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ANALYSIS OF THE PATTERN OF ADVERSE DRUG REACTIONS AT A TERTIARY CARE HOSPITAL: A CROSS-SECTIONAL STUDY

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ABSTRACT

Background: Adverse drug reaction (ADR) contributes to drug-related morbidity and mortality, and increases the economic burden of the country. It is important to monitor the effects of drugs, both intended and unwanted, to get an evidence-based assessment of risk / benefit ratio. Today it is well recognized that a reliable Pharmacovigilance system is essential for rational, safe and cost-effective use of medicines and therefore has clear advantages in relation to cost for public health. **Aims and Objectives:** Evaluation of ADRs in various departments of a tertiary care government hospital. **Methodology:** A cross-sectional observational study was carried out for a duration of 4 weeks from 16 February 2023 to 15 March 2023. The ADRs were reported from patients attending out-patient department (OPD) and in-patient department (IPD), LLR Hospital of GSVM Medical college. ADR data was collected in a suspected ADR reporting form. **Result:** During the study period a total of 270 patients were observed in which 107 patients (39.62%) reported ADRs from different departments. Most of the patients were between 21 to 40 years old with male preponderance. The majority of ADRs are of Type–-A (81.30%) while the remaining are of Type-B (15.88%) and Type-C (2.80%). The most frequently involved organ system was GIT (28.97%) followed by CNS, Skin, Renal, Respiratory, CVS, and others. **Conclusion:** From the study, we conclude that most of the ADRs of type-A of mild severity and preventable, and GIT is the most common system affected. Careful attention is needed in monitoring and reporting of ADR's.

KEYWORDS: ADR, OPD, IPD, Pharmacovigilance.

INTRODUCTION

Adverse drug reaction (ADR) contributes to drug-related morbidity and mortality and increases the economic burden of the country. ADR is defined by WHO as "Any untoward response of a drug which is noxious unintended and which occurs at doses normally used in man for prophylaxis, diagnosis or therapy of disease or modification of physiological function or pathological state for the benefit of recipient".[1] It is important to monitor the effects of drugs, both intended and unwanted, to get an evidence-based assessment of the risk-benefit ratio.

ADRs are seen frequently in hospitals due to a combination of factors such as the complexity of diseases, drug interactions, polypharmacy, and possible negligence. Inadequate information or incompleteness in the reported ADR form hinders the analysis of ADR. Knowledge of the adverse effects of drugs is important for effective treatment. Communicating the potential harm of drug use to patients is a matter of high priority and should be carried out by every prescriber.[2] Children are especially vulnerable to adverse drug reactions (ADRs) and their incidence rates range from 0.6% to 16.8% of children exposed to a drug during a hospital stay.[3] These susceptibilities are explained in part by physiological changes during growth, influencing drug bioavailability and disposition. The lack of information from clinical trials increases the uncertainties about the benefit-risk profile of commonly used medicines in pediatrics.[4,5]

ADR monitoring in the hospital setting is vital because it helps to understand the nature and type of ADRs and to identify high-risk patients for developing ADRs. Pharmacovigilance (PV) is the pharmacological science relating to the collection, detection, assessment, monitoring, and prevention of adverse effects or any other drug-related problem.[6] PV in India is still in its infancy and ADR reporting rates are below 1% and require more data.[7] This might be due to a lack of ADR reporting due to guilt, lack of awareness, motivation, ignorance, training, and time limitations among healthcare personnel.

The significance of this study is to emphasize the awareness of the healthcare providers on vigilant monitoring of ADRs and promptly reporting to prevent the occurrence in populations. However, the present study has some limitations as it is an analytical study for

a very short duration and involves a small study population. This study would give an insight into the patterns in tertiary health care centers and may help to increase awareness for further Pharmacovigilance studies. This study aims to assess ADRs occurring in various departments of a tertiary care government hospital between 16 February 2023 to 15 March 2023 to evaluate the occurrence and completeness of the ADR form.

MATERIALS AND METHODS

A cross-sectional observational, study was conducted by the Department of Pharmacology, GSVM Medical College, Kanpur from 16 February 2023 to 15 March 2023. The ADRs were reported from patients attending the out-patient department (OPD) and in-patient department (IPD), at LLR Hospital of GSVM Medical College. ADR data was collected from various departments by suspected ADR reporting form of the Central Drugs Standard Control Organization (CDSCO) India. Analysis of data was done by anatomical classification of ADRs with suitable statistical methods.

