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Research Article

Incidence, Causality, Severity, and Preventability of Cutaneous Adverse Drug Reactions in a Tertiary Care Teaching Hospital in South India: A Prospective Observational Study

Chodipalli Kodandara¹, Ruchi Gupta², L. N. Patidar³, Siddela Johnson¹, Arbaz Khan⁴,
Soma Sekhar Pulamarasetti^{3*}

¹AU College of Pharmaceutical Sciences (AUCOPS), Andhra University, Visakhapatnam, Andhra Pradesh, India

²Faculty of Life Sciences, Mandsaur University, Mandsaur, Madhya Pradesh, India

³Department/Faculty of Pharmacy, B. R. Nahata College of Pharmacy, Mandsaur University, Mandsaur, Madhya Pradesh, India – 458001

⁴B. R. Nahata College of Pharmacy & Contract Research Center, Bhunyakhedhi, Mandsaur, Madhya Pradesh, India

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ABSTRACT

Background: Cutaneous adverse drug reactions (ACDRs) are the most frequently reported form of drug-induced injury, yet spontaneous reporting captures only a small fraction of cases in India relative to high-income settings. Data from tertiary dermatology units remain limited.

Methods: A hospital-based, prospective, observational study was conducted over 12 months (December 2023–December 2024) in the outpatient and inpatient wards of the Department of Dermatology, Venereology and Leprosy at King George Hospital, Visakhapatnam. Patients above 18 years receiving at least one allopathic drug were enrolled after informed consent. Causality was assessed with the WHO-UMC scale and Naranjo's algorithm, severity with the Hartwig and Siegel scale, and preventability with the Schumock and Thornton criteria.

Results: Seventy-one ACDRs were documented in 71 patients. Men accounted for 43 cases (60.6%) and women for 28 (39.4%); reactions were most frequent in the 31–40-year age band (21 cases, 29.6%). Oral drugs accounted for 49 reactions (69.0%), followed by intravenous (18, 25.4%), intramuscular (3, 4.2%) and topical (1, 1.4%) agents. Diclofenac (n=5), piperacillin-tazobactam (n=4) and methotrexate (n=4) were the most frequently implicated individual agents; by class, NSAIDs (19, 26.8%) and antibiotics (15, 21.1%) predominated. The WHO-UMC scale classified 55 reactions (77.5%) as probable and 15 (21.1%) as possible; Naranjo's algorithm classified 53 (74.6%) as probable. Under the Hartwig-Siegel scale, 30 reactions (42.3%) required hospitalization and 3 (4.2%) were life-threatening; 53 (74.6%) were judged definitely preventable under the Schumock-Thornton criteria. All 71 patients recovered fully, with no fatalities.

Conclusion: NSAIDs and antimicrobial agents administered orally were the leading causes of ACDRs in this cohort, and three in four reactions were judged preventable. Structured causality, severity and preventability assessment at the bedside, paired with closer prescribing oversight for these two drug classes, could meaningfully reduce the burden of drug-induced skin injury in similar tertiary-care settings.

***Corresponding Author:** Soma Sekhar Pulamarasetti

Address: Assistant Professor/Faculty, Department of Pharmacy, B. R. Nahata College of Pharmacy, Mandsaur University, Madhya Pradesh, India

Email ✉: dr.somasekhar@gmail.com

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INTRODUCTION

Adverse drug reactions (ADRs) are defined by the World Health Organization as responses to a medicinal product that are noxious and unintended and that occur at doses normally used for prophylaxis, diagnosis or therapy [1]. ADRs are a significant cause of morbidity in hospitalized patients [2], and among the organ systems affected, the skin is involved more often than any other: cutaneous signs are frequently the first, and sometimes the only, clinical clue that a medicine has turned harmful. Reactions of this kind, termed adverse cutaneous drug reactions (ACDRs), span a wide clinical range, from a self-limiting morbilliform rash or fixed drug eruption to fulminant, life-threatening presentations such as Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN) [3].

