IJPSR (2026), Volume 17, Issue 3 (Research Article)

INTERNATIONAL JOURNAL OF PHARMACEUTICAL SCIENCES AND RESEARCH

Received on 16 September 2025; received in revised form, 24 October 2025; accepted, 02 November 2025; published 01 March 2026

A STUDY ON CUTANEOUS ADVERSE DRUG REACTIONS DUE TO ANTI-RETROVIRAL THERAPY (ART) REPORTED IN THE DEPARTMENT OF DERMATOLOGY IN A TERTIARY CARE HOSPITAL-A RETROSPECTIVE STUDY

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Keywords:

Adverse Drug Reaction (ADR), Cutaneous ADR (CADR), Anti-retroviral therapy (ART), Human immunodeficiency virus (HIV), Toxic Epidermal Necrosis (TEN), Steven Johnson Syndrome (SJS)

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ABSTRACT: Objective: This study aimed to analyse the demographic profile, incidence, types, nature, and severity of cutaneous adverse drug reactions (CADRs) associated with antiretroviral therapy (ART) among patients attending the Department of Dermatology, Gauhati Medical College and Hospital (GMCH), Guwahati. **Methods:** A retrospective observational study was conducted following approval from the Institutional Ethics Committee, GMCH. Patient case records from January 2018 to December 2022 were reviewed. Relevant demographic and clinical data were extracted and analysed using Microsoft Excel 2021. Causality assessment was performed using the World Health Organization–Uppsala Monitoring Centre (WHO– UMC) scale, and severity was graded using the Modified Hartwig and Siegel Scale. **Results:** A total of 189 cases of CADRs were identified. The majority of affected patients were male (61.9%), and most cases (42.8%) occurred in the 31–40-year age group. The most frequent CADR was maculopapular rash (36%), followed by erythema (20.6%). Based on the WHO– UMC scale, 88.3% of reactions were classified as "possible" and 11.6% as "probable." According to the Modified Hartwig and Siegel Scale, most reactions were mild (76.2%), followed by moderate (22.2%) and severe (1.6%). **Conclusion:** The findings indicate that CADRs are a common and significant complication of ART, with maculopapular rash being the predominant presentation. Although most reactions were mild, the occurrence of severe forms emphasizes the need for continuous pharmacovigilance, early identification, and timely management to enhance patient safety and adherence to therapy.

INTRODUCTION: Human immunodeficiency virus (HIV) is a lentivirus responsible for Acquired Immunodeficiency Syndrome (AIDS) [1]. HIV infection is not hereditary; it cannot be transmitted from one generation to the next through genetic inheritance. However, it can be acquired through transmission from an infected individual to a healthy person. The virus progressively weakens the body by targeting and destroying CD4+ T cells, leading to immune system deficiency and the development of disease [2].

QUICK RESPONSE CODE

DOI: 10.13040/IJPSR.0975-8232.17(3).971-76

This article can be accessed online on www.ijpsr.com

DOI link: https://doi.org/10.13040/IJPSR.0975-8232.17(3).971-76

In India, the National AIDS Control Organization (NACO) regularly issues guidelines for the diagnosis and treatment of HIV infection. According to the National Guidelines for HIV Care and Treatment 2021, dolutegravir (DTG)–based regimens have been recommended since July 2020 as the preferred first-line therapy for HIV-positive

adults, adolescents, and children weighing over 20 kg (or aged over six years) under the National AIDS Control Programme (NACP) [3]. At the global level, the Joint United Nations Programme on HIV and AIDS (UNAIDS) plays a pivotal role in advocating for coordinated action against HIV/AIDS. Among its international targets, the "90–90–90 goal" aimed to ensure that by 2020, 90% of all people receiving antiretroviral therapy (ART) would achieve and sustain viral suppression [4]. In India, the Government provides free ART through the Ministry of Health and Family Welfare. By March 2019, HIV care services had expanded to 544 ART centres and 1,108 link ART centres across the country. These centres not only supply free ART but also provide systemic HIV care, counselling for psychosocial support, and monitoring for adverse drug reactions (ADRs), with a strong focus on adherence [5].

Furthermore, once a person becomes infected with HIV, treatment is required for life. Although ART has significantly improved survival and quality of life, it is also associated with both short- and long-term toxicities. Despite these challenges, India's national ART programme the second largest in the world is recognized as one of the most successful public health initiatives, providing comprehensive HIV care and treatment services across the country [6].

