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A Clinical study on steroid abuse

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I. Introduction

Abuse of topical corticosteroids (TC) is prevalent worldwide, including India. It is more common among young people. The practice is associated with significant adverse effects among the general public. The most serious concern is its inappropriate use in symptomatic treatment for varied dermatological disorders like acne, primary bacterial and fungal infections, undiagnosed skin rash and as fairness cream as advised by unqualified medical practitioners or pharmacist.

These people are not qualified to treat dermatological disorders and prescribe topical steroids which often provide quick symptomatic relief, without treating the underlying pathology of the disease. Ironically, the Indian market is flooded with several fixed dose combinations (FDCs) of corticosteroids with antibacterial and fungal agents, which in no way can be considered as scientific and rational. We have selected this study to evaluate various aspects of steroid abuse.

Aims and objectives

To know the side effects of the steroid abuse. To study epidemiological aspects of topical steroids abuse. To know the awareness of the problem due to improper use of corticosteroids among the people. To know the source of recommendation and various factors leading to steroid abuse.

II. Methods

A Questionnaire Based Analysis was done among patients attending the dermatology out-patient department to find out demographic variables, type and name of corticosteroid used, source of prescription and adverse effects in all eligible patients. A detailed clinical history regarding topical corticosteroid use was taken and adverse effects analyzed. Counseling of the each patient about adverse effects of the various available corticosteroids and treatment was initiated.

Study Design: Prospective observational study.
Study site: Dermatology out patient, Sri Venkateswara Medical College, Tirupati.
Study period: Over a period of 6 months, from march 2019 to august 2019.
Sample size: 600 patients
Sample size calculation:
Cochran's Sample Size Formula

The Cochran formula allows you to calculate an ideal sample size given a desired level of precision, desired confidence level, and the estimated proportion of the adverse effects among the general public.

Cochran's formula is considered especially appropriate in situations with **large populations.** A sample of any given size provides more information about a smaller population than a larger one, so there's a 'correction' through which the number given by Cochran's formula can be reduced if the whole population is relatively small.

The Cochran formula is:

$$n_0 = \frac{Z^2 pq}{e^2}$$

Where:

- e is the desired level of precision (i.e. the margin of error), (95% confidence level)
- p is the (estimated) proportion of the inappropriate use in symptomatic treatment.
- q is 1 – p.

so we're going to assume that half of the clients suffered inappropriate use in symptomatic treatment for varied dermatological disorders like bacterial and fungal infections undiagnosed rash and as fairness cream : this gives us maximum variability. So p = 0.5. Now let's say we want 95% confidence, and at least 1 percent—plus or minus—precision. A 95 % confidence level gives us Z values of 1.96, per the normal tables, so we get z =1.96 p=0.5 q =1-0.5 =0.5 ; margin error e =0.04

$$= ((1.96)^2 (0.5) (0.5)) / (0.04)^2 = 600.25$$

Inclusion criteria: All patients with skin lesions who had given informed consent, who were using any ointment, cream, lotion or injection that contain corticosteroid were included in the study.

patients were asked about whether they were using any ointment/ cream/lotion/injections or not. Patients with positive response were asked about the product and products were verified whether it contained corticosteroid or not. All those patients who were found to be using steroidal products were included in the study.

Exclusion criteria: Patients who had not given consent or who had not given the details of the drug where excluded.

Statistical analysis: Statistical analysis of our study was performed using the software Statistical Package of Social Science version 21 (SPSS). The demographic data analysis was performed dividing the cohort based on following factors age, gender etc. in detail clinical history regarding corticosteroid used. categorical data were expressed as numbers and percentages. Chi-square test was used for statistical testing of the difference in epidemiological factors, influencing various factors leading to steroid abuse and TCS. p<0.05 was considered to be statistically significant.

III. Results

Table no-1. Distribution of the patients: According to age, sex, education.

1.Age distribution of the patients:	
Age range	**Number of patients**
<15 yrs	36 (6%)
15-30 yrs	294 (49%)
30-45 yrs	198 (33%)
>45 yrs	72(12%)
2.Gender distribution of the patients:	
Gender	**No. of patients**
Male	359 (59.8%)
Female	241 (40.2%)
3.Educational status of the patients	
Education	**Number of patients**
Illiterate	114 (19%)
Primary	132 (22%)
Secondary	228 (38%)
Graduation	90 (15%)
Post graduation	36 (6%)

Table no-2. Different corticosteroids used by the study patients:

Different topical corticosteroids used by the study patients:	
Topical corticosteroids	**Number of Patients**
Betamethasone valerate cream	166 (27.7%)
Clobetasol propionate cream	294 (49%)
Mometasone furoate cream	123 (20.5%)
Beclomethasone dipropionate	15 (2.5%)
Hydrocortisone butyrate	2 (0.3%)
Different systemic corticosteroids used by the study patients in addition to topical steroids:	
Systemic Steroids	**Number of Patients**
Dexamethasone (decadron, dexona)	16
Prednisolone (omnacortil, wysolone)	5
Triamcinolone (kenocart)	8