The true burden of ACDRs is difficult to establish because spontaneous reporting systems capture only a fraction of cases: India contributes a strikingly small share of the adverse-event reports logged globally relative to the size of its pharmaceutical market and patient population, a gap attributed less to a lower true incidence of reactions than to inconsistent recognition and documentation by prescribers [4]. The reactions themselves are not rare. Hospital-based studies in India have repeatedly found antimicrobials, non-steroidal anti-inflammatory drugs (NSAIDs) and antiepileptics to be the dominant causes of ACDRs, with fixed drug eruption, maculopapular rash and urticaria as the most common presentations [5]. What individual departments more often lack is the routine, prospective application of causality, severity and preventability instruments that would let them compare their own drug-safety profile against this literature and act on it.

Several validated instruments exist for this purpose. The WHO-Uppsala Monitoring Centre (WHO-UMC) scale [6] and Naranjo's Adverse Drug Reaction Probability Scale [7] independently estimate the likelihood that a given drug caused a given reaction; the Hartwig and Siegel scale grades the clinical severity of a confirmed reaction [8]; and the Schumock and Thornton criteria classify how far a reaction could have been avoided with more careful prescribing or monitoring [9]. Applied prospectively rather than reconstructed from records afterward, these four scales together turn a case series into something a department can act on: evidence for formulary review, prescriber feedback, or targeted monitoring of specific drug classes.

King George Hospital, Visakhapatnam, is a high-volume tertiary referral centre whose Department of Dermatology, Venereology and Leprosy sees a broad cross-section of both outpatient and inpatient drug-related skin disease, yet no prospective causality-graded account of its own ACDR profile existed before this work. We therefore undertook a 12-month prospective observational study to identify, assess and document ACDRs among patients attending this

department, with the specific aims of characterising the causative drugs and drug classes involved and of grading each reaction for causality, severity and preventability using the four instruments above.

Materials and Methods

Study design, setting and duration

This was a hospital-based, prospective, observational study conducted in the outpatient and inpatient wards of the Department of Dermatology, Venereology and Leprosy (DVL), Andhra Medical College, King George Hospital (KGH), Visakhapatnam, Andhra Pradesh, India. Data collection ran for 12 months, from 1 December 2023 to 1 December 2024. Ethical approval was obtained from the Institutional Ethics Committee, King George Hospital (Reg. No. ECR/197/Inst/KGH/2013/RR-20; Protocol No. AU/AUCoPS/M.Pharm/MPP/2022-2024/09), approved at the committee meeting of 12 July 2024, and the study was carried out in accordance with ICH-GCP guidelines and the ICMR ethical guidelines for biomedical research on human participants.

Study population

Inclusion criteria

Patients of either sex, above 18 years of age, presenting as outpatients or admitted to the inpatient wards of the DVL department, and receiving at least one allopathic drug, were eligible for enrolment after providing written informed consent.

Exclusion criteria

Infants, patients with a known mental illness precluding informed consent, and any patient not meeting the inclusion criteria above were excluded.

Data collection procedure

A structured ADR data-collection form, modelled on the Central Drugs Standard Control Organization (CDSCO) ADR reporting form, was used to capture patient demographics, presenting complaints, past medication history, current drug therapy (including over-the-counter and herbal preparations where volunteered), and relevant laboratory investigations. Information was gathered from treating physicians, nursing staff, patient case sheets and medical records. Every suspected reaction was captured through active, spontaneous case-finding by the study team embedded in the department rather than through retrospective chart review.

Assessment scales

Each confirmed ACDR was independently graded on four instruments:

- Causality was assessed using both the WHO-UMC causality assessment scale (categories: certain, probable/likely, possible, unlikely, conditional/

unclassified, unassessable/unclassifiable) [6] and the Naranjo Adverse Drug Reaction Probability Scale [7], which assigns a numerical score corresponding to definite (≥ 9), probable (5–8), possible (1–4) or doubtful (≤ 0) causation.

