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Research Article

Cutaneous adverse drug reactions and their impact on the quality of life of patients: a study at a tertiary care centre.

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Abstract

Background and objective: Cutaneous adverse drug reactions (CADRs) encompass a wide spectrum of drug-induced skin and mucosal manifestations, ranging from mild rashes to severe cutaneous adverse reactions (SCARs), such as toxic epidermal necrolysis. Early recognition and prompt withdrawal of the causative drug are vital for better outcomes. CADRs are increasingly common due to polypharmacy, yet regional data on their patterns and causative agents remain limited. This study aims to identify the clinical and epidemiological patterns of CADRs and to assess their impact on quality of life using the Dermatology Life Quality Index (DLQI).

Materials and methods: This cross-sectional observational study included 84 patients with clinically suspected CADRs from January to December 2024. Data were collected through patient interviews, clinical examinations, and the assessment using the Naranjo causality scale. DLQI was used to evaluate the psychosocial burden associated with CADRs.

Results: Fixed drug eruption was the most common presentation (25%), followed by maculopapular eruptions (11.9%) and urticaria (9.5%). SCARs accounted for 17.9% cases. Antimicrobials (57.2%) were the most frequently implicated drugs. Generalized lesions and pruritus were significantly associated with higher DLQI scores. DLQI Score interpretation reveals that 3.6% patients have no effects whereas 46.7% patients are moderately affected. Based on the Naranjo algorithm, causality was classified as probable in 76.2%, possible in 14.3%, and definite in 9.5% of cases.

Conclusion: CADRs significantly impact quality of life, especially in severe cases or those with strong drug causality. Antimicrobials, nonsteroidal anti-inflammatory drugs (NSAIDs), and antiepileptics were major causative agents. These findings underscore the importance of early detection, comprehensive drug history-taking, and a patient-centred approach to mitigate both the physical and psychological burdens of CADRs.

Introduction

Adverse drug reactions (ADRs) are unintended and harmful responses to drugs administered at therapeutic doses, posing a major challenge to patient safety and treatment efficacy [1]. They contribute to increased morbidity, hospitalizations, and overall healthcare costs [2].

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CADRs affect approximately 2–3% of hospitalized patients and account for 10–30% of all reported ADRs [3-5]. They encompass a broad clinical spectrum, ranging from mild conditions like fixed drug eruptions (FDE) and maculopapular rashes to severe and life-threatening disorders, including Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN), acute generalized exanthematous pustulosis (AGEP), drug reaction with eosinophilia and systemic symptoms (DRESS), and generalized bullous fixed drug eruption (GBFDE) [6].

The likelihood that a specific drug was responsible for the adverse cutaneous reaction was assessed using the Naranjo algorithm [7], a validated and standardized tool consisting of ten structured questions. This algorithm evaluates various aspects including the temporal relationship between drug administration and onset of the reaction, dechallenge and rechallenge outcomes, the existence of alternative causes, known drug associations, prior patient experience, and objective evidence. The Naranjo algorithm was chosen for its widespread use in pharmacovigilance and its structured, reproducible format, which makes it well-suited for assessing causality in diverse types of CADRs.

To systematically assess the impact of CADRs on health-related quality of life (HRQoL), the Dermatology Life Quality Index (DLQI) is commonly used. Developed by Finlay and Khan in 1994, the DLQI is a 10-item questionnaire covering symptoms and feelings, daily activities, leisure, work and school, personal relationships, and treatment [9].

In CADRs, lesions on visible areas such as face and hands can negatively affect self-esteem and social interactions; while symptoms like pruritus, burning, and pain further impair quality of life [8]. DLQI scores often reflect not only just physical symptoms but also the emotional and social consequences of visible skin damage [10].

Importantly, although drug withdrawal is critical for managing CADRS, it can disrupt treatment of underlying diseases, potentially leading to anxiety, disease relapse, or reliance on less effective therapies, thereby compounding the patient's overall burden.

Despite their prevalence, regional data - especially from underrepresented areas like Bihar, India - remain limited. This study aims to characterize the clinical spectrum of CADRs, identify causative drugs, assess causality using the Naranjo algorithm, and evaluate the impact on quality of life using the DLQI.

Materials and methods

A hospital-based, cross-sectional observational study was conducted over one year (January–December 2024) in the dermatology outpatient department of a tertiary care centre in Eastern India, following Institutional Ethics Committee approval. A total of 84 patients of all ages and genders with clinically suspected CADRs caused bymodern medicine were enrolled consecutively. Inclusion criteria required documented recent drug use and informed consent. Reactions attributed to homeopathic, ayurvedic, or other indigenous medicines were excluded. A structured proforma was used to document demographic data, drug history, clinical features, comorbidities, and lab parameters. Causality was assessed using the Naranjo algorithm, in which each question is scored as +1, 0, or –1. The total score classifies the reaction as definite (≥9), probable (5–8), possible (1–4), or doubtful (≤0). In this study, responses to each question were determined based on a review of clinical history, drug exposure timelines, clinical course, and laboratory investigations.

