



TOPICAL CORTICOSTEROIDS USED IN DERMATOLOGY OPD: A CROSS-SECTIONAL DRUG UTILIZATION RESEARCH

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ABSTRACT

Background

The irrational use of medications represents a significant global public health concern, with a high prevalence in developing countries. Among these, the inappropriate and excessive use of topical corticosteroids is widely practiced. The study aimed to evaluate the prescription pattern of topical corticosteroid in Dermatology outpatient department (OPD) using World Health Organization (WHO) Drug Use Indicators as a framework for assessment.

Methods

A cross-sectional descriptive study was conducted over a period of one year. During this period, 329 prescriptions were randomly collected from patients attending the Dermatology OPD, following informed consent. The prescriptions were subsequently analysed.

Results

Average number of medicines per prescription was 3.41. Of the drugs prescribed, 44.73% written using generic names, 1.16% included antibiotics, and 0.27% involved injectable medications. Additionally, 33.48% of the prescribed medications were listed in the National List of Essential Medicines (NLEM) 2022. The calculated index of rational drug prescribing (IRDP) was calculated as 3.65, compared to optimal score of 5. The analysis indicated a substantial tendency toward prescribing brand-name and non-essential medications. Nevertheless, the use of antibiotics and injectable drugs, as well as indicators related to patient care and health facility practices, aligned with WHO standards. The demographic profile of patients showed a male predominance (55.62%), with the highest proportion of patients falling within the 41–50-year age group. Eczema was identified as the most prevalent dermatological condition, accounting for 24.62% of cases.

Conclusion

The findings underscore the need for regular educational initiatives and periodic training programs for healthcare providers to promote the rational use of medications. Furthermore, ensuring the

consistent availability of essential drugs is imperative for improving prescribing practices in clinical settings.

Keywords: Drug utilization research, Index of rational drug prescribing, Rational prescribing, Topical corticosteroids, WHO core prescribing indicators.

INTRODUCTION

Drug utilization research (DUR), as defined by World Health Organization (WHO) in 1977 refers to “the marketing, distribution, prescription, and use of medications within a given population, with particular focus on the medical, social and economic consequences” that result from these practices. The primary objective of DUR is to promote the rational use of pharmaceuticals, ensuring that patients receive well researched medications in appropriate doses, accompanied by accurate, information, and at an affordable cost.¹ In recent decades, the prevalence of dermatological conditions has steadily increased, posing a considerable burden on healthcare systems across the globe. This trend is well-documented in the Global Burden of Disease studies conducted in 2010, 2017, and 2021 wherein skin diseases were ranked 18th, 10th, and 8th respectively.^{2,3,4} Skin and subcutaneous disorders represent a substantial component of the global disease burden, affecting individuals across all age groups-from neonates to the elderly. These conditions are associated with considerable morbidity and can significantly impair quality of life while imposing a financial strain on both patients and their families. Although mortality linked to these diseases is relatively low, they contribute extensively to disability and constitute a major share of the non-fatal disease burden in India. This challenge is further exacerbated by the inappropriate and irrational use of medications. Conducting regular prescription audits in the form of DUR serves as an effective strategy to enhance the quality of prescribing practices and to mitigate the growing issue of irrational drug use.^{3,5}

Corticosteroids play a vital role in the management of numerous medical conditions and are especially important in dermatological practice, where they are most commonly administered in topical form. Due to their potent immunosuppressive, anti-inflammatory, antipruritic, atrophogenic, and melanopenic properties, along with their ability to provide rapid symptomatic relief, topical corticosteroids (TCs) are frequently prescribed for the treatment of a wide range of inflammatory dermatoses.^{6,7} TCs are considered a cornerstone in the management of various skin conditions and form the foundation of modern dermatotherapeutics. Often described as "magic molecules," their efficacy is highly dependent on careful and rational prescribing.⁸

