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Original Article

Factors influencing the use of topical steroid based medications in tinea infection in a tertiary care centre, Tamilnadu

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Abstract

Background Steroid modified tinea has become the worst nightmare to the society which delays the access to the proper treatment and sometimes leaves permanent mark on the user. This is because of the unawareness of the molecules in the medications used, both by the user and the prescriber.

Objectivem To elucidate the common social factors involved in the misuse of topical steroids in fungal infections.

Methods Over a period of 6 months, 187 patients were enrolled in the study with informed consent. Their demographic profile, socioeconomic status (SES), educational level, clinical picture, adverse events were noted in this study.

Results Equal sexual distribution was noted and 21-30 year age group is the commonest age in this study (37.5%). High school graders (49%) and undergraduate holders (26%) were using the irrelevant fixed dose combinations (FDCs) and also the class 3&4 (42.%&32%) of SES. Irrelevant FDCs (86.6%) were misused more than plain steroids. Pseudo imbricata pattern (27%), classical annular (25%) and psoriasiform patterns (21%) were common. Tinea cruris (40%) and tinea corporis (33%) were the common findings. KOH was positive in 91%.

Conclusion Limiting the production of the Irrelevant FDCs by stringent measures and including topical medication in medical undergraduate curriculum and health education to the community are all needed to combat this menace.

Key words
Irrelevant FDC, tinea, socio economic status (SES), OTC steroid, dermatophytosis.

Introduction

Dermatophytosis have always been among the commonest infection encountered in India. A disease that was taken for granted and hence treated with predictable results is now becoming a cause of anxiety and trepidation for the dermatologist.[1] Steroid modified tinea has become the worst nightmare to the society which delays the access to the proper treatment and sometimes leaves permanent mark on the user. This is because of the unawareness of the molecules in the medications used, both by the user and the prescriber (either self or advised by others). Awareness regarding the use of OTC

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(over the counter) steroids are lacking not only in the society but also in the healthcare fraternity. In India, OTC steroids doesn't mean only the relevant plain topical steroid but also steroid with antifungal/ antibiotic combination and the most dreaded combination is the irrelevant FDC-fixed drug combinations (potent steroid, antifungal, antibiotic, anti-inflammatory agents and other, minimum 3 to maximum 5 ingredients). This study evaluates the factors which could influence the use of these OTC steroids with/ without prescription in the society by a validated questionnaire.

Methods

The prospective study was conducted for 6 months in the Department of Dermatology from May-October 2019 which included 187 patients of males and females who have used OTC steroids for the treatment of dermatophytosis. After obtaining ethical clearance from the IEC, study was initiated with written consent, detailed demographic profile including socio economic status (Modified Kuppusamy scale),[2] valid reasons for usage, prescribed by whom and detailed clinical examination and the adverse effects. Scrapings were taken from the active border of the lesion and were analysed by 10% KOH. The findings were tabulated in excel and statistics were calculated by SPSS v16.0. The descriptive statistics were calculated for quantitative variables, Frequency and Percentages were calculated for Categorical data. The association between the variables established by Chi square and correlation at 5% level of significance.

Results

Out of 187 patients, 93 (49.7%) were males and 94 (50.3%) were females. Interestingly the most common age group involved was 21-30 years (37.5%) followed by 11-20 years (27.2%) and 31-40 years (18.5%). 4.5% of patients were <10 years. Educational status of the patient was classified into illiterate, up to primary school (class 1-5), high school (class 6-12), under graduates and postgraduates. According to literacy level, the person who went for high school (48.7%) was the one with the highest misuse of steroid creams followed by the person with an undergraduate degree (25.7%). According to the modified Kuppusamy scale, class 3 (lower middle) was the one used masala OTC steroids to maximum accounting for 42.5% followed by class 4-upper lower (32.3%). Marital status didn't influence the usage of steroids, unmarried (47.6%) and married (52.4%). Duration of the infection ranged from 2 weeks to maximum of 3 years. Dermatophytois in the family was 55.6%. Duration of application of steroid creams ranged minimally from 3 days to 1 year maximally. Majority of the patients used these OTC steroids from 2 weeks (16.1%) followed by 1 month (18.7%) and 2 months (13.9%), 27 patients had prior dermatological issues and were on treatment, in that 78% (n=21) used the irrelevant OTC while 9% used plain steroids which was given for other conditions.