Cutaneous adverse drug reactions (CADRs) are among the most frequently encountered adverse drug reactions and have become increasingly common in recent years. The reported incidence of CADRs among hospitalized patients ranges from 1–3% in developed countries and 2–5% in developing nations such as India. The clinical patterns of CADRs vary with different drug classes. Therefore, understanding the precise nature of these reactions is essential for early identification and prompt withdrawal of the offending agent to prevent serious complications or mortality. Furthermore, awareness of drugs commonly implicated in CADRs can assist physicians in selecting safer therapeutic alternatives and improving patient outcomes [7]. CADRs have a complex pathogenesis and present with diverse clinical manifestations, often making diagnosis challenging [8]. They encompass a broad spectrum of dermatologic manifestations, ranging from mild to severe. Common presentations include drug rashes, hyperpigmentation, alopecia, hypersensitivity reactions, injection-site reactions, urticaria, erythema multiforme, Stevens–Johnson syndrome (SJS), and toxic epidermal necrolysis (TEN) [9]. SJS and TEN are severe, life-threatening mucocutaneous disorders characterized by widespread blistering and extensive epidermal detachment. These reactions are most commonly triggered by medications, although infections such as those caused by Mycoplasma pneumoniae or herpes simplex virus can also serve as precipitating factors [10]. They may affect multiple organ systems, including ocular, respiratory, gastrointestinal, renal, and hematologic systems [11–14].

CADRs are an important concern for a healthcare practitioner. Comprehensive, accurate knowledge regarding pattern, severity and causative agents generated from a retrospective study can help physicians in choosing safer drugs and therefore can be helpful to the society at large [15]. This study was undertaken to evaluate the incidence, clinical types, and characteristics of CADRs associated with ART among patients attending the Department of Dermatology at Gauhati Medical College & Hospital.

MATERIALS AND METHODS: This retrospective observational study was conducted following approval from the Institutional Ethics Committee, Gauhati Medical College & Hospital (Approval No. MC/190/2007/Pt II/Oct 2022/1). Data were collected from patient case records after obtaining prior permission from the Head of the Department of Dermatology. The study included all spontaneously reported cases of cutaneous ADRs in HIV-infected individuals of any age or gender who had received ART and presented to the Dermatology Outpatient Department (OPD) or were admitted to the Inpatient Department (IPD) between January 2018 and December 2022. Causality assessment was performed using the World Health Organization–Uppsala Monitoring Centre (WHO-UMC) causality categories [16]. The severity of ADRs was graded according to the Modified Hartwig and Siegel Scale [17]. Data were analysed descriptively using Microsoft Excel 2021, and findings were presented in the form of tables and graphs.

RESULTS: A total of 189 cases of cutaneous ADR were evaluated in the study. The patients were classified according to their age, sex and the type of cutaneous reactions they exhibited. The ADRs are classified according to the World Health Organization (WHO)-UMC causality categories, and the severity assessment was done using the Modified Hartwig and Seigel Scale.

Gender Distribution: Out of the 189 patients' reports collected for the study, 117 (61.9%) were male and 72 (38.09 %) were female **Table 1.**

TABLE 1: GENDER DISTRIBUTION

Gender Distribution		
Gender	**Total Number (N)**	**Percentage (%)**
Male	117	61.9
Female	72	38.09

Age Distribution: Patients ranged from 18 to 70 years. Age was grouped into five categories with 10-year intervals. The highest proportion of cases (42.8%) occurred in the 31–40 years age group **Table 2.**

TABLE 2: AGE-WISE DISTRIBUTION

Age-wise Distribution			
Sl. no.	**Age Group in Years**	**Number of Cases (N)**	**Percentage (%)**
1	18-30 Years	52	27.51
2	31-40 Years	81	42.85
3	41-50 Years	47	24.86
4	51-60 Years	8	4.2
5	>61 Years	1	0.5

Types of Cutaneous ADRs: The most common cutaneous ADR was maculopapular rash, observed in 68 cases (36%), followed by erythema in 39 cases (20.6%) **Fig. 1.**

