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Original Research Article

Topical steroids more abused than used! A cross-sectional study in the outpatient department of dermatology in a tertiary care centre in coastal Karnataka

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ABSTRACT

Background: Topical corticosteroids (TCS) are one among the most commonly prescribed medications in the ambulatory setting. They exhibit anti-inflammatory effects, immunosuppressive effect, antiproliferative effects and vasoconstriction.
Methods: A total of 400 patients who had visited the outpatient department or was admitted in the department of dermatology and had applied topical corticosteroids for a duration of 2 or more weeks were included for the study over a period of 2 months in June and July 2018. This study is clinical and observational, to evaluate the topical corticosteroids abuse cases.
Results: Out of 400 people 304 [76%] patients were either recommended or prescribed TCS by a non-physician source. And the rest 96 [24%] patients were been prescribed by the medical fraternity. Majority of patients have applied TCS belonging to super potent class [294/400] duration of usage varied from 2 weeks to 2 years and amount from 10 to 240 g. The most common consequences of TCS abuse was rebound phenomenon followed by hypopigmentation, striae.
Conclusions: Prolonged and continuous use of TCS can cause many adverse effects with varying clinical presentation. Treatment is difficult as there is rebound phenomenon with discontinuation of TCS. Gradual withdrawals of TCS with supplementation of adequate treatment to the present clinical issue are usually recommended to get good clinical results.

Keywords: Topical corticosteroids, Adverse effects of TCS, Superficial fungal infections, *Tinea corporis*, *Tinea cruris*

INTRODUCTION

Abuse of topical corticosteroids has become a huge problem in India as well as in some other countries worldwide. Be it in pursuit for fairness or to get faster apparent cure, many are abusing topical corticosteroids.[1] There is a lack in the data regarding the abuse of topical corticosteroids.

The aim of this study was to document various side effects caused by inadvertent use of topical corticosteroid. Topical corticosteroids have anti-pruritic, atrophogenic, melanopenic, sex-hormone like and immunosuppressive effects on the skin. All this can lead to significant local adverse effect if used indefinitely.[2]

In the modern world, dermatotherapy includes the use of corticosteroids, and the use of these agents has been

manifold usually with remarkable but often temporary results.[1] Now topical steroids are perhaps most widely used in skin disorder treatment. They provide quick symptomatic relief in almost all inflammatory dermatoses, especially in short term.[1] Even its incorrect use for instance produces initial improvements in the symptoms of infectious dermatoses. But there other factors like atrophogenic, melanopenic, sex-hormones like and immunosuppressive like effects on the skin leads to significant local adverse effects if steroids are used indiscriminately.[1]

At least few of this drugs are available at every medical store regardless of prescription which is worsened by inadequate policing by the government where most of medicines can be sold without prescription.[1]

The present scenario is that our country has only about 10,000 qualified dermatologists against the population of 1.2 billion to prescribe these drugs. Hence the easy reach of these steroids than the dermatologists is making the common population to misuse these topical corticosteroids.[1]

Though topical steroidal drug abuse is taken seriously and has been subjected to studies from African, other Asian countries and even developed nations like USA.[3-6] In India it has been published only a single case series on this problem.[7]

Topical corticosteroid abuse was being seen all over the India by many dermatologists, whose incidence appeared to be increasing rapidly.

So in view of this study was planned to measure magnitude, clinical features and demographics of topical corticosteroids abuse and also to study the various spectrum of side effects caused by topical steroid abuse in the dermatology outpatient department (OPD) attendees.

METHODS

Study design

This was observational clinical study.

Study place and period

The study was carried out over a period of 2 month in June and July 2018 at the district hospital, KRIMS, Karwar, Uttara Kannada, Karnataka state, India.

Study population

Study sample was calculated as 400 by using the formula 4 pq/d^2, where prevalence (p) was considered to be 50% and relative error of 5%.

