"Topical Corticosteroids Abuse: A Prospective Observational Study Of Cutaneous Adverse Effects In Patients Attending Department Of Dermatology In Tertiary Care Hospital"

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Abstract:

Objective: Topical corticosteroids (TCs) have greatly influenced dermatology since the introduction of hydrocortisone. Today, they are commonly used for inflammatory skin diseases like lichen planus, vitiligo, psoriasis, eczema, and lupus erythematosus. However, despite their benefits, TCs are sometimes misused, especially because they can be bought over the counter and are believed to have cosmetic benefits. Misuse of these drugs can lead to serious health problems like Cushing's syndrome and skin reactions such as thinning of the skin and changes in pigmentation.

Methods: The main aim of the study is to evaluate Misuse of Topical corticosteroids conducted at Sri Balaji Medical College in Renigunta, Tirupatiover a period of six months. The study was done using a pre-designed questionnaire involving subjects with primary complaints linked to topical steroid misuse.

Results: The study involved 44 people, aged from 5-75, with 66% being women and 36% of men. Clobetasol, Betamethasone (21%) are the prominently mis-used topical steroids and the most common adverse reaction associated with those topical steroids were tinea incognito (61%), Acne (25%) with over-the-counter products being the main cause of the misuse (89%).

Conclusion: The findings of this study emphasize the need for better public awareness, stricter rules on overthe-counter sales, and better training for healthcare providers on the safe use of TCs. The significance of addressing these concerns to minimize the adverse outcomes associated with the misuse of topical corticosteroids and ensures better health management for patients.

Key Words: Topical Corticosteroids (TCs), Corticosteroid Abuse, Cutaneous Adverse Drug Reactions, Skin Thinning, Pigmentation Abnormalities, Inflammatory Skin Disorders, Over-the-Counter Corticosteroids

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I. Introduction

The field of dermatology has been transformed by the prevalent use of topical corticosteroids since compound hydrocortisone's introduction [1-2]. These medications are now the most prescribed in dermatology, crucial for managing inflammatory dermatoses like psoriasis, eczema, lichen planus, and lupus erythematosus, thanks to their anti-inflammatory and immunosuppressive properties [1-3]. However, their over-the-counter availability has led to misuse for purposes such as skin lightening and acne treatment, emphasizing the need for awareness and proper guidelines [1].

CORTICOSTEROIDS: Corticosteroids Are Steroid Hormones produced in the adrenal cortex in response to the pituitary adrenocorticotropic hormone and regulated by hypothalamic corticotrophin releasing hormone and comprise two main types: glucocorticoids and mineralocorticoids [4].

Types of Corticosteroids by Administration:

The route of administration of corticosteroids is quite flexible and includes oral ingestion, systemic/parenteral, intralesional injection as well as topical application [5].

Topical Corticosteroids: Topical corticosteroids (TCs) are one of the most commonly prescribed medications in dermatology clinics, and they serve as the cornerstone of therapy for numerous dermatoses, and their clinical effects are mediated by their anti- inflammatory, vasoconstrictive, anti-proliferative and immunosuppressive properties and topical application of these medications to the sites of inflammation bypasses the first pass effect

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of the liver ^[5, 6&7]. The Topical corticosteroids are classified into four groups according to their potency according to the British national formulary (BNF) and American system classifies them into seven classes, with class I the super potent or ultra potent and class VII represent the least potent ^[8].

