Int. J. Pharm. Investigation, 2025; 15(2):562-572.
https://www.jpionline.org

Original Article

A Pharmacovigilance Study on Adverse Drug Reaction Profile at a Tertiary Care Teaching Hospital from Western Part of India

Nirali Doshi[1], Bijal Prajapati[2,*], Lavanya Selvaraj[3]

[1]Research Scholar, Faculty of Pharmacy, Parul University, Vadodara, Gujarat, INDIA.
[2]Department of Pharmaceutics, Parul University, Vadodara, Gujarat, INDIA.
[3]Department of Pharmacy Practice, P.S.G College of Pharmacy, Tamil Nadu, INDIA.

ABSTRACT

Background: Pharmacovigilance studies analyzing Adverse Drug Reactions (ADRs) play a crucial role in understanding the ADR profile at tertiary care centers. The objective of this study is to identify, analyze and understand the ADR profile and contribute to the Pharmacovigilance Programme of India (PvPI) mission of drug and patient safety. **Materials and Methods:** This observational study was conducted from July 2022 to December 2023 at a tertiary care teaching hospital, following Institutional Ethics Committee approval. Data were collected using the Central Drug Standard Control Organization (CDSCO) ADR reporting form. ADRs were characterized based on patient demographics, drug class, system organ class, seriousness, outcome and causality using descriptive statistics. **Results:** A total of 125 ADRs were reported during the study period. The most affected population included females (60.44%) and individuals aged 18-65 years (73.65%). Antibiotics were most commonly associated with ADRs (28.8%). The majority of ADRs were classified as non-serious (62.6%). Causality assessment according to the World Health Organization Uppsala Monitoring Centre (WHO-UMC) criteria revealed that 50.4% of ADRs had a probable correlation, 48.8% had a possible correlation and 0.8% had an unlikely correlation to the suspect drug. **Conclusion:** This study highlights key aspects of ADR analysis and provides insights into the ADR profile at the tertiary care center. Pharmacovigilance studies are essential for addressing underreporting in busy hospitals and improving the culture of ADR reporting. Further research focusing on maternal and fetal exposure as well as medication errors is needed within the Indian healthcare system.

Keywords: ADR, Drug safety, MedDRA, PvPI.

Correspondence:
Dr. Bijal Prajapati
Department of Pharmaceutics, Parul University, Vadodara-391760, Gujarat, INDIA.
Email: bijal.prajapati@paruluniversity.ac.in

Received: 07-10-2024;
Revised: 21-11-2024;
Accepted: 12-12-2024.

INTRODUCTION

As known "No drug is absolutely free from side effects" in clinical practice. Adverse Drug Reaction (ADR), by World Health Organization (WHO) definition, is "a response to a medicinal product which is noxious, unintended and which occurs at doses normally used in man for prophylaxis, diagnosis or therapy of diseases or for the restoration, correction or modification of physiological function". Pharmacovigilance (PV) is the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other possible drug-related problems. To enhance patient care and patient safety is the primary aim of pharmacovigilance (Hamid *et al*., 2022; The Importance of Pharmacovigilance, 2002).

DOI: 10.5530/ijpi.20250144

Copyright Information :
Copyright Author (s) 2025 Distributed under Creative Commons CC-BY 4.0

Publishing Partner : Manuscript Technomedia. [www.mstechnomedia.com]

Need of systemic collection of adverse events and thus safety monitoring of drugs in post-marketing setup has been derived from past catastrophes. The first safety concern was raised in 1848 after death of a girl from England following administration of chloroform for anaesthesia for removal of an infected toenail. Thalidomide tragedy with its presence in 46 countries where thousands of children were born with limb deformities demanded a systemic approach for monitoring of post-marketing adverse events (The Importance of Pharmacovigilance, 2002). Unexpected Adverse Drug Reactions (ADRs) are mostly not identified prior to approval of drugs by regulators resulting in increased morbidity and mortality. Pharmacovigilance analysis allows collecting real-world drug safety information. This information is crucial for determining benefit-risk profile of a drug and thus building trust on drug therapies (Garashi *et al*., 2022).

WHO initiated Programme for International Drug Monitoring (PIDM) in 1968 with a goal to identify rare Adverse Reactions. Over the time, scope of PIDM was expanded to promote PV

at country level and collaborate internationally for drug safety monitoring (Olsson, 1998). India joined as a member country to WHO PIDM in 1998 with unsuccessful attempt. Later, National Programme of Pharmacovigilance was launched in 2005 and was renamed to Pharmacovigilance Programme of India (PvPI) in 2010 (Kalaiselvan *et al*., 2019). PvPI is continuously working hard creating awareness on ADR reporting among the Indian population and to build trust among patients and healthcare professionals with respect to medicines safety. Drug-related morbidity and mortality are reported in studies conducted in Indian tertiary care hospitals. ADRs are a significant concern in tertiary care hospitals, with a prevalence of 28.3% (Raikar *et al*., 2023). Despite of this fact and PvPI tremendous efforts to establish ADR reporting culture, rate of ADR reporting is less than 1% in India whereas worldwide, it is 5% (Shukla *et al*., 2024; Kalaiselvan *et al*., 2016; Singh *et al*., 2023). Lack of time, knowledge and attitude of Health Care Professionals (HCPs) towards ADR reporting responsibility are prime factors for under-reporting in India (Raju *et al*., 2022; Kumar *et al*., 2023). HCPs from both private and public hospitals, teaching institutions and pharmaceutical companies are key-players for ADR surveillance and thus for establishment of culture of drug safety (Olsson *et al*., 2015; Bansod *et al*., 2020).

