E-ISSN 2250-0944
ISSN 2250-1150
doi: 10.48047/ijprt/16.02.222

Research Article

CLINICO-EPIDEMIOLOGICAL PROFILE OF CUTANEOUS ADVERSE DRUG REACTIONS: A RETROSPECTIVE OBSERVATIONAL STUDY FROM A TERTIARY CARE TEACHING HOSPITAL IN KARNATAKA, INDIA

Sukruthi[1], Kiran Kumar S.[2]

[1]Senior Resident, Department of Dermatology, Leprology, Venereology, Shridevi Institute of Medical Science and Research Hospital Tumkuku, Karnataka, India.
[2]Senior Resident, Department of Dermatology, Venereology, Leprosy, S S Institute of Medical Sciences & Research Centre Davangere, Karnataka, India.

Received Date: 23/05/2026 Accepted: 22/06/2026 Published Date:31/07/2026

Corresponding Author: Dr. Sukruthi, Senior Resident, Department of Dermatology, Leprology, Venereology, Shridevi Institute of Medical Science and Research Hospital Tumkuku, Karnataka, India.
Email: sukruthi1995acharya@gmail.com

ABSTRACT

Background: Cutaneous adverse drug reactions (CADRs) represent one of the most frequently encountered adverse drug reactions in clinical practice, accounting for a significant proportion of dermatological consultations and hospital admissions [(1,2)]. Their clinical spectrum ranges from mild self-limiting eruptions to life-threatening severe cutaneous adverse reactions (SCARs), such as Stevens–Johnson syndrome (SJS), toxic epidermal necrolysis (TEN), drug reaction with eosinophilia and systemic symptoms (DRESS), and acute generalized exanthematous pustulosis (AGEP) [(2–4)]. The incidence and pattern of CADRs vary according to regional prescribing practices, patient characteristics, genetic predisposition, and healthcare accessibility [(1,5)]. Continuous pharmacovigilance is therefore essential to identify offending drugs, prevent recurrence, and improve patient safety [(5,6)]. **Objectives:** To evaluate the clinico-epidemiological characteristics, morphological patterns, causative drugs, severity, causality assessment, and prescription sources of cutaneous adverse drug reactions in patients attending a tertiary care teaching hospital in Karnataka, India. **Materials and Methods:** A retrospective observational study was conducted among patients diagnosed with CADRs between May 2022 and May 2023 in the Department of Dermatology of a tertiary care teaching hospital in Karnataka, India. Data regarding demographic profile, suspected offending drugs, clinical morphology, severity, causality assessment using the Naranjo Adverse Drug Reaction Probability Scale, and source of prescription were extracted from medical records. Descriptive statistics were used to summarize the findings as frequencies and percentages. **Results:** A total of 69 patients were included. Males constituted 72.5% (n=50) and females 27.5% (n=19), with the highest frequency observed in the 31–40-year age group (32%, n=22). Non-steroidal

anti-inflammatory drugs (NSAIDs) were the most frequently implicated drug class (31.9%, n=22), followed by antibacterial agents (27.5%, n=19). Diclofenac (8.7%, n=6) and aceclofenac (7.2%, n=5) were the commonest individual drugs. Fixed drug eruption was the predominant clinical presentation (52.2%, n=36), followed by urticaria (8.6%, n=6). Benign CADRs constituted 82.6% (n=57), while severe cutaneous adverse reactions accounted for 17.4% (n=12). According to the Naranjo causality assessment, 78.3% (n=54) were classified as probable and 8.7% (n=6) as possible. Medications prescribed by non-registered medical practitioners accounted for 27.5% (n=19) of cases, whereas over-the-counter drug use contributed to 14.5% (n=10). Conclusion: Fixed drug eruption was the predominant CADR observed, with NSAIDs being the leading causative drug class. The considerable contribution of medications obtained from non-registered medical practitioners and over-the-counter sources emphasizes the need for rational prescribing, patient education, and strengthening pharmacovigilance systems to reduce preventable adverse drug reactions.

Keywords: Cutaneous adverse drug reactions; Fixed drug eruption; NSAIDs; Pharmacovigilance; Naranjo scale; Karnataka; Drug safety.

INTRODUCTION

Adverse drug reactions (ADRs) remain an important cause of morbidity and mortality worldwide despite significant advances in drug development, regulatory surveillance, and pharmacovigilance programs. The World Health Organization (WHO) defines an adverse drug reaction as "a response to a medicinal product which is noxious and unintended, and which occurs at doses normally used in humans for prophylaxis, diagnosis, therapy of disease, or modification of physiological function" [(1)]. ADRs contribute substantially to emergency department visits, prolonged hospital admissions, increased healthcare expenditure, and preventable mortality, representing a major public health challenge [(2,3)].

Among the various manifestations of ADRs, cutaneous adverse drug reactions (CADRs) are among the most frequently recognized because of their visible clinical presentation. CADRs account for approximately 20–30% of all reported ADRs and occur in approximately 1–8% of hospitalized patients, although the frequency varies depending on patient characteristics, healthcare settings, prescribing patterns, and methods of surveillance [(4,5)]. They encompass a broad clinical spectrum ranging from mild self-limiting morbilliform eruptions to life-threatening severe cutaneous adverse reactions (SCARs), including Stevens–Johnson syndrome (SJS), toxic epidermal necrolysis (TEN), drug reaction with eosinophilia and systemic symptoms (DRESS), and acute generalized exanthematous pustulosis (AGEP) [(6–8)].