Regarding the OTC drug usage, most popular OTC was irrelevant FDC which accounted for 86.6% (162) followed by FDC containing steroid with antifungal or antibiotic 7% and plain steroid was used only in 4.8% (9). We found out 43 preparations containing steroids were used by the patient, 24 preparations were masala FDCs. In the combinations used, clobetasol dipropionate and Miconozole were the common ingredients used **(Figure 1)**.

Out of the OTC steroids, commonly misused were Dermi- 5 (68 patients), Fourderm (28 patients), Quadriderm (16 patients) and Betnovate (10 patients). 37.4% of patients repeatedly used the OTCs.

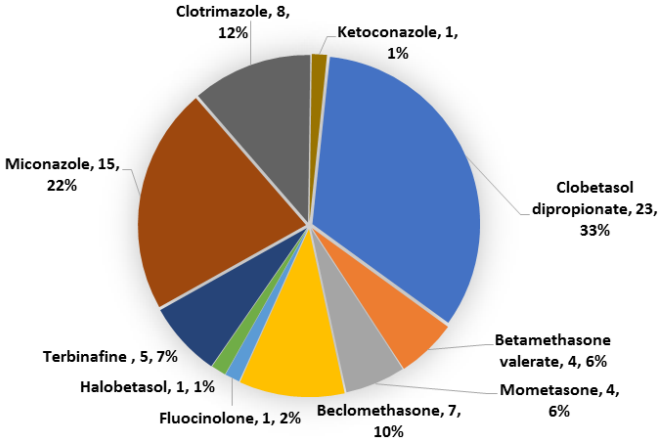

Figure 1 Major components in the topical medications used in this study.

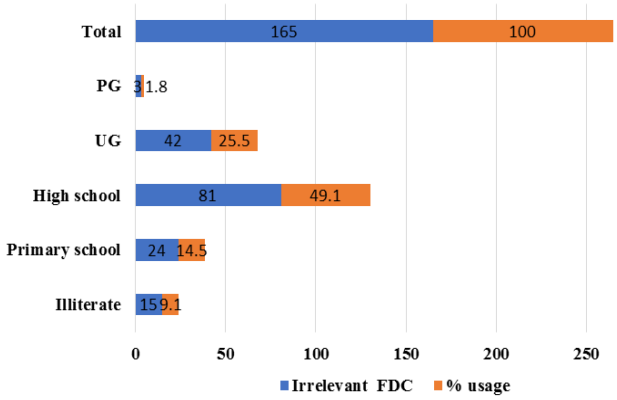

Figure 2 Correlation of literacy levels with Irrelevant FDC usage.

Table 1 Comparison of literacy rate and reason for using enlisted.

Education	*Illiterate n (%)*	*Primary n (%)*	*High n (%)*	*Undergraduate n (%)*	*Postgraduate (%)*
Recommended by others	5 (18.5)	11 (28.2)	29 (23.4)	16 (23.5)	1 (16.7)
Uneasy for examination	1 (3.7)	4 (10.3)	15 (12.1)	14 (20.6)	1 (16.7)
Trial application	2 (7.4)	1 (2.6)	4 (3.2)	5 (7.4)	0(0)
Cost factors	2 (7.4)	3 (7.7)	7 (5.6)	2 (2.9)	0 (0)
Time factors	12 (44.4)	11(28.2)	44 (35.5)	24 (35.3)	2 (33.3)
Recommended by GP	5 (18.5)	9 (23.1)	25 (20.2)	7 (10.3)	2 (33.3)
Total	27(100)	39(100)	124(100)	68(100)	6(100)

Prescription for the OTC steroids were mainly from the pharmacists for 83 persons (44.39%) followed by self-medication in 53 (28.34%), by general practitioners 52 (27.8%), by the relatives (20.86), other form of medical practitioner (3%) and by dermatologist accounting for <1%. Out of the users of irrelevant FDC, most of the patients were high school graders followed by undergraduates **(Figure 2)**.