The DLQI was used to assess the impact of CADRs on health-related quality of life (HRQoL), with a total score range of 0–30. Data were analysed using IBM SPSS version 23. Descriptive statistics were used to summarise the variables. Categorical variables were compared using the Chi-square test, while continuous variables were analysed using the Mann–Whitney U and Kruskal–Wallis tests, as appropriate. Inter-rater agreement for causality assessment was evaluated using the Kappa statistic. A p-value ≤0.05 was considered statistically significant. For multiple-response variables, each response was coded and analysed as a percentage of total responses.

Drug withdrawal was advised for all patients except those with acneiform eruptions from antitubercular therapy. Each patient received a drug card listing offending and cross-reactive drugs, along with counselling to avoid self-medication and to seek medical advice before future drug use.

Results

The study included 84 patients (49 females, 35 males), with a female-to-male ratio of 1.4:1. The mean age was 32.2 years, ranging from 3 to 71 years. (Table-1)

Associated symptoms such as fever, pain, itching, and swelling were reported in 77 patients (91.7%), with itching being the most frequently observed, present in 55 patients (65.5%) (Table-2). A prior history of drug reactions was noted in 22 patients (26.2%).

Fixed drug eruption (FDE) was the most common clinical pattern of CADRs, observed in 25% of patients, followed by maculopapular eruptions (11.9%) and drug-induced urticaria (9.5%) (Figures-1–3). Less frequent presentations included acneiform eruptions, pigmentary changes, angioedema, and severe reactions such as SJS-TEN (Table-3).

Table-1: *Age and sex distribution of patients*

Age (in years)	Female	Male	Total patients	Percentage of total patients (%)
<10	3	3	6	7.1
10-20	4	2	6	7.1
21-30	18	15	33	39.3
31-40	8	6	14	16.7
41-50	6	4	10	11.9
51-60	6	2	8	9.6
>60	4	3	7	8.3
Total	49	35	84	100

Table-2: *Basic parameters of CADRs among study participants*

Category	Subcategory	Frequency	Percentage
Extent of lesions	Generalized	46	54.8
	Localized	38	45.2
Naranjo algorithm	Definite	8	9.5
	Probable	64	76.2
	Possible	12	14.3
Symptoms	Fever	15	17.9
	Itching	55	65.5
	Pain	10	11.9
	Swelling	5	6

Table-3: *Frequency of distribution of cutaneous adverse drug reaction patterns*

Cutaneous adverse drug reaction	Frequency	Percentage
Fixed drug eruption	21	25
Maculopapular eruption	10	11.9
Drug induced urticaria	8	9.5
Acneiform eruption	7	8.3
Pigmentary changes	7	8.3
Angioedema	6	7.1
SJS-TEN	5	6
Photosensitive dermatitis	4	4.8
Lichenoid eruption	3	3.6
Exfoliative dermatitis	3	3.6
Acute generalized exanthematous pustulosis	3	3.6
Drug induced hypersensitivity syndrome	3	3.6
Erythema multiforme	2	2.3
Cutaneous ulceration	1	1.2
Drug induced hypertrichosis	1	1.2
Total	84	100

