

Prescription and Usage Pattern of Topical Corticosteroids among Out-patient Attendees with Dermatophyte Infections and Its Analysis: A Cross-sectional, Survey-based Study

Abstract

Background: There is scarce scientific data on topical corticosteroids (TCS) prescription by non-dermatologists including registered medical practitioners, ayurvedic, homeopathic practitioners, and over-the-counter (OTC) use of TCS-containing creams. **Objective:** The main objective of this study is to analyze the prescription and usage pattern of topical steroids among out-patient attendees with dermatophyte infection. To study health-seeking behavior of patients with dermatophyte infections. **Material and Methods:** An open, cross-sectional, duration-based study of 3 months. Inclusion criteria: Patients with dermatophytosis having a history of topical steroid application; either prescribed or purchased OTC and used themselves. Exclusion criteria: Patients who were not willing to give informed consent. Patient's data like socio-demographic profile, duration, frequency, site of application, contents of the topical cream used, prescriber information, and patients' desire to continue the use of topical steroids were recorded. **Results:** Total of 18.40% ($n = 503$) patients were already using cream-containing TCS at the time of presentation to the tertiary dermatology care center. The study shows that almost half of the patients (48.90%) were using unprescribed TCS. Registered medical practitioners were the most common source of TCS creams prescription (59.92%) in the prescribed group, while 26.07% patients were prescribed TCS by dermatologists. Clobetasol propionate (47.91%), was most common steroid agent used. **Conclusion:** Patients are able to get "prescription-only" drugs as OTC products. Such OTC use of TCS puts patients at risk of steroid modified dermatophytosis and topical steroid damaged skin. Even dermatologists may be culprit in creating menace of steroid abuse.

Keywords: Corticosteroid, health-seeking behavior, over-the-counter, prescription practice

Introduction

Majority of patients seek consultation of dermatologist only after applying over-the-counter (OTC) topical preparations for a month or two. They are influenced by the advertisements promoting the creams claiming dramatic cure of cutaneous fungal infection. Many of these creams contain steroids which provide rapid relief of symptoms and hence lead to subsequent abuse.^[1] With ongoing scenario of extensive dermatophytosis and tendency of the general population to not primarily visit a dermatologist for various reasons and to add to that craze for fairness creams and their OTC easy availability, vast sections of the Indian society have willingly or unknowingly become victims leading to a virtual epidemic of monomorphic acne, steroid atrophy, steroid rosacea,

telangiectasia, perioral dermatitis, striae, and other manifestations of a condition which has been collectively described as topical steroid damaged skin (TSDS).^[2] Despite being prescription-only drugs, they are widely being used among the general population for various indications. The usefulness of these has become a double-edged sword with constantly rising instances of abuse and misuse leading to serious local, systemic, and psychological side effects. These side effects occur more with topical corticosteroids (TCS) of higher potency and on particular areas of the body like face and genitalia.^[3] Though, there have been studies on corticosteroid prescription practices of a dermatologist^[4,5] very little is known about how the general population buys and uses these creams?! This study was carried out to know the following objectives.

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Aims and objectives

The main purpose of this study was to analyze the prescribed and unprescribed (self/OTC) use of topical steroids in out-patient attendees with dermatophyte infections. The study aimed to know health-seeking behavior of patient with dermatophytosis. Secondary objective of the study was to determine the type of TCS used for dermatophytosis and understand the desire to continue the application of topical steroids for symptomatic relief as perceived by patients.

Material and Methods

This was an open, cross-sectional, survey-based observational study. The study duration was for 3 months; conducted at a tertiary dermatology center in western India. The study began after approval by the Institutional Review Board. Written informed consent was taken for every patient included in the study. Sample size was duration-based. **INCLUSION CRITERIA:** Patients with dermatophytosis having a history of topical steroid application; either prescribed or purchased OTC and used themselves. Diagnosis of dermatophytosis was made by the combination of clinical presentation and potassium hydroxide (KOH) mount positivity. **EXCLUSION CRITERIA:** Patients who were not willing to give their written informed consent. Patient's data like socio-demographic profile, duration, frequency, area of topical steroid application including the contents of the topical cream used, and patients' desire to continue the use of topical steroids were recorded in a survey form developed by the investigators of the study. (Case record form: Annexure 1). Prescriber information (Medical Degree) was noted. Collected data were analyzed by standard statistical test.