The pathogenesis of CADRs is complex and involves both immunological and non-immunological mechanisms. Most delayed CADRs are mediated by drug-specific T-cell responses, whereas immediate reactions may involve IgE-mediated hypersensitivity mechanisms. Drug-induced immune responses may also result from direct interaction between drugs or their metabolites and immune receptors, including the pharmacological interaction with immune receptors (p-i concept) [(9)]. Several host-related factors, including age, sex, genetic predisposition, renal and hepatic dysfunction, infections, polypharmacy, and underlying systemic diseases, influence an individual's susceptibility to CADRs **(6,9)**. Pharmacogenetic factors have gained increasing importance, with specific human leukocyte antigen (HLA) alleles being strongly associated with severe reactions, such as HLA-B*15:02 with carbamazepine-induced SJS/TEN and HLA-B*58:01 with allopurinol-induced severe cutaneous reactions [(10,11)].

The pattern of drugs implicated in CADRs changes over time due to variations in prescribing practices and availability of newer therapeutic agents. Antimicrobial drugs, non-steroidal anti-inflammatory drugs (NSAIDs), antiepileptic drugs, antitubercular drugs, allopurinol, and antiretroviral medications remain among the commonly reported causes of CADRs worldwide [4,6,12]. In developing countries, including India, factors such as over-the-counter availability of medications, self-medication practices, polypharmacy, and irrational prescribing contribute significantly to the burden of preventable ADRs [13].

Early recognition and appropriate management of CADRs are essential because prompt withdrawal of the suspected offending drug is the cornerstone of treatment and may prevent progression to severe disease. Delayed identification, particularly in SCARs, may lead to extensive skin involvement, systemic complications, prolonged hospitalization, permanent sequelae, and death [7,8]. Therefore, effective pharmacovigilance systems are essential for detecting safety signals, monitoring drug-related harms, promoting rational prescribing, and improving patient safety [1,14].

Several studies from different regions have demonstrated considerable variation in the clinico-epidemiological profile of CADRs, including differences in causative drugs, clinical patterns, severity, and patient outcomes. These variations may reflect differences in genetic background, prescribing practices, drug availability, healthcare infrastructure, and reporting systems [4,6]. Although pharmacovigilance studies on CADRs have been reported from various parts of India, regional data remain limited, particularly from Karnataka. Region-specific information is important for identifying commonly implicated drugs, understanding local prescribing trends, improving early diagnosis, and developing targeted preventive strategies.

Furthermore, increasing self-medication and treatment by non-registered medical practitioners represent additional challenges to effective pharmacovigilance in India. Evaluation of prescription sources and patterns of drug use may provide valuable evidence for interventions aimed at reducing irrational drug consumption and preventing avoidable adverse reactions [13].

Against this background, the present retrospective observational study was undertaken to analyze the clinico-epidemiological profile, morphological spectrum, offending drugs, severity, causality assessment, and prescription sources of CADRs among patients attending a tertiary care teaching hospital in Karnataka, India.

MATERIALS AND METHODS

Study Design

A retrospective, observational, hospital-based study was conducted to evaluate the clinico-epidemiological profile of cutaneous adverse drug reactions (CADRs) among patients attending a tertiary care teaching hospital in Karnataka, India.

Study Setting

The study was carried out in the Department of Dermatology of a tertiary care teaching hospital located in Karnataka, India. The institution caters to patients from both urban and rural areas and receives referrals from multiple clinical departments. To maintain anonymity during peer review, the name of the institution has been withheld.

Study Duration

The study included all eligible cases diagnosed between **May 2022 and May 2023**.

Study Population

Medical records of patients diagnosed with CADRs in the Dermatology Outpatient Department (OPD) or referred from various inpatient departments during the study period were reviewed retrospectively.

Sample Size

A total of **69 patients** fulfilling the eligibility criteria were included in the analysis.

Inclusion Criteria

Patients fulfilling all of the following criteria were included:

- Patients of any age and either sex diagnosed clinically with cutaneous adverse drug reactions.
- Patients attending the Dermatology OPD or referred from other clinical departments.
- Availability of complete medical records, including demographic details, drug history, clinical findings, and treatment details.
- Cases diagnosed during the study period (May 2022–May 2023).

Exclusion Criteria

The following patients were excluded:

- Patients with incomplete or inadequate medical records.
- Patients with skin lesions attributable to infections, autoimmune disorders, or dermatological diseases unrelated to drug exposure.
- Cases in which the offending drug could not be reasonably identified.
- Duplicate patient records.

Data Collection

Data were extracted from hospital medical records using a structured data collection form prepared for the study.

The following variables were recorded:

Demographic Variables

- Age
- Gender

Clinical Variables

- Clinical diagnosis
- Morphological pattern of CADR
- Date of onset
- Duration between drug intake and onset of lesions (where documented)
- Mucosal involvement
- Systemic involvement
- Need for hospitalization
- Clinical outcome

Drug-related Variables

- Suspected offending drug
- Drug class
- Number of drugs consumed
- Indication for drug use
- Route of administration
- Source of prescription

Source of Prescription

The source of the suspected drug prescription was categorized into:

- Registered Medical Practitioner
- Non-Registered Medical Practitioner (NRMP)
- Over-the-counter (OTC) medication
- Self-medication
- Others

Clinical Diagnosis of CADRs

The diagnosis of CADR was established based on:

- Detailed drug history
- Temporal relationship between drug intake and onset of skin lesions
- Clinical morphology
- Improvement after withdrawal of the suspected drug (dechallenge)
- Exclusion of other dermatological conditions

Whenever multiple drugs had been administered simultaneously, the most likely offending drug was identified after reviewing the chronology of drug administration, previous history of reactions, and available clinical documentation.

Morphological Classification

CADRs were classified according to their predominant clinical morphology.

