

Comprehensive Evaluation of Cutaneous Adverse Drug Reactions in a Tertiary Care Centre

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Abstract:

Background: Cutaneous adverse drug reactions (CADRs) are among the most common manifestations of adverse drug reactions and contribute significantly to patient morbidity, healthcare burden, and pharmacovigilance concerns.

Aim: To comprehensively evaluate the demographic profile, clinical patterns, causative drugs, causality, severity, preventability, and outcomes of CADRs in a tertiary care dermatology department.

Methodology: A hospital-based observational descriptive study was conducted in the Department of Skin & VD, ANMMCH, Gaya ji, Bihar. Ninety patients with suspected or confirmed CADRs were enrolled. Detailed clinical evaluation was performed, and causality, severity, and preventability were assessed using Naranjo's Algorithm, Modified Hartwig and Siegel Scale, and Schumock and Thornton Scale, respectively.

Results: Most patients were aged 18–40 years (42.2%) and were male (57.8%). Maculopapular rash was the most common CADR (31.1%), followed by fixed drug eruption (20.0%) and urticaria (15.6%). Antimicrobials (35.6%) and NSAIDs (22.2%) were the leading causative drug classes. Most reactions were classified as probable (53.3%) and moderate in severity (46.7%). Nearly two-thirds of reactions were preventable. Complete recovery was observed in 64.4% of patients.

Conclusion: CADRs are common, largely preventable adverse events. Early recognition, rational prescribing, and strengthened pharmacovigilance can improve patient safety and clinical outcomes.

Keywords: Cutaneous adverse drug reactions, CADRs, Pharmacovigilance, Drug safety, Causality assessment, Dermatology.

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Introduction

Adverse drug reactions (ADRs) are still a major public health problem worldwide and are one of the most common causes of morbidity and health care costs [1]. Obviously, patients have benefited from the use of medicines to prevent, diagnose and treat diseases, but all medicines have side effects. ADRs may occur on multiple organ systems, including the skin. In addition to impacting patient quality of life, ADRs can lead to longer hospital stays, higher healthcare costs and in some cases, death. As a consequence of the growing number and use of pharmaceutical agents, the monitoring and evaluation of ADRs is a critical part of patient safety and pharmacovigilance programmes around the world [2].

One of the more common types of ADRs is cutaneous adverse drug reaction (CADR) which contrib-

utes to a significant number of reported adverse events. CADRs are adverse reactions to a drug that manifest themselves as unwanted changes in the skin, mucous membranes, hair or nails. These reactions can occur after taking prescription medicines, some medicines you can buy, vaccines, herbal remedies and biological products. The skin is a highly visible organ with an immune function which is frequently the first to demonstrate a negative drug reaction. CADRs can be of many different clinical types from benign and transient eruptions to more serious, life-threatening illnesses that require prompt medical attention [3].

CADRs are different among populations and healthcare delivery environments. The incidence of ADRs through the skin is reported to be about 2–6%

of the patients who are administered medications, and cutaneous manifestations make up about 10–20% of all ADRs. Polypharmacy, multiple co-morbidities and exposure to multiple therapeutic agents may increase the prevalence in hospitalized patients. CADR [4] are affected by age, gender, genetic susceptibility, underlying diseases, immune system and drug use. The burden of CADR is high in developing countries, especially in India, where medicines are easily accessible, self-medication, and multiple drug therapy adopted by people.

CADR are highly variable clinically. Common reactions include maculopapular eruptions, urticaria, fixed drug eruptions, acneiform eruptions and photosensitivity reactions. Most reactions are mild and reversible if the offending agent is withdrawn, however, severe reactions including Stevens–Johnson syndrome (SJS), toxic epidermal necrolysis (TEN), drug reaction with eosinophilia and systemic symptoms (DRESS) and acute generalized exanthematous pustulosis (AGEP) can result in morbidity and mortality [5]. Identifying and withdrawing causative medications early and promptly is essential for preventing complications and for providing optimum patient outcomes. Hence, a comprehensive knowledge of the clinical pattern of CADR is vital for dermatologist and other health care professionals involved in the care of patients.”

“There are several drug classes that have been associated with CADR. Some of the most commonly reported offenders include antimicrobial agents, non-steroidal anti-inflammatory drugs (NSAIDs), antiepileptic drugs, antitubercular drugs, and allopurinol [6]. Drug-induced skin reactions can occur in different patterns depending on the region, the prevalence of the disease and genetic predisposition. As a result, data collected in one geographic area may not necessarily be applicable to another. There is therefore a need to monitor the trend and local epidemiological studies are required to identify the commonly implicated drugs as well as the changing trends in adverse reactions.