Results

Among 2730 new patients presenting to our outpatient department (OPD) over a 3-month period of study duration, 503 patients (18.4%) presented with a history of using TCS-containing cream for suspected dermatophytosis either prescribed or unprescribed. The study included total 503 subjects out of which 296 were males and 207 were females with male to female ratio being 1.4:1. Of 503 patients, 8.95% ($n = 45$) were children and 91.05% ($n = 458$) were >12 years of age. The study also shows 8.95% ($n = 45$) of study participants were belonging to 12 years or less suggestive of role of parental guidance/inappropriate medical decision by parents to apply OTC creams to their children. Genitalia and perineum were the most common body sites where TCS was applied 41% ($n = 191$) followed by trunk (including both upper and lower limbs) 30% ($n = 151$), face 23% ($n = 116$), respectively, and 9% ($n = 45$) of study participants applied TCS over two or more body sites.

As seen in Table 1, 51.09% ($n = 257$) were using TCS-containing topical preparations as prescription

products. Registered medical practitioners were the most common source of TCS creams prescription 59.92% ($n = 154$). Following which, dermatologists (M.D./D.V.D) 26.07% ($n = 67$) and Ayurveda, Yoga and Naturopathy, Unani, Siddha, and Homoeopathy practitioners (AYUSH) were 14.01% ($n = 36$) of total study as a source TCS prescription. The study shows that almost half of the patients, (48.90%; $n = 246$) were already using unprescribed (self/OTC use) TCS when they visited dermatology OPD. Table 2 analyzes the buying pattern of the individual when TCS are used as OTC products (self use/unprescribed). It shows that 41.36% ($n = 103$) of patients bought it on their own from a chemist store, 28.86% ($n = 71$) of patients took advice from the chemist and bought such creams for their skin condition. Degree/education of the person at chemist sale counter could not be verified in the study. About 19.91% ($n = 49$) of patients in the study relied on the advice of friends/relatives for their skin condition and bought such creams directly from the chemist store. About 9.34% ($n = 23$) patients in the study were using shared product of the close relatives/family members.

Table 3 shows the content/type of corticosteroid formulation used in such creams. Contents of the cream used were noted down from the tube cover/used tube directly when patient had bought it. Those who had not bought but remembered the names of the tube, for them an online search was made to know the contents of the tube and recorded accordingly. Only those patients who could bring the tube at the time of consultation or on follow up or who remembered the brand name of the tube were included in the study. Most common steroid agent used in such creams is clobetasol propionate

Table 1: Prescribed vs non-prescribed

| Prescribed | Self-use | Total (ratio) |
|--|----------|---------------|
| Prescriber information | | |
| Registered medical practitioner | 154 | |
| Dermatologist (M.D./D.V.D.) | 67 | |
| AYUSH system of medicine | 36 | |
| Total | 257 | 246 |
| 503 (1.04) | | |
| AYUSH (Ayurveda, Yoga and Naturopathy, Unani, Siddha, and Homoeopathy practitioner as per the Ministry of Health, Government of India) | | |

Table 2: Buying pattern when unprescribed use/self-use

| Unprescribed | Number(%) |
|---|--------------|
| Self (over-the-counter) | 103 (41.86%) |
| Suggested by person at pharmacy counter | 071 (28.86%) |
| Suggested by friend/relative | 049 (19.91%) |
| Shared product of close relatives with similar complaints | 23 (9.34%) |
| Total | 246 |

used in 47.91% ($n = 241$) of study participants, followed by betamethasone 17.89% ($n = 90$) and beclomethasone 12.92% ($n = 65$). In 13.91% ($n = 70$), there was a history of applying two or more TCS creams.