The morphological patterns included:

- Fixed Drug Eruption (FDE)
- Urticaria
- Maculopapular Rash
- Stevens–Johnson Syndrome (SJS)
- Toxic Epidermal Necrolysis (TEN)
- Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS)
- Acute Generalized Exanthematous Pustulosis (AGEP)
- Erythema Multiforme
- Exfoliative Dermatitis

- Others

Severity Assessment
Patients were categorized into:
Benign CADRs
These included reactions such as:

- Fixed Drug Eruption
- Urticaria
- Morbilliform eruption
- Maculopapular rash
- Pruritus
- Mild erythematous eruptions

Severe Cutaneous Adverse Reactions (SCARs)
The following were considered SCARs:

- Stevens–Johnson Syndrome
- Toxic Epidermal Necrolysis
- DRESS Syndrome
- AGEP
- Extensive exfoliative dermatitis
- Other life-threatening CADRs

Severity classification was based on clinical diagnosis documented in the patient's medical record.

Causality Assessment

The relationship between the suspected drug and the adverse reaction was assessed using the **Naranjo Adverse Drug Reaction Probability Scale**.
Each case was categorized as:

- Definite (score ≥9)
- Probable (score 5–8)
- Possible (score 1–4)
- Doubtful (score ≤0)

The Naranjo scale is a validated and widely accepted instrument used in pharmacovigilance to estimate the probability that an adverse event is related to a drug rather than other factors.

Management

Patients were managed according to institutional treatment protocols. The principal management strategies included:

- Immediate withdrawal of the suspected offending drug.
- Oral or intravenous antihistamines.
- Topical corticosteroids for localized lesions.
- Systemic corticosteroids when clinically indicated.
- Supportive care, including fluid and electrolyte management.
- Admission to intensive care or burn unit for patients with severe cutaneous adverse reactions, where necessary.

Outcome Assessment

Patient outcomes were categorized as:

- Complete recovery
- Recovery with residual pigmentation
- Ongoing treatment during follow-up
- Mortality (if any)

Ethical Considerations

The study was conducted after obtaining approval from the Institutional Ethics Committee of the participating tertiary care teaching hospital.
As this was a retrospective record-based study, the requirement for individual informed consent was waived by the Ethics Committee.
Patient confidentiality was maintained throughout the study by anonymizing all identifying information. Data were used exclusively for research purposes in accordance with the ethical principles outlined in the Declaration of Helsinki.
Statistical Analysis
The collected data were entered into Microsoft Excel and analyzed using **IBM SPSS Statistics (Version _29.0__)** or equivalent statistical software.
Descriptive statistics were used for data analysis.
Categorical variables were expressed as:

- Frequencies (n)
- Percentages (%)

Continuous variables, wherever applicable, were summarized using:

- Mean ± Standard Deviation (SD)
- Median with Interquartile Range (IQR)

Results were presented using tables and graphs to facilitate interpretation.
Since the study was descriptive in nature and intended primarily to evaluate the clinico-epidemiological profile of CADRs, no inferential statistical tests were applied.

Study Flow

Medical records screened (May 2022–May 2023)
↓
Patients diagnosed with CADRs
↓
Eligibility assessed
↓
Incomplete records excluded
↓
Eligible patients included (n = 69)
↓
Data extraction
↓
Clinical analysis
↓
Drug analysis
↓
Severity assessment
↓
Causality assessment (Naranjo Scale)
↓
Statistical analysis
↓
Interpretation of results

RESULTS

A total of **69 patients** diagnosed with cutaneous adverse drug reactions (CADRs) were included in the study during the period from **May 2022 to May 2023**.

Demographic Characteristics

Of the 69 patients, **50 (72.5%) were males** and **19 (27.5%) were females**, resulting in a male-to-female ratio of **2.6:1**.

The majority of patients belonged to the **31–40 years** age group (32.0%), followed by the 21–30 years age group. CADRs were observed across all age groups, indicating that adverse cutaneous reactions can occur irrespective of age

.**Table 1. Age-wise distribution of study participants (n = 69)**

Using 69 as the total number of observations, the percentage distribution is:

Age Group (Years)	Frequency (n)	Percentage (%)
1–10	4	5.80
11–20	13	18.84
21–30	10	14.49
31–40	22	31.88
41–50	6	8.70
51–60	10	14.49
61–70	4	5.80
Total	**69**	**100.00**

Table 2. Gender distribution

Gender	Number (n)	Percentage (%)
Male	50	72.5
Female	19	27.5
Total	**69**	**100**

Offending Drug Classes

NSAIDs were the most frequently implicated drug class, accounting for **31.9%** of all CADRs, followed by antibacterial agents (**27.5%**). The remaining reactions were attributed to other drug groups such as antiepileptics, antitubercular drugs, corticosteroids, and miscellaneous medications

.

Table 3. Drug classes implicated in CADRs

	Frequency	Percent
Anti Bacterial	19	27.5
Anti Convulsant	3	4.3
Anti Fungal	1	1.4
Anti leprosy	2	2.8
Anti Tb	4	5.8
Antibacterial & Nsaid	1	1.4
Antifungal	1	1.4
Antihelminth	1	1.4
Art	2	2.9
Nsaid	22	31.9
Steroid	2	2.9
Sulpha	2	2.9
UKN	1	1.4
NA	8	11.6
Total	69	100.0

Individual Offending Drugs

Among individual drugs, **diclofenac** was the commonest offending drug, followed by **aceclofenac**.

Table 4. Common individual drugs responsible for CADRs

Drug	Number (n)	Percentage (%)
Diclofenac	6	8.7
Aceclofenac	5	7.2
Others	58	84.1
Total	**69**	**100**

Morphological Pattern of CADRs

Fixed drug eruption (FDE) was the predominant clinical presentation and constituted more than half of all CADRs. Urticaria was the second most common morphology

.

Table 5. Morphological pattern of CADRs

		Frequency	Percent
	Acnaeform Eruption	2	2.9
	Angioedema	1	1.4
	Agep	1	1.4
	Bullous Fde	3	4.3
	Dress	1	1.4

	Drug Induced Hyperpigmentation	1	1.4
	Drug Induced Purpura	1	1.4
	EDE	4	5.8
	Emmin	1	1.4
	Emmjr	1	1.4
	Erythroderma	2	2.9
	FDE	36	52.2
	Generalised Lichenoid Eruption	1	1.4
	SJS	4	5.8
	TEN	3	4.3
	Urticaria	6	8.6
	Vasculitis	1	1.4
	Total	69	100.0

Severity of CADRs

Most patients presented with benign CADRs (82.6%), whereas severe cutaneous adverse reactions (SCARs) constituted 17.4%.