The objective of this study was to identify, analyse and understand characteristics of ADRs arise during clinical practice at Parul Sevashram-a tertiary care teaching hospital and thus to contribute in preventing reoccurrence of ADRs. Parul Sevashram is the NABH (National Accreditation Board for Hospitals and Healthcare Providers) accredited multispecialty hospital providing advanced treatments and procedures for wellbeing of the patients in Waghodia region of Vadodara, Gujarat, India. This present study also contributes towards increasing awareness and improving culture of ADR reporting among hospital staff and intern students.

MATERIALS AND METHODS

This prospective, non-interventional, observational study was carried out from July 2022 to December 2023 at general medicine department. Study was initiated after obtaining Institutional ethics committee permission (Reference No. PUIECHR/PIMSR/00/081734/4915).

Inclusion criteria

Patients or their guardian who provided consent voluntarily for collection of their treatment and safety data and developed ADR were included in this study.

Exclusion criteria

- ADR associated with use of alternative system of medicines like Ayurveda, Homeopathy, Unani, etc.
- Adverse event developed following vaccine/immunization.
- Adverse drug events due to medical devices.

Patients were included after obtaining their consents. Patients and their guardian were explained about ADR and were encouraged to report and HCPs were informed for reporting of observed ADR. Data were collected by interviewing patients or their guardian and/or reviewing their case records. Any untoward event was labelled as ADR. Data on Patient's demographics, medical history, prescription medicine and ADR and its outcome were collected on Central Drug Standard Control Organization (CDSCO) ADR reporting form (Central Drug Standard Control Organization (CDSCO), 2022) and then transferred to structured datasheet for further analysis. Data were kept confidential at all levels of handling. Confirmed ADR were submitted to respective unit for reporting to PvPI. Analysis of ADR was performed at Preferred Term (PT) level of the Medical Dictionary for Regulatory Activities (MedDRA) terminology (Medical Ddictionary for Rregulatory Aactivities (MedDRA), 2023). ADR were analysed for the demographic profile of patients, system organ class and causative drugs on the drug substance level, ADR outcome and causality assessment. The seriousness was assessed following standard criteria given by the PvPI and following Important Medical Event (IME) list (Indian Pharmacopoeia Commission (IPC), 2019; EudraVigilance ExpertWorking Group (EV-EWG), 2015). The causality was assessed following World Health Organization Uppsala Monitoring Centre (WHO-UMC) system for standardised case causality assessment (The use of the WHO-UMC system for standardised case causality assessment, 2020). Treating physician's opinion was considered as final for ADR consideration and related assessment.

The study used descriptive statistics and the values were expressed in absolute numbers and percentages as appropriate with the help of Microsoft Excel.

RESULTS

Total of 125 ADRs were reported among 91 patients during study duration at the study site.

Analysis of the ADR data based on patient demographics

Gender-wise distribution

Sex-distribution showed more ADR were reported in female patients (N=55, 60.44%) than in male patients (N=36, N=39.56%).

Age-wise distribution

Overall mean age was 41.66±20.54 years. The age group in the range of 18-65 years with mean age of 45.62 years was most commonly involved in ADR reporting (N=67, 73.63%) followed by below 18 years age group with mean age of 9.37 years (N=16, 17.58%) and above 65 years age group with mean age of 73.36 years (N=8, 8.79%).

Department wise distribution

Outpatient department cases were in predominance (*N*=54, 59.34%) compared to inpatient department cases (*N*=37, 40.6%).

Co-morbidity

Out of 91 patients, 53 patients (58.24%) reported to have presence of other illness along with treating diseases for which suspect drug was prescribed. Most observed co-morbidity was hypertension (16.98%) followed by renal disorder (13.21%) and hyperchlorhydria (9.43%) and diabetes mellitus (9.43%) among 53 patients who reported comorbidity.

Polypharmacy

Majority of the patients (*N*=44, 48.35%) were reported use of other medications concomitantly with suspect drug experienced ADRs. Twenty-four patients (26.37%) were not receiving any concomitant medication and administration of concomitant medication was unknown for 23 patients (25.27%). Out of 44 patients who were on polypharmacy, pantoprazole was found most frequently taken concomitant medication (25%), followed by aspirin and multivitamins each of them accounting 20.45% and ondansetron (18.8%). Analysis of patient demographics was presented in Table 1.

