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Research Article

A RETROSPECTIVE PHARMACOVIGILANCE ANALYSIS AT TERTIARY CARE HOSPITAL: AN OBSERVATIONAL STUDY

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ABSTRACT

Objective: Pharmacovigilance Program of India is a robust program extending from government hospitals to non-government hospital for implementation of policy of safe and rational use of drugs and early signal generation for adverse effects of drugs. Department of Pharmacology, Institute of Medical Sciences, Banaras Hindu University is part of this program since 2004. Retrospective analysis of adverse drug reaction (ADR) reported to the adverse drug monitoring center at tertiary Care Hospital.

Methods: The study site was Sir Sundar Lal Hospital, Institute of Medical Sciences Banaras Hindu University, Varanasi. The study was performed after the approval of the Institutional Ethics Committee, letter number: Dean/2020/EC/2153. It was a retrospective observational study. Data collected through VigiFlow software in standard IPC Pharmacovigilance Program of India prescribed suspected ADR form, from March 2020 to June 2021 were analyzed. Causality assessment was done using a World Health Organization Uppsala Monitoring Center scale.

Results: In the present study, the percentage of male patients affected is 58% and 42% female patient got suffered from adverse drug effects. About 64% of adverse effect are in possible category followed by probable, that is, 36%. The majority of adverse effects are due to antimicrobials, that is, Cephalosporins and Antitubercular group of drugs. About 20.1% adverse events show gastrointestinal symptoms. In the present study, we also observed that 5.17% adverse effects are due to hydroxychloroquine account for gastritis, headache, lethargy, and vomiting which were prescribed as prophylactic drug for COVID-19.

Conclusion: Medicine information OPD in every medical college is the need of the hour to increase awareness regarding adverse events. It is important to spread importance of reporting adverse events by spontaneous reporting under Pharmacovigilance Program of India to detect rare and unusual side effects.

Keywords: Adverse drug monitoring, Pharmacovigilance, Medicine information OPD.

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INTRODUCTION

In India, pharmacovigilance program initiated in the year 1986 under the supervision of drug controller General of India. Pharmacovigilance Program of India (PvPI) is recent running program having National Coordinating Center at Indian Pharmacopoeia Commission Ghaziabad. It is a robust program extending from government hospitals to non-government Hospital to implement policy of safe and rational use of drugs. Department of Pharmacology, Institute of Medical Sciences, BHU is part of this program since 2004. Pharmacovigilance is defined as science relating to collection detection assessment, monitoring and prevention of adverse effect [1]. Reporting is the key of prevention and future identification of potential adverse effect due to drugs. In India, we follow system of a spontaneous reporting at many centers across India [2,3].

Spontaneous reporting is the system which requires motivation of individual and public awareness. Report submitted by an individual is known as individual case safety reports. Multiple individual case safety reports are important to generate potential signals, causality assessment is required to show causal relationship between the drug event and drug. The World Health Organization-Uppsala Monitoring Center (WHO-UMC) is one such causality assessment scale which is used worldwide. It classify the event as certain, probable possible based on the temporal relationship, severity of the event [4,5].

Risk and benefit ratio play a crucial role in therapeutic decisions. Adverse drug reaction (ADR) is clinicoepidemiological problem affecting the clinical outcome of patients. Near about 20% of the health budget is spent to deal with the of drug-related adverse events, having huge impact on the health-care system. Lack of awareness, lack of motivation, ignorance, and lethargy, these are some of the reason for under-reporting of ADR. In COVID period, active surveillance is difficult as Outpatient and Inpatient department are running with limited number of patients. In this period, we can very well appreciate that spontaneous reporting will definitely help to maintain the crucial chain of reporting and for that spreading awareness about Pharmacovigilance Program in society is of paramount importance [6]. The objective of the study is retrospective analysis of ADR reported to the adverse drug monitoring center at tertiary care hospital.

METHODS

Study site

This study was Sir Sundar Lal Hospital, Institute of Medical Sciences Banaras Hindu University, Varanasi.

Ethical consideration

The study was performed after the approval of the Institutional Ethics Committee, letter number: Dean/2020/EC/2153. The confidentiality of the reports was maintained at all level of assessment.