- Severity was graded using the Hartwig and Siegel severity assessment scale [8], which ranks reactions from level 1 (no change in treatment required) through level 7 (contributed to death).
- Preventability was assessed using the Schumock and Thornton preventability assessment scale [9], which classifies each reaction as definitely preventable, probably preventable, or not preventable based on responses to a structured questionnaire covering dosing appropriateness, monitoring, drug history and prior hypersensitivity.

Data analysis

Data were entered into a Microsoft Excel worksheet and summarised as frequencies and percentages for categorical variables (demographic characteristics, implicated drugs and drug classes, route of administration, causality, severity, preventability and clinical outcome). Results are presented as tables and figures; no inferential statistical testing was pre-specified given the descriptive aim of the study.

Termination of the study

The principal investigator reserved the right to discontinue a participant's involvement for safety reasons, with reasons communicated to the participant, and the Institutional Ethics Committee retained authority to terminate the study in the event of a major protocol deviation.

RESULTS

Overall incidence and demographic distribution

Seventy-one ACDRs were documented over the 12-month study period. Thirty reactions (42.3%) occurred among inpatients (9 female, 21 male) and 41 (57.7%) among outpatients (19 female, 22 male) (Table 1). Men accounted for 43 of the 71 reactions (60.6%) and women for 28 (39.4%), a pattern consistent across both care settings. Reactions clustered in early-to-mid adulthood: the 31–40-year band contributed the largest share (21 cases, 29.6%), closely followed by the 41–50-year band (20 cases, 28.2%). Together, patients between 18 and 60 years accounted for 64 of the 71 reactions (90.1%), while only 7 (9.9%) occurred beyond age 60, and none in patients over 80 (Figure 1, Table 2).

Drugs and drug classes implicated

Forty-seven distinct drugs or fixed-dose drug combinations were identified as the suspected trigger across the 71 reactions (Table 3). Diclofenac was the single most frequently implicated agent (5 cases), followed by piperacillin-tazobactam and methotrexate (4 cases each),

Table 1: In-patient and out-patient distribution of ACDRs by gender (N = 71)

Gender	Total, n (%)	In-patients, n	Out-patients, n
Female	28 (39.4%)	9	19
Male	43 (60.6%)	21	22
Total	71 (100%)	30	41

Percentages are column totals as a proportion of all 71 reactions.

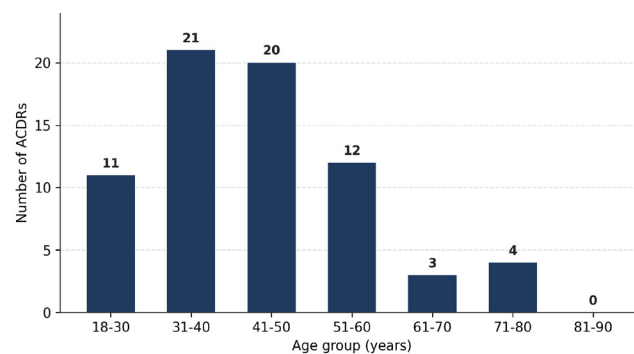


Figure 1: Age-wise distribution of cutaneous adverse drug reactions (N = 71).

Table 2: Age-wise distribution of ACDRs (N = 71)

Age group (years)	Number of ACDRs	Percentage
18–30	11	15.5%
31–40	21	29.6%
41–50	20	28.2%
51–60	12	16.9%
61–70	3	4.2%
71–80	4	5.6%
81–90	0	0.0%
Total	71	100.0%

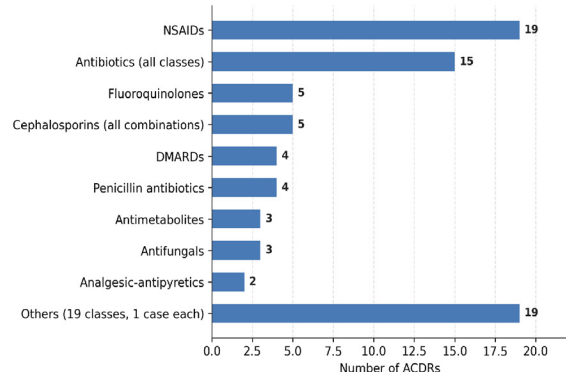
and piroxicam, aceclofenac, amoxicillin and levofloxacin (3 cases each). A further 34 drugs or combinations were each responsible for one or two reactions.

