International Journal of Medical and Pharmaceutical Research

Online ISSN-2958-3683 | Print ISSN-2958-3675
Frequency: Bi-Monthly
Available online on: https://ijmpr.in/

Original Article

Cutaneous Adverse Drug Reactions with Fixed Dose Combinations: Special Reference to Self-Medication and Preventability

Aniket Tripathi[1], Vijay Kumar Yadav[2], Hitesh Mishra[3]

[1]Assistant Professor, Department of Pharmacology, Prasad Institute of Medical Sciences, Lucknow, U.P, India
[2]Associate Professor, Department of Pharmacology, Prasad Institute of Medical Sciences, Lucknow, U.P., India
[3]Professor, Department of Pharmacology, IGIMS, Patna, Bihar, India

OPEN ACCESS

Corresponding Author:

Aniket Tripathi
Assistant Professor, Department of Pharmacology, Prasad Institute of Medical Sciences, Lucknow, U.P, India

Received: 20-02-2026
Accepted: 18-03-2026
Available online: 31-03-2026

ABSTRACT

Background: Fixed dose combinations (FDCs) are commonly utilized yet frequently linked to adverse drug responses (ADRs), especially cutaneous symptoms. Self-medication exacerbates the likelihood of improper drug utilization and avoidable adverse drug reactions (ADRs).
Methods: Prospective observational research was undertaken over one year comprising 350 patients with cutaneous adverse drug reactions related to fixed-dose combinations. Demographic data, FDC types, self-medication habits, clinical patterns, and preventability (utilizing standard measures) were gathered and examined.
Results: Of the 350 patients, maculopapular rash was observed in 32% and urticaria in 25%, making them the predominant manifestations. Self-medication was observed in 42% of patients and shown a strong correlation with the prevalence of adverse drug reactions ($p < 0.01$). Approximately 55% of adverse drug reactions were classified as avoidable. Combinations of antibiotics and NSAIDs were the most prevalent offending fixed-dose combinations (FDCs).
Conclusion: Cutaneous adverse drug reactions resulting from fixed-dose combinations are prevalent and predominantly avoidable. Self-medication significantly contributes to their prevalence. Stringent regulation, patient education, and judicious prescribing are crucial to mitigate the incidence of adverse drug reactions (ADRs).

Keywords*: adverse drug reactions, fixed-dose combinations (FDCs), Cutaneous adverse drug reactions, Self-medication, maculopapular rash.*

INTRODUCTION

Fixed dose combinations (FDCs) are extensively utilized in clinical practice owing to their convenience, cost-effectiveness, and capacity to enhance patient adherence by minimizing pill load (1). Notwithstanding these benefits, the growing utilization of FDCs has elicited substantial safety apprehensions, especially with irrational combos and their prevalent accessibility as over-the-counter pharmaceuticals (2). In numerous contexts, these combinations are administered or ingested without sufficient clinical rationale, heightening the likelihood of adverse drug reactions (ADRs)(3).

Cutaneous adverse medication reactions are among the most commonly documented symptoms of drug-induced toxicity(4). They may exhibit a broad array of clinical manifestations, from minor disorders such as maculopapular rashes and urticaria to severe and sometimes fatal reactions, including Stevens–Johnson syndrome and toxic epidermal necrolysis (5). These reactions not only impact patient quality of life but may also necessitate hospitalization and intense care (6).

Self-medication exacerbates this problem, particularly in underdeveloped nations where regulatory oversight of drug distribution may be inadequate (7). Unrestricted access to drugs without a prescription promotes misuse, polypharmacy, and heightened exposure to potentially detrimental fixed-dose combinations (FDCs) (8). A significant percentage of these

ADRs are deemed preventable through judicious prescribing, adequate patient education, and more stringent regulatory procedures (9).

This study is to assess the patterns of cutaneous adverse drug reactions (ADRs) linked to fixed-dose combinations (FDCs), focusing on the influence of self-medication and the preventability of these events (10). Comprehending these elements is crucial for enhancing drug safety and advocating for the judicious use of drugs (11).

