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# **Original Research Article**

# A drug utilization study of topical corticosteroids in the department of dermatology in a tertiary care teaching hospital in upper Assam

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#### **ABSTRACT**

**Background:** Topical corticosteroids form an important group of drugs in dermatology and are among the most commonly prescribed medications. However, despite their efficacy, they are associated with various adverse effects and as majority of the skin conditions are chronic, there is a need to ensure that there is rationality in drug use. Thus, this study was conducted with an aim to analyze the drug utilization pattern of topical corticosteroids.

**Methods:** The study was a hospital-based, prospective and observational study and conducted for a period of 12 months. The method of data collection was done based on one-on-one consultation with patients. Data collected were recorded prospectively in a specially designed proforma. Results were then entered and analyzed using Microsoft excel.

**Results:** In the study, it was observed that 48% of the patients were males while 52% were females. Most patients belonged to the age group of 21-30 years (30%). Scabies (30%) was the most common dermatological condition. With regard to the prescribing frequency of different topical corticosteroids, mometasone furoate (31.4%) was the preferred choice in most patients. H<sub>1</sub> antihistaminic drugs like levocetirizine (81.6%) were the most prescribed along with topical corticosteroids, followed by emollients (36.4%) and permethrin (29.2%). The average number of drugs per prescription was 3.6 and all drugs were prescribed by their generic names.

**Conclusions:** Periodic monitoring of the drug utilization pattern in the form of prescription auditing is an effective tool to constitute guidelines for improving the utilization pattern.

Keywords: Prescription auditing, Rationality, Pharmacology

#### **INTRODUCTION**

Skin is the largest organ in the body and many diseases manifest as skin disorders with a variety of symptoms. In India, the most commonly diagnosed skin conditions are scabies, dermatitis, urticaria, fungal skin infections, acne, alopecia, psoriasis, and adverse drug reactions. In dermatology clinics, the most commonly prescribed drugs are topical corticosteroids, antibiotics, antifungals, antihistaminics, emollients, keratolytics, vitamins, and sometimes systemic steroids. Among these, topical steroids form an important group of drugs and are among the most commonly prescribed medications. Topical corticosteroids have been in use for more than 50 years and were first used successfully by Sulzberger and Witten in

1952 and their success marked a cornerstone in the history of dermatology. They are highly effective drugs that are used for treating several autoimmune and inflammatory skin conditions and are extensively prescribed by dermatologists because of their strong immunosuppressive and anti-inflammatory actions. 5

The anti-inflammatory properties of the topical corticosteroids are the primary reason for their use. Despite their efficacy, they are associated with various adverse effects because, the mechanism of their same useful anti-inflammatory properties is also the reason for their adverse effects and their long-term use can result in both local and systemic side effects. With the ever-increasing incidence of adverse drug reactions and

inappropriate use of topical steroids through over-thecounter use, there is a need to ensure that there is rationality in drug use. This is where the need for drug utilization studies comes to light. Periodic monitoring of the drug utilization pattern is one of the methods to analyze the rationality of drug use and are organized quality enhancement processes that are designed to review drug usage and prescribing patterns with current recommendations or guidelines for the treatment of certain diseases.<sup>7</sup>

Drug utilization research was defined by World Health Organization (WHO) in 1977 as the marketing. distribution, prescription, and use of drugs in a society, with special emphasis on the resulting medical, social and economic consequences.8 The principal aim of drug utilization research is to facilitate the rational use of drugs in the population. It also provides insight into the efficiency of drug use. 9 Prescription auditing in the form of a drug utilization study is an important tool to assess the rationality of prescriptions and drug use in society. Prescribing drugs is an important skill that must be continuously assessed and refined. It reflects the physician's attitude towards selecting the most appropriate and rational treatment which will help in enhancing the therapeutic effectiveness and minimize the risk of adverse effects. 10 The data relating to drug utilization patterns of topical corticosteroids in skin conditions are particularly lacking and keeping these facts into consideration, this study was conducted with an aim to analyze the drug utilization pattern of topical corticosteroids through regular monitoring of prescriptions.

