Original Article

A Clinico-Epidemiological Study of Cutaneous Adverse Drug Reactions in a Tertiary Care Centre

Vivek A B[1], Floyd Vernon Dsouza[2], Ajitha Sharma[3], Anjali P V[4]

[1]Assistant Professor, Department of Pharmacology, Srinivas Institute of Medical Sciences & Research Centre, Mukka, Mangalore, Karnataka, India.
[2]Associate Professor, Department of Pharmacology, Srinivas Institute of Medical Sciences & Research Centre, Mukka, Mangalore, Karnataka, India.
[3]Associate Professor, Department of Pharmacology, Srinivas Institute of Medical Sciences & Research Centre, Mukka, Mangalore, Karnataka, India.
[4]Assistant Professor, Department of Pathology, Srinivas Institute of Medical Sciences & Research Centre, Mukka, Mangalore, Karnataka, India.

Abstract

Background: Adverse drug reactions (ADRs) are leading cause of morbidity and mortality among hospitalized patients. The symptoms of cutaneous adverse drug reactions can range widely, from a minor rash to potentially fatal disorders like toxic epidermal necrolysis and Stevens-Johnson syndrome. The objective is to characterize the clinical spectrum of CADRs and to determine the drugs causing CADRs in a tertiary care centre. **Material and Methods:** This was a prospective, observational study conducted on 120 patients with CADRs attending Dermatology OPD or admitted to K R Hospital from January 2019 to June 2020.Data were collected using a structured questionnaire and were analyzed descriptively. **Results:** Patients with CADRs were most commonly between the ages of 21 and 30, with a mean age of 31.7 years. The male to female ratio was 1.03:1. Fixed drug eruption (24.17%), maculopapular rash (23.34%), and urticaria (11.67%) were the most common presentations. Antimicrobials (50%), NSAIDs (21.09%), and antiepileptics (19.53%) were the most common causative drug groups. Most reactions (46.67%) occurred within the first week of drug exposure. **Conclusion:** The most frequent cutaneous adverse drug reactions were urticaria, maculopapular rash, and fixed drug eruptions. Antimicrobials, NSAIDs/analgesics, and antiepileptics were the most frequently implicated medications. Early recognition of CADRs is essential for preventing severe outcomes.

Keywords: Cutaneous adverse drug reactions, Antimicrobials, Fixed drug eruption.

Received: 23 February 2026 **Revised: 12 March 2026** **Accepted: 30 March 2026** **Published: 07 April 2026**

Introduction

Adverse drug reactions (ADR) have been estimated to be the fourth to sixth leading cause of death among hospitalized patients.[1] It is considered as one among the leading causes of morbidity and mortality. The epidemiological importance of ADR is justified by its high prevalence rate. Skin is one of the major target organs for ADRs. Cutaneous ADRs (CADR) is any undesirable change in the structure or function of the skin, its appendages or mucous membrane and encompasses all adverse events related to drug eruption, regardless of the etiology. There is a wide spectrum of CADR ranging from a transient maculopapular rash to fatal toxic epidermal necrolysis (TEN).[2-7]

The wide range of pharmacology group of drugs can cause CADRs and its patterns could change due to different prescribing patterns, use of newer drugs, self-medications, and referral bias.[8] Commonly used drugs implicated in CADRs are Penicillin's, Sulfonamides, Anticonvulsants, Nonsteroidal anti-inflammatory drugs (NSAIDs), etc.[2]

Effective monitoring of CADRs, both hospital-based and population-based, forms an integral part of ADR monitoring programmes as well as part of Pharmacovigilance, not only to generate valid data but also to identify and assess predisposing/underlying risk factors and to evaluate treatment outcome. Hence, the present study is designed to obtain information about drug induced CADRs in our setup.

Objectives

1. To characterize the clinical spectrum of cutaneous ADRs
2. To determine the incriminating drugs causing cutaneous ADRs.

