International Journal of Medical and Pharmaceutical Research

Online ISSN-2958-3683 | Print ISSN-2958-3675
Frequency: Bi-Monthly
Available online on: https://ijmpr.in/

Original Article

To Study the Pattern of Adverse Drug Reactions and Their Causality Assessment in a Tertiary Care Centre in South Kerala: A Retrospective Study

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Received: 06-01-2026
Accepted: 02-03-2026
Available online: 16-04-2026

ABSTRACT

Background: Adverse drug reactions (ADRs) are a major cause of morbidity and healthcare burden worldwide. Monitoring ADRs is essential to ensure drug safety and rational use of medicines.
Aim: To evaluate the pattern, causality, and outcomes of ADRs reported in a tertiary care centre.
Materials and Methods: This retrospective study was conducted in a tertiary care hospital over a period of 6 months. A total of 582 ADRs reported between May 2023 and May 2025 were analyzed. Data were collected from ADR reporting forms and assessed for demographic details, drug characteristics, route of administration, causality using WHO-UMC scale, and outcomes. Statistical analysis was performed using SPSS trial version 26.
Results: Among 582 ADRs, the majority occurred in the age group 21–40 years (34.4%) with female predominance (63%). Most ADRs were reported in inpatients (66%). Intradermal route (43.1%) was the most common route associated with ADRs. Anti-infective for systemic use drugs were the most frequently implicated (40%), with ciprofloxacin being the leading drug (19.3%). Most ADRs were classified as probable (90.4%). Drug withdrawal was the primary intervention (99.5%). Majority of patients recovered (73.3%).
Conclusion: ADRs are common in clinical practice, particularly with anti-infective drugs. Strengthening pharmacovigilance and early detection can reduce ADR burden and improve patient safety.

Keywords*: Adverse drug reactions, pharmacovigilance, WHO-UMC, anti-infectives, causality assessment.*

INTRODUCTION

Adverse drug reactions (ADRs) represent a significant global public health concern, contributing substantially to patient morbidity, mortality, and healthcare costs. According to the World Health Organization, an ADR is defined as "a response to a medicinal product that is noxious, unintended, and occurs at doses normally used in humans for prophylaxis, diagnosis, or therapy of disease, or for the modification of physiological function" [1]. Despite advances in drug development and regulatory oversight, ADRs continue to pose challenges in clinical practice, particularly in developing countries where pharmacovigilance systems are still evolving.

Pharmacovigilance, defined as the science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problems, plays a crucial role in ensuring drug safety [2]. The establishment of structured pharmacovigilance programs such as the Pharmacovigilance Programme of India has

strengthened ADR monitoring in India. These programs facilitate systematic collection, analysis, and reporting of ADRs through Adverse Drug Reaction Monitoring Centres (AMCs), thereby contributing to safer healthcare delivery [3].

ADRs are among the leading causes of hospital admissions and prolonged hospital stays worldwide. Studies suggest that ADRs account for approximately 5–10% of hospital admissions and occur in 10–20% of hospitalized patients [4,5]. In addition to clinical consequences, ADRs impose a significant economic burden on healthcare systems due to increased treatment costs, additional investigations, and extended hospital stays [6]. Importantly, a considerable proportion of ADRs are preventable, highlighting the need for effective monitoring and early detection systems [7].

The occurrence of ADRs is influenced by multiple factors, including patient-related variables such as age, gender, genetic predisposition, comorbidities, and polypharmacy, as well as drug-related factors such as dose, route of administration, and duration of therapy [8]. Elderly patients are particularly vulnerable due to altered pharmacokinetics and pharmacodynamics, whereas female patients have been reported to exhibit a higher incidence of ADRs in several studies [9,10]. Additionally, the use of multiple medications increases the risk of drug interactions and subsequent ADRs [11].

Healthcare settings, especially tertiary care centres, serve as critical points for ADR detection due to the high patient load and the use of complex therapeutic regimens. In such settings, the pattern of ADRs can vary widely depending on the patient population, prescribing practices, and availability of healthcare resources [12]. Understanding the pattern of ADRs in a specific institution is essential for identifying high-risk drugs, vulnerable patient groups, and common types of reactions, which can guide targeted interventions to improve patient safety.

