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Original Research Article

Evaluation of Adverse Drug Reactions in Patients Attending a Dermatology Outpatient Department: A Prospective Observational Study

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Abstract

Background: Adverse drug reactions (ADRs) remain an important cause of patient morbidity and may compromise treatment outcomes, particularly in dermatology where prolonged therapy and multiple medications are frequently prescribed.

Objective: To evaluate the pattern of adverse drug reactions associated with medications prescribed in a dermatology outpatient department and to assess their causality and severity.

Materials and Methods: A hospital-based prospective observational study was conducted over 18 months among 406 patients attending the dermatology outpatient department of a tertiary care teaching hospital. Suspected ADRs were documented using a structured case record form and assessed using the WHO-UMC causality scale and Hartwig severity scale.

Results: Out of 406 patients included in the study, 26 (6.4%) experienced documented adverse drug reactions. Doxycycline was the most frequently implicated medication, followed by Adapalene and Luliconazole. According to the WHO–UMC causality assessment, 12 (46.2%) ADRs were classified as probable/likely and 12 (46.2%) as possible, while all ADRs were graded as mild (Level 1) on the Modified Hartwig Severity Assessment Scale. A higher frequency of ADRs was observed among patients receiving polypharmacy; however, the association was not statistically significant.

Conclusion: Active pharmacovigilance in dermatology practice facilitates early detection of ADRs and promotes safer and more rational prescribing practices.

Keywords: Adverse Drug Reactions; Dermatology; Pharmacovigilance; WHO-UMC Scale; Hartwig Severity Scale; Outpatient Department.

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Introduction

Dermatological disorders constitute a major public health concern and are among the most frequent reasons for outpatient consultations worldwide. Although many skin diseases are not life-threatening, they substantially impair quality of life through persistent symptoms, cosmetic disfigurement, psychological distress, and reduced social functioning. The burden of dermatological diseases is particularly high in low- and middle-income countries, where infectious dermatoses, inflammatory disorders, and chronic skin diseases remain common causes of healthcare utilization [1,2]. Pharmacotherapy forms the cornerstone of dermatological management. Treatment commonly involves topical and systemic corticosteroids, antifungal agents, antibiotics, antihistamines, retinoids, and immunomodulators. While these medications provide significant therapeutic benefits, their widespread use also increases the risk of adverse drug reactions (ADRs), especially in patients receiving prolonged treatment or multiple medications simultaneously. ADRs may range from mild cutaneous manifestations to severe reactions requiring drug withdrawal or hospitalization [3,4]. The World Health Organization defines an ADR as a harmful and unintended response to a drug

administered at doses normally used for prophylaxis, diagnosis, or treatment. Dermatological ADRs are among the most frequently reported drug-related events because the skin is highly susceptible to immunological and toxic reactions. Continuous pharmacovigilance is therefore essential to identify drug-related risks, improve patient safety, and promote rational prescribing practices [5].

Although several studies have evaluated cutaneous ADRs, institution-specific evidence from tertiary care dermatology outpatient departments remains limited. Assessing the frequency, causative medications, causality, and severity of ADRs provides valuable information for optimizing prescribing practices and strengthening pharmacovigilance programmes. Therefore, the present study was undertaken to evaluate adverse drug reactions among patients attending a tertiary care dermatology outpatient department.

Materials and Methods

This hospital-based prospective, observational study was conducted in the Dermatology Outpatient Department of People's College of Medical Sciences and Research Centre, Bhopal, over a period of 18 months. Adult patients (≥18 years) attending the dermatology outpatient department and receiving new prescriptions during the study period were considered eligible. Although 612 participants were initially enrolled, 406 patients completed follow-up and were included in the final analysis.

Inclusion Criteria

- Patients aged 18 years and above of either gender.
- Patients attending the Dermatology OPD with newly prescribed medications.
- Patients presenting with adverse drug reactions related to medications prescribed from the same Dermatology OPD.

Exclusion Criteria

- Patients younger than 18 years.
- Patients attending follow-up visits with old prescriptions.
- Patients presenting with adverse drug reactions caused by medications prescribed outside the study centre.

Data Collection: After obtaining written informed consent, prescriptions were collected prospectively from eligible patients attending the Dermatology OPD. Demographic details, diagnosis, and drug-related information including dose, frequency, duration, and route of administration were recorded in a structured proforma.

