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Original Research Article

Hospital-Based Retrospective Study on Adverse Cutaneous Drug Reactions and Their Clinical Patterns

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Abstract:

Background: Among the most reported adverse medication responses are cutaneous adverse drug reactions (CADRs), which can vary from minor, self-limiting outbreaks to serious, potentially fatal disorders. They add to the burden of healthcare, longer hospital stays, and higher morbidity. To avoid problems and recurrence, early detection of the clinical pattern and identification of the offending medication are crucial.

Aim: To analyses the latency duration, suspected drug groups, clinical patterns, demographic profile, and aetiology of cutaneous adverse medication responses in hospitalized patients

Methodology: A tertiary care teaching hospital served as the site of this hospital-based retrospective observational investigation. 115 individuals with clinically identified CADRs had their medical records examined. Descriptive statistics were used to gather and analyses data on demographics, latency time, suspected drug groups, related comorbidities, and causality evaluation using the Naranjo scale.

Result: Most patients were male and in the 21–40 age range. The most often offending medicine class was antibiotics, which were followed by NSAIDs and antiepileptics. The first week of drug use was when most responses happened. Based on the evaluation of causation, the majority of CADRs were classified as plausible or possible.

Conclusion: CADRs are common and largely preventable adverse events. Rational prescribing, early identification, and vigilant pharmacovigilance are crucial in reducing their incidence and improving patient safety.

Keywords: Cutaneous Adverse Drug Reactions, CADRs, Pharmacovigilance, Naranjo Scale, Adverse Drug Reaction.

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Introduction

The most frequent adverse medication responses documented in the literature are cutaneous adverse drug reactions (CADRs) [1]. According to studies, the total incidence of CADRs is between 1% and 3% in wealthy nations and between 2% and 5% in underdeveloped nations [2]. Different medications can induce a wide range of cutaneous symptoms, from maculopapular rashes to toxic epidermal necrolysis.

Disabling impairments during hospitalization and difficulties after outdoor medication therapy have been caused by CADRs. Such cutaneous medication responses appear to be more common in some patient populations. As more medications are given, the likelihood of experiencing a cutaneous response rises [3]. Doctors can select safer medications if they are aware of the offending substances. A particular questionnaire called the Naranjo Scale is used to assess the likelihood of probability. The scores are categorized as certain, likely, potential, and questionable [4]. Establishing a causal relationship between a medication and a drug response is essential to stop future recurrences. Causality assessment is the appraisal of the likelihood that a certain therapy is the cause of an observed adverse event.

As novel medications are introduced, the pattern of drug responses and the offending drugs exhibit shifting tendencies. The responses might resemble collagen vascular disorders, neoplastic illnesses, or viral exanthems. Due to the fact that many of these instances typically go unreported, comprehensive information about the frequency, intensity, complications, and long-term health effects of these kinds of

cutaneous eruptions is currently lacking [5]. Drug side effects are an unavoidable cost to humanity in exchange for the many advantages of contemporary medicine.

Drug responses, which range from minor erythema to serious diseases classified as severe cutaneous adverse drug reactions (SCARs), are unanticipated side effects that happen when a medicine is administered. Despite being uncommon, they have a significant death rate and impact around 0.04% of hospitalized patients [6]. An adverse drug reaction is an unpleasant and unexpected reaction to a medication that happens with dosages that are typically used in humans. Cutaneous adverse drug responses (CADRs) account for 10%–30% of all reported adverse drug reactions, making them the most common indication of drug sensitivity [7].

None of the causality assessment tools have been widely recognized as the gold standard despite the variety of approaches that are available. However, the most used are WHO UMC scales and Naranjo's algorithm. Clinical judgement or global introspection, algorithms, and probabilistic methods are the major categories into which the many approaches for determining the causal relationship between a medicine and adverse events may be divided. The Adverse Drug Reactions Advisory Committee guidelines, the Swedish method, the World Health Organization Uppsala Monitoring Center (WHO UMC) scale, Naranjo's algorithm, Kramer algorithm, Jones algorithm, Karch algorithm, Bégaud algorithm, and the Bayesian Adverse Reaction Diagnostic Instrument are a few examples [8].