Drug classes such as anti-infectives, non-steroidal anti-inflammatory drugs (NSAIDs), antiepileptics, and cardiovascular agents are commonly implicated in ADRs [13,14]. Among these, antibiotics have been consistently reported as leading contributors due to their widespread use and potential for hypersensitivity reactions [15]. Cutaneous reactions such as rashes, urticaria, and erythema are among the most frequently reported ADRs, particularly in dermatology settings [16]. Severe reactions such as Stevens-Johnson syndrome and toxic epidermal necrolysis, although rare, can be life-threatening and require prompt recognition and management [17].

The route of drug administration also plays a significant role in the occurrence of ADRs. Parenteral routes, including intravenous and intradermal administration, are often associated with a higher incidence of immediate hypersensitivity reactions compared to oral routes [18]. Topical preparations, although generally considered safer, can also cause local adverse effects such as dermatitis and allergic reactions [19].

Causality assessment is a critical component of pharmacovigilance, as it helps determine the likelihood that a drug is responsible for an observed adverse event. Standardized tools such as the WHO-Uppsala Monitoring Centre (WHO-UMC) causality assessment scale are widely used for this purpose [20]. This scale categorizes ADRs into certain, probable/likely, possible, unlikely, conditional/unclassified, and unassessable/unclassifiable categories based on clinical and temporal relationships, dechallenge and rechallenge information, and alternative explanations.

The management of ADRs typically involves withdrawal of the suspected drug, dose modification, or substitution with an alternative agent [21]. Early recognition and appropriate intervention are essential to minimize patient harm and improve outcomes. Most ADRs are reversible upon discontinuation of the offending drug, although some may lead to permanent damage or require long-term treatment [22].

In recent years, there has been increasing emphasis on strengthening pharmacovigilance systems in developing countries, including India. The Pharmacovigilance Programme of India (PvPI), launched by the Indian Pharmacopoeia Commission, has established a network of ADR monitoring centres across the country [23]. These centres play a pivotal role in collecting and analyzing ADR data, promoting awareness among healthcare professionals, and contributing to global drug safety databases such as VigiBase.

Despite these efforts, underreporting of ADRs remains a major challenge. Factors such as lack of awareness, time constraints, fear of legal consequences, and uncertainty about causality contribute to underreporting by healthcare professionals [24]. Addressing these barriers through education, training, and simplified reporting systems is essential to enhance ADR reporting rates.

Given the importance of ADR monitoring and the variability in ADR patterns across different settings, it is essential to conduct institution-based studies to generate local data. Such studies provide valuable insights into the epidemiology of ADRs, identify commonly implicated drugs, and help in developing strategies to minimize their occurrence. Furthermore, they contribute to the national and global pharmacovigilance databases, thereby improving overall drug safety.

Therefore, the present study was undertaken in a tertiary care centre in South Kerala to evaluate the pattern of adverse drug reactions reported over a specified period. The study aims to analyze the demographic characteristics of patients experiencing ADRs, identify the most commonly implicated drugs and drug classes, assess the causality of ADRs using standardized tools, and evaluate the outcomes and management of ADRs. The findings of this study are expected to contribute to improved understanding of ADR patterns and support the development of targeted interventions to enhance patient safety and rational drug use.

MATERIALS AND METHODS

This study was a **retrospective study** conducted in a tertiary care teaching hospital in South Kerala. The study was carried out in the Department of Pharmacology in collaboration with the Adverse Drug Reaction Monitoring Centre (AMC).

Study Duration

- Study period: December 2025 to March 2026
- Data collection period: December 2025 to February 2026
- ADR data analyzed: May 2023 to May 2025

Study Population

The study population included all the ADRs reported (inpatients and outpatients) by the healthcare professionals from this institution and from various hospitals to the AMC at a tertiary care centre using ADR reporting forms designed by the Indian Pharmacopoeia Commission

Sample Size

Sample size was calculated using the formula:

$N=4pq/d^2$

Where:

- p = prevalence (16.7%)
- q = 100 – p
- d = allowable error (20% of p)

The calculated sample size was approximately 498. However, **all reported ADRs (n=582)** during the study period were included.

Inclusion Criteria

1.
2. All ADR reports received from inpatients and outpatients
3. All age groups
4. ADR forms with complete data

Exclusion Criteria

1. Patients using alternative medicine systems (Ayurveda, Homeopathy, Unani)
2. Incomplete ADR forms

Sampling Technique

Universal sampling method was used, including all ADRs reported during the study period.