Patients were subsequently followed for the occurrence of adverse drug reactions, which were documented using a standardized coding system. The causality of each suspected ADR was assessed using the WHO–UMC causality assessment scale, while severity was evaluated using the Modified Hartwig Severity Assessment Scale.

Statistical Analysis: All data recorded in the structured proformas were compiled, tabulated, and analysed using appropriate statistical methods. Categorical variables were summarized as frequencies and percentages. Descriptive statistics were used to describe the pattern of adverse drug reactions, while Fisher's exact test was applied to assess the association between polypharmacy and the occurrence of adverse drug reactions. A p-value of <0.05 was considered statistically significant.

Ethical Approval: The study was conducted after obtaining approval from the Institutional Ethics Committee (IEC) and the Research Advisory Committee (RAC) of People's College of Medical Sciences and Research Centre, Bhopal.

Results

A total of 406 patients attending the Dermatology Outpatient Department were included in the study. During the study period, 26 patients (6.4%) experienced documented adverse drug reactions (ADRs), while 380 patients (93.6%) had no reported ADRs.

The demographic profile, prevalence of ADRs, causality assessment, severity grading, and association between polypharmacy and ADR occurrence are presented below.

Table 1: Demographic Characteristics of the Study Population (n = 406)

Demographic Characteristics		Frequency (n=406)	Percentage (%)
Age Category in Years	≤ 20 years	37	9.1%
	21 – 30 years	140	34.5%
	31 – 40 years	115	28.3%
	41 – 50 years	54	13.3%
	51 – 60 years	36	8.9%
	≥ 61 years	24	5.9%
Gender	Female	227	55.9%
	Male	179	44.1%

Most participants belonged to the 21–30 years age group (34.5%), followed by the 31–40 years group (28.3%). Female patients constituted a slightly higher proportion of the study population (55.9%) than males (44.1%)

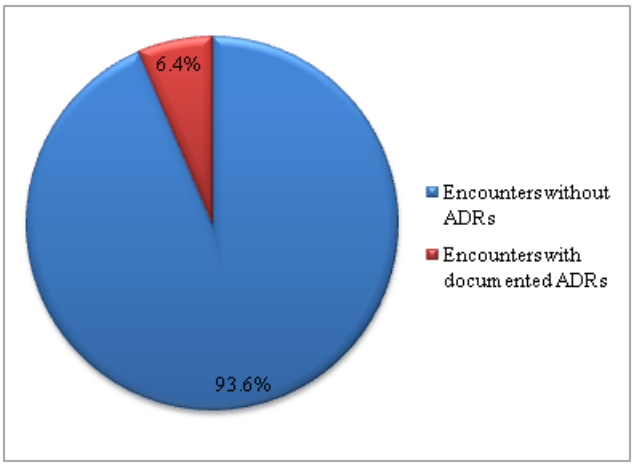

Figure 1: Prevalence of Adverse Drug Reactions among the Study Population

Among the 406 study participants, 26 patients (6.4%) experienced documented adverse drug reactions, whereas 380 patients (93.6%) completed treatment without any reported ADRs, indicating a relatively low prevalence of ADRs in the study population.