Table 6. Severity of CADRs

Severity	Number (n)	Percentage (%)
Benign CADRs	57	82.6
Severe CADRs (SCARs)	12	17.4
Total	**69**	**100**

Causality Assessment

Using the Naranjo Adverse Drug Reaction Probability Scale, the majority of reactions were classified as **probable**.

Table 7. Naranjo causality assessment

Category	Number (n)	Percentage (%)
Definite	0	0
Probable	54	78.3
Possible	6	8.7
Doubtful	0	0
Others/Not classified*	9	13.0
Total	**69**	**100**

Source of Prescription

A considerable proportion of CADRs occurred following medications obtained from **non-registered medical practitioners (27.5%)**, followed by **over-the-counter drug use (14.5%)**.

Table 8. Source of prescription

Source	Number (n)	Percentage (%)
Registered medical practitioner	40	58
Non-registered medical practitioner	19	27.5
Over-the-counter medications	10	14.5
Self-medication	0	0
Total	**69**	**100**

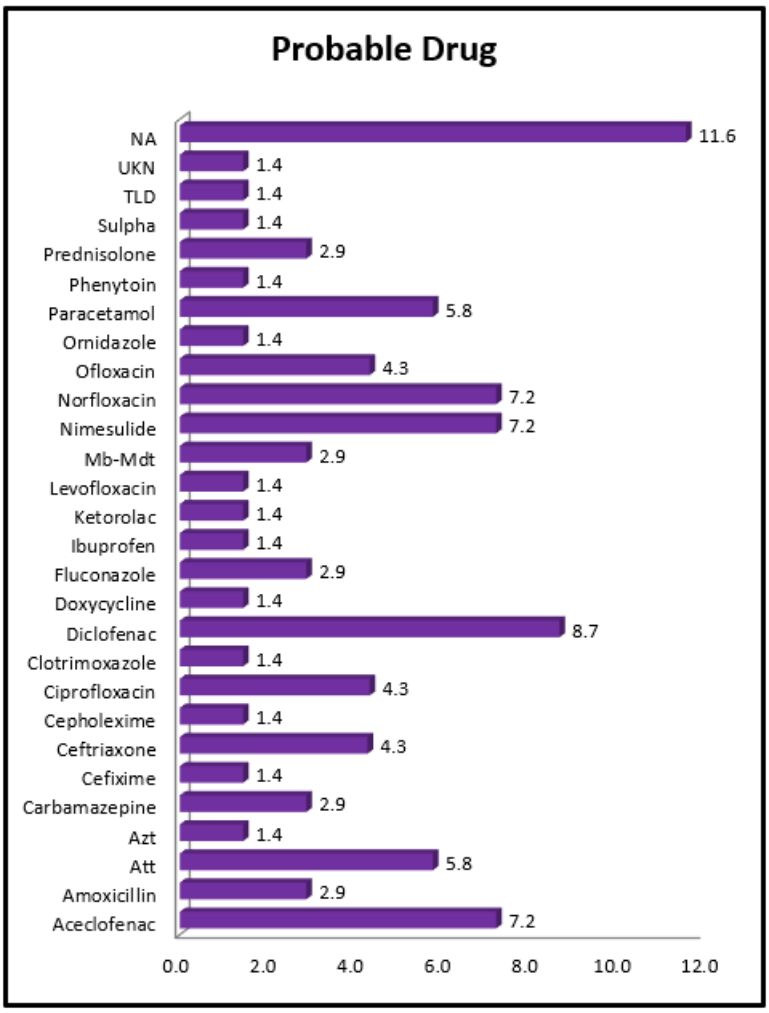

Figure 1. Distribution of CADRs according to the offending drug.