Patients who had visited the OPD or were admitted in the department of dermatology and had applied topical corticosteroids for duration of two or more weeks were included for the study.

Inclusion criteria

All patients reporting to the investigator were asked the following screening question. "*Are you currently using any cream/ointment/lotion on your face or body that is available in medical stores*?" In the event of a positive answer, the investigator ascertained whether the cream in question contained a corticosteroid by seeing the prescription/ used tube or by showing samples of popularly used preparations.

Current use was defined as any continuous use of seven or intermittent use over a period of 15 or more days. This use should have been going on till the day of presentation to the center, or if stopped, not more than 15 days before. Investigators were asked to judge whether the TC use in each case was appropriate and justified. Wrong indication (e.g., acne), undiagnosed dermatosis (in investigator's opinion), inappropriate potency or more than 1 month's use after the last consultation were criteria used to define unjustifiable/inappropriate use.

Exclusion criteria

Patients with co morbidities like polycystic ovary syndrome, Cushing's disease, thyroid disorder, diabetic patients and patients on oral corticosteroids were excluded from the study.

Study tool/ procedure

Data was collected by a predefined and pre-structured tested questionnaire and patients are educated regarding adverse effects of TCS. Written informed consent was taken from the patients in the local language script.

Ethical consideration

This study was done after getting approval from the Institutional ethical committee, KRIMS Karwar.

Data analysis

The data collected was analyzed by using Excel sheet with frequencies and percentages using SPSS software.

RESULTS

This study was done for duration of 2 month, where about 35.8% [400 out of 1115] of the OPD attendees had abused topical corticosteroids.

In all the 400 patients with TCS abuse screened, 226 were males and 174 were females. Out of 400 patients in the study group, the largest number [n=87; 23.75%] was

in 20-30 year age group and 52.75% patients were from the rural area, while 47.25% are from urban area.

A total of 20 brands containing 6 different topical corticosteroids alone or in different combinations with antifungal, antibacterial or antipruritic agents were identified. Details of the most commonly used topical corticosteroids are shown in Table 1. As for the brand names, Clop GM™ [67; 16.75%], Panderm™ [n=63; 15.75%], Dermi 5™ [n=55; 13.75%], Fourderm™ [n=49; 12.26%], Quadriderm™ [n=39; 9.75%], Terbina-forceplus™ [n=29; 7.25%], Betnovate™ [n=25; 6.25%], Betamil GM™ [n=22; 5.5%] are the most used ones, given in Table 2.

Table 1: Most commonly abused TCS in this study.

S. no.		N (%)
1	**Mometasone furoate 0.1% cream**	7 (1.75)
2	**Clobetasol proprionate 1% cream**	294 (73.5)
3	**Beclometasone cream**	18 (4.5)
4	**Betamethasone valerate scream**	94 (23.5)

Table 2: Most commonly used steroid brands.

S. no.	Steroid brands	Frequency %	Steroid
1	**Clop GM™**	67 (16.75)	Clobetasol propionate 0.05% topical
2	**Panderm +™**	63 (15.75)	Clobetasol propionate 0.05% topical
3	**Dermi 5™**	55 (13.75)	Clobetasol propionate 0.05% topical
4	**Fourderm™**	49 (12.25)	Clobetasol propionate 0.05% topical
5	**Quadriderm™**	39 (9.75)	Betamethasone 17α valerate
6	**Terbinaforceplus™**	29 (7.25)	Clobetasol propionate 0.05% topical
7	**Betnovate™**	25 (6.25)	Betamethasone valerate 0.1%

While majority of patients have applied TCS belonging to super potent class [n=294], followed by high potent [n=94], and intermediately potent [n=25] individually or in combination. The duration of use varied widely, ranging from 2 weeks to 2 years and amount of usage varied from 10 to 240 g.

