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Original Research Article

Pattern of Cutaneous Adverse Drug Reactions reported at a Tertiary Care Hospital in Southern Rajasthan: A Descriptive Study

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Abstract:

Background: Cutaneous adverse drug reactions (CADRs) are among the most frequently encountered adverse drug reactions and represent an important challenge in clinical practice and pharmacovigilance. They range from mild self-limiting eruptions to severe life-threatening conditions, contributing significantly to patient morbidity and healthcare burden. Monitoring the pattern and causative agents of CADRs is essential for improving patient safety and promoting rational drug use.

Aim: To evaluate the pattern, causality, severity, and outcomes of cutaneous adverse drug reactions reported at a tertiary care teaching hospital in Southern Rajasthan.

Methods: This retrospective observational study was conducted at a tertiary care teaching hospital in Southern Rajasthan. All suspected CADRs reported by the Department of Dermatology between January 2023 and December 2025 under the Pharmacovigilance Programme of India (PvPI) were analysed. Incomplete reports were excluded. Data regarding demographic profile, clinical presentation, suspected drugs, severity, outcomes, and causality assessment were collected and analysed using descriptive statistics. Causality assessment was performed using the WHO–UMC causality assessment scale.

Results: A total of 127 CADR reports were analysed. The majority of patients belonged to the 21–40 years age group (43.5%), with male predominance (55.2%). Fixed drug eruption was the most commonly reported CADR (43.3%), followed by hyperpigmented patches, urticaria, erythematous plaques, and maculopapular rashes. Ofloxacin (37.0%) and ornidazole (34.6%) were the most frequently implicated drugs, followed by paracetamol and diclofenac. Most suspected drugs were administered orally (98.4%). According to WHO–UMC causality assessment, 86.6% of ADRs were classified as probable and 13.4% as possible. Most reactions were non-serious (93.7%), and the majority of patients were recovering or had recovered following withdrawal of the suspected drug.

Conclusion: Fixed drug eruption was the most common CADR observed in the study, with antimicrobials and non-steroidal anti-inflammatory drugs being the major causative agents. Most reactions were non-serious and showed favourable outcomes after prompt withdrawal of the offending drug. Strengthening pharmacovigilance activities and increasing awareness regarding early recognition and reporting of CADRs can significantly improve patient safety and rational drug use.

Keywords: Cutaneous adverse drug reaction, Pharmacovigilance, Fixed drug eruption, WHO–UMC scale, ADR monitoring, Drug safety.

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Introduction

Adverse drug reactions (ADRs) are unintended and harmful effects associated with the administration of medicines used for prophylaxis, diagnosis, therapy, or modification of physiological functions. [1,2] They remain a major concern in pharmacovigilance because they contribute substantially to morbidity, prolonged hospitalization, and economic burden. Pharmacovigilance encompasses the science and activities related to the detection, assessment, understanding, prevention, and communication of adverse effects and other drug-related problems. It also evaluates interactions between medicines, chemicals, foods, and herbal products, thereby supporting the safe and effective use of medicines. [3,4]

The Pharmacovigilance Programme of India (PvPI) was initiated in 2010 to monitor drug safety nationwide. Its primary objective is to establish an effective system for the collection, assessment,

monitoring, and dissemination of information related to ADRs. [5,6] Pharmacovigilance activities help identify previously unknown adverse effects, detect changes in the frequency or severity of known reactions, and assess the overall risk–benefit profile of medicines in clinical practice. The programme also ensures that accurate and updated safety information is communicated to healthcare professionals and patients through patient information leaflets. [7,8]

Cutaneous adverse drug reactions (CADRs) are among the most common and clinically significant. They range from mild skin eruptions to severe and life-threatening conditions, contributing considerably to patient morbidity and healthcare costs. Many CADRs are preventable if recognized early and managed appropriately. Prompt identification and withdrawal of the offending drug are essential for improving patient outcomes. Observational studies on CADRs provide valuable insights into their clinical patterns, causative agents, and risk factors, thereby strengthening pharmacovigilance practices and promoting safer medication use. [9] With the increasing use of medications in clinical practice, cutaneous adverse drug reactions (CADR) are being reported more frequently. However, limited data are available regarding the pattern of CADRs in India, particularly in Southern Rajasthan region. Hence, the present study was conducted to assess the pattern, causality and severity of cutaneous adverse drug reactions reported at a tertiary care hospital in Southern Rajasthan.

Material and Method

This retrospective observational study was conducted at tertiary care teaching hospital in southern Rajasthan. The study involved retrospective analysis of all suspected cutaneous adverse drug reactions (CADRs) reported by the Department of Dermatology between 1st January 2023 and 31st December 2025. All eligible ADR reports submitted through spontaneous suspected ADR reporting forms under the Pharmacovigilance Programme of India (PvPI) were included in the study. Incomplete reports were excluded from the analysis.

