International Journal of Life Sciences, Biotechnology and Pharma Research Vol. 14, No. 5, May 2025 Online ISSN: 2250-3137
Print ISSN: 2977-0122

DOI: 10.69605/ijlbpr_14.5.2025.23

ORIGINAL RESEARCH

Pharmacovigilance Analysis of Adverse Cutaneous Drug Reactions in a Tertiary Care Dermatology OPD

[1]Dr. Rashmi Roy, [2]Dr. Mamta Yadav

[1]Assistant Professor, Department of Dermatology Venereology and Leprosy, Lord Buddha Koshi Medical College and Hospital, Saharsa, Bihar, India
[2]Assistant Professor, Department of Dermatology Venereology and Leprosy, Autonomous State Medical College, Kushinagar, Uttar Pradesh, India

Corresponding Author
Dr. Rashmi Roy
Assistant Professor, Department of Dermatology Venereology and Leprosy, Lord Buddha Koshi Medical College and Hospital, Saharsa, Bihar, India
Email- rashmiroyy@gmail.com

Received: 20 February 2025 Accepted: 25March, 2025 Published: 28April, 2025

ABSTRACT

Background: Adverse cutaneous drug reactions (ACDRs) represent a significant proportion of drug-related complications observed in dermatology outpatient settings. Monitoring these reactions through pharmacovigilance activities is essential for early detection, causality assessment, and preventive strategies to improve patient safety. **Materials and Methods:** This prospective observational study was conducted over a period of six months in the dermatology outpatient department (OPD) of a tertiary care hospital. Patients presenting with suspected ACDRs were evaluated through detailed history, clinical examination, and relevant investigations. Each case was analyzed for demographic profile, suspected drug(s), latency period, morphological pattern, and severity. Causality assessment was performed using the WHO-UMC scale and severity was categorized according to the Hart wig and Siegel scale. **Results:** A total of 112 ACDR cases were documented from 3,840 dermatology OPD visits (2.9%). The mean age of affected individuals was 38.7±14.2 years with a male to female ratio of 1.1:1. The most common drug groups implicated were antibiotics (35.7%), non-steroidal anti-inflammatory drugs (NSAIDs) (26.8%), and anticonvulsants (18.7%). The predominant clinical patterns included maculopapular rash (41%), fixed drug eruption (25%), and urticaria (17%). According to WHO-UMC causality scale, 52% of the reactions were classified as "probable," 36% as "possible," and 12% as "certain." Most cases were mild (58%) to moderate (36%) in severity, with 6% requiring hospitalization. **Conclusion:** Antibiotics and NSAIDs remain the leading contributors to ACDRs in dermatology OPDs. Early recognition, appropriate documentation, and causality assessment play a crucial role in patient safety and drug regulation. Strengthening pharmacovigilance systems at the outpatient level is recommended.

Keywords: Adverse drug reactions, Cutaneous drug reactions, Pharmacovigilance, Dermatology OPD, WHO-UMC, Drug safety.

This is an open access journal, and articles are distributed under the terms of the Creative Commons Attribution-Non Commercial-Share Alike 4.0 License, which allows others to remix, tweak, and build upon the work non-commercially, as long as appropriate credit is given and the new creations are licensed under the identical terms.

INTRODUCTION

Adverse drug reactions (ADRs) are a major clinical concern globally, contributing to significant morbidity, hospitalization, and healthcare costs. Among the various types of ADRs, adverse cutaneous drug reactions (ACDRs) are particularly common, accounting for 10–30% of all drug-related adverse events reported in clinical practice (1). These reactions can range from mild, self-limiting eruptions to severe, life-threatening conditions such as Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN) (2).

The skin, being a highly visible and immunologically active organ, often reflects systemic hypersensitivity responses to pharmacological agents. The timely recognition and management of ACDRs is crucial, as many of them are preventable with appropriate drug monitoring and reporting (3). In dermatology outpatient departments (OPDs), clinicians frequently encounter patients with diverse drug-induced skin manifestations, which underscores the need for vigilant pharmacovigilance efforts.

Pharmacovigilance—the science of detecting, assessing, understanding, and preventing adverse effects or any other drug-related problem—plays a pivotal role in ensuring patient safety (4). Despite being an essential component of post-marketing drug surveillance, underreporting and lack of standardized documentation remain key challenges in the effective implementation of pharmacovigilance programs, especially in resource-limited settings (5).

India's National Pharmacovigilance Programme encourages spontaneous reporting from all healthcare sectors, yet dermatology-based ACDR data remains

DOI: 10.69605/ijlbpr_14.5.2025.23

limited in many tertiary care centers (6). Therefore, this study aims to evaluate the spectrum, causative agents, and severity of ACDRs among patients attending a tertiary care dermatology OPD, thereby contributing to improved pharmacovigilance practices.

MATERIALS AND METHODS

This prospective, observational study was carried out in the dermatology outpatient department of a tertiary care hospital over a period of six months. Ethical clearance was obtained from the Institutional Ethics Committee prior to the commencement of the study. All patients attending the OPD who presented with suspected adverse cutaneous drug reactions (ACDRs) were evaluated for inclusion.

