Section: Miscellaneous

Original Research Article

CLINICAL SPECTRUM OF CUTANEOUS ADVERSE DRUG REACTIONS IN A TERTIARY CARE HOSPITAL – A CROSS-SECTIONAL STUDY

M. Vairaprabha Devi[1], M. Gowri Sankar[2], R.Nalini[3]

[1]Associate Professor, Department of DVL, Government Medical college, Tiruppur.
[2]Associate Professor, Department of General Medicine, Government Medical College, Tiruppur.
[3]Associate Professor, Department of Pharmacology, Government Medical college, Tiruppur.

Received : 11/03/2026
Received in revised form : 03/05/2026
Accepted : 19/05/2026

Keywords:
CADRs, cutaneous adverse drug reactions, pharmacovigilance, causality, severity, preventability.

Corresponding Author:
Dr. M. Vairaprabha Devi,
Email: drncm@yahoo.com

DOI: 10.47009/jamp.2026.8.3.114

Source of Support: Nil,
Conflict of Interest: None declared

Int J Acad Med Pharm
2026; 8 (3); 624-628

ABSTRACT

Background: Cutaneous adverse drug reactions are among the most common type of drug hypersensitivity reactions. This study concentrated on observing and documenting the clinical presentation of cutaneous adverse drug reactions encountered in patients. The purpose of this study is to evaluate causality, severity and preventability of Dermatological ADRs using different scales. The objective is to determine the morphological patterns of ADRs in patients related to causative drugs (self medication or prescribed). To determine the ADRs causality by using WHO-UMC assessment scale, severity by using Hartwig's Severity Assessment scale and preventability by using the Schumock and Thornton scale. **Materials and Methods:** This study was conducted at a tertiary care hospital in south India by the Institutional ADR monitoring centre. 90 ADRs filled between July 2024 and September 2025 were analyzed retrospectively and 50 new patient forms were assessed prospectively. Individual causality assessment was undertaken using WHO-UMC causality assessment scale. Severity of the reaction was assessed using Modified Hartwig and Siegel Assessment Scale and Preventability was assessed using Schumock and Thornton scale. **Result:** A total of 140 patients were analyzed in this study. Majority of the reporting ( ) patients were aged between 40 to 49 and 21 to 39. There was a female preponderance (1.1 : 1.5) in reporting CADRs. Antibiotics (50%) were the commonest medications implicated followed by NSAIDS (28.57%). The commonest clinical spectrum of CADRs encountered was fixed drug eruption (FDE) (25%) followed by urticaria and angioedema (21.43%). Most of the CADRs manifested within 24 hours of drug consumption (70.71%). Majority of the associations were probable only (75.71%) as per the WHO-UMC scale. Modified Hartwig and Siegel scale for the assessment of severity of the CADRs concluded that most of the cases (65%) were mild. Schumock and Thornton scale found that majority of the CADRs were not preventable (68.57%). **Conclusion:** Proper Pharmacovigilance and education of patients regarding CADRs is the need of the hour.

INTRODUCTION

Cutaneous Adverse drug reactions (CADRs) are considered as one among the leading causes of morbidity and mortality and a major problem of drug therapy. According to World Health Organization, an adverse drug reaction is defined as 'a response to a drug that is noxious and unintended and occurs at a dose used in man for prophylaxis, diagnosis or therapy of a disease or for modification of physiological function'. ADRs may also lead to a diminished quality of life, increased health care costs, hospitalizations and may even cause death.

A wide range of cutaneous manifestations ranging from maculopapular rashes to Toxic epidermal necrolysis (TEN) can be caused by different classes of drugs. The mechanism is either immune or non-immune mediated cumulative toxicity, photosensitivity, drug interactions etc. TEN is the most serious form of adverse reaction with an acute onset involving > 30% of body surface area (BSA) and is differentiated from Steven Johnson Syndrome (SJS) in which only < 10% of BSA is involved. Most of the time, the diagnosis of ADR is difficult because of the similarity of signs and symptoms of different diseases. Therefore, Dermatologists and practising Physicians should be familiar with these

ISSN (O): 2687-5365; ISSN (P): 2753-6556

type of conditions to enable early diagnosis and prompt withdrawal of the causative agent to prevent morbidity and mortality.

The incidence of CADRs (Cutaneous ADRs) in developed countries is less (1 to 3%) than in the developing countries (2 to 5%). Most cases of cuatneous ADRs are mild or moderate and can be treated on an outpatient basis. However, severe and life threatening cases require prompt diagnosis and intensive treatment as in cases of SJS and TEN.

