

**Clinico-Epidemiological Study of Cutaneous Adverse Drug Reactions**

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Abstract

Background: Cutaneous adverse drug reactions (CADRs) are among the most commonly encountered adverse drug reactions in clinical practice and contribute significantly to patient morbidity, healthcare burden, and treatment discontinuation. Early identification and appropriate management are essential to prevent severe complications and improve patient outcomes.

Aim: To evaluate the clinico-epidemiological profile, causative drugs, clinical patterns, severity, and outcomes of cutaneous adverse drug reactions among patients

attending the dermatology outpatient department of a tertiary care hospital.

Materials and Methods: A hospital-based prospective observational study was conducted in the Department of Dermatology, Venereology and Leprosy, SVBP Hospital, LLRM Medical College, Meerut. A total of 140 patients with suspected CADRs were included. Detailed demographic and clinical data were recorded using a structured proforma. Causality assessment was performed using the WHO–UMC causality assessment scale, while severity was evaluated using the Modified

Hart wig and Siegel severity scale. Statistical analysis was performed using SPSS version 24.0, and $p < 0.05$ was considered statistically significant.

Results: The overall incidence of CADR was 2.12 per 1000 dermatology OPD patients. Adults constituted the majority of cases (83.57%), with a male predominance (60.71%). Fixed drug eruption was the most common clinical pattern (40%), followed by urticarial and maculopapular drug rash. Antibiotics were the most frequently implicated drug group (55%), followed by NSAIDs (16.43%) and anti-tubercular drugs (9.29%). Most reactions were associated with oral medications (92.14%) and developed within 2–7 days of drug intake (77.14%). According to WHO–UMC assessment, 70% of reactions were categorized as probable. Severity assessment revealed that most reactions were moderate in severity (95.71%). The majority of patients recovered completely (86.43%), while one fatality (0.71%) was observed.

Conclusion: CADR predominantly affected adult males and were most commonly associated with antibiotics. Fixed drug eruption was the most frequent clinical presentation. Most reactions were moderate in severity and showed favorable outcomes following withdrawal of the offending drug. Strengthening pharmacovigilance systems and promoting rational drug use are essential to reduce the burden of CADR and improve patient safety.

Keywords: Cutaneous Adverse Drug Reactions, Pharmacovigilance, Fixed Drug Eruption, Antibiotics, Stevens–Johnson Syndrome, Drug Hypersensitivity.

Introduction

The rapid expansion of pharmaceutical drug production has led to the introduction of numerous new therapeutic agents each year. While these advancements have

significantly improved disease management, they have also increased the potential for adverse drug reactions (ADRs), necessitating vigilant monitoring and reporting systems. According to the World Health Organization (WHO), an ADR is defined as “any harmful and unintended response occurring in humans due to the use of a drug for prevention, diagnosis, or treatment of disease”¹. Even drugs considered safe and effective carry an inherent risk of producing adverse effects, which may result in treatment modification, discontinuation, or reduced patient compliance.

ADRs contribute substantially to global morbidity and mortality and impose a significant burden on healthcare systems. In several countries, including India, ADRs rank among the leading causes of mortality². Among various organ systems, the skin is one of the most frequently affected sites. Cutaneous adverse drug reactions (CADRs), also referred to as toxidermia, are among the most commonly reported manifestations of ADRs³. The incidence of CADR ranges from approximately 1–3% in hospitalized patients in developed countries^{4–6}, whereas in developing nations such as India, it ranges between 2–5% among inpatients^{7–10}. However, comprehensive data regarding CADR in outpatient settings remain limited.

CADR exhibit a wide spectrum of clinical presentations. Drugs may induce new dermatological conditions or exacerbate pre-existing skin disorders. Although many CADR are mild and self-limiting, certain reactions can be severe and life threatening. These include Acute Generalized Exanthematous Pustulosis (AGEP), Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS), also known as Drug-Induced Hypersensitivity Syndrome (DiHS), Stevens–

Johnson Syndrome (SJS), Toxic Epidermal Necrolysis (TEN), and SJS–TEN overlap^{11,12}.