Grouped by pharmacological class (Table 4, Figure 2), NSAIDs accounted for the largest share of reactions (19, 26.8%), followed by antibiotics (15, 21.1%). Disease-modifying antirheumatic drugs (DMARDs, principally methotrexate and leflunomide) accounted for 4 reactions (5.6%), and antifungal agents 3 (4.2%). The remaining reactions were distributed across a further 24 drug classes, most implicated in only a single case each, reflecting the wide range of therapeutic agents in use across the departments referring to dermatology.

Three of the four methotrexate-related reactions were classified as drug toxicity rather than a hypersensitivity-type eruption, presenting with mucocutaneous ulceration, oral lesions and constitutional symptoms (fever, vomiting) consistent with antifolate toxicity. One reaction (a case of SJS-TEN overlap following an injectable diclofenac-vitamin B combination product) was the most severe presentation recorded in the series and was independently graded as “certain” on both the WHO-UMC and Naranjo scales.

Table 3: Drug-wise distribution of cutaneous adverse drug reactions (agents implicated in ≥ 2 cases shown individually, N = 71)

Drug / combination	Dose	Route	No. of ACDRs
Diclofenac	50–100 mg	Oral	5
Piperacillin + Tazobactam	4.5 g	IV	4
Methotrexate	7.5–10 mg	Oral	4
Piroxicam	20 mg	Oral	3
Aceclofenac	100 mg	Oral	3
Amoxicillin	500 mg	Oral	3
Levofloxacin	250 mg	Oral	3
Fluconazole	150 mg	Oral	2
Ofloxacin	200 mg	Oral	2
Ceftriaxone ($\pm$ phenytoin)	1–2 g	IV	2
Diclofenac sodium (injectable)	75 mg	IV/IM	2
Paracetamol (injectable)	1 g	IV	2
Cefotaxime sodium	1 g	IV	2
34 other individual agents / combinations (1–2 cases each)	—	Mixed	34
Total			71

**Figure 2:** Drug classes implicated in cutaneous adverse drug reactions (N = 71)

Route of administration

Oral formulations accounted for the large majority of implicated drugs (49 reactions, 69.0%), followed by the intravenous route (18, 25.4%). Intramuscular and topical preparations were responsible for 3 (4.2%) and 1 (1.4%) reactions, respectively (Table 5, Figure 5).

Causality assessment

On the WHO-UMC scale, 55 reactions (77.5%) were classified as probable, 15 (21.1%) as possible, and 1 (1.4%) as certain; no reaction was classified as unlikely, conditional or unassessable. Probable causality

Table 4: Drug classes implicated in cutaneous adverse drug reactions (N = 71)