Table no-3. Brand names and composition of topical corticosteroid-containing products used by study patients:

Brand name(s)	Composition	Number of patients
Betnovate	Betamethasone valerate	75
Betnovate-N	Betamethasone valerate 0.1%, neomycin sulphate 0.5%	29
Betnovate-GM	Betamethasone valerate 0.1%, gentamicin 0.1%, miconazole nitrate 2%	38
Melacare	Mometasone furoate 0.1%, hydroquinone 2%, tretinoin 0.025%	30
CLOP-G	Clobetasol propionate 0.05%, gentamicin 0.1%,	28
Momet cream	Mometasone furoate 0.1%	26
Lycor	Hydrocartison butyrate 1%	2
Panderm plus/panderm cream	Ofloxacin, ornidasole, clobetasol propionate, terbinafine hydrochloride	145
Skinlite cream	Hydroquinone, tretinoin, mometasone furoate	63
Fusiwal-b cream	Beclomethasone dipropionate , Fusidic acid	30
Fourderm/ forederm plus & Closat-GM cream	clobetasol propionate, neomycin sulphate 0.5%, Miconazole nitrate, chlorhexidine gluconate.	118
Castor-nf cream	clobetasol propionate, ciprofloxacin, metronidazole, terbinafine HCl.	3
Wabcon-t cream	terbinafine HCl, mometasone furoate	1
Phytoral –b	Beclomethasone dipropionate & ketoconazole	9
Ezimet	Mometasone furoate	3

Table no-4. Source of recommendation of the drug:

Advised by	No. of patients
Quacks	142
Pharmacists	245
Friend/ family member	95
Self	74
MBBS doctor	38
Dermatologist	6

Table no-5. Table representing duration and frequency of the drug used.

Duration of the drug used:	
Duration	**Number of patients**
1 week to 1 month	12% (72)
1 month to 3 months	55% (330)
3 months to 6 months	9% (54)
6 months to 1 year	6% (36)
More than one year	18% (108)
Frequency of application:	
Frequency	**Percentage**
Once a Day	12% (72)
Twice a day	55% (330)
Thrice a day	9% (54)
Infrequently	6% (36)
Irregularly	18% (108)

Table no-6. On examination, dermatological adverse effects observed in our study:

Adverse effects	Numbers of patients (%)
Tinea incognito	329 (54.8%)
Facial erythema	69 (11.5%)
Acneiform eruptions	66 (11%)
Secondary bacterial infections	59 (9.8%)
Atrophic striae	45 (7.5%)
Hypopigmentation	37 (6.2%)
Topical steroid dependant face	27 (4.5%)
Telangiectasia	19 (3.2%)
Hypertricosis	16 (2.7%)

Table no-7. Table depicting the steroidal drug with source of recommendation.

TCS	Quacks	Pharmacists	Friend / family member	Self	MBBS doctor	Dermatologist	Total
Betamethasone valerate cream	76	60	18	10	2	0	166
Clobetasol Propionate Cream	62	117	48	40	22	5	294
Mometasonefuroate cream	2	59	27	24	10	1	123
Beclomethasonedipropionate	1	9	2	0	3	0	15
Hydrocortisone butyrate	1	0	0	0	1	0	2
Total	142	245	95	74	38	6	600
Chi-square	χ2:108.285; df= 20; p=0.000**; **P<0.001 Sig. at 0.01 Level						

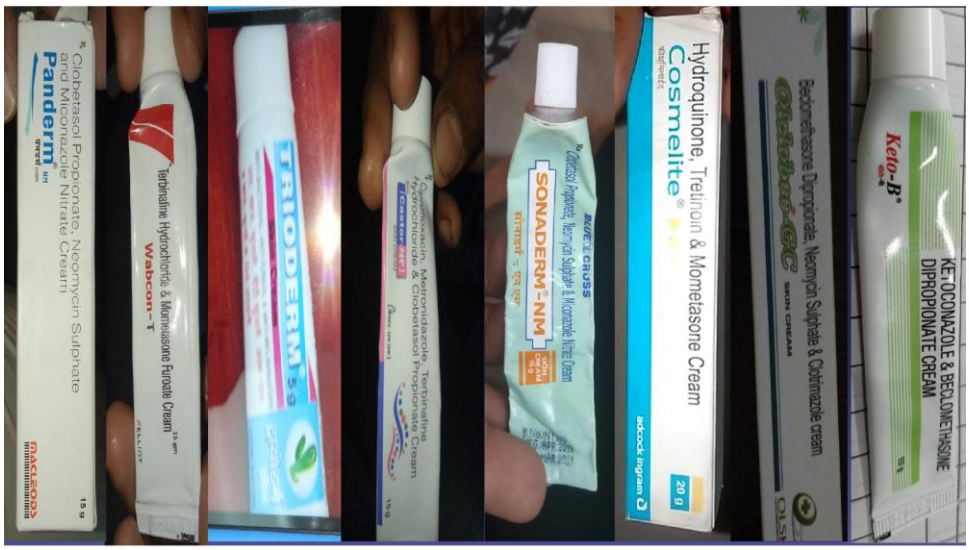
Table No.8. Table depicting topical corticosteroids with Adverse effects

