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Original Research Article

A Retrospective Study of the Characteristics of Cutaneous Adverse Drug Reactions (CADRs) Reported to the ADR Monitoring Center (AMC)

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Abstract:

Background: Cutaneous adverse drug reactions (CADRs) are common manifestations of adverse drug reactions (ADRs), posing significant clinical challenges due to their variable severity and potential for serious outcomes. Monitoring CADRs is essential for patient safety.

Aim: To analyze the characteristics, drug associations, severity, and outcomes of CADRs reported to the Adverse Drug Reaction Monitoring Center (AMC) at a tertiary care hospital.

Methodology: A retrospective descriptive study was conducted over 8 months, including 322 CADR cases reported to the AMC. Data on demographics, clinical patterns, suspected drugs, severity, causality (WHO–UMC scale), and outcomes were extracted and analyzed using descriptive statistics.

Results: Females (54%) and middle-aged adults (41–50 years, 22.4%) were most affected. Pruritus (38.5%), maculopapular rash (26.7%), and erythema (19.3%) were the most common manifestations. Antibacterial drugs (57.1%) were the leading cause, followed by NSAIDs (11.8%) and antiepileptics (9%). Most reactions were mild (66.5%) or moderate (26.7%), with 6.8% severe. Causality was predominantly probable (92.5%), and 85.1% of patients fully recovered.

Conclusion: CADRs are generally mild, commonly associated with antibiotics, and show favorable outcomes. Continuous pharmacovigilance, early detection, and careful drug use are essential to prevent serious reactions and improve patient safety.

Keywords: Cutaneous Adverse Drug Reactions, Pharmacovigilance, Antibiotics, NSAIDs, ADR Monitoring Center, WHO–UMC Causality.

Introduction

Adverse drug reactions (ADRs) pose a serious issue to healthcare systems across the globe, and they are a great source of morbidity and mortality among patients. Of all the forms of ADRs, the most common ones are those that relate to the skin and mucous membranes and are the most common in clinical practice. A cutaneous adverse drug reaction (CADR) is any unwanted or unwanted reaction on the skin or mucous membranes that has been caused by drug intake. This grouping of reactions makes up about 2-3 percent of ADRs reported and constitutes a significant percentage of dermatological visits in outpatient and inpatient care [1].

The issue of CADRs has become heavier during the past decades because of various factors. The pharmaceutical market is filled with newer drugs that keep being introduced on a regular basis, and with a growing prevalence of chronic diseases, an abundance of comorbid conditions, and polypharmacy becoming an everyday practice, the risk of ADRs including CADRs has grown sharply. Moreover, the convenient access to over-the-counter drugs and self-medication habits also contribute to the subsequent increase in the number of such reactions. Drugs are frequently used and administered in combination to treat many indications, and it is difficult to find the culprit agent, which makes it hard to diagnose and treat.

A large number of pharmacological agents may lead to CADRs. The most frequently used classes of drugs included are the beta-lactam family of antibiotics, sulfonamides, non-steroidal anti-inflammatory medications (NSAIDs) and the anti-epileptic medications [2]. These drugs are increasingly

prescribed to different age groups and diverse ailments, and this adds chances of adverse reactions on the skin. The use of antibiotics and NSAIDs is common without a prescription in numerous environments, and it could also increase the risk of CADRs. The process of reaction can be different in response to the drug, dosage, length of exposure, and the patient's susceptibility.

CADRs occur clinically in various morphological patterns. The most common ones are the maculopapular rash, urticaria, angioedema, fixed drug eruption (FDE), and erythema multiforme. These reactions are usually mild and self-limiting in nature but onset; nevertheless, they may escalate into severity when they are not detected early and dealt with as such. Mild CADRs can result in discomfort, itch or cosmetic issues but severe reactions can be life-threatening and thus need immediate medical care.

Among the more severe CADRs, there are erythroderma, drug reaction with eosinophilia and systemic symptoms (DRESS), and the Stevens–Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN) spectrum [3]. These extreme types are related to a large area of skin involvement, systemic complications, lengthy hospital stay, and higher mortality rates. SJS/TEN spectrum in particular is also linked to high mortality rates and such long-term sequelae as ocular complications and scarring. These responses also result in a significant economic impact on the patients, families, and health care systems because of extended treatment time and hospitalization and productivity.

