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Original Research Article

The pattern of reported adverse drug reactions with reference to specific drug class and organ system

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ABSTRACT

Background: Adverse drug reactions (ADRs) represent a major public health problem. The overall ADR rate is estimated to be 6.5 and 28% of these are preventable. ADR incidence in Indian population ranges between 1.8-25% with 8% resulting in hospitalization. Hence, the present study was undertaken to study the pattern of reported adverse drug reactions with reference to specific drug class and organ system in a tertiary care hospital.
Methods: A cross-sectional retrospective study was carried to analyse the ADRs reported over a period of one year (January-December 2019). Individual case safety reports (ICSRs) of all patients of suspected adverse drug reactions seen in various out-patient departments and admitted in the wards of the hospital were included in the study. The ICSRs were analysed for patient demography, causality, severity and with reference to specific drug class and organ system.
Results: Among 382 reported ADRs, 27.2% of the ADRs were reported as serious. The most common therapeutic class of drugs causing ADRs where Antimicrobial agents (36.07%). The skin is the most common affected organ system (25.39%).
Conclusions: A coordinated system of identifying the ADRs early in the course of treatment and recognizing the preventable ADRs is required by the health care system. The coordination of prescribing physicians and pharmacovigilance personnel can produce better trend of reporting the ADRs.

Keywords: ADRs, Pharmacovigilance, WHO causality assessment, Seriousness criteria, Therapeutic class of drugs, Specific organ system

INTRODUCTION

Adverse drug reactions (ADRs) represent a major public health problem. ADRs can cause significant morbidity, mortality, increasing health care costs in clinical practice and may have a dramatic impact on the clinical and the economic perspectives.[1,2] The world health organization (WHO) defines an adverse drug reaction as "one which is noxious, unintended and which occurs in doses normally used in humans for prophylaxis, diagnosis or therapy of the disease or for the modification of physiological functions.[3]

It has been reported that ADRs account for 5% of all hospital admissions and occur in 10-20% of hospitalized patients.[4] An overall incidence of serious and fatal ADR among the hospitalized patients is 6.7 and 0.32% respectively.[4,5] The overall ADR rate is estimated to be 6.5 and 28% of these are preventable.[5] ADR incidence in Indian population ranges between 1.8-25 with 8% resulting in hospitalization.[6] The recent epidemiological studies have estimated that adverse drug reactions are the fourth to sixth leading causes of death.[7,4]

Identification and reporting of these ADRs is extremely crucial as it may possibly help the treating physicians on being vigilant while prescribing those drugs and achieving substantial reduction in health care cost.[8] The pharmacovigilance programme of India (PvPI) is an initiative to address this issue. Activities under PvPI

include collection, reporting and follow up of ADRs occurring in the patients.[9] The spontaneous reporting system has resulted in many marketed drugs being withdrawn for safety concerns.[10,11] It is important to identify the risks for ADRs, henceforth the common drugs causing ADRs, their therapeutic class and concomitant drugs used should be known. Also, ADR specific data such as type of reaction, system affected and probable causes will be of great help to minimize the ADRs.[12]

Hence, the present study was undertaken to study the pattern of reported ADRs with reference to specific drug class and organ system in a tertiary care hospital.

METHODS

A cross-sectional retrospective study was carried to analyse the ADRs reported over a period of one year (January-December 2019) at Gandhi medical college/hospital, Secunderabad, Telangana. It has approximately 1200 beds and provides all medical and surgical specialities including obstetrics, gynaecology, paediatrics and the centre of excellence-anti retroviral therapy (ART) centre.

The study was approved by the institutional ethics committee. The department of pharmacology, Gandhi medical college has been a recognized ADR monitoring centre (AMC) under the PvPI. A patient safety pharmacovigilance associate was appointed by the PvPI, Indian pharmacopoeia commission (IPC), Ghaziabad. The AMC also spreads awareness about the need and importance of the pharmacovigilance. This is achieved by regular sharing of drug safety alerts in the in-patient and out-patient departments and also by emphasizing the need for reporting ADRs and conducting sensitization sessions to health care professionals (HCPs) and the para-medical staff. In parallel to pharmacovigilance, hemovigilance and adverse event following immunization (AEFI) surveillance is also conducted at AMC.

