Original Research Article

Clinicoepidemiological profile of steroid modified dermatophytosis following abuse of irrational combination of topical corticosteroid containing preparations (ICSP)

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ICSP - Irrational combination of topical corticosteroid containing preparations
OTC - Over the counter preparations
FDC - Fixed dose combination
Tinea Incognito

A B S T R A C T

Background: Topical corticosteroids are the most commonly used drug and mainstay of dermatotherapeutics for many dermatoses. Topical corticosteroids are irrationally combined with other medications and widely available as the over the counter preparations (OTC) and are widely misused for various conditions. Dermatophytosis is a superficial fungal infection which is becoming resistant and difficult to treat because of inappropriate usage of irrational combination of topical corticosteroid containing preparations (ICSP).

Aims and Objective: To study the prevalence and factors which promotes the abuse of Irrational combination of topical corticosteroid containing preparations (ICSP) in dermatophyte infection.

Materials and Methods: A Prospective observational study conducted at department of Dermatology, Venerology & Leprosy in a tertiary care centre, South India. The sample size of this study is n=55.

Results: Out of 55 patients most common age group is 15 -30 years (n=16,29.09%). Females (n=30,54.54%) predominated over males with male:female ratio of 0.83:1. The most common complaint was intractable itching (n=46,83.64%). The majority of study group had disease duration was 0-1 months (n=27,49.1%) with mean duration of 4 months. The main source of referral was Over the counter (OTC) (n=32,58.18%). The most common irrational combination was FDC 3 combination (30.9%). Most commonly abused brand was betnovate GM (n=17,30.9%). Most of the patients used Clobetasol propionate 0.05% (n=25,45.5%). Patients were using ICSP mostly for less than 1 month (n=27,49.1%), with intermittent (n=19,34.5%) frequency of application. Most common side effect was tinea incognita (n=33,60%). Potassium hydroxide mount was positive in 25 patients (45.45%). Fungal culture was done in all patients and 12 patients (21.81%) showed growth. The commonest organism isolated among culture positive specimen was Trichophyton rubrum (12.72%).

Conclusion: Inappropriate usage of irrational combination of topical corticosteroid containing preparations (ICSP) in dermatophyte infection induces short term clearance whereas the long term side effects results in variable presentation. Awareness of this problem leads to prevention of steroid modified dermatophytosis which is the rising menace.

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1. Introduction

Topical corticosteroids were introduced in the year 1952 by Schulzberger and Witten.¹ Since then topical corticosteroids becomes most commonly used drug in dermatology practices. The clinical effects are mediated by their anti-inflammatory, vasoconstrictive, anti-proliferative and immunosuppressive properties.² Topical corticosteroids are irrationally combined and become available as the over the counter preparations and are widely misused for various conditions. Dermatophytosis is the superficial fungal infection which is becoming resistant and difficult to treat because of inappropriate usage of irrational combination of topical corticosteroid containing preparations (ICSP). These
steroid containing preparations are known to suppress the immune response against dermatophytes and also have the potential to produce a wide variety of cutaneous adverse effects. In this study we aimed to highlight the adverse effects of topical steroid combination preparations abuse on fungal infection.

2. Aims and Objectives

To study the prevalence and factors which promotes the abuse of Irrational combination of topical corticosteroid containing preparations (ICSP) in dermatophyte infection.

2.1. Inclusion criteria

1. Patients with the history of usage of irrational combination of topical corticosteroid containing preparations.
2. Patients who are willing to participate in the study after getting written & informed consent.

2.2. Exclusion criteria

1. Patients on systemic corticosteroids, antihistamines.
2. Cosmetic preparations not mentioned any steroids on their label officially and ayurvedic preparations available in open market.
3. Patients not willing to participate in the study and dropped out cases and irregular follow up cases.

3. Materials and Methods

This is a prospective observational study performed on 55 patients conducted at department of Dermatology, Venereology & Leprosy, Rajah Muthiah Medical College and Hospital, Annamalai University for a period of 2 years from Oct 2018- Sep 2020. Ethical clearance was sought from institutional ethical committee. Patients were included according to the inclusion criteria. Present study aimed to find out the outcome of dermatophytosis following abuse of ICSP. Patients were asked about their personal details such as age, sex, education, occupation, and residence were noted. Patients were asked to bring the used topical preparations or previous prescriptions. Information regarding irrational combination of topical corticosteroid containing preparations such as source of referrals, their combinations type of steroid abused, potency of steroid, duration of therapy, frequency of application, were collected. Detailed history regarding duration of disease, family history as well as any co-morbid conditions were asked. On examination dermatological signs of steroid abuse such as atrophy, striae, telangiectasia and other changes were noted. Photographic documentation of patients was done with their consent participated in the study. Diagnosis was made clinically and confirmed by potassium hydroxide (KOH)mount. Fungal culture was done in all cases.