These agents are primarily indicated for the treatment of non-infectious, inflammation-related dermatological conditions and may be used either as monotherapy or in combination with other topical agents. Clinical indications include, but are not limited to, psoriasis, vitiligo, lichen sclerosus, lichen planus, lichen simplex chronicus, bullous pemphigoid, discoid lupus erythematosus, pemphigus foliaceus, hand eczema, nummular eczema, hyperkeratotic eczema, asteatotic eczema, alopecia areata, seborrheic dermatitis, atopic dermatitis, contact dermatitis, otitis externa, post-scabidical scabies management, intertrigo, and perianal inflammation.^{9,10} To support effective and measurable improvements in rational drug use, particularly in resource-limited settings, the World Health Organization (WHO) has developed standardized drug use indicators. These are categorized into prescribing indicators, patient care indicators, and health facility indicators.^{11,12} Although various drug utilization studies have been conducted across different populations and healthcare settings within India, limited research has specifically focused on dermatology outpatient departments. In light of this gap, the present study seeks to investigate the patterns and determinants of drug utilization-particularly with regard to topical corticosteroids-in the dermatology OPD setting.

MATERIAL AND METHODS

The present study was conducted at the Dermatology Outpatient Department (OPD) in collaboration with the Department of Pharmacology at Assam Medical College and Hospital (AMCH), Dibrugarh, Assam. The study period spanned over a period of six months, from February 1, 2022, to July 31, 2022, following approval from the Institutional Ethics Committee (H) of the institute (AMC/EC/192-

Dt 17/01/2022). The study was a hospital-based, non-interventional, cross-sectional study that enrolled all new patients attending the Dermatology OPD. Prescriptions of new outpatient patients of all age groups and genders and that contained TCs were included in the study. Prescriptions without TC, patients with chronic medical illnesses or psychological illnesses, were excluded from the study. Clinical impressions were considered as the diagnosis. Fixed dose combinations (FDCs) were numbered as a single entity and included in the study¹¹. Prescriptions not possessing requisite essential information such as drug names, dosage forms, diagnosis, or demographic details were excluded from the study. WHO guidelines mandate that a minimum of 600 prescriptions need to be included in any cross-sectional study to accurately describe the current prescribing patterns of a healthcare facility¹¹. However, during the period of study, only 329 prescriptions containing TCs could be accessed and were analyzed for further evaluation.

Data was collected through one-on-one consultations with patients. Each participant was provided with a patient information sheet and proper written consent was obtained in their vernacular language. Prescription data were then prospectively recorded using a specially designed proforma.¹² Additionally, patients were informed to report any adverse effects either via telephone or by reporting to the OPD. The necessary details were recorded in a case report form. The collected data were carefully reviewed to ensure completeness before being entered into Microsoft Excel 2021. After data entry, the information was verified for accuracy to ensure reliable results. All prescriptions were coded and anonymized in view of maintaining patient confidentiality.

Outcome and Data analysis

The data collected were analyzed using the methodology outlined in the WHO manual for prescribing indicators [Table 5]. In addition to the core WHO prescribing indicators, several supplementary parameters were evaluated, including patient demographic information, the use of FDCs containing TCs, and documentation of clinical diagnoses on prescriptions. The Index of Rational Drug Prescribing (IRDP) was determined using a previously validated methodology,¹³ as described by Dong et al.¹⁴ and other researchers.^{15,16,17,18} This index comprises five individual measures derived from the WHO's core prescribing indicators. The optimal level for each indicator is shown Table 6. Each indicator has an optimal value of 1; the closer an individual score is to this value, the more rational the prescribing behavior is considered to be. The IRDP, therefore, has a maximum possible cumulative score of 5, reflecting the highest standard of rational drug use. A total score approaching 5 indicates optimal prescribing practices.