Data Collection Method

Data were collected from standardized ADR reporting forms (version 1.4) available at the AMC. The forms included:

- Demographic details
- Drug information
- Reaction characteristics
- Laboratory findings
- Medical history

Data Collection Tools

- ADR reporting forms (PvPI format)
- WHO-UMC causality assessment scale
- Anatomical Therapeutic Chemical (ATC) classification system

Variables Studied

Outcome Variables

- Causality assessment
- Outcome of ADR

Other Variables

- Age, gender
- Route of administration
- Drug class
- Department reporting
- Action taken

Causality Assessment

Causality was assessed using **WHO-UMC scale**, categorizing ADRs into probable, possible, etc.

Statistical Analysis

Data were entered into Microsoft Excel and analyzed using **SPSS trial version 26**.

- Qualitative data: frequencies and percentages
- Quantitative data: mean and standard deviation

Ethical Considerations

Ethical clearance No:SMCSIMCH/EC(PHARM) 09/01/09 was obtained from the Institutional Ethics Committee. Patient confidentiality was maintained. No direct patient interaction was involved.

RESULTS

A total of 582 adverse drug reactions were analyzed in the study. The highest number of ADRs were observed in the age group 21–40 years (34.4%), followed by 41–60 years (29.2%), while the least were reported in patients above 80 years (1.7%). Females constituted a higher proportion of ADR cases (63%) compared to males (37%).

Most ADRs were reported among inpatients (66%) compared to outpatients (34%). The majority of reports originated from within the tertiary care centre (96%), with only a small proportion from peripheral hospitals (4%).

In terms of route of administration, intradermal route was the most commonly associated with ADRs (43.1%), followed by topical (31.3%), intravenous (18.4%), oral (6%), and intramuscular routes (1.2%).

Causality assessment using WHO-UMC scale revealed that most ADRs were categorized as probable (90.4%), while 9.6% were possible. In almost all cases (99.5%), the suspected drug was withdrawn following the reaction.

Regarding outcomes, the majority of patients recovered (73.3%), while 17.4% were recovering and 9.3% had not recovered during the study period.

Anti-infective for systemic use drugs were the most commonly implicated group (40%), followed by dermatological drugs (23.9%) and musculoskeletal drugs (17.5%). Among anti-infective for systemic use, ciprofloxacin (19.3%) and amoxicillin-clavulanic acid (18.5%) were the most frequently associated drugs.

Department-wise, the highest number of ADRs were reported from dermatology (33.5%), followed by general medicine (22.6%) and general surgery (17.4%).

Age distribution of study participants [n=582]

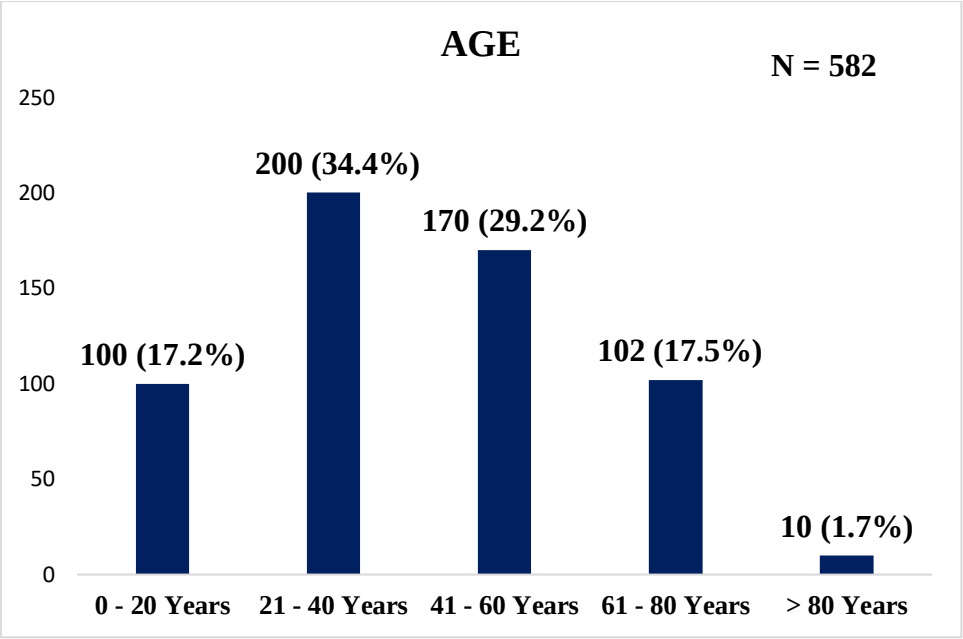

Figure 1: Bar diagram showing distribution of study participants based on age

Among the 582 reported ADRs, the highest number of ADRs were reported in the age group 21 – 40 years, 200 (34.4%) followed by 41 – 60 years, 170 (29.2%). Only 10 (1.7%) were belonged to more than 80 years age group.