Causality assessment of ADRs was performed using the World Health Organization–Uppsala Monitoring Centre (WHO–UMC) causality assessment scale [7,8,9]. The outcomes of all reported ADRs were also documented.

Prior approval from the Institutional Ethics Committee was obtained before commencement of the study. Patient confidentiality and privacy were strictly maintained throughout the study by excluding all personal identifiers from the analysis. The study was conducted in accordance with standard ethical principles for biomedical research.

All data were entered into Microsoft Excel spreadsheets and analysed using descriptive statistical methods.

Results

A total of 127 cutaneous adverse drug reaction (CADR) reports were analysed during the study period. Most reports contained a single ADR (81.9%), while 16.5% of the reports documented two ADRs per patient and rest of the reports contained more than two ADRs. The majority of patients belonged to the 21–40 years age group (43.5%), followed by the 41–60 years age group (37.1%). Male patients constituted 55.2% of the cases, whereas females accounted for 44.8%.

In 98.4% of patients, the suspected drugs were administered via the oral route, while the remaining patients received the drugs intravenously.

The suspected drug was withdrawn in 118 (92.9%) patients. No action was taken in one patient, while the dose of the suspected drug was reduced in another patient. In the remaining patients, this was not applicable because either the suspected drug had been administered as a single dose or the patients had completed the full course of therapy before reporting the ADR. According to WHO–UMC causality assessment, for majority of ADRs it was “probable” (86.6%), while the remaining ADRs were categorized as “possible” (13.4%). No ADRs were classified as certain or unlikely.

Discussion

Cutaneous adverse drug reactions (CADRs) are among the most commonly reported adverse drug reactions and contribute significantly to patient morbidity, healthcare burden, and reduced quality of life. The present study evaluated the pattern, causality, severity, and outcomes of CADRs reported to a tertiary care teaching hospital in Southern Rajasthan.

In the present study, the majority of ADRs were reported in the 21–40 years age group (43.5%), followed by the 41–60 years age group (37.1%). Similar findings have been reported by Patel et al. [5], where adults constituted the majority of affected patients, possibly due to greater exposure to medications and increased self-medication practices. Male predominance (55.2%) observed in the present study is also comparable with findings reported in study by Nayak and Acharjya [6]

Fixed drug eruption (FDE) was the most commonly reported CADR (43.3%), followed by hyperpigmented patches, maculopapular rash, and urticaria. Similar observations have been reported in previous Indian studies where FDE and maculopapular eruptions were among the most frequent CADRs. [5,6] The high frequency of FDE in the present study may be attributed to the

widespread use of antimicrobials and non-steroidal anti-inflammatory drugs (NSAIDs).

Among the suspected drugs, ofloxacin and ornidazole were the most commonly implicated agents, followed by paracetamol and diclofenac.

Another study conducted by Sharma et al. [10] and Pudukadan and Thappa [11] reported that fixed drug eruption and maculopapular rash were the most frequently observed CADRs, with antimicrobials and NSAIDs were also the major offending drug groups. Their findings closely parallel the present study, where ofloxacin, ornidazole, diclofenac, and paracetamol were commonly implicated drugs. Similar prescribing patterns and widespread over-the-counter use of these medications may explain the comparable observations.

Most ADRs were categorized as non-serious (93.7%), while only a small proportion (6.3%) were serious and required hospitalization or prolonged hospital stay. Causality assessment was done using the WHO–UMC scale[7] showed that most ADRs were categorized as "probable" (86.6%), Similar results have been reported in study by Ashifha S et al. [12] however, they used the Naranjo scale for causality assessment. Their study further highlighted the importance of early withdrawal of the suspected drug in achieving favourable clinical outcomes.