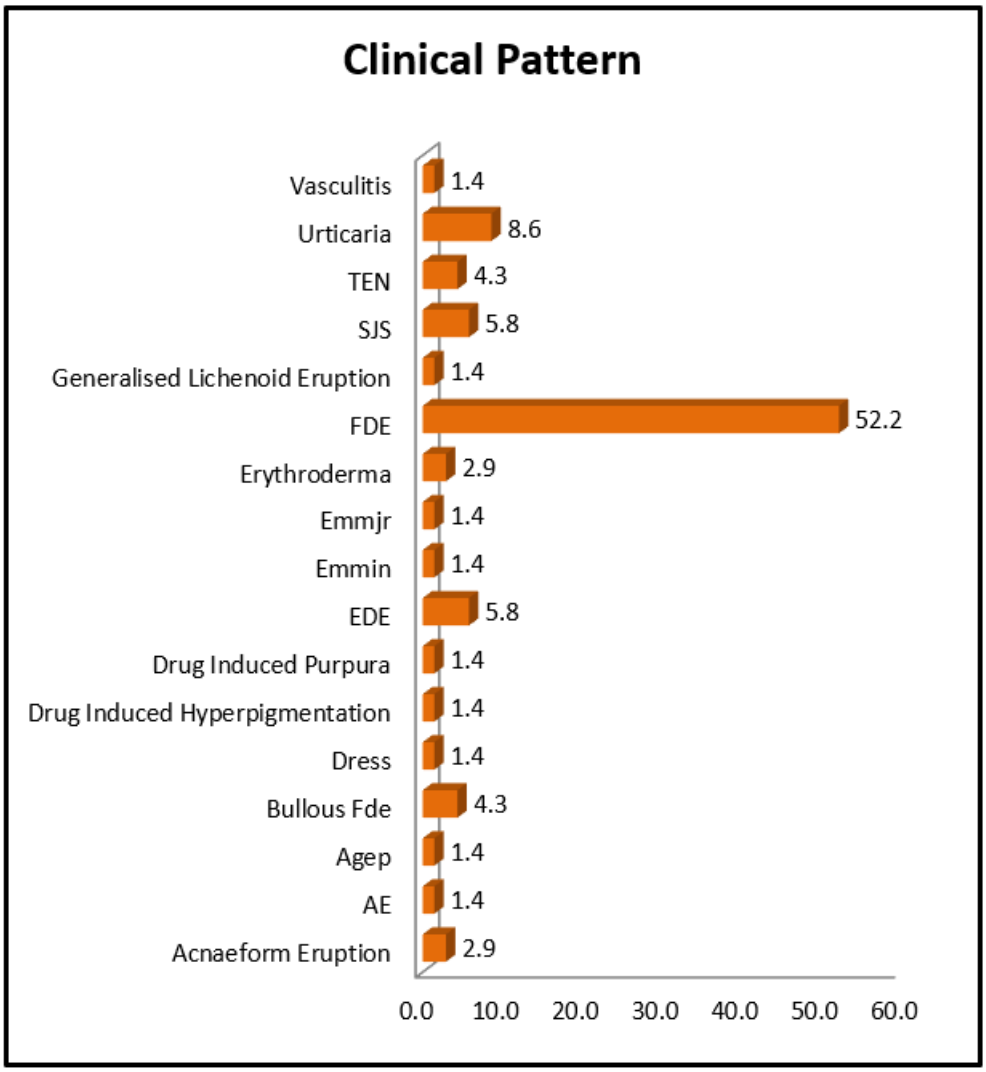

Figure 2: Distribution of clinical morphological patterns of cutaneous adverse drug reactions.

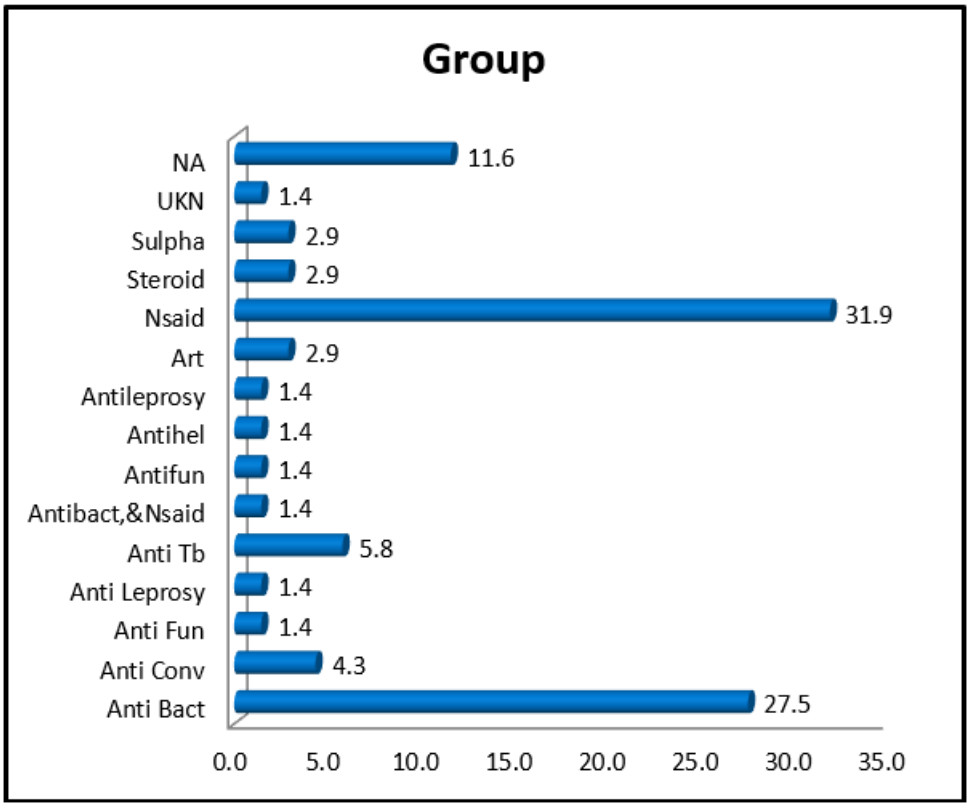

Figure 3:Distribution of CADRs according to the offending drug class.

