



A cross sectional study to identify the adverse effects of topical corticosteroids at tertiary care hospital

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ABSTRACT

Background: Misuse of topical corticosteroids is quite common problem among the people in India. Misuse of TC is not only by general public but also by physicians and pharmacist in different dermatological condition. **Aim:** A Cross Sectional Study to identify the adverse effects of topical corticosteroids at tertiary care hospital. **Objective:** The objective of the study was to determine the frequency of topical corticosteroids misuse, the adverse effects resulting from various topical corticosteroids and to find out the indications for which topical corticosteroids are used **Method:** Data collected from patients presenting with at least one of the adverse effects of topical corticosteroids as the principal complaint, patients were interviewed using self-made questionnaire. **Result:** A total 40 patients were included in our study as per inclusion and exclusion criteria 62.5% were males and 37.5% were females Most of the patients belongs to age group of 21 -30 years (32.5%). Steroids of varying potency were used by the patients commonest was Clobetasol Propionate 0.05% (40%). The majority of patients applied topical steroids twice or fewer times (75%). The duration of usage of TC by patients was for more than one month. Most common side effects noticed were tinea incognito (35%) followed by acneiform eruption (17.5%). The most common indication for misuse of steroids was itching over the skin. 95% patients were unaware of the side effects. **Conclusion:** This study creates an awareness and educates the people on the adverse effects of steroids, with their chronic use and thus the measures that can be applied to stop steroid abuse.

Keywords: Misuse, Topical corticosteroid

INTRODUCTION

Topical corticosteroids were introduced by Sulzberger and written in 1952; this is the most remarkable introduction in dermatology therapeutics. Nowadays topical corticosteroids are the most commonly prescribed medication in dermatology. Moreover, Topical corticosteroids are extensively used in the treatment of many skin diseases for instance, in dermatitis, Papulosquamous: Lichen planus, Lichen simplex chronicus, Pityriasis rosacea, Psoriasis, Bullous dermatoses, other uses are Alopecia and Acne. They are approved and suggested by food and drug administration for the use of inflammatory and itchy, skin presentations. Inadvertent use of topical corticosteroids results in several adverse effects.^{[1] [2]} The

misuse of topical corticosteroids is associated with significant adverse effects like vitiligo, Striae, Stellate scar, Combined dermal and epidermal effects like Telangiectasia, Rosacea, Facial erythema, Glaucoma/cataract, tinea incognito, Alopecia, Hypertrichosis, acne eruption. Furthermore, topical corticosteroids have large impact on dermatological practice as it is responsible for a significant proportion of visit to dermatology clinics. Formulations available for topical corticosteroids are according to the type of skin lesion and its location. Creams and lotions are widely used formulations. Creams are generally used for large area lesion type, lotions are used in a moist and weeping type of lesions, and ointment is generally used for dry, non-hairy skin. Ointment do not need preservatives and this reduces the risk for contact allergy and irritation. Gel or solution is mostly useful in hair bearing skin. Other formulations are foam, spray, and shampoo. It's also common to re-use a prior prescription to treat a fresh rash or lesion.^[3] Apart from this, misuse of topical corticosteroids are widespread phenomenon among young people. Nowadays friends and family members also share the same prescription, assuming that similar-looking skin disorders may be self-treated by just replicating the previous one. In recent years, there has been an increase in the usage of strong fluorinated topical steroids by the general public. However, it lead to increase in the number of adverse effects. The present study was conducted to assess the adverse effects of topical corticosteroids moreover, to study the frequency of topical corticosteroids misuse and to find out the indications for which topical corticosteroids are used.

