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Research Article

PHARMACOVIGILANCE: CURRENT SCENARIO IN A TERITARY CARE HOSPITAL-AN CROSSSECTIONAL OBSERVATIONAL STUDY IN SOUTH INDIA

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A B S T R A C T

Background: Now a days the incidence of adverse drug reactions has been increasing gradually. Thus to promote rational and safe use of medicines and ensuring public confidence regarding the use of medicines pharmacovigilance is essential.
Methodology: Observational cross sectional study was conducted to assess the ADR's, Severity and preventability for a period of six months in a tertiary care hospital in south India. All patients of either sex who were admitted in different departments .During the study period we evaluated the drugs that were dispensed according to the prescription to all inpatients, drugs which induced adverse reactions, patients who developed adverse drug reactions during hospital stay or hospitalized due to adverse drug reactions were included in the present study. Patients previously used or newly started drugs were monitored and followed up for detecting and recording of adverse drug reaction.
Results: In the study ADR's mostly occurred in the age group 31-40 (20.3%). Integumentary system was found to be the most commonly affected organ system (22.1 %) among which rashes and urticaria were the most common type of ADR'S reported, majority of the adverse drug reactions were due to antibiotics (19.9%). Similarly Severity assessment shows majority of the reactions as mild (65.5%).
Conclusion: In our study we observed that there is not enough knowledge, attitude and practice of pharmacovigilance among medical professionals. This certainly shows that there is necessary need to improve the awareness of Pharmacovigilance among all healthcare professional and importance of ADR reporting. Reporting of adverse drug reactions should be intensively taught, reinforced during undergraduate study itself and periodically thereafter through continuous education programs.

INTRODUCTION

The field of Patients" drug safety has been receiving a great deal of attention, since adverse drug reactions (ADRs) are recognized as hazards of drug therapy. Although some ADRs are minor and resolve without sequelae, others can cause permanent disability or death. [1]

In addition, ADRs have a major impact on public health by imposing a considerable economic burden on patients, society and the already stretched health care system.[2]

Several definitions of ADR exist in literature, including those of World Health Organization (WHO), Karch and Lasagna, American Society of Health- system Pharmacists (ASHP), and United States Food and Drug Administration (USFDA).

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WHO defines ADR as "A response to a drug which is noxious and unintended, and which occurs at doses normally used in man for the prophylaxis, diagnosis, or therapy of disease, or for the modification of physiological function."[3] Karch and Lasagna have defined an ADR as "Any response to a drug that is noxious and unintended and that occurs at doses used in man for prophylaxis, diagnosis, or therapy, excluding failure to accomplish the intended purpose."[4] American Society of Hospital Pharmacists (ASHP) has defined an ADR as "Any unexpected, unintended, undesired, or excessive response to a drug that

1. Requires discontinuing the drug (therapeutic or diagnostic),
2. Requires changing the drug therapy,
3. Requires modifying the dose (except for minor dosage adjustments),
4. Necessitates admission to a hospital,
5. Prolongs stay in a health care facility,

6. Necessitates supportive treatment,
7. Significantly complicates diagnosis,
8. Negatively affects prognosis,
9. Results in temporary or permanent harm, disability or death." [5]

United States Food and Drug Administration (USFDA) has defined an ADR as "Any events relating to drugs or devices in which the patient outcome is death, life-threatening (real risk of dying), hospitalization (initial or prolonged), disability (significant, persistent, or permanent), congenital anomality, or required intervention to prevent permanent impairment or damage."

Benefits of ADR Reporting

Following are the benefits of ADR reporting

1. Provide information regarding risk profile of the drug.
2. Harmonizes the risk-management activities and efforts to minimize the drug related problems.
3. Assess the safety profile of drugs, especially recently approved drugs.
4. Quantify the ADR incidence rate.
5. Awareness development in health care professionals and patients about potential drug related problem and monitoring them to report ADRs
6. Assessment of economic impact due to ADRs and strategies to minimize the same by assessing severity and preventability. [5]

WHO defines Pharmacovigilance as "the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drugrelated problem."[8]

Pharmacovigilance plays a key role in ensuring that patients receive safe drugs. It is the process of being alert to the possible unwanted or harmful effects of therapeutic medications so that they could be detected early and remedial measures instituted. [9], [10]

After the thalidomide disaster in the 1960s, most of the countries developed national pharmacovigilance systems. These systems use spontaneous reporting or other pharmacoepidemiological methods to systematically collect and analyze adverse events associated with the use of drugs, identify signals or emerging problems, and communicate how to minimize or prevent harm. [11]

AIM & OBJECTIVES

Aim: To identify, analyze and report the suspected Adverse reactions and adverse events from each department in a tertiary care hospital.