The creation of pharmacovigilance programs has been very helpful in the identification and reporting of ADRs, including CADR [7]. The World Health Organization (WHO) noted that adverse event monitoring is one of the most important strategies to make medicines safe. The Pharmacovigilance Programme of India (PvPI) has enhanced the Pharmacovigilance system in India and has provided useful data to the worldwide drug safety database. Despite these efforts, underreporting of CADR is still a major problem and the need to evaluate and document adverse reactions systematically in clinical practice is still a challenge.

Tertiary care dermatology departments are critical units for the diagnosis and treatment of CADR, with common and significant cases being referred to

them. A thorough review of CADR in these environments can offer important information about their clinical features, etiology, severity, morbidity and preventability. Knowing the local pattern of CADR can help clinicians to make informed decisions about therapy, minimise risk of repeat reactions and enhance patient safety. The present study on comprehensive evaluation of the Cutaneous Adverse Drug Reactions in a Tertiary care Dermatology Department is therefore very crucial to generate region specific data, thereby boosting up Pharmacovigilance activities in order to facilitate safer and more rational use of medicines.”

Methodology

Study Design: This study was a hospital-based observational descriptive study conducted to comprehensively evaluate the clinical patterns, causative drugs, severity, causality, and outcomes of cutaneous adverse drug reactions (CADRs) among patients attending a tertiary care dermatology department.

Study Area: The study was conducted in the Department of Skin & VD, Anugrah Narayan Magadh Medical College and Hospital (ANMMCH), Gaya ji, Bihar, India.

Study Duration: The study was carried out over a period of 8 months from February 2025 to September 2025.

Study Participants: A total of patients presenting with suspected or confirmed cutaneous adverse drug reactions to the Department of Skin & VD during the study period was screened for eligibility.

Inclusion Criteria

- Patients of any age and gender presenting with suspected or confirmed cutaneous adverse drug reactions.
- Patients attending either the outpatient department (OPD) or admitted to the inpatient department (IPD).
- Patients willing to provide written informed consent for participation in the study.
- In the case of minors, consent obtained from parents or legal guardians.
- Patients with adequate clinical information regarding the suspected drug exposure and adverse reaction.

Exclusion Criteria

- Patients unable to provide a reliable history of drug intake.
- Patients who cannot recall the suspected medication and for whom medical records are unavailable.
- Patients with skin manifestations attributed to infectious diseases such as viral exanthems rather than drug reactions.

- Patients unwilling to participate or provide informed consent.
- Patients with incomplete clinical records that prevent proper assessment of causality and severity.

Sample Size: The study was including a total of 90 patients diagnosed with or suspected to have cutaneous adverse drug reactions during the study period and fulfilling the eligibility criteria.”

Procedure: All eligible patients presenting to the Department of Skin & VD with suspected or confirmed cutaneous adverse drug reactions were enrolled consecutively until the required sample size of 90 participants is achieved. Written informed consent were obtained from each participant or from a legally authorized guardian in the case of minors. A detailed history was collected using a predesigned and pretested case record form. Information regarding demographic characteristics, presenting complaints, medical history, previous drug allergies, comorbid conditions, and details of the suspected adverse reaction were documented.

Particular attention was given to the identification of suspected drugs, including generic and brand names, dosage, route of administration, duration of therapy, indication for prescription, and concurrent medications. Detailed dermatological examination were performed to classify the type and pattern of cutaneous adverse drug reaction. Clinical features such as morphology of lesions, distribution, mucosal involvement, extent of body surface area affected, onset of reaction, duration of illness, and associated systemic manifestations were recorded.

Relevant laboratory investigations and diagnostic findings available in-patient records was also be reviewed and documented whenever required. Patients attending the outpatient department will be followed up during subsequent visits whenever feasible, while admitted patients were monitored throughout their hospital stay to assess disease progression, treatment response, and final outcome. Re-challenge with the suspected drug were not be attempted because of ethical and safety concerns.

The causality assessment of adverse drug reactions was performed using Naranjo’s Algorithm, categorizing reactions as definite, probable, possible, or doubtful. Severity assessment were carried out using the Modified Hartwig and Siegel Severity Scale, while preventability was evaluated using the Schumock and Thornton Preventability Scale. Seriousness of reactions were categorized according to standard regulatory criteria. All collected information were maintained confidentially and used exclusively for research purposes.