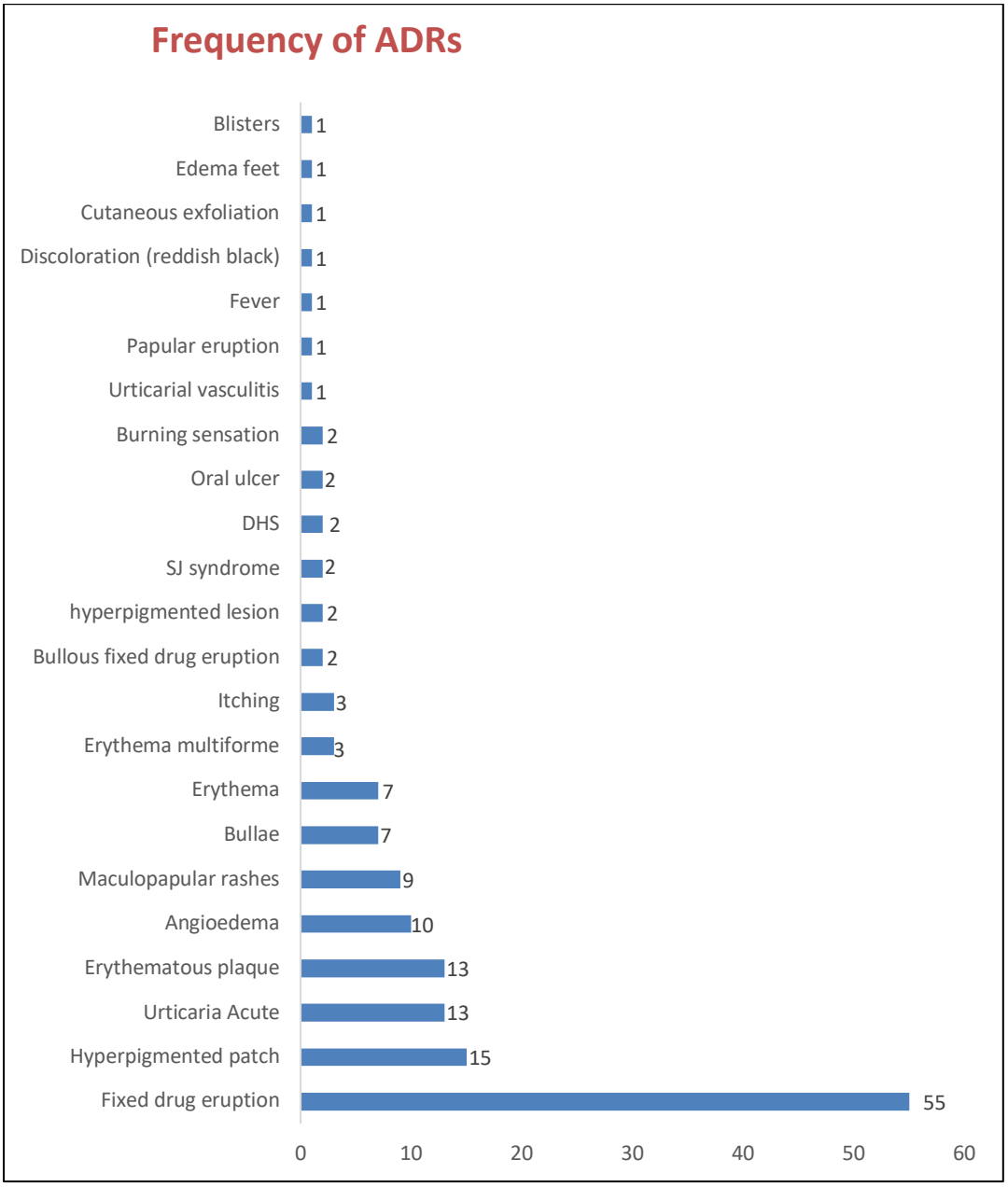

Figure 1: CADR

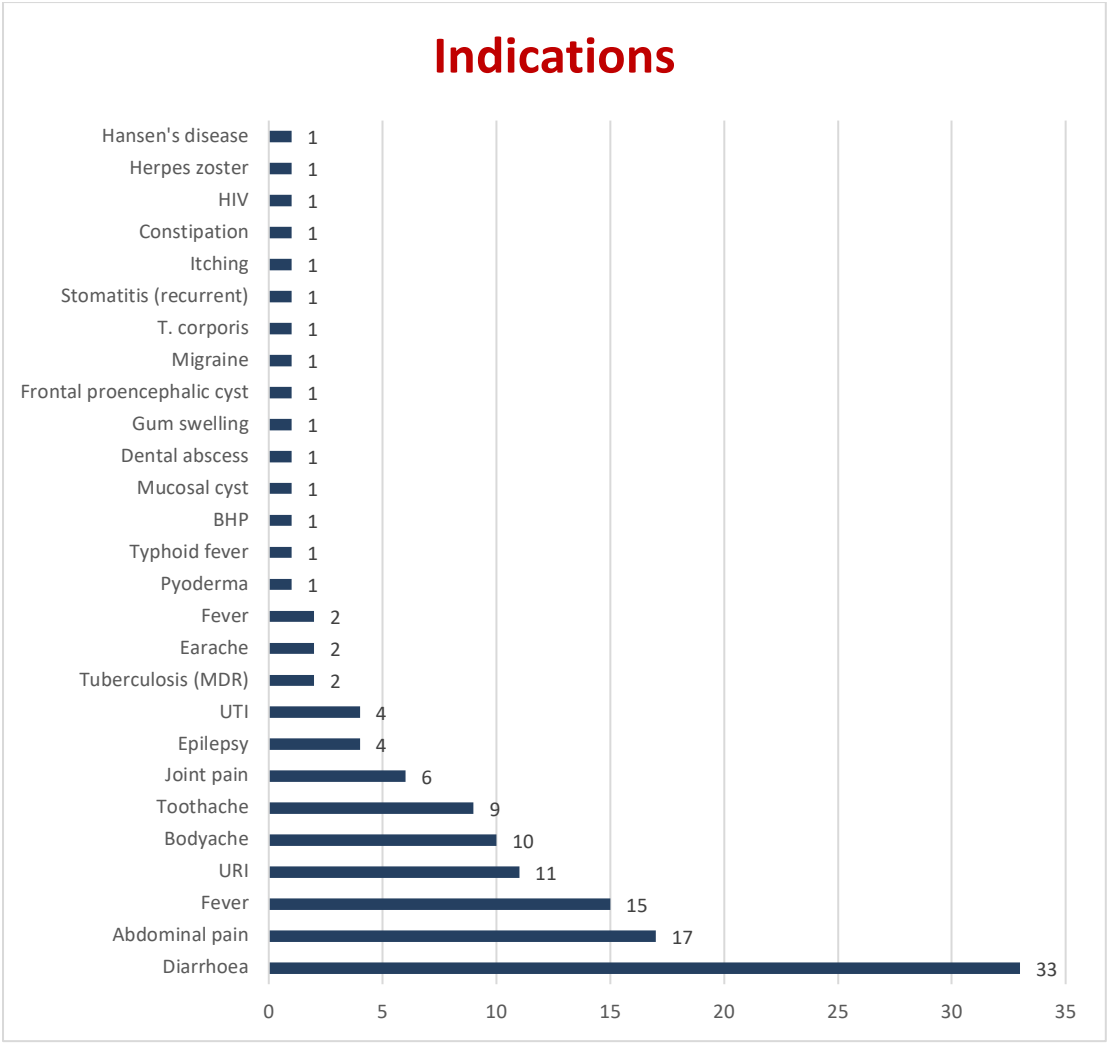

Figure 2: Indications for which drugs were used

Table 1: Common suspected drugs causing CADRs

Drug	Frequency	Percentage
Ofloxacin	47	37.0%
Ornidazole	44	34.6%
Paracetamol	25	19.7%
Diclofenac	15	11.8%
Ciprofloxacin	11	8.7%
Etoricoxib	11	8.7%
Norfloxacin	7	5.5%
Aceclofenac	7	5.5%
Mefenamic acid	5	3.9%
Ibuprofen	4	3.1%
Nimesulide	4	3.1%
Amoxicillin	4	3.1%

The majority of patients were recovering or had recovered completely at the time of reporting, indicating favourable outcomes with early diagnosis and withdrawal of the offending drug. Prompt recognition and discontinuation of the suspected medication remain the cornerstone in the management of CADRs.

The findings of the present study highlight the importance of continuous pharmacovigilance activities and hospital-based ADR monitoring programmes, as recommended by the World Health Organization. [2] Strengthening ADR reporting systems and increasing awareness among healthcare professionals regarding commonly implicated drugs and early reporting of CADRs can significantly

improve patient safety and promote rational drug use.

One of the major strengths of the study is the use of data obtained from spontaneous ADR reporting by health professionals, which enhances the reliability and standardization of ADR reporting. The study also utilized validated assessment tools, thereby improving the scientific validity of the findings.

