

CLINICO-EPIDEMIOLOGICAL STUDY OF TOPICAL CORTICOSTEROIDS ABUSE AND THEIR ADVERSE EFFECTS

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Abstract:

Aim and Objective: To evaluate the clinico-epidemiological aspects of TCs abuse and their adverse effects in patient.

Introduction: Corticosteroids creams and ointments have been extensively embraced by the general public for providing rapid symptomatic relief in various inflammatory skin conditions including their use as a fairness cream has made them very popular.

Material and Methods: The research was carried out in a specialty care center in Udaipur. A total of 472 patients out of 12370 having dermatological problems due to TCs abuse were recruited in the study as per inclusion and exclusion criterias.

Result: Among 472 patients who were using TCs injudiciously, commonest indication (38.13%) for misuse of TCs was fungal infection. Most Common TCs usage found in our study was a blend of Clobetasol Propionate combined with antimicrobial and antifungal components (74.14%), with Betamethasone Valerate cream (16.94%) as the next most common option. About 39.19% of patients were not conversant about frequency of application and 97.6% were not conversant about dosage of TCs to be applied. Commonest source of advice for initiating TCs application were from family members and friends (44.49%) followed by pharmacists (40.04%) & General Practitioner (15.46%). The commonest side effect seen were Tinea Incognito (39.19%), telangiectasia (15.04%), acneiform eruption (14.61%), dyspigmentation (14.18%), striae (6.99%), atrophy (6.14%), rosacea (0.84%), hypertrichosis (1.27%), perioral dermatitis (1.05%), demodicosis (0.63%).

Conclusion: TCs induced dermatosis is gaining traction in affecting the dermatological fitness of the population. Hence, educating the patients and management of TCs induced dermatosis has become a challenge and absolute necessity.

Keywords: Topical corticosteroids, Topical steroid Abuse, self-Medication, Over-The-Counter Drugs, Tinea Incognito, Adverse Reaction

INTRODUCTION:

Topical corticosteroids (TCs) were introduced into dermatological practice in the 1950s, following the seminal report by two American dermatologists demonstrating the therapeutic efficacy of 17-hydroxycorticosterone-21-acetate cream in the treatment of various dermatoses.[1] Since then, TCs have become among the most frequently prescribed medications in dermatology because of their potent anti-inflammatory and antiproliferative properties. These effects are mediated through binding to intracellular glucocorticoid receptors, resulting in modulation of gene transcription and suppression of inflammatory pathways.[2,3]

Topical corticosteroids are recommended for a wide range of dermatological conditions, including inflammatory dermatoses and connective tissue disorders.[4] However, their extensive availability and rapid symptomatic relief have contributed to widespread misuse. In recent years, TCs have increasingly been used as over-the-counter (OTC) products and are often marketed or perceived by the general population as “anti-acne,” “anti-blemish,” and “fairness” creams. Their ability to rapidly suppress inflammation in infective dermatoses and induce temporary skin lightening has made them particularly prone to misuse in conditions such as acne, melasma, and facial dermatoses.

In India, topical corticosteroids are readily available without prescription, despite regulations mandating their sale only upon prescription by a licensed medical practitioner.[5] Inadequate regulatory enforcement and insufficient oversight of pharmaceutical outlets have facilitated unrestricted access to these agents. This problem is further compounded by the limited availability of qualified dermatologists approximately 6,500 serving a population exceeding 1.2 billion. Poor access to specialist dermatological care, combined with the easy availability of potent

topical corticosteroids, creates a conducive environment for unsupervised, prolonged, and inappropriate use of these drugs.[6]

The misuse of topical corticosteroids is associated with a broad spectrum of adverse cutaneous effects, including steroid-induced acne, rosacea-like dermatitis, perioral dermatitis, tinea incognito, skin atrophy, telangiectasia, and pigmentary alterations. These adverse effects not only complicate the primary dermatosis but also pose therapeutic challenges and may result in long-term cosmetic and psychological morbidity. Despite the increasing prevalence of topical corticosteroid misuse, there is a paucity of data documenting the clinico-epidemiological profile, demographic determinants, and clinical outcomes of corticosteroid-induced dermatoses, particularly from this region of the country.

