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Research Article

EVOLUTION FROM ESSENTIALITY TO EXPLOITATION: CUTANEOUS DERMATOSES TO MISHANDLING OF TOPICAL CORTICOSTEORIDS

Naina Jain., Arvind Krishna*., Bhagirath Singh Rathore and Garima Singh

Department of Dermatology, Venereology and Leprology, Swami Vivekanand Subharti University, Chhatrapati Shivaji Subharti Hospital, Meerut, Uttar Pradesh, India (250002)

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ABSTRACT

Misuse of corticosteroids, either topical or systemic, has been alarming to the dermatologists in the recent years that results in concerning, hard-to-treat cutaneous dermatoses. **Objectives:** We aim to study the clinical pattern and relative frequency of cutaneous adverse effects induced by misapplication of topical corticosteroids. **Materials and Methods:** A single contact, descriptive clinical trial including 300 patients with history and signs suggestive of topical corticosteroid abuse, presenting to the out-patient department of dermatology in a tertiary hospital. **Results:** Most frequent indication for use was acne vulgaris (39.7%), followed by for various infections (30.7%), mostly by individuals aged between 19 and 25 years (41%). The commonest topical preparation exploited was betnovate, containing betamethasone valerate 0.1% (58.3%), belonging to the potency class III, with large number of patients applying the concerned product once a day (69.33%), intermittently (75.0%) and using an amount of less than one fingertip unit (57.3%); frequently recommended by one's friends/relatives (36.0%). Most patients started experiencing problems after application of the concerned product between 1 and 6 months (44.0%). Major related symptoms complained of were photosensitivity (71.9%) and itching on withdrawal over the face (61.4%) and, 5 most common signs observed were hypertrichosis (49.3%), acneiform eruptions (45.3%), facial erythema (37.7%), infections (36.3%) and cutaneous atrophy (36.3%). **Conclusion:** The evolution of this essential class of drugs over time has led to their exploitation, in turn resulting in preventable adverse effects. Therefore, it is of utmost importance that consistent steps be taken against their abuse, particularly byspreading the right word and by discouraging their over-the-counter dispense.

INTRODUCTION

Corticosteroids are a class of steroid hormones that are either synthesized naturally in the adrenal cortex of vertebrates or produced synthetically. They are involved in a wide range of physiological processes including regulation of stress response, immune response, inflammation, carbohydrate metabolism, protein catabolism, blood electrolyte levels and behaviour. Their ability to potently suppress inflammation, and hence, their use in a variety of inflammatory and autoimmune diseases makes them among the most frequently prescribed classes of drugs. (1)

However, their anti-inflammatory and anti-proliferative actions of topical corticosteroids result not only in their therapeutic effect but also in their side effects. Thus, it is important to use them with utmost caution. (2) A major concern for dermatologists in recent years has been the injudicious use of TCs due to unscrupulous selling by chemists not only as prescription but also as non- prescription drugs. (3) Because of easy availability of corticosteroids and inefficient regulations, unregulated use and self-abuse of corticosteroids have reached to an alarming level and have become a "public health problem" as far as skin health is concerned. (4)

In 2014, at the "International Dermatology Update-2014", a social initiative, "Movement Against Topical Steroid Abuse (MATSA) was endeavoured, and thereafter, in 2015, IADVL had started a nationwide campaign against Topical Steroid Abuse under the banner of IADVL's Taskforce {IADVL Taskforce Against Topical Steroid Abuse (ITATSA)} to sensitize doctors; chemists; pharmaceutical and cosmetic industries; regulatory agencies; and the general public regarding this menace and thereby, prevent the misuse of topical corticosteroids. (4) In support of this recently recognized, ever rising crisis of incorrect use of topical

Corresponding author:* **Arvind Krishna
Department of Dermatology, Venereology and Leprology, Swami VivekanandSubharti University, ChhatrapatiShivajiSubharti Hospital, Meerut, Uttar Pradesh, India (250002)

steroids, the present study was conducted to determine the clinical pattern and relative frequency of cutaneous adverse effects caused due to misuse of topical corticosteroid containing preparations, in patients attending the out-patient department of dermatology in a tertiary hospital.

MATERIAL AND METHODS

This is a prospective, questionnaire based, clinical study of 300 patients with history and signs suggestive of topical corticosteroid misuse, conducted at an out-patient department of Dermatology, at a tertiary care centre in western Uttar Pradesh, India, during the period October 2015 to May 2017.Written informed consent was taken from the patient or her/his guardian (in cases of minor) before being included in the study.

The studied variables included demographic profile of the patients, indication for primary use, details about the exploited topical corticosteroid, source of recommendation of use, and the related symptomatology and signs suggestive of topical abuse.