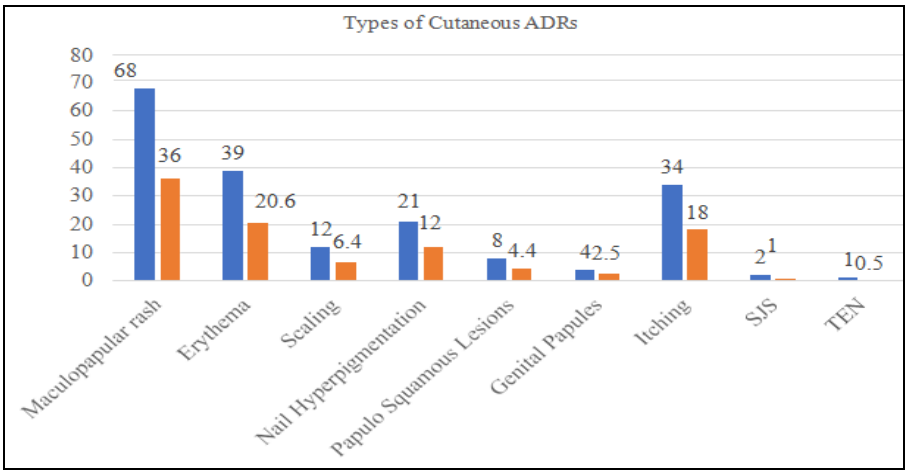

FIG. 1: DIFFERENT TYPES OF CUTANEOUS ADRs. ADR: Adverse drug reactions

Causality Assessment: Among the 189 ADRs observed, 22 were classified as probable and 167 were classified as possible **Fig. 2.**

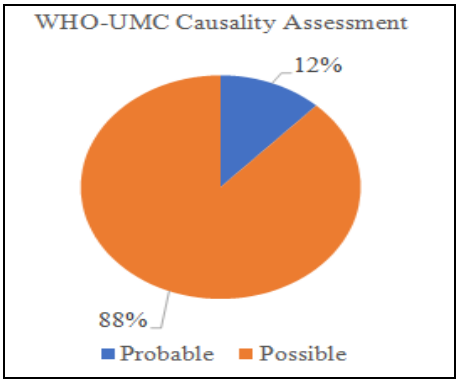

FIG. 2: THE WHO-UMC CAUSALITY ASSESSMENT

Severity Assessment: Severity was assessed using the Modified Hartwig and Siegel Scale. The majority of ADRs were mild (144 cases, 76.2%), followed by moderate (42 cases, 22.2%) and severe (3 cases, 1.6%) **Fig. 3.**

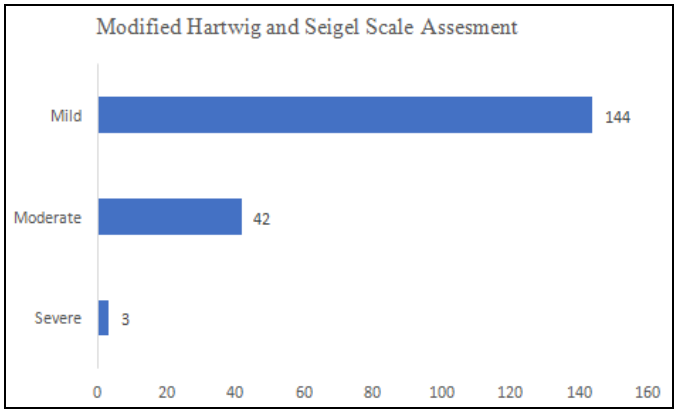

FIG. 3: MODIFIED HARTWIG AND SEIGEL SCALE

Distribution of Art Regimen: Among the antiretroviral therapy (ART) regimens, most cutaneous ADRs were associated with the Tenofovir/Lamivudine/Efavirenz (TLE) regimen (126 cases, 66.7%), followed by Tenofovir/ Lamivudine/Dolutegravir (TLD) (55 cases, 29.1%). Less frequent regimens included Zidovudine/Lamivudine/ Atazanavir/Ritonavir (ZLAR), Tenofovir/ Lamivudine/ Atazanavir/Ritonavir (TLAR), Zidovudine/ Lamivudine/Nevirapine (ZLN), and Abacavir/ Lamivudine/L opinavir/Ritonavir (ALLR) **Table 3.**

TABLE 3: DISTRIBUTION OF ART REGIMEN

Regimen-Wise Distribution		
ART Regimen	**No. of cases (N)**	**Percentage (%)**
TLE	126	66.66
TLD	55	29.10
ZLAR	5	2.73
TLAR	1	0.5
ZLN	1	0.5
ALLR	1	0.5