Research Plan

It is a retrospective observational study. Data collected through VigiFlow software in standard IPC PvPI prescribed suspected ADR form, from

March 2020 to June 2021 were analyzed. Causality assessment was done using a WHO-UMC scale. The parameters which were analyzed are Demographic data, System affected, Causality assessment, Drug-drug Interaction. The result were analyzed in the form of percentage and tabulated.

Causality assessment

In causality assessment, it is the judgment about the degree to which reported adverse event associated with the drugs. Consistency, strength, specificity, temporal relationship, and biological plausibility of association are observed. There are different method for causality assessment Unrestricted evaluation like WHO-UMC criteria, Algorithms, for example, Naranjo's algorithm and Bayesian probabilistic methods. The criteria used in the study is WHO-UMC criteria which are used by the WHO center for Drug monitoring, Uppsala Sweden notably for spontaneous ADR reports.

Certain means ADR is having temporal relationship, not explained by other concurrent drugs or underlying diseases, dechallenge and rechallenge is positive and ADR also shows causal relationship with the drug.

Probable means ADR is having temporal relationship, not explained by other concurrent drugs or underlying diseases, dechallenge is positive and rechallenge not done. ADR also shows causal relationship with the drug.

Possible means ADR is having temporal relationship, May be due to other concurrent drugs or underlying diseases, dechallenge and rechallenge not done or not feasible. ADR also shows causal relationship with the drug.

Unlikely means ADR is not having any temporal relationship, it is explained by concurrent drugs or underlying diseases, dechallenge and rechallenge not done or not feasible. ADR do not also shows any causal relationship with the drug.

Potential drug - Drug interaction

The concurrent medication mentioned in the suspected ADR form was tabulated. The potential drug-drug interaction were observed, the medscape software was used for analysis of reactions.

RESULTS

Total number of ADR detected was 396, the highest number of ADR was detected in the month of April 2020 (total: 45 reports), the lowest number of ADR was detected in the month of March 2021 (total: 16 reports) (Fig. 1).

Mean age group was 34.8; the percentage of male patients affected is 58% and 42% female patient got suffered from adverse drug effects. About 20.1% adverse events show gastrointestinal symptoms (Fig. 2). Most of the adverse effects were in the category of probable and possible category according to WHO-UMC scale. About 64% of adverse effects are in possible category followed by probable 25% (Fig. 3). In analysis of reaction of drug prescribed and adverse event observed, we observed that 23.4% of adverse effect are from single drug prescription followed 22. Four are from multi drug, that is, four drug prescription, followed by 24.5% from five drug prescription (Fig. 4). In analysis, it was observed that 64% ADR may be explained by concurrent medication, diseases or may be due to drug-drug interaction hence classified in possible category. One hundred and fifty-eight suspected ADR reporting form shows that there is potential drug-drug interaction.

DISCUSSION

India contributes to WHO-UMC VigiBase is currently more than 280 000 ICSRs [7]. India contributes significant number of ADRS to global database. The pharmacovigilance tool kit was prepared to spread awareness and making reporting more feasible; now, ADR forms are available in regional languages which facilitate the Patients reporting along with improved compliance to outreach as many areas and population, PvPI has provided a toll free number (1800 180 3024) and patient friendly PvPI app [8].

In a study by Sood and Sood *et al.,* the number of cases of ADRs in the 30–50 age groups was higher than in the other age groups. In this study, higher number of ADR was observed in age group 49–60, that is, 25% and 27% of ADR observed in age group of 60 and above, which is analogous with above stated study [9]. In a study by Zhao *et al.*, the mean age was 47.6 years, and 732 (61.6%) ADR were observed in the age group of 18–59 years. A total of 627 patients (52.7%) were female.