Early recognition, accurate diagnosis, and prompt management of CADR are critical in minimizing patient morbidity and preventing fatal outcomes. Despite their clinical importance, underreporting of dermatological ADRs remains a major concern, often attributed to lack of awareness and inadequate pharmacovigilance practices¹³. Hospital-based ADR monitoring systems play a crucial role in identifying, evaluating, and preventing drug-related risks in clinical practice.

Therefore, the present study was undertaken to evaluate the clinico-epidemiological profile of cutaneous adverse drug reactions among patients attending the Dermatology outpatient department.

The study aims to estimate the incidence of CADR, analyze their clinical patterns in relation to causative drugs, and assess their severity using standardized assessment scales. Additionally, it seeks to identify patient characteristics, reaction types, outcomes, and commonly implicated medications. Enhanced awareness and systematic reporting of CADR can contribute to improved patient safety, rational drug use, and reduction in the overall socio-economic burden associated with adverse drug reactions.

Materials and Methods

Study Design and Setting

This was a hospital-based, prospective observational study conducted in the Department of Dermatology, Venereology and Leprosy at SVBP Hospital, LLRM Medical College, Meerut, Uttar Pradesh. The study setting included patients attending the dermatology outpatient department, where cases of suspected cutaneous adverse drug reactions (CADRs) were

identified and evaluated from 1 May 2024 to 30 November 2025

Study Population

The study population comprised patients of all age groups and both genders presenting with suspected CADR during the study period. Patients were enrolled consecutively after fulfilling the inclusion criteria. A detailed clinical history, including drug intake and temporal relationship with onset of skin lesions, was obtained for all participants. Patients admitted to other departments who were referred to the Dermatology OPD for evaluation of suspected cutaneous adverse drug reactions were also included

Inclusion and Exclusion Criteria

Inclusion Criteria

Patients with “certain”, “probable”, and “possible” association in causality assessment of suspected CADR based on the WHO algorithm were included in our study. Patients of all age groups with a relevant drug history attending the outpatient department. Patient giving Consent.

Exclusion Criteria

Topical medication induced Cutaneous adverse drug reaction were not evaluated. Category of “unlikely”, “unclassifiable”, according to causality assessment of suspected CADR based on the WHO algorithm was not included in our study

Data Collection Procedure

Data were collected using a predesigned and structured case record form. Detailed information regarding demographic characteristics (age, gender), clinical presentation, suspected drugs, indication for drug use, duration between drug intake and onset of reaction, and past history of drug allergy was recorded.

Clinical examination was performed to categorize the type of CADR. Relevant laboratory investigations were carried out wherever necessary to support the diagnosis.

Assessment of Causality

The causality of the adverse drug reactions was assessed using the WHO–Uppsala Monitoring Centre (WHO-UMC) causality assessment scale. Based on this scale, reactions were categorized as certain, probable, possible, unlikely, conditional, or unassessable depending on the temporal association, dechallenge/ rechallenge information, and alternative explanations.

Assessment of Severity

The severity of CADR was evaluated using a standard severity assessment scale such as the Modified Hartwig and Siegel scale. Reactions were classified as mild, moderate, or severe based on the level of clinical intervention required, hospitalization status, and outcome of the reaction.

Outcome Measures

Patients were followed up to assess the outcome of the reaction. Outcomes were categorized as recovered, recovering, not recovered, or fatal. The need for drug withdrawal, symptomatic treatment, or hospitalization was also recorded.

Statistical Analysis

The collected data were entered into Microsoft Excel and analyzed using appropriate statistical software such as SPSS version 24.0.

Descriptive statistics were used to summarize demographic and clinical variables. Categorical variables were expressed as frequencies and percentages. Where applicable, inferential statistics such as chi-square test were applied to assess associations, and a p-value of <0.05 was considered statistically significant.

