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Misuse of Topical Corticosteroids in Dermatological Disorders at a Tertiary Care Centre in Central India: A Clinical Study.

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Abstract
Background: *Since their debut in 1952, topical corticosteroids (TCs) have been a mainstay of dermatological treatment. Despite their demonstrated effectiveness, over-the-counter availability, improper prescribing practices, and a lack of awareness have made irrational use and misuse a serious public health concern.*
Methods: *A hospital-based cross-sectional observational study was conducted over 18 months (Nov 2019–May 2021). A total of 430 patients with a history of TC use (alone or in combination) were enrolled. Data on demographic profile, indication, source of recommendation, type and class of TCs, duration of misuse, and adverse effects were recorded.*
Results: *Among 430 patients, the most frequently misused formulation was betamethasone valerate 0.1% (27.9%), followed by fixed-dose combinations. The most common adverse effect observed was tinea incognito (40%), followed by steroid-dependent face (14.9%) and cutaneous atrophy (13.5%). The majority of patients misused TCs based on non-medical recommendations, highlighting the easy availability and inadequate regulation of these drugs.*
Conclusion: *Misuse of topical corticosteroids is widespread and associated with considerable dermatological morbidity. Strict enforcement of prescription regulations, along with public and practitioner education, is urgently needed to curb irrational use. Chemists, general practitioners, and healthcare workers must be sensitized to ensure safe and rational application of these potent agents.*
Keywords: *Topical corticosteroids, misuse, adverse effects, dermatology, tinea incognito, steroid-dependent face, over-the-counter drugs.*

I. Introduction:

The modern era of Dermacotherapy began with the introduction of compound F (hydrocortisone) by Sulzberger and Witten in 1952. This was considered the most significant landmark in the history of the therapy of dermatological disorders. [1,2] The clinical effects of TCs are mediated by their anti-inflammatory, vasoconstrictive, antiproliferative, and immunosuppressive properties. [3,4]
Topical corticosteroid misuse continues to rise in the field of medicine. Lack of awareness among clinicians, practitioners, cosmeticians, as well as the patients, is the major underlying cause for this irrational utilization of this potent class of drugs. Timely identification and proper management of systemic side effects are highly essential in order to prevent a public health crisis. [5,6]

Use of topical corticosteroids in dermatology
Eczema is a non-infectious, chronic, inflammatory dermatological entity manifesting as inflamed, pruritic, erythematous, and/or asteatotic skin. [7]
Vitiligo is an acquired pigmentary disorder, attributed to the destruction of melanocytes. [8]
Psoriasis Topical corticosteroids are the mainstay for mild-to-moderate plaque psoriasis, with Class IV being more effective than Class III. Tapering frequency and duration is essential to reduce risks like skin atrophy, striae, and systemic effects. [9]
Lichen planus is a common chronic inflammatory dermatosis associated with disrupted cell-mediated immunity. Cutaneous lesions are often extremely pruritic and require rigorous intervention. [10]
Mycosis fungoides (MF), the most common cutaneous T-cell lymphoma (~60% of cases), has been treated with topical corticosteroids (TCs), showing good results in early patch-stage disease, though strong evidence is limited.

Current recommendations support potent (Class I) TCs for temporary clearance of patches and plaques in early-stage IA/IB MF. [11,12]

Bullous pemphigoid is an acquired common autoimmune blistering dermatosis characterized by the development of autoantibodies against the components of the basement membrane zone of the skin. [13]

Cutaneous sarcoidosis is a granulomatous disease with multisystem involvement. Topical high-potency fluorinated corticosteroids (with or without occlusive dressing) have been successfully used in localized cutaneous Sarcoidosis. [13,14]

Infantile hemangiomas

Superficial infantile cutaneous hemangiomas are difficult to manage.

Alopecia areata

One RCT demonstrated that potent TCs are marginally more effective than placebo when used continuously for a minimum of 3 months. [15]

Anogenital pruritus

A short course of mild to moderately potent TCs is recommended for a few weeks, followed by a reduction in potency. Caution is to be taken with prolonged use of potent agents, as the area is prone to atrophy. [16]

Cutaneous lupus erythematosus

All the controlled trials of TC were of short duration, but the evidence supports the use of potent TCs in DLE (Discoid Lupus Erythematosus). [17]

Melasma

There are benefits and harms of using TCs in the treatment of melasma, especially since long-term use on the face can cause skin thinning and telangiectasia.

Perioral dermatitis

There is insufficient evidence (level of evidence: D) on the effects of nonfluorinated steroids in patients with perioral dermatitis.

Seborrheic dermatitis

TCs are considered to be the first-line therapy for the management of seborrheic dermatitis, there is an absence of high-level evidence supporting the use of TCs. [18]

Mechanism of action

Topical corticosteroids diffuse through the stratum corneum barrier (a rate-limiting step in the drug delivery) and through the plasma membrane (easily passes due to their lipophilic structure) to reach the cytoplasm of cells in epidermis and dermis. Binding to glucocorticoid response elements in host DNA represents the most important pathway for most glucocorticoid actions. Cytoplasmic interaction of the glucocorticoid receptor with cellular transcription proteins is the other proposed mechanism of action.