Many medication types can cause a wide range of cutaneous symptoms, from severe toxic epidermal necrolysis (TEN) to maculopapular rash. Serious morbidity and even death are possible outcomes of certain severe cutaneous adverse drug reactions. It can be challenging to determine the likelihood of a drug-induced incident and, ultimately, to identify the offending substance. A standardized approach that produces consistent, accurate, and repeatable ADR identification should be employed in order to reach a definitive determination of causation [9].

When novel medications are introduced and therapeutic practices change, the pattern of CADRs and the causative pharmaceuticals typically changes as well. Additionally, a number of international studies revealed inconsistent prevalence, highlighting the necessity of local data considering various socioeconomic, demographic, and prescription practices.

Thus, the goal of this study is to determine the clinical spectrum and possible risk factors as well as to assess the frequency of patients who present with adverse cutaneous medication responses. These reported cutaneous adverse medication responses are not yet evaluated by any local published data. This study's incidence and clinical spectrum pattern would enable local healthcare providers to better comprehend CADRs and provide efficient treatment options for these individuals.

Methodology

Study Design: This study was a hospital-based retrospective observational study conducted to evaluate the clinical patterns, causative drugs, and risk factors associated with cutaneous adverse drug reactions (CADRs) among hospitalized patients.

Study Duration: The study was carried out over a period of six months from June 2025 to November 2025.

Study Area: The study was conducted at Department of Pharmacology, Bhagwan Mahavir Institute of Medical Sciences (BMIMS), Pawapuri, Nalanda, Bihar, India.

Sample Size: A total of 115 patients with documented cutaneous adverse drug reactions were included in the study.

Sampling Technique: A non-probability consecutive sampling technique was used. All eligible patients who met the inclusion criteria during the study period were included until the required sample size of 115 was achieved.

Inclusion Criteria

- Patients of all age groups and both genders
- Hospitalized patients with clinically diagnosed cutaneous adverse drug reactions
- Patients with complete and retrievable medical records
- CADRs confirmed by consultant dermatologist
- Patients receiving drugs at therapeutic doses

Exclusion Criteria

- Patients with incomplete or illegible medical records.
- Cutaneous reactions due to poisoning, overdose, or drug abuse.
- Skin manifestations are due to infections, autoimmune diseases, or systemic illnesses.
- Patients with pre-existing dermatological conditions are not related to drug intake.
- Suspected reactions to alternative or herbal medicines without adequate documentation.

Data Collection: Data were collected retrospectively from hospital medical records of patients diagnosed with cutaneous adverse drug reactions during the study period. Information was obtained from inpatient case sheets, dermatology consultation notes, adverse drug reaction (ADR) reporting forms, and departmental registers. A structured data extraction proforma was used to record demographic details such as age and gender, clinical characteristics of the cutaneous reaction, suspected offending drug(s), indication for drug use, dose, route of

administration, duration of therapy, and the time interval between drug intake and onset of the reaction. Details regarding history of drug allergy, associated comorbidities, management provided, and clinical outcomes were also documented. The diagnosis of CADRs was confirmed by a dermatologist, and completeness and accuracy of data were ensured by cross-verification of records from the departments of Dermatology and Pharmacology.

Procedure: All identified cases were reviewed in detail. Cutaneous adverse drug reactions were classified based on clinical morphology. Causality assessment was performed using the Naranjo Causality Assessment Scale, and reactions were categorized as definite, probable, possible, or doubtful. Data consistency was ensured by cross-verification of dermatology notes and pharmacology ADR records.

Statistical Analysis: The collected data were entered into Microsoft Excel and analyzed using Statistical Package for the Social Sciences (SPSS) software. Descriptive statistical methods were employed to summarize the data. Continuous variables such as age were expressed as mean and standard deviation, while categorical variables such as gender, types of cutaneous adverse drug reactions, and offending drug classes were presented as frequencies and percentages. Where applicable, appropriate statistical tests were applied to assess associations between variables, and a p-value of less than 0.05 was considered statistically significant. The results were organized and presented using tables and graphical representations for clarity."

