

## TOPICAL CORTICOSTEROID ABUSE – RISK FACTORS AND CONSEQUENCES

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### Abstract

**Background:** Topical corticosteroids are one of the most widely prescribed class of topical drugs. They have been abused in developing countries as they provide rapid symptomatic relief in inflammatory dermatoses.

**Aims:** This study was done to find the risk factors related to topical corticosteroids abuse and consequences thereof.

**Methods:** A hospital-based cross-sectional study was conducted in the dermatology OPD from July 2017 to June 2018. All patients were enquired for topical steroid abuse in the last 3 months and were interviewed via structured proforma.

**Results:** Of 2032 patients abusing steroids, 1365 (67.2%) patients were recorded with adverse effects of topical corticosteroids. The majority (60.78%) were from urban areas. 20.9% were abusing topical steroids for more than 12 months. The most common abused steroid formulation was mixed combination consisting of steroids, anti-fungals and anti-bacterials (47.9%). Fungal infection (59.5%) and acne (15.3%) were the most common indications of steroid abuse. Quacks (31.9%) and pharmacists (26.8%) were the most common prescribers of these topicals. Most common adverse effects of topical corticosteroid abuse were tinea incognito (41.1%), steroid-induced acne/aggravation of acne vulgaris (18.2%) and telangiectasia (14.1%).

**Limitations:** As this study was conducted at a tertiary care hospital, it does not accurately reflect the prevailing situation in the community.

**Conclusion:** We found that the most common source of abuse was non-prescriptional and it was mainly due to easy availability of mixed combinations of steroid containing creams. The adverse effects of topical corticosteroids are related to duration to their use. Hence, they must be used only for specific indications under a close watch of a qualified medical practitioner.

**Keywords** – topical steroids; adverse effects; drug abuse

### Introduction

Topical corticosteroids have become the mainstay of treatment of a wide range of dermatological conditions since 1952 when topical hydrocortisone was first used to treat eczematous dermatitis by Sulzberger and Witten.<sup>1</sup> The clinical effects of steroids occur due to their anti-inflammatory, anti-proliferative, immune-suppressive, anti-pruritic, melanopenic, atrophogenic and vasoconstrictive properties.<sup>2</sup> The 'potency' of topical corticosteroids is the intensity of their clinical effect and determines their anti-inflammatory and atrophogenic potential. The vasoconstriction assays roughly correspond to the potency of these agents and has been used to classify corticosteroids into various classes. Choice of potency of a topical steroid preparation depends on several factors such as patient's age, type, severity, extent and location of the disease and expected duration of the treatment.<sup>1</sup>

In the Indian market, at least 18 different corticosteroid molecules are available for topical use on the skin and more than 1000 brands are sold. They are available in various combination of anti-bacterial and anti-fungal drugs. In 2013, the annual sales figure of topicals containing corticosteroids was 14 billion rupees, which accounted for almost 82% of total dermatological product sale in the country.<sup>3</sup> People use and abuse these topical corticosteroids for all types of dermatological problems like infectious disease, inflammatory diseases, as skin lightening agents etc. They are easily available as over the counter drug,

despite the fact that steroids can be sold strictly upon the prescription of a registered medical practitioner only.

As they provide quick relief, are cheaper and easily available, so they are used by people for a long period of time, may be for years. This abuse can produce a number of adverse effects like atrophy of skin, telangiectasia, change of morphology of lesions, hypertrichosis etc. Abuse of topical corticosteroids is very common, especially in Asian and African countries as people are highly conscious of their skin colour.<sup>4</sup> Despite the widespread misuse of topical corticosteroids, studies regarding their adverse effects were done only in the last few years.<sup>5-15</sup> Strong focus on the problem of topical steroid abuse needs to be continued. Regional differences in the abuse pattern will help in the better understanding of the problem and formulation of an effective response to tackle the menace. This study was undertaken to assess the magnitude of topical corticosteroid abuse, the risk factors and consequences of abuse in North India.