4. Results

In our study a total of 100 cases were enrolled out of which 45 cases were excluded due to irregular follow up.

Table 1: Age and gender distribution of the study patients

| Age (in years) | Male(N) % | Female(N) % | Total % |
|---------------|-----------|-------------|---------|
| 0 – 14        | 05 20     | 07 23.3     | 12 21.81|
| 15 – 30       | 08 32     | 08 26.7     | 16 29.09|
| 31 – 50       | 06 24     | 08 26.7     | 14 25.45|
| >50           | 06 24     | 07 23.3     | 13 23.63|
| Total         | 25 100    | 30 100      | 55 100  |

Table 1 Shows that, the most common age group in which ICSP abuse were more include 15-30 years in 16 patients (29.09%) followed by 31-50 years in 14 patients (25.45%). Females(54.54%) predominated over males(45.45%) with male: female ratio was 0.83:1.

Table 2: Complaints

| Complaints | Number | %    |
|------------|--------|------|
| Itching    | 46     | 83.64|
| Darkness   | 05     | 9.09 |
| Burning    | 02     | 3.63 |
| Dryness    | 02     | 3.63 |
| Total      | 55     | 100  |

Table 2 Shows that the most common complaint was Itching in 46 patients (83.64%).

Table 3: Duration of the disease

| Duration     | Number | %    |
|--------------|--------|------|
| 0 – 1 Month  | 15     | 27.3 |
| 1 – 2 Months | 07     | 12.7 |
| 3 – 6 Months | 21     | 38.2 |
| 7 – 12 Months| 02     | 3.6  |
| > 12 Months  | 10     | 18.2 |
| Total        | 55     | 100  |

The duration of the disease is presented in Table 3. The major disease duration was 3-6 months in 21 patients (38.2%).

Table 4 Shows that Tinea corporis was the most common clinical diagnosis seen in 15 patients (27.27%) followed by Tinea cruris in 13 patients (23.63%).

Table 5 Shows that the commonest source of referral of ICSP was Over the counter (OTC) in 32 patients (58.18%).

Table 6 Shows that most common irrational combination was FDC 3 combination in 17 patients (30.9%) which was used for 0-1 month in 7 patients (25.9%) on an intermittent basis in 7 patients (36.8%) causes most common side effect of Tinea Incognita in 14 patients (25.45%), followed by FDC
Table 4: Clinical diagnosis

| Parameters                          | No of patients | %   |
|-------------------------------------|----------------|-----|
| Tinea corporis                      | 15             | 27.27 |
| Tinea cruris                        | 13             | 23.63 |
| Tinea faciei                        | 10             | 18.18 |
| Tinea corporis+Tinea cruris         | 12             | 21.81 |
| Tinea corporis+Tinea cruris+Tinea faciei | 6         | 10.9  |
| Total                               | 55             | 100  |

Table 5: The Source of referral of ICSP

| Indications                        | Number | %    |
|------------------------------------|--------|------|
| Self /Over the counter (OTC)       | 32     | 58.18|
| Friends                            | 7      | 12.72|
| General practitioner               | 6      | 10.9 |
| Physician                          | 4      | 7.27 |
| Chemist                            | 3      | 5.45 |
| Paediatrician                      | 2      | 3.63 |
| Gynaecologist                      | 1      | 1.81 |
| Total                              | 55     | 100  |

Fig. 1: Tinea Corporis

Fig. 2: Tinea faciei

Fig. 3: Tinea corporis et cruris

Fig. 4: Tinea corporis
Table 6: Irrational combinations used by the patients

| Irrational combinations | N (%) | Duration N (%) | Side effects N (%) |
|-------------------------|-------|----------------|-------------------|
|                         |       |                |                   |
| 0-1 month               |       |                |                   |
| 1-2 months              |       |                |                   |
| 3-6 months              |       |                |                   |
| 7-12 months             |       |                |                   |
| Once daily              |       |                |                   |
| Twice daily             |       |                |                   |
| Inter mittent Alternate days | |                |                   |
| Weekly once             |       |                |                   |
| Total                   | 55(100%) | 27(49.1%) | 6(10.9%) |

Drug Halobetasol propionate 0.05%, Salicylic acid 3.0%

Table 7: Showed that most common brand name abused was Betnovate GM in 17 patients (30.9%) which was used for 0-1 month in 7 patients (25.9%) on an intermittent basis in 7 patients (36.8%) causes most common side effect of Tinea Incognita in 14 patients (25.45%), followed by Dermi 5 in 14 patients (25.5%) which was used for 0-1 month in 8 patients (29.6%) on twice daily basis in 5 patients (35.7%) causes most common side effect of Tinea Incognita in 5 patients (15.2%).

