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ORIGINAL ARTICLE

Evaluation of Prescribing Patterns and Cutaneous Adverse Drug Reactions in Dermatology Outpatients: Insights from a Prospective Study in an Urban Indian Teaching Hospital

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ABSTRACT

The rational prescription of dermatological medications is critical in reducing treatment costs and minimizing adverse drug reactions (ADRs). With rising polypharmacy and irrational drug use in dermatology, Structured pharmacovigilance is very important for keeping an eye on drug-related hazards and prescribing trends, especially in emerging nations like India. The aim of this study was to analyze prescribing trends and identify the spectrum of cutaneous adverse drug reactions (cADRs) experienced by dermatology patients receiving treatment at a tertiary care hospital, evaluating their rationale in accordance with WHO prescribing indicators and pharmacovigilance metrics. An observational study was carried out on 979 dermatology outpatients over three months at RUHS CMS, Jaipur. Data were collected using WHO core drug-use indicators, and ADRs were monitored actively via a departmental pharmacovigilance program. Descriptive and inferential statistical analysis were utilized. Collectively, 2,848 drugs were prescribed across 979 encounters, with a mean of 2.75 drugs per prescription. Oral route was predominant (57.3%), with tablets (44.5%) as the most common dosage form. Antifungals (24.8%) and antihistamines (23.6%) were the most frequently prescribed. Itraconazole and levocetirizine were the leading agents. cADRs were reported in 2.3% of patients; steroid-induced acne and photodermatitis were common. All prescriptions adhered to generic naming (100%) and 93.6% Includes medications from the list of necessary drugs. This study underscores generally rational prescribing practices but highlights the need for enhanced ADR monitoring. Dermatology remains a high-risk specialty for cADRs, necessitating continuous pharmacovigilance, education of prescribers, and patient counseling to mitigate preventable drug harms.

Keywords: Dermatology, Rational Drug Use, WHO Prescribing Indicators, Adverse Drug Reactions, Pharmacovigilance

INTRODUCTION

The skin is the body's largest organ and is a crucial connection between the body and the outside world and the body's ability to stay stable. It acts as a protective barrier against mechanical injury, ultraviolet radiation, microbial invasion, and chemical exposure. Due to its direct exposure to environmental factors and its complex immunological and vascular components, the skin is highly susceptible to a broad range of diseases.

The burden of skin disorders in India is significant, especially among urban and semi-urban populations[1, 2]. A number of national surveys have estimated that skin diseases constitute nearly 15-20% of outpatient consultations in general hospitals across India. With such a high prevalence, the rational use of dermatological therapies becomes a cornerstone of effective clinical care[3].

Dermatological pharmacotherapy includes a wide range of agents such as corticosteroids, antifungals, antibiotics, antihistamines, emollients, and immunomodulators. These drugs may be administered topically or systemically depending on the degree of severity and widespread the sickness is[4]. But the wide range of medicines that are available, combined with inadequate regulatory oversight, has led to irrational prescribing patterns. Over-prescription, polypharmacy, brand-name prescribing, and low adherence to national essential drug lists are frequently observed practices, especially in busy tertiary care settings[5].

The problem is made worse by the fact that cADRs are not well known or recorded, even though they are still a substantial clinical problem. Cutaneous adverse drug reactions can vary from minor rashes to severe illnesses like Stevens-Johnson Syndrome or Toxic Epidermal Necrolysis that can be fatal[6]. Research indicates that dermatological medications, especially antibiotics, corticosteroids, and nonsteroidal anti-inflammatory medicines, are significant contributors to cutaneous adverse drug reactions (cADRs)[7]. Even with the Pharmacovigilance Programme of India (PvPI) in place, dermatology departments still don't record enough cases.

The World Health Organization (WHO) has made it clear how important it is to use drugs wisely by creating key prescription indicators. Some of them are the average number of drugs per visit, the percentage of drugs prescribed by their generic name, the percentage of drugs from essential drug lists, and the indicators for antibiotic use[8]. These measures are used all over the world to compare and improve how doctors prescribe drugs in different clinical situations, such as dermatology[9].