Polypharmacy index was assessed by calculating the proportion of prescriptions classified as non-polypharmacy, with those containing four or fewer drugs considered within the non-polypharmacy range.¹⁶ Polypharmacy is commonly defined as the concurrent use of five or more medications in a single prescription.¹⁹ The index for rational antibiotic use was calculated by dividing the WHO-recommended optimal value of 30% by the actual percentage of prescriptions containing antibiotics. Similarly, the index for safe injection use was calculated by dividing the optimal level of 10% by the observed percentage of prescriptions that included injectable medications. The index for generic prescribing was determined by dividing the percentage of drugs prescribed using their generic names by the optimal level of 100%, and the same method was applied to assess the index of essential medicine use.^{16,17} Furthermore, the potency classification of topical corticosteroids was assessed using the classification system of the United States of America (USA), which categorizes corticosteroids into seven classes, with Class I representing the most potent and Class VII the least potent.²⁰

Statistical Analysis

Data obtained from the standardized proformas were systematically entered and analyzed using Microsoft Excel. The findings were presented through descriptive statistics, including proportions, frequencies, and percentages. These observed values were subsequently compared against the WHO reference standards for prescribing indicators to evaluate the rationality of the prescribing practices.

RESULTS

Demographic Data of Patients

The majority of patients were within the 41–50 years age group (19.76%), followed by those aged 31–40 years (18.54%), 21–30 years (18.24%), and 51–60 years (14.59%). Males accounted for 55.62% of the patients, indicating a male preponderance represented in Table 1.

Age Group (Years)	Male	Female	Total	Percentage (%)
0-10	17	13	30	9.12
11-20	18	24	42	12.76
21-30	28	32	60	18.24
31-40	34	27	61	18.54
41-50	38	27	65	19.76
51-60	30	18	48	14.59
61-70	14	05	19	5.77
>70	04	00	04	1.22
Total	183	146	329	100

Table 1: Age and gender-wise distribution of patients

Fixed-Dose Combination (FDCs) of TCs

In the studied population, various FDCs containing TCs and other agents were identified in the prescribed treatments. The most commonly prescribed FDCs were Clobetasol (0.05% w/w) + Salicylic Acid (6% w/w) at 28.29%, followed by Clobetasol (0.05% w/w) + Salicylic Acid (3% w/w) at 27.63%, and other FDCs as detailed in Table 2. These results highlight the wide variety of FDCs utilized in the pharmacological management of different dermatological conditions.

	Frequency (n=152)	Percentage (%)
Clobetasol (0.05% w/w) + Salicylic Acid (6% w/w)	43	28.29
Clobetasol (0.05% w/w) + Salicylic Acid (3% w/w)	42	27.63
Mometasone (0.1% w/w) + Fusidic Acid (2% w/w)	16	10.53
Betamethasone (0.05% w/v) + Zinc Sulfate (0.5% w/w)	11	7.24
Clobetasol (0.05% w/w) + Fusidic Acid (2% w/w)	9	5.92
Betamethasone (0.05%w/v) + Salicylic acid (3%w/v)	7	4.61
Hydrocortisone (0.25% w/w) + Crotamiton (10% w/w)	6	3.95
Mometasone (0.1% w/v)+ Sertaconazole (2% w/v)	4	2.63
Clobetasol (0.05% w/w) + Lactic Acid (12% w/w)	3	1.97
Betamethasone (0.05% w/w) + Gentamicin (0.1% w/w) + Zinc Sulfate (0.5% w/w)	3	1.97
Clobetasol (0.05% w/w) + Calcipotriol (0.005% w/w)	2	1.32
Mometasone (0.1% w/w) + Salicylic Acid (5% w/w)	1	0.66
Betamethasone (0.05% w/w) + Gentamicin (0.1%w/w)	1	0.66
Clobetasol (0.05% w/w) + Miconazole (2% w/w) + Neomycin (0.1% w/w)	1	0.66
Fluocinolone (0.01 %) + Hydroquinone (2.0 %) + Tretinoin (0.025 %)	1	0.66
Fluticasone Furoate + Benzalkonium Chloride IP	1	0.66
Mometasone IP + Tretinoin IP	1	0.66

Table 2: Fixed dose combinations of TCs

Disease Pattern of Patients Receiving TCs

The most frequently diagnosed skin conditions were eczema (24.62%), followed by lichen simplex chronicus (LSC) (11.25%), psoriasis (7.60%), polymorphous light eruption (PMLE) (7.30%), allergic contact dermatitis (5.47%), scabies (3.95%), irritant contact dermatitis (3.95), prurigo (3.65%), vitiligo (3.34%), SD (3.34%), papular urticaria (2.74%), diabetic dermopathy (2.74%) and atopic dermatitis (1.82%). A detailed breakdown is provided in Table 3.