Gender distribution of the ADR cases [n=582]

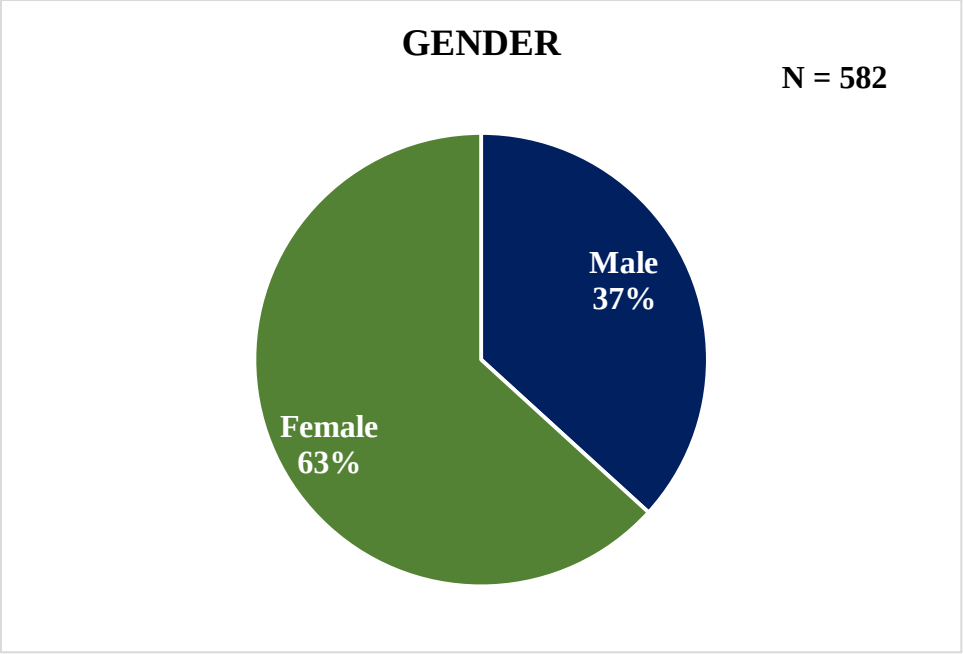

Figure 2: Pie diagram showing distribution of ADRsbased on gender

Among the 582 ADRs reported, 368 (63%) were reported in females and 214 (37%) were reported in males.

Distribution of ADRs based on hospital services [n=582]

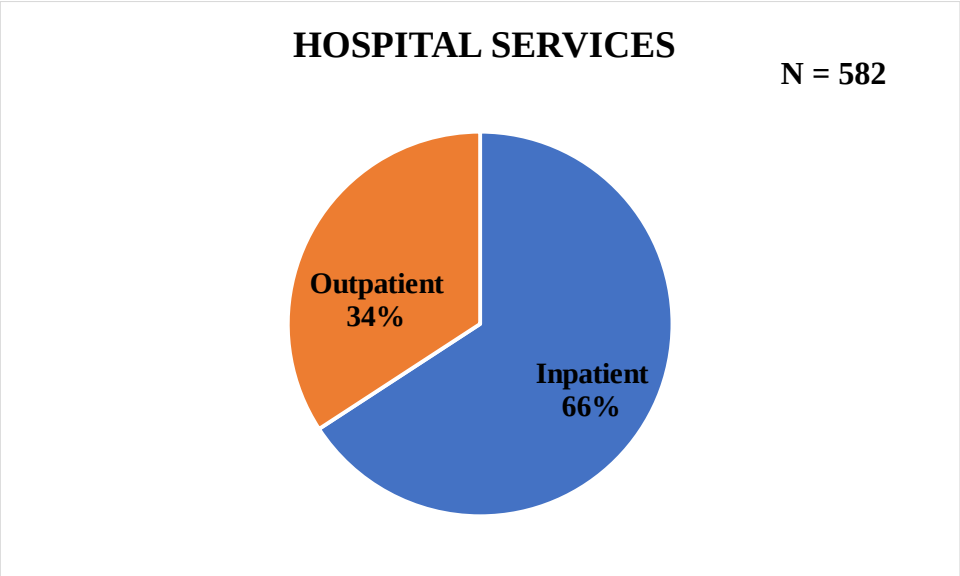

Figure3: Pie diagram showing distribution of ADRs based on hospital services

Among the 582 ADRs reported majority, 383 (66%) were reported in inpatients and 199 (34%) were reported in outpatients.