ART: Antiretroviral Therapy, TLE: Tenofovir, lamivudine, efavirenz, TLD: Tenofovir, lamivudine, dolutegravir, ZLAR: Zidovudine, lamivudine, atazanavir, ritonavir, TLAR: Tenofovir, lamivudine, atazanavir, ritonavir, ZLN: Zidovudine, Lamivudine, nevirapine, ALLR: Abacavir, lamivudine, lopinavir, ritonavir

DISCUSSION: This study was undertaken to evaluate the incidence, types, and nature of cutaneous adverse drug reactions (CADRs) among patients receiving ART. A total of 189 CADRs were recorded. A higher proportion of CADRs was reported in males (61.9%) compared to females (38.09%), which is in agreement with the findings of Chauhan *et al*. study [18]. However, studies by Reddy *et al.* [19], Singh *et al.* [20], Anbessa *et al* [21] and Adiningtyas *et al.* [22] observed a higher prevalence in females. These differences may be explained by variations in body mass index and fat composition, hormonal influences on drug metabolism, and genetic differences in enzyme activity between sexes. The majority of CADRs occurred in the age group of 31–40 years (42.85%), followed by the 18–30 years group (27.51%) and 41–50 years group (24.86%). Similar age-related trends were reported in studies by Rukmangathen *et al.* [23] and *Reddy et al.* [19].

The most common CADR in the present study was maculopapular (MP) rash, observed in 68 patients (36%), followed by erythema in 39 patients (20.6%). This aligns with the findings of Pawar *et al.* [15] who reported MP rash in 76.67% of cases, most of which were Grade 3 in severity. Srikanth *et al.* [24] also reported MP rash (28.57%) as the most frequent CADR. In contrast, Rather *et al.* [25] (18.2%) and Sinha *et al.* [26] (11.11%) studies found a lower incidence of rash. Among ART regimens, the TLE regimen accounted for the highest proportion of CADRs (66.6%), followed by the TLD regimen (29.1%), findings consistent with those of Bansal *et al.* [27] and Jain *et al* [28] studies. The higher frequency of cutaneous reactions with TLE has been attributed to the synergistic effects of tenofovir and efavirenz [29]. Conversely, Sharma *et al.* [30] reported fewer rashes in patients on efavirenz-based regimens compared to other ART combinations. Causality assessment using the WHO-UMC scale revealed that 88.3% of CADRs were classified as “possible” and 11.64% as “probable.” According to the Modified Hartwig and Siegel Severity Scale, most CADRs were mild (76.19%), followed by moderate (22.2%) and severe (1.5%). These results are in line with the findings of Rukmangathen *et al* [23] and Chindhalore *et al* [31] studies However, Pawar *et al.* [15] reported a higher proportion of “probable” cases (57.78%), and their severity assessment showed 96% of reactions as mild-to-moderate, with about 4% severe. Patel *et al.* [32] and Anjaneyan *et al.* [33] also reported similar severity patterns. Overall, this study underscores the importance of continuous monitoring of HIV/AIDS patients on ART to

improve patient care, reduce adverse outcomes, and lower healthcare costs [34].

Limitation: The present study was limited by its relatively small sample size and single-centre design, which may restrict the generalizability of the findings. Additionally, the reliance on spontaneous reporting of ADRs may have led to underreporting or misclassification. Future multicentre studies with larger populations, longer follow-up periods, and pharmacogenomic profiling are needed to better understand patient-specific risk factors for CADRs. Such efforts will aid in tailoring ART regimens to minimize adverse reactions and improve treatment adherence.

CONCLUSION: HIV/AIDS remains one of the most challenging chronic diseases, and with the widespread availability of highly active ART (HAART), the incidence of ADRs has also risen. In this study, ADRs were more prevalent among patients on the TLE regimen compared to those on TLD. Most reactions were classified as possible or probable. Prompt recognition, early detection, and efficient management of ADRs are essential to reduce economic burden, improve medication adherence, and achieve better therapeutic outcomes. Careful selection of appropriate ART regimens is equally important to minimize adverse events and optimize patient care.

ACKNOWLEDGEMENT: We are thankful to the authorities of Department of Dermatology for their support to the research study and also express our gratitude to the staff of Medical Record Department of Dermatology for their help during data collection period.

CONFLICT OF INTEREST: None

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How to cite this article:
Borah L, Boro B, Bhattacharyya M and Das MC: A study on cutaneous adverse drug reactions due to anti-retroviral therapy (ART) reported in the department of dermatology in a tertiary care hospital a retrospective study. Int J Pharm Sci & Res 2026; 17(3): 971-76. doi: 10.13040/IJPSR.0975-8232.17(3).971-76.