Result

Table 1 illustrates the demographic profile of patients who experienced cutaneous adverse drug reactions (CADRs). Many patients were between the ages of 21 and 40 (40%), followed by those between the ages of 41 and 60 (33.9%), suggesting that CADRs were more prevalent in the community of economically active adults. 10.4% of patients were younger than 20, while 15.7% were older than 60. There was a masculine preponderance, with 60% of instances involving men and 40% involving women. The research participants' average age was 42.6 ± 16.8 years, indicating that while CADRs can affect people of all ages, they are more common in middle-aged individuals.

Table 1: Demographic Characteristics of Study Participants (n = 115)

Variable	Number (n)	Percentage (%)
Age group (years)		
< 20	12	10.4
21–40	46	40
41–60	39	33.9
> 60	18	15.7
Gender		
Male	69	60
Female	46	40
Mean age (years)	42.6 ± 16.8	—

In Table 2, you can see how long it takes for skin adverse drug responses to start after taking a drug. The majority of CADRs appear within the first week after medication exposure, as shown by the most prevalent latency time of 4–7 days (35.7%) and responses appearing within ≤3 days (28.7%). 11.3% of cases had delayed start after 21 days, and about 24.3% of responses appeared between 8 and 21 days. This suggests that while CADRs frequently manifest shortly after starting a medication, delayed responses are not unusual and call for a thorough assessment of the patient's medication history.

Table 2: Latency Period Between Drug Intake and Onset of CADRs (n = 115)

Latency period	Number of cases (n)	Percentage (%)
≤ 3 days	33	28.7
4–7 days	41	35.7
8–21 days	28	24.3
> 21 days	13	11.3
Total	**115**	**100**

Table 3 shows the drug groups that are thought to be responsible for CADRs. The most often offending medicine class was antibiotics (33%), which were followed by antiepileptic medications (20.9%) and non-steroidal anti-inflammatory drugs (NSAIDs) (18.3%). 12.2% of cases used anti-tubercular medications, while 7.8% involved antiretroviral treatment (ART). A little percentage (7.8%) was also provided by other medications, such as proton pump inhibitors, antidiabetic medications, and anti-

hypertensive medications. The extensive usage of these medication classes in clinical practice and their recognized propensity to result in cutaneous adverse effects are reflected in this distribution.

Table 3: Suspected Drug Groups Associated with Cutaneous Adverse Drug Reactions (n = 115)		
Drug group	**Number of cases (n)**	**Percentage (%)**
Antibiotics	38	33
Antiepileptic drugs	24	20.9
Non-steroidal anti-inflammatory drugs (NSAIDs)	21	18.3
Anti-tubercular drugs	14	12.2
Antiretroviral therapy (ART)	9	7.8
Others*	9	7.8
Total	**115**	**100**

Table 4 shows the Naranjo scale's causality assessment of CADRs. A significant temporal link and improvement upon medication cessation were shown by the majority of responses being categorized as likely (55.7%). In cases where other explanations could not be totally ruled out, possible responses accounted for 30.4%. Just 3.5% of responses were classified as questionable, but 10.4% of responses were definitive. These results imply that there was a fair chance that the adverse cutaneous reaction was caused by the suspected medication in the majority of the instances.

Table 4: Causality Assessment Based on Naranjo Scale (n = 115)		
Causality category	**Number of cases (n)**	**Percentage (%)**
Definite	12	10.4
Probable	64	55.7
Possible	35	30.4
Doubtful	4	3.5
Total	**115**	**100**

Table 5 shows the presence of other diseases that go along with CADRs in patients. Of the patients, 57.4% had no related systemic disease, whereas 42.6% had comorbidities. Comorbidities may make a person more susceptible to negative medication responses, polypharmacy, and drug exposure. This finding highlights the importance of cautious medication selection and monitoring, particularly for individuals with underlying medical issues.