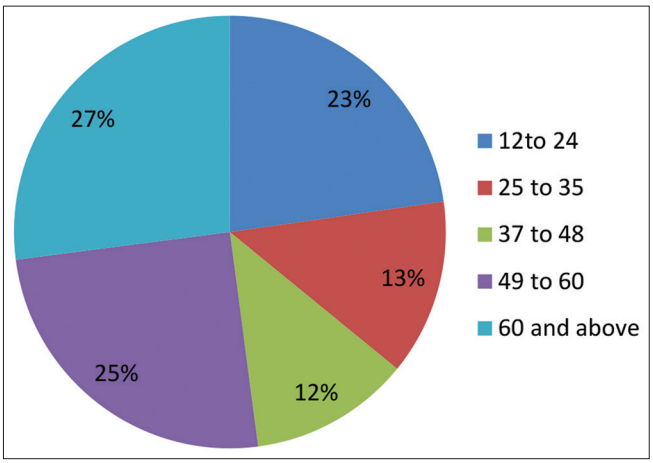

Fig. 1: Age-wise distributions of adverse drug reactions

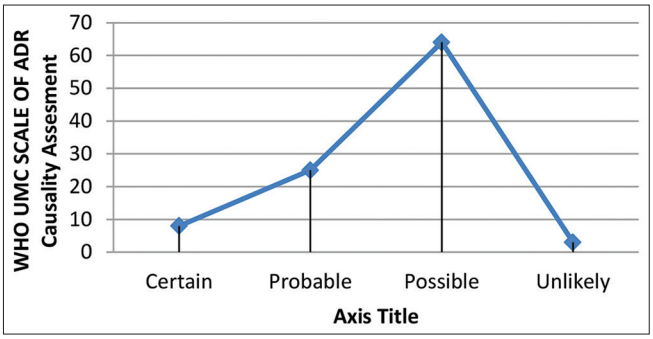

Fig. 2: Causality assessments according to WHO UMC scale

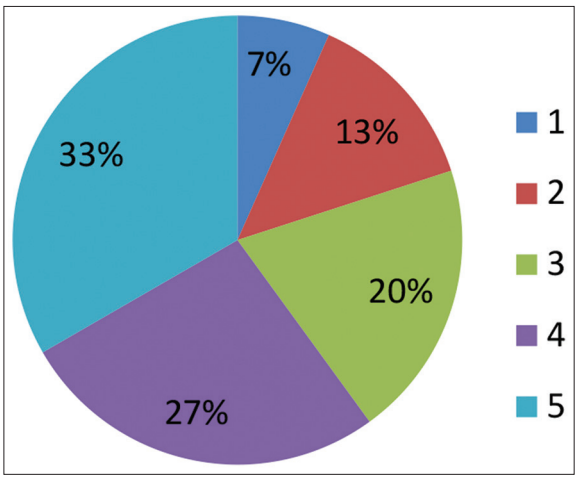

Fig. 3: Relation between Number of drug prescribed and adverse event observed

In the present study, the percentage of male patients affected is 58% and 42% female patient got suffered from adverse drug effects. In a study by Sen *et al.*, the range of age group was 41–50 years with mean age 45.6 years (n=15.25%), in which ADR was commonly observed followed by >60 years age group (n=12.20%) and 50–60 years age group (n=10.16.66%) [10-16].

In a study by In a study by Pugi *et al.*, 3.3% and 64.3% were determined to be definite or probable ADRs, respectively, and 32.4% were deemed possibly drug related ADRs. In this study, we found that 64% of adverse effect are in possible category followed by probable, that is, 25%. In the same study stated above by by Pugi *et al.*, they reported that frequency of adverse effect was mostly observed in Anticancer group of drugs, in the present study, 31% of adverse effect was observed from antimicrobial group of drugs (Fig. 5) [11], the results are in concurrence with the result of Gor and Desai as they found that majority of ADR (72.22%) occurred due to chemotherapeutic agents. About 66.67% of ADR involved the symptoms of gastrointestinal tract involvement. Similarly, in this study, 20.1% adverse events are Gastrointestinal in nature [14].