#### **METHODS**

### Study setting

This study was conducted in the department of dermatology, Jorhat Medical College and Hospital (JMCH), Assam and further analysis was carried out in the department of pharmacology, Jorhat Medical College.

#### Study design

It was a hospital-based, prospective and observational study.

#### Study period

The study was conducted for 12 months starting from 01 June 2019 to 31 May 2020.

#### Sample size

A total of 140 patients were selected and enrolled in the study.

#### Sampling method

The purposive sampling technique was used.

#### Approval by institutional ethics committee

The study was conducted after the approval of the institutional ethics committee (IEC) of Jorhat Medical College and Hospital, Jorhat filed under number SMEJ/JMCH/MEU/841/Pt-1/2011/3707.

#### Inclusion criteria

Prescriptions of new OPD patients containing topical corticosteroids; patients of all age groups whose prescriptions contained topical corticosteroids; and patients of all genders whose prescriptions contained topical corticosteroids were included in the study.

#### Exclusion criteria

Prescriptions that did not contained topical corticosteroids; patients with chronic medical illness and psychological disorders; and patients using over-the-counter topical corticosteroids were excluded.

#### Method of data collection

The method of data collection was conducted based on one-on-one consultations with patients. The patient's information sheet was provided to all the participating patients and after obtaining informed written consent, new OPD patients prescribed with topical corticosteroids were enrolled in the study, and their prescriptions were analyzed.

Data collected from prescriptions were then recorded prospectively in a specially designed proforma containing relevant details such as demographic, disease, and drug data. Patients were also advised to communicate through a telephonic medium or report to OPD in case any adverse effects/side effects appear.

## Statistical analysis

The data collected from standard proformas were entered and analyzed using Microsoft excel. Data were then expressed using descriptive statistics such as proportions, frequencies, mean and percentages.

#### Assessment tools

#### WHO core drug indicators

Prescribing indicators include: average number of drugs per encounter (optimal value 1.6-1.8), percentage of drugs prescribed with generic name (optimal value 100%), percentage of encounters with antibiotics prescribed (optimal value 20.0-26.8%), percentage of encounters with injections prescribed (optimal value 13.4-24.1%), and percentage of drugs prescribed from the essential drug list (optimal value is 100%).<sup>11</sup>

#### Potency assessment of topical corticosteroids

Potency assessment of topical corticosteroids was done based on the United States of America (USA) system of classification that recognizes seven groups with class 1 being the most potent and class VII being the least potent.<sup>12</sup>

#### **RESULTS**

A total of 140 prescriptions were analyzed during the study. The total number of drugs prescribed was 500 out of which 141 topical corticosteroids were prescribed. The average number of topical corticosteroids prescribed per prescription was 1.

#### Gender distribution

In this study, out of 140 prescriptions analyzed, 73 (52%) were females and 67 (48%) were males showing a female preponderance. Figure 1 depicts the gender-wise distribution of patients during the study.

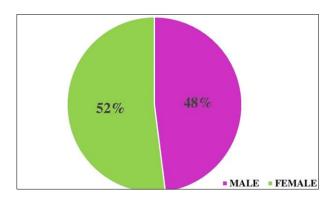


Figure 1: Gender distribution of patients.

#### Age distribution

In this study, most patients belonged to the age group of 21-30 years (30%) followed by age groups of 31-40 years (15.7%) and 41-50 years (15.7%). The age-wise distribution of patients is shown in Table 1.

# Disease pattern of patients receiving topical corticosteroids

It was observed that scabies was the most common dermatological condition (30%), followed by atopic eczema (22.8%) and contact dermatitis (15%). Figure 2 illustrates the disease patterns of patients receiving topical corticosteroids.

#### Topical corticosteroids in the treatment of skin diseases

In this study, mometasone furoate (31.4%) was the most prescribed topical corticosteroid followed by hydrocortisone (30%) and clobetasol propionate (20.7%). The distribution of several topical steroids used for treating skin diseases is represented in Table 2.

Table 1: Age distribution of patients (in years).

Age (in years)	Number of patients (n=140)	Percentage (%)
0–10	19	13.5
11-20	12	8.5
21–30	42	30
31–40	22	15.7
41–50	22	15.7
51–60	14	10
>60	9	6.42
Total	140	100

Table 2: Distribution of topical steroids in the treatment of skin diseases.