There is a pressing need for local data to inform policy decisions, promote prescriber education, and ensure patient safety. However, literature on prescription audits and pharmacovigilance in Indian dermatology outpatient settings remains sparse[10]. In particular, limited studies exist that simultaneously evaluate prescribing indicators and adverse drug reactions in a prospective design. This dual focus is critical for improving the quality of dermatological care[11].

Consequently, this study aimed to assess prescribing patterns and monitor cutaneous adverse drug reactions (cADRs) in patients visiting the dermatology outpatient department (OPD) of a tertiary care teaching hospital in North India[12]. The objectives were to assess adherence to WHO prescribing indicators, understand the drug utilization trends across various dermatological conditions[13, 14].

MATERIAL AND METHODS

Study Design and Setting

This was a prospective, observational, cross-sectional study carried out over a period of three months in the Department of Dermatology in association with the Department of Pharmacology at RUHS College of Medical Sciences, Jaipur, Rajasthan. The study was designed to assess the prescribing trends, drug utilization, and occurrence of cutaneous adverse drug reactions (cADRs) in dermatology outpatients attending the tertiary care hospital associated with the institution.

The study adhered to the principles of Good Clinical Practice (GCP) and the Declaration of Helsinki and was reviewed and approved by the Institutional Human Ethics Committee (IHEC) prior to initiation.

Study Objectives

Primary Objective:

- To evaluate the prescribing patterns of dermatological drugs using WHO core prescribing indicators.

Secondary Objectives:

- To determine the average number of drugs per prescription, percentage of drugs prescribed by generic name, percentage of drugs prescribed from the Essential Drug List (EDL), and the frequency of antibiotic use.
- To monitor and analyze cutaneous adverse drug reactions associated with prescribed dermatological medications.

Study Population

The study included patients of either gender attending the dermatology outpatient department (OPD) for the first time during the study period and who presented with a new dermatological condition.

Inclusion Criteria:

- Patients aged 18 years and above.
- Patients visiting dermatology OPD for the first time during the study period.
- Patients with a newly diagnosed dermatological condition.
- Patients willing to provide written informed consent for participation.

Exclusion Criteria:

- Patients coming for follow-up or review visits.
- Patients who refused to give consent.
- Patients with incomplete or illegible prescriptions.
- Known psychiatric or communication disorders that hinder understanding or reporting.

Sample Size Determination

A total of 1,000 dermatology OPD cases were screened during the study period. After applying inclusion and exclusion criteria, 979 prescriptions were found suitable and included in the final analysis. The sample size was determined based on the average monthly patient flow in the dermatology OPD and the feasibility of data collection within the designated time frame.

Data Collection Process

A structured and pre-validated case record form (CRF) was used to capture detailed patient and prescription-related information. Data were collected by the research investigators immediately after the consultation by the dermatologist. The CRF included:

- Patient demographics: age, gender, education, occupation.
- Clinical diagnosis and type of skin condition.
- Detailed prescription audit: name of the drug, dosage, route, dosage form, frequency, duration, and combination patterns.
- WHO prescribing indicators.
- Documentation of any adverse drug reactions, if reported during the visit or through follow-up.

Each prescription was examined in real-time, and no modifications were made to the physician's decisions. Any doubts about diagnosis or drug names were clarified with the prescriber on the same day to ensure accuracy.

Pharmacovigilance and ADR Monitoring

An active surveillance system was implemented for identifying cutaneous ADRs. The following measures were taken:

- Sensitization sessions were conducted for dermatologists, interns, and nursing staff regarding the importance of ADR reporting.
- ADR reporting forms were made available in consultation rooms.
- A locked ADR drop-box was installed in the dermatology OPD.
- Reported ADRs were evaluated by the Pharmacovigilance Committee, and causality was assessed using the WHO-UMC causality assessment scale (certain, probable, possible, unlikely, unclassified, and unassessable).
- Severity was evaluated using the Modified Hartwig and Siegel's Scale.

WHO Prescribing Indicators Used

The WHO core drug use indicators were used to assess the quality of prescribing:

1. Average number of drugs per encounter

$$= \frac{\text{Total number of drugs prescribed}}{\text{Total number of encounters}}$$

2. Percentage of drugs prescribed by generic name

$$= \frac{\text{No. of drugs prescribed by generic name}}{\text{Total drugs prescribed}} X100$$

3. Percentage of encounters with an antibiotic prescribed

$$= \frac{\text{Encounters with} \geq 1 \text{ antibiotic}}{\text{Total encounters}} X100$$

4. Percentage of drugs prescribed from EDL

$$= \frac{\text{No. of drugs from National EDL}}{\text{Total drugs prescribed}} X100$$

These indicators are globally recommended to monitor the rationality of prescriptions and provide comparative benchmarks across facilities and regions.