Materials and Methods

Source of Data: A prospective, observational, questionnaire-based study on patients with drug induced Cutaneous Adverse Drug Reactions attending Dermatology OPD and/or admitted to ward, K.R. Hospital which comes under Mysore Medical College and Research Institute, Mysore from January 2019 to June 2020, was conducted after receiving approval from the Institutional Ethics Committee and documented informed consent from the patients. The personal, past and family history of the patients are recorded. Clinical details of cutaneous adverse drug reactions are recorded in ADR form of Central Drugs Standard Control Organization (CDSCO).

Address for correspondence: Dr. Anjali P V,
Assistant Professor, Department of Pathology, Srinivas Institute of Medical Sciences & Research Centre, Mukka, Mangalore, Karnataka, India.
E-mail: puthanveetilanjali@gmail.com

DOI:
10.21276/amit.2026.v13.i1.572

How to cite this article: Vivek AB, Dsouza FV, Sharma A, Anjali P V. A Clinico-Epidemiological Study of Cutaneous Adverse Drug Reactions in a Tertiary Care Centre. Acta Med Int. 2026;13(1):930-934.

Study design: Observational study

A. Study period: 18 months (January 2019 – June 2020)
B. Sample design: Purposive sampling
C. Sample size: Sample size (s) is calculated to be 120 using estimation technique with α error of 5% and prevalence (p) of 5% in drug induced adverse cutaneous reaction in India.

$s = Z^2pq/d^2(z = 2.51)$
p = prevalence (5%)
q = (100-p) = (100-5) = 95
s = 2.51 x 2.51 x.05 x.95/.05 x.05 = 119.3 = approximately 120

Inclusion Criteria

Patients following below mentioned criteria will be included in the study

1. Those in which the diagnosis of the cutaneous adverse reaction was in accordance with the definition of ADRs which was provided by the WHO.
2. Cutaneous drug reactions from any drug/drug group in any age and gender.
3. Those in which there was a plausible time relationship between the introduction of the drug and the onset of a reaction.

Exclusion Criteria

Patients following below mentioned criteria will be excluded in the study

1. Subjects who complained of only symptoms (e.g., itching) without visible skin lesions.
2. Those who could not recall the name of the suspect medicines consumed, and those whose lesions turned out to be disease related (e.g., viral exanthems, rash of rickettsial infections, and collagen vascular disease) on closer examination.
3. Subjects who reported to have consumed indigenous (ayurvedic and homeopathic) medicines were also excluded as the herbal ingredients could not be identified in their case.

Results

In this study, 120 participants had their clinical pattern and range of CADRs, underlying risk factors, predisposing variables, and causative medications evaluated. The majority of patients with CADRs were between the ages of 21 and 30; the youngest patient was 3 years old, and the oldest was 78. Age extremes revealed the fewest patients, with 11 in the 0–10 age group and 6 and 2 in the 61–70 and >71 age categories, respectively. Mean age of study population was 31.74 years. Gender distribution was almost equal with male to female ratio of 1.03:1 with 61 males and 59 females.

Table 1: Presenting history

Sl.no.	Presenting history	No. of cases	Percentage
1	Edema	3	1.32%
2	Erythema	9	3.95%
3	Skin discoloration	5	2.19%
4	Pain	21	9.21%
5	Pruritus	14	6.14%
6	Pustules	26	11.40%
7	Skin rash/eruption	64	28.07%
8	Vesicle/bulla	22	9.65%
9	Papule	35	15.35%
10	Macule	29	12.72%

The commonest presenting history was skin rash/eruption (28.07%) followed by papules (15.35%). The presenting complaints had a lot of overlap. Least common presenting complaints were edema in 3 cases and skin discoloration in 5 cases. Other clinical features were erythema, pain, pruritus, pustules, vesicle/bulla and macules. [Table 1]

