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CLINICAL SPECTRUM AND CAUSATIVE AGENTS OF ADVERSE CUTANEOUS DRUG REACTIONS: A RETROSPECTIVE STUDY FROM BARAU DIKKO

TEACHING HOSPITAL KADUNA, NIGERIA

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ABSTRACT

Background: Adverse cutaneous drug reactions (ACDRs) are significant causes of dermatological morbidity, ranging from mild eruptions to severe life-threatening conditions. Their patterns and implicated drugs vary across settings, and local data are essential to inform clinical practice and pharmacovigilance.

Aim: To describe the clinical patterns of ACDRs, identify implicated drug classes, and assess associations with patient demographics at a tertiary dermatology clinic in Kaduna, Nigeria.

Methods: Electronic Medical Records (EMRs) of patients diagnosed with ACDRs over a 10-year period (2015–2024) were reviewed. Diagnosis was based on clinical evaluation documented by dermatologists. Causality assessment was performed using standard clinical judgment, and severity was classified into mild and severe forms (including Stevens–Johnson syndrome and toxic epidermal necrolysis). Data extracted included socio-demographic characteristics, clinical patterns, suspected causative drugs, and severity. Descriptive statistics were used, and associations were tested using the chi-square test, with $p < 0.05$ considered statistically significant.

Results: Of 4,426 dermatology patients seen during the study period, 62 had ACDRs, giving a proportion of 1.4%. The mean age was 28.0 ± 17.3 years, with a slight female predominance (51.6%). Fixed drug eruption was the most common pattern (85.5%), while severe reactions accounted for 14.5%. Sulfonamides (48.4%) and non-steroidal anti-inflammatory drugs, particularly diclofenac (27.4%), were the most frequently implicated medications. Other implicated drugs included antiepileptics and antifungals. Angiotensin-converting enzyme inhibitors (ACEIs) were associated with angioedema. Two patients (3.2%) had suspected reactions to the COVID-19 vaccine (generalized hypopigmentation and pityriasis rosea). No statistically significant association was found between reaction type and age group or gender (chi-square test, $p > 0.05$).

Conclusion: ACDRs in this setting are predominantly fixed drug eruptions, with sulfonamides and NSAIDs as the leading implicated drug classes. These findings highlight the need for strengthened pharmacovigilance and cautious use of high-risk medications

Keywords: Adverse cutaneous drug reaction, pharmacovigilance, retrospective study.

INTRODUCTION

Adverse cutaneous drug reactions (ACDRs) are undesirable skin manifestations that occur

following the administration of medications and represent one of the most common forms of adverse drug reactions encountered in clinical practice (Getova *et al.*, 2018).



ACDRs comprise a broad spectrum of dermatologic manifestations associated with systemic or topical medications, ranging from mild self-limiting eruptions such as exanthematous drug eruptions to severe and potentially life-threatening conditions like Stevens–Johnson syndrome/toxic epidermal necrolysis (SJS/TEN) and drug reaction with eosinophilia and systemic symptoms (DRESS) (Al Aboud *et al*, 2023).

ACDRs constitute an important cause of patient morbidity worldwide and contribute substantially to healthcare utilization and hospital admissions. Hospital-based incidence estimates of cutaneous adverse drug reactions range from 0.4% to 2.2%, although severe reactions such as SJS/TEN account for a disproportionate share of morbidity and mortality (Halevy *et al*, 2018). Studies from Africa have similarly shown that adverse drug reactions contribute significantly to patient morbidity, with approximately 4.5%–8.4% of hospital admissions attributed to adverse drug reactions (Gonzalez-Martin 1999; Rawlins 1977). In low- and middle-income countries, the burden of ACDRs may be amplified by limited pharmacovigilance systems, coexisting infectious diseases, widespread antimicrobial use, and variations in prescribing practices.

The pattern of ACDRs often reflects local prescribing habits and prevalent disease conditions. Anticonvulsants, sulfonamides, antibiotics, nonsteroidal anti-inflammatory drugs (NSAIDs), allopurinol, and antiretroviral agents are among the medications most frequently implicated in cutaneous drug reactions. Exanthematous eruptions remain among the most commonly reported clinical presentations, while severe cutaneous adverse reactions, although less

frequent, are associated with considerable morbidity and mortality. Several factors, including polypharmacy, advanced age, female sex, HIV infection, malnutrition, intercurrent infections, and concurrent therapies, have been associated with increased risk of ACDRs (Chen *et al* 2022; Singh *et al.*, 2023).