Table 1: Demographics of patients with ADR/s.

Parameter	Variables	Number of patients N (%)
Gender	Female	55 (60.44%)
	Male	36 (39.56%)
Age group	Below 18 years	16 (17.58%)
	18-65 years	67 (73.63%)
	Above 65 years	8 (8.79%)
Department	Outpatient	54 (59.34%)
	Inpatient	37 (40.66%)
Co-morbidity	Presence of other illness	53 (58.24%)
	Absence of other illness	38 (41.76%)
Polypharmacy	Concomitant medication administration	44 (48.35%)
	No concomitant medication administration	24 (26.37%)
	Unknown	23 (25.27%)

Characterization of drugs causing ADRs

Out of 20 noted drug classes, highest number of ADRs were reported from the antibiotics class (*N*=36, 28.8%). This was followed by analgesics (*N*=15, 12.0%) and then equal number of ADRs from antithrombotic agents and antineoplastic agents (*N*=12, 9.6%). Detailed list of causative drugs is shown in Table 2. The highest observed drug-ADR pair was spironolactone-Gynecomastia (*N*=4), followed by polymyxin-acute kidney injury (*N*=3) and ceftriaxone-eye swelling (*N*=3).

ADR profile based on System Organ Class (SOC)

ADRs were spanning among nineteen SOCs as detailed in Table 3. In our study, general disorders and administration site conditions and skin and subcutaneous tissue disorders were found most frequently affected SOCs recording 19 (15.2%) ADRs. These were followed by SOC gastrointestinal disorders (*N*=18, 14.4%) and then nervous system disorders (*N*=14, 11.2%).

Nature and causality of ADR and case outcome management

As depicted in Table 4, majority of the ADRs were non-serious (*N*=82, 65.6%) in nature. There were 43 (34.4%) serious ADRs, out of which one (0.80%) was resulted into death, four (3.20%) were life-threatening, 23 (18.40%) were resulted into hospitalization or prolong hospitalization and 15 (12%) were found to be important medical events.

According to WHO-UMC causality scale, association of 63 ADRs (50.4%) were probable to suspect drugs, 61 ADRs (48.8%) were possible and one (0.8%) ADR was unlikely.

Suspect drug withdrawal was noted (dechallenge) in most of the cases (*N*=70, 76.92%). Treatment with suspect drug was continued in 15 (16.48%) cases and suspect drug was continued at reduced dose in six cases (6.59%). Information on re-challenge was lacking as it was not performed. Among 91 patients, complete recovery was noted in 46 (50.55%) cases and 20 (21.98%) patients were recovering during study period. One case (1.10%) was resulted into fatal outcome; two (2.20%) patients did not recover during study period, while outcome of 22 (24.18%) cases was unknown. Positive dechallenge was observed among 56 (61.54%) patients, who were recovered or under recovery stage upon withdrawal of suspected drug. Case outcome and action with suspect drug were demonstrated in Table 4.

DISCUSSION

Underreporting of ADRs in India remains a challenge in achieving goal of PvPI towards patient and drug safety. On the other hand, a robust PV system is a need since India is developing as a hub for global clinical studies (Singh *et al.*, 2023). Limitation of underreporting can be minimized by educating health care professionals periodically, developing and maintaining a culture of ADR reporting and reiterating goals of PvPI within organization (Singh *et al.*, 2023; Raju *et al.*, 2022). Studies on evaluation of knowledge, attitude and practice of pharmacovigilance conducted in various parts of India suggested rate of spontaneous ADR reporting by patients and health-care professionals is low and there is a great need to improve perception for the reporting (The use of the WHO-UMC system for standardised case causality assessment, 2020; Sidhu *et al.*, 2023; Panneerselvam *et al.*, 2022).

Table 2: Causative drug associated with ADRs.