Reasons for using these combinations were pre-framed, validated and analysed. The results were time for consultation topped the list with n=93,35% followed by recommended by family, friends and relatives (n=62, 23.5%),recommended by Registered medical Practitioners/GP (n=48, 18.6%), uneasy for examination (n=35, 13%) and about 5% contribution each from trial basis application and cost factors.

On correlating the literacy rate with the reasons for using FDC, invariably time constraints was the commonest followed by recommended by others (relatives, friends, neighbours, pharmacists etc.). UG degree holders were uneasy for examination as 3rd reason. Recommended by the Registered medical practitioner was equally in all cadres **(Table 1)**.

When SES was taken to account, overall patient's concern was the time factor. Class 3 had time factors, advice from others and as a trial in contrast to cost factors in class 4 and uneasy for examination in class 2. Advice from the GPs was common with class 3 & 4 **(Table 2)**. We found pseudo-imbricata pattern is more common accounting for 27% followed by classical annular (24%) and psoriasiform (21%) pattern. We have not encountered lichenoid, PR like or bullous patterns **(Figure 3)**.

Table 2 Correlating the factors with SES in steroid abuse dermatophytosis.

SES (Modified Kuppusamy scale)	*Time factors* %	*Cost factors* %	*Trial application* %	*Uneasy for examination* %	*Advise from others* %	*Advise from RMP* %
1	2.8	0.0	2.9	2.8	0.0	0.0
2	16.7	14.3	19.1	33.3	22.6	20.8
3	47.2	28.6	42.6	30.6	50.0	35.4
4	22.2	42.9	30.9	30.6	25.8	35.4
5 (Lower)	11.1	14.3	4.4	2.8	1.6	8.3
	100.0	100.0	100.0	100.0	100.0	100.0

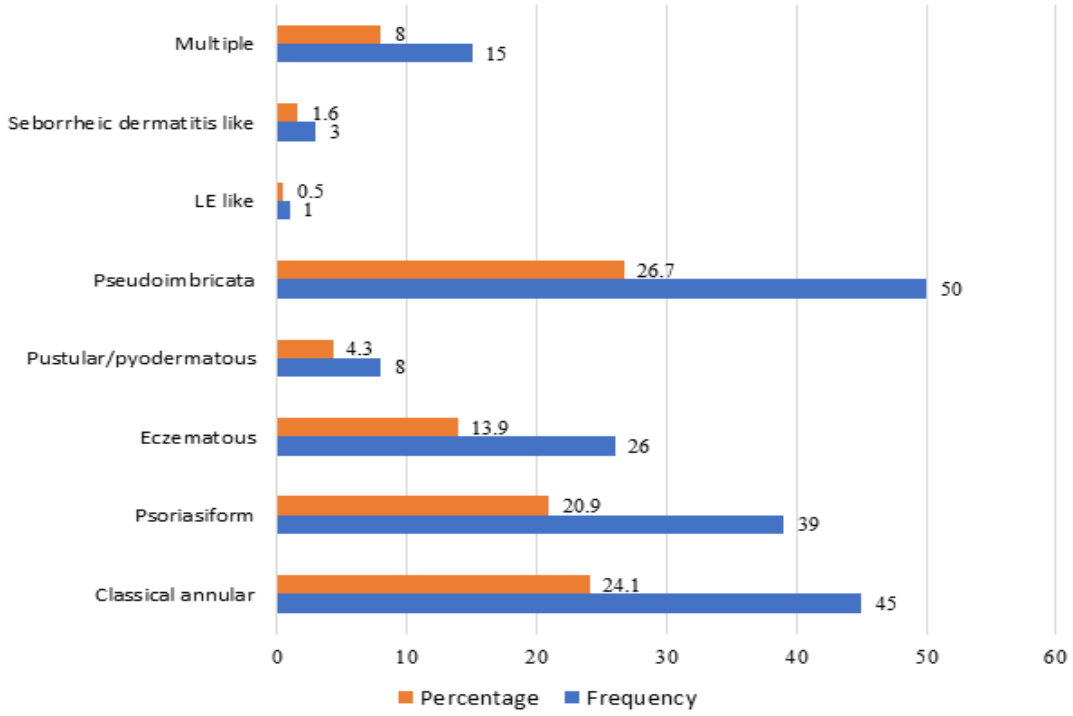

Figure 3 Clinical pattern of steroid modified dermatophytosis.