1. Anti-inflammatory effect
2. Antiproliferative and anthropogenic effects
3. Vasoconstrictive effect
4. Effects following systemic absorption on metabolic and other areas are similar to those seen with systemic corticosteroids. [5&19]

Classification

Class I: superpotent (clobetasol propionate 0.05%, halobetasol propionate 0.05%, desoximetasone 0.25%),
Class II: high-potent (betamethasone dipropionate 0.05% cream, halcinonide 0.1%),
Class III: medium-high potency (fluticasone propionate 0.005% ointment),
Class IV medium potency (mometasone furoate 0.1% cream),
Class V: medium potency (betamethasone valerate 0.1% cream, fluocinolone acetonide 0.025% cream),
Class VI: low potency (desonide 0.05% cream, fluocinolone acetonide 0.01% cream), and
Class VII: low potency (hydrocortisone acetate, dexamethasone acetate 0.1%). [20]

Factors affecting the choice of corticosteroid

- Anatomic area of application
- Disease responsiveness
- Severity of disease
- Extent of body surface area
- Age of patient
- Suitability of the vehicle
- Potency of the corticosteroid molecule. [21]

Topical steroid misuse:

Most of the adverse effects associated with topical steroid use depend upon multiple factors such as the chemical structure of the topical corticosteroid, vehicle employed, site of application, frequency, and the method of application. [22]

Local effects include cutaneous atrophy, tachyphylaxis, contact dermatitis, stellate pseudoscars, hypopigmentation, hypertrichosis, purpura, milia, erythema, acneiform dermatitis, rosacea, and cataract. Skin atrophy, characterized by epidermal thinning and dermal changes, is the most frequent localized effect. Other local effects, such as telangiectasia, localized fine hair growth, bruising, and erythema, are relatively less common. Delayed wound healing and local hypersensitivity are other manifestations. Systemic effects, namely hypothalamic pituitary adrenal axis suppression, Cushing's syndrome, and femoral head osteonecrosis, can be potentially serious. [23]

AIMS & OBJECTIVES:

- To study dermatological adverse effects amongst patients using TCs and the duration of misuse.
- To study the source of recommendations and reasons for using TC.
- To study demographic details of patients using TCs.
- To study the type and class of TC formulations misused by the patients

II. Materials And Methods

1. Study Design

A hospital-based cross-sectional observational study was conducted over 18 months (Nov 2019–May 2021) in the Dermatology OPD/IPD of a tertiary care center in central India to evaluate topical corticosteroid misuse. The study included 430 patients who had used TCs (alone or in combination) and met the inclusion criteria.

Study Duration: 18 months (Nov 2019 – May 2021)

Study population: All patients who had used TCs either stood alone or in combination with other drugs in the Dermatology Outpatient department at our Tertiary care Hospital who fulfilled the inclusion criteria

Inclusion criteria:

- All patients who had used TCs either stand alone or in combination with other drugs.
- All patients who had used TCs incorrectly, i.e., for conditions where TCs were not indicated.
- All patients in whom TCs were indicated but were applied in an inappropriate dose/ frequency/duration.
- Patients presenting with acneiform eruptions, facial hypertrichosis, plethoric face and telangiectasia, cutaneous atrophy, striae, hyper/hypo pigmentation, tinea incognito, perioral dermatitis, infantile gluteal granuloma, pyoderma, topical steroid-dependent face, irritant contact dermatitis, or any other cutaneous side effect(s) attributed to TC.

Exclusion criteria:

- Patients not willing to participate in the study.
- Patients not having confirmatory evidence (prescription/ photograph of product(s)/ used container) of TCs used.

Method of study:

After approval from the Institutional Ethics Committee, a valid informed consent was obtained. Once the patients were enrolled in the study, a thorough history and physical examination were done as per the proforma. Informed consent was taken in writing from patients or the patient's attendant.

Patients of all ages and sexes were included in the study. Demographic characteristics of study participants (age, gender, employment, marital status, educational level), Type of TC used, duration and frequency of application of TC, and the reason for using the drug, awareness of proper dosing and adverse effects.