S. No	Topical Corticosteroids British classification	Common examples		
1	I (Very Potent)	Clobetasol propionate 0.05% cream/ointment Halobetasol propionate 0.05% cream/ointment		
2	II(Potent)	Betamethasonepropionate 0.05% cream Fluocinonide 0.05% ointment		
3	III(Moderate)	Betamethasonevalerate0.1%cream Fluocinoloneacetonide0.025%cream Fluticasone propionate 0.05% cream		
4	IV(Mild)	Hydrocortisone 1%/2.5% cream, lotion& ointment Hydrocortisone acetate 1%/2.5% cream or lotion		

Indications: Topical corticosteroids are effective for treating a variety of conditions involving hyperproliferation, inflammation, and immune dysfunction, including atopic dermatitis, eczema, vitiligo, lichen sclerosis, bullous pemphigoid, pemphigus foliaceus, and phimosis, providing symptomatic relief for burning and pruritic lesions ^{[9].}

Mechanism of action of topical corticosteriods: Topical corticosteroids play a key role in treating psoriasis by reducing epidermal mitosis through increased lipocortin, inhibiting dermal cell proliferation and collagen synthesis, while also suppressing immune responses by inhibiting humoral factors and immune cell maturation. Their effects are mediated through binding to the glucocorticoid receptor, which translocate to the nucleus to alter gene transcription [10, 11].

Misuse of Topical Corticosteroids:

The misuse of topical corticosteroids is widespread due to their easy availability as over-the- counter drugs. Steroids exert various effects on the skin, including anti-inflammatory, antipruritic, melanogenic, atrophogenic, and immunosuppressive effects. Prolonged or unwarranted use of these drugs can lead to adverse effects [3&12]. The effectiveness of the most used topical therapeutic agent in dermatology has become a two-sided issue due to rising misuse, resulting in severe consequences [13].

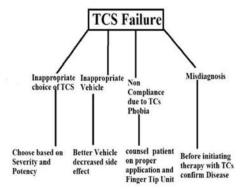


Figure: 1.1 Showsthe Topical Corticosteroid Failure [13].

Adverse Effects of Topical Corticosteroids:

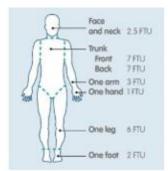
Local side effects of topical steroids (TS) include skin atrophy, striae, rosacea, Perioral dermatitis, acne, purpura, and hypo/hyper pigmentation, with less common effects such as Hypertrichosis, allergic contact dermatitis, delayed wound healing, and exacerbation of skin infections. The occurrence and severity of these side effects depend on factors such as the potency of the steroid, its formulation, the site and duration of application, the dosage, and the specific drug used. Systemic adverse effects are more likely with prolonged use of highly potent TS on thin or inflamed skin, such as the face, and may be more pronounced when used over large areas or for extended periods [8, 9&14].

Topical steroid withdrawal (TSW) is rare with appropriate, short-term use or intermittent treatments. Symptoms like redness, burning, itching, peeling, and oozing sores may appear days or weeks after discontinuation [15]. Topical corticosteroids are contraindicated in bacterial infections, as their effects can mask symptoms, delaying treatment. Avoid use in conditions like impetigo, cellulitis, and erysipelas. They are relatively contraindicated in fungal infections (e.g., Candida or dermatophytes), which may worsen due to immunosuppression, resulting in tinea incognito with increased spread and inflammation [16]. Irrational and inappropriate prescribing of potent

corticosteroids without FDA indications is common [17].

Clinicians should employ low-potency corticosteroids for mild cases, medium-high for moderate, and superhigh for severe conditions on thickened skin. Prioritize low potency for paediatricand delicate areas, reserving superhigh potency for rare, brief use. Align formulations with lesions: ointments for xerosis, creams for exudative lesions, and solutions for pilose regions [18]. AnFTU is defined as the amount that can be squeezed from the fingertip to the first crease of the finger with a 5mm diameter nozzle. Using a standard nozzle tube one FTU equals 0.5g cream/ointment [8, 19].]. *Figure 1.5*: Showing the Quantity of FTU [19]





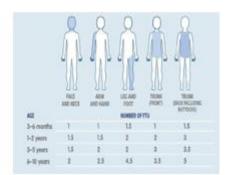


Figure 1.6, 1, 7: Showing Amount of FTU for Different Parts of Body in Children and adult [19]