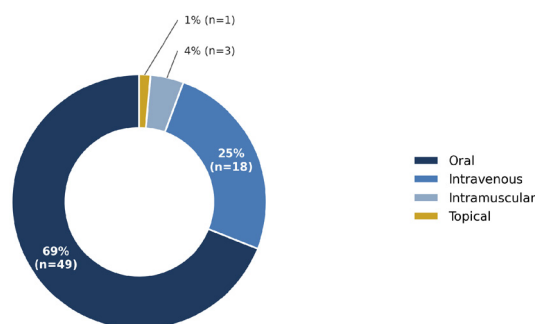
Drug class	No. of ACDRs	% of reactions
NSAIDs	19	26.8%
Antibiotics (aggregate)	15	21.1%
Fluoroquinolones	5	7.0%
Cephalosporin $\pm$ antiepileptic / antibiotic combinations	5	7.0%
Penicillin antibiotics	4	5.6%
DMARDs	4	5.6%
Antimetabolites	3	4.2%
Antifungals	3	4.2%
Analgesic-antipyretics	2	2.8%
Anticonvulsants / antiepileptics	2	2.8%
Proton pump inhibitor	1	1.4%
Phosphodiesterase-5 inhibitor	1	1.4%
Tetracycline antibiotic	1	1.4%
Vasodilator	1	1.4%
Antimalarial (aminoquinoline)	1	1.4%
β -lactamase inhibitor	1	1.4%
Quinolone antibiotic (non-fluoro)	1	1.4%
Alkylating agent	1	1.4%
Antituberculosis agents	1	1.4%
Iron replacement therapy	1	1.4%
Neuromuscular blocking agents	1	1.4%
Muscle relaxant	1	1.4%
Antipyretic	1	1.4%
Antimicrotubular agent	1	1.4%
Potassium channel activator	1	1.4%
Topical corticosteroid	1	1.4%
Aminoglycoside antibiotic	1	1.4%
Tyrosine kinase inhibitor	1	1.4%
Antihistamine	1	1.4%
Thrombolytic (fibrinolytic) agent	1	1.4%

Because a small number of reactions involved fixed-dose combination products or co-suspected agents spanning more than one pharmacological category, and because named antibacterial sub-classes are also captured within the aggregate "Antibiotics" row, class totals sum to slightly more than the case total and should be read as the number of reactions in which that class was implicated rather than as fully mutually exclusive categories.

predominated in both sexes (37 of the male reactions and 18 of the female reactions), with possible causality accounting for most of the remainder in each group (7 male, 8 female).

Table 5: Route of administration of drugs implicated in ACDRs (N = 71)

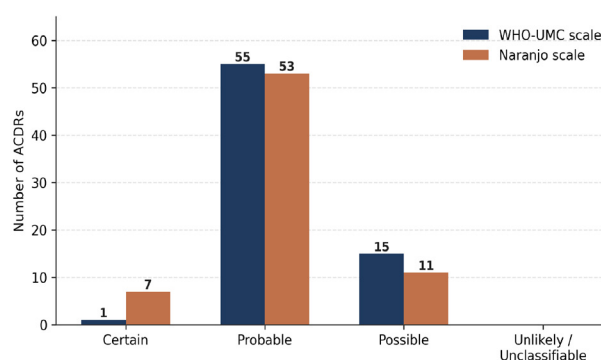
Route of administration	No. of ACDRs	Percentage
Oral	49	69.0%
Intravenous	18	25.4%
Intramuscular	3	4.2%
Topical	1	1.4%
Total	71	100.0%

**Figure 5:** Route of administration of drugs implicated in ACDRs (N = 71)

Naranjo's algorithm classified a broadly similar profile, with 53 reactions (74.6%) probable, 11 (15.5%) possible and 7 (9.9%) certain (Table 6, Figure 3). The higher proportion of "certain" ratings under the Naranjo algorithm relative to WHO-UMC (7 vs 1) reflects the additional weight the Naranjo instrument places on objective rechallenge and dechallenge information, which was available for a small number of reactions, including the SJS-TEN overlap case and several fixed drug eruptions with a documented history of prior reaction to the same agent.

Severity and preventability

Under the Hartwig and Siegel scale, 30 reactions (42.3%) were severe enough to necessitate hospitalization, 20 (28.2%) were moderate, 18 (25.4%) mild, and 3 (4.2%) life-threatening; there were no fatalities (Table 7, Figure 4A). Preventability assessment using the Schumock and Thornton criteria classified 53 reactions (74.6%) as

**Figure 3:** Causality assessment of ACDRs: WHO-UMC scale vs Naranjo scale (N = 71)

definitely preventable and 18 (25.4%) as probably preventable; no reaction was judged non-preventable (Table 7, Figure 4B). Definitely preventable reactions were more frequent among men (33/43, 76.7%) than women (20/28, 71.4%), broadly proportionate to the overall gender split in the cohort.