Diagnosis and timely removal of the drug causing the condition has a very big role to play in ensuring that CADRs do not advance to serious and even deadly stages. Thus, thorough understanding of the different patterns of CADRs, their clinical course, prognosis, and drugs that often partake in them is vital to the health care facility personnel. Recognition and knowledge of these responses will help clinicians to promptly diagnose them, implement relevant management interventions, and teach the patients about drug avoidance in future. This is not only beneficial in enhancing patient outcomes but also healthcare costs are incurred due to severe adverse reactions [4].

Pharmacovigilance is a major area in monitoring and reporting ADRs, such as CADRs. ADR Monitoring Centers (AMC) are also the essential elements in the national pharmacovigilance practices: they receive, analyze, and interpret adverse drug reaction reports. The information produced through AMCs offers useful information on the safety profile of drugs in the real clinical practice. Historical analysis of CADRs reported to AMCs assists in defining trends, drugs with high risks, populations at risk, and frequent clinical patterns.

It is established that prevalence and pattern of CADRs is different in various countries and population [5]. Genetic predisposition, prescription habits, drug availability, disease prevalence, and healthcare infrastructure are some of the factors that may lead to CADRs incidence and reporting. Such heterogeneity highlights the need to create region-specific data to comprehend local trends and risk intent. The local pharmacovigilance information is critical in the development of localized guidelines, better prescription, and patient safety.

Although CADRs are clinically important, underreporting is a significant problem in pharmacovigilance. Most mild to moderate reactions are not reported because of the unawareness of the reactions, time, or because the reactions are doubtful. Enhancing reporting and promoting active involvement in the ADR reporting among healthcare professionals can go a long way to increase the quality of the available data and help to make the medication usage safer.

In that regard, the given retrospective study was conducted to examine the nature of the cutaneous adverse drug reactions reported to the ADR Monitoring Center (AMC) of one of the tertiary care centers. The aims of the research were to outline the trend in the reported CADRs, their clinical presentation, and determine the most frequently involved drugs. It is believed that the results of the given study will help to understand the CADRs among the local population better and facilitate enhanced pharmacovigilance behavior, timely diagnosis, and efficient management of these reactions.

Methodology

Study Design: This was a retrospective descriptive study conducted to analyze the characteristics of cutaneous adverse drug reactions (CADRs) reported to the Adverse Drug Reaction (ADR) Monitoring Center (AMC).

Study Area: The study was carried out in the Department of Pharmacology, Darbhanga Medical College and Hospital, Laheriasarai, Darbhanga, Bihar, India.

Study Duration: The study was conducted over a period of 8 months from March 2025 to October 2025.

Sample Size: A total of 322 cases of suspected cutaneous adverse drug reactions (CADRs) were included in the study.

Study Population: The study population consisted of patients of all age groups and both genders who had experienced suspected ADRs affecting the skin and mucous membranes and were reported to the AMC.

Data Collection: Data were collected from suspected adverse drug reaction (ADR) reporting forms

submitted to the Adverse Drug Reaction Monitoring Centre (AMC) during the study period for 8 months from the total ADR reports received, only those reactions that involved skin and mucous membranes were included in the analysis. These selected reactions were categorized as cutaneous adverse drug reactions (CADRs).

A structured proforma was used to systematically extract relevant information from each eligible ADR form to ensure uniform and complete data capture. The extracted details included the age and gender of the patient, as well as the pattern and specific type of CADR reported. Information regarding the suspected drug and its therapeutic group was also recorded for each case. In addition, the seriousness of the reaction was documented, along with the action taken (such as discontinuation, continuation, or modification of therapy) and the clinical outcome of the reaction.

Causality assessment was performed for all included CADRs using the World Health Organization–Uppsala Monitoring Centre (WHO–UMC) causality assessment scale, and each case was assigned an appropriate causality category based on the available clinical information and the temporal relationship between drug exposure and the reported reaction.

Inclusion Criteria

- All ADR forms submitted to the AMC between January 2019 and August 2021
- ADRs involving the skin or mucous membranes
- Complete ADR forms with adequate patient and drug information

Exclusion Criteria

- ADRs not related to cutaneous or mucous membrane manifestations
- Incomplete ADR forms lacking essential patient or drug information

Study Procedure: ADR reports submitted to the Adverse Drug Reaction Monitoring Centre (AMC) were systematically screened to identify cases specifically involving reactions affecting the skin and mucous membranes. After identifying eligible reports, relevant information from each selected ADR form was extracted and recorded using a structured proforma to ensure uniformity and completeness of data capture.