Therefore, the present study was undertaken to evaluate the clinico-epidemiological characteristics of topical corticosteroid-induced dermatoses, document the spectrum of cutaneous manifestations and clinical outcomes associated with their misuse, and assess the demographic profile and magnitude of this problem among patients predominantly from Udaipur.

METHODOLOGY

The present study was designed as an observational across one-time point. It was carried out in the Dept of Dermatology, Venereology and Leprology in a specialty care center, PIMS, Udaipur, Rajasthan.

Study Period & Population: The study was conducted during December 2023 to January 2024. The study population were including of all patients with dermatoses attributable to topical corticosteroid misuse reporting as outpatients/inpatients to the Dept of Dermatology Venereology and Leprology, PIMS Hospital, Udaipur.

Sample Size: A total of 472 patients were included in the study.

This study will include all clinical cases presenting with topical corticosteroid-induced dermatoses. Eligible participants must have a history of continuous use of topical corticosteroid preparations for at least 15 days or intermittent use for one month or more. There will be no restrictions based on age or sex, allowing for a comprehensive analysis across different demographics.

Exclusion Criteria

Patients who deny any history of topical corticosteroid use will be excluded from the study. Additionally, individuals with co-morbid conditions that mimic or contribute to skin changes similar to corticosteroid-induced dermatoses will not be considered. These conditions include polycystic ovarian disease (PCOD), Cushing's syndrome, rosacea, and collagen vascular diseases, as they may confound the diagnosis and affect the study outcomes.

Statistical Analysis: After collecting data, it was summarized as percentages and depicted as bar diagrams and pie-charts using the SPSS software.

RESULTS:

Research revealed that 472 out of 12370 evaluated patients (3.81%) had improper usage habits with TCs although 376 patients used their prescribed TCs for different dermatological conditions.

The research subject group consisted mostly of patients between 11-20 years old (32.62%). The research population included 66.94 percent males together with 33.05 percent females. The study population indicated 24.9% among those with no reading or writing abilities.

Doctors reported dermatophytosis or fungal infection as the primary reason for steroid misuse among patients (38.13%). [Table 1] displayed the reasons for steroid misuse.

Patients employed steroid medications with different strengths and among them clobetasol propionate topical combination with antibiotics and anti-fungal products was the most popular treatment (55.93%) while betamethasone valerate cream was employed second most frequently (16.94%) [Table 2].

Among our patients 97.6% lacked knowledge regarding medicine dosage through correct determination of a specific body area application quantity. Among all studied patients 185 individuals (39.19%) applied the TC at improper intervals. The records showed that 63% of the treated patients applied one of the reviewed products once or twice per day yet 29 patients exceeded their doctor-prescribed time of usage. Pharmacological advice from the pharmacist led one female patient to consume a total of four topical steroid tubes throughout seven days.

Patients primarily obtained their first TC treatment advice from friends and relatives (44.49%), Local pharmacists (40.04%) and General Practitioners (15.46%) [Table 3].

Most patients exhibited ignorance regarding adverse effects of TCs since 76.69 percent were aware of these effects in addition to 23.30 percent who possessed limited knowledge about them.

Cutaneous side effects because of topical steroid abuse which appeared in our research examples can be found in [Table 4] and [Fig-1 to 6]. Most patients experienced tinea incognito (39.19%), telangiectasias (15.04%) among other skin complications. Acneiform eruptions (14.61%), Cutaneous dyspigmentation (14.18%), least common adverse reactions include striae (6.99%), steroidal atrophy (6.14%), Hypertrichosis (1.27%), Perioral dermatitis (1.05%), Steroidal rosacea (0.84%), Demodicosis (0.63%) in these patients.

