Original Article

Hypothalamus-pituitary-adrenal axis (HPA axis) suppression with inappropriate use of steroids in recalcitrant dermatophytosis – A cross-sectional study

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Abstract

Background: Improper use of over-the-counter (OTC) steroid medication has been linked to recalcitrant dermatophytosis. There is proven evidence of HPA axis suppression by the use of long-term oral steroids. This study aims to determine the prevalence and pattern of inappropriate OTC steroid use and its effects on the hypothalamus-pituitary-adrenal (HPA) axis in adults with recalcitrant dermatophytosis. **Materials and Methods:** This cross-sectional study of 2 months was conducted in a hospital setting and included patients of recalcitrant dermatophytosis with a history of OTC steroid use. Clinico-demographic details and basal serum cortisol levels were recorded in all and analyzed. **Result:** Of a total of 103 patients, 59.22% (n = 61/103) were males, and the mean duration of steroid abuse was 17.78 months. About 48.54% (n = 50/103), 3.88% (n = 4/103), and 47.57% (n = 49/103) patients reported the use of topical steroids, oral steroids, and both oral and topical steroids, respectively. Among all the topical steroid users (n = 99), clobetasol propionate 48.48% (n = 48/99), while among oral steroid users (n = 53), prednisolone 45.28% (n = 24/53) were the most commonly used agents, respectively. The morning serum cortisol levels (8–9 AM) were found to be decreased in 42.7% (n = 44/103), with a mean value of 44.28 ± 17.34 μg/dL. **Conclusion:** Improper OTC steroid use in recalcitrant dermatophytosis leads to HPA axis suppression. This highlights the need for intervention from apex health officials.

Keywords: Dermatophytosis, hypothalamus-pituitary-adrenal (HPA) axis, OTC, over-the-counter, recalcitrant, steroids

Introduction

Superficial dermatophytosis is one of the most common dermatological diagnoses, affecting 20–25% of patients worldwide.[1] According to recent Indian studies, the incidence of dermatophytosis is increasing at an alarming rate, resulting in an epidemic-like situation with a prevalence, ranging from 6.09% to 61.5%.[2] Recalcitrant dermatophytosis refers to the relapse, recurrence, reinfection, persistence, and possibly microbiological resistance of dermatophytosis.[3] Various factors like increased urbanization, overpopulation, poverty, host factors associated with immuno-suppression like diabetes, acquired immunodeficiency syndrome, and use of immunosuppressive agents are predisposing factors for dermatophytosis. More recently, the unregulated availability of affordable irrational corticosteroid–antifungal–antibacterial combinations available as over-the-counter (OTC) agents in India has become an increasing concern. These drugs are rampantly being prescribed for all types of dermatoses as a blanket treatment by general physicians and alternative medicine practitioners.[4] In addition, even patients

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are also using these so-called fairness or anti-itch creams for self-medication for any type of skin ailment.[4]

Recent studies have revealed that the use of steroid-based combination creams by Indian patients with dermatophytosis ranges between 42% and 81%.[5,6] This rising trend of steroid use is a public health concern, and monitoring its consumption at the primary care level is essential. Self-medication of steroids can be assessed at community level. Information about the adequate dosage, frequency, and their adverse effect profile is necessary. Therefore, the intervention of primary care physicians, nurses, and healthcare policymakers is required. Although there is proven evidence of HPA axis suppression by oral and topical steroids, studies about OTC steroid abuse in recalcitrant dermatophytosis and its effect on the hypothalamus-pituitary-adrenal (HPA) axis are lacking.

Materials and Methods

Study design and setting

The was a cross-sectional study carried out in outpatient settings of the Department of Dermatology and Pharmacology, over a period of 2 months, after the approval of the protocol by the Indian Council of Medical Research (Reference Id 2022-06557) and Institutional Ethics Committee (AIIMS/IEC/22/119).

Study population

Consecutive patients diagnosed with recalcitrant dermatophytosis and reporting a history of OTC use of steroid-based topical/oral preparation were included. Recalcitrant dermatophytosis was defined as the recurrence of the dermatophyte infection within a few weeks, after completion of at least 6 weeks of treatment.[7] Patients with superficial dermatophytosis of less than a 6-week duration, patients with a history of any other dermatological/systemic illnesses requiring steroid therapy, and patients having known pituitary/adrenal suppression were excluded.

Sample size

The study was time-bound, and of 2-month duration, 103 patients were included after written informed consent.