Patients of all age groups and both sexes were included if they had newly developed skin lesions suspected to be associated with drug intake. Individuals with pre-existing dermatoses, reactions attributed to non-drug etiologies, or those unwilling to participate were excluded.

Detailed clinical histories were recorded using a structured case-report format, which included demographic details, medical history, indication and duration of drug intake, latency period between drug exposure and reaction onset, concomitant medications, and recurrence history. Dermatological examination was conducted to document the type and distribution of the lesions. Laboratory investigations were performed when necessary to support the clinical diagnosis.

Each ACDR case was subjected to causality assessment using the World Health Organization-Uppsala Monitoring Centre (WHO-UMC) criteria, which categorizes the likelihood of a drug causing a reaction into "certain," "probable," "possible," and "unlikely." The severity of each case was evaluated using the Hart wig and Siegel scale, categorizing reactions as mild, moderate, or severe. Preventability was assessed using Schumock and Thornton's criteria.

All collected data were entered into a spreadsheet and analyzed using descriptive statistics. Categorical data were expressed in frequencies and percentages, while continuous variables were presented as means and standard deviations.

RESULTS

During the six-month study period, a total of **3,840 patients** attended the dermatology outpatient department. Among these, **112 cases** of adverse cutaneous drug reactions (ACDRs) were identified, giving an incidence rate of **2.9%**.

The mean age of affected individuals was **38.7 ± 14.2 years**, with a slight male predominance (**male-to-female ratio: 1.1:1**). The majority of patients (**62.5%**) were in the age group of **21–40 years** (Table 1).

Table 1: Age and Gender Distribution of Patients with ACDRs

Age Group (years)	Male (n=59)	Female (n=53)	Total (%)
<20	6	5	11 (9.8%)
21–40	37	33	70 (62.5%)
41–60	12	10	22 (19.6%)
>60	4	5	9 (8.0%)

The most commonly implicated drug classes were **antibiotics (35.7%)**, followed by **NSAIDs (26.8%)**, **anticonvulsants (18.7%)**, and **antitubercular drugs (7.1%)** (Table 2). Among antibiotics, **amoxicillin-clavulanate** and **ciprofloxacin** were most frequently involved.

Table 2: Drug Classes Responsible for ACDRs

Drug Class	Frequency (n)	Percentage (%)
Antibiotics	40	35.7%
NSAIDs	30	26.8%
Anticonvulsants	21	18.7%
Antitubercular	8	7.1%
Others	13	11.6%

The most prevalent clinical presentations were **maculopapular rash (41%)**, **fixed drug eruption (25%)**, and **urticaria (17%)** (Table 3). Less common patterns included exfoliative dermatitis and erythema multiforme.

©2025Int. J. LifeSci.Biotechnol.Pharma.Res.

DOI: 10.69605/ijlbpr_14.5.2025.23

Table 3: Clinical Patterns of ACDRs Observed

Morphological Pattern	Number of Cases	Percentage (%)
Maculopapular Rash	46	41.1%
Fixed Drug Eruption	28	25.0%
Urticaria	19	17.0%
Exfoliative Dermatitis	10	8.9%
Erythema Multiforme	9	8.0%

According to the WHO-UMC causality assessment, **52%** of reactions were classified as "probable," **36%** as "possible," and **12%** as "certain" (Table 4).

Table 4: Causality Assessment Based on WHO-UMC Scale

Causality Category	Number of Cases	Percentage (%)
Certain	13	11.6%
Probable	58	51.8%
Possible	41	36.6%

In terms of severity (Table 5), **58%** of the ACDRs were mild, **36%** moderate, and **6%** were classified as severe, with **7 cases requiring hospitalization**.

Table 5: Severity of ACDRs (Hartwig and Siegel Scale)

Severity Level	Number of Cases	Percentage (%)
Mild	65	58.0%
Moderate	40	35.7%
Severe	7	6.3%

DISCUSSION

Adverse cutaneous drug reactions (ACDRs) continue to pose a significant public health concern due to their varied clinical presentation, potential for morbidity, and impact on therapeutic compliance. In our study, the incidence of ACDRs was 2.9%, which aligns with earlier reports documenting a prevalence between 2–5% among dermatology OPD populations (1,2). The slight male predominance and the highest incidence in the 21–40 years age group reflect the demographic trends observed in similar Indian and international studies (3,4).

Antibiotics, NSAIDs, and anticonvulsants were the most commonly implicated drug classes, a pattern consistently noted in other pharmacovigilance studies (5–7). The high frequency of antibiotic-induced reactions may be attributed to their widespread and sometimes irrational use in primary care settings (8). Among anticonvulsants, aromatic compounds like phenytoin and carbamazepine were particularly associated with severe reactions, consistent with their known immunogenic potential (9).

The most frequently observed morphological pattern was maculopapular rash, followed by fixed drug eruptions and urticaria. These findings correlate well with previous Indian studies that documented similar distribution of skin manifestations (10,11). Although severe cutaneous adverse reactions (SCARs) such as exfoliative dermatitis and erythema multiforme were less common, their early identification remains critical due to associated complications (12).