Ethical Considerations

The study was conducted after obtaining approval from the Institutional Ethics Committee of LLRM Medical College, Meerut. Written informed consent was obtained from all participants prior to enrollment. Confidentiality of patient information was strictly maintained throughout the study.

Results

A total of 140 patients with cutaneous adverse drug reactions (CADRs) were included in the present study conducted in the Department of Dermatology, Venereology and Leprosy, SVBP Hospital, LLRM Medical College, Meerut. During the study period, 66,000 dermatology OPD patients were evaluated, yielding an overall CADR incidence of 2.12 per 1000 patients (0.21%).

The majority of CADR cases were observed among adults aged 19–59 years (83.57%), followed by elderly patients (8.57%) and pediatric patients (7.86%).

Table 1: Demographic and Clinical Characteristics of CADR Patients

Variable	Category	Number (n)	Percentage (%)
Age Group	Pediatric (0–18 years)	11	7.86
	Adult (19–59 years)	117	83.57
	Elderly (≥60 years)	12	8.57
Gender	Male	85	60.71
	Female	55	39.29

Source of Dermatology Consultation	Dermatology OPD	123	87.86
	Referred from inpatient departments	17	12.14
Extent of Skin Involvement	Localized	98	70.0
	Generalized	42	30.0
Mucosal Involvement	Present	9	6.43
	Absent	131	93.57

Table 1 shows the demographic and clinical characteristics of patients with CADR. The majority of cases were observed among adults aged 19–59 years (83.57%), followed by elderly (8.57%) and pediatric patients (7.86%). Male patients (60.71%) were more commonly affected than females (39.29%).

Most CADR cases (87.86%) were identified among patients attending the Dermatology OPD directly, while

12.14% were patients admitted to other departments who were referred to the Dermatology OPD for dermatological evaluation. Localized skin involvement was more common (70%) than generalized involvement (30%). Mucosal involvement was present in only 6.43% of cases, indicating that severe mucocutaneous reactions were relatively uncommon.

Table 2: Morphological Pattern of Cutaneous Adverse Drug Reactions

Morphological Pattern	Number (n)	Percentage (%)
Fixed Drug Eruption	56	40.0
Urticarial Drug Rash	25	17.86
Maculopapular Drug Rash	24	17.14
Erythema Multiforme Minor	10	7.14
Lichenoid Drug Rash	7	5.0
Erythema Multiforme Major	4	2.86
Bullous Fixed Drug Eruption	4	2.86
Stevens–Johnson Syndrome	2	1.43
SJS–TEN Overlap	2	1.43
Photosensitivity	2	1.43
AGEP	1	0.71
TEN	1	0.71
Palmoplantar Erythema	1	0.71
Nail Pigmentation	1	0.71
Total	140	100

Table 2 shows the morphological patterns of CADR observed in the present study. Fixed drug eruption (FDE) was the most common clinical presentation, accounting for 40% of all cases. Urticarial drug rash

(17.86%) and maculopapular drug rash (17.14%) were the next most frequent patterns.

Less commonly observed patterns included erythema multiforme minor (7.14%) and lichenoid drug rash (5%).

Severe cutaneous adverse reactions such as Stevens–Johnson syndrome (SJS), SJS–TEN overlap, and Toxic Epidermal Necrolysis (TEN) were infrequent, indicating

that most CADR_s in the present study were non-severe reactions.