Statistical Analysis

The collected data were entered into Microsoft Excel 2021 and analyzed using SPSS version 21.0 (Statistical Package for the Social Sciences). Descriptive statistics including frequency, mean, standard deviation, and percentages were computed. Wherever relevant, comparisons with WHO standards and findings from previously published studies were made.

Outcome Measures

- **Primary outcomes** included WHO prescribing indicators and patterns of dermatological drug utilization.
- **Secondary outcomes** involved characterization of cADRs - type, frequency, severity, and suspected drug class.

Ethical Considerations

The study received ethical clearance from the Institutional Human Ethics Committee (IHEC) of RUHS College of Medical Sciences, Jaipur, under the approval number RUHS-CMS/Ethics Comm./2022/126, dated 01/09/2022.

Prior to participation, informed written consent was obtained from all enrolled subjects, ensuring voluntary involvement with full awareness of the study's purpose and procedures. To safeguard the participants' privacy and maintain ethical standards, confidentiality was rigorously upheld by anonymizing personal identifiers and restricting access to raw data exclusively to the authorized research investigators.

RESULTS

A total of 979 dermatology outpatients were analyzed over the 3-month study period. The prescribing patterns, patient demographics, and adverse drug reactions (ADRs) were evaluated using WHO prescribing indicators and pharmacovigilance metrics.

The majority of dermatology OPD patients (37.07%) were in the 28-37 years age group, followed closely by the 18-27 years group (32.48%). This suggests that young adults form the largest demographic seeking dermatological care. Male patients slightly outnumbered females (53.11% vs 46.89%), although this difference was not statistically significant.

Table 1: Demographic Profile of Patients

Age Group (Years)	No. of Patients	Percentage (%)
18-27	318	32.48
28-37	363	37.07
38-47	95	9.71
48-57	101	10.32
58-67	63	6.44
68-77	39	3.98

Table 2: Gender-wise Distribution

Gender	No. of Patients	Percentage (%)
Male	520	53.11
Female	459	46.89

1. Pattern of Drug Prescriptions

A total of 2,848 individual drugs were prescribed during the study.

Out of the 2,848 drugs prescribed, oral administration was preferred (57.3%) over topical (42.7%). Tablets were the most common dosage form (44.49%), followed by creams (24.05%) and capsules (12.82%). These findings align with the therapeutic need for systemic antihistamines and antifungals in many dermatoses.

Table 3: Individual drugs prescribed

Route	No. of Drugs	Percentage (%)
Oral	1,632	57.3
Topical	1,216	42.7

Table 4: Dosage Forms Used

Dosage Form	Frequency	Percentage (%)
Tablets	1,267	44.49
Creams	685	24.05
Capsules	365	12.82
Lotions	255	8.95
Gels	207	7.27
Ointments	69	2.42

2. WHO Prescribing Indicators

The average number of drugs per prescription was 2.75, falling within the WHO standard range (2-3). Impressively, 100% of prescriptions used generic names, and 93.64% of drugs were prescribed from the Essential Drug List (EDL), reflecting high-quality, rational prescribing practices. The antibiotic prescribing rate was 19.28%, well below the WHO upper limit of 40%, further supporting rational antibiotic use.

Table 5: Study value as per WHO standard

Indicator	Study Value	WHO Standard
Average number of drugs per prescription V	2.75	2.0-3.0
Percentage of drugs prescribed by generic name	100%	100%
Percentage of drugs from Essential Drug List	93.64%	≥80%
Percentage of prescriptions with antibiotics	19.28%	<40%

3. Class-wise Drug Utilization

Among therapeutic classes, antihistamines (23.6%) and antifungals (18.6%) were most frequently prescribed, followed by antibiotics (19.3%) and corticosteroids (11%). Levocetirizine and itraconazole were the top agents within their respective classes.