METHODS

Study Design:
Prospective observational study

Study Duration:
1 year

Sample Size:
350 patients

Inclusion Criteria:

- Patients presenting with suspected cutaneous ADRs
- History of FDC drug intake

Exclusion Criteria:

- Non-drug-related skin conditions
- Incomplete patient history

Data Collection:

- Demographic details
- Type of FDC consumed
- History of self-medication
- Clinical pattern of ADR
- Causality assessment (WHO scale)
- Preventability assessment (Schumock and Thornton scale)

Statistical Analysis:

- Data analyzed using Chi-square test
- p-value < 0.05 considered significant

RESULTS

Table 1: Demographic Distribution

Variable	Number (%)
Total patients	350
Male	210 (60%)
Female	140 (40%)
Mean age	36 ± 12 years

Table 2: Types of Cutaneous ADRs

ADR Type	Frequency (%)	p-value
Maculopapular rash	32%	
Urticaria	25%	
Fixed drug eruption	18%	
Stevens–Johnson Syndrome	5%	<0.05
Others	20%	

Table 3: Self-Medication and ADR Association

Category	Number (%)	p-value
Self-medication	147 (42%)	

Category	Number (%)	p-value
Prescribed	203 (58%)	<0.01

Table 4: Preventability of ADRs

Category	Percentage	p-value
Preventable	55%	
Probably preventable	25%	
Not preventable	20%	<0.05

Table 5: Common Offending FDCs

Drug Class	Percentage
Antibiotic combinations	40%
NSAID combinations	30%
Steroid combinations	15%
Others	15%