IPC, NCC-PvPI and the National AIDS Management Agency formally agreed on September 15, 2014 to team up to develop procedures for the reporting, analysis and control of ADRs attributable to antiretroviral medicinal products used in NACP to ensure the protection of antiretroviral (ARV) medicinal products used in the program [12]. Adverse drug monitoring plays very crucial role in prevention of antimicrobial resistance (AMR). NFI-2016 contained an appendix implementing the policy to include antimicrobial resistance in line with the National Strategic Framework, identifying the activities involved in AMR and conveying the measures to prevent AMR in health-care settings [13]. Pharmacovigilance tracking approach is also suggested to improve ADR report collection; mandatory Nursing and Paramedical staff training will improve the quality and frequency of reporting [14].

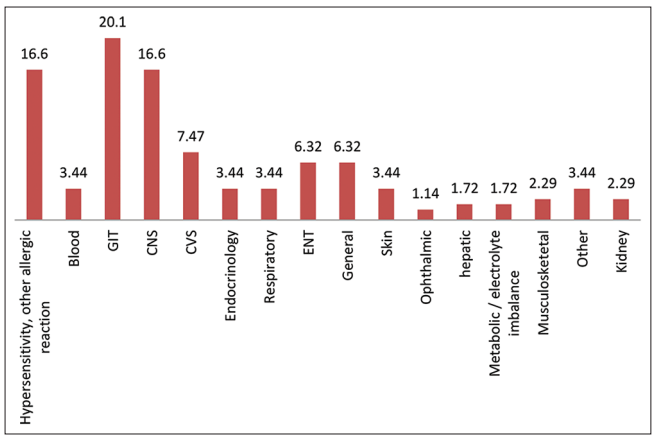

Fig. 4: System wise distribution of adverse events

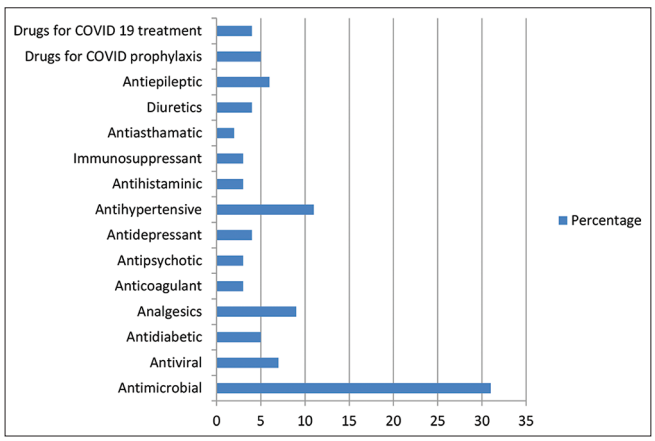

Fig. 5: Percentage of adverse event observed from different class of drugs

In the prospective study by Gor and Desai, they stated that as the number of drugs increased, the incidence of ADR also increased [15]. The result of this study is similar as 23.4% of adverse effect are from single drug prescription followed 22.4 are from multi drug, that is, 4 drug prescription, followed by 24.5% from 5 drug prescription.

In a study of Beijing Pharmacological database by Zhao *et al.*, it was noted that the largest (34.5%) of antibiotic-induced anaphylaxis are caused by cephalosporins, followed by fluoroquinolones (29.6%), beta-lactam/beta-lactamase inhibitors (15.4%), and penicillin inhibitors (154%) (7.9%). Other essential contributors were blood products and biological agents (3.1%) and plasma replacements (2.1%) [16]. The results are in concurrence with this study, in this study, we found that majority of adverse effects are due to antimicrobial drugs, that is, Cephalosporins and Antitubercular group of drugs (Table 1), that is, 31.6%.

In the Kumar BN study, the highest number of cases were correlated with antimicrobial therapy (28.57%), followed by antihypertensive therapy (24.02%) and antidiabetic therapy, respectively (14.28%). This result are similar with the present study, we found that 31.6% ADRs are due to antimicrobial drugs, 10.34% are due to antihypertensive (Table 2). Gastrointestinal ADRs were a major component of the affected organ systems (39.61%), followed by skin-related ADR s (28.57%). In this study, majority of ADR are observed from gastrointestinal system, that is, 20.1%, but skin-related adverse effect account for 3.44% ADRS in total [17].