Table 5: Presence of Associated Comorbidities (n = 115)		
Comorbidity status	**Number of cases (n)**	**Percentage (%)**
Present	49	42.6
Absent	66	57.4
Total	**115**	**100**

Discussion

Adverse bodily reactions that follow medication delivery and are not indicative of the intended pharmacodynamic impact are known as drug reactions. With the introduction of new pharmaceuticals, the pattern of drug responses and offending substances shows changing trends. Most drug responses are not well documented, and there are still a lot of pathogenesis-related questions that need to be answered. One of the most common types of medication responses is cutaneous [10]. The rechallenge, which confirms a drug's relationship with the CADR, particularly in circumstances of simultaneous multiple drug ingestion, is responsible for a larger percentage of certain/definite causality assignments in our study utilizing both scales."

While some studies found that up to 2% to 5% of inpatients had CADRs, the prevalence of CADRs among patients in poor nations ranges from 1% to 3%. Nevertheless, thorough information regarding the clinical range of medication rashes is lacking. Lack of knowledge and resources, as well as diagnostic challenges, may be the cause of the inadequate data [11]. Patients' health may be severely impacted by these responses, which frequently result in hospitalization and, in extreme situations, even death. Antimicrobials were the most often occurring medication class linked to CADR, followed by NSAIDs, a finding shared by several other research.

Focusing on acneiform eruption and occupation was one of the study's implications. The results of the present study were statistically significant, and few prior studies had shown a comparable significant association. The current study demonstrates that a positive family history of acneiform eruption might be a predictor of CADR. Additionally, a substantial statistical correlation between acneiform and education

was discovered, indicating that the development of acneiform eruption is significantly influenced by inaccurate myths and insufficient information [12].

It was consistent with the fact that men were more likely than women to have CADRs. The majority of patients were between the ages of 51 and 60 (39.36%), followed by those between the ages of 41 and 50 (32.12%). These findings are consistent with other studies that have made similar findings. Adults between the ages of 20 and 60 had the largest risk of medication reactions, according to their data [13]. Multiple drug use has grown to be a significant issue that makes it difficult to identify the offending substance. This may be explained by the fact that paracetamol is frequently used or misused as an over the counter (OTC) medication since it is typically seen as harmless when compared to other antipyretics and analgesics. Paracetamol was the most often suspected drug. The most reliable technique for determining causation in CADRs is oral provocation or medication rechallenge.

The lack of important cofactors throughout the test process (light, medicine, viral infection, physical activity), desensitization brought on during testing, and the refractory phase after the reaction are some of the reasons for negative rechallenge. More rigorous and objective criteria, such as placebo and medication administration information, hazardous drug levels in the body, and confirmation by objective data, must be met to classify a CADR into a definite or probable category in the Naranjo scale [14]. Compared to the Naranjo algorithm, which demonstrated a small degree of judges' agreement, the WHO UMC algorithm demonstrated fair repeatability and has been recommended as the most reliable method for determining the causation of adverse drug reactions (ADRs) that occur in hospitals.

Further research is required to determine the extent of CADRs in local settings, as the current study demonstrated the prevalence of the clinical spectrum of CADR. Furthermore, our trial did not allow long-term patient monitoring and follow-up. Notwithstanding these drawbacks, the study demonstrates that medical professionals should understand how crucial it is to record every medication reaction. The patterns of CADRs are evolving annually due to the introduction of new medications. To reduce these occurrences and successfully manage them, doctors should be well informed on adverse drug reactions (ADRs), particularly about more recent medications.

Conclusion

This retrospective research conducted in a hospital emphasizes that cutaneous adverse medication responses are a significant clinical issue that arises in everyday medical practice. The study showed that middle-aged persons with a male preponderance had a greater incidence of CADRs. The most frequently used drug classes in clinical settings were found to be antibiotics, antiepileptic medications, and non-steroidal anti-inflammatory medications. Most responses appeared within the first week of medication delivery, highlighting the importance of careful observation in the early stages of treatment. The Naranjo scale's causality evaluation revealed that most responses were categorized as probable or plausible, highlighting the importance of a thorough drug history and prompt medication removal. A significant percentage of patients have comorbidities, which suggests that they are more susceptible to negative medication responses, most likely because of polypharmacy. To reduce morbidity, stop recurrence, and enhance patient safety, the study's overall conclusions highlight the significance of prudent prescription, early detection of cutaneous drug responses, and bolstering pharmacovigilance efforts.

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