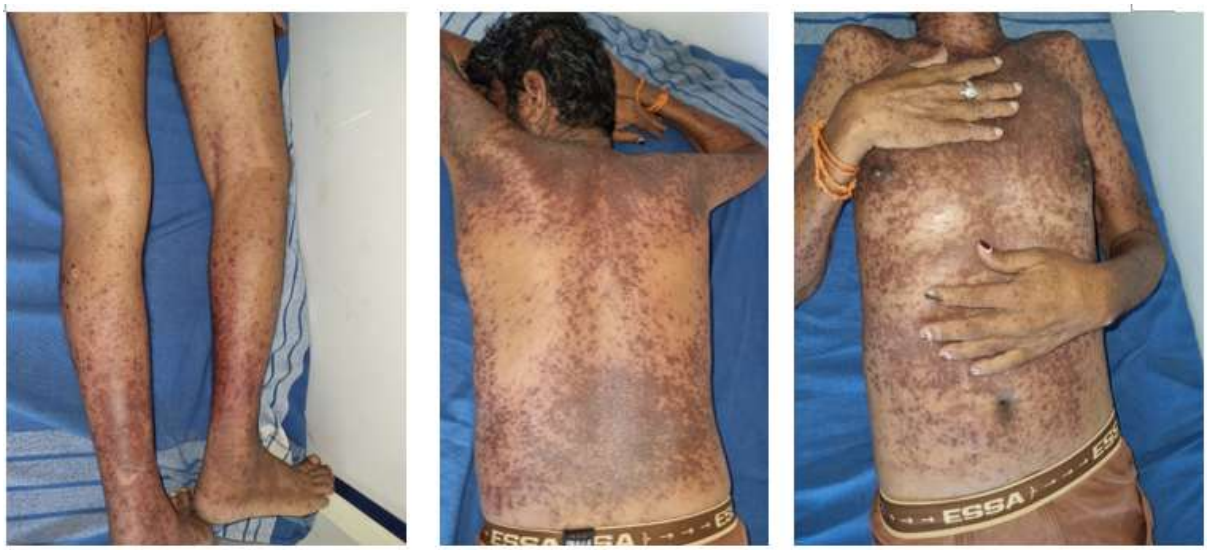

Figure 4a,4b,4c:ATT induced SJS

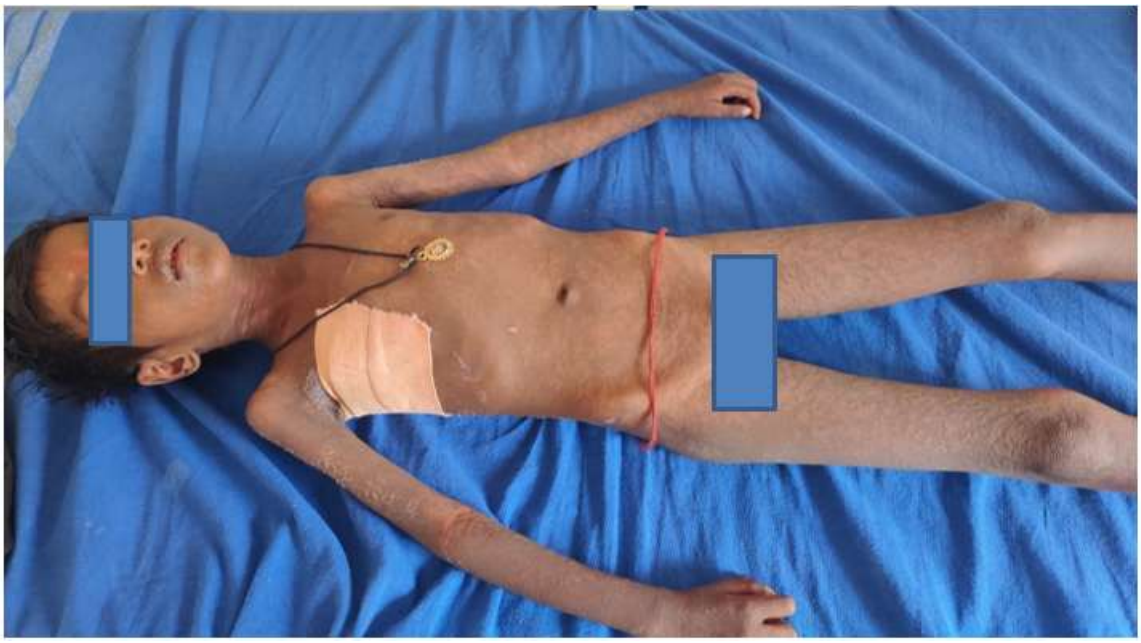

Figure 5: drug induced erythroderma

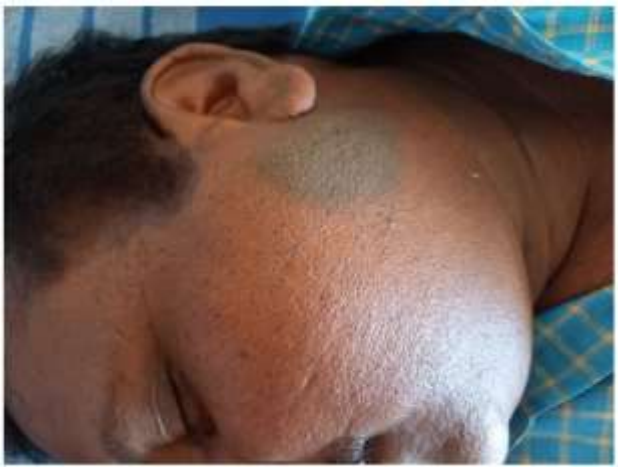

Figure 6: FDE to NSAID

DISCUSSION

The present retrospective observational study evaluated the clinico-epidemiological profile of cutaneous adverse drug reactions (CADRs) among patients attending a tertiary care teaching hospital in Karnataka, India. The study highlights the demographic characteristics, offending drugs, clinical manifestations, severity, causality assessment, and prescription patterns associated with CADRs. The findings contribute to the growing body of evidence on regional variations in CADRs and emphasize the importance of pharmacovigilance and rational prescribing practices.

A total of 69 patients with CADRs were included during the one-year study period. Male patients constituted 72.5% of the study population, with a male-to-female ratio of approximately 2.6:1. Similar male predominance has been reported in several Indian studies, although some investigators

have observed either female predominance or nearly equal gender distribution. The observed predominance among males in the present study may be attributed to greater healthcare utilization among working-age men, increased occupational exposure requiring analgesics, and a higher likelihood of receiving medications for acute illnesses. Regional healthcare-seeking behavior and prescribing practices may also influence gender distribution.

The highest frequency of CADRs was observed in the 31–40-year age group. This finding is comparable with reports from various Indian studies where CADRs were more common among young and middle-aged adults. Individuals in this age group are more likely to receive medications for infections, musculoskeletal disorders, and febrile illnesses, thereby increasing their exposure to potential offending drugs. In addition, this population often practices self-medication and has easier access to over-the-counter medications.

Non-steroidal anti-inflammatory drugs (NSAIDs) emerged as the leading drug class responsible for CADRs in the present study, accounting for 31.9% of cases. This observation is consistent with several studies from India where NSAIDs remain one of the most frequently implicated drug groups because of their widespread availability and frequent use for pain and fever. Diclofenac and aceclofenac were the most commonly implicated individual drugs in the present study. These findings reflect the continued extensive prescription and over-the-counter availability of these medications despite increasing awareness regarding their adverse effect profile.