Statistical Analysis: The collected data were entered into Microsoft Excel and analyzed using Statistical Package for Social Sciences (SPSS) version 27.0. Quantitative variables such as age and duration of reaction were expressed as mean $\pm$ standard deviation (SD), whereas qualitative variables such as gender, type of CADR, causative drugs, severity category, causality assessment, preventability status, and clinical outcomes were presented as frequencies and percentages. Appropriate statistical tests such as the Chi-square test or Fisher’s exact test were used to determine associations between categorical variables. A p-value of less than 0.05 were considered statistically significant. The findings were presented through tables, charts, and graphs for comprehensive interpretation and evaluation of cutaneous adverse drug reactions.”

Result

Table 1 shows the distribution of 90 patients according to their demographic characteristics. The majority of patients belonged to the 18–40 years age group, accounting for 38 (42.2%) cases, followed by the 41–60 years age group with 28 (31.1%) cases. Patients aged below 18 years and above 60 years each constituted 12 (13.3%) of the study population. Regarding gender distribution, males were more prevalent, comprising 52 (57.8%) patients, whereas females accounted for 38 (42.2%) patients. Overall, the study population was predominantly composed of young and middle-aged adults, with a higher representation of male patients compared to female patients.

Table 1: Distribution of Patients According to Demographic Characteristics (n = 90)		
Variable	Frequency (n)	Percentage (%)
Age Group (Years)		
<18	12	13.3
18–40	38	42.2
41–60	28	31.1
>60	12	13.3
Gender		
Male	52	57.8
Female	38	42.2

Table 2 depicts the clinical pattern of cutaneous adverse drug reactions (CADRs) among the 90 study

participants. The most common presentation was maculopapular rash, observed in 28 (31.1%) pa-

tients, indicating that it was the predominant manifestation of drug-related skin reactions. Fixed drug eruption (FDE) was the second most frequent CADR, reported in 18 (20.0%) cases, followed by urticaria in 14 (15.6%) patients. Severe reactions such as Stevens–Johnson syndrome (SJS) and toxic

epidermal necrolysis (TEN) were identified in 8 (8.9%) and 4 (4.4%) cases, respectively. Erythema multiforme, drug-induced hyperpigmentation, DRESS syndrome, and other reactions constituted smaller proportions of the total CADR observed."

Table 2: Clinical Pattern of Cutaneous Adverse Drug Reactions (n = 90)

Type of CADR	Frequency (n)	Percentage (%)
Maculopapular Rash	28	31.1
Fixed Drug Eruption (FDE)	18	20
Urticaria	14	15.6
Stevens–Johnson Syndrome (SJS)	8	8.9
Toxic Epidermal Necrolysis (TEN)	4	4.4
Erythema Multiforme	7	7.8
Drug-Induced Hyperpigmentation	6	6.7
DRESS Syndrome	3	3.3
Others	2	2.2
Total	90	100

Table 3 shows the distribution of suspected drug classes responsible for cutaneous adverse drug reactions (CADRs) among the 90 study participants. Antimicrobials were the most frequently implicated drug class, accounting for 32 (35.6%) cases, indicating that they were the leading cause of CADRs in the study population. This was followed by non-steroidal anti-inflammatory drugs (NSAIDs), which contributed to 20 (22.2%) cases. Antiepileptic drugs

were responsible for 14 (15.6%) reactions, while antitubercular drugs accounted for 8 (8.9%) cases. Allopurinol was implicated in 5 (5.6%) cases, whereas antiretroviral drugs and other medications each contributed 4 (4.4%) cases. Antidiabetic drugs were the least common cause, accounting for 3 (3.3%) CADRs. Overall, antimicrobials and NSAIDs emerged as the major contributors to CADRs.