Objectives

- To understand the type of reactions being reported from various posted departments
- To understand the prevalence of ADR's among various age groups and gender
- Educating patients to report the Adverse reactions directly to nearby PV centres by themselves or with the help of doctors, Pharmacists and to make them aware about the importance of reporting Adverse drug reactions ((Toll free: 1800-180-3024)
- Issuing Adverse reactions alert card to the patients.

METHODOLOGY

Observational cross sectional study was conducted to assess the ADR's, Severity and preventability for a period of six months in a tertiary care hospital in south india. This study was approved by institutional human ethical committee (IHEC), Guntur medical college, Guntur. All patients of either sex who were admitted in different department. During the study period were evaluated, the drugs were dispensed according to the pricription to all inpatient. Drugs which induced adverse reactions, patients who developed adverse drug reactions during hospital stay or hospitalized due to adverse drug reactions were included in the present study. Patients previously used or newly started drugs were monitored and followed up for detecting and recording of adverse drug reaction. adverse drug reaction detected by daily counselling patients, consulting with physicians & reviewing patients charts

RESULTS

A total of 226 adverse drug reactions (ADRS) were identified in a study period of 6 months and the table states that out of 226 Adverse drug reactions majority of Adverse drug reactions were reported from General medicine (86%) followed by psychiatry(47%), Oncology (43%) ,Pediatrics (31%) , Dermatology (8%), Gynecology (7%) and Neurology (4%)

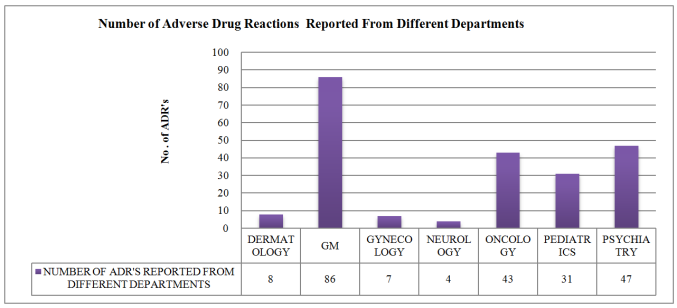

Figure 1 Number of adverse drug reactions reported from different departments

It describes about the Adverse drug reactions mostly occurred in the age group between 31-40 (46%) followed by the age group of 51-60 (45%) and least susceptible age group was 81-90 (2%) &71-80 (8%). The male patients (50.88%) experienced more number of adverse drug reactions compared to female patients (49.55%). The male to female ratio is 115:111, this can be because of social habits of men.

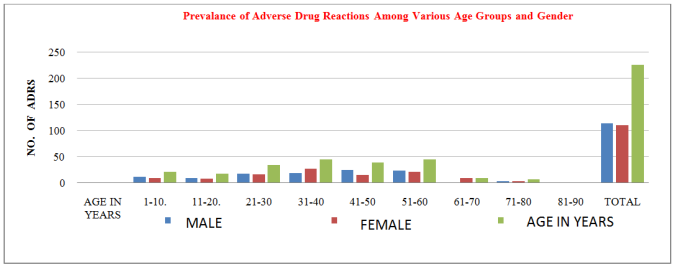

Figure 2 Prevalence of adverse drug reactions among various age groups and gender

It describes that Integumentry was found to be the most commonly affected organ system (50 %) among which rashes and urticaria were the most common type of adverse drug reactions reported, followed by Gastro-intestinal System (46%), Central nervous system (28%), Musculoskeletal (18%),Hematological (9%) least affected was Ear, Throat (1%) and others included oedematous reactions.