Being a retrospective observational study, underreporting and reporting bias were few limitations. ADRs were categorized only in a broad manner; therefore, the different types of same ADR could not be described in detail. The sites involved and the number of lesions could also not be specified. Further multicentred studies with larger sample sizes and extended follow-up periods on ADRs are needed to make the results more specified and generalisable.

2: Severity, outcome, and causality assessment of CADRs

Parameter	Frequency	Percentage
Severity		
Serious	8	6.3%
Non-serious	119	93.7%
Outcome		
Recovered	13	10.2%
Recovering	102	80.3%
Unknown	10	7.9%
Not recovered	2	1.6%
Causality assessment		
Probable	110	86.6%
Possible	17	13.4%

Conclusion

The present study highlights that fixed drug eruption was the most common cutaneous adverse drug reaction, with antimicrobials and non-steroidal anti-inflammatory drugs being the most frequently implicated drug groups. Most ADRs were non-serious in nature and showed favourable outcomes following withdrawal of the suspected drug. The findings emphasize the importance of active pharmacovigilance, early recognition of CADRs, prompt withdrawal of the offending drug, and rational prescribing practices to improve patient safety. Strengthening ADR monitoring and increasing awareness among healthcare professionals regarding drug safety can contribute significantly to reducing the burden of cutaneous adverse drug reactions.

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