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Original Research Article

Clinico-Demographic Profile and Drug Patterns in Cutaneous Adverse Drug Reactions: A Retrospective Analysis from Southern India

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Conflict of interest: Nil

Abstract

Background: Cutaneous adverse drug reactions (CADRs) are among the most frequently encountered forms of drug-induced morbidity, ranging from benign rashes to life-threatening severe cutaneous adverse reactions (SCARs). In India, underreporting and inconsistent surveillance hinder early detection and response, despite pharmacovigilance being a critical pillar of patient safety.

Keywords: Cutaneous adverse drug reactions, pharmacovigilance, fixed drug eruption, Stevens– Johnson syndrome, antimicrobials, India.

Introduction

Cutaneous adverse drug reactions (CADRs) are among the most visible and frequent manifestations of drug hypersensitivity, ranging from mild eruptions to severe, potentially fatal conditions such as Stevens–Johnson Syndrome (SJS) and Toxic Epidermal Necrolysis (TEN). According to the World Health Organization (WHO), pharmacovigilance is the science and activities associated with the detection, assessment, understanding, and prevention of adverse effects or other drug-related problems [1]. Among these, dermatological manifestations are particularly important due to their early visibility and potential to escalate into systemic emergencies if unrecognized.

The incidence of CADRs is estimated at around 2%–3% in hospitalized patients globally, with higher frequencies reported in developing countries like India, where monitoring systems and reporting mechanisms vary widely [2,3]. Antimicrobials, non-steroidal anti-inflammatory drugs (NSAIDs), and antiepileptics are consistently implicated as leading contributors to CADRs [8,]. The clinical presentation can vary widely—from maculopapular rashes and urticaria to severe cutaneous adverse reactions (SCARs) such as Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS) and SJS/TEN [,7].

Given the increasing availability of newer drug molecules and complex prescribing practices, it is essential to maintain robust pharmacovigilance systems, particularly at the level of tertiary care centers. Periodic regional analyses of ADR patterns can help clinicians recognize emerging trends, avoid high-risk prescriptions, and tailor patient monitoring strategies more effectively.

This study was undertaken to retrospectively analyze the clinicodemographic patterns, causality, and drug classes associated with CADRs reported in a tertiary care teaching hospital in South India, with the goal of contributing to improved dermatologic pharmacovigilance and patient safety practices.

Objective

This study aimed to retrospectively analyze the clinical spectrum, demographic profile, and drug classes most commonly implicated in CADRs reported at a tertiary care teaching hospital in South India. The findings are intended to assist clinicians in identifying risk factors and modifying prescribing behavior to improve dermatologic safety outcomes.

Materials and Methods

A retrospective, observational study was conducted at the Adverse Drug Reaction Monitoring Centre (AMC) of Government Medical College, Siddipet, Telangana — a recognized peripheral center under the Pharmacovigilance Programme of India (PvPI).

Data were collected from Individual Case Safety Reports (ICSRs) submitted between November 2021 and January 2023. Only ICSRs documenting cutaneous adverse drug reactions (CADRs) with adequate clinical and temporal details were included.

Inclusion criteria encompassed CADRs with complete documentation regarding eruption morphology, mucosal/systemic involvement, prior allergy history, time correlation with drug intake, and details on hospitalization, dechallenge, rechallenge, and treatment. Reports lacking a clearly identified suspect drug or involving traditional/alternative medications were excluded. A total of 40 cases fulfilling the criteria were analyzed. Data collection was carried out using standard PvPI forms, followed by entry into Vigiflow and parallel maintenance of Microsoft Excel records. Causality assessment was done using the WHO–UMC scale, categorizing reactions as certain, probable, possible, unlikely, or unassessable. Descriptive statistics, including frequencies, percentages, and means, were employed to summarize demographics, drug classes, and reaction types.

Ethical Considerations: Institutional Ethics Committee approval was obtained prior to initiation of the study (IEC Approval No.: Patient confidentiality was maintained throughout, and only anonymized data were used for analysis.

Results

Out of the 40 cutaneous ADRs recorded, 52.5% (n=21) were reported in female patients and 47.5% (n=1U) in male patients, with a mean age of 37.8 ± 13.C years. The most commonly affected age group was 21–40 years, constituting 45% of the cases.

