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PATTERN AND OUTCOMES OF SPONTANEOUSLY REPORTED CUTANEOUS ADVERSE DRUG REACTIONS AT A TERTIARY CARE TEACHING HOSPITAL IN NORTHEAST INDIA: A RETROSPECTIVE PHARMACOVIGILANCE STUDY

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ABSTRACT:
Background: Cutaneous adverse drug reactions (CADRs) are an important component of medicine safety, and spontaneous reporting provides useful information on the patterns encountered in routine clinical practice.
Objective: To describe the demographic profile, reaction morphology, suspected medications, seriousness, outcomes and reporting departments of spontaneously reported CADRs at a tertiary care teaching hospital in Northeast India.
Methods: A retrospective descriptive analysis was conducted on 104 CADR reports recorded from August 2021 to November 2024. Demographic and report characteristics were summarised using frequencies, percentages and standard descriptive statistics.
Results: The mean age was 37.16 ± 13.35 years; 54 (51.92%) reports involved males and 93 (89.42%) involved adults aged 19–60 years. Maculopapular rash accounted for 63 (60.58%) reports and fixed drug eruption for 41 (39.42%). Suspected medications were grouped as non-antiretroviral antimicrobials in 81 (77.88%) reports, paracetamol in 14 (13.46%) and antiretrovirals in 9 (8.65%). The most frequently recorded individual medications were the ofloxacin–ornidazole fixed-dose combination (35; 33.65%) and co-trimoxazole (24; 23.08%). Most reports originated from Dermatology (73; 70.19%), followed by the ART Centre (28; 26.92%). Sixty-nine (66.35%) reports were non-serious. Outcomes were recovered in 73 (70.19%), recovering in 8 (7.69%), not recovered in 19 (18.27%) and unknown in 4 (3.85%).
Conclusion: Maculopapular rash was the predominant reported CADR, and non-antiretroviral antimicrobials constituted the largest suspected medication category. The findings support continued pharmacovigilance and systematic follow-up of cutaneous drug reactions in routine care.

KEYWORDS: cutaneous adverse drug reactions; pharmacovigilance; spontaneous reporting; maculopapular rash; fixed drug eruption; antimicrobials

INTRODUCTION

Adverse drug reactions (ADRs) are harmful or unpleasant responses related to the use of medicinal products and may require treatment, dose modification or withdrawal of the suspected medicine.1 Cutaneous adverse drug reactions (CADRs) form a clinically important subset of ADRs, ranging from limited eruptions to severe reactions involving the skin and mucous membranes. Spontaneous-reporting systems provide real-world information on the patterns of suspected reactions encountered in routine clinical practice.2 ADRs can also increase the burden of care through longer hospital stays and higher treatment costs.3

Indian studies have shown considerable variation in the morphology of CADRs and in the medicines implicated. Antimicrobials are frequently represented among suspected drug groups, while maculopapular or exanthematous eruptions are common clinical patterns.4–9

Because prescribing practices and reporting pathways differ between institutions, centre-specific pharmacovigilance data can provide useful information for local clinical practice. The present study aimed to characterise the demographic profile, reaction morphology, suspected medications, seriousness, outcomes and reporting departments of spontaneously reported CADRs at a tertiary care teaching hospital in Assam.

MATERIALS AND METHODS

Study design and setting

This retrospective descriptive pharmacovigilance study was conducted at the Department of Pharmacology and Adverse Drug Monitoring Centre, Silchar Medical College & Hospital, Silchar, Assam. The report was prepared in accordance with applicable STROBE reporting principles.10

Study duration

The study included CADR reports recorded from August 2021 to November 2024.

Ethics approval

The study was approved by the Institutional Ethics Committee, Silchar Medical College & Hospital (SMC/ETHICS/M2/2025/23) at its meeting held on 3 July 2025; the approval certificate was issued on 16 October 2025. No patient-identifying information is reported in this manuscript.

Data source and variables

Institutional pharmacovigilance records of spontaneously reported CADRs were reviewed. The unit of analysis was the ADR report, and 104 reports were included. Variables analysed were year and month of reporting, age, sex, CADR morphology, suspected medication, seriousness, outcome and reporting department.