Table 3: Drug-Related Characteristics of CADR_s

Variable	Category	Number (n)	Percentage (%)
Route of Administration	Oral	129	92.14
	Intravenous	11	7.86
Drug Category	Antibiotics	77	55.0
	NSAIDs	23	16.43
	Anti-tubercular Drugs	13	9.29
	Analgesic/Antipyretic	10	7.14
	Anti-fungal	4	2.86
	Anti-epileptics	4	2.86
	Others	9	6.43
Latent Period	≤1 day	12	8.57
	2–7 days	108	77.14
	8–14 days	6	4.29
	>14 days	14	10.0

Table 3 shows the drug-related characteristics associated with CADR_s. The majority of reactions were associated with orally administered medications (92.14%), whereas intravenous drugs accounted for only 7.86% of cases. Antibiotics were the most frequently implicated drug category (55%), followed by NSAIDs (16.43%) and anti-tubercular drugs (9.29%). This finding highlights the major contribution of commonly prescribed drugs to

the burden of CADR_s. The majority of reactions developed within 2–7 days of drug intake (77.14%), suggesting an early onset pattern for most CADR_s. A smaller proportion of patients developed reactions either within one day (8.57%) or after prolonged exposure of more than two weeks (10%).

Table 4: Causality, Severity, Outcome and Statistical Associations of CADR_s

Parameter	Category	Number (n)	Percentage (%)
WHO–UMC Causality	Probable	98	70.0
	Possible	42	30.0
Hartwig Severity	Moderate (Level 3)	134	95.71
	Severe (Level 5–7)	6	4.29
Outcome	Recovered	121	86.43
	Recovering	18	12.86

	Fatal	1	0.71
Management	Drug Withdrawn	125	89.29
	Drug Substituted	14	10.0
	Drug Continued	1	0.71

Statistical Associations

Association Tested	Statistical Significance
Morphological Pattern vs Mucosal Involvement	$p < 0.001$
SCAR vs Mucosal Involvement	$p < 0.001$
Drug Class vs Morphological Pattern	$p < 0.001$
Drug Class vs Severity	$p > 0.05$
Drug Class vs Route of Administration	$p = 0.4611$

Table 4 shows the causality assessment, severity grading, clinical outcome, management strategies, and statistical associations of CADR. According to the WHO–UMC causality assessment scale, most reactions were categorized as probable (70%), while the remaining were classified as possible (30%).

Severity assessment using the Hart wig scale revealed that the majority of reactions were moderate in severity, with 95.71% categorized as Level 3 reactions. Severe reactions were relatively uncommon (4.29%).

The majority of patients recovered completely (86.43%), while 12.86% were improving at the time of assessment. Only one fatal case (0.71%) was recorded. Withdrawal of the offending drug was the most common management strategy (89.29%), followed by substitution with an alternative drug.

Statistical analysis demonstrated a highly significant association between morphological pattern and mucosal involvement ($p < 0.001$), as severe reactions such as SJS, SJS–TEN overlap, and TEN were strongly associated with mucosal lesions. A significant association was also observed between drug class and morphological pattern of CADR ($p < 0.001$). However, no statistically significant association was found between drug class and

severity of CADR ($p > 0.05$) or between drug class and route of administration ($p = 0.4611$).

CLINICAL PHOTOGRAPHS

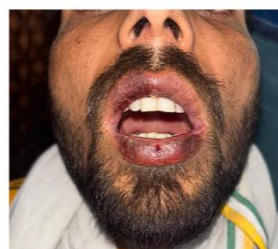


IMAGE 1: Fixed Drug Eruption LIP



IMAGE 3: Acute Generalized Exanthematous Pustulosis



IMAGE 2: Fixed Drug Eruption LEG



IMAGE 4: Acute Generalized Exanthematous Pustulosis



Figure 1: Representative clinical photographs of various cutaneous adverse drug reactions: (A) Fixed drug eruption, (B) Acute generalized exanthematous pustulosis, (C) SJS–TEN overlap, and (D) Maculopapular drug rash.

Discussion

The present study evaluated the incidence, demographic characteristics, clinical patterns, causative drugs, severity, and outcomes of cutaneous adverse drug reactions (CADRs) among patients attending the dermatology outpatient department of a tertiary care center. CADRs continue to represent an important group

of adverse drug reactions encountered in dermatological practice because of their potential to produce a wide spectrum of manifestations ranging from mild self-limiting eruptions to severe life-threatening reactions such as Stevens–Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN).