Materials and methods

Data was collected in a pre-designed case report form capturing the clinico-demographic details, medication use characteristics, prescription source, and adverse effects. History of OTC use of steroid-based topical/oral preparation was elicited by looking into the documentation of past treatment and/or the following method(s): pictures of the common OTC topical antifungals and topical corticosteroid–antifungal–antibacterial preparations available in the market were shown, patients were asked to bring back empty/near empty blister packs and topical preparations used in the past or they were asked to enquire and report about the medication given to them, on next visit one week later. Basal serum cortisol levels (8–9 AM) were recorded to assess the HPA axis suppression. The reference normal serum cortisol level range was taken as 4.3–22.4 microgram/dl as per the standard of the hospital lab.

Outcome parameters

The study's outcome was evaluated on the following parameters: source of OTC medication prescription, contents of the OTC medication, percentage of patients with deranged serum cortisol levels, and adverse effects encountered.

Statistical method

Descriptive statistics were used to describe the results of the study. The data is presented as a percentage. An unpaired *t*-test was used to assess the difference among the study population with normal, decreased, and increased serum cortisol levels. A Chi-square test was applied to find out the difference between the number of patients receiving topical or oral steroids with respect to decreasing serum cortisol levels.

Results

One hundred and three patients were enrolled in this study. There were 59.22% ($n = 61/103$) males and 40.78% ($n = 42/103$) females with a M: F ratio of 1.45:1. The mean age of the study sample was 37.05 years ± 13.69, ranging from 8 to 78 years. The maximum patients were of the age group between 21 and 50 years (middle-aged), comprising 82 (79.6%) patients. The mean duration of steroid use was 17.78 months ± 9.72, ranging from 7 to 56 months. Table 1. shows the demographic profile of the study population.

Steroid use pattern

The total number of patients who reported using topical steroids was 96% ($n = 99/103$), and that of oral steroids was 51% ($n = 53/103$). About 48.54% ($n = 50/103$) patients reported the use of only topical steroids, 3.88% ($n = 4/103$) patients used oral steroids, and 47.57% ($n = 49/103$) patients used both oral and topical steroids.

Out of all topical steroid users ($n = 99/103$), 76.76% ($n = 76/99$) patients used a single agent, whereas 23.23% ($n = 23/99$) admitted using more than one topical steroid cream. Among total oral steroid users $n = 53/103$, 75.47% ($n = 40/53$) patients used a single oral steroid agent, and 24.53% ($n = 13/53$) patients used multiple oral steroid combinations.

Table 2 shows the various steroids used by the study participants. Among all the topical steroids users ($n = 99$), Clobetasol propionate 48.48% ($n = 48/99$) was most commonly used, followed by betamethasone valerate 23.23% ($n = 23/99$) and beclomethasone dipropionate 21.21% ($n = 21/99$). Among all the oral steroid users ($n = 53$), prednisolone was most commonly used 45.28% ($n = 24/53$), followed by dexamethasone 24.53% ($n = 13/53$) and methylprednisolone 22.64% ($n = 12/53$).

Miconazole was the most common constituent, 48.19% ($n = 40/83$) among antifungals, followed by clotrimazole. Among the antibacterials, neomycin was most commonly found, followed by gentamycin. A small proportion of combination creams contained

Table 1: Demographic profile of the patients included in the study (*n*=103)

	Patients *n* (%)
Gender distribution	
Male	61 (59.22%)
Female	42 (40.78%)
Age distribution (years)	Mean age: 37.05±13.69 yrs Range: 8 to 78 yrs
1–20	7 (6.8%)
21–50	82 (79.6%)
51–80	14 (13.6%)
Duration of steroid use (months)	Mean duration: 17.78±9.72 Range: 7–56 months.
6–12	41 (39.81%)
13–18	27 (26.21%)
19–24	15 (14.56%)
25–36	17 (16.51%)
37–48	2 (1.94%)
49–60	1 (0.97%)
Clinical presentation	
Tinea corporis	18 (17.48%)
Tinea cruris	8 (7.77%)
Tinea faciei	1 (0.97%)
Overlap of >2 above types	76 (73.79%)
Source of prescription	
Chemist	42 (40.78%)
General/Local practitioner	26 (25.24%)
Friends	12 (11.65%)
Relatives	11 (10.68%)
Nurse	6 (5.82%)
Homeopathic/Ayurvedic doctor	3 (2.91%)
Paramedics	2 (1.9%)
Other specialist	1 (0.97%)