Distribution of ADR reports received based on source of hospital[n=582]

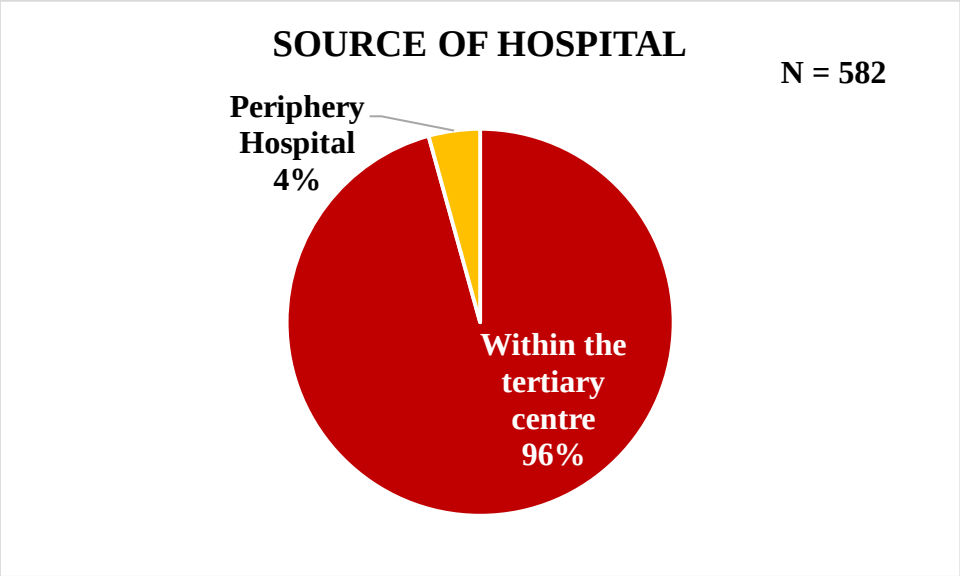

Figure 4: Pie diagram showing distribution of source of ADR reports received

Majority, 557 (96%) of the ADRs were reported from various departments within this tertiary care centre and the rest 25 (4%) of the ADRs were reported from periphery hospitals including cases from 4 different hospitals.

Route of drug administration

Table 1: Route of administration of the drugs involved in the occurrence of ADR

Route of drug administration	Frequency [n=582]	Percentage (%)
Topical	182	31.3
Oral	35	6
Intradermal	251	43.1
Intravenous	107	18.4
Intramuscular	7	1.2

Out of the 582 reported ADRs, the intradermal route of drug administration has the maximum occurrence of ADR 251 (43.1%) followed by topical route 182 (31.3%)

Causality Assessment

Table 2: WHO-UMC Causality assessment of ADRs

Causality	Frequency [n=582]	Percentage (%)
Probable	526	90.4
Possible	56	9.6

Out of the 582 reported ADRs, 90.4% were Probable ADRs

Action taken after drug reaction

Table 3: Action taken after drug reaction

Action taken	Frequency [n=582]	Percentage (%)
Drug withdrawn	579	99.5
Dose reduced	2	0.3
Dose not changed	1	0.2

Out of the 582 ADRs reported, in 99.5% of the ADRs , the offended drug was withdrawn