Each identified ADR was then classified and characterized in terms of the clinical type of cutaneous adverse drug reaction (CADR), the suspected drug implicated (and its therapeutic category), and the seriousness of the reaction. In addition, details regarding the clinical outcome and causality assessment were documented for every case to support comprehensive interpretation. All finalized and verified data were subsequently entered into Microsoft Excel to facilitate organization, coding, and preparation for statistical analysis.

Statistical Analysis: Descriptive statistical analysis was performed using SPSS (version 16). Categorical variables such as the type of CADR, suspected drug class, seriousness, outcome, and causality categories were summarized using frequencies and percentages. Continuous variables, such as patient age, were summarized using the mean and standard deviation to describe central tendency and variability. The analyzed results were presented in the form of tables and charts to enable clear visualization and interpretation of the distribution, patterns, and key characteristics of CADRs reported to the AMC."

Result

Table 1 summarizes the age and gender distribution of 322 patients with cutaneous adverse drug reactions (CADRs). Overall, females were slightly more affected than males, comprising 174 cases (54.0%) compared to 148 males (46.0%). The most affected age groups were 41–50 years (72, 22.4%) and 51–60 years (66, 20.5%), followed by 31–40 years (58, 18.0%) and 21–30 years (44, 13.7%). Children (0–10 years) represented 18 cases (5.6%), and older adults (>60 years) accounted for 38 cases (11.8%). Overall, middle-aged adults, particularly females, were the most commonly affected by CADRs in this study population.

Table 1: Age and Gender Distribution of Patients with CADRs (N = 322)

Age group (years)	Male n (%)	Female n (%)	Total n (%)
0–10	9 (2.8)	9 (2.8)	18 (5.6)
11–20	12 (3.7)	14 (4.4)	26 (8.1)
21–30	20 (6.2)	24 (7.5)	44 (13.7)
31–40	26 (8.1)	32 (9.9)	58 (18.0)
41–50	32 (9.9)	40 (12.4)	72 (22.4)
51–60	30 (9.3)	36 (11.2)	66 (20.5)
>60	19 (5.9)	19 (5.9)	38 (11.8)
Total	**148 (46.0)**	**174 (54.0)**	**322 (100)**

Table 2 presents the pattern of cutaneous adverse drug reactions (CADRs) among 322 cases. The most common reaction was pruritus, reported in 124 patients (38.5%), followed by maculopapular rash in 86 patients (26.7%) and erythema in 62 patients (19.3%). Less frequent reactions included urticaria

(18, 5.6%), Stevens–Johnson syndrome (14, 4.3%), angioedema (7, 2.2%), photosensitivity (5, 1.6%), and both mucositis and hyperpigmentation in 3 patients each (0.9%). Overall, the majority of CADRs were mild manifestations such as pruritus, rash, and erythema, with serious reactions like Stevens–Johnson syndrome being relatively rare.

Table 2: Pattern of Cutaneous Adverse Drug Reactions (N = 322)	
Type of CADR	**Number of cases, n (%)**
Pruritus	124 (38.5)
Maculopapular rash	86 (26.7)
Erythema	62 (19.3)
Urticaria	18 (5.6)
Stevens–Johnson syndrome	14 (4.3)
Angioedema	7 (2.2)
Photosensitivity	5 (1.6)
Mucositis	3 (0.9)
Hyperpigmentation	3 (0.9)
Total	**322 (100)**

Table 3 summarizes the drug groups implicated in cutaneous adverse drug reactions (CADRs) among 322 cases. Antibacterial drugs were the most frequently associated, causing 184 reactions (57.1%). Non-steroidal anti-inflammatory drugs (NSAIDs) accounted for 38 cases (11.8%), antiepileptics for 29 cases (9.0%), antiemetics for 16 cases (5.0%), antitubercular drugs for 14 cases (4.3%), and cardiovascular drugs for 13 cases (4.0%). Other drug groups collectively contributed to 28 cases (8.7%). Overall, antibacterial agents were the predominant contributors to CADRs in this study population.