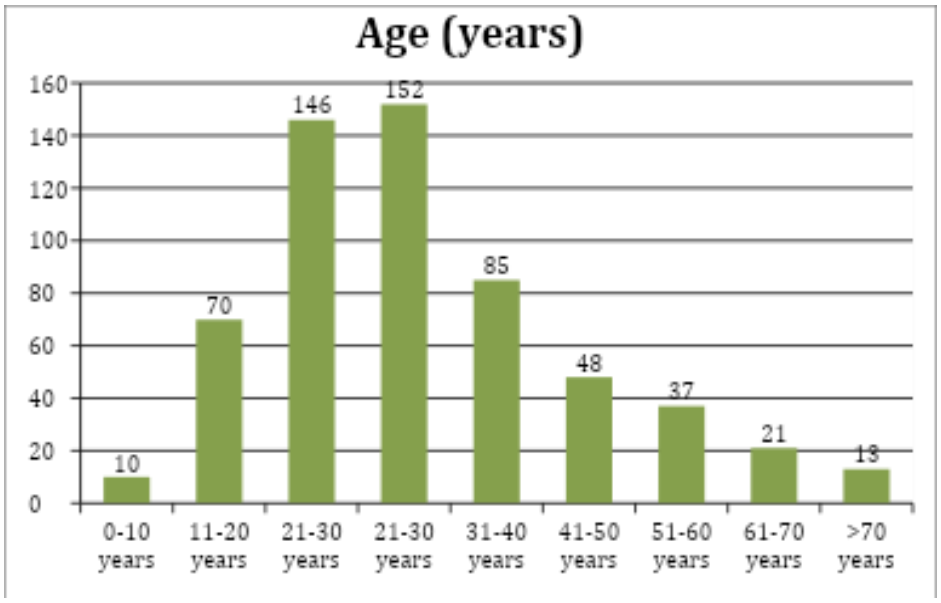
A full skin examination was done to detect any condition related to misuse of TCs. Most of the diagnoses were exclusively clinical and were based on the typical, classical features. Examination of the dermatological adverse effects and photographic documentation were done for future reference. All patients received appropriate treatment depending on the underlying condition.

- **Ethical approval number:** SKNMC/Ethics/App/2019/545
- **Study registration number:** MUHS/PG/E-1/1210/4080/2019

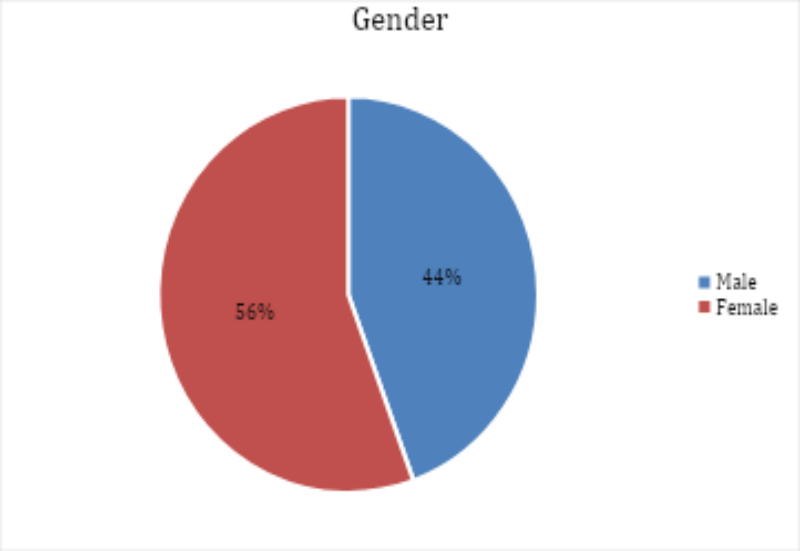
Statistical analysis:
Results were graphically represented where deemed necessary. Appropriate statistical software, including but not restricted to MS-Excel. SPSS version 20 was used for statistical analysis. Graphical representation was done in MS-Excel 2010.

III. Results

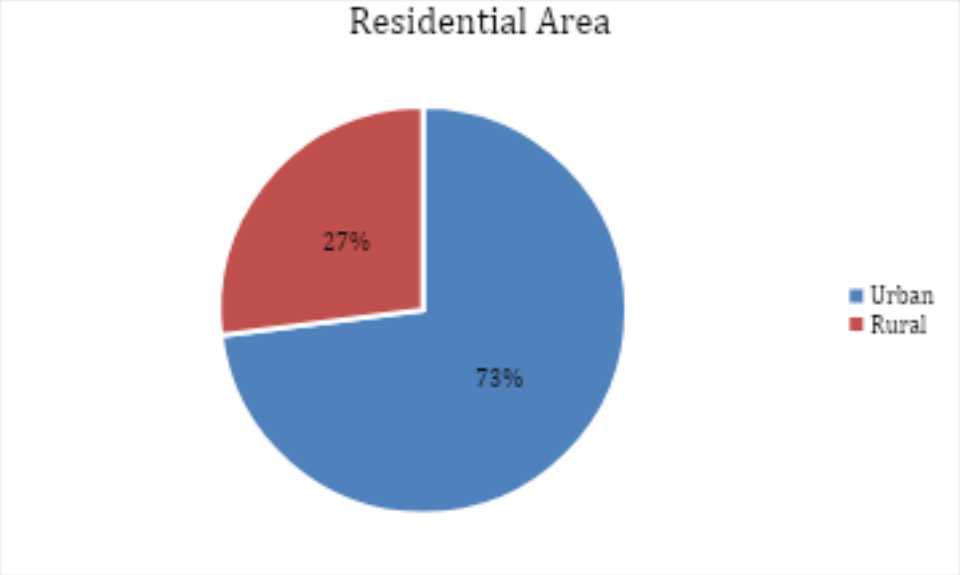
A hospital-based cross-sectional, observational study was conducted with 430 patients to evaluate the misuse of topical corticosteroids in dermatological disorders at a tertiary care centre in central India.
Most patients were aged 21–30 years (33.9%), with a mean age of 33.73 ± 16.11 years. Females comprised 55.6% of the group, and 73% were from urban areas.
Tinea infections (44.9%) were the leading reason for topical corticosteroid (TC) abuse, followed by melasma (25.6%), acne (10.2%), depigmentation (10%), fairness (5.8%), hypopigmentation (1.2%), and night cream use (0.5%); 1.9% had unspecified reasons.
Recommendations came mainly from pharmacists (36.1%), followed by friends/relatives (23.1%), general practitioners (18.8%), non-allopathic doctors (6.9%), dermatologists (5.8%), beauticians (3.7%), media (2.3%), nursing staff (2.1%), and self (1.2%).