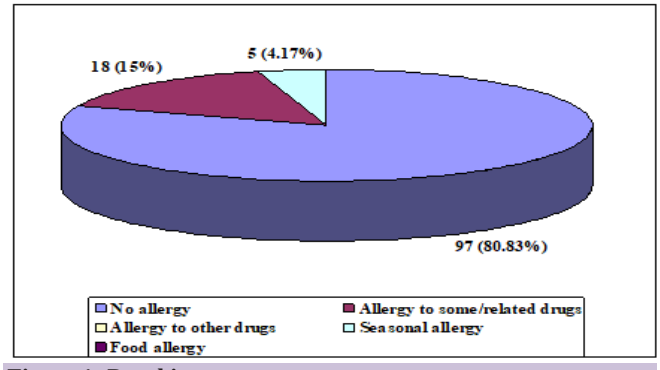

Figure 1: Past history

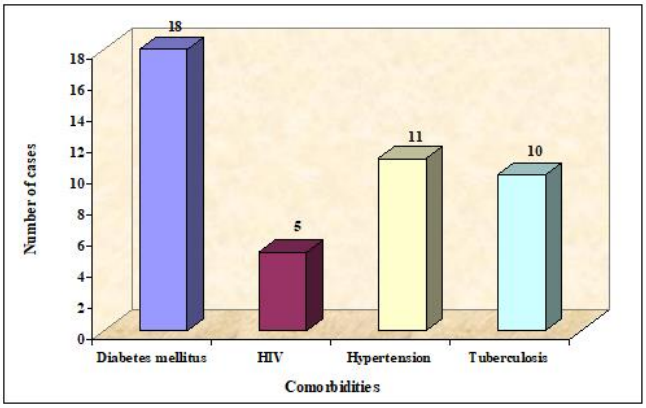

Figure 2: Comorbidities

A history of allergic disorders and previous reactions was documented, including seasonal allergies in 4.17% (5 cases) and allergies to causative medicines and related pharmaceuticals of the same class in 15% (18 instances). None of the patients had history of allergy to unrelated

drugs and food allergy [Figure 1]. Out of 120 cases, 7 cases (5.83%) had family history of allergy.

Thirty-nine instances (32.5%) of the research population were treated with appropriate treatment procedures for a variety of comorbid illnesses, including diabetes mellitus, HIV, hypertension, and tuberculosis. It was unable to completely rule out the chance that the concurrent medications would interact with the causal medications. [Figure 2].

Table 2: Clinical types of cutaneous adverse drug reactions

Sl.no.	Cutaneous reactions	No. of cases	Percentage
1	Acneiform drug eruption	6	5%
2	Angioedema	3	2.50%
3	Drug hypersensitivity syndrome	8	6.67%
4	Eczema	1	0.85%
5	Erythema multiforme	5	4.13%
6	Fixed Drug Eruption	29	24.17%
7	Hyperpigmentation	2	1.67%
8	Maculopapular rash	28	23.34%
9	Photosensitivity	3	2.50%
10	Steven Johnson Syndrome	12	10%
11	Toxic Epidermal Necrolysis	9	7.50%
12	Urticaria	14	11.67%
	Total	120	100%

The commonest clinical types of cutaneous ADRs were Fixed Drug eruption in 29 cases followed by maculopapular rash in 28 cases. Least common types were eczema, photosensitivity and angioedema. [Table 2]

The pattern of cutaneous reaction was localized in 41 cases (34.17%) including angioedema, acneiform eruption, eczema, fixed drug eruption and hyperpigmentation. Generalized cutaneous reaction was present in 76 cases (63.33%) comprising of Drug Hypersensitivity Syndrome, erythema multiforme, maculopapular rash, Steven-Johnson Syndrome, Toxic Epidermal Necrolysis and urticaria. 3 cases (2.50%) of photosensitivity showed photo distributed cutaneous reaction. [Table 2]