Sr. No.	Drug class	Causative drug	Various ADRs	Total number of ADRs N (%)
1.	Analgesics	Diclofenac	Angioedema, Dizziness, Dyspnoea, Pruritus, Drowsiness, Dry mouth, Peripheral swelling, Mouth ulceration, Nausea, Vomiting, Epigastric discomfort, Skin lesion.	15 (12.0%)
		Gabapentin		
		Nortriptyline		
		Methylcobalamin		
		Naproxen		
		Paracetamol		
		Pregabalin		
		Tramadol		
		Ketorolac		
2.	Anthelmintics	Albendazole	Headache	1 (0.8%)
3.	Antibiotics	Azithromycin	Peripheral swelling, Urticaria, Gingival bleeding, Rash, Eye swelling, Maculopapular rash, Syncope, Chills, HELLP syndrome, Chest pain, Acute kidney injury, Seizure, Pruritus, Stevens-Johnson Syndrome (SJS) Constipation, Tachycardia, Nasopharyngitis, Dyspnoea, Thrombocytopenia, Dizziness, hypotension, Flushing, Oculogyric crisis.	36 (28.8%)
		ceftriaxone		
		Cefoperazone		
		Sulbactam		
		Doxycycline		
		Linezolid		
		Meropenem		
		Norfloxacin		
		Piperacilin		
		Tazobactam		
		Polymyxin		
		Vancomycin		
4.	Antidiabetics	Insulin	Dizziness, Peripheral swelling	3 (2.4%)
		Metformin		
5.	Antiepileptics	Phenobarbital	Gingival hypertrophy, Drug interaction, Infusion related reaction, Respiratory depression	5 (4.0%)
		Phenytoin		
6.	Anti-hypertensives	Amlodipine	Abdominal pain, Acute kidney injury, Blood sodium decreased, Bradycardia, Cough, Chronic kidney diseases, Dizziness, Gynecomastia, Fatigue.	10 (8.0%)
		Carvedilol		
		Chlorthalidone		
		Nifedipine		
		Ramipril		
		Telmisartan		
		Propanolol		
7.	Anti-malarials	Hydroxychloroquin	Thrombocytopenia	1 (0.8%)
8.	Antimycobacterials	Dapsone	Swelling, Drug-induced liver injury, Hepatitis, Pyrexia.	4 (3.2%)
		Ethambutol		
		Pyrazinamide		
		rifampicin		
		isoniazide		

Sr. No.	Drug class	Causative drug	Various ADRs	Total number of ADRs N (%)
9.	Antineoplastic agents	Carboplatin	Anaemia, Abdominal pain, Blood alkaline phosphatase increased, Leukopenia, Neutropenia, Thrombocytopenia.	12 (9.6%)
		Gemcitabine		
		Ifosfamide		
		Oxaliplatin		
		Paclitaxel		
		Hydroxyurea		
10.	Anti-parkinson drugs	Pramipexol	Substance-induced psychotic disorder	(0.8%)
11.	Antipsychotics	Aripiprazole	Pain, Pyrexia, Seizure	3 (2.4%)
		Olanzapine		
12.	Antithrombotic agents	Acenocoumarol	Brain oedema, Cerebral Haemorrhage, Hyperchlorhydria, Dyspnoea exertion, Erythema, Hematuria, Peripheral swelling, Skin lesion, Thrombocytopenia.	12 (9.6%)
		Aspirin		
		Clopidogrel		
		Heparin		
		Ticagrelor		
13.	Antiulcer and Antacids	Ranitidine	Pruritus	1 (0.8%)
14.	Antivirals	Acyclovir	Injection site reaction	1 (0.8%)
15.	Anxiolytics	Lorazepam	Delirium	1 (0.8%)
16.	Bronchodilator	Levosalbutamol	Tremor	1 (0.8%)
		Ipratropium		
17.	Cardiac therapy	Amiodarone	Abdominal pain, Atrial fibrillation, Constipation, Decreased appetite, Hypothyroidism, Nausea, Vomiting, Toxicity to various agents.	8 (6.4%)
		Digoxin		
18.	Corticosteroids	Methylprednisolon	Drug-induced liver injury, Swelling face.	3 (2.4%)
		Prednisolone		
19.	Diuretics	Spironolactone	Chest pain, Gynaecomastia, Hyperkalaemia	6 (4.8%)
		Frusemide		
		Torsemide		
20.	Immunosuppressants	Azathioprine	Leukopenia	1 (0.8%)

By means of this study, we contributed to overcome limitation of underreporting and analyse the profile of ADR occurring at Parul Sevashram extensively. In our study we coded all ADRs with standardised terminology using MedDRA and thus introduced the culture of MedDRA for analysis in the institute. The study results were compared with prospective studies conducted in various parts of India to behold ADR pattern among them. Comparison of prospective study results conducted in various parts of India has been demonstrated in Table 5.

In our study, we found more ADR occurrences in females (60.44%) than males (39.56%) which are in concordance to prospective studies carried out by Raju S *et al.*, Singh P. *et al.*, and Vohra A *et al.* In contrary, significant number of male patients with severe ADR incidence was reported in the prospective studies carried out by Chhabra M *et al.*, from north India while incidence of ADRs was found similar in males and females by Venkatasubbaiah M *et al.*, from south India. Many drugs manifested elevated blood concentrations and longer eliminations times in women and this sex-biased pharmacokinetics attribute higher ADR incidence in women than men (Zucker and Prendergast, 2020).

In this study, population was classified mainly into three age-groups: paediatric (0-17 years), adult (18-65 years) and geriatrics (>65 years) and adults were found with highest ADR incidence (73.63%). Similar results are also discovered in northern India study (81.48%) conducted by Vohra A *et al.* Six age-groups were stratified by Raju S *et al.*, with highest ADR recorded from 31-45 years age-group and four age-groups were used by Singh P *et al.*, with highest recorded ADR from 31-60 years age-group as

Table 3: Classification of ADRs based on SOC.