Before analysis, spelling and formatting were harmonised, reaction terms were standardised, and medicines were expressed using consistent generic nomenclature. Fixed-dose combinations were retained as combination products. Suspected medications were classified into non-antiretroviral antimicrobials, antiretroviral agents and paracetamol; paracetamol was retained as a separate analgesic/antipyretic category. Age was grouped as ≤12, 13–18, 19–60 and >60 years. Seriousness was analysed using the recorded serious/non-serious classification, with terminology aligned to ICH E2A.11

Statistical analysis

Microsoft Excel 365 and descriptive statistics were used throughout the analysis. Age is presented as mean ± standard deviation (SD), median with interquartile range (IQR), and range. Categorical variables are presented as frequency and percentage, with 104 CADR reports as the denominator unless stated otherwise. As the study was descriptive, no inferential hypothesis testing was undertaken.

RESULTS

Demographic profile and temporal distribution

A total of 104 CADR reports were analysed. Twenty-one (20.19%) were recorded in 2021, 52 (50.00%) in 2022, 23 (22.12%) in 2023 and 8 (7.69%) in 2024. The mean age was 37.16 ± 13.35 years, the median was 36 years (IQR 29–46), and the age range was 10–80 years. Adults aged 19–60 years accounted for 93 (89.42%) reports. (Table 1) Males accounted for 54 (51.92%) reports (Figure 1).

Table 1. Age group distribution of CADRs (n=104)

Age group (in years)	n (%)
≤12 years	4 (3.85)
13–18 years	3 (2.88)
19–60 years	93 (89.42)
>60 years	4 (3.85)

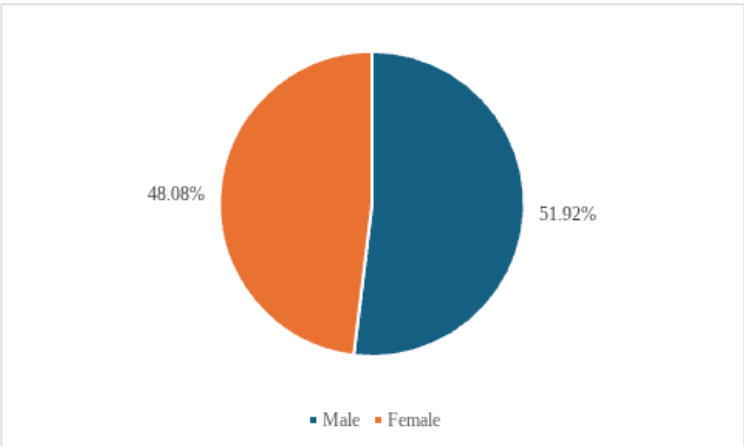

Figure 1. Sex distribution of CADRs (n=104).

Clinical morphology and suspected medications

Maculopapular rash was the predominant morphology, accounting for 63 (60.58%) reports, while fixed drug eruption accounted for 41 (39.42%) (Figure 2).

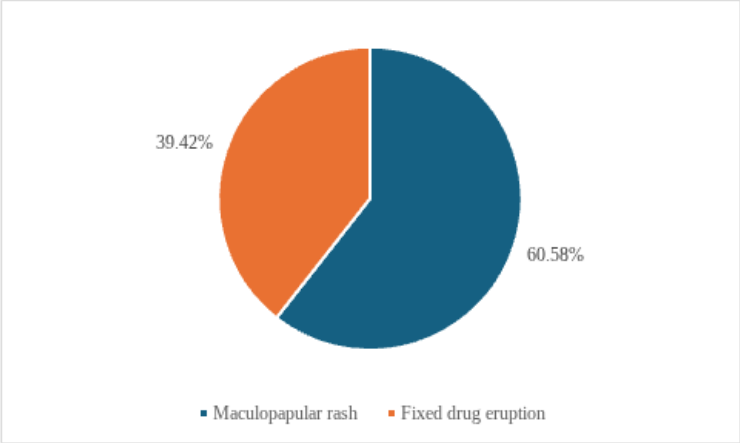

Figure 2. Distribution of clinical morphology of CADRs (n=104).

At the medication-category level, non-antiretroviral antimicrobials accounted for 81 (77.88%) reports, paracetamol for 14 (13.46%), and antiretroviral agents for 9 (8.65%) (Table 2).