### Material and method

This was a hospital-based cross-sectional study performed at Outpatient Department of Dermatology over a period of one year from July 2017 to June 2018. Institutional ethical clearance was obtained for the study. All patients visiting the dermatology outpatient during the study period were enquired regarding the recent use (past 3 months) of any topical preparation for their skin disease. The presence of topical corticosteroid in these preparations was assessed by direct name recall by the patient,

**Table 1:** Epidemiological characteristics of the patients abusing topical corticosteroids

Parameters	No. of patient	%
<b>Age groups</b>		
< 10 yrs	21	01.03
11-20	671	33.02
21-30	894	44.03
31-40	223	11.01
41-50	162	07.97
51-60	40	01.96
>60	21	01.03
<b>Mean Age</b>	<b>25.7 years</b>	
<b>Gender</b>		
Male	1104	54.33
Female	928	45.66
<b>Residence</b>		
Urban	1235	60.78
Rural	797	39.22
<b>Status of Education</b>		
Illiterate	241	11.9
Primary Education	511	25.1
Secondary Education	764	37.6
Graduation	437	21.5
Post-Graduation	79	3.9

inspection of prescriptions or the preparation itself or by visual identification of the products by showing photographs of commonly used topicals containing corticosteroids. Abuse was defined as the (a) application of a steroid containing topical formulation for a cutaneous dermatosis where steroids are not

**Table 2:** Distribution of patients according to the abused corticosteroid

Drugs	Class (Potency)	No. of Patients	%
Clobetasol propionate	I	1274	62.6
Betamethasone valerate	II	762	37.5
Mometasone	IV	146	7.2
Beclomethasone dipropionate	II	17	0.9
Fluticasone	V	6	0.3
Hydrocortisone	VII	4	0.2

indicated, (b) the application of such topical for a period beyond the time limit prescribed by the physician or (c) application of a super potent or potent steroid over face, axilla, groin or genital area. Final decision regarding the appropriate usage of steroids relied on the investigator. Patients with co-morbidities (Cushing's disease, thyroid disorders, Polycystic ovarian disease) that could cause

**Table 3:** Distribution of patients according to the contents of the topical steroid preparation

Type of Formulation used	No. of Patients	%
Steroid alone	282	13.9
Steroid + Antibiotics	410	20.2
Steroid + Antifungals	245	12.1
Mixed Combination	973	47.9
Triple Combination	122	6.1

similar changes to those of the side effects produced by topical steroid were excluded from the study. Patients who could not provide details of the abused steroid were excluded from the study. An informed consent was obtained from all patients.

**Table 4:** Source of information leading to use of topical steroid in the patients

Source of Information	No. of patients	%
<b>Prescriptional</b>		
Dermatologists	41	2.01
General Practitioners	79	3.9
<b>Quacks</b>	<b>649</b>	<b>31.9</b>
Non-allopathic doctors	183	9.01
<b>Non-Prescriptional</b>		
<b>Pharmacists</b>	<b>544</b>	<b>26.8</b>
Nursing staffs	11	0.5
Friends	238	11.7
Relatives	250	12.3
Media	37	1.9

Patients fulfilling the study criteria were interviewed via pre-decided structured proforma, which included: demographic variables (age, sex, residence, educational status), indication of use, brand name, potency of steroid, frequency of application, duration of therapy, source of information and cutaneous adverse effects. Photographic documentation of the patients was done after taking informed consent.

**Table 5:** Indications for the use of topical corticosteroids in the patients

Indications	No. of Patients	%
Dermatophytosis	1209	59.5
Acne	311	15.3
Melasma	217	10.7
Skin lightening	102	5.2
Oily skin	79	3.9
Itching	18	0.9
Pyoderma	17	0.8
Facial dryness	11	0.5
Others	68	3.3

**Table 6:** Distribution of patients depending upon the duration of use of topical steroid

Duration of Steroid Use	No. of Patients	%
<1 month	459	22.6
1-6 months	749	36.9
6-12 months	399	19.6
12-24 months	233	11.5
>24 months	192	9.4

The data collected was tabulated and mean and percentages calculated. The appropriate statistical tests (Chi square test and student t test) were used to assess significance of results. p value of <0.05 was considered to be significant. All statistical analysis was done using Statistical Package for Social Sciences version 17.