MATERIAL AND METHODS

This cross sectional observational study was conducted in the outpatient from dermatology department at tertiary teaching hospital for 5 months. This study was initiated after getting approval from the Institutional Ethics Committee. The patients were selected based on exclusion and inclusion criteria. Inclusion criteria included were Patients of all ages and both sexes, patients of all ages and both sexes applying topical corticosteroids for more than 1 month in steroid responsive conditions with cutaneous adverse effects of topical corticosteroids, patients of all ages and both sexes misusing topical corticosteroids (inappropriate use of topical steroid on the skin in terms of incorrect dosing, frequency, duration, or indication). And patients on oral immunosuppressive therapy, patients who do not give consent and patients with poor general condition were excluded from the study. The study was explained to patient and a Patient Information Sheet was given to the patients who fulfil the study criteria. Informed consent of the patients were taken after explaining to them about the study. Patients were interviewed using predesigned proforma. That included, Socio-demographic data such as name, age and gender, marital status, education. Chief complaints, diagnosis, past History, formulation misuse, dermatological adverse effects, reason for using, frequency, source, cost of preparation and the clinical photographs were taken. Following that, patients were counselled on the proper use of topical corticosteroids.

RESULT

Total 40 patients were included in the study period, who were presented with the adverse effects of topical corticosteroids and those patients were found to be misusing these drugs. In the study 62.5% were male and 32.5% were female. Most of the patients belongs to age group of 21-30 years. Moreover, 72.5% were married and 27.5% were unmarried. Compare to other profession housewife and students reported more adverse effects. Demographics characteristics are listed in Table 1.

The topical corticosteroids misused are encapsulate in Table 2. Corticosteroids of different potency were used by the patients the most common was Clobetasol propionate 0.05% (40%) followed by mixed preparation (combination with steroids), Betamethasone valerate 0.1%, Mometasone furoate 0.1%, Halobetasole propionate and Fluticasone propionate.

The common reasons for using topical steroids was itching over skin in 40%. Another 17.5% of patients used for the treatment of skin lesions over the body. Other reasons were redness, flushing over face, dark

lesions over face, red lesions over face, skin lesion over feet, pus filled with lesions over face, fungal infection and rashes with itching over genital area. The number of applications varied from once daily to 3-4 times a day. The frequency of applied topical corticosteroids was twice or fewer times a day in 75% once daily in 20% and thrice or more times a day in 5%. Furthermore, 75% of patients were there who used topical corticosteroids for more than one month, 20% applied steroids for exactly one month and only 5% were therewho used topical corticosteroids for less than one month. Summarized in Table 3.

Table 1: Demographic details of collected cases

| Gender | Total | Percentage (%) |
|--------------------------|--------------|-----------------------|
| Male | 25 | 62.5 |
| Female | 15 | 37.5 |
| Age | | |
| 10 - 20 | 7 | 17.5 |
| 21 - 30 | 13 | 32.5 |
| 31 - 40 | 10 | 25 |
| 41 - 50 | 6 | 15 |
| 51 - 60 | 2 | 5 |
| 61 – 70 | 2 | 5 |
| Marital Status | | |
| Married | 29 | 72.5 |
| Unmarried | 1 | 27.5 |
| Employment Status | | |
| Company employee | 6 | 15 |
| Farmer | 4 | 10 |
| Housewife | 10 | 25 |
| Labourer | 3 | 7.5 |
| Shopkeeper | 5 | 12.5 |
| Student | 8 | 20 |
| Teacher | 2 | 5 |
| worker | 2 | 5 |

Table 2: Topical Corticosteroids causing adverse effects

| Drugs | No. of patients | % |
|-------------------------|-----------------|------|
| Clobetasole Propionate | 16 | 40 |
| Bethamethasone valerate | 5 | 12.5 |
| Mometasone Furoate | 4 | 10 |
| Fluticasone Propionate | 1 | 2.5 |
| Holobetasole Propionate | 2 | 5 |
| Mixed Preparation | 12 | 30 |

The dermatological adverse effects seen after utilization of corticosteroids are recorded in Table 4. The most common adverse effect was tinea incognito in 35% of patients chronologically others reaction accounted were acneiform eruption (17.5%). Furthermore, other side effects were striae, telangiectasia, post-inflammatory hypopigmentation, hypertrichosis and acne. Photographs addressing a portion of the unfavorable impacts are displayed below.