Topical corticosteroid name	Frequency (n)	Percentage (%)
Clobetasol propionate	29	20.7
Mometasone furoate	44	31.4
Hydrocortisone acetate	42	30
Desonide	15	10.7
Fluoccinolone acetonide	3	2.14
Betamethasone dipropionate	7	5

#### Potency of topical corticosteroids

Figure 3 depicts a bar diagram highlighting the distribution of topical corticosteroids based on potency. It is evident that class III - potent topical corticosteroids (31%) were the most prescribed followed by class VII - least potent (29%) and class I - super potent steroids (22.8%).

# Topical corticosteroids as fixed-drug combination (FDCs)

The most commonly prescribed FDCs were hydrocortisone and crotamiton (44.6%) followed by FDCs of mometasone and fusidic acid (24.4%). Other drugs and their distributions are elaborated in Figure 4.

#### Dosage forms of topical corticosteroids

According to the study, creams were the most common dosage forms prescribed (82.8%) followed by lotions (13.5%) and ointments (2.14%). The distribution of various dosage forms is provided in Table 3.

Table 3: Dosage forms of topical corticosteroids prescribed.

Dosage forms	Frequency (n)	Percentage (%)
Creams	116	82.8
Ointments	3	2.14
Lotions	19	13.5
Gel	2	1.42
Total	140	100

#### Drugs prescribed along with topical corticosteroids

Figure 5 highlights the distribution of drugs prescribed along with topical corticosteroids.

From the study, it was observed that antihistamines were the most prescribed drugs with topical corticosteroids (85.7%) followed by scabicidal agents (42.1%) and emollients (36.4%).

#### WHO core prescribing indicators

In our study, the average number of drugs per counter was 3.6 and there were no encounters with any injectables. The percentage of encounters with an antibiotic prescribed was 7.85% and maximum drugs (100%) were prescribed by their generic names. The percentage of drugs prescribed from the essential list of medicine was 2%.

Table 4 outlines the various prescribing indications and their numbers.

#### Additional information recorded from prescriptions

In this study, we observed that the frequency of administration, duration of treatment, and instruction to patients were mentioned in all prescriptions. The strength of topical corticosteroids was mentioned in 70% of the prescriptions whereas the fingertip unit method was not mentioned or explained in any prescription. Diagnosis of the patient was mentioned in 90% of the prescriptions.

Table 5 depicts a list of additional information recorded from prescriptions.

Table 4: WHO core prescribing indicators.

Prescribing indicators	Numbers and percentages
Average number of drugs per encounter	3.6
Percentage of encounters with an injection prescribed	Nil
Percentage of encounters with an antibiotic prescribed	7.85
Percentage of drugs prescribed with a generic name	100
Percentage of drugs prescribed in the essential list or formulary	2

Table 5: List of additional information recorded from prescriptions.

Specified parameters in prescriptions	Number of prescriptions mentioned	Percentage (%)
Frequency of administration	140	100
<b>Duration of treatment</b>	140	100
Strength	100	71
Dosage unit (FTU)	-	-
Diagnosis	124	90
<b>Instruction to patients</b>	140	100
Name of patient	140	100
Age of patient	140	100
Date of OPD visit	140	100
Prescribers name	140	100
Prescribers signature	140	100

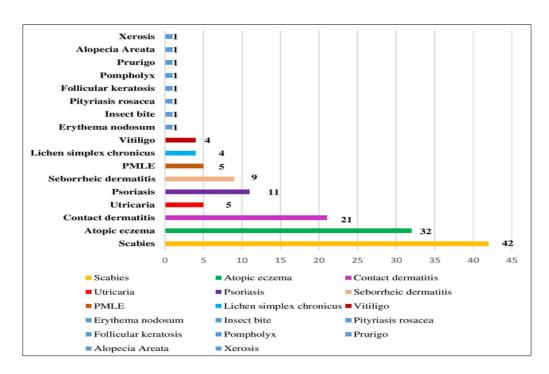


Figure 2: Disease pattern of patients receiving topical corticosteroids.