Clinical outcome

All 71 patients recovered fully from their reaction with appropriate management, which typically involved withdrawal of the offending drug, symptomatic treatment and, for the more severe reactions, a short course of systemic corticosteroids. No deaths were recorded during the study period.

DISCUSSION

This 12-month prospective study documented 71 ACDRs among patients attending a South Indian tertiary-care dermatology department, with NSAIDs and antimicrobial agents together accounting for roughly half of all reactions, oral administration as the dominant route, and three-quarters of reactions judged preventable under a structured causality and preventability framework. These findings sit close to the pattern reported across Indian tertiary centres over the past decade, and they also point to specific, addressable gaps in prescribing practice at this site.

Table 6: Causality assessment of ACDRs: WHO-UMC scale and Naranjo's algorithm (N = 71)

Causality category	WHO-UMC, n	WHO-UMC, %	Naranjo, n	Naranjo, %
Certain	1	1.4%	7	9.9%
Probable / likely	55	77.5%	53	74.6%
Possible	15	21.1%	11	15.5%
Unlikely / conditional / unassessable	0	0.0%	0	0.0%
Total	71	100.0%	71	100.0%

Gender-wise sub-totals recorded for the WHO-UMC scale in the underlying dataset (44 male- and 27 female-attributed reactions) do not sum exactly to the overall 43/28 gender split reported in Table 1; this minor discrepancy reflects the original data collection and is noted here for transparency. It does not affect the overall totals shown above.

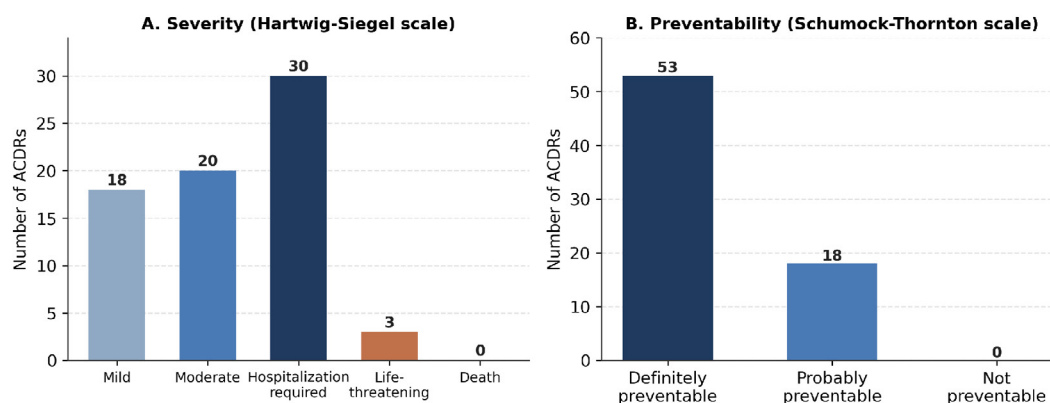


Figure 4: Severity and preventability assessment of ACDRs (N = 71).

Table 7: Severity and preventability assessment of ACDRs (N = 71)

Severity (Hartwig-Siegel scale)	No. of ACDRs	%
Mild	18	25.4%
Moderate	20	28.2%
Hospitalization required	30	42.3%
Life-threatening	3	4.2%
Death	0	0.0%
Total	71	100.0%

Preventability (Schumock-Thornton scale)	No. of ACDRs	%
Definitely preventable	53	74.6%
Probably preventable	18	25.4%
Not preventable	0	0.0%
Total	71	100.0%