**Table 7:** Comparison of patients with adverse effects and duration of use of topical steroids

Duration	ADRs present	ADRs absent	Total patients	P value
≥12 Months	1041 (64.78%)	566 (35.22%)	1607 (100%)	<0.001
<12 Months	321 (75.47%)	104 (24.53%)	425 (100%)	
Total	1362	670	2032	

## Results

Topical corticosteroid abuse was identified in 2032 patients in our study. The age of patients ranged from 6 years to 67 years with mean age of 25.7 years. Majority of the population belonged to age group of 11-30 years, accounting for 77.05% (1565/2032) of cases. There was slight male preponderance with male: female ratio of 5.4:4.5 (1104:928). Around 12% (241/2032) patients were illiterate and 62.7% (764/2032) patients were educated till secondary level. Most of the patients belonged to urban area (1235/2032, 60.78%). The basic epidemiological characteristics of the patients has been mentioned in [Table 1].

**Table 8:** Adverse effects of topical steroid abuse by the patients

Adverse Effects	No. of patients	%
Tinea Incognito	561	41.1
Steroid-induced Acne/Aggravation of acne vulgaris	248	18.2
Telangiectasia	193	14.1
Striae /skin atrophy	159	11.6
Steroid induced rosacea	113	8.3
Hypertrichosis	102	7.5
Hypopigmentation	99	7.3
Status cosmeticus	43	3.2
Tachyphylaxis	37	2.7
Photosensitivity	27	1.9
Purpura	19	1.4
Perioral dermatitis	13	0.95
Hyperpigmentation	12	0.87
Others -Contact dermatitis, pyoderma, trichostasis spinulosa	29	2.12

More than 100 brands of topical corticosteroids were used by patients, either containing steroid alone or in combination with



**Figure 1a:** Tinea incognito

anti-bacterial or anti-fungal agents, 470 (23.17%) patients had used multiple brands. Majority of them contained clobetasol propionate or betamethasone valerate, which are superpotent type of steroids. [Table 2] About one-half (47.9%) of patients had applied a topical preparation containing steroid, anti-bacterial and anti-fungal creams followed by a combination of steroid and anti-bacterial agents. Triple combination (containing hydroquinone, tretinoin and steroid) for melasma was used by 6.1% (122/2032) patients. [Table 3].2,3



**Figure 1b:** Tinea incognito with extensive striae

About 85.08% patients abused topical corticosteroids without proper prescription from doctors, of which most of them used these on advice of quacks (649/2032, 31.9%) and pharmacists (544/2032, 26.8%). [Table 4] Dermatophytosis (1209/2032, 59.5%), acne (311/2032, 15.3%) and melasma (217/2032, 10.7%) were the most common indications for which patients had applied these preparations. [Table 5] The duration of use varied from 1 week to 3 years. Majority of them used them for 1-6months (749/2032, 36.9%) duration. [Table 6] Patients who had applied topical corticosteroids for longer period of time developed more number of side effects (p value <0.001). [Table 7] A large proportion of patients (1708/2032, 84.05%) had applied them for at least two times in a day and only 324 patients had applied once in a day. 4,5,6,7

Out of 2032 patients, 1365(67.2%) patients developed cutaneous





**Figure 1c:** Tinea cruris with hypopigmentation

adverse effects due to topical corticosteroids. [Table 8] A total of 1655 cutaneous adverse effects were recorded. The most common adverse effects were Tinea incognito (561/1365, 41.1%), Steroid-induced Acne/ Aggravation of acne vulgaris (248/1365, 18.2%) and Telangiectasia (193/1365, 14.1%). Other adverse effects were striae, steroid-induced rosacea, hypertrichosis, hypopigmentation and status cosmeticus. Rare side effects include tachyphylaxis, photosensitivity, purpura, perioral dermatitis, hyperpigmentation, contact dermatitis, pyoderma, trichostasis spinulosa etc. Female preponderance was found in patients who had applied topical steroids for melasma and fairness purpose. It was observed that when steroids were applied over face, side effects developed earlier than other sites.