Exclusion criteria: Patients with history of use of systemic corticosteroids and systemic diseases known to cause androgenetic imbalance, were excluded.

RESULTS

In the present study, age of patients with history of topical corticosteroid user anged from 5 to 56 years with a mean of 24.95 years. The most common age group affected was between 19 and 25 years, constituting 41% of the total (Table I). Of 300 patients, 153 patients (51%) were male and 147 (49%) were female patients; equating the male: female ratio to almost 1. Illiteracy was noted in 23.34% of patients.

Table I Age distribution of the study group.

Age of the study group	Number of patients	%
<19 (Adolescence and below)	72	24
19-25 (Early adulthood)	123	41
26-40 (Young adulthood)	90	30
41-60 (Middle adulthood)	15	5

Table II Primary indication of use of topical corticosteroid containing product by the study group.

Indication	Number of patients	%
Acne vulgaris:	119	39.7
Infections:	92	30.7
Fungal- Dermatophytes; Pityriasisversicolor; Candidiasis.	83	27.7
Viral- Warts; Herpes simplex infection.	2	0.7
Parasitic- Scabies (Generalized itching)	6	2.0
Bacterial- Furuncle.	1	0.3
Pigmentary conditions:	62	20.7
Melasma; Freckles	42	14.0
Hyperpigmentation Face (As a fairness cream)	19	6.3
Vitiligo	1	0.3
Specific dermatological conditions	6	2.0
Papulosquamous disorders: Lichen planus	2	0.7
Photodermatoses	3	1.0
Immunobullous disorders: Dermatitis Herpetiformis	1	0.3
OTHERS:	21	7.0
Xerosis	14	4.7
As a routine moisturizer	7	2.3

Majority of the patients, i.e., 119 patients, exploited the concerned product for acne vulgaris (39.66%), followed by 92 patients, applying it for different infections (30.66%),and 62 patients for various pigmentary concerns (20.66%), mostly as fairness creams (Table II). Most patients, i.e. 175 patients (58.33%), included in the present study, revealed using betamethasone valerate of strength 0.1% (Table III) sold majorly under the trade name of betnovate and belonging to the potency class IV (mid-strength).

Table III Characteristics of the exploited topical corticosteroid.

Name With % of The Corticosteroid Contained In The Preparation:	Potency class of the topical Corticosteroid	Number of patients	%*
Clobetasol Propionate 0.05%	I (Ultra potent)	82	27.3
Betamethasone Dipropionate 0.05%	I (Ultra potent)	2	0.67
Betamethasone Dipropionate 0.025%	II (Potent)	36	12.0
Betamethasone Valerate0.1%	III (Mid-strength)	175	58.3
MometasoneFuroate 0.1%	IV (Mid-strength)	64	21.3

*More than one product was used by some patients.

Face was the most common region of application, noted in 227 patients (75.67%), and hence, also the most frequently affected site, in 235 patients.

Duration of application ranged from 7 days to 20 years. Majority of the patients, i.e., 132 patients had applied the product for more than a month to 6 months' duration (44.00%) (Table IV).

Table IV Duration of application of the concerned topical corticosteroid by the study group.

Duration of application	Number of patients	%
1 week to 1 month	67	22.3
>1 month to 6 months	132	44.0
>6 months to 1 year	42	14.0
>1 year	59	19.7

Large number of patients had applied the concerned product once a day (69.33%), intermittently (75.00%) and using an amount of less than one fingertip unit of the topical corticosteroid (57.33%) (Table V).

Table V Frequency, mode of use, and the amount of the product in terms of Finger Tip Unit (FTU) by the study group.

Frequency (per day)	Numeber of patients	%	Mode of use	Number of patients	%	Amount Used (ftu)*	Number of patients	%
ONCE	208	69.3	Intermittent*	225	75.0	<1	172	57.3
TWICE	83	27.7	Continuous	25	25.0	1-2	114	38.0
≥ THRICE	9	3.0				3-4	11	3.6
						>4	3	1.0

*Finger Tip Unit (FTU) is defined as the amount of ointment, cream or other semi-solid dosage form expressed from a tube with a 5mm diameter nozzle, applied from the distal skin-crease to the tip of the index finger of an adult.

According to these observations, it can be inferred that duration of application plays an essential role in determining the incidence of side effects by topical corticosteroids than the mode of application and the amount of the product used. The most common source of recommendation for topical corticosteroid use for varied reasons was found to be relatives in 36.00% of cases, followed by general practitioners in 29.33%, and medical stores in 22.33% cases (Table VI).

Table VI Source of recommendation of the misuse.