Despite the growing clinical importance of ACDRs, pharmacovigilance and dermatologic surveillance systems remain underdeveloped in many low- and middle-income countries. Existing African studies have largely focused on hospitalized patients, while data on outpatient presentations remain limited. Furthermore, there is a paucity of published data describing the clinical spectrum and causative agents of ACDRs in Northern Nigeria. The implementation of an Electronic Medical Records (EMR) system and the availability of specialist dermatology services in this teaching hospital provided an opportunity to evaluate the pattern of ACDRs in this setting.

This study therefore aimed to determine the clinical spectrum and causative agents of ACDRs among patients presenting to a teaching hospital in Kaduna, Nigeria.

MATERIALS AND METHODS

This was a retrospective observational study conducted at the dermatology outpatient clinic of Barau Dikko Teaching Hospital, Kaduna, Nigeria, over a 10-year period from January 2015 to December 2024. Barau Dikko Teaching Hospital is a major tertiary referral centre serving Kaduna State and neighboring regions in Northwestern Nigeria. Ethical approval for the study was obtained from the Barau Dikko Teaching Hospital Health Research Ethics Committee (HREC) (Approval No: BDTH/HREC/MARCH/2026



/597/VOL.1). Patient confidentiality was maintained throughout the study through anonymization of extracted data and restricted access to study records.

Data extracted from patient records included socio-demographic characteristics, clinical diagnosis and type of cutaneous drug reaction, suspected causative drugs, severity of reaction, treatment administered, and clinical outcomes. Data extraction was performed using a structured proforma, and records were cross-checked for completeness and consistency before analysis.

The diagnosis of ACDRs was based on clinical evaluation documented in patient records, including temporal relationship between drug exposure and onset of cutaneous manifestations, compatible clinical features, and improvement following withdrawal of the suspected medication were documented. Severity classification was based on clinical documentation in the medical records, including identification of severe cutaneous adverse reactions such as SJS/TEN and DRESS.

Data were entered and analyzed using Statistical Package for the Social Sciences (SPSS) version 27.0 (IBM Corp., Armonk,

NY, USA). Quantitative variables such as age were summarized using means and standard deviations, while categorical variables were presented as frequencies and percentages. Associations between categorical variables were assessed using the Chi-square test or Fisher's exact test where appropriate. Cases with missing data for specific variables were excluded from analyses involving those variables. A p-value <0.05 was considered statistically significant.

RESULTS

During the 10-year study period from January 2015 to December 2024, a total of 4,426 patients attended the dermatology outpatient clinic of Barau Dikko Teaching Hospital, Kaduna. Of these, 62 patients were diagnosed with adverse cutaneous drug reactions (ACDRs), representing 1.4% of all dermatology clinic presentations during the study period.

The ages of the patients ranged from 1 to 70 years, with a mean age of 28.0 ± 17.3 years. Females constituted a slight majority of cases, with a male-to-female ratio of 1:1.1. Most patients were single (58.1%) and of Islamic faith (56.5%) (Table 1).

Table 1: Socio-demographic Characteristics of patients with adverse cutaneous reactions seen in B.D.T.H. Kaduna (n = 62)

Variable	Frequency	Percentage
Age group (years)		
0-10	9	14.5
11-20	11	17.7
21-30	13	21.0
31-40	8	12.9
41-50	9	14.5
>51	5	8.0
Mean $\pm$ SD=27.98 $\pm$ 17.26 years		
Gender		
Male	30	48.4
Female	32	51.6
Male : female ratio = 1:1.07		
Marital Status		
Unmarried	36	58.1
Married	26	41.9
Religion		
Islam	35	56.5
Christianity	27	43.5
Total	62	

Pattern of cutaneous adverse drug reaction

Fixed drug eruption (FDE) was the predominant clinical presentation, accounting for 53 cases (85.5%). Severe cutaneous adverse reactions were relatively uncommon and included Stevens–Johnson syndrome (SJS) in four patients (6.5%) and toxic epidermal necrolysis syndrome (TENS) in two patients (3.2%). Other less frequent reactions included angioedema, blistering drug reaction, and a COVID-19 vaccine–associated pityriasis rosea-like eruption. FDE occurred across all age groups and represented the predominant reaction pattern in both males and females (Table 2). Representative clinical images of FDE and angioedema are shown in Figures 1 and 2, respectively.