Antibacterial agents constituted the second most common offending drug class, accounting for 27.5% of cases. Antimicrobials are among the leading causes of CADRs globally because of their extensive utilization in outpatient and inpatient settings. Beta-lactam antibiotics, sulfonamides, fluoroquinolones, and nitroimidazoles have consistently been associated with a wide range of cutaneous reactions. Although the present study did not categorize individual antibacterial agents, the findings reinforce the need for judicious antibiotic prescribing and adherence to antimicrobial stewardship principles.

Fixed drug eruption (FDE) was the most common morphological pattern observed, accounting for 52.2% of all CADRs. This finding agrees with several Indian studies that have reported FDE as the predominant presentation, particularly in association with NSAIDs and antimicrobial agents. FDE is characterized by recurrence of lesions at identical anatomical sites following re-exposure to the offending drug, making careful drug history and patient counselling essential to prevent recurrence. The predominance of FDE in the present study may reflect the high consumption of analgesics and antimicrobial drugs in the community.

Urticaria was the second most common clinical manifestation. Acute drug-induced urticaria typically develops within hours of drug exposure and is commonly associated with NSAIDs, antibiotics, and other medications capable of inducing immediate hypersensitivity reactions. Although less frequent than FDE in the present study, urticaria remains an important cause of dermatological consultation because of its abrupt onset and potential association with angioedema and anaphylaxis.

Most CADRs observed in the present study were benign (82.6%), whereas severe cutaneous adverse reactions (SCARs) constituted 17.4% of cases. Although SCARs represented a relatively small proportion, they warrant particular attention because of their significant morbidity, prolonged hospitalization, and risk of mortality. Early recognition of warning signs such as mucosal involvement, epidermal detachment, extensive erythema, and systemic symptoms is essential for timely referral and initiation of appropriate management. Prompt withdrawal of the offending drug remains the single most

important intervention in reducing morbidity associated with SCARs.

Causality assessment using the Naranjo Adverse Drug Reaction Probability Scale demonstrated that the majority of reactions (78.3%) were categorized as probable. This finding indicates a strong temporal association between drug exposure and the occurrence of CADRs. The Naranjo scale is widely used because of its simplicity and reproducibility; however, its application in retrospective studies may be limited by incomplete documentation and the inability to perform rechallenge, particularly in severe reactions where rechallenge is contraindicated. Nevertheless, its use provides a standardized approach for evaluating the likelihood of drug causation.

One of the most significant observations in the present study was the high proportion of CADRs associated with medications prescribed by non-registered medical practitioners (27.5%). In addition, over-the-counter drug use accounted for 14.5% of cases. These findings underscore an important public health concern in many parts of India where unrestricted access to prescription medications and treatment by unqualified practitioners remain common. Such practices increase the risk of inappropriate drug selection, polypharmacy, delayed recognition of adverse reactions, and recurrent exposure to culprit drugs. Strengthening regulatory oversight, promoting public awareness regarding the hazards of self-medication, and ensuring access to qualified healthcare providers are important measures to reduce preventable CADRs.

The findings of the present study have important implications for pharmacovigilance. Continuous reporting of CADRs contributes to the identification of high-risk drugs, detection of regional prescribing trends, and formulation of preventive strategies. Establishing dedicated ADR monitoring centres, encouraging spontaneous reporting by clinicians, and maintaining electronic drug allergy records can substantially improve patient safety. Patient education regarding previous drug allergies and provision of written drug alert cards may further reduce recurrence of CADRs.

Compared with studies from other regions of India, the present study demonstrates a similar predominance of NSAIDs and antimicrobial agents as causative drugs but also highlights the contribution of irrational prescribing practices. Regional differences in the frequency of specific CADRs may be explained by variations in drug utilization patterns, prescribing habits, healthcare access, and local disease epidemiology. Therefore, institution-specific pharmacovigilance data remain valuable for developing targeted interventions.

The study also emphasizes the importance of multidisciplinary collaboration among dermatologists, pharmacologists, physicians, and pharmacists. Accurate documentation of suspected drug allergies, timely referral of severe cases, and regular pharmacovigilance training for healthcare professionals can significantly improve early recognition and management of CADRs.

Strengths of the Study

The present study provides valuable regional data on the clinico-epidemiological profile of CADRs from Karnataka, where published literature remains relatively limited. Inclusion of causality assessment using the Naranjo Adverse Drug Reaction Probability Scale adds methodological strength and facilitates comparison with other studies. The analysis of prescription sources offers additional insight into the contribution of irrational drug use, an aspect that has not been consistently evaluated in many previous studies.

Limitations

The present study has certain limitations. First, its retrospective design depended on the accuracy and completeness of medical records, resulting in the possibility of missing clinical information. Second, the

study was conducted at a single tertiary care centre with a relatively small sample size, thereby limiting the generalizability of the findings. Third, detailed information regarding latency period, rechallenge, laboratory investigations, and long-term follow-up was not consistently available in all patients. Finally, inferential statistical analysis was not performed because of the descriptive nature of the study.

Clinical Implications

The findings of this study reinforce the importance of careful drug history, early identification of CADRs, and prompt withdrawal of the suspected offending medication. Clinicians should exercise caution while prescribing NSAIDs and antibiotics, particularly in patients with a previous history of drug allergy. Strengthening pharmacovigilance systems, promoting rational prescribing, restricting indiscriminate over-the-counter drug sales, and increasing public awareness regarding the risks of self-medication are likely to reduce the burden of preventable CADRs. Prospective multicentre studies with larger sample sizes are recommended to further characterize regional trends and improve strategies for prevention, diagnosis, and management.