Table 6: Frequency of Drug Classes Prescribed

Drug Class	Frequency	Percentage (%)
Antihistamines	673	23.63
Antibiotics	549	19.28
Antifungals	530	18.61
Corticosteroids	314	11.03
Emollients & Keratolytics	255	8.95
Antiparasitics	206	7.23
Others (vitamins, antivirals, FDCs)	321	11.27

4. Adverse Drug Reactions (ADRs)

A total of 23 cases of cutaneous ADRs were reported from 979 patients (2.35%).

A total of 23 cADRs were documented (2.35%), with steroid-induced acne (1.1%) being the most commonly reported event. All ADRs were mild to moderate in severity, and no serious events were observed during the study. ADRs were more frequently linked to corticosteroids and fixed-dose topical combinations.

Table 7: Types of Reported cADRs

ADR Type	No. of Cases	Percentage (%)
Steroid-induced acne	11	1.1
Photodermatitis	8	0.82
Urticaria	4	0.42
Total ADRs	**23**	**2.35**

5. Polypharmacy and Prescription Load

The majority of prescriptions contained three drugs (58.3%), and only a small fraction (0.9%) had five or more drugs. These values indicate that polypharmacy was minimal, and prescription loads were reasonable.

Table 8: Number of Drugs per Prescription

No. of Drugs	No. of Patients	Percentage (%)
1	6	0.62
2	272	27.78
3	571	58.32
4	121	12.36
≥5	9	0.92

6. Statistical Correlation Between Variables

- A Chi-square test revealed a significant association between age group and number of drugs prescribed ($p = 0.008$), suggesting that middle-aged patients received more multi-drug therapy.
- ADR occurrence was significantly higher in patients receiving corticosteroids ($p < 0.001$).
- Prescriptions with fixed-dose combinations (FDCs) were associated with increased incidence of topical ADRs.

DISCUSSION

The current prospective observational study was conducted to evaluate prescribing patterns and monitor cutaneous adverse drug reactions (cADRs) in dermatology outpatients attending a tertiary care teaching hospital in North India[15]. The findings shed light on both the rationality of drug use and the safety profile of common dermatological pharmacotherapies. As dermatological disorders often require prolonged or combination drug therapy, it becomes crucial to ensure judicious prescribing, minimize polypharmacy, and actively monitor adverse drug reactions to prevent avoidable complications and economic burden[16].

Demographic Interpretation and Disease Burden

In our study, the age group of 28-37 years was the most frequently affected cohort, comprising 37.07% of the dermatology OPD population. This finding is consistent with previous Indian studies that reported a similar age distribution, often attributing it to hormonal changes, occupational exposure, increased cosmetic concern, and greater lifestyle-related dermatologic triggers in this demographic[17]. The younger age groups, particularly 18-37 years, are also more likely to seek dermatologic consultation for acne, fungal infections, and allergic dermatitis due to increased awareness and digital health-seeking behaviour[18].

Gender-wise, male predominance (53.11%) was observed in our sample, which is in line with the findings of Sumana *et al*. However, other studies from rural and semi-urban regions have reported female predominance, suggesting possible regional or sociocultural variations in healthcare-seeking behavior[19], occupational exposures, or cosmetic dermatology utilization[20]. It is also important to note that women may be underrepresented due to stigma associated with skin conditions or restricted access to tertiary care facilities.

Disease Spectrum and Therapeutic Classes[21]

The most common dermatological conditions reported were dermatophytosis (24.82%), acne vulgaris (21.14%), and urticaria (12.97%). Dermatophytosis has become a public health challenge in India, with recurrent or steroid-modified fungal infections being increasingly

reported in both urban and rural populations[22]. The widespread use of irrational fixed-dose combinations (FDCs) of corticosteroids with antifungals has contributed to this surge[23].

Acne remains a highly prevalent condition, particularly among young adults and adolescents, often requiring a combination of antibiotics, retinoids, and topical agents. Urticaria and dermatitis cases likely reflect increased environmental allergen exposure and poor barrier protection, particularly among lower socio-economic groups.

From a therapeutic standpoint, antihistamines (23.6%), antifungals (18.6%), antibiotics (19.3%), and corticosteroids (11.0%) were the most prescribed drug classes. This pattern mirrors the findings of Pathak *et al*. and Patil *et al*., who documented similar prescribing trends in dermatology[24]. The predominance of antihistamines is understandable given the high frequency of allergic dermatoses. Levocetirizine and cetirizine were the preferred agents, likely due to their favorable side-effect profiles and once-daily dosing[25].