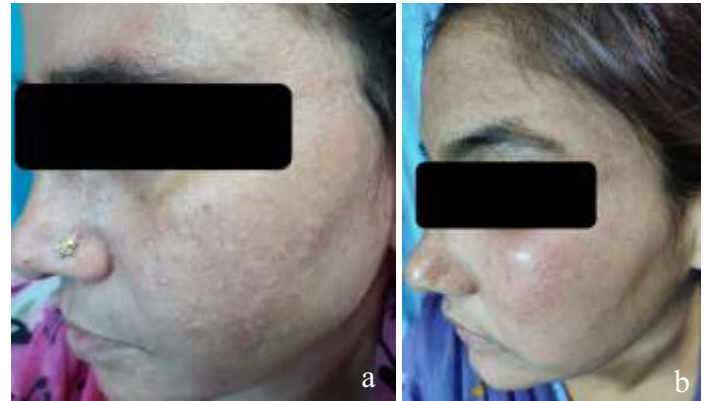
**Figure 2a, b:** a. Monomorphic acne b. Aggravation of acne

Some representative photographs of the study subjects with adverse effects are shown in [Figure 1a], [Figure 1b], [Figure 1c], [Figure 2a], [Figure 2b], [Figure 3a], [Figure 3b], [Figure 4], [Figure 5].

### Discussion

Topical steroids are very important and efficacious drugs for management of various dermatological disorders. However, it is this rapid relief provided by topical corticosteroids that has prompted the physicians to prescribe these products

indiscriminately, often reversing the basic doctrine of diagnosis followed by treatment.<sup>16</sup> Patients often resort to indiscriminate use of topical steroids to suppress the troublesome inflammatory dermatosis. An abrupt discontinuation may lead to rebound flare, prompting reapplication of the preparation and the cycle continues ultimately leading to atrophogenic adverse effects. Calnan used the term 'habituation' for this phenomenon<sup>17</sup> but Klingman preferred the term 'addiction' as stopping steroids is associated with exacerbations.<sup>16</sup>



**Figure 3a, b:** a. Steroid induced rosacea with telangiectasia b. Topical steroid dependent face

Two-thirds of the patients abusing topical steroids had developed cutaneous adverse effects. A study by Nagesh et al. from Bengaluru, India also showed that 51.9% of the 612 patients who admitted to the use of topical corticosteroids, developed adverse effects.<sup>18</sup> The abuse of topical steroids seems to be more prevalent in the northern parts of India compared to South India and can arguably be attributed to socio-economic differences. The most common affected age group was 11-30 years, which was consistent with results of other studies.<sup>6,10,19,20</sup> The younger age group is more cosmetically conscious and therefore vulnerable to medications claiming to lighten the skin or provide rapid clearing of their skin ailments. There was slight male preponderance in our study. Sexual predilection has been variable in different studies with most showing abuse to be more common in women<sup>9,10,19-21</sup> and this has been attributed to greater awareness for skin tone and cosmesis



**Figure 4 (a, b):** a. Perioral dermatitis b. Hypertrichosis of face

in women from Asia. Other studies show a male predilection.<sup>6</sup> Urban population outnumbered rural, this may be due to location of hospital in urban area leading to hospital bias. More than a quarter of the patients in our study were graduates or more educated. Our findings show that topical steroid abuse appears to be independent of educational status. Reaching the educated section of the society regarding adverse effects of topical steroids should thus be prioritized.

More than 100 brands of steroids were used by patients. Clobetasol propionate 0.05% was the most commonly abused steroid (62.6%) followed by betamethasone valerate 0.1% and mometasone furoate 0.1%. While most studies show that betamethasone abuse is more common,<sup>9,10,20</sup> clobetasol has been reported to be more common in other studies.<sup>6,19,22</sup> The widespread use of these molecules is due to their low cost, over the counter availability and decades of presence in Indian market. Despite the fact that most topical steroids are now under schedule H of Drug and Cosmetic Rules 1945 i.e. they can only be used under the supervision of qualified physician and not sold as over-the-counter drug<sup>23</sup> these preparations are easily available from the chemist in the absence of adequate enforcement of law. Around half of the patients (47.9%) had applied steroids in combination with other agents (anti-bacterial/anti-fungal agents). Only 13.9% patients had used steroid alone. This shows that fixed dose combinations of steroids are commonly abused by the patient as a blanket treatment of various skin diseases.