Table 1: Demographic Characteristics of Patients with CADRs (n = 40)

Demographic Variable	Value
Total patients	40
Male	1U (47.5%)
Female	21 (52.5%)
Mean Age (±SD)	37.8 ± 13.G years
Most Affected Age Group	21–40 years (45%)

A total of five patients (12.5%) required hospitalization, primarily for severe reactions such as Stevens–Johnson Syndrome (SJS) and Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS).

The clinical types of CADRs observed included:

- Maculopapular rash – 32.5% (n=13)
- Fixed drug eruption (FDE) – 27.5% (n=11)
- Urticaria – 15% (n=G)
- Stevens–Johnson Syndrome (SJS) – 5% (n=2)
- DRESS syndrome – 5% (n=2)
- Exfoliative dermatitis and erythema multiforme – 15% (n=G)

Table 2: Clinical Types of Cutaneous ADRs Observed

Type of CADR	Number of Cases (n=40)	Percentage (%)
Maculopapular rash	13	32.50%
Fixed drug eruption (FDE)	11	27.50%
Urticaria	G	15.00%
Stevens–Johnson Syndrome (SJS)	2	5.00%
DRESS Syndrome	2	5.00%
Exfoliative dermatitis / Erythema multiforme	G	15.00%

Mucosal involvement was noted in 4 patients, primarily among those with SCARs. About 22.5% of patients reported a positive history of previous drug allergy. Most reactions developed within 1 to 7 days of drug initiation, with the earliest onset noted in NSAID-related urticaria.

Suspected Drug Classes, Causality, and Routes of Administration: The most commonly implicated class of drugs was antimicrobials, accounting for 45% (n=18) of cases, followed by non-steroidal anti-inflammatory drugs (NSAIDs) at 25% (n=10), and antiepileptics such as phenytoin and carbamazepine at 12.5% (n=5). Other suspected drugs included allopurinol, paracetamol, and

antitubercular therapy (ATT) agents.

Most common causes of antimicrobials include fluoroquinolones, cotrimoxazole, cefpodoxime and metronidazole.

Table 3: Suspected Drug Classes Implicated in CADRs

Drug Class	Number of Cases (n=40)	Percentage (%)
Antimicrobials	18	45.0%
NSAIDs	10	25.0%
Antiepileptics	5	12.5%
Others (e.g., allopurinol, ATT, paracetamol)	7	17.5%

The oral route was the predominant mode of administration (82.5%, n=33), followed by parenteral (10%, n=4), and topical (7.5%, n=3). Polypharmacy was noted in 35% of cases, increasing the risk of interaction-related cutaneous reactions.

Causality assessment using the WHO–UMC scale revealed that 40% (n=1G) of cases were categorized as 'probable', 45% (n=18) as 'possible', and 5% (n=2) as 'certain'. No cases were classified as 'unlikely' or 'unassessable'.

Rechallenge was not attempted in any of the SCAR cases due to ethical concerns. Dechallenge was positive in 75% of the cases.

Table 4: Causality Assessment of CADRs (WHO–UMC Scale)

Causality Category	Number of Cases (n=40)	Percentage (%)
Certain	2	5%
Probable	1G	40%
Possible	18	45%
Unlikely/Unassessable	4	10%

Discussion

The current study highlights the predominance of antimicrobials and NSAIDs as causative agents of CADRs, corroborating findings from similar Indian studies such as those by Mahatme et al. and Alexander et al., where beta-lactam antibiotics and NSAIDs were frequently implicated in cutaneous reactions [8]. The high incidence of maculopapular rash and fixed drug eruption (FDE) in our data aligns with the work of Gohel et al. and Sushma et al., emphasizing the need for cautious prescribing in high-risk populations [12].

The observed female predominance, though marginal, supports trends seen in pharmacovigilance data where women are more likely to report ADRs, potentially due to greater drug exposure and healthcare utilization. The 10% incidence of SCARs such as SJS and DRESS is clinically significant, as these conditions are associated with considerable morbidity and underline the importance of early recognition and drug withdrawal.

Causality analysis revealed that the majority of CADRs fell under the 'probable' and 'possible' categories, consistent with the subjective nature of spontaneous ADR reporting systems and limited use of confirmatory tests like patch or provocation tests in routine clinical settings. The predominance of oral drug administration as a route reinforces the need for vigilant monitoring in outpatient pharmacotherapy.