Demographic pattern

The predominance of reactions in men (60.6%) and in the 31–50-year age range mirrors several recent Indian series. Ashifha et al., studying 102 patients with ACDRs at a tertiary centre in Srikakulam, Andhra Pradesh, similarly found the third and fourth decades of life most heavily represented [10], and an earlier, larger Gujarat cohort of 200 patients with cutaneous drug eruptions reported the same age concentration alongside a comparable male excess [11]. A comparable age distribution has also been reported from Jammu [12] and North India [13]. This clustering likely reflects exposure rather than biological vulnerability: adults in this age band are the group most often prescribed NSAIDs for musculoskeletal complaints and antimicrobials for infection, the two classes that dominated our own causative-drug list. Where our findings diverge from some other Indian series is in the near-absence of reactions beyond the seventh decade (7/71, 9.9%, from age 61 onward). This more likely reflects lower overall prescribing volumes in this age group at our centre than any protective effect of age itself, and it would benefit from confirmation in a larger, multi-centre sample.

Causative Drugs and Drug Classes

NSAIDs (26.8%) and antibiotics (21.1%) were the two leading drug classes in our cohort, a ranking consistent with the wider Indian literature. Patel and colleagues' systematic review of Indian ACDR studies found antimicrobials (45.5%) and NSAIDs (20.9%) to be the two dominant causative groups nationally [5], and more recent single-centre series from Mumbai [14], Kolkata [15] and a retrospective analysis from a South Indian teaching hospital [16] have reported the same two classes occupying the top positions, even where their relative order varies by setting. Diclofenac's position as the single most frequently implicated individual drug in our series (5/71 cases) is consistent with case-series data specifically describing NSAID-induced fixed drug eruption, in which diclofenac, aceclofenac, piroxicam and naproxen recur as culprit agents across Egyptian and Tunisian cohorts [17,18] as well as an Indian pharmacovigilance case series in which fixed drug eruption accounted for a similar share of the overall ACDR burden [19]. Jadhav et al. likewise identified fixed drug eruption as the most common ACDR type in a prospective Indian teaching-hospital cohort and, using the Naranjo scale, found the majority of reactions to be probably drug-related, a causality profile essentially identical to the one reported here [20].

The methotrexate-related findings merit separate comment. Four of our 71 reactions involved methotrexate, and three of these were toxicity presentations (mucocutaneous ulceration with constitutional symptoms) rather than classical hypersensitivity eruptions. This pattern echoes other recent Indian case series describing methotrexate toxicity presenting first as oral and cutaneous ulceration, often precipitated by dosing errors, most commonly inadvertent daily rather than weekly administration [21,22]. Because methotrexate toxicity is reversible with prompt leucovorin rescue but can be fatal if recognition is delayed, our finding reinforces the case for explicit weekly-dosing counselling and pharmacist-led prescription

verification wherever methotrexate is dispensed from this department.

Route of Administration

The predominance of the oral route (69.0%) in our series is unsurprising given that oral NSAIDs and oral antibiotics were the two leading causative classes, and is consistent with the route distribution reported in comparable Indian cohorts [12,13]. It also carries a practical implication: because oral drugs are frequently self-administered or taken outside directly observed settings, reactions to them may be more prone to delayed recognition than reactions to inpatient intravenous therapy, where a clinician is more likely to be at the bedside when symptoms first appear.

Causality, Severity and Preventability

Probable causality dominated under both the WHO-UMC scale (77.5%) and the Naranjo algorithm (74.6%), a pattern typical of prospective ACDR studies where a clear temporal relationship exists between drug exposure and reaction onset but formal rechallenge is rarely performed for ethical reasons. The modest divergence between the two instruments in the “certain” category (1 case by WHO-UMC versus 7 by Naranjo) is a recognised feature of parallel causality assessment, reflecting differences in how each tool weights a documented history of prior reaction to the same drug; Manjhi and colleagues’ recent review of these assessment instruments notes this same source of inter-scale disagreement and recommends reporting both scales side by side rather than treating either as a gold standard [23], which is the approach we have followed here.