Figure 1: TCS induced Tinea incognito

Table 3: Reason, frequency and duration of topical corticosteroid used

| Reason for usingpreparation | No. of patients | % |
|----------------------------------|-----------------|------|
| Red lesion over face | 3 | 7.5 |
| Itching over skin | 16 | 40 |
| Redness and flushing over face | 4 | 10 |
| Skin lesions over body | 7 | 17.5 |
| Pus-filled lesions over body | 1 | 2.5 |
| Dark lesions over face | 3 | 7.5 |
| Skin lession over feet | 2 | 5 |
| Pus filled red lesions over face | 2 | 5 |
| Fungal infection | 1 | 2.5 |

| | | |
|---------------------------------|------------------------|-----------------------|
| Rashes & itching over genitals | 1 | 2.5 |
| Frequency of Application | No. of patients | Percentage (%) |
| Once daily | 8 | 20 |
| Thrice or more | 2 | 5 |
| Twice or Fewer times | 30 | 75 |
| Duration of usage | No. of patients | Percentage (%) |
| Less than one month | 2 | 5 |
| More than one month | 30 | 75 |
| One month | 8 | 20 |

Table 4: Adverse effects observed in patients

| Dermatological Adverse effects seen | No. of Patients | % |
|--------------------------------------------|------------------------|----------|
| Acne | 2 | 5 |
| Acneiform eruption | 7 | 17.5 |
| Hyperitchosis | 2 | 5 |
| Post inflamatory Hypopigmentation | 3 | 7.5 |
| Striae | 6 | 15 |
| Telangiectasia | 6 | 15 |
| Tinea incognito | 14 | 35 |



Figure 2: TCS induced Hypopigmentation

32.5% of patients (N= 13) applied topical corticosteroids on the groin area followed by, 30% who applied on the face, 22.5% and 12.5 patients applied on trunk region and extremities respectively. Only 2.5% (N=1) patients applied TCS on the genitals area. (Table 5)

Table 5: Parts over which TCS were applied

| Parts over which TCS were applied | No. of patients | % |
|------------------------------------------|------------------------|----------|
| Face | 12 | 30 |
| Groin | 13 | 32.5 |
| Trunk (Abdomen Andblack) | 9 | 22.5 |
| Extremities | 5 | 12.5 |
| Genitals | 1 | 2.5 |

Table 6: Initial treatment given by and Awareness of side effects

| Initial treatment given by | No. of Patients | Percentage |
|-----------------------------------|------------------------|-------------------|
| Physician (NonDermatologist) | 12 | 30 |
| Pharmacist | 10 | 25 |
| Paramedical Personnel | 6 | 15 |
| Self | 3 | 7.5 |
| Friends/Relatives | 5 | 12.5 |
| Dermatologist | 4 | 10 |
| Awareness of side effects | | |
| Aware | 2 | 5 |
| Not Aware | 38 | 95 |

Most of the patients were using topical corticosteroids as advised by the physician (non - dermatologist) and pharmacist others were advised by friends, paramedical personnel and some of them had applied corticosteroids by themselves Only in a few patients, topical corticosteroids were prescribed by a dermatologist (10%). 95% patients were unaware about the adverse effects resulting from topical corticosteroids and only 5%, patients were having some idea of the adverse effects. (Table 6).

DISCUSSION

Nowadays topical corticosteroids are widely use among people. As there is no doubt, that they are very useful in treating various skin diseases. Nevertheless, inappropriate use of topical corticosteroids leads to adverse effects.

Very few studies have been done on misuse of topical corticosteroids and the cause behind it in India. We enrolled 40 patients with adverse effects based upon the inclusion criteria and exclusion criteria. Out of them, 25 (62.5%) were males and 15 (37.5%) were females with 1.66:1 male to female ratio which is similar to the study conducted by Meena S et al. ^[4] (1.68:1). However study done by Dev VK et al. ^[5] had shown lower male to female ratio. (0.3:1).

Most of the patients belong to the age group of 11 to 70 years. 32.5 % of patients were in the age group of 21-30 years with mean age of 32.75 ± 13.25 years. This observation is in concordance with the study conducted by Meena S et.al ^[4] and Dey VK et al. ^[5] in where the majority of patients, 74.5% and 68.16% respectively belonged to the age group of 11-29 years. This study was contrary to the result of Manchanda K et al ^[7] study (11 to 20 years – 55%).