Table 3: Drug exposure and time taken for onset of reaction

Sl. No.	Clinical types	Reaction time			
		<24 hours	Upto 1 week	1 week- 4 week	>1 month
1	Acneform drug eruption			3	3
2	Angioedema	3			
3	Drug hypersensitivity syndrome			8	
4	Eczema				1
5	Erythema multiforme		5		
6	Fixed Drug Eruptions		25	2	2
7	Hyperpigmentation			1	1
8	Maculopapular rash	7	14	7	
9	Photosensitivity		2	1	
10	Steven Johnsons Syndrome		3	9	
11	Toxic Epidermal Necrolysis		3	6	
12	Urticaria	8	4	2	
Total		18 (15%)	56 (46.67%)	39 (32.5%)	7 (5.83%)

Majority of the cutaneous ADRs were reported within 1 week of starting drug treatment. This comprised of 56 cases (46.67%). This was followed by 39 cases (32.5%) reported within time interval of 1 to 4 weeks. Least number of cases were reported in > 1-month time interval comprising of 3 cases of acneform drug eruption, 1 case of eczema, 2 cases of fixed drug eruption and 1 case of hyper-pigmentation. Eighteen cases (15%) were reported in time interval of <24 hours which included 3 cases of angioedema, 8 cases of urticaria and 7 occurrences of maculopapular rash. [Table 3]

A total of 128 drugs comprising of 112 single drugs and 8 drug combinations were implicated in causing the 120 cutaneous adverse drug reactions. The more common drugs among them were Cotrimoxazole in 14 cases (10.94%) and Phenytoin in 15 cases (11.73%). This was followed by Ciprofloxacin in 12 cases (9.38%).

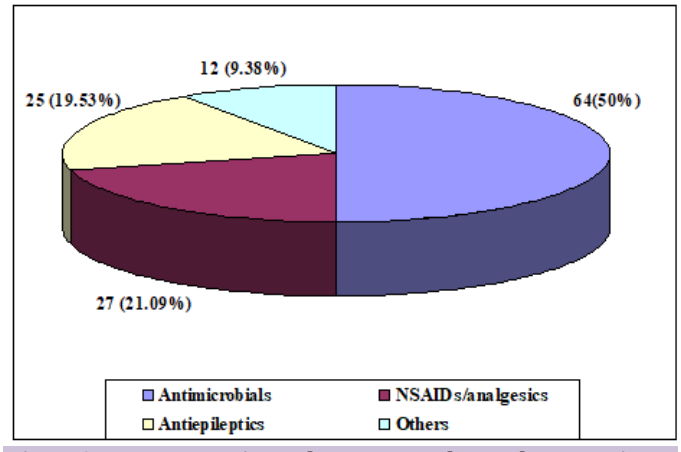

Figure 3: Drug categories and cutaneous adverse drug reactions.

Antimicrobials, NSAIDs/analgesics, antiepileptics, and other medications were widely classified as the causal medicines. Others included antihypertensives, antipsychotics and corticosteroids which were involved in 12 cases (9.38%). The commonest causative drug category was antimicrobials (50%) followed by NSAIDs/analgesics (21.09%) and antiepileptics (19.53%). [Figure 3]

The majority of the medications (92.18%) were administered orally, whereas only 3.13% were administered intravenously, 3.91% were administered intravenously, and 0.78% were administered nasally. Since the oral route is the most often used method of administering drugs, there were undoubtedly more reactions with this route of administration.