Table 8: Shows that clobetasol propionate 0.05% was the most commonly abused steroid in 25 patients (45.45%) which was used for 0-1 month in 13 patients (48.1%) on an twice daily basis in 7 patients (63.63%) causes most common side effect of Tinea Incognita in 12 patients (36.36%), followed by Betamethasone valerate 0.1% in 17 patients (30.9%) which was used for 0-1 month in 7 patients (36.8%) on an intermittent basis in 7 patients (36.8%) causes most common side effect of Tinea Incognita in 5 patients (35.7%).

Table 9: Shows that Potassium hydroxide mount was positive in 25 patients (45.45%). Fungal culture was done in all patients and 12 patients (21.81%) showed growth.

Organism isolated is presented in the Table 10. The most common organism isolated was Trichophyton rubrum in 7 patients (12.72%), and Trichophyton mentagrophytes in 3
### Table 7: Brand names used by the patients

| Brand names | N (%) | 0-1 month | 1-2 months | 3-6 months | 7-12 months | Frequency | N (%) | Intermittent | Alternate Weekly | Side effects | N (%) |
|-------------|-------|-----------|------------|------------|-------------|-----------|-------|-------------|-----------------|-------------|-------|
| Betnovate GM | 17(30.9%) | 7(25.9%) | 2(33.4%) | 7(36.8%) | 3(33.3%) | Once daily | 3(27.2%) | 3(27.2%) | 7(36.8%) | 3(50%) | 1(20%) |
| Derma 5 | 14(25.5%) | 8(29.6%) | 2(33.4%) | 3(15.7%) | 1(33.3%) | 2(14.2%) | 5(35.7%) | 3(15.7%) | 2(33.3%) | 2(40%) | 5(15.2%) |
| Candid B | 11(20%) | 5(18.5%) | 1(16.7%) | 4(21.1%) | 1(33.3%) | 5(35.7%) | 1(9.1%) | 4(21.1%) | - | 1(20%) | 5(15.2%) |
| Fourderm | 6(10.9%) | 2(7.4%) | - | 4(21.1%) | - | 2(14.2%) | 1(9.1%) | 2(10.5%) | - | 1(20%) | 5(15.2%) |
| Panderm plus | 5(9.1%) | 3(11.1%) | 1(16.7%) | 1(5.2%) | - | 1(7.1%) | 1(9.1%) | 2(10.5%) | - | 1(20%) | 2(6.1%) |
| Halovate S | 2(3.7%) | 2(7.4%) | - | - | - | 1(7.1%) | - | - | - | 2(6.1%) | - |
| Total | 55(100%) | 27(49.1%) | 6(10.9%) | 19(34.5%) | 3(5.5%) | 14(25%) | 11(20%) | 19(34.5%) | 6(10.9%) | 5(9.1%) | 33(60%) |

Betnovate GM = Betamethasone valerate 0.1%, Gentamycin 0.1%, Miconazole nitrate 2.0%.
Derma 5 = Clobetasol propionate 0.05%, Iodochlorohydroxyquinolone 1.0%, Gentamycin 0.1%, Ketaconazole 2.0%, Tolnaftate 1.0%.
Candid B = Beclomethasone dipropionate 0.025%, Clotrimazole 1%.
Fourderm = Clobetasol propionate 0.05%, Miconazole nitrate 2.0%, Neomycin sulphate 0.5%, Chlorhexidine gluconate 0.2%.
Panderm plus = Clobetasol propionate 0.05%, Ofloxacin 0.75%, Ornidazole 2.0%, Terbinafine hydrochloride 2.0%.
Halovate S = Halobetasol propionate 0.05%, Salicylic acid 3.0%.

### Table 8: Topical corticosteroid used by the patients

| Name of steroid | N (%) | 0-1 month | 1-2 months | 3-6 months | 7-12 months | Frequency | N (%) | Intermittent | Alternate Weekly | Side effects | N (%) |
|-----------------|-------|-----------|------------|------------|-------------|-----------|-------|-------------|-----------------|-------------|-------|
| Clobetasol propionate 0.05% | 25(45.4%) | 13 (48.1%) | 3 (50%) | 8 (42%) | 1 (33.3%) | Once daily | 1 (35.7%) | 5 (63.6%) | 7 (26.31%) | 5 (50%) | 3 (60%) |
| Betamethasone valerate 0.1% | 17 (30.9%) | 7 (25.9%) | 2 (33.4%) | 7 (36.8%) | 3 (33.3%) | Once daily | 2 (35.7%) | 3 (15.7%) | 2 (33.3%) | 2 (40%) | 5 (15.2%) |
| Beclomethasone dipropionate 0.025% | 11 (20%) | 5 (18.5%) | 1 (16.7%) | 4 (21.1%) | 1 (33.3%) | 2 (14.2%) | 1 (9.1%) | 2 (10.5%) | - | 1 (20%) | 5 (15.2%) |
| Halobetasol propionate 0.05% | 2 (3.6%) | 2 (7.4%) | - | - | - | 1 (7.1%) | - | - | - | 2 (6.1%) | - |
| Total | 55 (100%) | 27 (49.1%) | 6 (10.9%) | 19 (34.5%) | 3 (5.5%) | 14 (25%) | 11 (20%) | 19 (34.5%) | 6 (10.9%) | 5 (9.1%) | 33 (60%) |
Table 9: Investigations