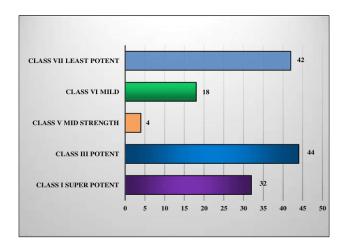


Figure 3: Distribution of topical corticosteroids as per their potency.

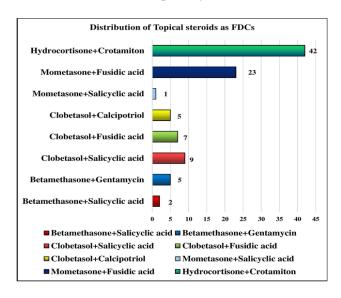


Figure 4: Distribution of topical corticosteroids as fixed drug combinations (FDCs).

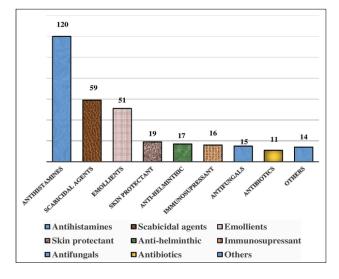


Figure 5: Distribution of drugs prescribed along with topical corticosteroids.

#### **DISCUSSION**

In this study, the demographic details pooled from a total population of 140 patients, revealed that the percentage of females (52%) were more than that of males (48%). These findings were in accordance with a study conducted by Manju et al.<sup>13</sup> In contrast, studies conducted by Nerukar et al and Saravanakumar et al showed a higher male preponderance. 14,15 Most patients belonged to the age group of 21-30 years (30%), followed by patients from the age group of 31-40 years (15.7%). Similar findings were observed in a study conducted by Nerukar et al.14 However, Sarvanakumar et al in his study highlighted that most patients belong to the age group of 51-60 years (21.82%).<sup>15</sup> The most common indications requiring topical corticosteroids were scabies (30%), followed by atopic eczema (22.8%) and contact dermatitis (15%). Topical corticosteroids are usually not the preferred choice for treating scabies, as they usually mask the clinical picture of scabies leading to another uncommon presentation called scabies incognito. 16,17 In a study conducted by Purushotham et al, dermatitis was the most commonly diagnosed dermatological condition. 18 With regard to the prescribing frequency of different topical corticosteroids, mometasone furoate was the preferred choice in most patients. This is attributed to its mediumhigh potency, greater anti-inflammatory activity, and long duration of action.<sup>19</sup> However, these current findings were not in accordance with a study conducted by Bhuvana et al which stated that clobetasol propionate was the most prescribed among all topical corticosteroids.<sup>20</sup> In this study, medium potency (class III) topical corticosteroids were the most prescribed (31%), followed by steroids of lowest potency (29%). This was because most dermatological conditions were highly steroid-responsive dermatoses, therefore the use of low to medium potency corticosteroids were sufficient to induce rapid remission.<sup>21</sup> Interestingly our study findings were in contrast to studies conducted by Purushotham et al and Bhuvana et al where high potency topical corticosteroids were the most prescribed for treating several steroid-responsive dermatological conditions. 18,20

Topical corticosteroids were prescribed as fixed drug combinations (FDCs) in 67.8% of the prescriptions, which was on the higher side. The reasons may include potentially improved response rates, reduced adverse reactions, increased adherence rates, and reduced costs.<sup>22</sup> Among the FDCs, hydrocortisone and crotamiton were the most prescribed (44.6%) followed by FDCs of mometasone and fusidic acid (24.4%) and clobetasol and salicylic acid (9.57%). In a study conducted by Bhuvana et al topical corticosteroids were prescribed as FDCs in 42% of the prescriptions.<sup>20</sup> In this study, the most prescribed topical dosage forms were creams (82.8%) followed by lotions (13.5%) and ointments (2.14%). This is because creams are non-irritating, easily washable, and less greasy as compared to ointments.<sup>23</sup> The current findings conformed to studies conducted by Manju et al and Nerukar et al. 13,14 H<sub>1</sub> antihistaminic drugs like levocetirizine (81.6%) were the most prescribed along with topical corticosteroids, followed by emollients (36.4%) and permethrin (29.2%). The reason for the high prescribing rates of antihistaminic drugs is the prevalence of itching as a non-specific symptom and antihistamines are believed to cause suppression of pruritus through decreased mast cell number and reduces tissue histamine levels.<sup>24</sup> The present findings agreed with studies conducted by Manju et al and Bhuvana et al. <sup>13,20</sup> However, in a study conducted by Purushotham et al. H<sub>2</sub> receptor blockers/proton pump inhibitors were the most prescribed concomitant drugs.<sup>18</sup>