Lastly, they were asked if they had desire to continue use of such creams, to which most patients wanted an honest opinion of the physician and were happy to change the cream. However, small proportion of patients (7.33%; $n = 45$) liked the symptomatic benefit provided by the use of such creams and had desire to continue the same [Table 4].

Sample case record sheet used in this study can easily be converted into web form/google survey form and details of the patients can be recorded in uniform manner. The same tool can be used nationally by dermatologists to further report the TCS prescription practice.

Discussion

Panda and Verma^[6] in their editorial discuss the putative role of topical steroid misuse behind the sudden outbreak of the complicated, atypical, chronic, recalcitrant dermatophytosis, and need to generate country-specific evidence. This study is an attempt to know how many patients with dermatophytosis use OTC TCS creams? when do they contact the dermatologist? and which is the common type of corticosteroid component in steroid-antifungal combinations?

The public interest litigation (PIL) filed by the Indian Association of Dermatologists, Venereologists, and Leprologists (IADVL) has sought ban on manufacture and sale of several skin creams-containing steroids being marketed for skin conditions like pigmentation, itching,

fairness, and inflammation. However, there is very little scientific data in the published literature about such use in general population. This study draws attention to the widely prevalent prescription practices of general practitioner, health-seeking behavior of patients suffering from dermatophytosis when it comes to skin diseases and drug-dispatching practice by the pharmacies.

The study draws attention to the fact that when consulted at a tertiary dermatology care institute, 18.4% patients already had a history of using TCS-containing topical creams for dermatophytosis. Of these 503 patients, as evident from the current study, 48.90% of study participants bought the creams unprescribed. Way back in 1985, in a letter to the editor in the British Medical Journal, Shuster felt the need for debate on OTC sale of hydrocortisone.^[7] Coondoo describes a similar concern in Indian scenario suggesting various forms of TCS misuse. Misuse of TCS may occur at various stages during its journey from the factory to the face. Factors contributing to misuse are: manufacturing misuse, marketing misuse, prescription misuse, sales misuse, and misuse by lay persons.^[8]

Also, important to see is the source of such cream when unprescribed which shows that apart from many patients self-using it, a large proportion of them (28.86%) also rely on the person at sale counter of pharmacy. However, education (degree) of such person could not be ascertained. This shows complete disregard to the prevalent drug dispatch/sale rules as formed and revised by government agencies from time to time. This data substantiates the claims of the study by Sharma *et al.*, mentioning role of errant chemists. There are approximately 700,000 chemists in India. They are known to become “medical advisors” who advise and sell topical steroids, most often potent topical steroids, and unscientific steroid combinations.^[9]

Use of TCS by dermatologists as seen in results could possibly be due to presence of inflammatory variant of dermatophytosis. However, upon analysing the prescription bought to us by patients, most prescription did not mention the specific type and extent of dermatophytosis in a given patient. So, it becomes really difficult to judge whether they have been prescribed legitimately or even we as dermatology community are contributing to steroid-modified dermatophytosis?

The study shows that all age groups and both sexes are vulnerable to self-use/current prescription practices of TCS creams. The study reveals that genitalia and perineal region are the most common body areas where such creams are applied and as the risk of developing adverse effects are higher in occlusive areas/flexures such, practice put them at risk of developing local cutaneous adverse effects. This study shows the current wide prevalence of dermatophytosis in the general population.^[10] It is alarming to see that most common constituent of such combination creams used is clobetasol propionate 0.05% which is

Table 3: Steroid content of the topical formulation applied

| Steroid formulation | Number(%) |
|--|--------------|
| Clobetasol propionate 0.05% | 241 (47.91%) |
| Betamethasone dipropionate 0.05%/valerate 0.1% | 90 (17.89%) |
| Beclomethasone 0.05% | 65 (12.92%) |
| Fluocinolone acetonide 0.025% | 15 (2.98%) |
| Mometasone furoate 0.1% | 17 (3.37%) |
| Halobetasol propionate 0.05% | 3 (0.59%) |
| Desonide 0.05% | 1 (0.19%) |
| Fluticasone propionate 0.05% | 1 (0.19%) |
| Two or more steroids applied | 70 (13.91%) |
| Total | 503 (100%) |