Inclusion criteria

- Patients attending OPD/IPD in all Departments
- All age group Patients agreeing to participate
- Patients of either sex

Exclusion criteria

- Patients refusing to give consent.

For each patient, the form was completed regarding

- Age of patient
- Gender of patient
- Number of drugs prescribed
- Severity assessment of ADR
- Types of ADRs

The severity of the ADRs were analyzed by using Hartwig's severity scale.

The Scale is classified as:

1. Mild: A reaction that does not require treatment or hospital stay.
2. Moderate: A reaction that requires treatment and prolongs hospitalization by at least one day.
3. Severe: A reaction that is potentially life-threatening and contributes to the death of the patient or permanently disabling, and requires intensive medical care.

RESULTS

During the study period, a total of 270 patients were observed in which 107 patients (39.62%) reported ADRs from different departments of GSVM Medical College Kanpur and Associated Hospital in a time period of 4 weeks. A total of 1080 drugs were prescribed out of which 51 drugs were suspected to cause the ADRs. All reported ADR cases were divided into four age groups (< 20 years, 21-40 years, 41-60 years, and more than 60 years) and analyzed. The majority of patients belong to the 21-40 years (42.05%) age group followed by the age group 41-60 years (28.97%) more than 60 years (20.56%) and less than 20 years (8.41%) with male (57.00%) preponderance.

Table 1: Age and Gender wise distribution of ADRs.

Age Group (in Years)	Number of Males with ADR	Number of Females with ADR	Total Number of ADR	Percentage (%) of ADR's
<20	5	4	9	8.41
21-40	26	19	45	42.05
41-60	17	14	31	28.97
>60	13	9	22	20.56
Total	61	46	107	

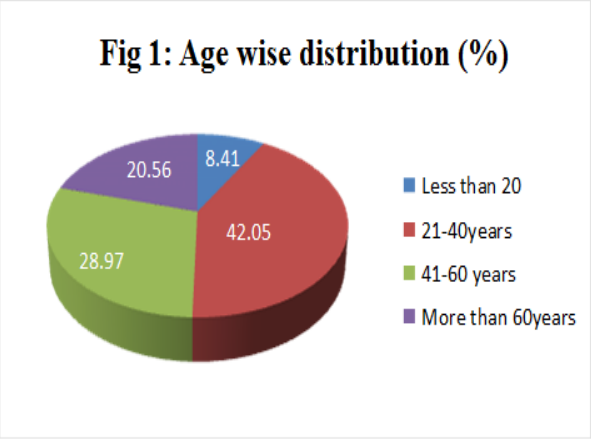
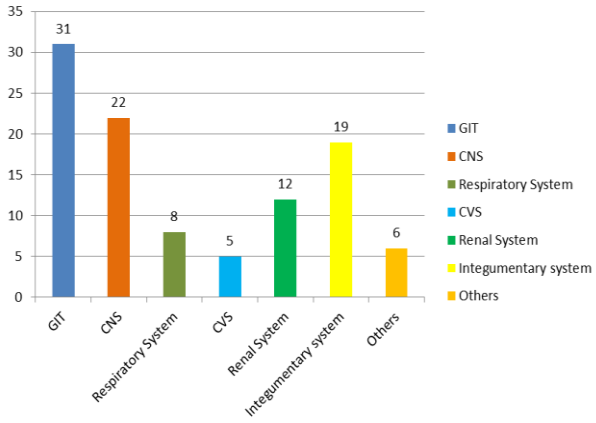


Fig 2: Organ System wise ADR classification



The most commonly affected organ system was the gastrointestinal (28.97%) followed by Central Nervous System (20.56%)] and integumentary system (17.75%) followed by Renal (11.21%), Respiratory (7.47%), Cardiovascular System (4.67%), and others (9.34%).

Table 2: ADRs and Suspected drug.