Table 3: Drug Groups Implicated in CADRs (N = 322)	
Drug group	**Number of cases, n (%)**
Antibacterial drugs	184 (57.1)
NSAIDs	38 (11.8)
Antiepileptics	29 (9.0)
Antiemetics	16 (5.0)
Antitubercular drugs	14 (4.3)
Cardiovascular drugs	13 (4.0)
Others	28 (8.7)
Total	**322 (100)**

Table 4 presents the severity of cutaneous adverse drug reactions (CADRs) among 322 cases. Most reactions were mild, occurring in 214 patients (66.5%), while moderate reactions were observed in 86 patients (26.7%). Severe CADRs were relatively uncommon, affecting 22 patients (6.8%). Overall, the findings indicate that the majority of CADRs were mild to moderate in severity, with only a small proportion classified as severe.

Table 4: Severity of CADRs (N = 322)	
Severity category	**Number of cases, n (%)**
Mild	214 (66.5)
Moderate	86 (26.7)
Severe	22 (6.8)
Total	**322 (100)**

Table 5 shows the causality assessment of cutaneous adverse drug reactions (CADRs) using the WHO–UMC scale among 322 cases. The vast majority of reactions were classified as probable (298 cases, 92.5%), indicating a strong likelihood that the suspected drug caused the reaction. Possible reactions accounted for 18 cases (5.6%), while only 6 cases (1.9%) were considered certain. Overall, the data suggest that most CADRs had a clear and probable association with the administered drugs.

Table 5: Causality Assessment by WHO–UMC Scale (N = 322)	
Causality category	**Number of cases, n (%)**
Certain	6 (1.9)
Probable	298 (92.5)
Possible	18 (5.6)
Total	**322 (100)**

Table 6 presents the outcomes of cutaneous adverse drug reactions (CADRs) among 322 cases. The majority of patients recovered fully, with 274 cases (85.1%) reporting complete recovery. An additional 38 patients (11.8%) were still in the process of recovering, while 10 patients (3.1%) had not recovered at the time of assessment. Overall, the data indicate that CADRs were largely self-limiting, with most patients experiencing complete resolution.

Table 6: Outcome of CADRs (N = 322)	
Outcome	**Number of cases, n (%)**
Recovered	274 (85.1)
Recovering	38 (11.8)
Not recovered	10 (3.1)
Total	**322 00)**

Discussion

The cutaneous adverse drug reactions (CADR) were somewhat more frequent in females in the current work, with 54 vs 46% cases representing the female population. This observation is in line with the past studies, which indicate that females tend to be more prone to adverse drug reactions owing to disparities in the pharmacokinetic, pharmacodynamic, hormonal, and increased use of medications (Tran et al., 1998) [6]. This tendency can be also affected by immunological factors, as they are gender-specific variations in T-cell activity, as well as the greater rates of such conditions as systemic lupus erythematosus and photosensitivity (Rademaker, 2001) [7]. Nevertheless, other research studies have indicated no significant gender difference in CADRs, which suggest that other factors, including comorbidities, polypharmacy, and age-related changes in metabolism, can mediate risk (Palappallil et al., 2017) [8]."

CADRs were more prevalent with respect to middle-aged adults, especially the 4150-year (22.4%), 5160-year (20.5%), and 3140-year (18%). The age extremes (010 years 5.6% and >60 years 11.8 years) were not so much influenced. Partially, this trend is opposite to some works that reveal an increased prevalence of ADR among geriatric populations because of poor renal and hepatic clearance, polypharmacy, and comorbidities (Palappallil et al., 2017) [8]. The reduced prevalence in the elderly patients in our study could however be a result of the prudent approach of the prescriber or underreporting of the elderly. The trend has been supported by previous Indian studies that have also reported peak CADR in the middle-aged adults as opposed to the elderly (Tripathy et al., 2018; Patel et al., 2014) [9,10].

The trend of CADRs in this research was pruritus (38.5%), followed by maculopapular rash (26.7%), and erythema (19.3%). Other presentations like urticaria, Stevens Johnson syndrome (SJS), angioedema, photosensitivity, mucokit and hyperpigmentation were quite rare. Such results are in line with prior reports of pruritus and rashes as the most common CADRs and those involving severe manifestations like SJS and toxic epidermal necrolysis (TEN) as rare (Chatterjee et al., 2006; Kashyap et al., 2021) [11,12]. Our cohort had a significant prevalence of pruritus, which was further confirmed by the use of quinolones and specifically ciprofloxacin, and it fulfills the prior research that demonstrated drug-induced pruritus as a frequent but not life-threatening phenomenon (Neuman et al., 2015; Huang et al., 2019) [13,14]. Maculopapular rash, which was mainly associated with phenytoin in the current research supports the findings of the previous studies that the arenes oxide metabolites of phenytoin are factors in the development of hypersensitivity reactions (Ferner, 2017; Vazquez et al., 2014) [15,16].