Individual case safety reports (ICSRs) of all patients of suspected adverse drug reactions seen in various out-patient departments and admitted in the wards of the hospital were included in the study. The central drug standard control organization (CDSCO) ADR reporting forms were used for collection of the data. The ADRs identified and reported by the physicians of the hospital were collected and reported to the AMC. The collected information included patients initials, age, gender, reporting department of the hospital, details of the suspected adverse drug reaction, duration of the reaction, suspected drug history, temporal correlation with the drug and concomitant medications. Relevant lab investigations and relevant medical history were recorded in the ADR form. All ADRs were submitted to national coordination centre (NCC) through Vigiflow software to NCC-PvPI, IPC, Ghaziabad, which further sends reports after analysing to Uppsala monitoring centre (UMC), Sweden.

The ICSRs were analysed for patient demography, causality and severity. Causality assessment of the ADR were done by the causality assessment committee by using the WHO-UMC causality assessment scale. The seriousness criteria of the reaction and the outcome of the patient were monitored by using guidance document for spontaneous adverse drug reaction reporting version: 1.0 IPC, NCC– PvPI.[13] The anatomical therapeutic chemical classification (ATC) and the medical dictionary for regulatory activities (MedDRA) version-23.0 are used to code active principles and reactions respectively. The different types of reported ADRs were classified according to the medical dictionary for regulatory activities (MedDRA) and system organ class (SOC).[14]

The ADR reports were analysed for the above data using descriptive statistics.

RESULTS

Total number of ADRs reported during the study period were 382. Among them, 191 ADRs were reported in male patients and 191 ADRs in female patients (Table 1).

Table 1: Gender wise distribution of the ADRs.

Gender	No. of patients (n=382)	Percentage (%)
Male	191	50
Female	191	50

The highest percentage of ADRs 21.46% were reported among the age group of 40-49 years followed by 17.54% of ADRs among the age group of 50-59 years (Table 2).

Table 2: Age wise distribution of the ADRs.

Age (Years)	No. of patients (n=382)	Percentage (%)
0-9	28	7.32
10-19	18	4.72
20-29	53	13.88
30-39	61	15.96
40-49	82	21.46
50-59	67	17.54
60-69	45	11.78
70-79	22	5.76
80-89	6	1.58

The seriousness criteria include hospitalization, life-threatening, disability, congenital anomaly and required intervention, of the 382 ADRs reported, 104 ADRs were reported as serious accounting for 27.2% of the ADRs. 89% of serious reports required hospitalization, 4% reported were life-threatening and 4% required intervention, 2% were of congenital anomaly and 1% showed disability (Table 3).

Table 3: Classification of seriousness criteria.

Seriousness criteria	No. of patients (n=104; 27.2%)
Hospitalization	93 (89)
Life-threatening	4 (4)
Required intervention	4 (4)
Congenital anomaly	2 (2)
Disability	1 (1)

The outcome of the reported ADRs were grouped as recovered, recovering, recovered with sequelae, fatal, not recovered and unknown. Out of 382 ADRs reported, 52.10% patients were recovering and 44.5% patients have recovered (Table 4).

Table 4: Outcome parameters of reported ICSRs.

Outcome	No. of patients (n=382)	Percentage (%)
Recovering	199	52.10
Recovered	170	44.5
Recovered with sequelae	6	1.58
Unknown	4	1.04
Not recovered	2	0.52
Fatal	1	0.26

The WHO-UMC causality assessment scale has grouped ADRs as certain, probable, possible, unlikely, unclassified and unclassifiable. Majority of the reports were rated as probable (n=310; 81%) and 72 (19%) ICSRs were possible (Table 5).

Table 5: WHO causality assessment.