We found that 304 [76%] patients were either recommended or prescribed TCS by a non-physician source, i.e., directly from medical shop [n=142; 35.5%], and other non-medical sources [n=162; 40.5%] and the rest 96 [24%] patients were been prescribed by the medical fraternity, i.e., general medical practitioner [n=64; 16%] and other medical specialists [n=37; 8%].

Table 3: Most common consequences of TCS abuse in general.

S. no.	Consequences	N (%)
1	**Hypopigmentation**	69 (17.25)
2	**Striae**	49 (12.25)
3	**Rosasea**	5 (1.25)
4	**Steroid induced acne**	10 (2.5)
5	**No adverse effects observed**	50 (12.5)
6	**Atrophy**	56 (14)
7	**Rebound phenomenon**	120 (30)
8	**Hirsutism**	9 (2.25)
9	**Perioral dermatitis**	3 (0.75)
10	**Telagiectasia**	2 (0.5)

The most common consequence of TCS abuse was rebound phenomenon (n=120; 30%), followed by hypo pigmentation (n=69; 17.25%), then atrophy (n=56; 14%), given in Table 3.

Table 4: Most common consequences of TCS abuse on face.

S. no.	Consequences	Frequency (%)
1	**Rebound phenomenon**	20 (5)
2	**Hirsutism**	5 (1.25)
3	**Perioral dermatitis**	3 (0.75)
4	**Rosasea**	5 (1.75)
5	**No adverse effect**	7 (1.75)
6	**Steroid induced acne**	10 (2.5)
	Total	50 (12.5)

Figure 1: Telangiectasia in over cheek in elderly female.

On face common TCS abuse consequences were again the rebound phenomenon (n=20; 5%), followed by the steroid induced acne (n=10; 2.5%), then hirsutism and steroid induced rosasea (n=5; 1.25%), given in Table 4 and in case of rest of the body rebound phenomenon [n=100; 25%], hypo pigmentation [n=69; 17.2%], atrophy [n=56; 14%], straie [n=49; 12.25%].

Figure 2: Steroid induced acne over face in an young adult female.

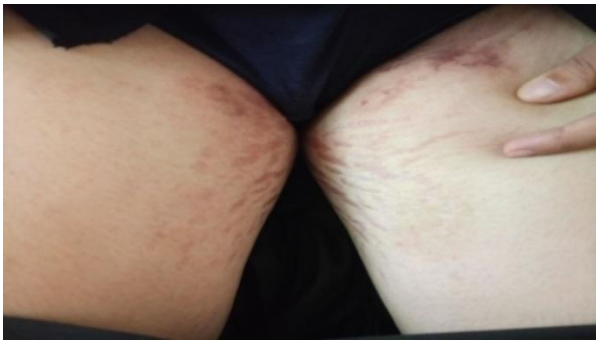

Figure 3: Atrophic striae in an adolescent female.

Figure 4: Hypo pigmentation in a middle aged female.

DISCUSSION

The chief abuse of TCS is because of its rapidity of symptomatic relief in almost any dermatosis.

The problem is worsened when a patient is able to easily get an indefinite number of refills of a single prescription from the local pharmacy, leading to production of spectrum of adverse effects.[1] This situation is faced many countries, which was described more than 30 years ago as "serious" in a classic paper by Frosch et al.[8]

In India the problem is even worse since anyone can easily get a class 1 or 2 TCS without getting it prescribed by the physician. Over that TCS have acquired a reputation as anti-acne, anti-blemish and fairness creams in general population, especially in countries with darker-pigmented races.[3]

Similar studies have been reported from China and Iraq and other parts of India. We have seen in our study that the suggestions to use them were given by pharmacists, non-medical personnel, general medical practitioners, and other medical specialist without a specific indication.

Basic purpose of starting the steroid in our study was to treat tinea which was not a known indication.

The patient had good response to whatever skin problems they had, but on discontinuation of the application they started to develop flare up of the disease, i.e., rebound phenomenon. So, to prevent this effect, they resumed the use of the cream. The reason for consulting a doctor by most of them is that they found their skin problem no longer Responding to the TCS.