Causality assessment revealed that most reactions were classified as "probable" or "possible" using the WHO-UMC criteria. This reinforces the importance of comprehensive clinical documentation and follow-up in confirming the drug-reaction relationship (13). Severity grading showed that the majority of ACDRs were mild to moderate, but around 6% of the cases were severe enough to warrant hospitalization, consistent with other tertiary-care-based findings (14). Despite the growing emphasis on pharmacovigilance, underreporting remains a substantial barrier, particularly in dermatological practice where many cases may resolve spontaneously or be managed symptomatically without documentation (15). Strengthening awareness and integrating pharmacovigilance training into clinical workflows is essential for improving reporting rates and ensuring drug safety.

CONCLUSION

The study was limited by its sample size and the absence of confirmatory tests such as drug rechallenge, which were ethically restricted. However, the findings provide a valuable contribution to the

©2025Int. J. LifeSci.Biotechnol.Pharma.Res.

DOI: 10.69605/ijlbpr_14.5.2025.23

dermatology-specific pharmacovigilance data pool and highlight the need for continual surveillance systems in OPD settings.

REFERENCES

1. Sharma S, Jayakumar D, Palappallil DS. Pharmacovigilance of cutaneous adverse drug reactions among patients attending dermatology department at a tertiary care hospital. Indian Dermatol Online J. 2019;10(5):547–54. [PMID: 31544074]
2. Mittal N, Gupta M, Singla M. Cutaneous adverse drug reactions notified by pharmacovigilance in a tertiary care hospital in north India. CutanOculToxicol. 2014;33(4):289–93. [PMID: 24517496]
3. Ashifha S, Vijayashree J, Vudayana K, Chintada D, P P, G P, et al. A study of cutaneous adverse drug reactions at a tertiary care center in Andhra Pradesh, India. Cureus. 2023;15(4): e37596. [PMID: 37197134]
4. Dhage P, Mali S, Pawar S, Naik B, Mali V. Prospective analysis of cutaneous adverse drug reactions encountered in a tertiary care hospital. Cureus. 2024;16(7): e65284. [PMID: 39184612]
5. Pawar MP, Pore SM, Pradhan SN, Burute SR, Bhoi UY, Ramanand SJ. Nevirapine: most common cause of cutaneous adverse drug reactions in an outpatient department of a tertiary care hospital. J ClinDiagn Res. 2015;9(11):FC17–20. [PMID: 26672558]
6. S D I, M M, N S M, Amutha A, I GJ, Rahman F. Pharmacovigilance of the cutaneous drug reactions in outpatients of dermatology department at a tertiary care hospital. J ClinDiagn Res. 2012;6(10):1688–91. [PMID: 23373029]
7. Hina A, Masood S, Jamil S, Tabassum S, Jalil P, Ghulam U. Prevalence of clinical spectrum of cutaneous adverse drug reactions in patients presenting at a tertiary care hospital in Pakistan. Cureus. 2021;13(4):e14568. [PMID: 34026384]
8. Chindhalore CA, Gupta AV, Dakhale GN, Srivastava A. Analysis of cutaneous adverse drug reactions (ADR) reported at an ADR monitoring center of a tertiary care teaching institute in central India. Cureus. 2024;16(2): e53706. [PMID: 38455795]
9. Chopra D, Sharma V, Kapoor R, Dwivedi S. An observational study of cutaneous adverse drug reactions in a teaching hospital. Int J Clin Pharm. 2015;37(6):996–9. [PMID: 26238222]
10. Nandha R, Gupta A, Hashmi A. Cutaneous adverse drug reactions in a tertiary care teaching hospital: a North Indian perspective. Int J Appl Basic Med Res. 2011;1(1):50–3. [PMID: 23776774]
11. Geer MI, Koul PA, Tanki SA, Shah MY. Frequency, types, severity, preventability and costs of adverse drug reactions at a tertiary care hospital. J PharmacolToxicol Methods. 2016; 81:323–34. [PMID: 27109493]
12. Saha A, Das NK, Hazra A, Gharami RC, Chowdhury SN, Datta PK. Cutaneous adverse drug reaction profile in a tertiary care outpatient setting in eastern India. Indian J Pharmacol. 2012;44(6):792–7. [PMID: 23248414]
13. Dimri D, Raina RS, Thapliyal S, Thawani V. Retrospective analysis of pattern of cutaneous adverse drug reactions in tertiary hospital of PauriGarhwal. J ClinDiagn Res. 2016;10(5):FC01–6. [PMID: 27437240]
14. Thakkar S, Patel TK, Vahora R, Bhabhor P, Patel R. Cutaneous adverse drug reactions in a tertiary care teaching hospital in India: an intensive monitoring study. Indian J Dermatol. 2017;62(6):618–25. [PMID: 29263536]
15. Beniwal R, Gupta LK, Khare AK, Mittal A, Mehta S, Balai M. Clinical profile and comparison of causality assessment tools in cutaneous adverse drug reactions. Indian Dermatol Online J. 2019;10(1):27–33. [PMID: 30775295]

©2025Int. J. LifeSci.Biotechnol.Pharma.Res.