II. Material And Methods

Aim &Objectives:

- To study the frequency patterns of misuse or overuse of topical corticosteroids
- To identify the various skin conditions for which topical corticosteroids are prescribed
- > To document and classify the cutaneous adverse effects associated with topical corticosteroids use
- > To evaluate the prevalence and demographic characteristics of subjects using topical corticosteroids
- > To examine the knowledge and awareness of subjects regarding the proper use of these medications

Method of Study

A pre-determined questionnaire-based clinical study was conducted for 6months among 44 patients presenting with chief complaints due to topical steroid abuse. The study included demographic data collection, physical examination, past medical history, medication history, topical corticosteroid usage, dermatological examinations, personal habits, lifestyle factors, adverse effects, and misuse assessment.

Patients who overused topical corticosteroids beyond the prescribed time limit or applied super potent or potent steroids on sensitive areas like the face, genitalia, axillae, knee, hands, abdomen, or groin and presented with side effects were included. Those with cutaneous adverse effects suggestive of topical corticosteroids without detailed information were excluded. The study received ethical approval from the institutional ethics committee. Patients were registered for further evaluation based on a standardized pro forma. Information on the type, potency, frequency of application, duration of therapy, reason, and source of information for topical steroid use was recorded, and photographic documentation of the patients was performed.

Inclusion criteria:

- ☐ Subjects of age5to75yearsofbothsexes.
- ☐ Subjects who have using TC for a specified duration
- ☐ Subjects who have presented one or more side effects followed by application of TC
- ☐ Subjects who provide informed consent to be part of the study

Exclusion criteria:

- $\hfill\square$ Subjects who are allergic to the TC
- ☐ Subjects with Cushing syndrome
- ☐ Subjects with Chronic alcoholism
- ☐ Subjects who are pregnant.

Statistical analysis:

Statistical analysis is done by using Microsoft Excel version. P value is calculated by using Student t. test (T. Test). Standard deviation and mean of age group was assessed using the **Microsoft 2016 Excel data sheet**. The results are shown below tables.

III. Results

A Prospective observational study was conducted for 6 months [September 2023-February 2024] in Dermatology OPD unit in Sri Balaji Medical College, Hospital, and research institute, Renigunta, Tirupati. A total of 44 subjects were recruited into the study based upon the inclusion criteria upon receival of ICF. Out of 44 subjects 28(64%) were females and 16 (36%) were males.

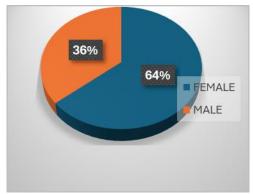


Figure 3.1 Explains the distribution of the gender in total study population

We categorized the subjects to their age group. The average age of the total study population is 31.4 years, and the average of male and female is found to be 31.8 and 31.2 respectively. Out of 44 subjects, 20(45%) of them were from age group of 20-29 years, followed by 9(20%) from 30-39 years, 8(18%) from 40-49 years, 3(7%) from 10-19 years, 1(3%) from 50-59 years, 2(4%) from 60-69 years and then finally by 1(3%) of age group <10 years.

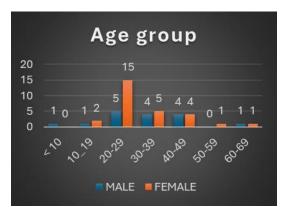


Figure 3.2 Explains Distribution Of Age Group In Total Study Sample.

We have assessed the types of steroid abuse in the study subjects and found that 12 (27%) were abused the Clobetasol, Betamethasone 9 (21%), Unknown steroid 8 (18%), mometasone furoate 5 (12%), hydrocortisone 4 (9%), fluocinolone acetonide 2 (5%) ,1 (2%) for Dexamethasone, Beclomethasone, Diflucortolone valerate, Halobetasol respectively.