Around 36% of patients had inflammatory pattern whereas 64% had noninflammatory pattern of dermatophytosis. When classified according to body surface area (BSA) involvement, 41.7%, 35.3% and 23% had <5%, 5-10% and >10% accordingly. Patients had multiple sites of involvement 76.5% compared to single area involvement 23.5%. Most common sites of involvement were genitalia (60%), extremities and chest region. Tinea cruris was the commonest dermatophytosis (40%) followed by Tinea corporis (33%), Tinea glutealis (17%), Tinea faciae (9%) and others (1%). 145 patients had multiple adverse reactions (78%), only 2% did not have any adverse reactions. In the descending order of adverse reactions, commonest was epidermal atrophy, erythema, hypopigmentation, hyper-pigmentation. striae, lichenification, telangiectasia and irritant contact dermatitis formed a substantial amount. 1 patient had cushingoid features and hypertrichosis. Growth retardation and glaucoma were not encountered in our study **(Table 3)**.

In the 187 samples tested for 10% KOH, 171 (91%) showed positive for hyphae, either mycelium or hyphae. In 126 samples (67%), bunches of mycelia/hyphae were present and were spotted on the very first focus itself.

Table 3 Adverse drug reaction related to the steroid abuse in dermatophytosis.

OTC vs ADR	*Irrelevant FDC (n)*	*Steroid with antibiotic / antifungal (n)*	*Steroid only (n)*	*Total (n)*
Nil	4	1	0	5
erythema	65	7	1	73
Hyperpigmentation	41	2	1	44
Hypopigmentation	58	5	5	68
Epidermal atrophy	86	6	5	96
Telangiectasia	9	1	1	11
Secondary bacterial infection	5	0	0	5
Irritant contact dermatitis	11	0	1	12
Lichenification	20	0	0	20
Acneform eruption	6	1	0	7
Hypertrichosis	0	1	0	1
Striae	29	1	1	31
Cushingoid features	1	0	0	1

Discussion

In India, irrational combinations of the steroids are the highest grosser in the pharma industry and these are the ones highly abused/ misused in the society more often without the prescription.[3] On achieving some response, patients tend to continue using these products indefinitely and repetitively in case of recurrence.[4] We found 37% of patients reused on the appearance of symptoms. Topical steroids in dermatophytosis is a double edged sword, as it can alleviate the symptoms and aggravate the fungal growth by blocking the cell mediated immunity. We found both noninflammatory (36%) and rest are inflammatory that proves the above statement.

Another important factor to note is the younger age group (up to 10 years) accounted for 4.8% followed by rampant increase in the next decade (27%) which proves the ignorance of the parent or the patient about the molecule.

On the contrary to the belief, educational level or SES didn't have any influence on the usage of these FDCs, as maximum contributors were the high school graders and undergraduate holders which coincides with the study from Karnataka.[4] Similarly SES was not compared with the use of topical steroids in any of the studies, class 3 & 4 were the ones who used these preparations. Class 1 & 5 of SES in this study were lower, the conclusion is not possible with this regard. This implies the unawareness of the molecules and its adverse effects in the public even in the educated population.

An under‑discussed fact is the financial burden that superficial dermatophytosis imposes on the patient and family.[5] Unfortunately when one person from the family takes treatment from the dermatologist while others follow the same without prescription due to lack of economic resources. Surprisingly in our study, patients didn't complain that financial reasons were the factors hindering treatment from dermatologists except class 4, but the time factors (lack of time) in class 4 and uneasy for examination in class 2. In the class 3 & 4, other reasons for OTC usage was advised by the family, friends and by GP.