Graph 1: Distribution of patients according to Age



Graph 2: Distribution of patients according to Gender



Graph 3: Distribution of patients according to Residential Area

Table 1: Distribution of patients according to Duration of Misuse

Duration of Misuse	N	%
<3 weeks	87	20.2%
3 weeks – 3 months	95	22.1%
3-6 months	73	16.9%
6 months – 1 year	51	11.9%
1-5 years	98	22.8%
6-10 years	20	4.6%
>10 years	4	0.9%
Not specified	2	0.5%
Total	430	100%

Table 2: Distribution of patients according to Indication for TC abuse

Indication for TC abuse	N	%
Tinea infections	193	44.9%
Melasma	110	25.6%
Acne	44	10.2%
Depigmentation	43	10%
Fairness	25	5.8%
Hypopigmentation	5	1.2%
Regular night cream	2	0.5%

Not specified	8	1.9%
Total	430	100%

Table 3: Distribution of patients according to Source of recommendation

Source of recommendation	N	%
Pharmacist	155	36.1%
Friends/relatives/neighbours	99	23.1%
General practitioner	81	18.8%
Non- allopathic doctors	30	6.9%
Dermatologist	25	5.8%
Beauticians	16	3.7%
Media	10	2.3%
Nursing staff	9	2.1%
Self	5	1.2%
Total	430	100%

Table 4: Distribution of patients according to Type and Class of TC formulations

Composition	Class (Potency, USA Classification)	N	%
Betamethasone valerate 0.1%	Class III	120	27.9%
Betamethasone valerate 0.1% + neomycin sulphate 0.5%	Class III	103	23.9%
Mometasonefuroate 0.1% + hydroquinone 2% + tretinoin 0.025%	Class IV	55	12.8%
Betamethasone valerate 0.1% + gentamycin 0.1% + tolnaftate + clioquinol	Class III	30	6.9%

Clobetasol propionate 0.05% + gentamycin 0.1% + miconazole nitrate 2%	Class I	23	5.3%
Betamethasone valerate 0.1% + gentamycin 0.1% + miconazole nitrate 2%	Class III	21	4.9%
Clobetasol propionate 0.05% + Gentamycin 0.1% + Clotrimazole 1% + Clioquinol (Iodochlorhydroxyquin) 1%+Tolnaftate 1%	Class I	19	4.4%
Betamethasone valerate 0.1% + clioquinol 3%	Class III	16	3.7%
Beclomethasone Dipripionate 0.025% + Clotrimazole 1%	Class III	8	1.9%
Clobetasol propionate 0.05% + Neomycin 0.5% + Miconazole 2% + Chlorhexidine 0.2%	Class I	7	5.4%
Clobetasol propionate 0.05% + Neomycin 0.5% + Miconazole 2%	Class I	6	1.4%
Clobetasol propionate 0.05% + Ofloxacin 0.75% + Ornidazole 2% + Terbinafine 1%	Class I	5	1.2%
Mometasone furoate 0.1%	Class III	2	0.5%
Halobetasol propionate 0.05%	Class I	2	0.5%
Total		430	100%

Table 5: Distribution of patients according to Adverse Effects

Adverse Effects	**N**	**%**
Tinea incognito	172	40%
Steroid addiction (topical steroid-dependent face)	64	14.9%
Cutaneous atrophy	58	13.5%
Hypopigmentation	45	10.5%
Acneform eruption	22	5.1%
Telangiectasia	20	4.6%
Perioral dermatitis	13	3.1%
Hirsutism	12	2.8%
Atrophic striae	12	2.8%
Pyoderma secondary infection	5	1.2%