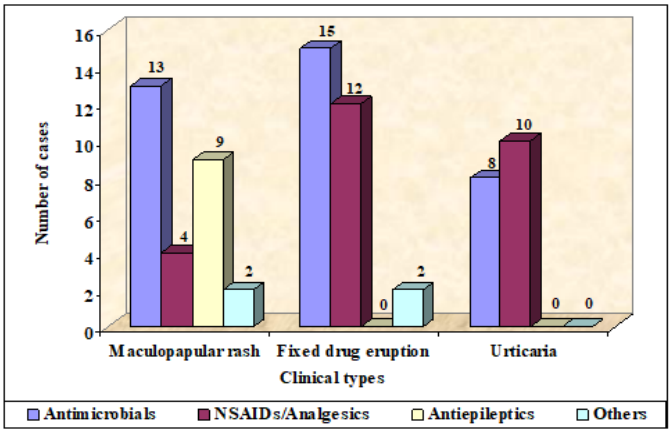

Figure 4: Drugs causing Maculopapular rash, Fixed drug eruption and Urticaria

In this study, there were 28 cases of maculopapular rashes. Antimicrobials accounted for 46.43% of the leading causal medicines, with antiepileptics coming in second (32.15%). A total of 4 cases were caused by NSAIDs/analgesics and 2 cases by other drug categories.

This investigation has identified 29 instances of Fixed Drug Eruptions. 51.72% (15 cases) of these eruptions were caused by antimicrobials followed by 41.38% (12 cases) caused by NSAIDs/analgesics. 2 cases were caused by other drugs.

Among total cases of urticaria, 55.56% were caused by NSAIDs/analgesics and 44.44% by antimicrobials. [Figure 4]

Discussion

Cutaneous adverse drug reactions form an important and common problem in both inpatient and outpatient setting. CADRs are distressing to both the patients and physicians. In our study, the mean age of patient was 32.74 years, which is similar to studies done by Agrawal et al,[3] Sharma et al,[4] and Saha et al,[5] who reported mean age of 30.26 years, 33.26 years and 33.8 years respectively.

Fixed drug eruption was the most common morphology followed by maculopapular rash and urticaria in the present study. This was similar to the study done by Agrawal et al.[3] In contrast to this, maculopapular rash was the most common morphology in the study done by Thakkar et al,[6] and Modi et al.[7] This could be because the majority of the medications the patient in our study used were analgesics and antibiotics, which are known to produce maculopapular eruptions and Fixed Drug Eruptions. The difference in incidence of morphology of rash among different study populations could be due to variation in the local trends of drug usage and ethnic characteristics.

In the present study, the most common drug category causing cutaneous adverse drug reactions were found to be antimicrobials (50%) followed by NSAIDs/ analgesics (21.09%). This was similar to the study done by Agrawal et al,[3] Sharma et al,[4] and Malhotra et al.[7] This could be due to widespread use of Antimicrobials and NSAIDs in our setup.

In our study, antimicrobials were the most common drugs causing maculopapular rash. Studies done by Thakkar et al[6] and Agrawal et al,[3] also showed the same trend.

Antimicrobials constituted the major causative drugs for fixed drug eruptions in our study. Study done by Agrawal et al,[3] also showed similar findings.

In the present study, urticaria was most commonly caused by NSAIDs/ analgesics in contrast to S. Malhotra et al,[6] and Agrawal et al.[3]

This information suggests that NSAIDs, fixed-dose combinations, and antibiotics may be used as self-medication. Patients must be made aware of the potential risks associated with self-medication by the regulating body. It should monitor and limit community pharmacists' ability to dispense over-the-counter medications.

The present study showed that 32.5% of the patients with CADR had underlying comorbid diseases whereas Khoo et al[8] showed a proportion of 45%. This may be due to the fact that patients with comorbid diseases are usually put on multiple drugs and hence there is more chance and risk of drug eruptions.

This study also frequently found underlying conditions that have been identified in numerous investigations as risk factors for CADRs, namely diabetes mellitus, hypertension, tuberculosis, and human immunodeficiency virus infection.

In the present study, Oral medication administration was shown to be the most popular method. Similar findings were observed by studies done by Thakkar et al,[6] and Modi et al.[7] Oral route being the most commonly employed route for drug administration, the reactions were obviously more with this route in all the studies. Because of its many benefits, the oral route of drug delivery is chosen above the other administration routes. These benefits include safety, good patient compliance, convenience of consumption, pain avoidance, and versatility to accommodate different types of medications.

Conclusion

With increase in number of drugs, adverse drug reactions have become very common in recent times. Among them cutaneous reactions play a major role and have attracted importance.