SJS- Stevens-Johnson Syndrome, TEN- Toxic Epidermal Necrolysis

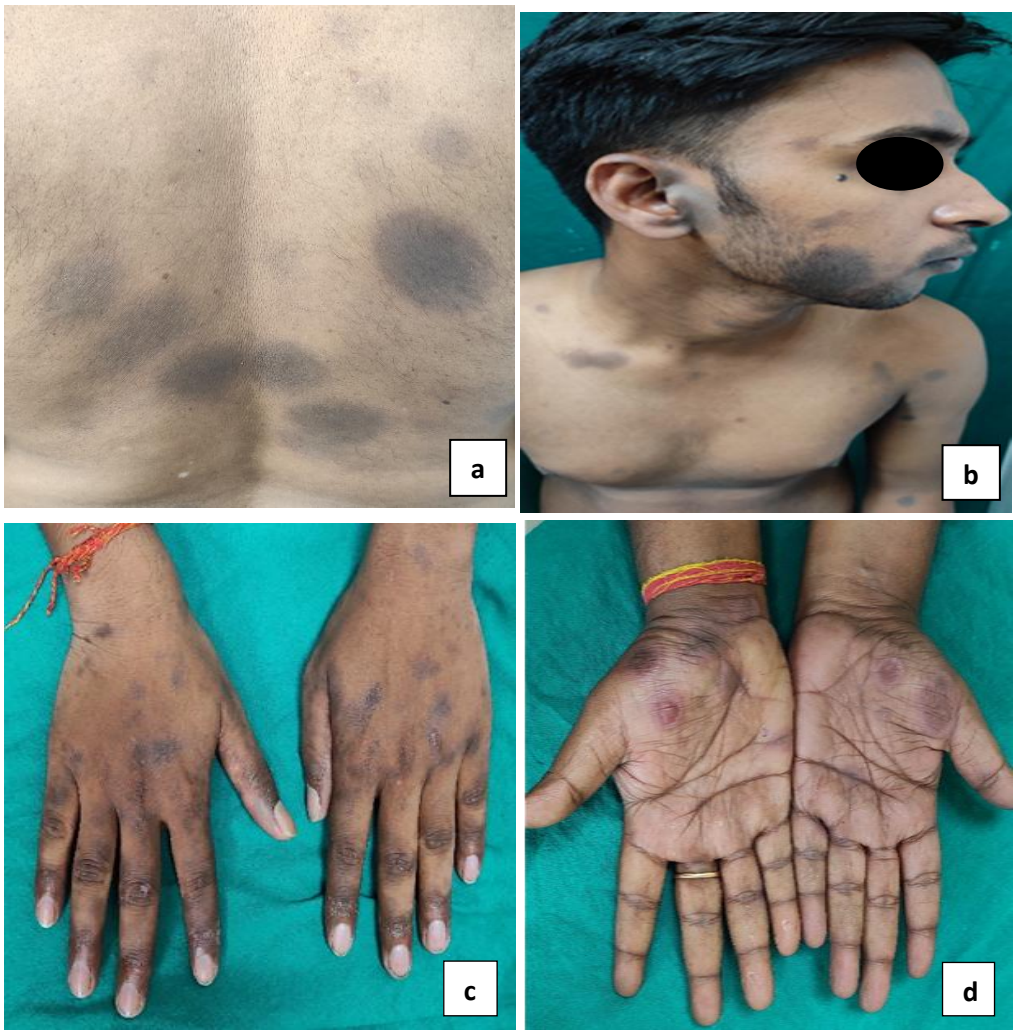

Figure-1: *Fixed drug eruption secondary to metronidazole.*

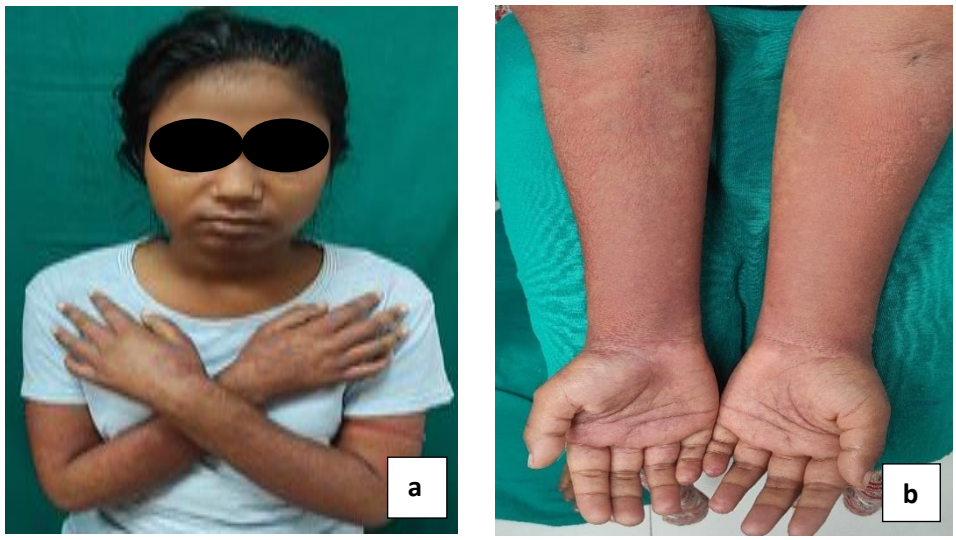

Figure-2: *Maculopapular eruption secondary to amoxicillin.*

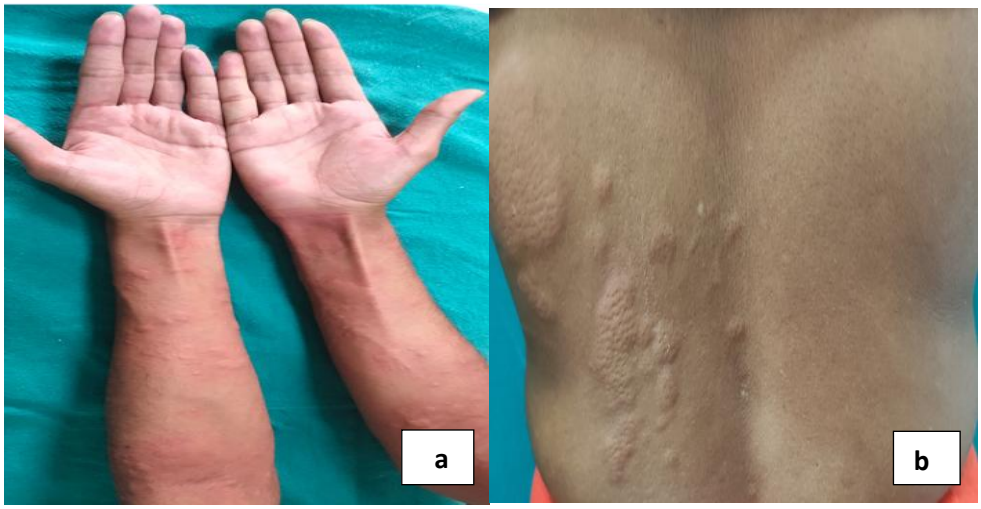

Figure-3: *Urticaria secondary to co-trimoxazole.*

Antimicrobials were the most commonly implicated drug class in CADRs (57.2%), followed by NSAIDs (13.1%) and antiepileptics (11.9%) (Table-4).

Table-4: *Distribution of various drugs causing CADRs*

Class of drugs Causing CADR	Number of patients	Percentage (%)
Antibiotic	34	40.48
Antifungal	5	5.95
Antitubercular	9	10.71
Antigout	2	2.38
Antiepileptic	10	11.9
Analgesic	11	13.1
Oral contraceptive	2	2.38
Corticosteroid	3	3.57
Immunosuppressant	5	5.95
Antihypertensive	2	2.38
Anticancer	1	1.19
Total	84	100

Among antimicrobials, beta-lactams (41.7%) and fluoroquinolones (22.9%) were most frequently involved. FDEswere primarily caused by fluoroquinolone–nitroimidazole combinations (33.3%), fluoroquinolones