Sr. No.	SOC	ADR (MedDRA preferred term)	Number of ADR N (%)
1.	Blood and lymphatic system disorders.	Anaemia	12 (9.6%)
		Leukopenia	
		Neutropenia	
		Thrombocytopenia	
2.	Cardiac disorders.	Atrial fibrillation	3 (2.4%)
		bradycardia	
		Tachycardia	
3.	Endocrine disorders.	Hypothyroidism	1 (0.8%)
4.	Eye disorders.	Eye swelling,	4 (3.2%)
		Oculogyric crisis	
5.	Gastrointestinal disorders.	Abdominal pain	18 (14.4%)
		Constipation	
		Dry mouth	
		Epigastric discomfort	
		Gingival bleeding	
		Gingival hypertrophy	
		Hyperchlorhydria	
		Mouth ulceration	
		Nausea	
		Vomiting	
6.	General disorders and administration site conditions.	Peripheral swelling	19 (15.2%)
		Drug interaction	
		Swelling	
		Pyrexia	
		Injection site swelling	
		Fatigue	
		Chest pain	
		Swelling face	
		Injection site reaction	
		Injection site swelling	
		Swelling	
		Pain	
7.	Hepatobiliary disorders.	Drug-induced liver injury	3 (2.4%)
		Hepatitis	
8.	Infections and infestations.	Nasopharyngitis	1 (0.8%)
9.	Injury, poisoning and procedural complications.	Infusion-related reaction	2 (1.6%)
		Toxicity to various agent	

Sr. No.	SOC	ADR (MedDRA preferred term)	Number of ADR N (%)
10.	Investigations	Blood alkaline phosphatase increased	3 (2.4%)
		Blood sodium decreased	
11.	Metabolism and nutrition disorders.	Decreased appetite	2 (1.6%)
		Hyperkalaemia	
12.	Nervous system disorders.	Brain oedema	14 (11.2%)
		Cerebral haemorrhage	
		Dizziness	
		Drowsiness	
		Headache	
		Seizure	
		Syncope	
		Tremor	
13.	Pregnancy, puerperium and perinatal conditions.	HELLP syndrome	1 (0.8%)
14.	Psychiatric disorders.	Delirium	2 (1.6%)
		Substance-induced psychotic disorder	
15.	Renal and urinary disorders.	Acute kidney injury	5 (4%)
		Chronic kidney diseases	
16.	Reproductive system and breast disorders.	Gynecomastia	5 (4%)
17.	Respiratory, thoracic and mediastinal disorders.	Cough	7 (5.6%)
		Dyspnoea	
		Dyspnoea exertion	
		Respiratory depression	
18.	Skin and subcutaneous tissue disorders.	Angioedema	19 (15.2%)
		Erythema	
		Maculopapular rash	
		Pruritus	
		Rash	
		Skin lesion	
		Stevens-Johnson Syndrome (SJS)	
		Urticaria	
19.	Vascular disorders	Flushing	4 (3.2%)
		Hematuria	
		hypotension	

Table 4: Nature, Causality and case outcome management.

Parameter	Number of ADRs (%)
Nature	
Non-serious	82 (65.6%)
Death	1 (0.80%)
Life-threatening	4 (3.20%)
Hospitalization initial/ prolonged	23 (18.40%)
Important medical event	15 (12%)
Causality	
Certain	0
Probable	63 (50.4%)
Possible	61 (48.8%)
Unlikely	1 (0.8%)
Unclassified	0
Unclassifiable	0
Action taken with suspect drug	
Drug withdrawn	70 (76.92%)
Dose reduced	6 (6.59%)
Drug continued	15 (16. 48%)
Case Outcome	
Recovered	46 (50.55%)
Recovering	20 (21.98%)
Fatal	1 (1.10%)
Not recovered	2 (2.20%)
Unknown	22 (24.18%)
Dechallenge	
Positive	56 (61. 54%)
Negative	2 (2.20%)
Unk	26 (28. 57%)
NA	7 (7.69%)

depicted in Table 5. However, older adults (>65 years) are found with more ADR occurrences than younger adults (19-65 years) in study carried out by Dubrall D *et al*., using ADR database of the German Federal Institute for Drugs and Medical Devices (BfArM).

ADR characteristics found in our study are similar to studies from southern (Raju *et al*., 2022), east-central (Singh *et al*., 2017) and northern India (Vohra *et al*., 2023). The drug mostly associated with ADR was found to be antibiotics class (Raju *et al*., 2022; Singh *et al*., 2017; Vohra *et al*., 2023). and a large number of ADRs were observed from dermatological body system class (Raju *et al*., 2022; Singh *et al*., 2017). Vohra A *et al.* noted highest ADR incidences from Gastro-intestinal followed by dermatology (Vohra *et al*., 2023). Several other studies across India (Raikar *et al*., 2023; Kumar *et al*., 2023; Bansod *et al*., 2020) also have analogous observation. It is because most of the drugs are capable to cause cutaneous ADRs whereas antibiotics, antiepileptics, antineoplastics, NSAIDs are commonly implicated class of drugs causing cutaneous ADRs (Bettuzzi *et al*., 2024). ADR like Stevens-Johnson syndrome reported in this study is a serious type of cutaneous reaction, mostly drug induced and can be life threatening if timely detection and management are not done and leads to economic burden (Hazin *et al*., 2008). Therefore, health care professionals should thoroughly review and understand medical history of the patient for any drug allergy. ADRs from general disorders and administration site conditions system organ class was also equally distributed in current study.