In our study, quacks and pharmacists were the most common source of prescription. They are often the first point of contact for most of the patients. So, there is an immediate need for strict regulation regarding the sale of these products with prescription from qualified doctors only. Responsibility for misuse of steroids could also be attributed to non-allopathic doctors, general physicians and even few dermatologists as they prescribe anti-fungal agents with steroids for dermatophytosis. Training and sensitizing them regarding steroid abuse may also help in reducing their adverse effects. Similar observation has been found in other studies too.

Topical corticosteroids are frequently misused due to their anti-inflammatory action in different dermatoses. We found the most common indication for their use was fungal infections (59.5%). It may be due to high prevalence of fungal infections in community and dermatology OPD. The other indications were acne, melasma, as a skin lightening agent, for oily skin and itching. The results were consistent with study conducted by Meena S et al.<sup>6</sup> Around 1/3rd of the patients used them for 1-6 months and had come to the Dermatology OPD either because of their adverse effects or if their skin problem no longer responds to the so called "magical effect" of the cream. Persistent use can lead to epidermal and dermal atrophy resulting in thinning of the skin as well as dependency on the steroid. The appearance of these adverse effects depends on the potency of steroid, duration of use and the site of application.

We found that the nature and number of side effect can be correlated with the duration of the usage of topical steroid. However, many of the patients were not aware of problems they were facing due to this abuse. The most common

adverse effect found in our study was tinea incognita (41.1%) and steroid-induced acne/aggravation of acne vulgaris (18.2%). As corticosteroids suppresses the normal cutaneous immune response, thus they enhance fungal infections while modifying the clinical picture.<sup>24</sup> Steroid induced acne occurs due to degradation of follicular epithelium, resulting in extrusion of follicular content. The percentage of patients with acne was lower than other studies where around a third of all patients showed aggravation of acne.<sup>10,19,20</sup> Others common side effects were telangiectasia (14.1%), striae (11.6%), rosacea (8.3%) and hypertrichosis (7.5%). While Hameed et al.<sup>25</sup> reported rosacea in 86.3% patients in a study from Iraq, Indian studies show a much lower percentage of patients developing steroid related rosacea.<sup>26,27</sup> Steroid-induced telangiectasia occurs due to sudden cessation of vasoconstrictor effect and release of nitric oxide leading to abnormal dilation of capillaries and striae occur due to inhibitory effect on keratinocyte proliferation and collagen synthesis.

### Limitations

As ours is an OPD-based study therefore, it may or may not accurately reflect the community data. However, it does give a clue to the prevailing rampant abuse of topical steroids in the country. The situation appears to be graver than that depicted in this study as we had included patients with abuse of steroids in last 3 months and excluded patients applying topical preparations where the name could not be elicited.

### Conclusion

Our study reveals that problem of topical misuse of corticosteroids is very common. People use these preparations irrespective of their literary and residential status. As they provide quick relief so, they are used for many dermatological conditions. Most of the people are unaware of their side effects and using them for years. The widespread abuse of topical steroids is compounded by poor health infrastructure, lack of adequate specialist services in country, practice of self-medication, poor affordability and easy access over the counter. Therefore, there is need of strict implementation of the existing laws that ban the use of over-the-counter availability of topical corticosteroids. Awareness should be created among public about the adverse effects related to topical steroids. There should be a proper check on the advertisement of the drugs that directly or indirectly gives a false impression regarding the true character of the drug or makes a false claim for the drug. The campaign against topical steroid abuse needs to be given further impetus regarding sensitizing doctors, chemists, pharmaceutical and cosmetic industries, regulatory agencies, and the general public regarding this menace of topical steroid abuse. Dermatologists and their organizations need to take the lead in this regard.

Declaration of patient consent: The authors certify that they have obtained all appropriate patient consent forms. In the form the patient(s) has/have given his/her/their consent for his/her/their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

### How to cite this article:

Varshney I, Amin SS, Adil M, Mohtashim M, Bansal R, Khan HQ. Topical Corticosteroid Abuse- Risk factors and Consequences. JDA Indian Journal of Clinical Dermatology. 2019;2:72-77.

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