Globally CADRs affect millions worldwide, though exact numbers are difficult to ascertain due to under-reporting. Indian studies suggest 31.3% of CADRs are attributed to antibiotics, 24.2% to anti-tubercular drugs, 21.3% to anti-retroviral drugs, 10% to anti-epileptics and other miscellaneous drugs.

This study aims to investigate the clinical spectrum of CADRs in a tertiary care hospital, providing valuable insights to the treating Physicians. By characterizing CADRs, this study will inform clinicians about potential culprit drugs, common reaction patterns and effective management strategies ultimately enhancing patient care and safety. The findings of this study will contribute to the existing literature on CADRs, supporting evidence based practice and improve pharmaco-vigilance.

Objectives:

To determine the morphological patterns of CADRs in patients and the causative drugs (self medication or prescribed).

To determine the ADRs causality by using WHO-UMC assessment scale, severity by using Hartwig's Severity Assessment scale and preventability by using the Schumock and Thornton scale.

MATERIALS AND METHODS

This study was conducted at a tertiary care hospital in south India after obtaining approval of the Institutional Human Ethical Committee (IHEC) bearing Reg. No. : EC/NEW/INST/2022/3218. The ADR monitoring centre of the Institute i.e. Department of Pharmacology sensitized the treating Physicians for inquiry and recording of suspected ADRs before the commencement of the study. Informed consent will be obtained from all participants in vernacular language. Participant's privacy and confidentiality will be maintained throughout the study.

In this study, out of a total of 140 patients, 90 ADR forms filled between July 2024 and September 2025 were enrolled and 50 new patient forms from 3 months with CADRs were analyzed and assessed.

Individual causality assessment was undertaken using WHO-UMC causality assessment scale which classifies drug reactions into definite, probable, possible and unlikely. The severity of the reaction was assessed using ADR Severity Assessment Scale (Modified Hartwig and Siegel) which classifies ADR into mild, moderate and severe. Preventability was assessed using Schumock and Thornton scale.

Inclusion criteria:

Patients of all ages and genders presented with cutaneous manifestations associated with ADRs after taking any class of modern medicines.

Exclusion criteria:

1. Patients with generalized pruritus without skin lesions
2. Patients who developed skin reactions due to intake of native medications
3. Patients who could not recall the names of the medicines consumed
4. Patients having food allergy and viral exanthematous fever.

RESULTS

A total of 140 patients were enrolled in our study.

Table 1: Age distribution

Age in years	Number of patients
< 20	16
21 to 39	50
40 to 59	54
> 60	20

Age group between the years 21 to 59 was the commonest age group reporting CADRs [Table 1].

Table 2: Gender distribution

Gender	Number of patients
Adult male	55
Adult female	75
Male child <12 years	7
Female child <12 years	3

CADRs were most commonly reported by adult females followed by adult males [Table 2].

Table 3: Classification of medicines consumed:

Antibiotics	No. of patients
Quinolones	26
Cephalosporins	13
AntiTuberculous	9
Cotrimoxazole	8

ISSN (O): 2687-5365; ISSN (P): 2753-6556

Penicillin group	7
Metronidazole	5
Doxycycline	2
Total	70
NSAIDS	**No. of patients**
Aceclofenac	10
Aceclofenac + Paracetamol	6
Piroxicam	5
Ketorolac	5
Diclofenac	4
Diclofenac + Paracetamol	4
Nimesulide	2
Ibuprofen	2
Paracetamol	2
Total	40
Anticonvulsants	
Carbamazepine	12
Phenytoin	7
Total	19
Injections	
Doxorubicin	2
Iron sucrose	1
Ferric carboxymaltose	1
Ranitidine	1
Paracetamol	1
Vancomycin	1
Anti snake venom	2
Total	9
Miscellaneous	
Sulfasalazine	1
Tranexamic acid	1
Total	2

Antibiotics were the commonest medications causing CADRs followed by NSAIDS and Anticonvulsants [Table 3].

Table 4 Clinical spectrum of manifestations

Fixed drug eruption (FDE)	35
Urticaria + angioedema	30
Maculopapular rash	24
Bullous FDE	12
Exfoliative dermatitis	9
Steven Johnson Syndrome / Toxic Epidermal Necrolysis	6
Lichenoid dermatitis	5
Acute generalized exanthematous pustulosis (AGEP)	4
Erythema multiforme (EMF)	4
Symmetrical drug-related intertriginous & flexural exanthema (SDRIFE)	3
Drug induced bullous pemphigoid	3
Hand foot syndrome	2
Drug reaction with eosinophilia and systemic symptoms (DRESS)	2
Drug induced hypersensitivity syndrome (DIHS)	1

Fixed drug eruptions were the commonest clinical spectrum (25%) encountered followed by urticaria + angioedema and maculopapular rash [Table 4].