Figure 3: TCS induced Acneiform eruption



Figure 4: TCS induced Tinea incognito



Figure 5: TCS induced Striae

Maximum steroid abuse was observed among housewives (25%), which is similar to the study conducted by Dey VK et al. ^[5]. In contrast to this, the study done by Mukunda S et al. ^[9] where students (25%) abused the topical steroids the most. Surprisingly, very few (5%) patients in our study were illiterate. 25% had either done or were doing their graduation. There was 37.5% proportion of patients attended primary school and 32.5% studied till secondary school

In the current study, majority of the patients (75%) used topical corticosteroids twice or fewer times a day while 20% patients used the preparation once daily and 5% used it thrice or more. In compare to a study conducted by Dey VK et al. ^[5] 90.24% patients used topical corticosteroids twice or fewer times. In our study, majority of the patients (75%) misused TC for more than a month while 5% patients used the preparation for less than a month and 20% used for exactly month, Contrary to our study, a study conducted by Saraswat A et al ^[10] majority of patients (117; 27%) used the topical steroids for a period of 1 to 3 months, with only 92 (21%) patients using TC for more than a year. In another study conducted by Dey VK et.al ^[5] duration of application of topical corticosteroids was <1 year (69.39%) in majority of patients.

The most common adverse effects in our study was found to be tinea incognito (35%), followed by acneiform eruption (17.5%), striae, telangiectasia, Post inflammatory Hypopigmentation, Hypertrichosis and acne. A study, which was conducted by Mahar S. et al ^[6] showed that tinea incognito and facial acne (26%) were the commonest adverse effects similar to our study. In comparison to a study conducted by Dey VK et al ^[5] it was observed facial acne (37.99%), plethoric face and telangiectasia (18.99%) and facial hypertrichosis were predominant adverse effects.

The reason for TC abuse in our study was found to be itching over skin in 40%, followed by skin lesion over body (17.5%), flushing over face (10%) and dark lesions over face (4%). In Contrast to this, a study done by Dey VK et al ^[5] showed that lightening of skin was the main reason for using TC (50.39%). A study conducted Mahar S et al ^[6] dermatophytosis (38.4) and acne vulgaris (29.2%) was main reason for using TC.

Topical corticosteroids causing adverse effects in our study were Clobetasol propionate 0.05%, Betamethasone Valerate 0.1%, Mometasone 0.1%, Fluticasone propionate 0.05%, Halobestol propionate 0.05% and steroids combination topical preparation. In our study Clobetasol propionate 0.05% was the commonest (16, 40%) abused TC. This observation was similar to the study conducted by Meena S et.al ^[16] (164, 44.32%). In contrast to this, studies conducted by Manchanda K et al ^[7] & Mahar S.et.al^[6] showed that the most commonly abused TC was Betamethasone Valerate 0.1%. The study done by Dey VK et.al ^[5] also showed, that steroids combination was most common abused TC.

In our study, the General practitioner (non-dermatologist) 30% (Homeopathy 15%, Family doctor, 7.5% and physician 10%) prescribed maximum topical corticosteroids followed by Pharmacist 25%, and

paramedical personal 15%. These findings were in contrast to the studies conducted by Manchanda K. et al^[7] and Skandashree B. S^[8] et al relatives/ friends prescribed the topical steroids the most. The study done by Dey VK et.al^[5] showed, that the pharmacist prescribed the maximum TCS.

Regarding awareness in our study 5% participants were only aware of adverse effects of topical corticosteroids whereas in a study by Dey VK et.al^[5] and Mahar S et al^[6] where only 3.43% and 3.2 % patients were aware of the same.

CONCLUSION

The study that took place in the Department of Dermatology has drawn our attention towards some conclusions. This study creates an awareness and educates the people on the adverse effects of steroids, with their chronic use and thus the measures that can be applied to stop steroid abuse. There are several reasons behind the abuse but the lack of education, lack of restriction, profitable for sellers and low prices are the main. Strict laws along with proper education of patients should be given chief importance to prevent this epidemic. This situation is expected to get worse until control measures are taken on multi-dimensional fronts

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CONFLICT OF INTEREST

The authors declare that they have no conflict of interest

ABBREVIATIONS

TS-Topical steroids

TCS-Topical corticosteroids

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