ADRs	Suspected Drug	Total Number of Patients	Number of Drugs that caused ADR
GIT		**31(28.97%)**	**26**
Nausea and Vomiting	Propranolol, Pantoprazole, Theophylline, montelukast, Diclofenac, Cefpodoxime, Metformin, Glimepiride, Rosuvastatin, Metronidazole, torsemide, rifaximin, ciprofloxacin, Doxycycline	9(8.41%)	14
Loose motion/ Diarrhea	Acebrophyllin, Montelukast, Spironolactone, Diclofenac, Esomeprazole, Ursodeoxycholic acid, Vitamin K, Pantoprazole, Lactulose, Doxycycline	7(6.54%)	10
Constipation	Calcium, Ondansetron, Rosuvastatin	4(3.73%)	3
Abdominal pain	Esomeprazole, Acetomophen (overdose), Rifaximin, Diclofenac, metronidazole, lactulose	3(2.80%)	6
Black tarry stool,	Ursodeoxycholic acid, Aluminum magnesium Hydroxide	1(0.93%)	2
Heartburn Flatulence	Diclofenac	2(1.86%)	1
Bloating	Lactulose	1(0.93%)	1
Metallic Taste	Metronidazole, Glimepiride, Metformin, Vitamin K	1(0.93%)	4
Dry mouth	Formeterol and budesonide, esmoparazole, labetolol	3(2.8%)	4
CNS		**22(20.56%)**	**20**
Altered Sensorium	Acetomophen	2(1.86%)	1
Dizziness	Telmisartan,Tamsulosin,Spiranolactone, Ondansetron, Ceftriaxone, Cetrizine , torsemide, levitracetam, rifaximin, monteleukast	5(4.67%)	
Headache	Piracetam, Citicoline, Spironolactone, Ceftriaxone, Deriphyllin, Monteleukast, Insulin, Acebrophyllin, Hydrocortisone, Nifedipine, Cetrizine, sodium Valproate,	7(6.54%)	14
Anxiety	Levetiracetam, Deriphyllin,	3(2.80%)	2
Insomnia	Atenolol, Hydrocortisone, salbutamol	1(0.93%)	3
Sleepiness	Citrizine , Monteleukast	2(1.86%)	2
Agitation	Levetiracetam	1(0.93%)	1
Lethargy	Piperacillin, metformin	1(0.93%)	2
Respiratory System.		**8 (7.47%)**	**4**

Difficulty in Breathing	Tranexamic acid,Ceftriaxone	2 (1.86%)	2
Chest pain	Ceftriaxone	1 (0.93%)	1
Sore Throat	Budesonide, Formoterol	5 (4.67%)	2
Cardio Vascular System		**5 (4.67%)**	**2**
Palpitation	Ceftriaxone, metformin	5 (4.67%)	2
Renal system		**12 (11.21%)**	**3**
Urine Discolouration	Rifampicin, Metronidazole	7 (6.54%)	2
Painful urination	Ursodeoxycholic acid	5 (4.67%)	1
Integumentary system		**19 (17.75%)**	**11**
Rash	Furosemide & Spironolactone, Cefpodoxime, Amoxicillin, Doxycyclin	9 (8.41%)	5
Urticaria	Vancomycin	2 (1.86%)	1
Anaphylaxis	Vancomycin, Amoxycillin	1 (0.93%)	2
Redness And Swelling at injection site	Insulin, Vitamin K, Piperacillin	1 (0.93%)	3
Flushing	Vancomycin, Clinidipine, Vitamin B complex	3(2.80%)	3
Itching	Amoxicillin, piperacillin	3 (2.80%)	2
Others		**10 (9.34%)**	**7**
Fever	Vancomycin, DNS	2 (1.86%)	2
Chills, Rigors	Vancomycin	1 (0.93%)	1
Myopathies and Thrombosis	Tranexamic Acid	2 (1.86%)	1
Numbness Of Limbs	Propranolol, pyrazinamide	2 (1.86%)	2
Dryness of nose	Fluticasone nasal Spray	1 (0.93%)	1
Nasal Irritation	Fluticasone	1 (0.93%)	1
Jaundice	Isoniazid	1 (0.93%)	1

ADRs are classified into various types and are figured Out of all 107 ADRs, the majority of ADRs are of Type –A (N=87, 81.30%) while the remaining of Type-B (N=17, 15.88%), and Type- C (N=3, 2.80%).

Table 3: Types of ADRs.