Table 2: Steroid medications used by patients

	n (%)
Topical steroids	
Ultra-high potency	
Clobetasol propionate	48 (48.48%)
Halobetasol	3 (3.03%)
High potency	
Betamethasone dipropionate	14 (14.14%)
Beclomethasone dipropionate	21 (21.21%)
Moderate potency	
Fluocinolone acetonide	4 (4.04%)
Betamethasone valerate	23 (23.23%)
Mometasone furoate	4 (4.04%)
Fluticasone	3 (3.03%)
Low potency	
Hydrocortisone	2 (2.02%)
Oral steroids	
Long-acting	
Dexamethasone	13 (24.53%)
Betamethasone	10 (18.87%)
Intermediate-acting	
Prednisolone	24 (45.28%)
Methylprednisolone	12 (22.64%)
Deflazacort	2 (3.77%)
Short-acting	
Hydrocortisone	5 (9.43%)

tretinoin, a retinoid, and keratolytic agent like salicylic acid. Among all the topical steroid users (n = 99), 6.1% (n = 6/99) patients applied topical drugs 1–2 times a day, followed by 2–3 times a day by 44.44% (n = 44/99) patients, 3–4 times a day by 40.4% (n = 40/99) patients, >4 times a day by 9.1% (n = 9/99) patients.

Source of prescription

Patients were also enquired about the source of the prescription of the drugs. A significant proportion of the patients used medications prescribed by chemists 40.78% (n = 42/103), followed by general/local practitioners 25.24% (n = 26/103), friends 11.65% (n = 12/103), relatives 10.68% (n = 11/103), nurse 5.82% (n = 6/103), ayurvedic doctor/homeopathic doctor 2.91% (n = 3/103), paramedics 1.9% (n = 2/103) and other-specialists 0.97% (n = 1/103).

Serum cortisol levels

The morning serum cortisol levels (8–9 AM) were found to be decreased in 42.7% (n = 44/103), elevated in 5.8% (n = 6/103), and within the normal range in 51.5% (n = 53/103) patients. Figure 1 shows the route of steroid consumption having normal or deranged serum cortisol levels in study participants. The results revealed that

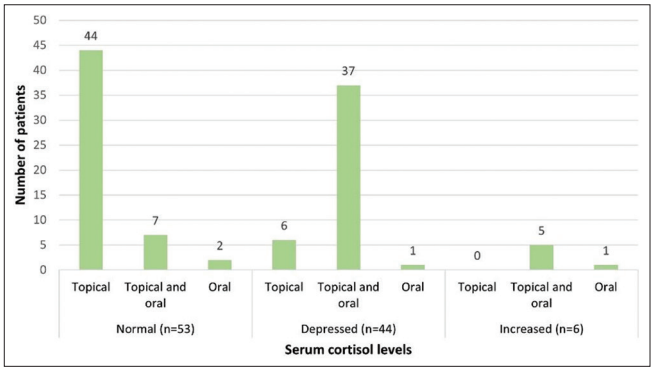

Figure 1: Number of patients with normal and deranged values of morning serum cortisol levels (*n*=103)

75.51% (n = 37/49) of patients having depressed cortisol levels were using both topical and oral steroids, and this was statistically significant (P-value < 0.0001). Elevated serum cortisol levels were reported in six patients who were referred to an endocrinologist for further workup. Figure 2 shows the mean ± SD serum cortisol level in patients having normal, decreased, and increased levels. The decrease and increase in serum cortisol levels were highly significant (P-value < 0.0001). Figure 3 shows the most common adverse effects observed with steroid use in the study population.

Discussion

Dermatophytosis has emerged exceedingly in high magnitude in India and has attained an epidemic-like situation. Earlier, dermatophytosis was considered as an easy-to-treat entity,