Preponderance of non-serious ADRs was noted as demonstrated in Table 5. One death was observed in this study though it was not directly attributed to ADR but due to co-morbidity. Incidence of fatal ADRs was less than 1% in other Indian studies also (Raju *et al*., 2022; Venkatasubbaiah *et al*., 2018). Recovery has been

Table 5: Comparison of prospective study results from various parts of India.

	Our study	Raju S *et al.*	Singh P *et al.*	Vohra A *et al.*
Part of India	**Vadodara, (Western India)**	**Bengaluru (Southern India)**	**Raipur (east-central India)**	**Haryana (Northern India)**
Study duration	1.5 years	3 years	1 year	1 year
Total ADR	125	114	232	189
Most affected gender	Female (60.44%)	Female (60.5%)	Female (67.67%)	Female (52%)
Most affected age group	18-65 years (73.63%)	31-45 years (27.2%)	31-60 years (52.15%)	18-65 years (81.48%)
Mean age	41.66±20.54 years	42.8±18.4 years	-	-
Most affected body system	Skin and subcutaneous tissue disorders (15.2%) and General disorders and administration site conditions (15.2%)	.	Skin and subcutaneous tissue disorders (41%)	Gastro-intestinal (29%)
Most causative drug class	Antibiotics (28.8%)	Antibiotics (53.5%)	Antimicrobials (45%)	Antibiotics (31.05%)
Nature of most ADR	Non-serious (65.6%)	Non-serious (89%)*	Non-serious (63.79%)	-
Death	N=1	N=0	-	-
Causality assessment scale	WHO-UMC scale	WHO-UMC scale	WHO-UMC scale	WHO-UMC scale
Most assessed causality	Probable (50.4%)	Probable (66%)	Probable (67.24%)	Probable (55.6%)
Most action taken	Drug withdrawn (76.92%)	Drug withdrawn (100%)*	-	-
Most case outcome	Recovered (50. 55%)	Recovered	-	-

*Percentage was inferred from the study result provided, - Data not available.

reported in majority cases in our study similar to southern India study (Raju *et al.*, 2022) suggesting capabilities of Indian health care system in managing the outcome well. Discontinuation of suspect drug was found as a common pattern in ADR management in this study and other Indian studies (Raju *et al.*, 2022; Singh *et al.*, 2017).

Causality assessment is an important parameter of ADR analysis to measure degree of likelihood. In pharmacovigilance, adverse reactions are rarely specific for the drug, diagnostic tests are usually absent and rechallenge is rarely ethically justified. WHO-UMC causality assessment offers assessment based on clinical-pharmacological aspects of the case history and the quality of the documentation and hence it is widely acceptable for real-life case reports (The use of the WHO-UMC system for standardised case causality assessment, 2020). Therefore, we choose WHO-UMC causality assessment for our study over other algorithms which are too specific for general use for spontaneous reporting system. In present study, little more than 50% ADR were found probably associated with suspect drug. Similar result was also found in studies from southern India (Raju *et al.*, 2022), east-central India (Singh *et al.*, 2017) and northern India (Vohra *et al.*, 2023) which reported 66%, 67.24% and 55.6% ADR probably related to suspect drug respectively. Through this comparison, we have tried to provide insights on characteristics of ADR originated from various regions for health care professionals practicing in diversified culture of India.

CONCLUSION

The pharmacovigilance study conducted at Parul Sevashram Hospital represents a pioneering effort using standardized MedDRA coding for Adverse Drug Reactions (ADR), ensuring consistent reporting and information exchange among healthcare professionals, regulators, academics and organizations. This study provided valuable insights into ADR analysis, offering a comprehensive understanding of the ADR profile specific to our hospital. It underscored increased awareness and reporting of ADRs within our institution, particularly noting antibiotics

as the primary contributors to ADRs in Indian healthcare settings. The widespread use of antibiotics poses a significant risk of antimicrobial resistance, carrying substantial economic implications.

Although the study did not identify any signals for serious conditions like Stevens-Johnson syndrome among patients receiving ceftriaxone, it emphasized the importance of monitoring and reviewing medical histories to detect drug hypersensitivity effectively. However, the study also highlighted challenges such as inadequate vigilance and time constraints among healthcare providers at tertiary care centers, leading to underreporting and compromising the quality of ADR data in India's pharmacovigilance system.

Notably, the study did not report any cases of medication errors, overdoses, abuses, misuses, or occupational exposures during its duration. To enhance ADR reporting, the study recommends periodic awareness sessions focusing on ADR reporting protocols, maternal and fetal exposures and other specialized scenarios. It advocates for more extensive observational studies in India to address these gaps, as such situations are often overlooked in controlled clinical trial environments.