Table 2. Suspected medication categories associated with CADRs (n=104)

Suspected medication category	n	%
Non-antiretroviral antimicrobial agents	81	77.88
Paracetamol	14	13.46
Antiretroviral agents	9	8.65
Total	104	100.00

Footnote: Percentages were calculated using n=104 as the denominator. Individual rounded percentages may not sum exactly to 100.00% because of rounding.

The ofloxacin–ornidazole fixed-dose combination was the most frequently recorded individual suspected medication (35; 33.65%), followed by co-trimoxazole (24; 23.08%) and paracetamol (14; 13.46%) (Table 3).

Table 3. Individual suspected medications associated with CADRs (n=104)

Suspected medication	n	%
Ofloxacin–ornidazole fixed-dose combination	35	33.65
Co-trimoxazole	24	23.08
Paracetamol	14	13.46
Amoxicillin–clavulanate	5	4.81
Ceftriaxone	5	4.81
Ofloxacin	3	2.88
Dolutegravir	3	2.88
Antitubercular therapy	3	2.88
Lamivudine	3	2.88
Zidovudine	3	2.88
Ciprofloxacin	2	1.92
Levofloxacin	1	0.96
Clindamycin	1	0.96
Metronidazole	1	0.96
Isoniazid	1	0.96
Total	104	100.00

Note: Percentages were calculated using n=104 as the denominator. Individual rounded percentages may not sum exactly to 100.00% because of rounding.

Morphology–medication pattern

Among fixed drug eruption reports, the ofloxacin–ornidazole fixed-dose combination accounted for 26 of 41 reports (63.41%), followed by paracetamol in 5 (12.20%). Co-trimoxazole was recorded in 24 of 63 maculopapular-rash reports (38.10%), while the ofloxacin–ornidazole combination was recorded in 9. The nine antiretroviral-associated reports comprised dolutegravir (n=3), lamivudine (n=3) and zidovudine (n=3).

Seriousness, outcomes and reporting departments

Sixty-nine (66.35%) reports were classified as non-serious and 35 (33.65%) as serious. Outcomes were recorded as recovered in 73 (70.19%), recovering in 8 (7.69%), not recovered in 19 (18.27%) and unknown in 4 (3.85%). No fatal outcome was recorded. Dermatology contributed 73 (70.19%) reports, followed by the ART Centre with 28 (26.92%), Cardiology with 2 (1.92%) and Medicine with 1 (0.96%) (Figure 3).

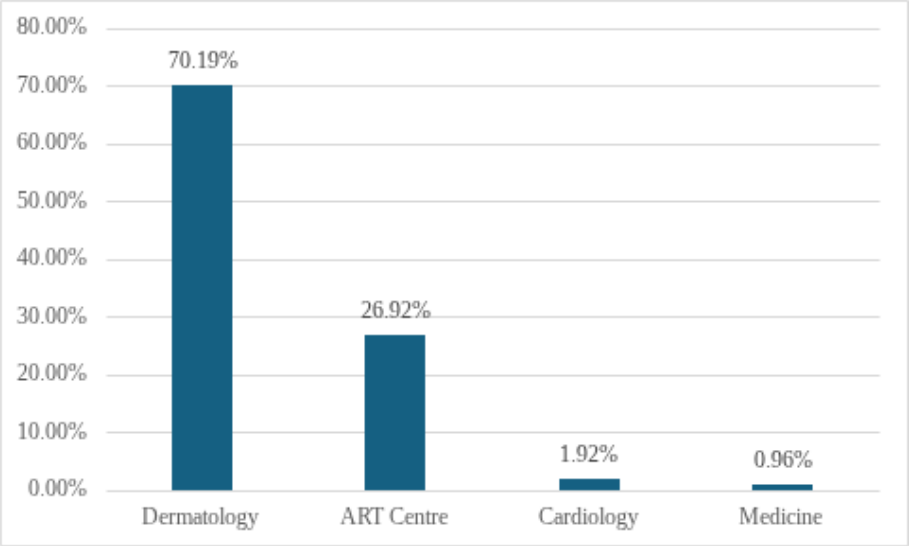

Figure 3. Department-wise distribution of CADRs (n=104).