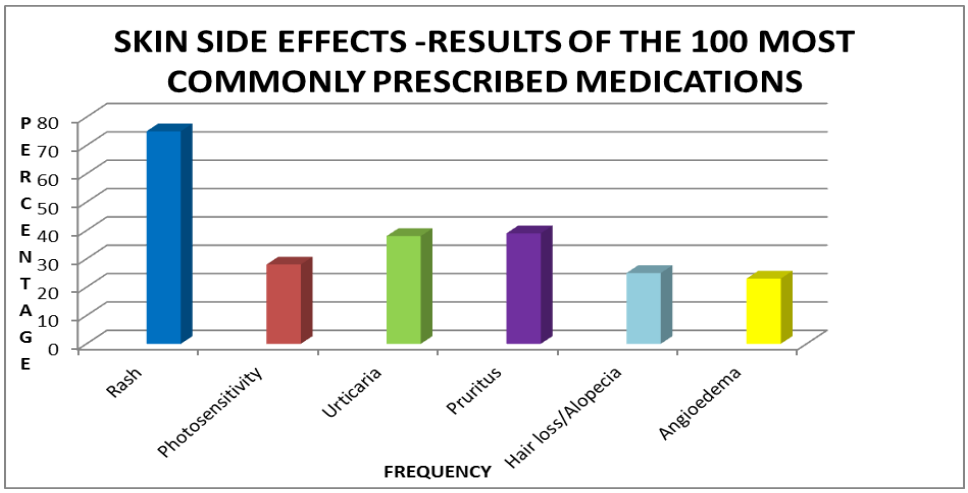

Figure 1: side effects of the most commonly prescribed medications

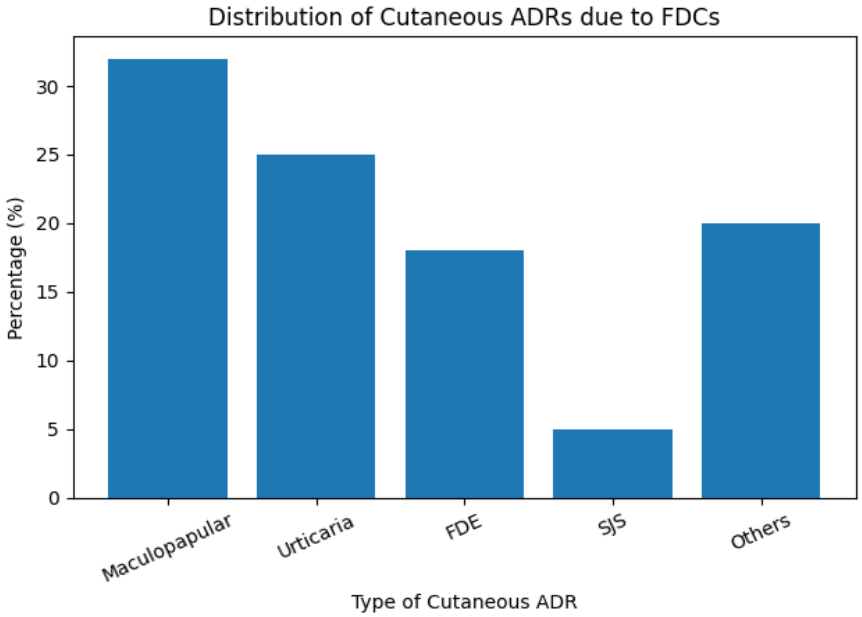

Figure 2: Distribution of cutaneous ADRs due to FDCs

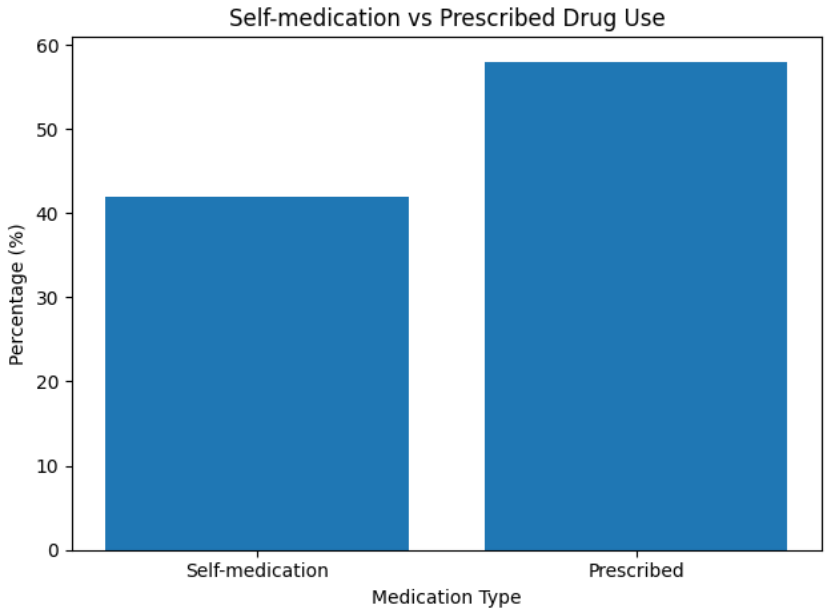

Figure 3: Self-medication vs prescribed drug use

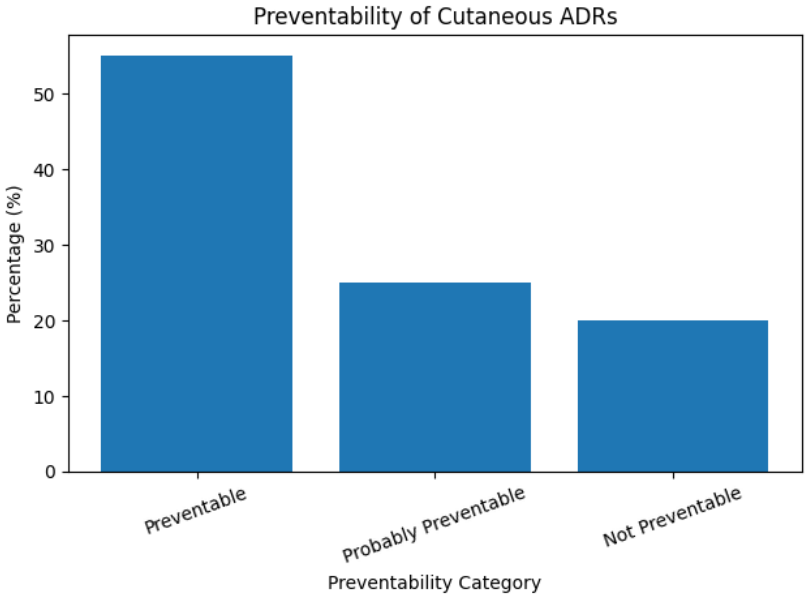

Figure 4: Preventability of cutaneous ADRs

DISCUSSION

This study emphasizes the considerable burden of cutaneous adverse drug reactions linked to fixed-dose combinations. Maculopapular rash and urticaria were the predominant manifestations, aligning with prior data (12), (13). Despite the infrequency of severe reactions such as Stevens–Johnson syndrome, their clinical significance remains substantial.

An important finding was the elevated incidence of self-medication (42%), which demonstrated a statistically significant correlation with the occurrence of adverse drug reactions ($p < 0.01$)(14), (15). The unrestricted accessibility to fixed-dose combinations (FDCs) without a prescription fosters irrational drug utilization and heightens the likelihood of adverse effects(16).