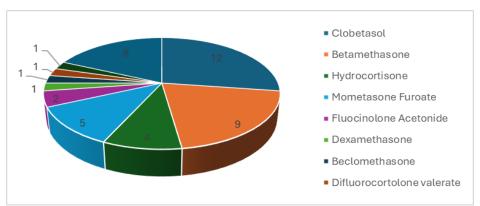


Figure 3.3 describes the type of steroid abuse.

We have assessed the type of cutaneous ADR of the study subjects and percentage of Tinea incognito is found to be 61% followed by Acne (25%), Erythema (7%), Hypopigmentation (5%) and Tinea with acne (2%) which is explained in the

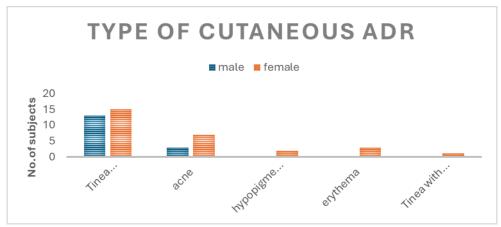


Figure 3.4: explains the distribution of type of cutaneous ADR in total study sample.



Figure: 3.5, 3.6& 3.7: shows tinea incognito, Post Steroidal Acneiform Eruption, Steroid Induced Erythema respectively. We have assessed the duration of steroid abuse of the total study subjects ranging from 2 -25 months 29(68%), followed by 6-10 months 12(28%), 11-15 months and 21-25 months 1(2%) and then finally 16-20 months none.

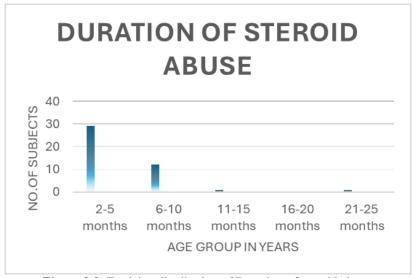


Figure 3.8: Explains distribution of Duration of steroid abuse.

We have assessed the dermatological examination in the total study population among the 44 subjects the most common dermatological examination in the steroid abuse subjects is the change in skin colour observed in 39 subjects, followed by change in skin appearance and skin texture 36, itching in 33 subjects, Burning skin in 18 subjects, abnormal skin growth in 15 subjects and finally pus and pain associated with ADR subjects respectively.

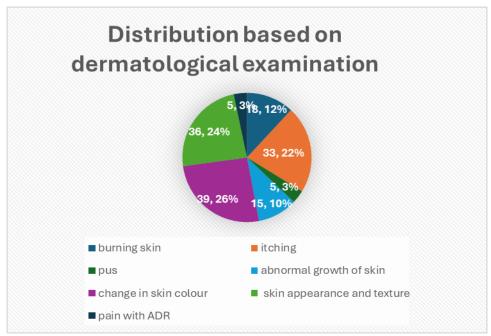


Figure 3.9: Explains distribution of type of dermatological examination.

We have assessed the source of steroid use in the total study population among the 44 subjects 39(89) Subjects were used the steroid without prescription among OTC was the most common source for the steroid abuse with 19 subjects followed by friends for 12 subjects, self for 8 subjects and Dr. Prescription for 5(11) subjects respectively.

	Steroid induced ADR	Source of steroid use		NT C	
S.no		With prescription	Without prescription	No. of subjects	Percentage (%)
1	Tinea incognito	3	25	28	64
2	Acne	1	9	10	23
3	Hypopigmentation	1	1	2	4
4	Erythema	0	3	3	7
5	Tinea with acne	0	1	1	2
Total		5	30	11	100

Table 3.9: Explains the source of steroid use.