alone (28.6%), NSAIDs (14.3%), and sulphonamides (9.5%). Significant associations were observed for fluoroquinolones and NSAIDs (Chi-square = 11.42, $p < 0.01$).

Maculopapular eruptions were primarily associated with beta-lactams (40%), NSAIDs (20%), and antiepileptics (10%), all showing statistically significant associations (Chi-square = 10.37, $p < 0.01$). Urticaria was most frequently triggered by NSAIDs (37.5%), beta-lactams (25%), and sulphonamides (12.5%), with NSAIDs showing a significant association (Chi-square = 9.15, $p < 0.05$).

Rare cases included two instances of generalized bullous fixed drug eruption (GBFDE), attributed to allopurinol and naproxen; one paediatric case of cyclosporine-induced reversible hypertrichosis in a patient with psoriasis; and one elderly patient who developed methotrexate-induced cutaneous ulceration while concurrently using NSAIDs (Figures-4 and -5).

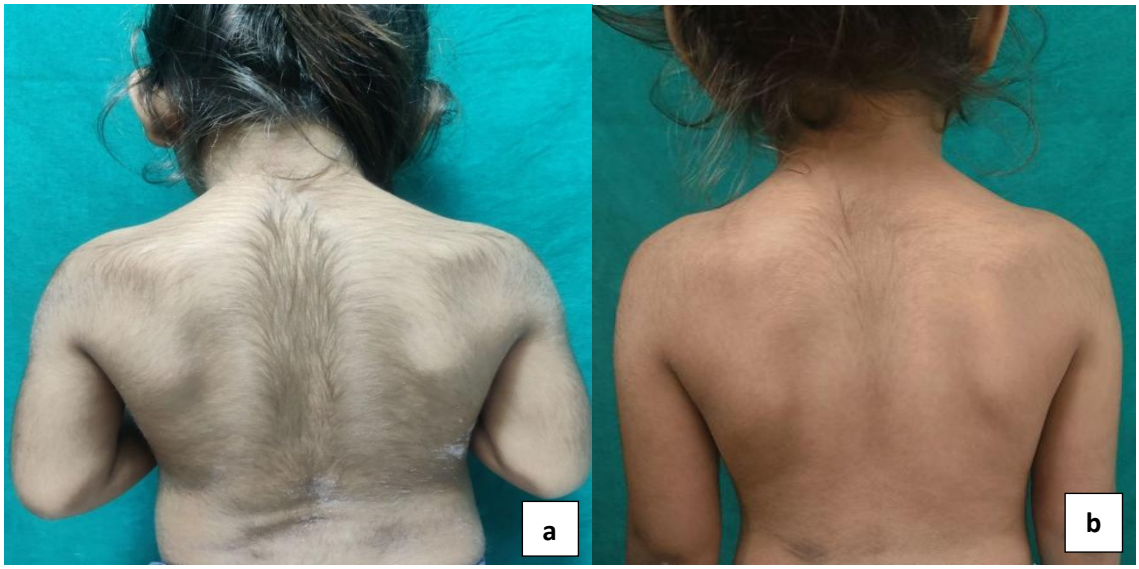

Figure-4: *Hypertrichosis secondary to cyclosporine in a paediatric psoriasis patient that reversed on stopping cyclosporine.*