Table 2: The Various Adverse Cutaneous Reactions Observed

Reaction type	Frequency	Percentage
Fixed drug reaction (FDR)	53	85.50
Steven Johnson's syndrome	4	6.45
Toxic epidermal necrolysis	2	3.23
Blistering drug reaction	1	1.61
Angioedema	1	1.61
Covid vaccine allergy (Pityriasis rosea)	1	1.61
Total	62	100.00



Figure 1: Fixed Drug Eruption shown as Multiple Hyper Pigmented Patches on the Hands

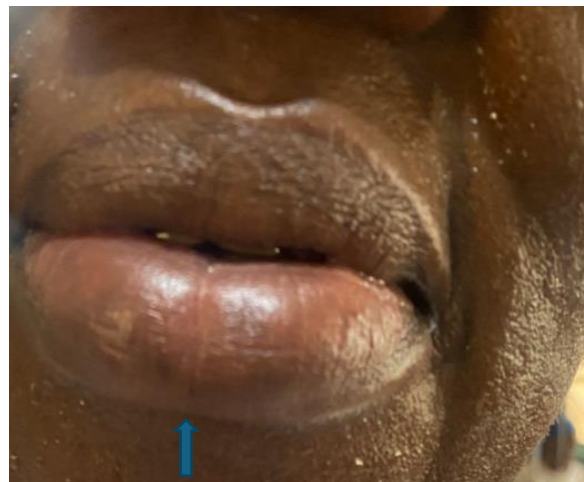


Figure 2: Angioedema Characterized by Swelling of the Lips due to side Effects of ACE inhibitor (Lisinopril)

Cotrimoxazole was the most frequently implicated medication, accounting for 48.4% of documented ACDRs, followed by nonsteroidal anti-inflammatory drugs (NSAIDs), predominantly diclofenac and piroxicam, which accounted for 37.1% of cases. Other implicated medications included Fansidar, ceftriaxone, nevirapine, lisinopril, paracetamol, and the AstraZeneca COVID-19 vaccine. Fixed drug eruption was the predominant clinical pattern associated with cotrimoxazole and NSAIDs. Severe cutaneous adverse reactions such as SJS and TEN were mainly associated with cotrimoxazole, nevirapine, and NSAIDs. Some patients had exposure to more than one suspected medication; therefore, percentages may exceed 100% (Table 3).

Table 3: Drugs Implicated in Adverse Cutaneous Drug Reactions (ACDR) in B.D.T.H Kaduna 2015–2024

Drug Class	Specific Drug	Frequency/%
Sulphonamides (Antibiotic)	Cotrimoxazole	30/48.4
NSAIDs	Diclofenac, piroxicam	23/37.1
Antimalarials	Sulphadoxine/Pyrimethamine	4/6.45
Antibacterials (Cephalosporin)	Ceftriazone	1/1.61
Analgesic	Paracetamol	1/1.61
Anti-retroviral	Nevirapine	1/1.61
Antihypertensive	ACE inhibitor (Lisinopril)	1/1.61
Covid vaccine	ChAdOx1 nCoV-19 (AstraZeneca)	1/1.61
Total		62/100

Table 4: Association Between Age Group and Type of Adverse Cutaneous Drug Reaction (n = 62)

Age group (years)	Type of ACDR		Total
	FDE	Others	
≤ 18	18	3	21
19 – 64	33	6	39
≥ 65	2	0	2

There was no statistically significant association between age group and type of ACDR (Fisher's exact test = 0.308, $p = 1.000$) (Table 4). Similarly, no statistically significant association was observed between gender and type of ACDR (Fisher's exact test = 1.409, $p = 0.294$) (Table 5).

Table 5-Association between gender and reaction Type. (n=62)

Gender	FDE	Other ACDR	Total
Male	24	6	30
Female	29	3	32

Fisher's exact test = 1.409; $p = 0.294$

DISCUSSION

This 10-year retrospective study evaluated the clinical spectrum and causative agents of ACDRs among patients attending a tertiary teaching hospital in Kaduna, Northwestern Nigeria. Adverse cutaneous drug reactions accounted for 1.4% of dermatology clinic presentations during the study period, highlighting that although relatively infrequent, ACDRs remain an important cause of dermatologic morbidity in this environment. Previous outpatient-based studies have reported widely varying frequencies of ACDRs ranging from 0.14% to 39.1%. 0.14% (Borch, 2006), 0.28% (Chatterjee, 2006), 2.9% (Henshaw, 2006), 39.1% (Opadeyi, 2024) and 2.6% (Saha, 2012). These variations may reflect differences in study design, case definitions, patient populations, reporting practices, access to specialist dermatology services, and pharmacovigilance systems across centres. The relatively low proportion observed in this study may also reflect underreporting,

management of milder reactions at primary healthcare facilities, or delayed presentation to specialist care.

The mean age of patients in this study was 28.0 ± 17.3 years, with most cases occurring among individuals aged 11–30 years. This finding is consistent with reports from previous studies demonstrating that ACDRs commonly affect adolescents and young adults (Goettler, 1997, Pudukadan, 2004, and Sharma, 2001). Increased exposure to antibiotics, over-the-counter medications, antimalarial agents, and self-medication practices among younger individuals may partly explain this pattern. In addition, younger adults are more likely to seek medical attention for visible dermatologic manifestations compared with older individuals.