The most frequent cutaneous adverse medication reactions in our study were urticaria, maculopapular lesions, and fixed

drug eruptions. Antimicrobials, NSAIDs/analgesics, and antiepileptics were the most frequently implicated medications. These clinical manifestations and implicated drugs can serve as useful clues for physicians in timely detection. Early detection of CADRs can help in preventing severe manifestations and can reduce morbidity and mortality. Important risk factors including polypharmacy and allergies can be avoided by taking a thorough medical history, recommending substitute medications, and informing patients about the dangers of self-medication. Self medication can lead to dangerous or serious situation, hence awareness must be brought among people, so that, the mortality and morbidity related to drug use is reduced.

Advantages of this study

This study has acquired accurate prospective data on the incidence and symptoms of cutaneous adverse medication reactions in a wide population base that includes both inpatients and outpatients.

In contrast to the majority of research, which relied on retrospective analysis for case verification, our study examined each case prospectively with the assistance of a dermatology consultant.

The database is a prospective source of information on medication and host-related risk factors for cutaneous adverse drug responses and offers more recent trends in these reactions.

Limitations of this study: Because the hospital largely serves a lower socioeconomic class, our research population's exposure to the majority of newer drugs was limited, and as a result, their drug use patterns were mostly limited to the medications provided by the hospital pharmacy. As a result, the medication data produced by this trial could not be generalized. Patients did not show up after they were treated, making long-term monitoring and follow-up impossible.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

References

1. Devi P, Kamath DY, Anthony N, Santosh S, Dias B. Patterns, predictors and preventability of adverse drug reactions in the coronary care unit of a tertiary care hospital. Eur J Clin Pharmacol. 2012;68(4):427-33.
2. Jayanthi CR, Ankita B, Kavitha R. Cutaneous adverse drug reactions from a teaching hospital in Bengaluru: An observational study to determine the spectrum and outcome. National Journal of Physiology, Pharmacy and Pharmacology Online. 2017;7(5):476-81.
3. Agrawal A, Ghate S, Gupta AK, Dhurat R. Clinical spectrum of cutaneous adverse drug reactions. Indian Journal of Drugs in Dermatology. 2018;4(2):61-6.
4. Sharma R, Dogra D, Dogra N. A study of cutaneous adverse drug reactions at a tertiary center in Jammu, India. Indian Dermatology Online Journal. 2015;6(3):168-71.
5. 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 Journal of Pharmacology. 2012;44(6):792-7.
6. Thakkar S, Patel TK, Vahora R, Bhabhor P, Patel R. Cutaneous adverse drug reactions in a tertiary care teaching hospital in India: An intensive monitoring study. Indian J Dermatol. 2017;62(6):618-25.
7. Modi A, Desai M, Shah S, Shah B. Analysis of cutaneous adverse drug reactions reported at the regional ADR monitoring center. Indian J Dermatol. 2019;64(3):250-2.
8. Khoo BP,Giam YC. Drug eruptions in children: a review of 111 cases seen in a tertiary skin referral centre.Singapore Med J.2000 Nov; 41(11):525-9.
9. ImpicciatoreP,Choonara I, Clarkson A, Provasi D,PandolfiniC,BonatiM.Incidence of adverse drug reactions in paediatric in/out patients: a systematic review and meta-analysis of prospective studies.Br J Clin Pharmacol.2001;52(1):77-83.
10. Romagosa R, Kapoor S, Sanders J, Berman B. Inpatient adverse cutaneous drug eruptions and eosinophilia. Arch Dermatol. 2001;137:511-2.
11. Demoly P, Adkinson NF, Brockow K, Castells M, Chiriac AM, Greenberger PA et al. International consensus on drug allergy. Allergy. 2014;69(4):420-37.
12. Dilek N, Ozkol HU, Akbas A, Dilek AR, Saral Y, Metin A. Cutaneous adverse drug reactions in children. Postepy Dermatol Alergol. 2014;31(6):368-71.