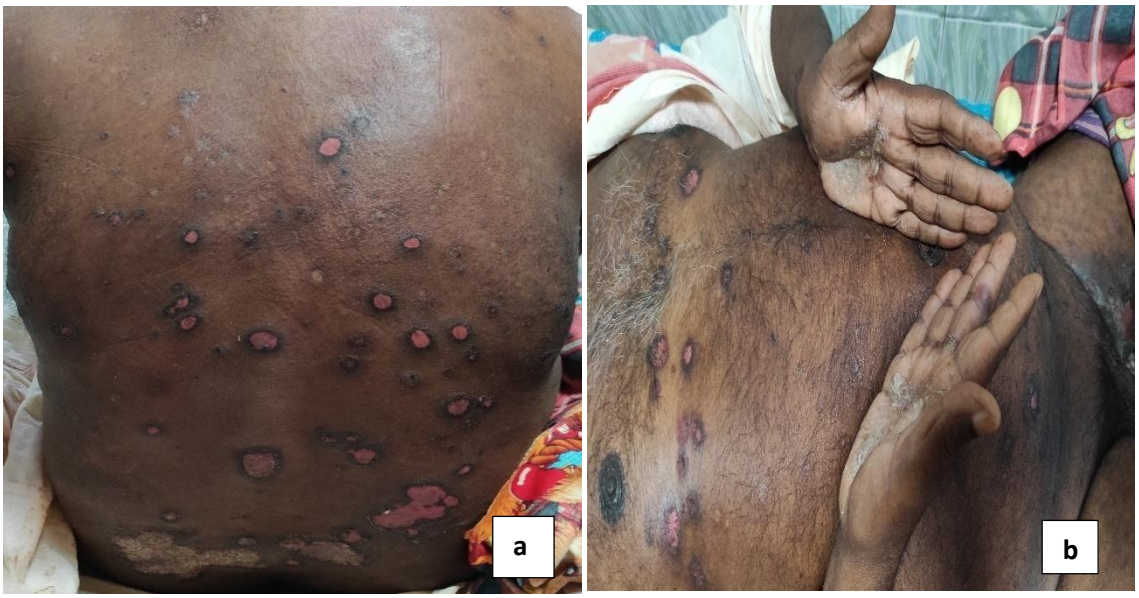

Figure-5: *Methotrexate induced mucocutaneous ulceration in a chronic plaque psoriasis patient.*

Severe cutaneous adverse reactions (SCARs) accounted for 17.86% of all CADRs, with SJS-TEN being the most common presentation (33.34%), followed by exfoliative dermatitis, AGEP, DRESS, and GBFDE (Figures-6–8). Anticonvulsants were the leading causative group (53.4%), with phenytoin implicated in 6 of 15 cases, followed by antimicrobials. The female-to-male ratio among SCAR cases was 1.5:1. Ophthalmic complications were observed in six patients, and one case of SCAR resulted in death due to sepsis.

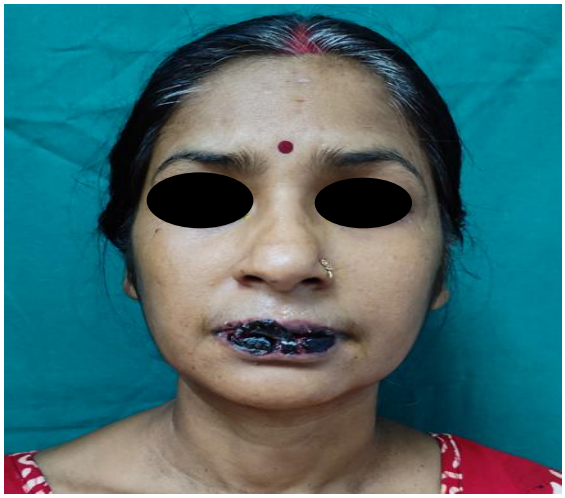

Figure-6: *Stevens- Johnson syndrome (SJS) in a patient secondary to cotrimoxazole.*