IV. Discussion

In present study we observed that the abuse of topical corticosteroids was more prone in females (64%) than in males (37%) and our results were supported by al^2 studywhere 78% are females are abused this topical corticosteroid. We categorized them patients with age groups and found the difference in both the groups P value =0.2695. The average age of the total study population 31.4 and the mean age and standard deviation of male and female is found to be $31.8 \pm .97$ and 31.2 ± 5.16 , respectively. We categorized cutaneous adverse effect with steroid and found that Clobetasol was the most commonly abused steroid, accounting for 28% of cases among the 12 subjects supported by the *AbirSaraswat et al* among these tinea incognito is the predominant ADR affecting 11 subjects (25%), Betamethasone abuse was observed in 9 subjects (21%) with 6 cases showing acne, 3 cases exhibiting tinea incognito followed by unknown steroid abuse involves 8 cases (18%), Mometasone furoate was abused by 5 subjects (11%), with 2 cases (11%) of Tinea incognito and 2 cases (11%) of erythema, Hydrocortisone abuse was observed in 4 subjects (9%) with (5%) with each case of hypopigmentation and erythema, Dexamethasone, Beclomethasone, Difluorocortolonevalerate and Halobetasol propionate each accounted for 1 case (2%) respectively. We assessed that the duration of steroid abuse among subjects categorized into different time intervals ranging from 2 to 25 months to assess the duration of steroid

abuse. The number of subjects decreases as the duration of abuse increases with the majority (68%) within the 2-5month range, followed by 6-10 months (28%) followed by only one subject each in the 11-15 and 21-25 However, there was a notable decl11-15- and 21-25- month subjects as the duration extended beyond 10 months, with only one subject each in the 11-15 and 21-25month categories, and none in the 16-20month range. We categorized data on the site of ADR abuse among the forty-four subjects the most frequently used site is on the face 39%, followed by inguinal 18%, hands and abdomen 11%, groin and axillae 9% and then finally knee 3%. Most commonly used over the counter medication is topical corticosteroids followed by triple combination under the trade names Clobate GM, Betnovate, skin lite etc., Patients used these medications cosmetically for skin lightening and to address pigmentation concerns for various reasons. Patients primarily consulted pharmacists for issues such as acne, skin lightening, groin rashes, and body pain. We categorized the source of steroid abuse among the study population of 44 subjects. It is evident from ourdata that OTC emerges as the primarysourceof steroid abusewith 19 subjects obtaining these medications without a prescription was supported by the Arijit Coondoo et al. Moreover, friends as a source of steroidfor 12 subject's influence of social networks and pressure enhancing the misuse of these medications. This suggest a need for targeted educational interventions aim that rising awareness among both the public and the peer groups about the risk associated with steroid abuse, the self- medication practices observed among 8 subjects and lastly the medications that are prescribed by the healthcare physicians with 5 subjects it is essential to examine circumstances under which these prescriptions were issued.

V. Conclusion:

Topical corticosteroids are among the most commonly utilized treatments in contemporary dermatologic practice. However, they are considered as double-edged sword drugs i.e., invaluable but need careful handling by the provider and the recipient for safe and effective use Misuse of topical corticosteroids has a massive impact on dermatological practice leading to significant proportion of visits to the dermatology. Over the counter (OTC) sources were the most common for steroid abuse, followed by friends, self-medication, and, least commonly, doctor prescriptions. These findings highlight the urgent need for comprehensive interventions addressing public awareness, regulatory measures, and healthcare provider education to control the misuse of topical corticosteroids and mitigate the associated adverse effects on dermatological practice and patient health.

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Author 1: **Dr. K.Thirumala Naik** conceptualized the study, designed the methodology, and oversaw the project implementation. Author 2: **J. Vanitha** contributed significantly to the planning, data collection, analysis, and interpretation of the study findings and preparation of manuscript. Author 3:**R. Pravalika** assisted in data collection, conducting dermatological examinations, and ensuring proper documentation. Author 4: **R. Sai Deekshith** supported the literature review, questionnaire design, and cross-validation of collected data, ensuring the accuracy and reliability of findings. Author 5: **K. Vedith Reddy** Contributed to statistical analysis, result interpretation, and generated relevant tables and figures.

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