DISCUSSION

In this series, maculopapular rash was the leading CADR morphology (60.58%), followed by fixed drug eruption (39.42%). Comparable Indian studies have likewise identified maculopapular or exanthematous eruptions as common presentations. Nandha et al. reported 42.85%, Jha et al. reported exanthematous eruptions in 42.63%, Sharma et al. identified maculopapular rash as the most frequent pattern, Modi et al. reported 58.92%, and Chindhalore et al. reported 33.6%.4–8 The proportion of fixed drug eruption in the present study was higher than that described in the recent series by Modi et al., Chindhalore et al. and Ashifha et al., illustrating the substantial variation in CADR morphology across centres.7–9

Differences in case mix, prescribing habits, referral patterns and reporting behaviour may contribute to this variation. The present findings therefore provide a centre-specific description of the CADRs captured through routine pharmacovigilance.

Non-antiretroviral antimicrobials represented 77.88% of reports in the present dataset. This proportion was higher than the antimicrobial proportions reported by Nandha et al. (48.30%), Modi et al. (46%) and Chindhalore et al. (63.2%).4,7,8 Antimicrobials were also the leading suspected group in the Indian series reported by Chatterjee et al. and Badar et al.12,13

Within the present dataset, the ofloxacin–ornidazole fixed-dose combination and co-trimoxazole were the most frequently recorded individual suspected medications. This distribution is most appropriately interpreted as the local reporting profile and may reflect the medicines commonly used in the population served.

The mean age in the present series was 37.16 years, close to the values reported by Chindhalore et al. (36.17 ± 17.71 years) and Sharma et al. (39.22 ± 20.47 years).6,8 Sex distribution was nearly balanced, with males accounting for 51.92% and females for 48.08% of reports. The predominance of adults aged 19–60 years may reflect the age distribution of medicine use and health-care attendance in the reporting population.

Approximately one-third of CADR reports were classified as serious, while two-thirds were non-serious. More than two-thirds were documented as recovered, although a smaller proportion remained recovering or not recovered at the recorded follow-up point. These findings emphasise the importance of continued follow-up after identification of a suspected CADR.

Dermatology and the ART Centre together accounted for the large majority of reports. This pattern is consistent with the clinical pathways through which cutaneous reactions and antiretroviral-associated events are commonly recognised and reported within the institution.

Strengths and limitations

A major strength of this study is its use of real-world pharmacovigilance data collected over more than three years from a tertiary-care centre in Northeast India. It provides a practical overview of the demographic profile, reaction patterns, suspected medicines, seriousness and outcomes of reported CADRs. The identification of individual suspected medicines also adds useful local prescribing and safety information.

The study is limited by its retrospective, spontaneous-reporting design, which is susceptible to under-reporting and incomplete follow-up. As medicine-exposure data were not assessed, the findings represent reporting patterns rather than incidence or comparative drug risk. Being a single-centre study with a relatively small number of reports may also limit generalisability.

Clinical importance of this study

The findings highlight the need for early recognition and careful monitoring of cutaneous reactions, particularly with commonly implicated antimicrobials. The prominent reporting of the ofloxacin–ornidazole combination and co-

trimoxazole provides useful local pharmacovigilance information for clinicians. Continued follow-up of reported reactions is also important, as some patients had not fully recovered at the time of documentation.

Future directions

Future studies should include larger multicentre populations and preferably use prospective designs with more detailed clinical follow-up. Linking ADR reports with medicine-utilisation data and incorporating standardised causality, severity and preventability assessments would allow more meaningful evaluation of drug-related safety patterns.

CONCLUSION

Maculopapular rash was the most frequently reported CADR, followed by fixed drug eruption. Non-antiretroviral antimicrobials constituted the largest suspected medication category, with the ofloxacin–ornidazole fixed-dose combination and co-trimoxazole recorded most often. Most reports were non-serious and had recovered by the recorded follow-up point. The study highlights the continuing value of structured pharmacovigilance, timely recognition of cutaneous reactions and consistent follow-up of reported cases.

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CONFLICT OF INTEREST

The authors declare no conflict of interest.

ETHICAL APPROVAL

Institutional Ethics Committee approval: Silchar Medical College & Hospital, reference SMC/ETHICS/M2/2025/23; dated: 16/10/2025.

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