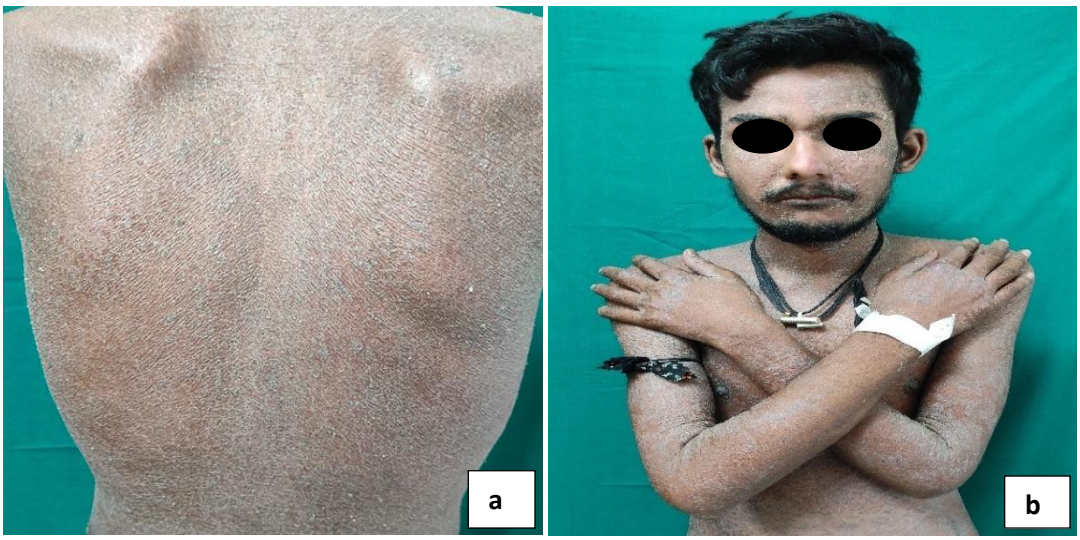

Figure-7: *Erythroderma secondary to phenytoin.*

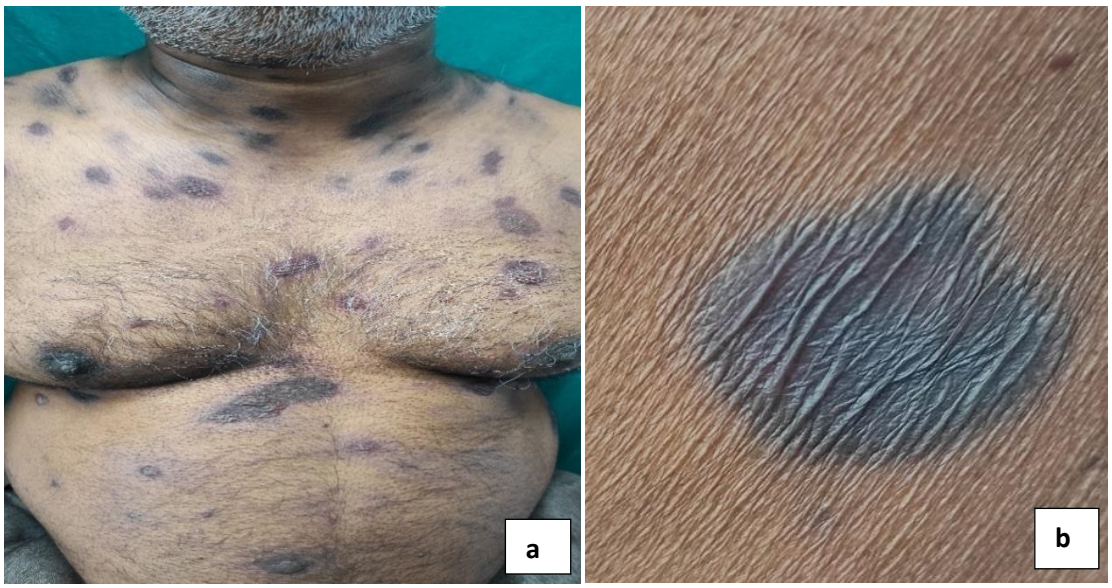

Figure-8: *Generalized bullous fixed drug eruption secondary to naproxen.*

Cutaneous involvement alone was observed in 48.8% of patients, while 51.2% exhibited both cutaneous and mucosal involvement. Among cases with mucosal involvement, the genital area was most commonly affected (46.5%), followed by oral cavity (32.5%) and both sites (20.9%). Most CADRs were associated with drugs prescribed for upper respiratory infections and fever (35.7%), diarrhoea (30.9%), and seizure disorders (26.2%).

Table-5: *Distribution of patients according to Dermatology Life Quality Index (DLQI) scores*

DLQI Score interpretation	No of patients	Percentage
No effect (0-1)	3	3.6
Small effect (2-5)	26	30.9
Moderate effect (6-10)	40	47.6
Very large effect (11-20)	11	13.1
Extremely large effect (21-30)	4	4.8

Using the Naranjo algorithm, causality was classified as probable in 76.2% of cases, possible in 14.3%, and definite in 9.5%.