Causality	No. of ICSRs (n=382)	Percentage (%)
Probable	310	81
Possible	72	19

The most common therapeutic class of drugs causing ADRs (Table 6) were antimicrobial agents (36.07%) followed by drugs acting on the central and peripheral nervous systems including the NSAIDS (7.49%), anti-epileptics (4.08%) and anti-depressants (2.72%). 12.92% of ADRs are caused by hormones like the corticosteroids and anti-diabetic drugs. 8.16% of ADRs were reported by the CVS drugs like the antihypertensive drugs and anti-angina drugs. 6.80% of ADRs were reported with anticoagulants, anti-platelets and statins.

A total 9.52% of ADRs were reported with other classes of drugs like drugs acting on the respiratory system, diuretics, anti-emetics, antacids and antihistaminic. Also, vaccines, immunosuppressants, vitamins and herbal medicines have been reported to cause ADRs.

The clinical presentation of affected system (Table 7) shows that, the skin is the most common affected organ system (n=97; 25.39%) and gastrointestinal tract system (n=74; 19.37%). Other organ systems involved are the central and peripheral nervous system, elevated liver and renal function tests and electrolyte disturbances.

Table 6: Most common therapeutic class of drugs causing ADRs.

Class of drug	Number of cases	Percentage of cases (%)
Anti-microbial agents	53	36.07
Antibiotics	37	25.19
Anti-retroviral	9	6.12
Anti-tubercular	3	2.04
Anti-amoebic	2	1.36
Anti-viral	2	1.36
Drugs acting on central nervous system	21	14.29
NSAIDS	11	7.49
Anti-epileptics	6	4.08
Anti-depressants	4	2.72
Hormones	19	12.92
Anti-diabetics	8	5.44
Corticosteroids	7	4.76
Other hormones	4	2.72
Others	14	9.52
Respiratory system	4	2.72
Anti-emetics	3	2.04
Antacids	3	2.04
Diuretics	2	1.36
Anti-histaminic	2	1.36
Drugs acting on cardiovascular system	12	8.16
Anti-hypertensives	7	4.76
Cardiac glycosides	3	2.04
Anti-anginal	2	1.36
Drugs acting on blood and blood forming organs	10	6.80
Anti-coagulants	6	4.08
Anti-platelets	2	1.36
Statins	2	1.36
Immunopharmacology	10	6.80
Immunosuppressants	6	4.08
Vaccines	4	2.72
Miscellaneous	8	5.44
Vitamins and minerals	6	4.08
Herbal medicines	2	1.36
Total	147	100

The major clinical presentation of skin and subcutaneous tissue is the generalized rash, itching, urticaria, lichenoid rash, exfoliative dermatitis and hyperpigmentation of the skin. Diarrhea, nausea, constipation, abdominal pain and vomiting are the common ADRs reported in the gastrointestinal system. In the central and peripheral

nervous system, headache, dizziness, involuntary movements, burning sensation of the feet and seizures are the commonly reported ADRs. The liver function tests showed increased triglycerides, increased total cholesterol and increased bilirubin levels. Blood and the lymphatic system reported anemia, pancytopenia and thrombocytopenia. Renal and urinary systems have reported acute kidney injury, hematuria and renal failure. The immune system has reported anaphylactic reactions, facial edema and red man syndrome.

Table 7: Details of affected body system and clinical presentation of the adverse drug reactions.