Outcome of ADRs

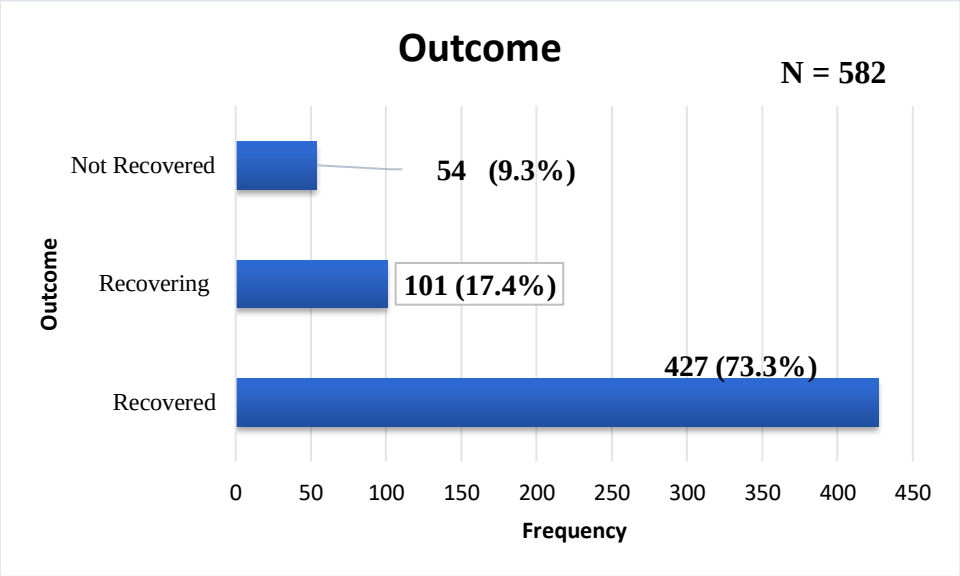

Figure 5: Bar diagram showing outcome of ADR

Out of 582 ADRs reported, 73.3% of the patients had recovered during the study period

Distribution of drugs based on System Organ Class distribution (ATC) and the ADRs associated with them

Table 4: Distribution of drugs based on System Organ Class distribution (ATC) and the ADRs associated with them

System Organ Class (ATC)	Frequency (%) [n= 582]	Types of ADR (n)
A Alimentary tract and metabolism	10 (1.7%)	Induration (2), exacerbation of skin lesion (1), itching (1), induration, itching (2), itching, redness (2), rashes (1), periorbitaledema (1)
B Blood and blood forming organs	4 (0.7%)	Induration (1), breathlessness (1), redness of face, urticaria (1), itching, redness (1)
C Cardiovascular system	1 (0.2%)	Headache, sweating (1)
D Dermatologicals	139 (23.9%)	Acneiform eruption (12), breathlessness (1), exacerbation of skin lesion (107), depigmentation (2), dermatitis (2), itching (3), induration, itching (2), erythema (3), itching, redness (4), atrophic exanthematous patches (1), swelling (1), striae (1)
G Genitourinary system & Sex hormones	2 (0.3%)	Itching (1), unconsciousness, drowsiness (1)

H Systemic hormonal preparations excluding sex hormones and insulin	7 (1.2%)	Acneiform eruption (3), exacerbation of skin lesion (1), itching (1), induration, itching (1), erythema (1),
J Anti-infective for systemic use	234(40%)	Induration (48), tremors, fever, rigidity (1), breathlessness (4), Exacerbation of skin lesion (1), depigmentation (2), acute exanthematouspustulosis (1), FDE (1), vomiting (1), dermatitis (1), itching (47), induration, itching (37), erythema (10), itching, redness (30), rashes (18), redness (11), redness of face, urticaria (3), tiredness, reduced appetite, nausea, vomiting (1), swelling (6), striae (1), periorbitaledema (2), redness eye, eye itching (1), blister (6)
L Antineoplastic &immunomodulating agents	2 (0.3%)	Acneiform eruption (1), erythematous macule, papule (1)
M Musculoskeletal system	102(17.5%)	Induration (34), tremors, fever, rigidity (1), breathlessness (2), acute exanthematouspustulosis (1), FDE (1), erythematous macule, papule (3), itching (14), induration, itching (10), itching, redness (15), oral erosions (1), rashes (7), redness (5), redness of face, urticaria (1), swelling (4), periorbitaledema (1), redness eye, eye itching (1), headache, sweating (1)
N Nervous system	29(5%)	Induration (6), burning in GIT (1), tremors, fever, rigidity (1), breathlessness (1), vomiting and loose stools (1), vomiting (1), erythematous macule, papule (1), itching (2), itching (4), itching, redness (6), rashes (2), redness (1), swelling (2)
P Antiparasitic products, insecticides & repellents	39(6.9%)	Induration (1), breathlessness (1), Exacerbation of skin lesion (32), depigmentation (1), dermatitis (1), itching (1), induration, itching (1), itching, redness (1)
R Respiratory system	1 (0.2%)	Breathlessness (1)
S Sensory Organs	1 (0.2%)	Dermatitis (1)
V Various	11 (1.9%)	Induration (1), tremors, fever, rigidity (2), breathlessness (3), vomiting (2), erythematous macule, papule (1), itching, redness (2)

Among the 582 ADRs reported, the most commonly involved drugs were belonged to anti-infective for systemic use 234 (40%) under ATC Classification.