Table 3: Distribution of Suspected Drug Classes Causing CADRs (n = 90)

Drug Class	Frequency (n)	Percentage (%)
Antimicrobials	32	35.6
Non-Steroidal Anti-Inflammatory Drugs (NSAIDs)	20	22.2
Antiepileptics	14	15.6
Antitubercular Drugs	8	8.9
Antiretroviral Drugs	4	4.4
Allopurinol	5	5.6
Antidiabetic Drugs	3	3.3
Others	4	4.4
Total	90	100

Table 4 depicts the causality, severity, and preventability assessment of cutaneous adverse drug reactions (CADRs) among the 90 study participants. According to the Naranjo causality scale, the majority of CADRs were classified as probable (53.3%), followed by possible (33.3%) and definite (13.3%) reactions, while no doubtful cases were identified. Severity assessment using the Modified Hartwig and Siegel Scale revealed that most reactions were mod-

erate (46.7%), followed by mild (42.2%), whereas severe reactions accounted for only 11.1% of cases. Preventability assessment showed that 44.4% of CADRs were probably preventable and 20.0% were definitely preventable, indicating that a substantial proportion of adverse reactions could potentially be avoided through appropriate prescribing and monitoring practices.

Table 4: Causality, Severity, and Preventability Assessment of CADRs (n = 90)

Assessment Category	Frequency (n)	Percentage (%)
Causality Assessment (Naranjo Scale)		
Definite	12	13.3
Probable	48	53.3
Possible	30	33.3
Doubtful	0	0

Severity Assessment (Modified Hartwig and Siegel Scale)		
Mild	38	42.2
Moderate	42	46.7
Severe	10	11.1
Preventability Assessment (Schumock and Thornton Scale)		
Definitely Preventable	18	20
Probably Preventable	40	44.4
Not Preventable	32	35.6

“Table 5 shows the clinical outcome and seriousness of cutaneous adverse drug reactions (CADRs) among the 90 study participants. The majority of patients, 58 (64.4%), recovered completely following appropriate management, while 24 (26.7%) patients were recovering or showing improvement at the time of follow-up. A smaller proportion, 6 (6.7%) patients, had not recovered by the last follow-up

visit. Mortality was observed in 2 (2.2%) cases, indicating the potential severity of some reactions. Regarding seriousness, most CADRs were classified as non-serious, accounting for 72 (80.0%) cases, whereas 18 (20.0%) cases were categorized as serious adverse drug reactions, highlighting the need for timely diagnosis and intervention.

Table 5: Clinical Outcome and Seriousness of CADRs (n = 90)		
Variable	Frequency (n)	Percentage (%)
Clinical Outcome		
Recovered Completely	58	64.4
Recovering/Improving	24	26.7
Not Recovered at Last Follow-up	6	6.7
Death	2	2.2
Seriousness of Reaction		
Serious ADR	18	20
Non-Serious ADR	72	80
Total	90	100

Discussion

In the present study, a comprehensive evaluation of CADRs was done in a tertiary care dermatology department and it was shown that CADRs still pose a substantial health care burden and cause patient morbidity. The age group with the highest occurrence in the current study was 18-40 years (42.2%) and the 41-60 group was 31.1%. The results are similar to that of Pudukadan and Thappa 2004 [8] that most CADRs were found in young and middle-aged adults and Sharma et al. 2015 [9] which showed that maximum number of patients were between 21-50 years of age. Patel and Marfatia (2008) [10] also noted similar observations with exposure to medications being higher in economically productive age groups and thus, they continue to be at a higher risk of developing CADRs. Younger adults were overrepresented in the current study possibly because of higher drug exposure levels from infectious diseases, chronic conditions, as well as higher levels of healthcare utilization.”

“Our study revealed a male predominance with 57.8% of male cases. This finding is in keeping with Sharma et al. (2015) who found that males accounted for about 55% of patient cases of CADR. The results however, differ from those reported by Pudukadan and Thappa (2004) who found it to be more prevalent in females. These variations could be

explained by differences in health-seeking patterns, prescriptions, population characteristics and sociocultural differences among regions. However, the findings suggest that CADRs are significantly impacting both sexes and should be equally addressed in clinical practice.

In terms of clinical spectrum of CADRs, maculopapular rash was the most frequent reaction in the present study with a frequency of 31.1% of all reactions. Chatterjee et al. 2006 [11] documented maculopapular eruptions in about 33% of the cases and Sharma et al. 2001 [12] identified exanthematous as the most common pattern of CADRs. The second most common manifestation of our study was fixed drug eruption (20.0%) and urticaria (15.6%). Fixed drug eruption has been reported as one of the common CADRs by Patel and Marfatia (2008). The fact that these relatively harmless symptoms predominate means that the majority of CADRs can be identified and controlled if they are detected early. Severe reactions like Stevens-Johnson syndrome (8.9%) and toxic epidermal necrolysis (4.4%) were also seen. Sasidharan Pillai et al. (2015) [13] reported the proportion of SJS as 4–7%, which is slightly lower than the proportion we observed.