In the present study, the incidence of CADRs among dermatology outpatient attendees was relatively low. Similar incidence rates have been reported in previous hospital-based studies from India and other countries. Pudukadan and Thappa reported an incidence of approximately 0.3% among dermatology outpatients, while Patel et al. observed comparable findings.^{14,15} The incidence observed in the present study therefore falls within the range described in earlier literature. Variations in incidence rates across studies may be attributed to differences in study design, prescribing patterns, healthcare accessibility, and pharmacovigilance practices.

Adult patients constituted the majority of CADR cases in the present study. Similar observations have been reported by Noel et al. and Uppal et al., where adults represented the largest proportion of patients affected by adverse drug reactions.^{17,18} Adults are more frequently exposed to multiple medications for acute and chronic illnesses, thereby increasing the risk of drug-related adverse events. Polypharmacy, self-medication practices, and greater exposure to antibiotics and analgesics may further contribute to the increased occurrence of CADRs in this age group.

A male predominance was observed in the present study. Similar findings have been documented in several Indian studies.^{18,19} The predominance of males may reflect sociocultural differences in healthcare-seeking behavior and patterns of medication use. However, some studies

have reported female predominance in CADR, which may be related to hormonal influences, increased use of medications and cosmetics, and greater susceptibility to hypersensitivity reactions among females.²⁰

Fixed Drug Eruption (FDE) was the most common morphological pattern observed in the present study, followed by urticarial drug rash and maculopapular drug rash. Similar findings have been reported in studies by Pudukadan and Thappa and Sehgal et al.^{14,23} The predominance of FDE in the Indian population may be attributed to widespread availability of over-the-counter medications and repeated exposure to commonly implicated drugs such as NSAIDs, antibiotics, and analgesics. Maculopapular eruptions are also commonly reported worldwide and are generally associated with delayed T-cell mediated hypersensitivity reactions.²¹

Mucosal involvement was observed only in a limited proportion of patients in the present study. Severe mucocutaneous involvement is usually associated with SJS and TEN.^{11,28} The relatively low frequency of mucosal lesions in the present study corresponds with the lower prevalence of severe CADR within the study population.

The majority of CADR in the present study were associated with oral medications. This finding is expected because oral drugs constitute the most commonly prescribed route of administration in outpatient settings.³ Intravenous medications accounted for a smaller proportion of cases; however, they may occasionally produce severe reactions due to rapid systemic exposure and higher bioavailability.

Among the implicated drug categories, antibiotics emerged as the most common causative agents, followed by NSAIDs and antitubercular drugs. Similar observations have been consistently reported in earlier

Indian and international studies.^{14,16} Antibiotics such as beta-lactams, sulfonamides, and fluoroquinolones are well recognized for their ability to induce hypersensitivity reactions. NSAIDs are another major contributor because of their extensive use in the management of pain and fever and their easy availability without prescription.

Antitubercular drugs accounted for a notable proportion of CADR in the present study. This may reflect the high burden of tuberculosis in India and the widespread use of multidrug antitubercular therapy. Antiepileptics and antifungal agents were implicated less frequently but are known to cause severe hypersensitivity syndromes including SJS/TEN and DRESS syndrome.^{21,24}

The majority of CADR in the present study developed within 2–7 days after initiation of the offending drug. This latency period is characteristic of delayed hypersensitivity reactions mediated by activation of T lymphocytes.²⁵ Recognition of the latent period is clinically important in identifying the causative drug, particularly in patients receiving multiple medications simultaneously.

Causality assessment using the WHO-UMC scale demonstrated that most reactions were categorized as “probable,” while the remaining were classified as “possible.” Similar observations have been reported in pharmacovigilance-based studies.²⁶ No reactions were categorized as “certain” because drug rechallenge was not performed owing to ethical concerns and the risk of precipitating more severe reactions.