Body system affected as per SOC	Clinical presentation of the affected system (number of ADRs)	Number of ADRs	Percentage of ADRs (%)
Skin and subcutaneous system	Generalized rash (33), Itching (24), Urticaria (12), Maculopapular rash (10), Lichenoid rash (9), Exfoliative dermatitis (3), Erythematous rash (2), Sweating (2), Steven Johnson syndrome (1), Hyperpigmentation of skin (1).	97	25.39
Gastrointestinal system	Diarrhoea (18), Nausea (14), Constipation (10), Abdominal pain (7), Vomiting (5), Oral ulcer (5), Upper gastrointestinal bleed (4), Gum bleed (3), Gastritis (3), Flatulence (2), Rectal bleed (1), Hematemesis (1), Esophagitis (1).	74	19.37
Central and peripheral nervous system	Headache (14), Dizziness (7), Involuntary movements (6), Burning sensation of feet (5), Seizure (4), Peripheral neuropathy (2), Intracranial bleed (1).	39	10.21
Investigations (serum electrolytes, LFT, RFT)	Increased triglycerides (18), Hyponatremia (5), Hypokalaemia (4), Increased total cholesterol (4), Increased serum creatinine (3), Increased serum bilirubin (2), Hyperkalaemia (1).	37	9.68
Blood and lymphatic system	Anaemia (17), Pancytopenia (6), Thrombocytopenia (1), Lymphadenopathy (1).	25	6.54
General disorders and administration site conditions	Fever (7), Injection site pain (5), Fatigue (4), Injection site swelling (3), Injection site irritation (2), Chills (2), Pedal oedema (1).	24	6.28
Endocrine system	Hypoglycaemia (11), Hyperglycaemia (6), Hypothyroidism (1), Cushing syndrome (1)	19	4.98
Immune system	Anaphylactic reaction (8), Facial oedema (5), Fixed drug eruption (1), Red man syndrome (1)	15	3.93
Renal and urinary system	Acute kidney injury (9), Haematuria (2), Renal failure (2).	13	3.41
Cardiovascular system	Hypotension (3), Bradycardia (2), Palpitations (2), Prolonged QT interval (2), Chest pain (1).	10	2.62
Musculoskeletal and connective tissue disorders	Arthralgia (3), Myalgia (3), Back pain (2), Neck stiffness (1).	9	2.36
Hepatobiliary system	Jaundice (5), Hepatitis (3).	8	2.09
Respiratory system	Epistaxis (3), Haemoptysis (1), Cough (1).	5	1.30
Psychiatric disorders	Insomnia (3).	3	0.79
Eye disorders	Blurred Vision (2), Cataract (1).	3	0.79
Reproductive system	Vaginal itching (1)	1	0.26
Total		382	100

DISCUSSION

Spontaneous ADR reporting activity is important to monitor known and unknown adverse effects of medicines. It has played an important role in the detection of serious and unusual ADRs after marketing, when the drug is actually being prescribed by the clinicians. This activity of continuous vigil on the drug related ADRs has resulted in withdrawal of quite a few drugs in the past such as refecoxib, cisapride, terfenadine etc. ADRs have to be considered as one of the major causes of iatrogenic disease with detrimental effect on patient wellbeing and overall health care system.[15]

The present study was done to analyze the ICSR forms (n=382) collected from various departments, shows equal distribution of ADRs among both the genders. This was a comparable finding to that reported by Jose and Belhekar

et al.[15,16] However, the spontaneous reporting studies in our country had observed high percentage of ADRs in females.[17-22] The various factors influence the drug metabolism and response of individuals which include differences in body mass index, genetic constitution and differences in levels of various enzymes responsible for drug metabolism.[23]

In present study, 21.46% of ADRs were reported in age group of 40-49 years, 17.54% of ADRs were reported in age group 50-59 years and 19.12% of ADRs were reported in the elderly group. Since previous studies have stated that advanced age increases the risk of ADR due to pharmacokinetic and pharmacodynamics changes, the present study was comparable to the findings reported by Scheneiderjk, Belhekar, David, Ramesh, and Arulmani et al.[6,16-19,24,25]

The seriousness criteria as observed in the present study is 27.2% (n=382). The present study reports of seriousness criteria were different from the studies reported by Singh, Venkatasubbaiah and Sneha et al which was 14.93% (n=154); 5.12% (n=254) and 39% (n=177) respectively.[21,26,27]

The outcome parameter of the reported ICSRs showed 52.10% as recovering and 44.50% as recovered which were comparable with studies done by Sneha et.al, which reported cases with recovering outcome parameter as 79% and recovered as 13%, Hemavathy et al reported cases with recovering outcome parameter as 63.28% and recovered as 19.53%.[27,28]