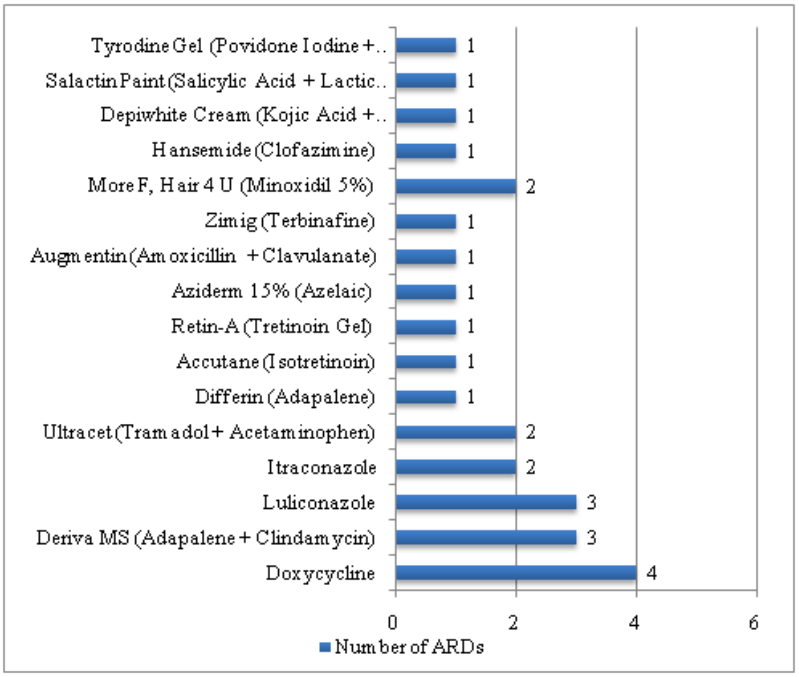

Figure 2: Frequency of Adverse Drug Reactions Stratified by Suspected Medication

Doxycycline was the most frequently implicated medication, accounting for four ADRs, followed by Deriva MS and Luliconazole with three ADRs each. Itraconazole, Ultracet, and Minoxidil were each associated with two ADRs, while the remaining suspected medications accounted for one ADR each, indicating that ADRs were distributed across a wide range of dermatological therapies.

Table 2: Causality Assessment of Adverse Drug Reactions According to the WHO–UMC Scale (n = 26)

WHO-UMC Causality Category	Frequency (n=26)	Percentage (%)
Certain	0	0%
Probable / Likely	12	46.2%
Possible	12	46.2%
Unlikely	2	7.7%
Conditional / Unclassified	0	0%
Unassessable / Unclassifiable	0	0%

Nearly half of the documented ADRs were classified as Probable/Likely (46.2%), while an equal proportion was categorized as Possible (46.2%). Only 7.7% of ADRs were considered Unlikely, and no reaction fulfilled the criteria for the certain category.

Table 3: Severity Grading of Adverse Drug Reactions According to the Modified Hartwig Severity Assessment Scale (n = 26)

Severity Category	Hartwig Scale Criteria	Frequency (n=26)	Percentage (%)
Mild (Level 1)	ADR occurred but required no change in treatment	26	100%
Level 2 through Level 7	Required treatment change, antidotes, or admission	0	0%

According to the Modified Hartwig Severity Assessment Scale, all 26 (100%) documented ADRs were classified as mild (Level 1). None of the reactions required discontinuation of the suspected drug, administration of antidotes, or hospital admission, indicating that the reported ADRs were clinically mild and manageable.

Table 4: Association between Polypharmacy and Occurrence of Adverse Drug Reactions (n = 406)

Prescribing Category	Total Encounters	Encounters WITH an ADR	Encounters WITHOUT An ADR	Percentage Experiencing ADR (%)
Standard Regimen (<6 Drugs)	354	19	335	5.4%
Polypharmacy (≥6 Drugs)	52	7	45	13.5%

Fisher's Exact Test p-value = 0.0618

Patients receiving polypharmacy (≥6 drugs) experienced a higher proportion of ADRs (13.5%) compared with those receiving fewer than six medications (5.4%). Although ADRs were more frequent in patients exposed to polypharmacy, the association did not reach statistical significance (p = 0.0618).

Discussion

The present prospective observational study evaluated adverse drug reactions among patients attending a dermatology outpatient department of a tertiary care teaching hospital. Among 406 patients included in the study, 26 (6.4%) developed documented ADRs, indicating that ADRs remain an important aspect of medication safety in routine dermatology practice [6].

The majority of the study population belonged to the 21–30-year age group, with a slight female predominance. Similar demographic findings have been reported in previous dermatology-based pharmacovigilance studies [7].

The prevalence of ADRs observed in the present study was 6.4%, which is comparable with findings reported in other hospital-based studies evaluating adverse drug reactions in dermatology practice [6].

WHO–UMC causality assessment showed that most ADRs were classified as probable or possible, consistent with observations from previous studies evaluating cutaneous adverse drug reactions [8]. According to the Modified Hartwig Severity Assessment Scale, all documented ADRs were mild, indicating that early recognition and appropriate management can prevent progression to severe reactions [9].

Although patients receiving six or more medications experienced a higher proportion of ADRs, the association with polypharmacy was not statistically significant. Similar trends have been described in previous studies evaluating medication safety in dermatology [10].

Conclusion

The present study demonstrated that adverse drug reactions were observed in a small proportion of patients attending the dermatology outpatient department, with an overall prevalence of 6.4%. Most ADRs were mild in severity and were classified as either probable or possible according to the WHO–UMC causality assessment scale. Although patients receiving six or more medications showed a higher frequency of ADRs than those on standard treatment regimens, the association was not statistically significant. These findings highlight the importance of continuous pharmacovigilance, careful prescription review, patient education, and early identification of ADRs to promote rational prescribing and improve medication safety in dermatological practice.

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