Severity assessment using the Hartwig severity scale revealed that most CADR were moderate in severity and responded well to withdrawal of the offending drug along with symptomatic treatment.²⁷ Severe reactions were relatively uncommon, although SCARs such as

SJS, TEN, SJS–TEN overlap, and AGEP were encountered in a small number of patients. Comparable findings have been reported in previous studies where mild to moderate reactions constituted the majority of CADR_s.²²

The overall clinical outcome in the present study was favorable, with most patients recovering completely following discontinuation of the offending drug and appropriate supportive care. However, one fatal outcome was recorded, emphasizing the potentially life-threatening nature of severe CADR_s.²⁸ Early recognitions, immediate withdrawal of the suspected drug, and prompt supportive management remain the cornerstone of successful treatment and reduction of morbidity and mortality.

The findings of the present study highlight the importance of strengthening pharmacovigilance systems and promoting rational prescribing practices. Increased awareness among healthcare professionals and patients regarding early recognition and reporting of CADR_s may help reduce the burden of adverse drug reactions and improve patient safety.

Conclusion

The present study demonstrated that cutaneous adverse drug reactions (CADR_s) constitute an important clinical entity encountered in dermatological practice. Adult males were more commonly affected, and the majority of reactions were observed in the outpatient setting. Fixed drug eruption emerged as the most common clinical pattern, while antibiotics were identified as the leading causative drug group, followed by NSAIDs and antitubercular drugs.

Most CADR_s in the present study were moderate in severity and showed favorable outcomes following prompt withdrawal of the offending drug and

appropriate symptomatic management. Severe cutaneous adverse reactions such as Stevens–Johnson syndrome and toxic epidermal necrolysis were relatively uncommon but carried significant morbidity and potential mortality.

The findings of the present study emphasize the importance of early recognition, accurate diagnosis, and timely management of CADR_s. Strengthening pharmacovigilance systems, promoting rational prescribing practices, and increasing awareness among healthcare professionals and patients regarding adverse drug reactions can help reduce the burden of CADR_s and improve overall patient safety.

Limitations of The Study

- The study was conducted at a single tertiary care center, which may limit the generalizability of the findings to the broader population.
- The sample size was relatively limited.
- Drug rechallenge was not performed because of ethical concerns and the risk of severe reactions.
- Long-term follow-up of patients was not feasible in all cases.
- Some reactions may have been underreported because mild cases often do not seek medical attention.

Recommendations

- Strengthening hospital-based pharmacovigilance programs and ADR monitoring systems.
- Encouraging healthcare professionals to actively report adverse drug reactions.
- Promoting rational prescription practices and minimizing unnecessary polypharmacy.
- Increasing awareness among patients regarding early symptoms of CADR_s and the importance of seeking prompt medical care.

- Conducting multicentric studies with larger sample sizes to better understand regional variations and risk factors associated with CADRs.

Abbreviations

Abbreviation	Full Form
ADR	Adverse Drug Reaction
CADR	Cutaneous Adverse Drug Reaction
WHO	World Health Organization
WHO-UMC	World Health Organization-Uppsala Monitoring Centre
FDE	Fixed Drug Eruption
SJS	Stevens-Johnson Syndrome
TEN	Toxic Epidermal Necrolysis
AGEP	Acute Generalized Exanthematous Pustulosis
DRESS	Drug Reaction with Eosinophilia and Systemic Symptoms
NSAIDs	Non-Steroidal Anti-Inflammatory Drugs
OPD	Outpatient Department
IPD	Inpatient Department
SCAR	Severe Cutaneous Adverse Reaction

Declarations

Ethics Approval and Consent to Participate: The study was approved by the Institutional Ethics Committee of LLRM Medical College, Meerut. Written informed consent was obtained from all participants prior to enrollment.

Consent for Publication: Written informed consent for publication of clinical photographs was obtained from the patients.

Availability of Data and Materials: The datasets used and analyzed during the current study are available from the corresponding author on reasonable request.

Authors' Contributions: All authors contributed substantially to the conception, study design, data collection, analysis, manuscript preparation, and final approval of the manuscript.

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