Table 5: Duration of CADR onset:

< 24 hours	99
1 to 7 days	16
8 to 28 days	12
> 4 weeks	13

Majority of the CADRs (70.71%) had their manifestation within 24 hours of drug consumption [Table 5].

Table 6: WHO-UMC Causality scale

Definite	8
Probable	106
Possible	22
Unlikely	4

In causality scale, probable association was the commonest and unlikely was the least common association [Table 6].

ISSN (O): 2687-5365; ISSN (P): 2753-6556

Table 7: Modified Hartwig and Siegel Severity scale

Mild (level 1 & 2)	91
Moderate (level 3 & 4)	31
Severe (level 5 to 7)	18

Most of the CADRs fell into the mild category only and severe forms were quite rare [Table 7].

Table 8: Schumock and Thornton scale

Not preventable	96
Probably preventable	37
Definitely preventable	7

Only 7 cases were found to be definitely preventable while most of the cases were not or probably preventable [Table 8].

DISCUSSION

CADRs manifest as various cutaneous signs and symptoms. Out of the 140 CADRs included in our study, majority of the reporting cases were between ages 40 to 49 and 21 to 39. This might be because of the independence and ease of access to healthcare by these age groups while the other two extremes of age depend on someone for healthcare access.

There was a female preponderance 1.1 : 1.5 which is in contrast to the study by Anand Vardhan et al.[1] This might be because of the increased reporting of symptom by the females due to the enhanced health and cosmetic awareness in them.

Among the drugs implicated in CADRs, antibiotics (50%) were the commonest medications followed by NSAIDS (28.57%). This is in accordance with the study done by Julia Chain Martins et al,[2] in Brazil who reported antibiotics as 36.5% . Quinolones were the commonest antibiotics causing CADRs followed by Cephalosporins and Anti-tuberculous agents. Surprisingly, the previously common agents like Cotrimoxazole caused only 8 cases probably because of reduced usage due to the advent of newer antimicrobials. The integration of National Pharmacovigilance program in Revised National TB Control Program (RNTCP) probably has caused increased reporting of CADRs due to ATT compared to the past.

Aceclofenac was the commonest NSAID causing CADRs. Interestingly 2 cases of CADRs were caused by Paracetamol and it is also seen in two formulations where Paracetamol was used in combination with other NSAIDs. Carbamazepine was the commonest anticonvulsant causing CADRs (8.57%). This might be because of the aromatic benzene ring in its structure.[2]

The commonest clinical spectrum of CADRs encountered was fixed drug eruption (FDE) (25%) followed by urticaria and angioedema (21.43%). This is in contrast to majority of other studies which reported maculopapular rash as the commonest.[2,3] In our study, maculopapular rash was seen in 24 cases (17.14%). This could be due to the fact that majority of the rash was mild in severity and self-limiting which could lead to under-reporting. On the other hand, FDE might have looked alarming to the patient to warrant immediate medical attention.

Severe forms of CADRs seen in our study were exfoliative dermatitis (6.43%), SJS / TEN (4.29%), lichenoid dermatitis (3.57%), AGEP and EMF 2.86% each, SDRIFE and drug induced bullous pemphigoid 2.14% each, Hand Foot syndrome and DRESS in 1.43% each and DIHS seen in 1 case. Interestingly, such a wide range of CADRs were not documented in other studies.[4,5] This might be because of the diverse population of cases received in our institute as it caters to a wide range of rural and urban population as well as referral cases.

Most of the CADRs manifested within 24 hours of drug consumption (70.71%). Others occurred more or less equally within a span of 1 week, 1 month and more than a month. This emphasizes the importance of close monitoring for CADRs within the first 24 hours of consumption of any drug.[5]

Another salient feature of our study was the use of WHO – UMC causality assessment scale to determine the temporal relationship and likelihood that a particular offending drug has caused a CADR. Majority of the associations were probable only (75.71%) which is accordance with the studies done by Subham Naik et al,[5] and SK Malhotra et al.[6] 22 cases had possible association (15.71%), 8 cases had definite association (5.71%) and 4 cases had unlikely association (2.86%).

On assessing the preventability of CADRs using the Schumock and Thornton scale which is one more unique feature of our study, we found that majority of the CADRs were not preventable (68.57%). This reflects the unpredictable nature of certain drug hypersensitivity reactions in spite of correct drug usage and application of standard therapeutic measures.[7]

37 cases were probably preventable which accounted for 26.43% and most of them were due to self-medication, improper drug selection, incorrect dosages and not eliciting proper history of prior drug allergy.[8] Only 7 cases (5%) were identified as definitely preventable where avoidable re-exposure and inappropriate prescribing practices were found to be the causative factors.[9,10]

Another notable feature of study is the use of Modified Hartwig and Siegel scale for the assessment of severity of the CADRs. Most of the cases (65%) were mild, 22.14% were moderate and 12.86% were severe. This corresponds to the results Aravind Bhaskar Murthy et al and Niharika Jha et al.[11,12]

All these findings reiterate the importance of Pharmacovigilance and rational medication prescription in minimizing the burden of CADRs.