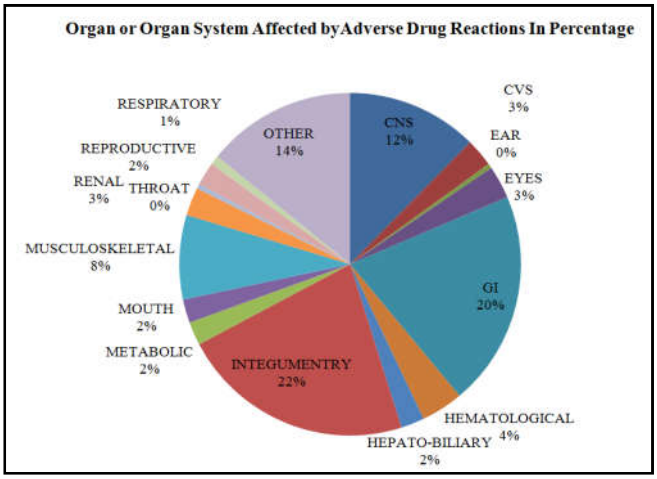

Figure 3 Organ or organ system affected by adverse drug reactions in percentage

It describes that majority of the adverse drug reactions were due to Antibiotics (19.9%). caused the highest percentage of Adverse drug reactions followed by Anti Psychotics (16.8%) and chemotherapy (9.73%) adverse reactions caused. The drug classes which caused least Adverse drug reactions were Antidotes and Anti-malarials, Antidotes, Anti diabetics (0.88%).

Table 1 Prescribed Class of Drugs and Adverse Drug Reactions

Class of Drugs	Adverse Drug Reactions	No of Adverse Drug Reactions	Percentage of Adverse Drug Reactions (%)
Antibiotics		**44**	**19.9**
Ceftriaxone	Rash (3) Nausea, Vomiting, Diarrhea(2)		
Vancomycin	Pain In Abdomen, Fever		
Amikacin	Fever, Redman Syndrome Rash(11)		
Amoxicillin	Nausea Vomiting, Diarrhea(2) Rash(2)		
Ciprofloxacin	Nausea, Vomiting, Diarrhea(2) Diziness		
Norfloxacin	Rash(2)		
Nitrofurantoin	Chills		
Metronidazole	Chills, Fever Rash (3)		
Piptaz	Nausea, Vomiting, Diarrhea (2) Constipation		
Doxycyline	Nausea, Vomiting,Diarrhea (3) SJS		
Amoxyclav	Nausea, Vomiting,Diarrhea (3) SJS		
Antipsychotics		**38**	**16.8**
Olanzapine	Weight Gain(4), Tremors, Blurred Vision, Pedal Edema, Itching In Both Limbs Rash(3)		
Carbamazepine	Tardive Dyskinesia, Sedation, Constipation		
Risperidone	Agitation, Infertility,Akathisia, Drowsiness, Dystonia		
Risperidone+THP	Somnolence(4)		
Clobazam	Somnolence(3), Leukopenia		
Haloperidol	Akathisia		
Alprazolam	Somnolence(4)		
Trihexyphenidyl	Dryness Of Mouth(3)		
Trifluoperazine	Tremors		
Lorazepam	Agressive Behaviour		
Lithium Carbonate	Hand Tremors		
Fluoxetine	Erectile Dysfunction		
Valproic Acid	Nystagmus		
Acitrom	Blood In Stools		
Chemotherapy		**22**	**9.73**
Paclitaxel	Rash(2)		
Oxaliplatin	Rash(3) Nausea, Vomiting,Diarrhea(2)		
Adriamycin	Rash(2)		
Cisplatin	Chills And Pain, Myelosupression, Dry Mouth, Oliguria, SOB		
Bleomycin	SOB, Cough		
Methotrexate	Fever,Chills,Head Ache		
5-fluoro Uracil	Chest Pain		
Imantnib	Hyper Pigmentation		
Carboplatin	Burning And Tingling Sensation		
Antiepileptics		**17**	**7.52**
Sodium Valproate	Rash(2) Hyperglycemia, Dystonia, Hand Tremors, Headache		
Carbamazepine	Ecezema,Ataxia		
Phenytoin	Rash(2) Gingival Hyperplaia,Agressive Behaviour, Ataxia, Blurred Vision		
Levetiracetam	Diplopia		
Eptoin	Rash(2)		
Syndopa	Muscle Cramp		
Pregabalin	Joint Swelling		
NSIADS		**15**	**6.63**
Naproxen	Heart Burn		
Tramadol	Rash(4) Nausea, Vomiting,Diarrhea(3)		
Diclofenac	Neck Stiffness, Pedal Edema(3)		
Paracetamol	Rash(2)		
Dolopar	Hyper Pigmentation Seizures		
Antihypertensives		**13**	**5.75**
Spironolactone	Increased Breast Size		
Mannitol	Chills And Rigors		
Chlorthiazide	Hypokalemia		
Clonidine	Dizziness,Constipation, Orthostatic hypertension		
Amlodipine	Rash(2) Pedal Edema(3)		
Proponolol	Increased Bilirubin Level, Hyperkalemia		
enalapril	Dry cough		
Immunizations		**7**	**3.09**
Equirab	Rash (3)		
Equine	Rash(3) Swelling,Itch At Site Of Action		
NRTI's		**9**	**3.98**
Lamivudine	Nausea, Vomiting,Diarrhea(4) Anemia		
Zidovudine	Anemia		
Efavirenz	Hepatits(3)		
Pyrazinamide	Anemia		
Corticosteroids		**12**	**5.30**
Prednisolone	Rash(5) Myopathy(3), Facial Puffiness(3), Hyperglycemia		
Desmopressin Nasal spray	Dry Mouth		
Anti Depressants		**5**	**2.21**
Amitryptline	Dry Mouth(3), Blurred Vision, Constipation		
Escitalopram	Thrombocytopenia		
Anti Diabetics		**2**	**0.88**
Metformin	Diabetic Keto Acidosis,Severe Head Ache		
Glimiperide	Hypoglycemia		
Anti Coagulants		**8**	**3.53**