Table 5: Distribution of drugs according to Anti-infective systemic use

Drug Name	Frequency [n=234]	Percentage (%)
Ciprofloxacin	45	19.3 %
Amoxicillin + Clavulanic Acid	43	18.5 %
Piperacillin+Tazobactam	24	10.3 %
Ceftriaxone	23	9.8 %
Clindamycin	22	9.4 %
Cefotaxime	15	6.4 %
Cefoperazone + Sulbactam	14	6.0 %
Cefuroxime	10	4.3 %
Metronidazole	8	3.4 %
Ceftriaxone + Sulbactam	5	2.1 %
Vancomycin	5	2.1 %
Doxycycline	4	1.7 %
Gentamicin	4	1.7 %
Clarithromycin	2	0.9 %

Levofloxacin	2	0.9 %
Acyclovir	1	0.4 %
Albendazole + Ivermectin	1	0.4 %
Amikacin	1	0.4 %
Amoxicillin	1	0.4 %
Ampicillin+ Cloxacillin	1	0.4 %
Cefoperazone + Tazobactam	1	0.4 %
Colistin Sulphate	1	0.4 %
Meropenem + Sulbactam	1	0.4 %

Out of the anti-infective for systemic use drugs, the most common ADR was reported with ciprofloxacin 19.3% followed by combination of Amoxicillin+ Clavulanic acid 18.5%

Department wise distribution of reported ADRs

Table 8: Distribution of ADR reports based on the reporting status from various departments

Department	Frequency (%) [n=582]
Dermatology	194 (33.5%)
General Medicine	132 (22.6%)
General Surgery	101 (17.4%)
OBG	43 (7.3%)
Emergency Medicine	43 (7.3%)
Orthopaedics	17 (2.8%)
Paediatrics	13 (2.3%)
ENT	11 (1.9%)
Urology	11 (1.9%)
Psychiatry	5 (0.9%)
Nephrology	4 (0.7%)
cardiology	2 (0.3%)
Neurosurgery	2 (0.3%)
Radiology	1 (0.2%)
Ophthalmology	1 (0.2%)
Neuro Medicine	1 (0.2%)
Respiratory Medicine	1 (0.2%)

Out of the 582 ADRs reported, 33.5% of ADRs were reported by Dermatology Department, followed by General Medicine Department (22.6%)

DISCUSSION

The present study provides a comprehensive evaluation of ADR patterns in a tertiary care centre, highlighting important trends in demographic distribution, drug classes, and clinical outcomes. The predominance of ADRs in the 21–40 years age group observed in this study is consistent with findings from previous studies, where young and middle-aged adults are more exposed to medications due to higher healthcare utilization [4,8].

The higher incidence of ADRs among females (63%) aligns with earlier reports suggesting that women are more susceptible to ADRs due to hormonal influences, differences in body composition, and pharmacokinetic variations [9,10]. Additionally, healthcare-seeking behavior among females may contribute to increased reporting.

The predominance of ADRs among inpatients (66%) reflects increased exposure to multiple drugs and more severe illnesses requiring hospitalization. Similar findings have been reported by Pirmohamed et al., who identified ADRs as a significant cause of hospital-related complications [5].

The intradermal route being the most common route associated with ADRs is notable and may be attributed to the high frequency of skin testing in the study setting. Parenteral routes are known to have higher risks of hypersensitivity reactions compared to oral routes [18].

The high proportion of ADRs classified as probable (90.4%) indicates a strong temporal relationship between drug administration and adverse events. The WHO-UMC scale is widely accepted for causality assessment and has been used in multiple pharmacovigilance studies [20].

Anti-infective agents for systemic use were the most commonly implicated drugs (40%), consistent with global trends [13,15]. Antibiotics are widely prescribed and are frequently associated with hypersensitivity reactions, particularly cutaneous manifestations such as rashes and urticaria [16]. Ciprofloxacin and amoxicillin-clavulanic acid being the most common drugs in this study is in agreement with previous studies highlighting their frequent use and associated ADR risk.