Irritant contact dermatitis	4	0.9%
Rosacea	3	0.7%

Clinical photographs:

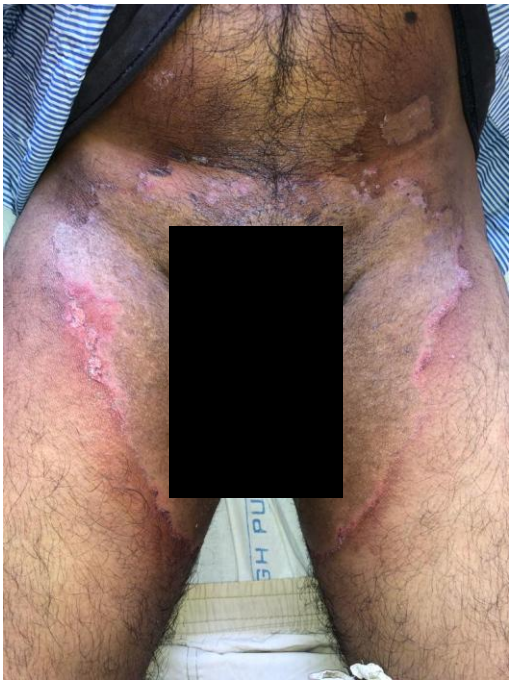


Image 1: Irritant contact dermatitis

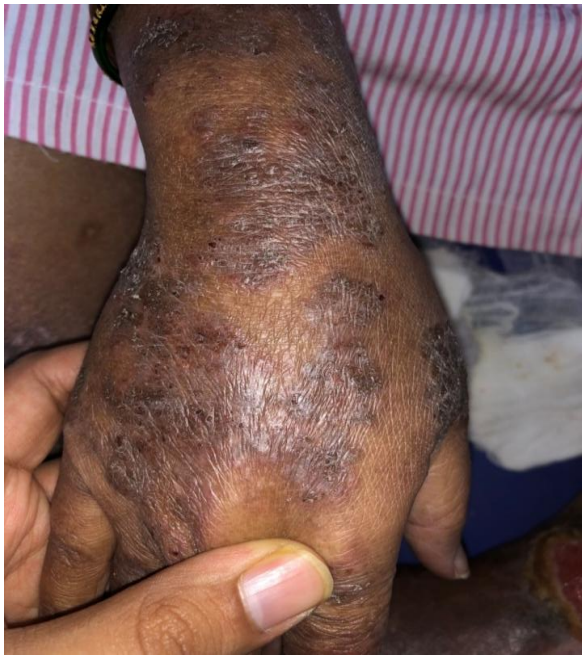


Image 2.a: Tinea incognito

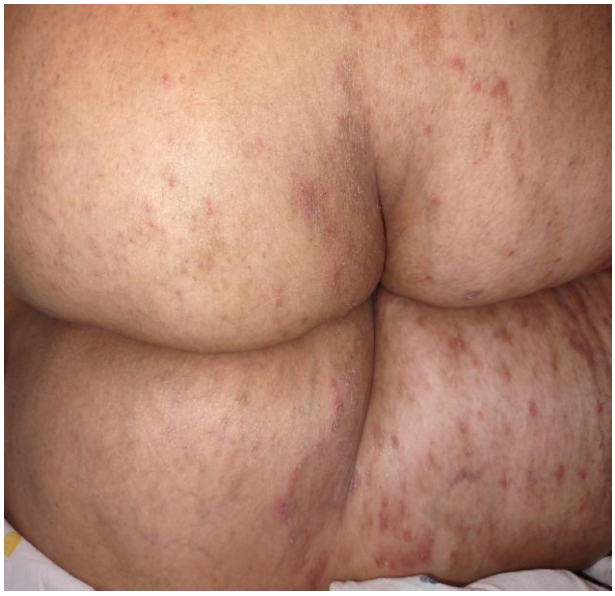


Image 2.b: Tinea incognito

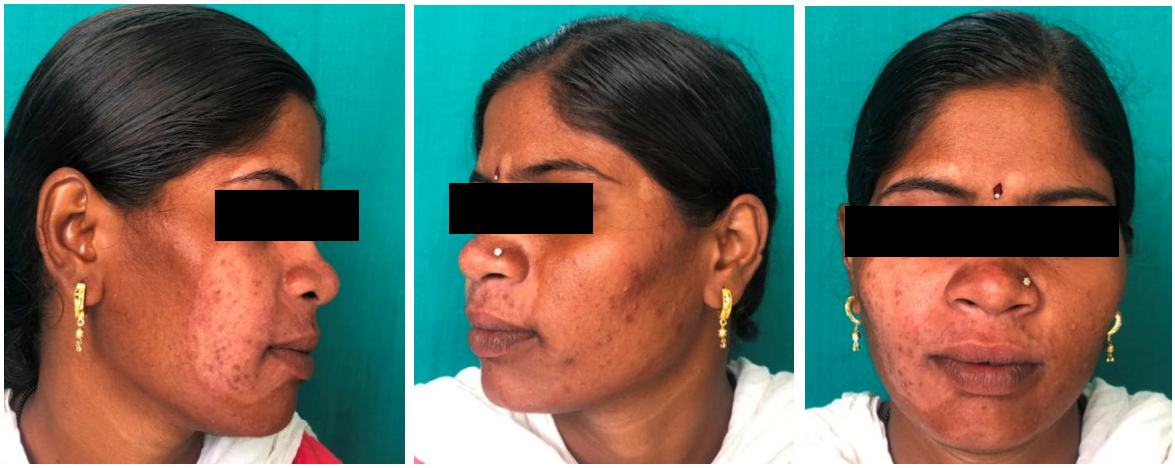


Image 2.c: Tinea incognito

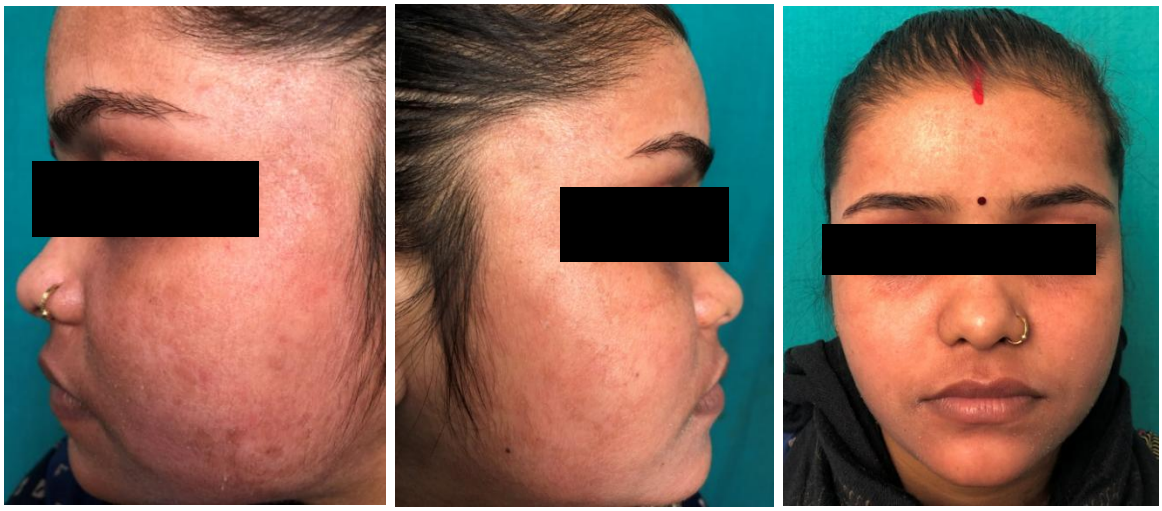