In an Iraqi study done by Al-Dhalimi et al it was reported that 7.9% of the dermatology clinic attendees had misused TCS.[5] In a study done by Abir et al the prevelance of TCS abuse was about 14.8% and in a Chinese study done by Lu et al the prevalence was 28.5%, but in our study it was 35.8% which is remarkably high, this can be explained by the prevalence of tinea in this coastal region which is increased many folds during rainy season, incidentally our study was done in June that coincides with monsoon and most of these are treated by TCS which is not a known indication because of non-availability of dermatologists.[1,4] Most of the abusers in Iraqi study were belonging to 10-19 year age group, in the study done by Abir et al the age group that abused TCS most was 21-30 years, where as in our study it is 20-30 years age group as tinea was prevalent in this age group.[1,5]

In the studies Al-Dhalimi et al, Lu et al and Abir et al there was female preponderance seen as TCS was mainly abused on face but in our study male preponderance was seen as tinea is more commonly seen in men.[1,4,5]

In the same Iraqi study, Clobetasol was the most commonly abused i.e., 42.1%, in the study done by Abir et al betamethasone was most commonly abused i.e., 50% and in our study clobetasol was abused about 73.5%.[1,5]

The most common source of prescription was by paramedical personnel (27.1%) in the Iraqi study, in Abir et al study source was non physician in 59% and in our

study non physician source had prescribed TCS the most among all (40.5%).[1,5]

Most common reason for the abuse of TCS is lightening of skin in Iraqi study, in Abir et al study fairness scream 46%, but in our study TCS was mainly used to treat tinea.[1,5] The most common adverse effect seen in the study Al-Dhalimi et al, was facial acne (36.4%), in Abir et al study the most common adverse effect was facial acne (57.5%), while in our study the most common consequence of TCS abuse was rebound phenomenon (30%) followed by hypopigmentation (17.25%) as it was predominantly abused for tinea.[1,5]

Effective treatment of TC addiction is possible, and results in improvement in the quality of life of these patients.[10] Treatment of facial adverse effects of TCs focuses on complete cessation of use, which can be sudden or gradual, depending on the class of the TCs and duration of use. In cases of addiction, progressively less-potent TCs are introduced over a period of weeks to months. Unpleasant symptoms, viz. burning, stinging and pruritus are treated using bland emollients, topical calcineurin inhibitors. Systemic agents include tetracyclines, isotretinoin, non- steroidal anti-inflammatory drugs and antihistamines. The subject of pathogenesis and treatment of TCs addiction has been reviewed.[11]

This study reveals a part of the problem of TC misuse that is becoming endemic in many countries of the world. Even countries like England, where only hydrocortisone and clobetasone can be sold over the counter (OTC), are facing the problem of overuse and misuse of these products by the lay public.[12] In India, it appears that the easy availability of all TCs without a prescription has made many of these brands to become common names, wherein they are no longer considered drugs at all. Patients are unaware of the risks that are sold with these products and continue to use them for longer time before seeking help from dermatologists. Even correct prescriptions are misused by getting repeated refills from the chemist. At present, loopholes in our laws allow pharmaceuticals to advertise even clobetasol containing creams on the television and to sell them as OTC products. As indicated by the data in this study, the problem of TC misuse is very significant, and unless all possible efforts done, the situation will more worsen.

Physician vigilance and patient education remain the main stay of tracking this grown problem.

Implications

The study was done to understand the side effects of topical corticosteroids and to reduce its incidence by patient education. The study also focused on misuse of topical corticosteroids by pharmacists, general practitioners and non-allopathic practitioners.

CONCLUSION

Prolonged and continuous use of TCS can cause many adverse effects with varying clinical presentation. Treatment is difficult as there is rebound phenomenon with discontinuation of TCS. Gradual withdrawals of TCS with supplementation of adequate treatment to the present clinical issue are usually recommended to get good clinical result.

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