Antibacterial agents became the most common cause of CADRs (57.1%), and beta-lactam antibiotics were the most affected group. The most frequent drug was determined to be ceftriaxone, but none of the reactions were severe. The second most common drug was quinolones, especially Ciprofloxacin, which produces mild and severe CADRs such as SJS and angioedema. The prevalence of antibiotic-induced CADRs is consistent with the prior literature of the Indian and foreign countries, along with the extensive use and immunogenic capacity of beta-lactam rings (Sokolewicz et al., 2021) [17]. Interestingly, even though paracetamol is generally regarded as safe, it was linked to SJS in our trial, which agrees with previous reports of the presence of rare and severe hypersensitivity reactions (Rajput et al., 2015) [18]. Smaller shares of CADRs were caused by antiepileptics (mainly phenytoin) and antiemetics (ondansetron), and NSAIDs

(paracetamol), consistent with previous Indian and international research (Ferner, 2017) [15].

On the severity scale, the majority of CADRs in this paper were mild of 66.5% and moderate (26.7%), and severe reactions were very few (6.8%). The current trend complies with the previous results in which most CADRs were not life-threatening, and a small part of them had to be hospitalized or put on intensive care (Patel et al., 2014; Chatterjee et al., 2006) [10,11]. The WHOUMC causality assessment classified 92.5% of reactions as likely, which means that reactions are temporally related to suspected drugs, and only 1.9% as certain, which is caused by the fact that it is not an easy task to confirm rechallenge in clinical practice (Pande, 2018) [19]. The results were positive in the majority and 85.1% of patients were fully recovered, which supports the overall self-limiting quality of CADRs with a timely withdrawal of the offending drug (Kashyap et al., 2021) [12].

Cases of SJS, angioedema, and mucocutaneous syndromes were serious examples of CADRs that were infrequent but interesting. Only ciprofloxacin was involved in all three categories of severe reactions, and enalapril and levodopa-carbidopa were involved in angioedema. These findings align with the literature that has implicated ACE inhibitors as angioedema culprits and fluoroquinolones as SJS/TEN triggers (Lerch, 2012) [20]. Notably, the majority of reactions were resolved after the withdrawal of the drugs, which highlights the importance of timely diagnosis and treatment.

On the whole, our research confirms the vulnerability of middle-aged adults and females to CADRs, the most common reactions are mild, and the most common trigger is antibiotics. The findings are mostly in line with the existing literature, with slight differences in the age structure and the prevalence of the rare severe reactions reflecting the impact of the local practice in prescribing and the population features. Knowledge of these trends is essential towards timely identification, prevention, and treatment of CADRs in clinical practice.

Conclusion

The paper on cutaneous adverse drug reactions (CADRs) reported to the ADR Monitoring Center (AMC) presents an overall picture of the demographic profile, clinical patterns, drug groups that contribute to the development of these reactions, the severity, causality, and outcomes of the given reactions. The patient demographics analysis showed that the CADRs affect persons of all ages, and the prevalence is slightly higher in females. Pruritus, maculopapular rash and erythema were the most common clinical manifestations with less common but clinically important more serious conditions such as Stevens-Johnson syndrome and angioedema being less common. Antibacterial agents were the major cause of CADRs, and they were followed by NSAIDs and antiepileptics, which is why it is necessary to closely monitor and to use these types of drugs cautiously. The majority of the responses were rated mild to moderate, with a minor percentage being severe in nature, which highlights the possibility of having critical clinical outcomes in others. Causality determination showed that most of the reactions were most likely attributable to the suspected drug which showed high level of association and significance of pharmacovigilance in the detection and management of ADRs. The good news was that most of the patients were cured with very few having long term or non-remitting symptoms. Overall, this study emphasizes the importance of continuous monitoring, early recognition, and timely management of CADRs to minimize patient morbidity and improve drug safety.

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