An Pharmacovigilance analysis by Singh *et al.* was done to determine the association between hydroxychloroquine (HCQ) and characterize HCQ-associated cardiovascular adverse events. "They performed a disproportionality analysis of HCQ-associated CV-AEs. The database used was the FDA adverse event reporting system (FAERS) database. It was observed that, the patients who received HCQ are at higher risk of various cardiac AEs, including QT prolongation and TdP. Risk benefit analysis is important before prescription of any drug on widespread basis for prophylaxis [18]. In the present study, we also observed 5.17% adverse effects due to HCQ account for gastritis, headache, lethargy, vomiting, weakness, anxiety, dizziness, dry mouth, and headache (Table 3).

Similar results were stated by Montastruc *et al.* that relative high percentage of cardiac ADRs showing that HCQ, that is, cardiomyopathy and arrhythmias account for 8.3% of total Individual case safety reports, this result gives emphasis on narrow therapeutic range of HCQ [19].

First released in September 1997, the Erice Declaration on Sharing Drug Safety Information offers a vision of vigorous, open, ethical, and patient-centered drug safety communication. The international community gathering in Erice and drawing up the Declaration, representing medicines should be publicly accessible. The declaration is a very brief paper, but it poses profound challenges. The basic change involved, such as accountability and honesty. The declaration supports the visionary participation of both stakeholders and all those interested with drug control [20].

India immunization program is one of the world's largest immunization program to eliminate vaccine preventable diseases, PvPI also play a very important role in vigilance of vaccine related adverse effects, In COVID period, we very well appreciate the need of robust Phase IV surveillance to ensure the safety and wellbeing of recipient. Pharmacovigilance division of human vaccine within the biological division of CDSCO headquarter is playing a pivotal role in collection and analysis of vaccine-related adverse effects. Health-care practitioners need more awareness to improve spontaneous reporting [21].

Table 1: Adverse effects observed due to antimicrobials and antitubercular

Drugs	Adverse drug reaction observed	Percentage
Piperacillin+Tazobactum	Swelling of injection site	2.8
	Rash all over	
	Hypokalemia	
	Dizziness	
	Vertigo	
Amoxycillin+Clavulanic Acid	Rashes	2.6
	Rash with Itching	
	Diarrhoea	
Artemether+Lumefantrine	Palpitation	3.6
	Decreased Appetite	
Cefoperazone	Swelling of injection site	2.2
Cefpodoxime+Clavulanic Acid	Headache	2.8
Ceftriaxone	Rash with Itching	1.3
	Rash All over	
	Rash with Itching	
	Erythematous Rash	
Cefuroxime+Clavulanic Acid	Rash All over	1.2
Ciprofloxacin+Tinidzole	swelling of lips	1.3
Clindamycin	Rash with Itching	1.3
Sulfamethoxazole+Trimethoprim	Joint Pain	1.8
Azithromycin	Loose Stools	2.1
	Vertigo	
Isoniazid	Rash All over	2.1
	Peripheral neuropathy	
	Peripheral neuropathy	
	Hepatitis	
	Numbness of legs	
	liver Disorder	
	Rash with Itching	
	Gastric Disorder	
	Numbness of legs	
	Pain in legs	
Isoniazid+Rifampicin+Pyrazinamide+Ethambutol	Induced Hepatitis	2.8
	Vomiting	
	Hypothyroidism	
	Gastritis	
	Rash All over	
	Vomiting	
	Dizziness	
Rifampicin+Isoniazid+Ehambutol	Rash with Itching	1.6
	Swelling of legs	
Kanamycin	Hearing Loss	1.3
	Decreased hearing	
	Deafness	

Table 2: Adverse effects observed due to antihypetensive

Amlodipine	Pedal Oedema	4.2
Amlodipine+Telmisartan	Tremor	
	Hypotension	
	Stomach Upset	
	Pedal Oedema	
	Muscle Pain	
	Hypotension	
Atenolol	Swelling all over	3.2
Clinidipine+Metoprolol	Swelling of feet	2.2
Telmisartan	Stomach upset	2.1
	Increased serum creatinine	