Table 4: Desire to continue steroid

| Desire to continue steroid | Number(%) |
|----------------------------|--------------|
| No | 458 (92.67%) |
| Yes | 45 (7.33%) |
| Total | 503 |

classified as ultra-high potent TCS as per annexure of the World Health Organization (WHO) model prescribing information.^[11] One can understand high risk of adverse effects from unsupervised, uncontrolled use of such TCS. Such patients typically suffers from TSDS comprising of steroid atrophy, telangiectasia, striae, purpura, stellate psuedoscars, ulceration, easy bruising, infections, steroid addiction, and tachyphylaxis.^[12]

When applied over face, this leads to development of topical steroid damaged/dependant face (TSDF), the skin of the face develops erythematous papules, pustules, acneiform eruptions, dryness, perioral dermatitis, telangiectasia, rosacea-like features, hypopigmentation, hyperpigmentation, or allergic contact dermatitis.^[5]

The easy OTC availability of TCS at chemist shops across the country without any valid prescription is further compounding this problem of abuse. According to the Drugs and Cosmetics (D and C) Act 1940, the TCS fall under the category of Schedule H drugs, meaning that they should be sold by retail shops only on the valid prescription of a qualified doctor.^[13] Ethical issues considering application of TCS surrounds use of media for public education, need to involve general practitioner, nurses and pharmacists, re-enforcing the implementation of existing legislation related to the control of these drugs. To address the current scenario, multidimensional approach is needed, involving political, educational, and legal aspects.^[14]

Conclusion

Dermatophytosis patients' reliance on opinion of chemist, family, and friends is evident from the current study. It is time now for strict implementation of the existing drug dispatching guidelines by the government authorities. This study also points towards the need to restrict the use of clobetasol propionate and other high potency steroids in the combination creams. This study may help to increase general awareness among the treating physicians and the patients which may influence the prescription pattern of topical steroids. Reporting of these topical steroid damaged cases is a small step in the direction of increased pharmacovigilance.

Limitation of the study

Many subjects were exactly not able to remember the name of creams used/contents of the creams. Such patients were excluded from the study. So, there is possible under-representation of the OTC steroid use.

Degree/education of some of the prescribers could not be verified and the same were excluded from the study.

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Conflicts of interest

There are no conflicts of interest.

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Annexure 1: Sample case record/survey sheet

Q.1 Patient demographic

- A. Male
- B. Female

Q.2 Age of the patient

Answer:

Q.3 Area of the body on which steroid was applied

- A. Face
- B. Trunk
- C. Arm
- D. Genitalia and perineum
- E. Lower limb
- F. Two or more body sites

Q. 4: Prescribed by whom?

- A. Registered medical practitioner
- B. Dermatologist
- C. AYUSH practitioner
- D. Non-prescribed

Q.5 If non-prescribed, how did patient buy it?

- A. Self, OTC
- B. Suggested by pharmacist, OTC
- C. Suggested by friend, OTC
- D. Shared product of close relative/family member with similar complaints

Q.6 Indication for use?

- A. Suspected fungal infection
- B. Acne
- C. Fairness
- D. Others

Q.7: Which steroid constituent as part of fixed drug combination cream?

Answer: Specify the name of steroid component

Q.8: If combination of drugs, how many active ingredients in the formulation?

- A. 2
- B. 3
- C. 4
- D. 5
- E. other – specify

Q.9: Duration of use?

Answer: Specify

Q.10: Adverse effects noticed?

- A. Acneiform eruption
- B. Photosensitivity
- C. Atrophy
- D. Telangiectasia
- E. Striae
- F. Steroid-modified dermatophytosis
- G. Other – specify

Q.11: Does patient have desire to further continue OTC product/steroid?

- A. Yes
- B. No