In this study, the average number of drugs per encounter was 3.6. The current findings were higher than the WHO recommendations (optimal value 1.6-1.8) and suggested a trend towards polypharmacy.<sup>25</sup> It is preferable to keep the number of drugs per prescription as low as possible to avoid an increased risk of adverse effects and drug interactions, thereby minimizing the cost of drug therapy. Our study findings were similar to studies conducted by Bhuvana et al and Padma et al.<sup>20,26</sup> In contrast, Purushotham et al in his study stated that the average number of drugs per prescription was 2.09.<sup>18</sup>

The percentage of encounters where an antibiotic was prescribed was 7.85%. Our findings conformed to the WHO recommended optimal value of <30%.<sup>27</sup> This is because most patients did not require any antibiotic treatment. Patients were prescribed an antibiotic only when there was a risk of secondary skin infections. The percentage of encounters where an injection was the route of administration was nil. This was in accordance with the WHO recommended optimal value (<20%).<sup>27</sup> This is because topical therapy was the preferred route of administration in most patients. The percentage of drugs prescribed with generic names was 100%, which agreed with the WHO recommendations, which propose that optimally, all medicines (100%) should be prescribed by generic names.<sup>11</sup>

It is important to highlight that as most patients in our study setting belonged to a lower socioeconomic status, so prescribing drugs by their generic name not only reduces the cost of treatment but also increases patient compliance. The percentage of drugs prescribed from the essential drugs list (EDL) was 2%.

Our study findings did not comply with WHO recommendations for the EDL (100%). The reason could be due to the prescriber's lacking the understanding and importance of essential drug concepts and the excessive use of several topical steroidal preparations which are excluded in NLEMs.

The appropriateness and completeness of the prescriptions were also analyzed. An incomplete prescription may predispose the patient to potential side effects, thus limiting therapeutic efficacy. Parameters like frequency of administration, duration of treatment, and instruction to

patients were mentioned in all prescriptions (100%). All these are important as the underuse of steroids may lead to sub-therapeutic effects, whereas overdosage /longer duration of steroids may result in different adverse effects. The diagnosis was mentioned in 124 (90%) prescriptions. The determination of diagnosis is a part of rational prescribing. If the diagnosis is not correct, proper treatment cannot be achieved. The patient's name, age, date, and their visit to the department were present in almost all prescriptions. The prescriber's name and signature were also mentioned in all, respectively.

The absence of prescriber detail or illegible handwriting can promote patients to purchase a self-prescribed medication. Therefore, the prescriber's details are required.

#### Study strengths

One of the strengths of the study is that it was done prospectively using the patient prescriptions attending the OPD rather than the data being collected retrospectively from case records which is often the design adopted in prescription pattern studies as it is much easier to collect information from patient records. In addition, the prospective design of this study positively ensures eliminating duplication of data.

#### Limitations

Firstly, the sample size was small and a bigger picture may not be drawn from the study. Secondly, the duration of the study was short. Thirdly, the WHO standard value taken for study, may not be exact for comparison as the number of medicines used may vary based on the pharmacotherapeutic aspects of patients.

#### **CONCLUSION**

There is a need to emphasize all prescribers to adhere to the prescription format, to keep the average number of drugs per prescription as low as possible, and encourage prescribing by generic name. Such studies will also help health care providers to learn about the epidemiological behavior of several dermatological conditions so as to make necessary medications available without interruption. This will not only constitute a rational therapy but also lead to economic benefit and easy identification of the problems related to drug use like polypharmacy, drug interactions, and adverse reactions.

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Ethical approval: The study was approved by the

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