Source	Number of patients	%
Dermatologist (For Instance, For Unrelated Dermatoses)	31	10.3
Non Dermatologist	88	29.3
Beautician	4	1.3
Medical Store	67	22.3
Friend/Relative	108	36.0
Any Other Media(TV, Radio)	2	0.66

Of 228 patients who had applied topical corticosteroids on the face, large number of patients, i.e., 71.9% experienced discomfort on sun exposure and 61.4% developing itching, especially on temporarily stopping the application (Table VII).

Table VII Symptomology related to topical steroid misuse on the face.

Symptom	Number of patients	%*
Itching	140	61.4
Burning	84	36.8
Flushing	125	54.8
Dryness	104	45.6
Aggravation On Sun Exposure	164	71.9

*More than one symptom was experienced by some patients.

More than one symptom was observed in some patients. In the current study, the pattern of cutaneous adverse effects induced by topical corticosteroids was studied under 10 subheadings. Many patients had more than one dermatosis at the time of examination. The most common side effects noted in our study were hypertrichosis in 49.33%, followed by the occurrence of acneiformeruption on the face, and the upper trunk in 45.33%, facial erythema in 37.66%, infections and cutaneous atrophy in 36.33%. (Table VIII).

Table VIII Incidence of various adverse effects induced by topical corticosteroid abuse on the face in the study group.

Signs	Number of Patients (n=300)	%*
Erythema	113	37.7
Acneiform Eruption	136	45.3
Telangiectasia	83	27.7
Cutaneous Atrophy	109	36.3
Hypertrichosis	148	49.3
Hyper/Hypo/Depigmentation	100	33.3
Perioral Dermatitis	2	0.7
Contact Dermatitis	0	0.0
Infections (Fungal, Bacterial, Viral, Parasitic)	109	36.3
Any Other (For example, Milia, Xerosis)	10	3.3

*More than one sign was observed in some patients.

Fig 1 Scabies Incognito

Fig 2 Tinea Incognito

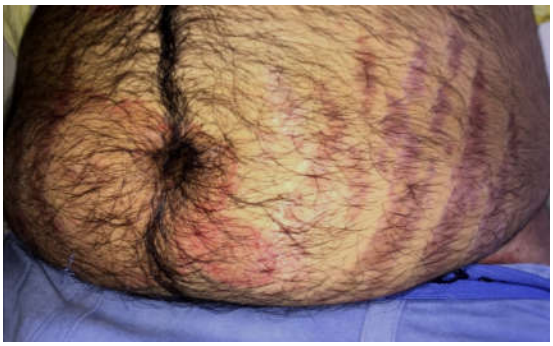

Fig 3 Striae in a patient using topical corticosteroids fungal infection.

Fig 4 Hypertrichosis, hyperpigmentation face for in a patient using steroids as a fairness cream.

Fig 5 Steroid modified monomorphic excessive acneiform eruption. patient.

Fig 6 Telangiectasia following the use of topical steroids in a vitiligo

DISCUSSION

Asonce rightly quoted 'the greater the power, the more dangerous the abuse' by Edward Burke, reports of cutaneous adverse effects of topical corticosteroids misuse started emerging almost a decade after its introduction. The current study of 300 patients was conducted in the region of Western Uttar Pradesh, India, to study the relative frequency and pattern of cutaneous dermatoses occurring secondary to topical corticosteroid misuse.

In the present study, the most common age group affected was between 19 and 25 years with a mean age of 24.95 years. Edith Nnoruka in his study on topical steroid abuse as a depigmentingagent reported the mean age of 29.0 ± 11.8 years, which was comparable with our study. (5) However, in a study by Anup KMishra and DeveshSaraswat, a relatively higher mean age of 32.3 years was observed. (6)Even though, the craze for fairness of skin is age old in our country, in the recent years, it has reached an epidemic level. Up till now, majorly females were craving for fairness. At present, even males have also joined the bandwagon, which is quite evident by the current data of male: female ratio of almost 1 and also, according to the slight male predominance (57%) as reported by Anup K Mishra and DeveshSaraswaton topical corticosteroid abuse in dermatology. (6)

George Benard Shaw once said 'beware of false knowledge; it is more harmful than ignorance'. The exploitation of topical corticosteroids was regardless of the literacy of the patients since most patients, 76.66%, in the present study had some level of institutional education, with only 23.34% being illiterate. The reported illiteracy rate in other studies was analogous to our study, being 18.73% in a clinical study by Vivek Kumar Dey (7); 16% observed by AbirSaraswat *et al* in his study on topical corticosteroid misuse on the face. (8)