According to WHO causality assessment of the ICSRs showing the relatedness or the likelihood of the drugs with reactions is probable (81%), in most of the cases. Where the earlier studies report by Badyal, Sood and Shrivastava et al showed probable (83.5, 55 and 55.89% respectively) were more.[12,29,30] However, compared with other studies, the study reported by Venkatasubbaiah and Hemavathy et al showed more possible (48.82 and 71.09%) followed by probable (27.17 and 28.12%) and none of the ICSRs of present study were reported as certain.[26,28]

In the present study, the most common therapeutic class of drug implicated in ADRs were the antimicrobial agents (36.07%) which included the antibiotics, anti-retroviral and anti-tubercular agents followed by other class of drugs like NSAIDS, anti-epileptics and hormones. Earlier studies have also reported ADRs due to same class of drugs.[15,31]

The ADRs due to anti-retroviral and anti-tubercular are immunologically mediated hypersensitivity reactions and are mostly dose dependent in nature. This indicates, that a dose monitoring and follow up of patients is essential in the initial month for early detection and prevention of serious ADRs. This information should help the clinicians to remain vigilant during this period and also educate the consumers.[32]

Kanjanarat et al noted cardiovascular drugs to be causative in 17.9% of ADRs, while Lakshmanan et al in a study of hospital admissions due to iatrogenic illness found antihypertensive agents to be responsible for most of the iatrogenic admissions.[33,34] Bates et al reported 30% ADRs to be due to analgesics, 24% due to antibiotics.[35] In present study, 8.16% of ADRs were due to cardiovascular drugs, 4.76% of ADRs were due to antihypertensives drugs, 7.49% of ADRs were due to NSAIDs and 25.19% of ADRs were due to antibiotics. Davies et al in UK have found the most frequent ADR causative drugs relative to usage to be opioid analgesics, anticoagulants, fibrinolytics, systemic glucocorticoids, diuretics and antibiotics.[36] Above studies are consistent with the present study with regard to therapeutic class of drugs implicated in ADRs. However, these differences seen in different places could also be due to variation in drug usage and disease prevalence in different places.[37]

As regard to the body system affected as per SOC in the present study, 25.39% ADRs have involved skin and subcutaneous system, 19.37% of ADRs involved the gastrointestinal system, 10.21% of ADRs involved the central and peripheral nervous system, 9.68% of ADRs are the deranged serum electrolytes, LFT and RFT. 6.54% of ADRs involving the blood and lymphatic system, 6.28% of ADRs are of general disorders and administration site conditions, 3.93% of ADRs involving the immune system and 3.41% of ADRs involving the renal and urinary system. Other systems included are the cardiovascular system, hepatobiliary system, respiratory, psychiatric disorders, eye disorders, endocrine and the reproductive system. The involvement of skin, GI system, central and peripheral nervous system in that order in our study was similar to that of other previous studies Belhekar and Lihite et al also reported skin is the most commonly affected organ system.[4,6,12,16,18,20,38]

The limitation of our study is that, re-challenge test was not done in any case due to medical and ethical issues and it's a retrospective study which is descriptive in nature. The ADRs are spontaneously reported so that the true incidence of ADRs cannot be determined by using this data. The role of other drugs that are used concomitantly with the primary suspect drug when the ADR has occurred cannot be completely ruled out.

CONCLUSION

A total of 382 ADRs were reported during the study period. The antimicrobial agents were implicated as the most common cause of ADRs. The skin and subcutaneous is the most commonly affected specific organ class. 104 ADRs were reported under the seriousness criteria. The outcome of reported ADRs was recovering in 52.10 and 81% of ADRs were probable as per WHO causality assessment scale. A coordinated system of identifying the ADRs early in the course of treatment and recognizing the preventable ADRs is required by the health care system. The sensitization programs are being conducted at our

Gandhi hospital and medical college, coordination of prescribing physicians and pharmacovigilance personnel can produce better trend of reporting the ADRs.

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