Dermatological Indication (n=329)	Frequency	Percentage (%)
Eczema	81	24.62
Lichen simplex chronicus (LSC)	37	11.25
Psoriasis	25	7.60
Polymorphous light eruption (PMLE)	24	7.30
Allergic Contact dermatitis (ACD)	18	5.47
Scabies	13	3.95
Irritant Contact dermatitis	13	3.95
Prurigo Simplex	12	3.65
Vitiligo	11	3.34
Seborrheic Dermatitis (SD)	11	3.34
Papular Urticaria	09	2.74
Diabetic Dermopathy	09	2.74
Photodermatitis	09	2.74
Hair dye dermatitis	09	2.74
Atopic dermatitis	06	1.82
Lichen planus	05	1.52
Insect bite dermatitis	05	1.52
Chronic urticaria	04	1.22
Pityriasis rosea	04	1.22
Palmoplantar Keratoderma	04	1.22
Acne Vulgaris	04	1.22
Pompholyx	03	0.91
Alopecia Areata	03	0.91
Chronic Paronychia	03	0.91
Herpes Zoster	02	0.60
Pityriasis alba	02	0.60
Fixed drug eruption	01	0.30
Cutaneous amyloidosis	01	0.30
Pemphigus Vulgaris	01	0.30

Table 3: Disease pattern of patients receiving TCs

Potency of Topical Corticosteroids

Clobetasol was the most commonly prescribed TC, accounting for 39.29% of prescriptions, followed by mometasone at 37.50% and desonide at 12.80%. The various TCs used for managing skin conditions are detailed in Table 4. The data indicates that Class I (super potent) corticosteroids were prescribed most frequently (39.29%), followed by Class II (potent) at 37.50%, and Class VI (mild potency) at 12.80%.

Prescribed TC	Frequency (n=336)	Percentage
Clobetasol (0.05% w/w) Class 1 (Superpotent)	132	39.29 %
Mometasone (0.1% w/w) Class 2 (Potent)	126	37.50%
Desonide (0.05% w/v) Class 6 (Mild)	43	12.80%
Betamethasone-0.05%w/v Class 5 (Midstrength)	20	5.95%
Hydrocortisone (0.25% w/w) Class 7 (Least potent)	06	1.79%
Triamcinolone Acetonide (0.1% w/w) Class 6 (Mild)	04	1.19%
Fluticasone Propionate (0.05% w/w) Class 5 (Midstrength)	03	0.89%
Fluocinolone acetonide (0.1% w/w) Class 4 (Midstrength)	02	0.59%

Table 4: Topical corticosteroids as per their potency

Analysis of Prescription Patterns

A total of 329 prescriptions containing TCs were analysed, encompassing a total of 1,123 prescribed medications. The mean number of drugs per prescription was 3.41, with the number of medications per prescription ranging from a minimum of one to a maximum of six. Other co-prescribed medications included antihistamines, antibiotics, antifungals, antivirals, scabidals, anthelmintics, immunosuppressants, emollient lotions and creams, vitamin B12, melatonin, benfotiamine, pantoprazole, calcium supplements, and multivitamins/multimineral. No prescription exceeded six medications. Among the 329 prescriptions, 288 (87.53%) contained four or fewer drugs, thus qualifying as non-polypharmacy prescriptions. Oral and parenteral corticosteroids were each prescribed in only six cases. In nearly all prescriptions, the chief complaints and provisional or confirmed diagnoses were appropriately documented.