ISSN (O): 2687-5365; ISSN (P): 2753-6556

CONCLUSION

This study was conducted to assess the occurrence of cutaneous adverse drug reactions and further analyzing the various drugs causing it, clinical spectrum of manifestation, time of onset, severity, causality and preventability. We found that antibiotics were the commonest implicated drugs, fixed drug eruptions were the commonest clinical manifestation and most reactions occurred within 24 hours of consumption of drug. Probable association was the commonest, most reactions were mild and majority of them were not preventable. Hence proper Pharmacovigilance and education of patients regarding CADRs is the need of the hour.

REFERENCES

1. Anand Vardhan, Dinesh M Naidu. Cutaneous manifestations of the adverse drug reactions reported by adverse drug monitoring centre of ANIIMS, Port Blair. Med. Res. Chron., 2017, 4 (1), 135-141.
2. Júlia Chain Martins, Camila Arai Seque, Adriana Maria Porro. Clinical aspects and therapeutic approach of drug-induced adverse skin reactions in a quaternary hospital: a retrospective study with 219 cases. Anais Brasileiros de Dermatologia 2022;97(3):284-290.
3. Natalia Machon, Julia Lewandowska, Natalia Zdanowska, Waldemar Placek and Agnieszka Owczarczyk-Saczonek. Cutaneous Adverse Drug Reactions (CADRs) - Statistical analysis of the Causal Relationship between the Drug, comorbidities, Cofactors, and the Cutaneous Reaction - A Single-Centered Study. Int. J. Environ. Res. Public Health 2022, 19, 798.
4. Al Mulla, F., B. Sridhar, S., Abu Al Hassan, G. and Sharif, A. 2019. Prospective monitoring of cutaneous adverse drug reactions in a secondary care hospital, UAE. International Journal of Research in Dermatology. 5, 2 (Apr. 2019), 231–238.
5. Shubham Naik, Ian A. Pereira, Ravina Naik, Jano Zore. Clinico-epidemiological study of cutaneous adverse drug reactions among the in-patients of dermatology department, Goa Medical College, Goa. Int J Res Dermatol. 2023 Jan;9(1):17-22.
6. SK Malhotra, Baljit Kaur, Inderpal Kaur. A prospective study of clinical spectrum of cutaneous adverse drug reactions and their incidence in Indian population. Indian Journal of Clinical and Experimental Dermatology 2021;7(2):143–147.
7. Lakshmi Rajendran, Anoop Thyvalappil, Rajiv Sridharan, S Ajayakumar, Sparshadeep E.M1, Binoo Divakaran. A Study of Cutaneous Adverse Drug Reactions in a Tertiary Care Center in South India. Clinical Dermatology Review. 5(2):131-138, Jul-Dec 2021.
8. Karma Tenzing Bhutia, Chandrakala Sharma, Rukma Lal Sharma. Profile of cutaneous adverse drug reactions in patients attending the dermatology outpatient department of a tertiary care hospital, Gangtok. Asian J Pharm Clin Res, Vol 16, Issue 11, 2023, 168-171.
9. Lubna Khondker, Md Abdul Wahab, Md shirajul Islam Khan. Adverse drug reaction: A common dermatological emergency. Bangladesh J Medicine 2010; 21 : 90-95.
10. Gurpoonam Jatana, MD, Sunil Kumar Gupta, MD, Sandeep Kaushal, MD, Shobhna Kajal, MD, Sandeep Kaur, MD. Cutaneous adverse drug reactions: A one year prospective study. Iran J Dermatol 2017; 20: 103-112.
11. Aravind Baskar Murthy, Amuthavalli K, Nirmaladevi P, Meenakshi B. Analysis of cutaneous adverse drug reactions in a tertiary care hospital in South Tamil Nadu. Int J Basic Clin Pharmacol. 2022 Mar;11(2):97-107.
12. Niharika Jha, Emy Alexander, Bimal Kanish, Dinesh K. Badyal. A Study of Cutaneous Adverse Drug Reactions in a Tertiary Care Center in Punjab. Indian Dermatology Online Journal: Volume 9 Issue 5. Sep – Oct 2018.

ISSN (O): 2687-5365; ISSN (P): 2753-6556