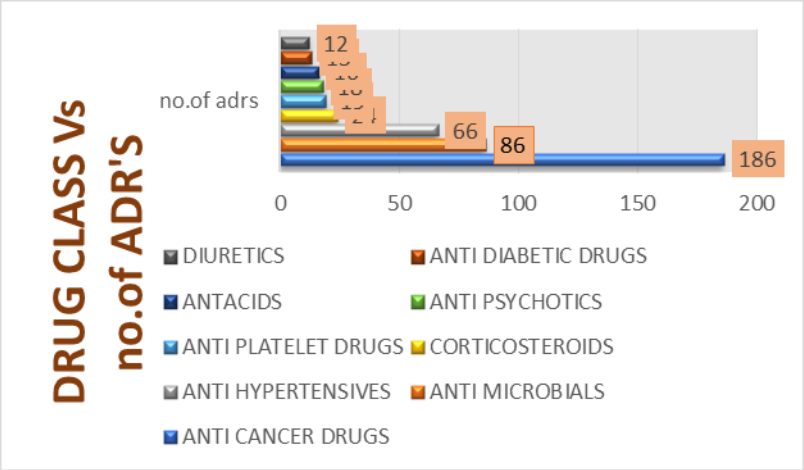

Fig 3: A graphical presentation of drug class Vs number of ADR'S

V. DISCUSSION:

The prevalence study revealed the pattern of adverse drug reactions of anti-retro viral therapy centres, Cardiology, General medicine, Nephrology, Neurology, OBG, Oncology, Orthopaedics, Paediatrics, Psychiatry, Surgery. Among the departments, majorly received ADR from oncology (28.3%) followed by general medicine (24.05%), cardiology (16%), neurology (7.23%), paediatrics (6.6%).

When I observe the data on sex ratio is quite different, that is female's ratio observed a greater number of adverse drug reactions than male sex ratio such as female (51.72%) and males (48.27%) respectively.

Mostly reported reactions belongs to Anti cancerous drugs like PACLITAXEL, DOCETAXEL, ADRIAMYCIN majorly causes alopecia, myalgia, facial puffiness, followed by antimicrobial drugs like METRONIDAZOLE leads to major reactions followed by CEFTRIAXONE, CIPROFLOXACIN and antihypertensive drugs like FUROSEMIDE, METOPROLOL, TELMISARTAN are the causes for reported adverse drug reactions.

VI. CONCLUSION:

The results of our study which indicated the baseline information on the prevalence of adverse drug reactions and their distribution among the various age groups, gender, organ system affected & therapeutic class of drugs we conclude that measures should be implemented for the Systemic review of patients past & present medical/medication history for the early detection of adverse drug reactions targeting specific drugs of major systems i.e.

GI, SKIN, CNS, CVS, hepatic & renal systems and also regular monitoring of adverse drug reactions is an important tool to prevent organ damage, reducing the morbidity and mortality. Other measures to improve adverse drug reaction reporting are incorporation of adverse drug reaction drop boxes at strategic locations in hospitals, facilitating adverse drug reaction reporting by SMS, Email, Fax & Phone, conduction of pharmacovigilance workshops, accessibility of adverse drug reaction reporting forms & adverse drug reaction alert cards to physicians, having an adverse drug reaction specialist, giving acknowledgement to health care professionals for adverse drug reaction reporting, supplying adverse drug reaction information leaflets and also there a need for the strict government rules and regulations to be made compulsory for adverse drug reaction reporting. As a result to minimize adverse drug reaction, need to conduct patient awareness programs and workshops to nurse, interns and all other healthcare professionals.

The study concludes that involving clinical pharmacist services in patients care can significantly help to identify, resolve and prevent the DRPs in the hospital thereby enhancing the patient's outcomes. Furthermore, the suggestions provided by the clinical pharmacist during the intervention were well accepted by the physician thus the collaborative approach of physician and clinical pharmacist can provide better patient care outcomes.

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