The predominance of dermatology department reporting (33.5%) may be due to the visible nature of cutaneous ADRs, making them easier to identify and report. Cutaneous ADRs are among the most commonly reported reactions worldwide [16].

Drug withdrawal as the primary intervention in 99.5% of cases reflects adherence to standard management protocols for ADRs [21]. The high recovery rate (73.3%) further indicates that most ADRs were reversible upon discontinuation of the offending drug, consistent with previous studies [22].

Despite improvements in pharmacovigilance systems such as PvPI [23], underreporting remains a challenge [24,25]. Strengthening awareness and training among healthcare professionals is essential to improve ADR reporting rates.

A study by Patel et al. (2024) evaluated ADRs in a tertiary care setting over a 12-month period. A total of 634 ADRs were reported, with the highest incidence found in patients aged 41–60 years (28%), followed by those aged 21–40 years (25%). Among the drugs implicated, **antibiotics** were the most common (38%), particularly **cephalosporins** (22%). The study also found that the most frequent ADRs were cutaneous reactions, accounting for 32% of all reactions, followed by gastrointestinal disturbances (26%). **Causality assessment** using the WHO-UMC scale indicated that 85% of ADRs were classified as "probable," and 75% of reactions were reversible with appropriate management, such as drug withdrawal. The recovery rate was 78%, with 22% of cases requiring ongoing treatment due to severe complications [26].

In a prospective study by Sharma et al. (2025), 450 ADRs were reported in outpatient settings over 8 months. **NSAIDs** were the most frequently implicated drug class (30%), with **ibuprofen** being the primary culprit. The most common reactions included **gastrointestinal bleeding** (18%), **allergic rashes** (15%), and **renal impairment** (10%). The study revealed that **age** was a significant factor, with ADRs being more frequent in patients aged 60 and above (45%). **Causality assessment** indicated that **47% of ADRs were classified as certain**, while **35% were probable**. **Management** involved primarily **drug withdrawal** (90%) and **dose adjustment** (7%). The overall recovery rate was 80%, with the remaining 20% of patients requiring hospitalization [27].

Singh et al. (2024) conducted a multi-center study focusing on ADRs in elderly patients (aged 65 and above) across India. The study collected data from 5 different hospitals, identifying 1,023 ADRs in this cohort. The most commonly implicated drugs were **antihypertensives** (26%), followed by **antibiotics** (20%) and **analgesics** (18%). The most frequent ADRs were **hypotension** (14%), **dizziness** (12%), and **gastrointestinal disturbances** (10%). **Causality assessment** using the WHO-UMC scale revealed that **60% of ADRs were classified as probable** and **30% as possible**. The recovery rate was 85%, with many patients experiencing transient symptoms upon drug discontinuation [28].

A study by Kumar et al. (2025) [29] focused on the occurrence of ADRs in children under 12, studying 387 cases over a year in a pediatric hospital. **Antibiotics** were found to be the most common culprits (40%), with **amoxicillin** (15%) and **gentamicin** (10%) leading. **Cutaneous reactions** were the most common ADRs, observed in 27% of cases, followed by **gastrointestinal** issues (20%) and **respiratory symptoms** (15%). The **causality assessment** indicated that **80% of the ADRs were probable**, and a significant number of reactions were **reversible** (92%) with drug withdrawal. The recovery rate was 90%, and only 5% of the children required hospitalization.

Overall, the findings of this study emphasize the importance of continuous ADR monitoring, particularly for commonly used drug classes such as antibiotics. Identifying high-risk drugs and patient populations can help in developing preventive strategies and improving patient safety.

CONCLUSION

This study highlights that ADRs are a common occurrence in clinical practice, particularly among young adults and females. Anti-infective drugs for systemic use were the most frequently implicated, with intradermal route being a major contributor. Most ADRs were probable and resolved after drug withdrawal. Strengthening pharmacovigilance systems and promoting rational drug use are essential to minimize ADR burden.

LIMITATIONS

- Underreporting of ADRs cannot be ruled out
- Lack of long-term follow-up for ADR outcomes
- Dependence on spontaneous reporting may introduce bias
- Limited evaluation of severity and preventability

DECLARATIONS:

Conflicts of interest: There is no any conflict of interest associated with this study

Consent to participate: There is consent to participate

Consent for publication: There is consent for the publication of this paper

Authors contributions: Author equally contributed the work

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