Table 3: Adverse effects observed due to prophylaxis and treatment for COVID-19

Hydroxychloroquine	Gastritis	4.2
	Headache	
	Lethargy	
	Vomiting	
	Weakness	
	Anxiety	
	Dizziness	
	Dry Mouth	
	Headache	
Remdesivir	Nausea	3.2
	Severe headache	
	Abnormal liver function test	
Favipiravir	Hepatic enzyme increased	2.0
	Nausea, vomiting	
	Tachycardia	

In a study by Pugi *et al*., overall, 863 reports of suspected ADRs involve antiviral drugs. Renal colic, lactic acidosis, depression, anemia, hallucination, and neutropenia are the common side effects due to antiviral drugs. In the present study, we found that 6.32% adverse events are due to antiviral drugs. Zidovudine, Zidovudine and Lamivudine, Combination of Zidovudine, Lamivudine with Nevirapine causes severe anemia, Ritonavir causes increases in serum bilirubin, Tenofovir increases serum creatinin**e** (Table 4).

Table 4: Adverse effects observed due to antivirals

Drugs	Adverse drug reaction	Percentage
Zidovudine	Anaemia	1.3
Zidovudine+Lamivudine	Severe Anaemia	1.1
Zidovudine+Lamivudine+ Nevirapine	Severe Anaemia	1.2
Ritonavir	Increased serum Bilirubin	1.3
Tenofovir	Increased serum Creatinine	2.1

Table 5: Adverse effects observed due to antipsychotics/ antidepressants/antiepileptic

Drugs	Adverse drug reactions	Percentage
Amisulpride	Vomiting	1.4
Amitriptyline	Tingling Sensation	2.1
Amitriptyline+ Chlodiazepoxide	Nervousness Increased blood Pressure	
Quetiapine	Insomnia	2.1
Pregabalin	Burning Sensation. Rash with itching	2.3
Phenytoin	Motor Ataxia	2.2
Lorazepam	Drowsiness	2.1
Oxcarbazepine	Vertigo Headache	1.6

Table 6: Adverse effects observed due to antidiabetic

Drugs	Adverse effects	Percentage
Sitagliptin	Sore Throat Weakness	3.2
Metformin	Fever Fatigue Hypoglycemia	2.6

Of the 14,270,446 accounts included in VigiBase, 1,027,405 (7.2%) contained at least one antidepressant, 29,253 (2.8%) that causes motion disorders. Among the antidepressants, mirtazapine, vortioxetine, amoxapine, phenelzine, tryptophan, and fluvoxamine were associated with the highest levels of motion disorders in the study by Revet *et al.* [22]. In the present study, we found that vomiting, tingling sensation, nervousness, and increased blood pressure are the common adverse effects from antidepressants. In most of the cases, the drug amitriptyline and it combination with chlordizepoxide are responsible for most of the adverse effects (Table 5) [23].

In a study by Hosohata *et al.*, the strongest signals were detected for drug rash caused by lamotrigine, Stevens-Johnson syndrome caused by zonisamide [24]. In the present study, we found that antiepileptic drug phenytoin causes motor Ataxia, Lorazepam causes drowsiness, Oxcarbazepine causes vertigo, and headache.

In a study by Tarapués *et al.*, musculoskeletal disorders were strongly associated with gliptins. They found that out of 334 cases, 208 involved sitagliptin related musculoskeletal ADRS, 115 vildagliptin, and 09 saxagliptin associated myalgia and arthralgia. In the present study, it was reported that sitagliptin accounts for weakness and sore throat (Table 6) [25].

Limitation

Concurrent ADRs and drug interaction due to drugs form different pathies remain under reported and not included in this study [26].

CONCLUSION

Medicine information OPD in every medical college is the need of the hour to increase awareness regarding adverse events. It is important to spread importance of reporting adverse events by spontaneous reporting under Pharmacovigilance Program of India to detect rare and unusual side effects.

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AUTHORS' CONTRIBUTION

KG and RG-Concept and design of the study, prepared first draft of manuscript; KP- Interpreted the results; reviewed the literature and manuscript preparation; RG and KG- Coordination, statistical analysis and interpretation; KG and UA-preparation of manuscript, revision of the manuscript and correspondence of the manuscript.

COMPETING INTERESTS

None declared.

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None.

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