Overall, this pharmacovigilance study serves as a critical tool to raise awareness among the Indian population, address underreporting issues and support the PvPI mission of enhancing patient safety.

ACKNOWLEDGEMENT

The authors acknowledge the support received from medical director and hospital staff of Parul Sevashram and Department of Pharmacology.

CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

ABBREVIATIONS

ADR: Adverse drug reaction; **PvPI:** Pharmacovigilance Programme of India; **CDSCO:** Central Drug Standard Control Organization; **WHO:** World Health Organization; **UMC:** Uppsala Monitoring Centre; **PV:** Pharmacovigilance; **NABH:** National Accreditation Board for Hospitals and Healthcare Providers; **HCP:** Health care professionals; **PIDM:** Programme for International Drug Monitoring; **MedDRA:** Medical Dictionary for Regulatory Activities; **IME:** Important Medical Event; **SOC:** System organ class; **BfArM:** German Federal Institute for Drugs and Medical Devices; **NSAIDs:** Nonsteroidal anti-inflammatory drugs.

REFERENCES

Bansod, K. A., Bashir, M. S. M., & Ingle, S. S. (2020, April–June). Adverse drug reaction profile in Amravati region of India: A pharmacovigilance study. Journal of Pharmacy and Bioallied Sciences, 12(2), 155–162. https://doi.org/10.4103/jpbs.JPBS_226_19 [EPub].

Bettuzzi, T., Sanchez-Pena, P., & Lebrun-Vignes, B. (2024, March–April). Cutaneous adverse drug reactions. Thérapie, 79(2), 239–270. https://doi.org/10.1016/j.therap.2023.09.011 [EPub] 2023 Oct 31.

Chhabra, M., Jangra, M. S., Rashid, M., Sharma, P., & Vidyasagar, K. (2021, June 21). Pattern, severity and outcome of adverse drug reactions in a tertiary care hospital: Evidence from a cross-sectional study. Journal of Basic and Clinical Physiology and Pharmacology, 33(6), 815–822. https://doi.org/10.1515/jbcpp-2020-0218

Drug, C., & Standard Control Organization. CDSCO ADR reporting form (version 1.4). https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-documents/Consumer_Section_PDFs/ADRRF_2.pdf.

Dubrall, D., Just, K. S., Schmid, M., Stingl, J. C., & Sachs, B. (2020, March 23). Adverse drug reactions in older adults: A retrospective comparative analysis of spontaneous reports to the German Federal Institute for Drugs and Medical Devices. BMC Pharmacology and Toxicology, 21(1), 25. https://doi.org/10.1186/s40360-020-0392-9

EudraVigilance ExpertWorking Group (EV-EWG). (updated 2015/09/09). Important Medical Event Terms (IME) list. European Medicines Agency; Retrieved November 30, 2015. https://eudravigilance.ema.europa.eu/human/textforIME.asp

Garashi, H. Y., Steinke, D. T., & Schafheutle, E. I. (2022, September). A systematic review of pharmacovigilance systems in developing countries using the WHO pharmacovigilance indicators. Therapeutic Innovation and Regulatory Science, 56(5), 717–743. https://doi.org/10.1007/s43441-022-00415-y

Hamid, A. A. A., Rahim, R., & Teo, S. P. (2022, September). Pharmacovigilance and its importance for primary health care professionals. Korean Journal of Family Medicine, 43(5), 290–295. https://doi.org/10.4082/kjfm.21.0193

Hazin, R., Ibrahimi, O. A., Hazin, M. I., & Kimyai-Asadi, A. (2008). Stevens–Johnson syndrome: Pathogenesis, diagnosis and management. Annals of Medicine, 40(2), 129–138. https://doi.org/10.1080/07853890701753664

Hingorani, S. K., Shah, A. Y., & Mehta, C. D. (2023, April–June). Educational intervention to improve knowledge, attitude and practice of pharmacovigilance among resident doctors at a tertiary care hospital. Perspectives in Clinical Research, 14(2), 75–80. https://doi.org/10.4103/picr.picr_37_22

Indian Pharmacopoeia Commission (IPC) Guidance Document for Spontaneous Adverse Drug Reaction Reporting (version 1.0). https://ipc.gov.in/images/pdf/File268.pdf.