The severity profile (42.3% of reactions requiring hospitalisation, 4.2% life-threatening, no fatalities) sits within the wide range reported for Indian ACDR cohorts, where mortality from cutaneous drug reactions overall has been estimated at under 2%, rising sharply only for severe cutaneous adverse reactions such as SJS/TEN and drug reaction with eosinophilia and systemic symptoms (DRESS), neither of which, beyond the single SJS-TEN overlap case, was seen in this cohort [5,24]. That overlap case, linked to an injectable diclofenac combination product and independently rated “certain” on both causality scales, is consistent with the well-established association between NSAIDs and this class of severe reaction [3].

Three in four reactions (74.6%) were judged definitely preventable, with a further quarter probably preventable, and none judged unpreventable. This is somewhat higher than the pooled preventability figures reported in Patel and colleagues’ systematic review of Indian ACDR data [5], though it is not far out of line with hospital-based series elsewhere that have reported comparably high preventable fractions when preventability criteria are applied prospectively rather than retrospectively; a six-month French hospital survey, for instance, similarly found that a substantial share of cutaneous drug reactions

traced back to avoidable re-exposure or inadequate allergy screening once assessed at the bedside rather than reconstructed from the chart afterward [25]. A plausible explanation for our own high preventable fraction lies in the composition of our causative-drug list: reactions to agents such as diclofenac, aceclofenac and piroxicam frequently involved a history of prior use of the same or a related NSAID, precisely the kind of avoidable re-exposure that the Schumock and Thornton criteria are designed to flag. The more tractable target for intervention at this centre, then, is not drug safety science but documentation: recording and communicating prior drug-reaction history at the point of prescribing.

Strengths and Limitations

The principal strength of this study is its prospective, active case-finding design, conducted by a dedicated study team embedded in the department rather than relying on passive spontaneous reporting or retrospective chart review. Active surveillance of this kind is known to detect a substantially larger share of true ACDR incidence than either alternative [4]. The parallel application of four validated, internationally recognised assessment scales to every case also allows direct comparison with a wide body of published literature.

The study nonetheless has clear limitations. It was conducted at a single centre over 12 months, and the modest sample size ($n = 71$) limits the precision of subgroup estimates, particularly for the less common drug classes each represented by a single case. As an observational study without a denominator of total drug-exposed patients passing through the department, we are unable to report a true incidence rate of ACDRs per prescription or per admission, only an absolute case count. Rechallenge, the single most decisive piece of evidence for drug causality, was performed for very few patients for ethical reasons, which constrains how many reactions could be elevated to “certain” causality under either scale. Finally, the outcome data reflect status at the point of discharge or last follow-up within the study window and do not capture very long-term sequelae such as post-inflammatory pigmentary change, which several patients with fixed drug eruption in this series were noted to have at the time of assessment.

Implications for Practice

These findings support three concrete steps at this and comparable centres. The first is closer scrutiny of NSAID and antimicrobial prescribing in patients with a known or suspected prior cutaneous reaction to the same drug class. The second is structured, mandatory recording of drug allergy and prior-reaction history in the case sheet at the point of prescribing, given how many of the “definitely preventable” reactions in this series involved avoidable re-exposure. The third is explicit dosing counselling wherever methotrexate is prescribed, given the toxicity



pattern observed here. None of the three requires new infrastructure, only more consistent use of information already available at the bedside.

CONCLUSION

In this 12-month prospective observational study at a South Indian tertiary-care teaching hospital, 71 cutaneous adverse drug reactions were identified, most often in men in their thirties and forties, following oral administration of an NSAID or antimicrobial agent. The large majority of reactions were assessed as probable on standard causality scales, close to half required hospitalisation, and three in four were judged preventable. These findings point to two immediately actionable steps for reducing the burden of drug-induced skin injury in this setting: systematic recording of prior drug-reaction history, and closer oversight of NSAID and methotrexate prescribing in particular.

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

The study was approved by the Institutional Ethics Committee, King George Hospital, Visakhapatnam (Reg. No.ECR/197/Inst/KGH/2013/RR-20; Protocol No. AU/AUCoPS/M.Pharm/MPP/2022-2024/09), approved at the committee meeting of 12 July 2024. Written informed consent was obtained from all participants prior to enrolment.

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