The bar graphs indicate that maculopapular rash and urticaria are the predominant cutaneous adverse medication events linked to fixed dose combinations, although severe reactions such as Stevens–Johnson syndrome, albeit less prevalent, are clinically significant (17), (18). A significant percentage of patients indicated self-medication, highlighting its critical role in the incidence of adverse drug reactions (ADRs) (19), (20). The comparison indicates that prescribed usage is comparatively safer. The majority of adverse drug reactions (ADRs) were identified as preventable or likely preventable, highlighting deficiencies in rational prescribing and patient understanding (21), (22). These findings emphasize the

necessity for more stringent regulation of FDCs and more public education to mitigate preventable adverse drug reactions (23).

Over fifty percent of the adverse drug reactions (ADRs) were deemed preventable, highlighting deficiencies in prescribing practices, patient awareness, and regulatory oversight (24), (25). Combinations of antibiotics and NSAIDs were the predominant culprits, perhaps because to their prevalent and frequently improper utilization (26),(27). The statistically significant p-values for essential variables bolster the credibility of the results (28). The findings underscore the necessity for more stringent drug laws, enhanced pharmacovigilance, and public awareness about the dangers of self-medication (29),(30).

CONCLUSION

Cutaneous adverse drug reactions resulting from fixed-dose combinations are prevalent and highly avoidable. Self-medication is a significant contributing factor and is strongly correlated with the development of adverse drug reactions (ADRs). Enhancing regulatory policies, advocating for judicious prescribing, and elevating public knowledge are critical measures to mitigate the impact of adverse drug reactions (ADRs). Ongoing pharmacovigilance and additional multicentric investigations are advised.

REFERENCES

1. Chaudhari, P., et al. “Study of Cutaneous Adverse Drug Reactions in the Outpatient Department of Dermatology at a Tertiary Care Teaching Hospital.” *IP Indian Journal of Clinical and Experimental Dermatology*, vol. 12, no. 1, 2026, pp. 57–62.
2. Makwana, V. S., et al. “The Spectrum of Cutaneous Adverse Drug Reactions Following the Application of Topical Medications: An Observational Study at a Tertiary Care Center.” *Cureus*, vol. 14, no. 8, 2022, pp. 1–15.
3. Jiamsathit, W., et al. “Drug-Induced Serious Cutaneous Reactions in Hospitalized Patients: A Cross-Sectional Study.” *Journal of Clinical Medicine*, vol. 14, 2025, pp. 1–14.
4. Hadia, R., et al. “Assessment of Causality, Preventability and Severity of Cutaneous Adverse Drug Reactions: A Prospective Observational Study.” *Journal of Pharmaceutical Research International*, vol. 33, no. 32A, 2021, pp. 93–97.
5. Joshi, D. B., et al. “A Study of Cutaneous Adverse Drug Reaction Patterns with Causality and Severity Assessment at a Tertiary Care Centre.” *IP Indian Journal of Clinical and Experimental Dermatology*, vol. 4, no. 3, 2018, pp. 185–193.
6. Thakkar, Sejal, et al. “Cutaneous Adverse Drug Reactions in a Tertiary Care Teaching Hospital in India: An Intensive Monitoring Study.” *Indian Journal of Dermatology*, vol. 62, 2017, pp. 618–625.
7. Panattil, P., et al. “Retrospective Study on Cutaneous Adverse Drug Reactions in a Tertiary Care Center.” *National Journal of Physiology, Pharmacy and Pharmacology*, vol. 13, no. 5, 2023, pp. 1098–1102.
8. Chandra, V., et al. “Analysis of Spontaneously Reported Cutaneous Adverse Drug Reactions in a Tertiary Care Teaching Hospital in South India.” *International Journal of Basic & Clinical Pharmacology*, vol. 8, no. 1, 2019, pp. 27–33.
9. R., M. S., et al. “Pattern of Cutaneous Adverse Drug Reactions Due to the Use of Fixed Dose Drug Combinations.” *International Journal of Basic & Clinical Pharmacology*, vol. 2, no. 5, 2013, pp. 554–558.
10. Khaitan, B. K., et al. “Cutaneous Adverse Drug Reactions – Part A.” *Journal of Epidemiology Foundation of India*, vol. 2, no. 1 suppl., 2024, pp. S83–S84.
11. Shukla, A., et al. “ATT Induced Adverse Drug Reaction: A Prospective Hospital-Based Study.” *International Journal of Medical and Pharmaceutical Research*, vol. 7, no. 1, 2026, pp. 1302–1306.
12. Chiriac, A. E., et al. “Cutaneous Adverse Drug Reactions in Children with a Focus on Hypersensitivity to Systemic Drugs: A Narrative Review.” *Indian Journal of Skin Allergy*, vol. 3, no. 1, 2024, pp. 2–11.
13. Kehoe, J., et al. “Accurately Describing Drug Allergies and Adverse Drug Reactions: The Australian Delphi Consensus on Drug Allergy Terminology.” *Journal of Allergy and Clinical Immunology: Global*, vol. 5, no. 1, 2026, pp. 1–11.
14. Palaian, S., et al. “Pattern of Adverse Drug Reactions Reported by the Community Pharmacists in Nepal.” *Pharmacy Practice*, vol. 8, no. 3, 2010, pp. 201–207.
15. Ciddhavaduta, D. L., and D. Baloju. “Analysis of Cutaneous Adverse Drug Reactions Using Commonly Prescribed Drugs.” *Journal of Evidence Based Medicine and Healthcare*, vol. 5, no. 21, 2018, pp. 1621–1627.
16. Chang, C., et al. “Pharmacogenetic Testing for Prevention of Severe Cutaneous Adverse Drug Reactions.” *Frontiers in Pharmacology*, vol. 11, 2020, pp. 1–11.
17. Pal, A., and S. Sen. “A Case of Self-Treatment Induced Recurrent Fixed Drug Eruptions Associated with the Use of Different Fixed Dose Combinations.” *Indian Journal of Medical Sciences*, vol. 39, no. 6, 2014, pp. 4–8.
18. Jalloh, I., et al. “Trends and Patterns of Adverse Drug Reaction Reporting in Sierra Leone: A Retrospective Analysis of VigiFlow Data.” *Pharmacoepidemiology and Drug Safety*, vol. 35, 2026, pp. 1–14.