All topical corticosteroids, emollients, and other topical agents were prescribed using brand names. The strength, frequency, and duration of application were clearly stated across all prescriptions. However, essential information such as the quantity of corticosteroid to be applied and the specific site of application was not documented.

WHO Core Prescribing Indicators

The results of the study revealed that the average number of medications prescribed per patient visit was 3.41, which exceeds the WHO's recommended reference range of 1.6 to 1.8. In this study, prescriptions with four or fewer drugs were considered non-polypharmacy, accounting for 87.53% of the total. However, only 44.73% of medications were prescribed using their generic names, and just 33.48% were from the Essential Medicines List (EML)—both figures falling short of the WHO's reference value of 100%. On a positive note, the use of antibiotics (1.16%) and injections (0.27%) per encounter aligned with WHO standards. A detailed overview of prescribing, patient-care, and facility indicators is provided in Table 5.

No.	Prescribing indicators	WHO optimal values	Observed value
1	Average number of drugs per encounter (n)	1.6-1.8	3.41
2	Percentage of drugs prescribed by generic name (%)	100	44.73
3	Percentage of encounters with an antibiotic prescribed (%)	20.0-26.8	1.16
4	Percentage of encounters with an injection prescribed (%)	13.4-24.1	0.27
5	Percentage of drugs prescribed from the EML (%)	100	33.48
Patient Care indicators			
1	Average consultation time (min)	≥10	12.51
2	Average dispensing time (sec)	≥90	171
3	Percentage of drugs dispensed (%)	100	100
4	Percentage of drugs adequately labeled (%)	100	100
5	Percentage of patients' knowledge of correct dosage (%)	100	100
Health Facility indicator			
1	Availability of a Copy of the EML	100	yes
2	Availability of Key drugs (%)	100	100

Table 5: WHO prescribing indicators

Index of Rational Drug Prescribing (IRDP)

The comprehensive IRDP in this study was 3.65 out of a possible optimal score of 5 (Table 6). The observed value of non-polypharmacy was 87.53%. Although the rates for rational antibiotic use (1.16%) and safe injection practices (0.27%) were both below the optimal thresholds of 30% and 10%, respectively, they were still assigned an IRDP score of 1. The index for prescribing by generic name was calculated by dividing the percentage of drugs prescribed generically by the ideal value of 100%, and the same method was used to calculate the EML index.

Prescribing indicators	Optimal level (%)	Optimal index	Observed value (%)	Index of rational drug prescribing	Indices
Prescriptions including antibiotic	<30	1	1.16	Rational antibiotic index	1
Polypharmacy prescription	0	1	87.53	Index of non-polypharmacy	0.87
Prescriptions including injection	<10	1	0.27	Index of safety injection	1
Drugs prescribed by generic name	100	1	44.73	Generic name index	0.44
Drugs prescribed by EML	100	1	33.48	EML index	0.34
Total calculated IRDP value		5			3.65

Table 6: Index of Rational Drug Prescribing

DISCUSSION

Drug utilization studies are structured and reliable quality improvement tools formulated to evaluate pattern of drug use and prescriptions, against recent recommendations for specific diseases. Routine prescription audits play a key role in improving treatment outcomes, minimizing adverse drug reactions, offering constructive feedback to prescribers, and reinforcing adherence to established treatment guidelines.⁶ This study showed a higher prevalence of dermatological conditions among males (55.62%) in the 41–50 age group, indicating that men in this age range may be more frequently exposed to environmental triggers and irritants. These findings are consistent with those reported by Divya Shanthi CM et al.²¹ Eczema was the most prevailing skin condition encountered (24.62%) in this study. Hand eczema is a widely occurring skin condition and one of the most frequent occupation-related disorders. In as many as two-thirds of cases, it progresses to a chronic form, leading to significant personal hardship and occupational disability.²² In this study, super potent TCs like clobetasol (39.29%) were prescribed more frequently than Class 2 potent TCs such as mometasone (37.50%), followed by the mildly potent Class 3 desonide (12.80%). These findings are consistent with those reported by Jena M et al., indicating similar trends or outcomes across both studies.²³ The WHO core prescribing indicators offer valuable insight into prescribing practices and drug use patterns. The overall rationality of prescriptions can be assessed using the IRDP value. The study demonstrated favorable outcomes in terms of non-polypharmacy, rational antibiotic prescribing, and safe injection practices. However, the indices for generic prescribing and essential drug prescribing were found to be below WHO standards. Using generic names enhances flexibility for dispensing pharmacists and tends to be more cost-effective than branded drugs, but low generic prescribing may stem from physicians' preference and faith for branded medications. Strong policy and regulatory support can play a key role in promoting the adoption of generic and biosimilar medications. In line with this, the Indian Council of Medical Research (ICMR) has recently made a notable move by introducing the "ICMR National Virtual Centre Clinical Pharmacology (NvCCP) Prescribing Skills" course, specifically designed for Indian medical graduates.²⁴