OTCs were recommended by general practitioners, quacks, paramedics, pharmacists, friends, and family without adequate knowledge about the diagnosis and management of dermatophytosis. As with the fact, pharmacists were the ones dispensing the OTC steroids as with other studies from India[4,6] whereas GP

(28%) also form an ample number in our study. This indicates the lacunae in the curriculum which the medical graduates follow. But in other countries, GPs and dermatologists were the ones who prescribed the topical/systemic preparation,[8,9,10,11] as masala FDCs were not at all available due to the strict drug control policies.

Most common clinical presentation in our study was pseudo-imbricata, classical annular and psoriasiform in contrast to eczemas in the other studies,[6,8,9,11] this may be attributed to the partial clearance and regrowth with on and off application. Most common dermatophytosis was tinea cruris (40%) and tinea corporis (33%) as with other studies[4,7] except by Dutta *et al.*[6] and Romana,[11] tinea faciae was the commonest presentation **(Table 4)**.

Comparing the adverse events, only 2% patients didn't have any adverse events, as it indicates the predominant patients had adverse events, atrophy was the commonest comparable with Dabas *et al.*[4] followed by erythema which also goes along with Vineetha *et al.*[12] Adverse reactions were inversely proportional to the duration of application, thickness of skin and the potency of the steroids applied.

A simple bedside test KOH examination is almost positive in 91% comparable to all other studies.[6,9,10] It is very easy to do this investigation, and the interpretation is also easy as in most of the cases it was on the first focus (mycelia) which could not be missed.

In August 2016, The Drug Controller General of India (DCG I) included major topical steroid molecules as Schedule H drugs, but the pharma companies got to stay legally with some measures.[4] Even after 3 years of legislation (as it is still in infant stage), the masala FDCs continue to pour into the market without prescription. Misuse of topical steroids can happen at many levels starting from manufacturing, marketing, prescribing, selling and misuse at the personal level.[13] These all levels have to be curtailed to combat the topical steroid misuse in all dermatological conditions.

Table 4 Comparing the relevant findings in the available literature

Study	*Age*	*Sex M:F*	*Education*	*SES*	*Topical steroid used*	*Prescription by*	*Clinical picture*	*Diagnosis according to site*	*Adverse effects*	*KOH results*
Our	11-30	1:1	High school	3	Irrelevant FDC	Pharmacist>self > GP >relatives and friends	Pseudoimbricata> classical annular	Cruris> Corporis	Atrophy> erythema> hypopig-mentation	91%
Assam study [6]		1.17:1	-	Rural	Irrelevant FDC	Pharmacist	Eczema> SLE like	Faciae> corporis	-	85%
Karnataka study [4]	19-45		High school	-	Irrelevant FDC	Pharmacist> friend and relatives		Cruris> Corporis	Burning > atrophy> striae	-
Gujarat study [7]	-	-	-	Rural	Irrelevant FDC	-	-	Cruris> Glutealis	Striae> acneform eruption	-
Iran study[8]	20-39	1:1	-	Rural> urban	Topical steroids	Self and friends>GP	Eczema> seborrheic dermatitis	Corporis> Faciae	-	-
Korean study[9]	41-70	1.25:1	-	-	Topical/ systemic steroids	GP> dermatologist> self	Eczema >psoriasis	Corporis> Faciae>	-	91.9%
Turkey study [10]	12-76	1:1.6	-	-	Topical/ systemic steroids	-	-	Corporis> Manum	-	80.95%
Italy study [11]	-	1:1	-	-	Topical steroid	-	Lupus >eczema	Faciei>Co rporis	-	

Conclusion

At the manufacture level, irrelevant FDCs containing steroids should be banned strictly by DCGI guidelines and strict legislature. At the marketing level, masala FDCs should not be promoted not only to the dermatologist but also to the GP. Medical students should have the adequate knowledge regarding the topical agents especially steroids in their curriculum and the Dermatology should be made a compulsory posting in the internship period rather than elective postings. This will improve the prescribing skills in the upcoming GPs. At the community level, health education to use only prescribed medication from the school level and to be extended to each stage of evolution. Pharmacists should be insisted to dispense only the prescribed medications.

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