A slight female predominance was observed in this study, which is comparable to findings from several previous studies on cutaneous adverse drug reactions. This may partly reflect higher healthcare-seeking behavior



among females. Some studies have also suggested that women may have increased susceptibility to drug hypersensitivity reactions due to hormonal, genetic, and immunological differences influencing drug metabolism and immune responses (Lee *et al.*; 2023).

The principal finding of this study was the overwhelming predominance of fixed drug eruption (FDE), which accounted for 85.5% of all documented ACDRs. Similar patterns have been reported in studies from other developing countries where FDE remains the most frequently encountered form of cutaneous drug reaction (Chaudhari *et al.*, 2026; Qayoom *et al.*, 2015). The predominance of FDE may be attributable to the widespread use of commonly implicated medications such as sulfonamide antibiotics and NSAIDs, repeated exposure to culprit medications, and the relatively characteristic clinical appearance of FDE lesions, which facilitates diagnosis. Cotrimoxazole and NSAIDs, particularly diclofenac and piroxicam, were the leading causative agents identified in this study. This likely reflects prescribing patterns and widespread over-the-counter availability of these medications within the community. Although severe cutaneous adverse reactions (SCARs) such as SJS and TEN were relatively uncommon, they remain clinically important because of their associated morbidity and potential mortality. In this study, ACDRs were mainly associated with cotrimoxazole, nevirapine, and NSAIDs, which are well-recognized triggers of severe drug hypersensitivity reactions.

Angioedema associated with lisinopril use was observed in one patient. Angiotensin-converting enzyme inhibitor-associated angioedema is a well-documented adverse

effect and has been reported across different populations, with estimated incidence rates ranging from 0.1% to 0.7%. (Byrd 2006; Messerli 2000 and Qayoom, 2015). The reaction in this study presented with lip swelling occurring shortly after initiation of lisinopril therapy, which is consistent with previously described clinical patterns.

An uncommon finding in this study was a COVID-19 vaccine-associated pityriasis rosea-like eruption following administration of the Oxford/AstraZeneca COVID-19 vaccine. Cutaneous reactions associated with COVID-19 vaccines have increasingly been reported in the literature, including urticarial eruptions, pityriasis rosea-like reactions, morbilliform eruptions, and delayed hypersensitivity reactions (Quan *et al.*, 2009; Leerunyakul *et al.* 2021). The exact mechanisms underlying these reactions remain incompletely understood but may involve immune dysregulation, viral reactivation, or altered T-cell-mediated immune responses following vaccination (Adya *et al.*, 2021; Drago *et al.*, 2016).

No statistically significant association was observed between type of ACDR and either age group or sex. These findings suggest that the pattern of cutaneous drug reactions in this study was relatively similar across demographic categories. However, the highest absolute number of reactions occurred among individuals aged 19–64 years, likely reflecting greater medication exposure and healthcare utilization within this age group.

Limitations

This study has several limitations. The retrospective design depended on the accuracy and completeness of medical records, and some case notes had incomplete



documentation regarding drug dosages, timing of exposure, and clinical outcomes. Standardized causality assessment tools such as the Naranjo algorithm or WHO-UMC causality scale were not routinely applied, limiting objective assessment of drug causality. In addition, the relatively small sample size may have limited the statistical power to detect significant associations across some demographic subgroups. As a Single-Centre hospital-based study, the findings may not be fully generalizable to the wider population

CONCLUSION

AND

RECOMMENDATION

Adverse cutaneous drug reactions accounted for 1.4% of dermatology clinic presentations over the 10-year study period. Fixed drug eruption was the predominant clinical presentation, while sulfonamide antibiotics and NSAIDs were the leading implicated medications. Although severe cutaneous adverse reactions were relatively uncommon, their potential morbidity underscores the importance of early recognition and prompt intervention.

Strengthening pharmacovigilance systems, improving documentation of drug allergies, promoting rational prescribing practices, and increasing clinician awareness of commonly implicated medications may help reduce the burden of ACDRs in this environment. Prospective multicentre studies incorporating standardized causality assessment methods are recommended to further characterize the epidemiology and outcomes of ACDRs in Nigeria.

Conflicts of Interest: The authors declare that there is no conflict of interests.

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Authors Contributions

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Yakubu P.D- conceptualization, Manuscript writing

Ovosi-Bello B- Data analysis, manuscript writing

Zubairu H.D – Study design, manuscript writing, data analysis

Sarki G- Data collection, statistical analysis.

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All authors read and approved the final manuscript.

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