By implementing these strategies, healthcare systems can improve the acceptance and use of generic and biosimilar medicines, thereby enhancing patient access to more affordable treatments.²⁵ In this study, over 87% of prescriptions contained at least four drugs per encounter, indicating non-polypharmacy practices. However, the average figure of drugs per prescription was 3.41, which is not par with the WHO reference range of 1.6 to 1.8. This higher average may be due to the addition of co-prescribed medications, such as emollients and antihistamines. Emollients, in particular, have a 'steroid-sparing effect,' meaning they can reduce the need for TCs, especially in conditions like atopic dermatitis and eczema.²⁶ Polypharmacy can increase the risk of drug interactions, adverse drug

reactions, higher medication costs, errors in drug dispensing, non-adherence to prescribed drugs, and ultimately compromise with patients' quality of life. Therefore, prescribers should make certain that patients are prescribed medications that are clinically appropriate, cost-effective, and aligned with evidence-based guidelines to promote safe and effective treatment outcomes.²⁷

On the other hand, not specifying the amount of TCs may aggregate in underutilization of the drug resulting in sub-optimal outcome, while excessive usage may result in adverse effects. The fingertip unit (FTU) serves as a useful guideline for determining the appropriate amount of topical medication to apply in a single use.²⁸ FDCs of TCs with anti-inflammatory, antimicrobial, and antifungal agents were present in more than 50% of the total prescriptions. Atopic dermatitis (eczema) 2023 guidelines suggest against adding topical antimicrobials to topical anti-inflammatories in patient with no clear sign of infection.²⁹ Studies have suggested that topical combination of antimicrobial and steroid offer no additional benefit over steroids monotherapy in treating atopic eczema.³⁰ Antibiotics, in topical forms, should be reserved for cases where there is clear evidence of infection. In more severe cases, a brief regimen of an appropriate oral antibiotic may be prescribed. To minimize the risk of resistance, all antimicrobials, including topical formulations, should be used in a judicious manner and only when there is a clear clinical indication for their use.³¹

The strength of the study lies in its prospective design, which involved collecting data directly from patients' prescriptions on an individual basis. Furthermore, this approach helps prevent data duplication. However, the present study has few limitations. It involved a small sample size from a single tertiary healthcare facility, which however might not accurately represent a broader population, despite the one-year duration. Additionally, seasonal variations in drug prescription patterns could influence the findings. Including multiple tertiary care centers in the study could have produced more representative and generalizable results.

CONCLUSIONS

The drug utilization study at our tertiary care hospital showed results that generally aligned with WHO optimal values for various indices. However, some deviations from WHO recommendations were noted, particularly a high incidence of prescribing drugs by commercial name and use of unessential drugs. Some variables adhered to WHO standards. Based on these findings, key intervention goals include regularly sensitizing and periodically educating prescribers on rational use of drugs. Ensuring the sustainable accessibility of essential medicines is also crucial to promoting rational prescribing, which requires strong government commitment. Future studies should be carried out in diverse settings to investigate variable causes of unjustified medicine use and create strategies for further improvement.

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