19. Sonar, S., et al. “Evaluation of Adverse Drug Reactions Due to Fixed-Dose Combinations at a Tertiary Care Hospital: An Observational Retrospective Study.” *Journal of Clinical and Diagnostic Research*, vol. 17, no. 10, 2023, pp. 1–5.
20. Dhage, P., et al. “Prospective Analysis of Cutaneous Adverse Drug Reactions Encountered in a Tertiary Care Hospital.” *Cureus*, vol. 16, no. 7, 2024, pp. 1–13.
21. Vaman, R. S., et al. “Adverse Drug Reactions in Persons Initiated on Treatment for Drug-Resistant Tuberculosis in Kerala, India: A Non-Concurrent Cohort Study.” *IJID Regions*, vol. 15, 2025, pp. 1–9.
22. Sharma, Roohi, et al. “Assessment of Cutaneous Adverse Drug Reactions in a Health Centre.” *Journal of Advanced Medical and Dental Sciences Research*, vol. 7, no. 4, 2019, pp. 160–162.
23. Dwari, B. C., et al. “Fixed Drug Eruption Due to Co-Trimoxazole: A Case Report.” *Journal of Institute of Medicine*, vol. 28, no. 2, 2006, pp. 67–70.
24. Bose, Reetesh, et al. “Methods for Identifying Culprit Drugs in Cutaneous Drug Eruptions: A Scoping Review.” *medRxiv*, 2021, pp. 1–42.
25. Malhotra, S. K., et al. “A Prospective Study of Clinical Spectrum of Cutaneous Adverse Drug Reactions and Their Incidence in Indian Population.” *IP Indian Journal of Clinical and Experimental Dermatology*, vol. 7, no. 2, 2021, pp. 143–147.
26. Palappallil, D. S., et al. “Adverse Drug Reactions: Two Years’ Experience from a Tertiary Teaching Hospital in Kerala.” *National Journal of Physiology, Pharmacy and Pharmacology*, vol. 7, no. 4, 2017, pp. 403–411.
27. Roshi, V. R. T. “Adverse Drug Reactions Due to Fixed Dose Combinations: An Observational Cross-Sectional Study.” *International Journal of Basic & Clinical Pharmacology*, vol. 8, no. 11, 2019, pp. 2412–2415.
28. Vinimol, C., et al. “Cutaneous Adverse Drug Reactions among Patients.” *Journal of Population Therapeutics and Clinical Pharmacology*, vol. 32, no. 8, 2025, pp. 37–42.
29. Agrawal, A., et al. “Clinical Spectrum of Cutaneous Adverse Drug Reactions.” *Indian Journal of Drugs in Dermatology*, vol. 4, 2018, pp. 61–66.
30. Manne, N., et al. “Prevalence of Hypoparathyroidism and Growth Retardation in Patients of Beta-Thalassemia Major.” *International Journal of Advances in Medicine*, vol. 7, no. 2, 2020, pp. 158–163