DISCUSSION

This investigation aimed to measure OTC TC use frequency alongside the causes of this practice while simultaneously noting the prevalent dermatoses in PIMS Udaipur dermatology outpatient attendees and evaluating the availability of TC at PIMS Udaipur.

The research showed patients used TC compounds for dermatological purposes that medical experts do not find reasonable.

The study revealed that males accounted for 316 participants (66.09%) who used TC contrary to other research findings which reported 71%.^[8-10]

The majority of our study participants using TCs compounds for misuse belonged to the 11-30 years age bracket and this finding matched Saraswat et al.'s report showing 36% patients aged between 20 and 30.^[11] However, in Saraswat and colleagues^[11] study, the TCs compounds is delimited to the facial skin, whereas, in the present study, all dermatome has been considered. Another study from Iraq also found TC use maximally in the 10-19 years.^[10] However, in most studies, data was delimited to the use of the TCs compounds on the facial skin, whereas, in the present study, all dermatome has been considered.

TC skin application on OTC basis has become a widespread problem within dermatology practice which frequently leads to various dermatological issues. Spoiled fungal (39.19%) showed highest occurrence along with telangiectasia (15.04%) and acne (14.65) among OTC user patients based on this study. The rates of TACS usage on OTC basis were examined with results showing 52% from India,^[8] 57.5% from India,^[11] and 36.4% from Iraq.^[10]

The current study indicated that 399 out of 472 patients who applied TC skin medication obtained their treatment through over-the-counter (OTC) prescription-less purchases which amounted to 84.53% of the total cases. Research conducted by Saraswat et al.,^[11] found that lesser than two-thirds of all participants got the TC OTC and did not have a medical prescription. The study results from Ambica et al.,^[8] revealed a percentage of 64%.

TC has become one of the leading skin whiteners throughout recent times due to their strong bleaching abilities. The additional anti-inflammatory properties of TCs lower the probability of developing dermatitis so people commonly employ TCs for this use. The current study indicated that cosmetics usage representing acne treated with TC (acne, melasma or daily cream application) accounted for 49.7 percent of all patients who acquired TC through OTC availability. Results from previous research studies backed our findings since they revealed 29% in India^[11], 65.7% in Iraq^[10], 57.2% in Nigeria^[12] and 3% in another study in India.^[8] Dey VK et al.^[13] established that patients used TC primarily for lightening their skin because they lacked a dermatological condition (50.39%). The use of TC as a fairness cream showed a rising trend since 15.67% of our studied patients chose this product. Agarwal et al., evaluated different marketed brands of steroids creams over face. According to that, upwards of 60% dermatological derivatives that asserts instant fairness, contains TCs that gives rise to adverse harmful dermatosis.^[14]

Various studies of TC abuse on facial skin have already been done not only in India but across the globe where the most of the representatives were adolescent to adult females, to merely aesthetic purposes, totally ignorant of its adverse effects, whereas in our study, males were more in number.^[11,9,10]

The present study also found that the strength of the TC and its formulations differed considerably. The combination of antifungal and antibiotic manufactured by Panderm was the most preferred option followed by Betamethasone Valerate. The pattern of TC use suggests that skin bleaching was the biggest motivator. Aesthetic reasons for using TC have been found in China as well^[15] and differs from other studies^[9-12]. Betamethasone Valerate use has been estimated to be 76% in Pakistan,^[9] 58.9% in India,^[11] 37% and 42.1% in Iraq.^[10]

In our study, masked fungal infection/ steroid-modified ringworm is the most common reason for TC use. This could be attributed to the humid conditions during the rainy months that coincided for the greater part of the research time, along with the prevalence of tight-fitting formal clothing and long working hours in the Udaipur region.