Image 3: Topical Steroid Dependant Face

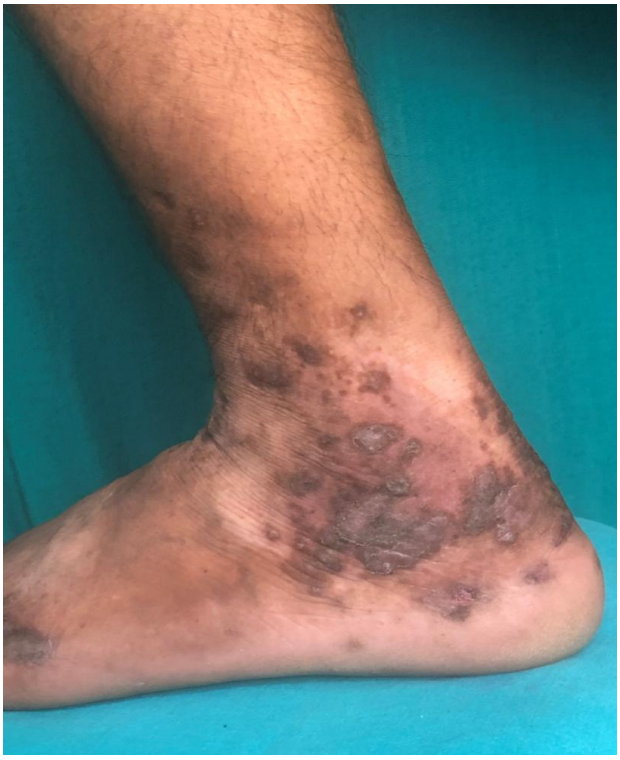


Image 4: Hypopigmentation

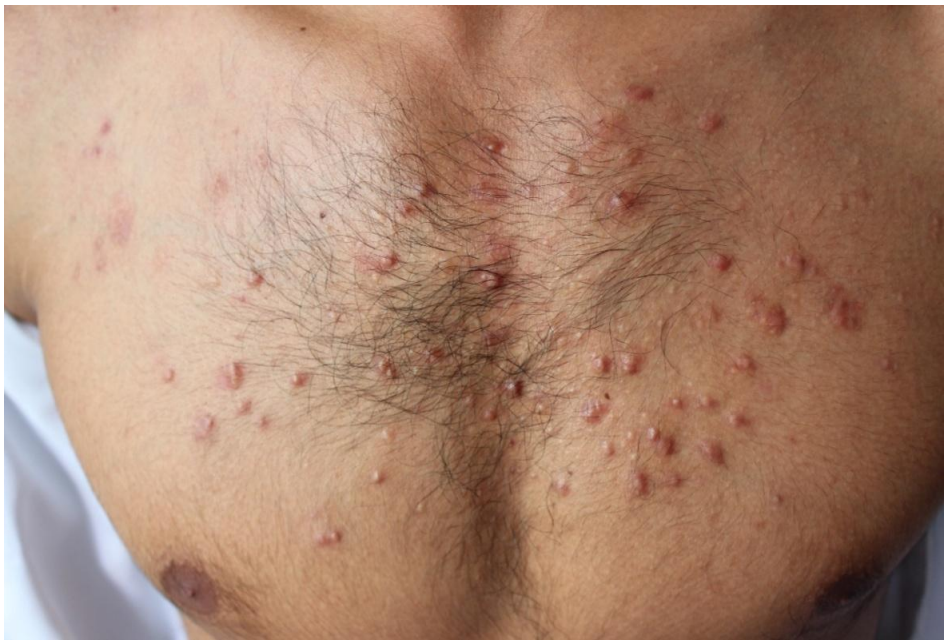


Image 5: Acneform eruption

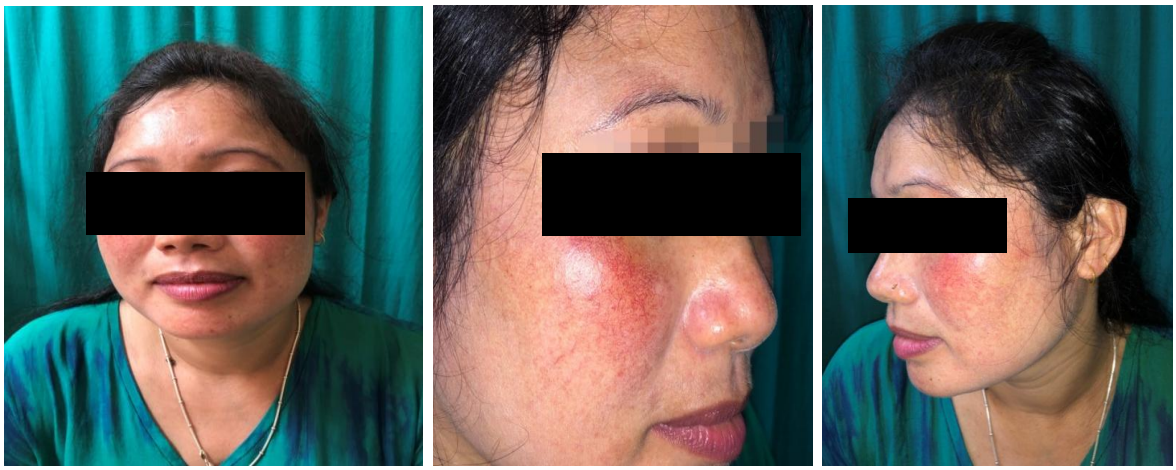


Image 6: Telengiectasia

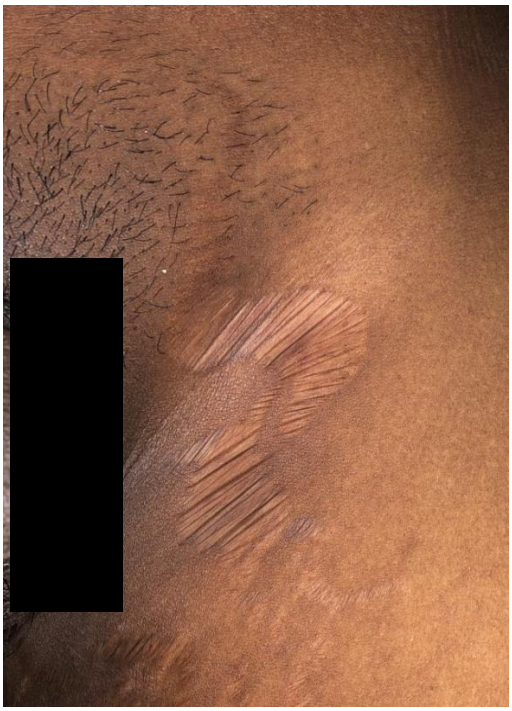


Image 6: Atrophic striae

IV. Discussion

There are various reasons for the misuse of these drugs, which vary from wrong prescription, marketing techniques by pharmaceutical companies, free availability, and lack of stringent regulations. The committee formed by the IAVDL (Indian Association of Dermatologists, Venerologists, and Leprologists) promises to bring down the ongoing misuse of these drugs by providing public awareness, running media campaigns, backed by central and state authorities. [24]