| Investigations              | Positive    | Negative     |
|----------------------------|-------------|--------------|
| Potassiumhydroxide mount (n=55) | 25(45.45%)  | 30(54.55%)   |
| Fungal culture(n=55)       | 12(21.81%)  | 43(79.19%)   |

Table 10: Organism isolated

| Organism                  | N  | %    |
|---------------------------|----|------|
| No growth                 | 43 | 79.19|
| Trichophyton rubrum       | 7  | 12.72|
| Trichophyton mentagrophytes | 3 | 5.45 |
| Trichophyton tonsurans    | 1  | 1.81 |
| Epidermophyton flocculosum| 1  | 1.81 |
| Total                     | 55 | 100  |

5. Discussion

There is a rising epidemic of superficial fungal infections in India. Dermatophyte infection is more common in India due to hot and humid climate, low hygiene, poor access to water, overcrowding, high interpersonal contact. Dermatophyte infection become resistant and difficult to treat because of the rising trend of misuse of potent topical steroids by medical and non medical fraternities including misuse in the form of self use. There is wide variety of irrational topical formulations available in India containing ultra high potency steroids in combination with antifungal and antibacterial. The commonest formulation available is a combination of clobetasol propionate 0.05%, orimazole 2.0%, terbinafine hydrochloride 1.0% and ofloxacin 0.75%. Ives and Marks in 1968 coined the term Tinea Incognito but later in 2002 Houltbar and Male pointed out the grammatical error but has been sadly ignored.

Females (54.54%) predominated males in our study. Whereas male predominated female in a study conducted by Lakhani J et al. Thakur R et al. Kothiwala R et al. This discordance in our study is because of inhibition of female to go to hospital particularly in private parts and so they purchased the easily available over the counter preparation and come to the hospital once it become severe. Most common age group was 15-30 years (29.09%). This was in concordance with the study conducted by Thakur R et al. Kothiwala R et al. Most of them resides in rural areas (45.45%). This was in concordance with the study conducted by Lakhani J et al. Most common duration of disease in our study was 3-6 months (38.2%). This was in concordance with the study conducted by Lakhani J et al. Most common source of referral was over the counter (58.18%). This was in concordance with the study conducted by Kothiwala R et al. Most common irrational combination was FDC 3 combinations (30.9%) showing that FDC 3 combination drugs were freely available in market. Paucity of literature regarding the Irrational combination of topical corticosteroid containing preparations. Most common brand name was Betnovate GM (30.9%) in our
study. Its composition was Betamethasone valerate 0.1%, Gentamycin 0.1%, Miconazole nitrate 2.0%. Whereas the most common brand name was Betnovate in a study conducted by Bains P. Most common steroid used was clobetasol propionate 0.05% (45.5%). Most common duration of therapy was < 1 months (49.1%). Whereas it is more than or equal to 1 month in a study conducted by Kothiwala R et al. Tinea Incognita (60%) was the most common side effect encountered in our study. Whereas it was striae in a study conducted by Lakhani J et al. Most common KOH and culture results were negative i.e 54.55% and 78.18% due to repeated application of topical steroid combination preparations. Whereas KOH and culture results were positive in study conducted by Thakur R et al. Most common organism isolated was Trichophyton rubrum (12.72%) in our study. Whereas Trichophyton interdigitale was the most common organism isolated in a study conducted by Thakur R et al.

6. Conclusion
Misuse of irrational combination of topical steroid formulations in dermatophyte infections can lead to untowards adverse effects like tinea incognita, atrophy, acneiform eruptions etc as well as chronicity. Thus the irrational FDC (Combination of topical antifungal, antibacterial, steroid) and various others available in the market freely should be banned by Drug Controller General of India (DCGI) and state licensing authorities to curb the epidemic of steroid modified dermatophytosis.

7. Limitations
This is a hospital based small scale study might not be a true problem in the community. Hence this study could not be generalized to entire population.

8. Source of Funding
No financial support was received for the work within this manuscript.

9. Conflict of Interest
The authors declare they have no conflict of interest.

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