Acitrom	Hematuria (3)		
Coumarin	Hepatitis (2)		
Warfarin	Hematuria, Neuropaty		
Heaparin	Nausea, Vomiting, Diarrhea(2)		
AntiPlatelets		**3**	**1.32**
Clopidogrel	Rash(3)		
Ecospirin	Thrombocytopenia		
Antifungal		**5**	**2.21**
Amphotericin-B	Nausea, Vomiting, Diarrhea (2) Renal Impairment (2)		
Clotrimoxazole	Rash(2)		
Antitubercular		**7**	**3.09**
ATT	Ototoxicity		
Pyrazinamide	Renal Cyst, Hyperglycemia		
HRZE	Rash(2) Tineacarposis Over Left elbow		
Rifampicin	Pancytopenia		
Ethambutol	Blurred Vision		
Antidote		**2**	**0.88**
Atropine	Diziness, Psychosis		
AntiMalarials		**2**	**0.88**
Chloroquine	Rash(2) Hepatits(2)		
Miscellaneous		**15**	**6.63**
Pregabalin	Vertigo, Diziness		
Tenecteplase	Bleeding Gums		
Ondansetron	Constipation		
Baclofen	Urinary Incontinence, Drug Withdrawal Syndrome		
Rituximab	Chills		
Cholestyramine	Nausea, Vomiting, Diarrhea(2)		
Serratopeptidase	Nausea, Vomiting, Diarrhea (2)		
Tranexmic acid	Hypotension		
calcium Gluconate	Nausea, Vomiting, Diarrhea(2)		
Zinc syrup	Nausea, Vomiting, Diarrhea(2)		
Inj.Albumin	Chills		

DISCUSSION

An observational cross sectional study was conducted in a period of 6 months on prevalence of adverse drug reactions and impact of educational intervention on health care members regarding Pharmacovigilance and adverse drug reporting. The study revealed the pattern of adverse drug reactions in General Medicine, Oncology, Neurology , Psychiatry , Paediatrics, and Dermatology departments [Figure-1]. The severity of adverse drug reactions reported by health care professionals were assessed.

Out of 226 adverse drug reactions reported and assessed, 20.3% of adverse drug reactions were in the age groups of 31-40yrs [Figure-2] similar results were observed in other studies. the reasons that could be responsible are patients at this age group suffer with many co-morbidities such as diabetes, hypertension so this age group used more number of medications and complained for drug related adverse events. males (50.88%) were more prone to adverse drug reactions than females (49.55%) [Figure-2]. this might be because of men in comparison to women have social habits like smoking and alcohol these differences can affect the way the body deals with drugs by altering the pharmacokinetics and pharmacodynamics, of the drugs including drug absorption, distribution, metabolism and elimination.

The most common organ systems associated with adverse drug reactions in our study were Integumentry, followed by Gastrointestinal and Central nervous system [Figure-3]. This finding was consistent with many studies.[12], Antibiotics were the drug class that led to major reactions as they were mostly prescribed drugs which were similar to other studies [table-1].[13]

CONCLUSION

By observing the results of our study which indicated the baseline information on 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. Integumentry system , Central nervous system (CNS), Cardio vascular sytsem (CVS), Hepatic & Renal systems and also regular monitoring of adverse drug reactions is an important tool to prevent organ damage. Increasing awareness on Pharmacovigilance among clinicians, nurses and pharmacist towards adverse drug reaction reporting to Pharmacovigilance centres (PVPI) by means of the continuous medical educational (CME) programmes .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, providing incentives 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.

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