Most of the patients in our study (74.14%) used in combination with Clobetasol Propionate alongside antifungal and antibacterial followed by very potent to potent TCs. Study done by Dey VK showed that 39,84% patients had applied fixed drug combinations due to low price and easy availability and can be procured using prescriptions.^[13] Further, we questioned the patients about the emollients and realised that in lions share for the source were their near and dear ones accounting to 44.49%, pharmacist to -40.04% and RMP's and quacks to 15.46% An uninterrupted supply of derivatives with topical corticosteroids by the pharmaceutical dispensaries (40.04%) can be attributed to laxity in the surveillance, and the commercial efforts by the industry. Similarly, the neighbour dispensary, near and dear ones, and extended family also play in part in the widespread use of topical corticosteroids.^[8,11]

The preliminary application of TC occurs because it shows anti-inflammatory effects. Unrestrained usage of topical corticosteroids generates various adverse effects including infections and acne-like reactions alongside vessel damage and marking, skin thinning, blood vessel changes, skin color changes and facial hair growth and rosacea-like face and eye conditions.^[15-17] Moreover, when corticosteroids are improperly applied beyond FDA-approved dermatology needs, they can change disease characteristics and hide fundamental diagnostic signs which complicates future treatment. The symptom most obviously observed in the study were ringworms, erythema is the most common symptoms in Pakistan.^[9] Monomorphic pimple/acne are globally the most common side-

effect.[15] Another well-documented side-effect is ‘Topical Steroid-Dependent Face’ that develops after prolonged TC use.[11]. It is commonly observed in female patients who use steroid products until achieving drastic results, then continue to prevent rebound flare-ups, ultimately leading to persistent lesions.

The study showed that patients used these topical corticosteroids from a period of 4-6 months up to 10 years. The majority of patients (76.60%) had knowledge about the possible adverse effects of steroid topical use yet they maintained its application because they observed positive initial treatment results. Female patients in the group that was unaware of medication side effects understood these effects less than male patients (77.53% vs 74.36%). In the Indian subcontinent, document eighteen TCs at various concentrations have been documented. The number of TCs reaches 119 but FDCA has approved only 27 products among those listed from 1961 to July 2014.[17] The country has prohibited both the manufacturing process and promotional activities related to those unapproved FDCs products. We need to develop strict laws to target both pharmaceutical drug manufacturers of non-approved FDCs and pharmacies that give out medications without proper written medical prescriptions. The country requires such measures to control the dermatological drug marketplace. It does not commonly occur in Western countries since FDCs are seldom prescribed and doctors always need prescriptions to provide topical steroids.[17] The IADVL Task Force Against Topical Steroid Abuse (ITATSA). ITATSA serves as a special surveillance league of dermatologists under the Indian Association of Dermatologists, Venereologists and Leprologists (IADVL) which focuses on monitoring TC mistreatment nationally.[18] It has brought into notice the serious issue of TC abuse at several platforms starting from the pharmaceutical companies, regulators, and physicians. Another additional step in this direction is an online petition notified to the Ministry of Health and Family Welfare, Government of India and Central Drugs Standard Control Organization (CDSCO). This petition emphasizes upon the burning issue in India caused because of an unexplainable and unsupervised consumption of topical corticosteroidal formulations unchecked by rules/ regulations in the Indian market. It also makes a serious attempt to create awareness among the laypeople about the potential issues attributed to their abuse/ misuse.

CONCLUSION

Patients benefit extensively from topical corticosteroid applications that present minimal hazards while costing less. The repeated application of strong steroid medications is not suitable for long periods when patients deal with inflammatory diseases that cannot be treated effectively or attack vulnerable areas. Patients avoid using these formulations because of legitimate worries about them which contributes to nonadherence when the treatment should be used. The lack of appropriate treatment exists for a significant number of affected patients. The dermatologist must teach patients about topical corticosteroids to eliminate fears while ensuring their safety.

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Figures legend:

Fig.1 (a and b) Steroid induced rosacea

Fig. 2 (a and b) Topical steroid dependent facies

Fig 3 (a and b) Tinea pseudo-imbricata

Fig 4 cutaneous atrophy following topical steroid application

Fig 5 tinea incognito with striae atrophicans (a) striae rubra (c and d)

Fig 6 (a,b and c) Acniform eruptions after TCs Abuse