Type of ADRs	Number of ADRs	Percentage (%)
Type A	87	81.30%
Type B	17	15.88%
Type C	3	2.80%
Total	107	100%

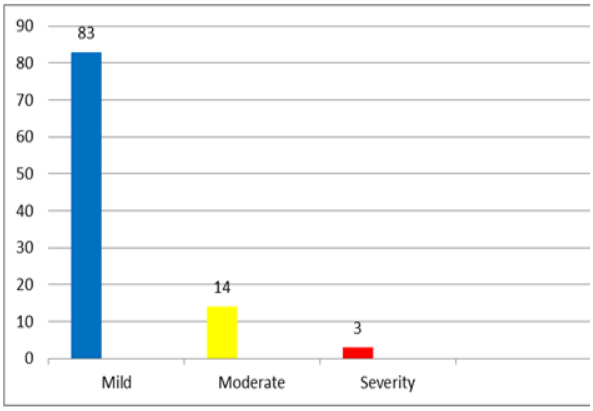


Fig. 3: Severity of ADRs

Table 4: Organ system wise types of ADRs.

Organ system	Types of ADRs		
	Type A	Type B	Type C
GIT	25	6	0
CNS	19	2	1
Respiratory System	6	1	1
CVS	4	1	0
Renal System	10	2	0
Integumentary System	15	3	1
Others	8	2	0
Total	87	17	3

Table5: Organ system wise severity of ADRs.

Organ system	Types of ADRs		
	Mild	Moderate	Severe
GIT	30	1	0
CNS	21	1	0
Respiratory System	7	1	0
CVS	4	1	0
Renal System	12	0	0
Integumentary System	17	2	0
Others	10	0	0
Total	101	6	0

DISCUSSION

Diagnosing adverse drug reactions is one of the most important aspects in healthcare, often emulating 'traditional diseases' and manifesting in all systems of the body. Drug-related problems in patients admitted to the hospital may present in many different ways, including weakness or drowsiness, biochemical or hematological derangements, bleeding, gastrointestinal disturbances, hypoglycemia, or healthcare-associated infections. Managing adverse drug reactions by altering a dosage regimen or withdrawing a medicine suspected of causing an ADR are common methods of controlling ADRs in practice. However, the course taken to manage an ADR is likely to vary from clinician to clinician. Drugs showing ADRs in our study were comparable with the study done by Raja et al.[8] Kushwaha et al,[9] Tandon et al[10] and Giri et al[11] revealed that the system most affected was the gastrointestinal system. The age group showing maximum ADRs was 21-40 years which was similar to a study done by Kushwaha et al.[7] while one study done by Gomathi et al showed 45-60 years.[12] Our study showed ADRs reported had male preponderance which was comparable to the study done by Kushwaha et al,[13] while some studies showed a female preponderance.[9,14,15] Thereby concluding that the influence of Age and gender is just an incidental finding which does not affect the number of ADRs reporting. The most commonly reported ADRs in this study were nausea & vomiting in GI and headache in CNS followed by rash in skin, while another study conducted by Aggrawal et al most common organ system involved was skin and soft tissue.[16] Out of all mostly patients suffered from mild ADRs followed by moderate no severe ADRs was found, while one study showed severe ADRs in Gomathi et al.[12] Out of all 107 ADRs, the most common type of ADR was type-A and similar result are seen in another study done by Bhattacharjee P et al.[17] while one study classified the majority of ADRs as type-B.[18]

ADRs can have a detrimental effect on a patient's well-being and overall healthcare system and ADR collecting program in a hospital helps to assess the safety of drug therapies. Measuring ADRs and its incidence rate over time will help educate healthcare professionals on drug effects and will increase their level of awareness regarding ADRs.

Currently, several methods and approaches are used for the detection of suspected ADRs for receiving and analyzing reports of safety. Spontaneous reporting of suspected ADRs is one of most important function of National Pharmacovigilance Centers, which is considered as a significant strategy that can be useful for the discovery of rare and previously unreported reactions.[19] The most common discouraging factor for ADR reporting is doctors not being educated on pharmacovigilance and the lack of knowledge on where to report indicating ignorance. This factor is adequately taken care by increasing the awareness about existing pharmacovigilance centers, as reflected in our results where more than 60% of doctors in the CME group were aware of as to where to report.[20]

Today it is well recognized that a reliable pharmacovigilance system is essential for the rational, safe, and cost-effective use of medicines and therefore has clear advantages concerning cost for public health.[21,22]

CONCLUSION

This study would give an insight into the pattern of ADRs in a tertiary health care center and may help to increase awareness for further pharmacovigilance studies. From our study, we conclude that most of the ADRs are of type A with mild severity. Among ADRs reported, GIT manifestations are the most common. The concept of ADR reporting is still in its infancy, especially in countries like India and reporting of ADRs is very less. Hence, there is a need for the active participation of all the departments of the hospital for ADR reporting and further overcoming the ill effects of drugs.

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