In our study, the primary indication of steroid use was divided into the following categories: acne, infections, pigmentary concerns, specific dermatological conditions like lichen planus, photodermatoses and miscellaneous, for instance, as a routine moisturizer or for dryness/redness face. Most patients in the current study utilized the concerned product for acne on the face (39.66%), followed by wrong application for varied infections (30.66%), predominantly fungal infections (27.66%) and then for different pigmentary concerns(20.66%), mostly for melasma/freckles (14.00%) or as a fairness cream for hyperpigmentation face (6.33%). This was in contrast to Vivek Kumar Dey who found that major use was for pigmentary concerns like for lightening of the skin (50.39%) and melasma (25.85%), followed byacne (17.94%)and then for dermatophytic infections (14.77%). (7)

Acne vulgaris is a self-limited disorder of the pilosebaceous unit that is seen primarily in adolescents and young adults, which was observed to be the most common indication of use in patients less than 25 years of age. On the other hand, pigmentary concerns, like melasma, usually manifest with cumulative exposure to sunlight, seen in the later years of life. Infections noted in the present study were more dependent on the socioeconomic conditions than the age of the patient, and no difference was noted in the two groups. The correlation of age of the patient with the indication of use in the study group was found to be statistically significant at $p < 0.01$, using chi square test. (Table IX)

Table IX Correlation of Age with Indication of Use in the study group.

	<25 YEARS	≥ 25 YEARS
Acne Vulgaris	96	23
Infections	46	46
Pigmentary Concerns	21	41
Others	11	16

Betamethasone valerate 0.1% was the most abused corticosteroid by the patients in the present study (58.33%) and also according to the data provided by Vivek Kumar Dey (34.83%) and AbirSaraswat *et al* (58.9%) in their respective studies. (7, 8) Maximum number of patients, i.e., 44% had used the questioned product from 1 month to 6 months duration in the present study. Similarly, in the study by AbirSaraswat *et al*, 48% of the patients fell in the above category. (8)This is in contrast to the study by Anup K Mishra and DeveshSaraswat where in, the bulk had misused the product for or less than a month's period (82%). (6)In an attempt to trace the source of advice for the unsuitable use of topical corticosteroids, it was found that in our study, the most common source arouse from within the family or neighbourhood, constituting about 36% of the total. However, according to Ammar F. Hameed (9), the major centres for dispensing the topical corticosteroids inaptly were beauty parlours (34%) and medical stores (35.36%) as reported byVivek Kumar Dey. (7)

In the current study, the pattern of cutaneous adverse effects induced by topical corticosteroids was studied under 10 subheadings. Many patients had more than one dermatosis at the time of examination. The five most common cutaneous adverse effects to inappropriate use of topical corticosteroids observed in the descending order of frequency were hypertrichosis in 49.33%, acneiform eruption seen in 45.33% of cases, followed by erythema in 37.66%, cutaneous atrophy and induction or exacerbation of cutaneous infections in 36.33% of patients each. In a similar prospective study on topical corticosteroid abuse in dermatology conducted by Anup K Mishra and DeveshSaraswat, the observed dermatoses in the descending order of frequency were infections in 44.3%, cutaneous atrophy in 15.9% and acneiform eruption in 11.4% of patients. (6) In the Vivek Kumar Dey study, themost frequent cutaneous sign was acneiform eruption, seen in

37.99%, followed by hypertrichosis in 18.46% and 10.2% patients each exhibiting cutaneous atrophy and infections. (7) The side effects of topical corticosteroids are dependent on the potency of the molecule and the duration of application and are subcategorized as acute and delayed complications. Majority of the patients in the present study gave the history of application of multiple steroid containing products with varying potency. However, it was observed that certain adverse effects, namely, hypertrichosis, cutaneous atrophy and telangiectasia were predominant in patients with relatively longer duration of application of atleast 3 months. The correlation of development of these signs with the duration of use was found to be statistically significant at $p < 0.10$ (p value, using pearson's chi square test = 0.098) in our study. (Table X)

Table X Correlation of Certain Signs observed with Duration of Application of Topical Corticosteroids in the study group.

	<3 Months	**≥3 Months**
Hypertrichosis (n=148)	23	125
Cutaneous Atrophy (n=109)	30	79
Telangiectasia (n=83)	21	69

CONCLUSION

To conclude, corticosteroids, both topical and systemic, are one of the mainstay treatment modalities in many dermatological conditions. However, the evolution of this miracle drug over time has led to its misuse, in turn resulting in avoidable adverse effects. Therefore, it is of utmost importance that consistent steps be taken against the inappropriate use of corticosteroids, particularly through education of the general public, medical and paramedical personnel and pharmacists and by discouraging over-the-counter dispense of topical corticosteroids, especially as beauty products.

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