Recently, the Delhi High Court issued notices to the Centre to ensure that potent topical steroids are sold only with a prescription. This plea also questioned CDSCO's approval for the use and sale of unscientific combinations of steroids. [25]

In the present study, the duration of misuse in 87 (20.2%) and 95 (22.1%) patients was <3 weeks and 3 weeks - 3 months respectively while it was 3-6 months and 6 months – 1 year for 73 (16.9%) and 51 (11.9%) patients, respectively. The duration of misuse for 98 (22.8%) and 20 (4.6%) patients was 1-5 years and 6-10 years respectively while it was >10 years for 4 (0.9%) patients (Table 1). The duration of misuse was not specified in 2 (0.5%) patients. This is concordant to the studies of Swaroop MR et al [31], Saraswat A et al [33], Bains P [35] and Pal D et al [32]

The most common TCS used by patients in our study was betamethasone valerate (67.4%) and there was maximum use of upper mid- potent steroid (Class III, USA Classification) (69.8%) in our study (Table 2). This finding was like the studies of Swaroop MR et al [31], Pal D et al [32], Rathod SS et al [30] and Meena S et al [34]

The most common adverse effect in the present study was Tinea incognito (40%) followed by Steroid addiction (topical steroid-dependent face) (14.9%), Cutaneous atrophy (13.5%), Hypopigmentation (10.5%), Acneform eruption (5.1%), Telangiectasia (4.6%), Perioral dermatitis (3.1%), Hirsutism (2.8%), Atrophic striae (2.8%), Pyoderma secondary infection (1.2%), Irritant contact dermatitis (0.9%) and Rosacea (0.7%) (Table 3). Similar observations were noted in the studies of Swaroop MR et al [31], Saraswat A et al [33] and Pal D et al [32].

A study conducted by Zewdu et al. [26] showed that out of the 384 outpatients in the Dermatology department of a tertiary care hospital, 27.1% presented with inappropriate use of topical steroids. [30] Another study by Sinha et al., aiming to evaluate the prevalence of steroid misuse among rural masses, revealed that 74% of all dermatology patients were prescribed one or more corticosteroids [27]

Limitations:

The CDSCO (Central Drugs Standard Control Organization) website provides information regarding the dermatological indications of topical corticosteroids; however, its off-label use seems to be predominant in India. Fixed dose combinations of topical corticosteroids with antibacterial or antifungal agents are flooding the Indian pharmaceutical market presently, carrying a potential threat. [12]

The increasing misuse as cosmetics

According to the Drugs and Cosmetics Act (D and C Act) of 1940, all the topical corticosteroids fall under the category of Schedule H drugs, but statistically, the topical corticosteroids are one of the most extensively sold OTC drugs.

Paediatric population and steroid misuse

The paediatric population is more susceptible to the side effects of topical drugs than adults. The effects and side effects of topical corticosteroids largely depend on the skin thickness, potency of the drug used, and the amount of absorption. [28]

Steroid therapy and opportunistic infections

Steroid therapy often renders an individual in an immunosuppressed state, thus elevating the risk of opportunistic infections. The risk of certain infections, such as Pneumocystis jiroveci pneumonia (PJP), herpes, and tuberculosis, is well documented. Individuals undergoing steroid therapy are at an increased risk for hyperinfection syndrome and disseminated strongyloidiasis.

Risk of Cushing's syndrome

Super-potent corticosteroids can cause Cushing's syndrome concomitant with hypothalamic-pituitary-adrenal axis suppression. Almost all the children with exogenous Cushing's syndrome have used or continue to use topical steroids, and surprisingly, more than 90% of all the children use these potent medications for diaper dermatitis.

V. Conclusion

It is the role of primary health care providers to educate the primary health care workers about the adverse effects of topical steroid abuse, especially on the face, and encourage them to seek a dermatology consultation for suitable and safe alternatives.

The problem of topical steroid misuse is already significant and needs immediate action to be taken on all possible fronts. If not, there will be a worsening scenario, and we may soon be facing a disastrous inflow of these unfortunate patients at our tertiary care hospitals.

Educating the public, chemists, and general practitioners, along with strict vigilance by concerned agencies, is needed for optimal and safe use of corticosteroids. Chemists also play an important role in this; dispensing medications without a prescription should be avoided, and medications on old prescriptions should not be given. Every healthcare personnel, along with a chemist, should take some responsibility to reduce the use of unsupervised and prolonged use of TC.

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