Among antifungals, Itraconazole was the most prescribed systemic agent, followed by topical Clotrimazole, reaffirming the shift toward systemic therapy in the era of chronic, resistant dermatophytoses. The low rate of fluconazole usage may reflect regional resistance patterns or prescriber preference. The high prescription rate of Clindamycin gel supports its continued role in acne management, often in combination with benzoyl peroxide or topical retinoids.

Evaluation of Prescribing Indicators

The WHO prescribing indicators used in this study serve as a powerful benchmarking tool for assessing the quality of drug use. The average number of drugs per prescription (2.75) fell within the WHO recommended range (2-3), indicating a low level of polypharmacy. This is crucial in dermatology where irrational multi-drug topical applications are not uncommon.

Notably, 100% of drugs were prescribed by generic names, which reflects excellent adherence to rational prescribing principles. This performance exceeds those reported in several Indian studies where generic prescribing rates were significantly lower, often due to prescriber habit, pharmaceutical marketing pressure, or patient demand[26].

Further, 93.64% of prescribed drugs were from the National Essential Drug List (EDL), which meets the WHO benchmark of ≥80%. This indicates alignment with national treatment guidelines and cost-effective care. The antibiotic prescribing rate was 19.28%, far below the WHO threshold of 40%, highlighting prudent use and awareness of antimicrobial resistance - an emerging threat in dermatology as well[27].

Cutaneous Adverse Drug Reactions (cADRs)

A total of 23 cADRs (2.35%) were observed, with steroid-induced acne and photodermatitis being the most commonly reported reactions. These were predominantly associated with topical corticosteroids, often used in combination preparations. All reactions were classified as mild to moderate based on severity scales and did not require hospitalization.

Similar patterns were reported by Shah *et al*. and Saha *et al*., who found corticosteroids, antimicrobials, and NSAIDs to be leading causes of cADRs in dermatology[28]. Under-reporting remains a major challenge in ADR surveillance, particularly in outpatient settings. Pharmacovigilance education, simplified reporting systems, and departmental feedback loops can significantly enhance ADR detection and prevention.

Our study further demonstrated that patients using corticosteroids had a significantly higher likelihood of developing ADRs ($p < 0.001$), confirming their high-risk profile. Additionally, a statistically significant association ($p = 0.008$) was found between age group and number of drugs prescribed, indicating that patients in their 30s and 40s were more likely to receive combination therapy, possibly due to cosmetically distressing conditions or chronicity.

CONCLUSION

This prospective, hospital-based observational study offers important insights into the prescribing patterns and pharmacovigilance practices within a dermatology outpatient setting in a tertiary care teaching hospital in North India. The analysis of 979 prescriptions and 2,848 drugs revealed a largely rational prescribing approach, with strong compliance to WHO prescribing indicators - including an average of 2.75 drugs per prescription, 100% generic name use, and over 93% adherence to the National Essential Drug List.

The most commonly prescribed classes were antihistamines, antifungals, antibiotics, and corticosteroids - consistent with the prevalent dermatological diagnoses of dermatophytosis, acne, and urticaria. The predominance of levocetirizine, itraconazole, and clindamycin reflects current treatment trends and therapeutic appropriateness for these conditions.

Importantly, the study also identified a 2.35% incidence of cutaneous adverse drug reactions, primarily associated with topical corticosteroid misuse and fixed-dose combinations. Although the overall ADR burden was low and non-serious, the findings underscore the need for active pharmacovigilance in dermatology - a specialty where

patients are often exposed to chronic topical and systemic therapies.

The results suggest that dermatology practitioners at the study site are adhering to rational prescribing norms; however, the occasional use of irrational fixed-dose combinations, especially those involving steroids, remains a concern. Regular prescription audits, ADR reporting sensitization, and stringent regulation of over-the-counter steroid formulations are recommended to address these gaps.

Limitations

While the study provides meaningful insights into dermatological prescribing practices and pharmacovigilance, the limitations should be considered are single-center study and lack of long-term ADR follow-up.

DISCLOSURE

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