The drugs were grouped into their respective categories for analysis, and antimicrobials were found to be the most common group (35.6%) followed by

NSAIDs (22.2%) and antiepileptic drugs (15.6%). The finding is quite similar to that reported by Pudukadan and Thappa 2004 [14] which showed that the highest percentage of reactions were caused by antimicrobials (47%) and Sharma et al. 2015 who also found antibiotics as the most common cause of reactions. Similarly, antimicrobials and NSAIDs were found to be the major contributors to CADR by Chatterjee et al., (2006). Antibiotics and analgesics probably account for most of the adverse cutaneous reactions because they are commonly prescribed in everyday clinical practice. Another significant group of drugs in our study was antiepileptics, similar to what Patel et al. observed (2014) [15] which showed that anti-convulsants were important contributors to the severe CADR, such as SJS and DRESS syndrome.

Causality was assessed on Naranjo scale with 53.3% of reactions being probable, 33.3% probable, and 13.3% definite. The results obtained are in general agreement with those of Nandha et al. (2011) [16] and Sharma et al. (2015) in which the probable reactions were the predominant CADR. This predominance of probable reactions may be attributed to the reduced possibilities for drug rechallenge because of both ethics and safety concerns. However, the rate of probable and definite reactions suggests a high suspected drug/clinical manifestation association rate."

"The severity assessment in the present study showed that 46.7% of the reactions were moderate, 42.2% were mild, and 11.1% were severe. Similar results were found by Hiware et al. (2013) [17] who noted that the majority of CADR were of mild to moderate severity. Likewise, Patel et al. (2014) noted that the proportion of severe reactions is a small percentage of CADR, but these reactions are responsible for a disproportionate amount of morbidity and health care costs. Our study showed that the majority of reactions were mild and moderate; this could be due to early diagnosis and prompt management, thereby avoiding the development of more severe reactions.

Nearly two-thirds (20.0% definitely and 44.4% probably preventable) of CADR were preventable. Inbaraj (2012) [18] also found that a significant fraction of CADR were related to rational prescribing and documentation of allergies, which could be avoided by proper drug history taking. The results underscore the value of pharmacovigilance programmes and patient counselling to limit the impact of adverse drug reactions.

The clinical outcome analysis showed complete recovery in 64.4% of the patients and continued improvement of clinical parameters during the follow-up period in 26.7% of the patients. These findings are similar to the findings of Nandha et al (2011), when the majority of patients were able to undergo

complete recovery after the offending drug was withdrawn and appropriate treatment was provided. But 6.7% of the patients in our study did not respond or improve at the end of follow-up, and death was seen in 2.2% of patients. In contrast, Sharma et al. (2015), and Hiware et al. (2013), reported no mortality among CADR patients. Severe reactions (Stevens-Johnson syndrome and toxic epidermal necrolysis) may have contributed to the deaths that occurred in the present study, and this may be because the reactions were more serious than other reactions, suggesting that CADR can be very serious and dangerous.

In conclusion, the results of the present study are generally similar to the results of previous national and international studies and validate the use of antimicrobials, NSAIDs, and antiepileptic drugs as the most common causes of CADR. Serious and life-threatening reactions still occur, although the majority are mild to moderate with good results. The observations emphasize the importance of the pharmacovigilance, rational prescribing, early detection of adverse reactions and timely therapeutic intervention to reduce the impact of CADR in tertiary care settings."

Conclusion

The present study concludes that cutaneous adverse drug reactions (CADR) constitute an important clinical concern in dermatology practice, affecting predominantly young and middle-aged adults, with a slight male predominance. Maculopapular rash was the most common clinical presentation, followed by fixed drug eruption and urticaria. Antimicrobials, NSAIDs, and antiepileptic drugs emerged as the leading causative drug groups. Most reactions were classified as probable in causality assessment and were of mild to moderate severity. A considerable proportion of CADR were found to be preventable, highlighting the importance of rational prescribing, careful drug selection, and vigilant patient monitoring. The majority of patients recovered completely following prompt identification and withdrawal of the offending drug; however, serious and potentially fatal reactions such as Stevens-Johnson syndrome and toxic epidermal necrolysis were also observed. Strengthening pharmacovigilance activities, early diagnosis, and timely intervention can significantly reduce the burden and adverse outcomes of CADR in tertiary care settings.

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