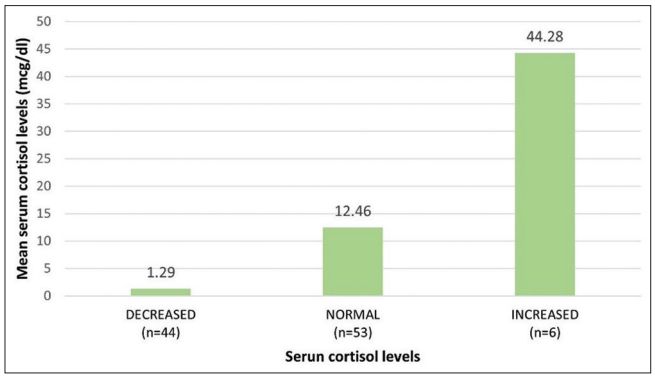

Figure 2: Mean morning serum cortisol levels (8-9am) of study population

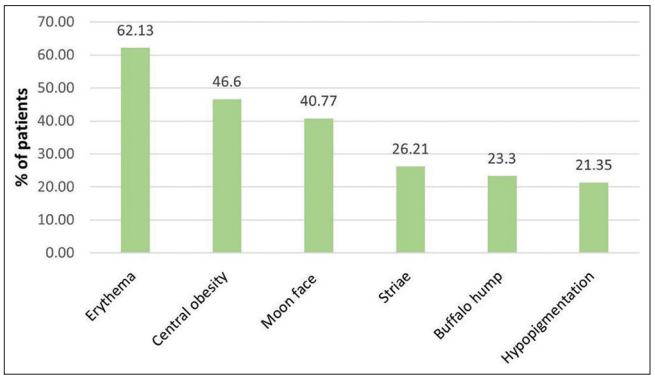

Figure 3: Adverse reactions following steroid use among study population (*n*=103)

but nowadays, it has undergone a significant change in clinical and epidemiological profile. In recent times, it presents more commonly with chronic, relapsing, and remitting course and is usually unresponsive to conventional antifungal therapy.[8,9] Trichophyton (T) mentagrophytes has now replaced T rubrum as the main causative agent of chronic dermatophytoses in India and has shifted from a zoophilic to an anthropophilic strain. This epidemiological shift is hypothesized to be precipitated by the unsupervised use of high-potency topical corticosteroids, antifungal and antibacterial combination creams.[5]

In this study, male preponderance of patients and a mean age of 37.05 years were in concordance with previous studies.[6,10,11] A relatively lower female ratio can be attributed to social factors and hesitancy to report the disease in India, especially when areas like groins are involved. The mean duration of OTC steroid use in this study was 17.78 months, and this is longer than other studies.[6,12] The longer duration may be because of our cohort of recalcitrant dermatophytosis. Also, itching in dermatophytosis may persevere even after the resolution of clinical lesions, possibly due to persistent hypersensitivity.[5] Hence, many patients continue to use these products indefinitely, and this further leads to recurrences. Also, access to a dermatologist and economic factors are pertinent issues in India, and hence, most patients visit dermatologists only after prolonged non-relief, relapses, and recurrences.

The majority, 73.79% ($n = 76/103$) of cases had involvement of more than three sites and this is in concordance with previous studies.[12,13] Extensive involvement meant that OTC preparations were applied over large body surface areas, and this led to more absorption of topical steroids. Absorption of topical steroids percutaneously also depends on a few other factors like the thickness of the stratum corneum, which correlates inversely with penetration of the topical drugs. As one side effect of topical steroids is skin atrophy, repeated application further enhances absorption. Percutaneous absorption also depends on the concentration and potency of topical steroids, and higher potency can increase the chances of systemic adverse effects. Repeated application of topicals increases the contact period and thus increases total absorption.[14] About 40.4% of patients in this study applied topical OTC preparations 3–4 times/day, and about 9.1% of patients applied more than four times a day. Primary care physicians can aid in educating the patients that there is no additional benefit from applying a topical steroid more than once daily despite it having more adverse effects. About 51.51% of patients in this study used ultra-high potency topical steroids (e.g., clobetasol propionate), and 35.35% of patients used high potency steroids (e.g., beclomethasone dipropionate). A study reported that a few days of therapy of clobetasol propionate (0.05%) at a dose of 2 g/day is associated with decreased morning cortisol level[15], and use over 100 g/week can lead to signs and symptoms of Cushing's syndrome or adrenal insufficiency.[16,17] Approximately 48% of patients treated with highly potent topical steroids were found to have a transient and reversible reduction of HPA axis function, but without any significant clinical symptoms.[14] Castela *et al.* reported that the majority of cases of prolonged HPA axis suppression were associated with prolonged daily application of topical steroids over several years on a larger body surface area.[18]

OTC recommendations/prescriptions in this study were most commonly obtained from chemists (40.78%), followed by general practitioners (25.24%). A study from north India reported that steroid use was mainly recommended by pharmacists, followed by general practitioners, alternative medicine practitioners (homeopathy/ayurveda), friends and family, and rarely by a dermatologist.[19] Alarmingly, pharmacists as the source of prescriptions of steroids in dermatophytosis range from 20% to 78% in India.[6,20,21] A study done on 179 pharmacists, has shown that 41.34% did not have adequate knowledge of topical steroids, and 19.55% were not aware that steroids are scheduled "H" drugs.[22]