The DLQI revealed a considerable impact on quality of life, with the domains of symptoms and feelings, daily activities, and leisure most affected (71.4%). (Table-5) Notably, 10.7% of patients reported significant distress related to the withdrawal of essential medications. Patients with generalized lesions had significantly higher DLQI scores than those with localized involvement ($p < 0.05$). Higher DLQI scores were also correlated with stronger drug-reaction causality ($p < 0.05$). SCARs, particularly SJS-TEN, had the greatest impact on quality of life ($p < 0.001$) (Table-6).

Table-6: *Association of DLQI with various parameters*

Variable	Subgroup (n)	Median DLQI	P-value	Interpretation
Extent of Lesions	Generalized (n = 46)	13	<0.01*	Generalized lesions were associated with significantly higher DLQI scores.
	Localized (n = 38)	6		
Symptoms	Itching (n = 55)	10	<0.001*	Presence of itching led to significantly greater QoL impairment.
	No Itching (n = 29)	4		
Drug Causality (Naranjo Algorithm)	Definite (n = 8)	14	<0.05**	Stronger drug causality correlated with higher DLQI (Definite > Probable > Possible).
	Probable (n = 64)	9		
	Possible (n = 12)	5		
Type of CADR	SJS-TEN (n = 5)	25	<0.001**	Severe CADRs (SJS-TEN, AGEP) had extremely high DLQI scores (range 21–30).
	Fixed Eruption (n = 21)	8		
	Maculopapular (n = 10)	6		

*Mann-Whitney U test, Kruskal-Wallis**; SJS- Stevens-Johnson Syndrome, TEN- Toxic Epidermal Necrolysis*

Discussion

This study found FDE to be the most common cutaneous adverse drug reaction (25%), followed by maculopapular rash (11.9%) and urticaria (9.5%). Antimicrobials were the leading causative group (57.2%), primarily beta-lactams and fluoroquinolones. SCARs comprised 17.86% of cases. DLQI scores indicated a moderate to severe impact on quality of life in the majority of patients (65.5%).

In this study, a slight female predominance (F:M = 1.4:1) was observed, which aligns with the findings of Padukadan and Thappa [11]. However, in contrast, Jha et al. [12] reported a male preponderance in their study. Rademaker [13], however, found that female patients have a 1.5 to 1.7-fold increased risk of developing an ADR compared to male patients. While the reasons for this increased risk are not fully understood, several factors may contribute, including differences in pharmacokinetics, immune responses, hormonal influences, and medication utilization patterns between genders [13, 14]. For example, females tend to have a higher body fat percentage, smaller organ sizes, and lower glomerular filtration rates, all of which can impact the pharmacodynamics and pharmacokinetics of drugs [15].

The largest proportion of patients (39.3%) in this study was in the 21–30-year age group, which is consistent with findings from previous studies by Sharma et al. [15] and Sinha et al. [16]. This trend may be attributed to the fact that drug reactions are more common in the middle-aged population, which also coincides with the significant proportion of the Indian population within this age group and likely reflects greater healthcare access and medication use among young adults.

The findings of this studyalign closely with previous studies conducted in India. Padukadan and Thappa [11] also reported FDE as the most common CADR (31.1%), followed by maculopapular rash (12.2%). Similarly, Sharma et al. [15] and Sinha et al. [16] documented FDE as the predominant pattern (33.3% and 48.61%, respectively). This suggests a consistent pattern in Indian populations, possibly due to high over-the-counter availability and frequent self-medication with antimicrobials and NSAIDs.

In this study, 57.2% of the total reactions were attributed to antimicrobials, followed by NSAIDs (13.1%) and anticonvulsants (11.9%). These findings are concordant with those reported by Patel et al., Sharma et al., Sinha et al., and Nandha et al. [6,15,16,17]. Easy access to antibiotics without prescription and widespread empirical antibiotic use in India could explain the higher incidence of antimicrobial-induced CADRs. In contrast, Noel et al. [18] found antiepileptics to be the most common offending drug, while Al-Raaie et al. [19] identified NSAIDs as the leading cause. These variations may be explained by differences in drug prescribing and usage patterns across different populations.

Among antimicrobials, beta-lactams were the most commonly implicated, accounting for 41.7% of cases, followed by fluoroquinolones (22.9%), sulpha drugs (12.5%), and nitroimidazoles (10.4%). Among NSAIDs, ibuprofen was the most frequently involved (45.3%), followed by diclofenac (26.7%) and naproxen (22.4%). Other drugs identified included acetaminophen, indomethacin, and mefenamic acid. Phenytoin (57%) was the most implicated anticonvulsant, followed by carbamazepine, which is consistent with findings by Sinha et al. and Sudharani et al. [16,20]

Among the FDE cases, fluoroquinolone-imidazole combination drugs, commonly used for gastrointestinal infections were the most commonly implicated, followed by fluoroquinolones, which aligns with the findings of Sinha et al. [16]. In contrast, earlier studies by Patel et al. [6] and Padukadan and Thappa [11] identified cotrimoxazole as the most implicated drug. The shift in the pattern of drug-related FDE cases may be attributed to changing prescription trends and the widespread over the counter (OTC) use of fluoroquinolones.