Medical dictionary for regulatory activities (MedDRA). Introductory guide MedDRA (version 26.1). (September 2023). https://admin.meddra.org/sites/default/files/guidance/file/intguide_26_1_English_1.pdf

Kalaiselvan, V., Srivastava, S., Singh, A., & Gupta, S. K. (2019, March). Pharmacovigilance in India: Present scenario and future challenges. Drug Safety, 42(3), 339–346. https://doi.org/10.1007/s40264-018-0730-7

Kalaiselvan, V., Thota, P., Singh, G. N., & Pharmacovigilance Programme of India. (2016, November–December). Pharmacovigilance Programme of India: Recent developments and future perspectives. Indian Journal of Pharmacology, 48(6), 624–628. https://doi.org/10.4103/0253-7613.194855

Kumar, R., Sr, Jindal, A., Sr, Garg, P., Kaur, A., Kumar, S., Tilak Raj, R., & Singh, S. (2023, September 10). Pharmacovigilance study of anticancer drugs in a tertiary care teaching hospital in North India: A retrospective study. Cureus, 15(9), Article e44984. https://doi.org/10.7759/cureus.44984

Olsson, S. (1998, July). The role of the WHO programme on International Drug Monitoring in coordinating worldwide drug safety efforts. Drug Safety, 19(1), 1–10. https://doi.org/10.2165/00002018-199819010-00001

Olsson, S., Pal, S. N., & Dodoo, A. (2015). Pharmacovigilance in resource-limited countries. Expert Review of Clinical Pharmacology, 8(4), 449–460. https://doi.org/10.1586/17512433.2015.1053391 [EPub].

Panneerselvam, N., Kathirvelu, P., & Manoharan, R. (2022, October–December). Impact of educational intervention on the knowledge, attitude and practice of pharmacovigilance among postgraduates of a tertiary care center, Kanchipuram, Tamil Nadu, India. Perspectives in Clinical Research, 13(4), 199–204. https://doi.org/10.4103/picr.PICR_239_20

Raikar, S. R., Raikar, S. R., Raikar, D. R., & Raikar, D. R. (2023). Analysis of adverse drug reactions in A Tertiary Care Hospital in Vijayapura. Latin American Journal of Pharmacy, 42(6), 46–52.

Raju, S. K., Kamble, S., & Kamble, S. (2022). A prospective, observational study of the spontaneous reporting patterns of adverse drug reactions in a tertiary care teaching hospital. Journal of Pharmacology and Pharmacotherapeutics, 13(3), 272–277. https://doi.org/10.1177/0976500X221130841

Shukla, S., Sharma, P., Gupta, P., Pandey, S., Agrawal, R., Rathour, D., Kumar Kewat, D., Singh, R., Kumar Thakur, S., Paliwal, R., & Sulakhiya, K. (2024). Current scenario and future prospects of adverse drug reactions (ADRs) monitoring and reporting mechanisms in the rural areas of India. Current Drug Safety, 19(2), 172–190. https://doi.org/10.2174/1574886318666230428144120

Sidhu, G. S., Kumar, J., Kumar, D., Dey, N., Ranjan, G., Sinha, T., & Pal, R. (2023, September). Knowledge and perception regarding adverse drug reactions among undergraduate

medical students of Bihar, Eastern India. Journal of Family Medicine and Primary Care, 12(9), 2082–2089. https://doi.org/10.4103/jfmpc.jfmpc_679_23

Singh, P., Agrawal, M., Hishikar, R., Joshi, U., Maheshwari, B., & Halwai, A. (2017, November–December). Adverse drug reactions at adverse drug reaction monitoring center in Raipur: Analysis of spontaneous reports during 1 year. Indian Journal of Pharmacology, 49(6), 432–437. https://doi.org/10.4103/ijp.IJP_781_16

Singh, P., Vaishnav, Y., & Verma, S. (2023). Development of pharmacovigilance system in India and paradigm of pharmacovigilance research: An overview. Current Drug Safety, 18(4), 448–464. https://doi.org/10.2174/1574886317666220930145603

The use of the WHO-UMC system for standardised case causality assessment https://www.who.int/docs/default-source/medicines/pharmacovigilance/whocausality-assessment.pdf.

Venkatasubbaiah, M., Dwarakanadha Reddy, P. D., & Satyanarayana, S. V. (2018). Analysis and reporting of adverse drug reactions at a tertiary care teaching hospital. Alexandria Journal of Medicine, 54(4), 597–603. https://doi.org/10.1016/j.ajme.2018.10.005

Vohra, A., Kumar, N., Ahuja, S., Budania, N., & Bharadwaj, V. K. (2023). Analysis and reporting of adverse drug reactions at a tertiary care teaching hospital in Mewat region of northern India. International Journal of Pharmaceutical Sciences and Research, 14(12), 5831–5840. https://doi.org/10.13040/IJPSR.0975-8232.14(12).5831-40

The importance of pharmacovigilance: Safety monitoring of medicinal products Geneva. (January 2002). World Health Organization. https://iris.who.int/bitstream/handle/10665/42493/a75646.pdf?sequence=1

Zucker, I., & Prendergast, B. J. (2020, June 5). Sex differences in pharmacokinetics predict adverse drug reactions in women. Biology of Sex Differences, 11(1), 32. https://doi.org/10.1186/s13293-020-00308-5

Cite this article: Doshi N, Prajapati B, Selvaraj L. A Pharmacovigilance Study on Adverse Drug Reaction Profile at a Tertiary Care Teaching Hospital from Western Part of India. Int. J. Pharm. Investigation. 2025;15(2):562-72.