In this study, the use of long and intermediate-acting oral steroids amounted to 43.39% and 71.69%, respectively, compared to the short-acting steroids, which were only used by 9.43% of the oral steroid users. Exact drug dosages could not be calculated due to lack of documentation and repeated, intermittent, self-medication. In a similar study, 100% of patients received oral/parenteral (intramuscular/intravenous) steroids accompanied by topical steroids, for at least 2 months

with a frequency of parenteral steroids ranging from a daily dose to once in 15 days, and the most common injection being dexamethasone and triamcinolone acetonide and tablet betamethasone.[23]

In our study, the mean ± standard deviation (SD) serum cortisol level was 1.29 ± 1.04 μg/dL in approximately 43% of patients, which was highly significant (*P*-value < 0.0001). A similar study reported low serum cortisol levels ranging from 0.66 to 6 μg/dL with a mean of 1.53 ± 1.27 μg/dL.[12] A few days of exogenous steroid administration, even in small doses, can lead to a significant suppression of the HPA axis. This occurs due to a decrease in corticotropin-releasing hormone (CRH) synthesis and secretion and a block of trophic and adrenocorticotropic hormone (ACTH)-releasing actions of CRH on the anterior pituitary. This ultimately suppresses the synthesis of proopiomelanocortin (POMC), ACTH, and other POMC-derived peptides, thereby leading to the atrophy of the corticotropin cells of the anterior pituitary. The final consequence of the absence of ACTH is the loss of the ability of the adrenal cortex to produce cortisol.[23]

Commonly cutaneous adverse effects noted were erythema (62%), striae (26%), and hypopigmentation (21%). Common features of Cushing's syndrome noted were central obesity (46.6%), moon faces (40.77%), and buffalo hump (23%). In a study by Thakran P *et al.,*[12] striae, buffalo hump, and hirsutism were observed in 69%, 65%, and 57% patients, respectively. We did not note any patient with an adrenal crisis. This study will also help primary care physicians in identifying the features of HPA axis suppression. This will help in early diagnosis and treatment of patients. Also, regular screening of blood pressure, glucose, and triglyceride levels can be performed at the primary level.

The burden of itch on patients of dermatophytosis is enormous. Antifungal creams and capsules are costly and require a longer duration of therapy, often a course of 4–6 weeks, leading to a preference for irrational combination creams and corticosteroids over them.[22] Thus, in an attempt to seek relief, patients often rely on advice from family, friends, local quacks, and chemists who advocate OTC corticosteroid–antifungal–antibacterial topicals and systemic steroids. Cell-mediated immunity (CMI) (Th1/Th17 immune responses) is mainly responsible for the clearance of fungal infection,[24] leading to an initial temporary improvement in the symptoms with the use of steroids. However, prolonged use of corticosteroids inhibits the local and systemic immunological responses, leading to inefficient clearance of the fungus and widespread recalcitrant infection. A double-blind study comparing naftifine cream with clotrimazole/betamethasone dipropionate fixed-dose combination [FDC] in tinea pedis revealed that 73% of those using naftifine achieved mycological cure vs 43% on FDC after 4 weeks. Also, FDC cream had 3–4 times higher relapse rates and experienced more adverse drug reactions.[25]

We did not explore the relationship between steroid dosage and HPA axis suppression, and this is a limitation of this study. This study also lacks data from pediatric and geriatric age groups.

A campaign has been launched by the Indian Association of Dermatologists, Venereologists and Leprologists (IADVL) against the Indian government's lax policies related to the manufacture and sale of irrational steroid-antifungal-antibacterial creams as there is enough evidence of their role in the current epidemic of dermatophytosis. There is an urgent need to review the drug policies at the national level, revise the existing ambiguity in the flaws, and check the unregulated manufacture, availability, and use of irrational and precarious FDC of potent steroids, antifungals, and antibacterials creams.[5]

Conclusion

The growing widespread problem of topical and oral steroid medication misuse and abuse in India in dermatophytosis and the resultant effect on the HPA axis is evident from this study. This highlights the need for intervention from primary physicians, nurses, and health policymakers.

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Conflicts of interest

There are no conflicts of interest.

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