Maculopapular rashes were primarily associated with beta-lactam antibiotics, especially amoxicillin, followed by NSAIDs and anticonvulsants. This is consistent with Sharma et al. [15] and likely reflects the extensive use of amoxicillin in both hospital and outpatient settings.

In this study, SCARs accounted for 17.86% of the cases, which is concordant with the findings of Sinha et al. [16] (25%) and Sasidharanpillai et al.

[21] (13.20%), but contrasts with Patel et al.'s study [6] (8.17%). The higher prevalence of SCARs in the current study may reflect differences in regional prescribing practices, genetic susceptibility, or comorbid conditions of the population studied.

The finding that anticonvulsants were the predominant drug class implicated in SCARs concurs with multiple prior studies [6,15,19]. This association can be explained by the unique pharmacokinetic and immunological properties of these agents. Anticonvulsants such as phenytoin, carbamazepine, and lamotrigine are well-known triggers of severe hypersensitivity reactions like SJS-TEN, primarily mediated through T-cell activation. Genetic susceptibility further modulates this risk, with specific alleles such as HLA-B*1502 strongly linked to carbamazepine-induced SJS-TEN, particularly in Southeast Asian and Indian populations [22]. Healthcare providers should, therefore, monitor patients closely when prescribing anticonvulsants, especially in populationat increased risk.

Although studies on the impact of CADRs on quality of life (QOL) are limited, existing studies consistently demonstrate that these reactions significantly impair patients' well-being. CADRs often cause discomfort, distress, and social embarrassment, leading to profound effects on both physical and emotional health [23,24]. In this study, symptoms and feelings, daily activities, and leisure were the most affected domains, with 71.4% of patients reporting significant impact. This highlights that CADRs extend beyond physical health, deeply influencing emotional well-being and social interactions. Furthermore, a significant association was found between DLQI scores and drug-reaction causality. Reactions that were more likely to be caused by a specific drug tended to cause greater concern or distress. This may be due to more severe symptoms or the need to stop essential medications. Severe cutaneous adverse reactions (SCARs), particularly Stevens–Johnson syndrome and toxic epidermal necrolysis (SJS-TEN), were associated with the greatest reduction in quality of life. These findings are not unexpected, given the life-threatening nature and long-term sequelae of these reactions.

Additionally, 10.7% of patients experienced significant psychological distress following the withdrawal of the offending drug, particularly when the drug was essential for managing chronic conditions. The anxiety related to discontinuing critical medication illustrates the complex relationship between physical and mental health challenges in managing CADRs. This emphasizes the importance for healthcare providers to address both the physical symptoms and psychological effects, implementing comprehensive care strategies that support the holistic well-being of patients.

The management of CADRs primarily focuses on supportive care, which includes the immediate withdrawal of the offending drugs. For alleviating pruritus, antihistamines, mild topical steroids, and moisturizing lotions are commonly prescribed. In more severe cases, systemic treatments such as steroids, cyclosporine, and immunoglobulins may be required. SCARs, including SJS, TEN, erythroderma, and DRESS, often necessitate hospitalization due to their severity. In this study, the suspected drugs were withdrawn in 95.87% of the cases, highlighting the importance of promptly discontinuing the causative agent to prevent further complications.

Regional variations observed in causative drugs underscore the need for localized pharmacovigilance data. Establishing institutional ADR reporting systems and contributing to national pharmacovigilance programs will strengthen collective efforts toward safer medication practices

Limitations

This study was limited by the absence of confirmatory in-vitro tests (e.g., lymphocyte transformation and patch tests) due to resource constraints. Furthermore, the relatively small sample size and single-centred, observational nature of the study may limit the generalizability of findings. Recall bias regarding drug history is another potential limitation.

Conclusion

CADRs range from mild rashes to severe, life-threatening conditions. In the absence of definitive diagnostic tools, clinical vigilance and early recognition of cutaneous patterns are critical. A

thorough drug history and cautious prescribing, especially in high-risk individuals are essential, along with minimizing the use of unnecessary medications. Patient education on the dangers of self-medication and over-the-counter drug use is crucial. Given the significant psychological and quality-of-life impact of CADRs, empathetic counselling and holistic care are necessary. Strengthening pharmacovigilance through timely reporting and adopting a multidisciplinary approach can enhance drug safety and help reduce the burden of CADRs.

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