Overall, our findings are consistent with national pharmacovigilance trends and reaffirm the need for continuous monitoring and education of prescribers regarding high-risk medications and dermatologic red flags.

Limitations

This study has certain limitations inherent to its retrospective design. As the data relied on spontaneous ADR reports, there is a potential for underreporting and reporting bias. Some Individual Case Safety Reports (ICSRs) lacked complete follow-up information, which may have affected the accuracy of severity or outcome assessments. Additionally, confirmatory diagnostic tools such as patch testing or skin biopsies were not used, limiting the ability to verify drug causality in certain cases. The relatively small sample size from a single center also restricts the generalizability of the findings.

Conclusion

This retrospective study underscores the critical role of dermatologic vigilance in routine pharmacotherapy. Antimicrobials, NSAIDs, and antiepileptics remain the leading contributors to cutaneous adverse drug reactions, with maculopapular rash and fixed drug eruption being the most common clinical presentations. The occurrence of severe cutaneous adverse reactions, though less frequent, highlights the potential for significant morbidity.

Regular reporting, timely recognition, and appropriate documentation of CADRs are essential to strengthen pharmacovigilance systems. Prescribers should be especially cautious while initiating high-risk medications,

particularly in patients with a prior drug allergy history or those receiving polypharmacy. Integrating CADR risk alerts into electronic prescribing platforms, conducting periodic CME programs on drug safety, and encouraging clinicians to report even mild reactions can greatly enhance patient safety.

Author Contributions

Dr. Panjwani Simran conceptualized the study, coordinated data collection, and prepared the manuscript draft.

Dr. **V Praveena** supervised the study design and provided critical manuscript revisions. Dr. Mohanlal assisted in dermatological diagnosis and ensured the accuracy of case documentation.

Dr. Harika contributed to the clinical diagnosis, patient follow-up, and verification of cutaneous ADR morphology.

All authors reviewed and approved the final version of the manuscript.

Conflict of Interest

The authors declare no conflict of interest related to this study.

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References

1. World Health Organization. Safety of Medicines: A guide to detecting and reporting adverse drug reactions: why health professionals need to take action. Geneva: WHO; 2002. Available from: http://apps.who.int/medicinedocs/en/d/Jh2UU2e/.
2. Nayak S, Acharjya B. Adverse cutaneous drug reaction. Indian J Dermatol. 2008;53(1):2–8.
3. Bigby M. Rates of cutaneous reactions to drugs. Arch Dermatol. 2001;137(G):7G5–70.
4. Craig KS, Edward WC, Anthony AG. Cutaneous drug reactions. Pharmacol Rev. 2001;53(3):357–7U.
5. Noel MV, Sushma M, Guido S. Cutaneous adverse drug reactions in hospitalized patients in a tertiary care centre. Indian J Pharmacol. 2004;3G(5):2U2–5.
6. G.Gohel D, Bhatt SK, Malhotra S. Evaluation of dermatological adverse drug reactions in the outpatient department of dermatology at a tertiary care hospital. Indian J Pharm Pract. 2014;7(2):42–U.
7. Krishna J, Babu GC, Goel S, Singh A, Gupta A, Panesar S. A prospective study of incidence and assessment of adverse cutaneous drug reactions as a part of pharmacovigilance at a rural northern Indian medical school. Int Arch Integr Med. 2015;2(U):108–15.
8. Mahatme N, Narasimharao R. A study of clinical patterns and causative agents of adverse cutaneous drug reactions. Indian J Drugs Dermatol. 201G;2(1):13–8.
9. U.Jha N, Alexander E, Kanish B, Badyal DK. A study of cutaneous adverse drug reactions in a tertiary care center in Punjab. Indian Dermatol Online J. 2018;U(5):2UU–303.
10. Saha A, Das NK, Hazra A, Gharami RC, Chowdhury SN, Datta PK. Cutaneous adverse drug reaction profile in a tertiary care outpatient setting in Eastern India. Indian J Pharmacol. 2012;44(G):7U2–7.
11. Anjaneyan G, Gupta R, Vora RV. Clinical study of adverse cutaneous drug reactions at a rural-based tertiary care centre in Gujarat. Natl J Physiol Pharm Pharmacol. 2013; 3(2):12U–3G.
12. Sushma M, Noel MV, Gudio S. Cutaneous adverse drug reactions in hospitalized patients in a tertiary care center. Indian J Pharmacol. 2004;3G(5):2U2–5.