CONCLUSION

Cutaneous adverse drug reactions continue to represent a significant proportion of adverse drug reactions encountered in dermatological practice. In the present retrospective study conducted at a tertiary care teaching hospital in Karnataka, the majority of CADRs occurred among males, with the highest incidence observed in the 31–40-year age group. Non-steroidal anti-inflammatory drugs, particularly diclofenac and aceclofenac, were the most frequently implicated medications, followed by antibacterial agents.

Fixed drug eruption emerged as the predominant clinical presentation, while most reactions were benign in nature. Nevertheless, a notable proportion of patients developed severe cutaneous adverse reactions, emphasizing the importance of early recognition, prompt withdrawal of the offending drug, and timely referral to specialized care.

The observation that a considerable proportion of CADRs resulted from medications prescribed by non-registered medical practitioners and through over-the-counter drug use highlights an important public health concern. Strengthening pharmacovigilance programs, promoting rational prescribing practices, restricting inappropriate over-the-counter dispensing of prescription drugs, and educating patients regarding previous drug allergies are essential strategies for reducing preventable adverse drug reactions.

Further prospective multicentric studies with larger sample sizes are recommended to better understand regional variations in CADRs and to strengthen evidence-based pharmacovigilance practices.

Key Messages

- Fixed drug eruption was the commonest CADR encountered.
- NSAIDs were the leading causative drug class.
- Diclofenac was the most frequently implicated individual drug.
- Most CADRs were benign and classified as probable according to the Naranjo ADR Probability Scale.
- Irrational drug use, including prescriptions from non-registered medical practitioners and over-the-counter medication use, contributed substantially to the occurrence of CADRs.
- Continuous pharmacovigilance and patient education remain essential for preventing recurrent adverse drug reactions.

Future Recommendations

Future studies should:

- Include multicentric hospitals from different regions of Karnataka.
- Recruit a larger sample size.

- Evaluate genetic predisposition for severe CADRs.
- Assess preventability using the Schumock and Thornton Preventability Scale.
- Assess severity using the Hartwig and Siegel Severity Assessment Scale.
- Include long-term patient follow-up to determine recurrence and outcomes.
- Evaluate healthcare costs associated with CADRs.

Acknowledgements

The authors sincerely acknowledge the Department of Dermatology and the Medical Records Department of the participating tertiary care teaching hospital in Karnataka for their assistance in retrieving patient records required for this study. The authors also acknowledge all healthcare professionals involved in the diagnosis and management of patients with cutaneous adverse drug reactions.

Funding

The authors declare that no external funding was received for this study.

Conflict of Interest

The authors declare that they have no conflict of interest.

Ethical Approval

The study was approved by the Institutional Ethics Committee of the participating tertiary care teaching hospital.

As this was a retrospective record-based study, the requirement for informed consent was waived by the Institutional Ethics Committee.

Availability of Data

The datasets generated and analyzed during the current study are available from the corresponding author upon reasonable request, subject to institutional regulations and ethical approval.

REFERENCES

1. World Health Organization. **The importance of pharmacovigilance: Safety monitoring of medicinal products.** Geneva: World Health Organization; 2002.
2. Pirmohamed M, James S, Meakin S, Green C, Scott AK, Walley TJ, et al. Adverse drug reactions as cause of admission to hospital: prospective analysis of 18 820 patients. **BMJ.** 2004;329(7456):15-19.
3. Hakkarainen KM, Hedna K, Petzold M, Hägg S. Percentage of patients with preventable adverse drug reactions and preventability of adverse drug reactions: A meta-analysis. **PLoS One.** 2012;7(3):e33236.
4. Mockenhaupt M. Epidemiology of cutaneous adverse drug reactions. **Chem Immunol Allergy.** 2012;97:1-17.
5. Bigby M. Rates of cutaneous reactions to drugs. **Arch Dermatol.** 2001;137(6):765-770.
6. Del Pozzo-Magaña BR, Liy-Wong C. Drugs and the skin: A concise review of cutaneous adverse drug reactions. **Br J Clin Pharmacol.** 2024;90(8):1838-1855.
7. Hung SI, Mockenhaupt M, Blumenthal KG, Abe R, Ueta M, Ingen-Housz-Oro S, et al. Severe cutaneous adverse reactions. **Nat Rev Dis Primers.** 2024;10(1):30.
8. Creamer D, Walsh SA, Dziewulski P, Exton LS, Lee HY, Dart JKG, et al. UK guidelines for the management of Stevens–Johnson syndrome/toxic epidermal necrolysis in adults 2016. **Br J Dermatol.** 2016;174(6):1194-1227.
9. Pichler WJ. Immune pathomechanism and classification of drug hypersensitivity. **Allergy.** 2019;74(8):1457-1471.
10. Phillips EJ, Sukasem C, Whirl-Carrillo M, Müller DJ, Dunnenberger HM, Chantratita W, et al. Clinical Pharmacogenetics Implementation Consortium guideline for HLA genotype and use of carbamazepine and oxcarbazepine. **Clin Pharmacol Ther.** 2018;103(4):574-581.
11. Ko TM, Tsai CY, Chen SY, Chen KS, Yu KH, Chu CS, et al. Use of HLA-B*58:01 genotyping to prevent allopurinol-induced

severe cutaneous adverse reactions in Taiwan. **Arthritis Rheumatol.** 2015;67(3):781-790.

12. Patel TK, Thakkar SH, Sharma D. Cutaneous adverse drug reactions in Indian population: A systematic review. **Indian Dermatol Online J.** 2014;5(Suppl 2):S76-S86.
13. Bennadi D. Self-medication: A current challenge. **J Basic Clin Pharm.** 2013;5(1):19-23.
14. Vora PR, Subramanian G, Bairy KL. Pharmacovigilance and adverse drug reaction monitoring: Current scenario and future perspectives. **Indian J Pharmacol.** 2020;52(6):471-476