Adverse effects	TCS(topical corticosteroids)					
	Betamethasone valerate cream	Clobetasol propionate cream	Mometasone furoate cream	Beclomethasonedi propionate	Hydrocortisone butyrate	Total
Tinea incognito	117	189	14	7	2	329
Facial erythema	12	18	36	3	0	69
Acneiform eruptions	26	14	24	2	0	66
Secondary bacterial infections	24	28	5	2	0	59
Atrophic striae	25	19	0	1	0	45
Hypopigmentation	11	19	4	3	0	37
Topical steroid dependent face	4	5	18	0	0	27
Telangiectasia	0	6	13	0	0	19
Hypertricosis	3	4	9	0	0	16
Chi-square	χ2: 240.009; df= 32; p=0.000**; **P<0.001 Sig. at 0.01 Level					

Table no-9. Table depicting adverse effects caused by steroid abuse in different age groups.

Adverse effects	Age				
	<15	15-30	30- 45	45	Grand Total
Tinea incognito	8	181	119	21	329
Facial erythema	11	36	18	4	69
Acneiform eruptions	16	41	9	0	66
Secondary bacterial infections	4	8	21	26	59
Atrophic striae	11	9	10	15	45
Hypopigmentation	5	7	17	8	37
Topical steroid dependant face	0	23	4	0	27
Telangiectasia	0	12	7	0	19
Hypertricosis	0	11	5	0	16
Chi-square	χ2: 223.703; df= 24; p=0.000**; **P<0.001 Sig. at 0.01 Level				

1.Different steroidal products used by study patients.



2.Steroid induced Telangiectasia & facial erythema

After 1 month of application of skinlite cream [twice daily application]

3.Tinea incognito

Due to multiple dexamethazone injections for Tinea infection

4.**Tinea incognito**

5.Tinea incognito

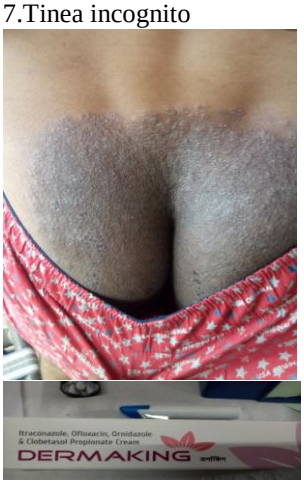
6.Software professional who used panderm cream over Tinea lesions

7.Due to multiple dexamethazone injections

6.Tinea psuedoimbricata

Application of QUADRIDERM for Tinea corporis

7.Tinea incognito



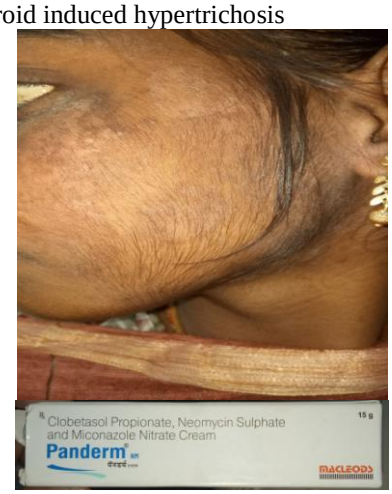
d/t application of DERMAKING cream Tinea infection

8.Steroid induced Atrophic Striae :

Application of BETNOVATE-GM cream over Tinea

Application of BETNOVATE-GM cream over Tinea lesions for 2 months

9.Steroid induced hypertrichosis



10.Non healing ulcer due to topical steroids:

Application of BETNOVATE cream over chicken pox lesions

11.Development of Facial Erythema:

Erythema secondary to misuse of skinlite cream

12.Steroid indused Acneiform eruptions

Total number of new patients attended to dermatology op in between march to August months of year 2019-15,708 (male-8,568; female-7,140). Many patients were using corticosteroids, among them 600 came with adverse effects of steroid abuse. The incidence of patients having adverse effects was 3.96%. The incidence among the male patients is 4.36%. The incidence among the female patients is 3.5%.

The percentage of the male patients predominates female patients with 59.8%. The mean age of the study group was 27.22±2.43 which is not significantly different from screening population 31±2. Age of the study group range from 8 to 75 yrs.

In this study majority of the patients belonged to 15-30 yrs (49%) followed by 31-45 yrs (33%). About 19% of the patients were illiterate and 38% of the patients have studied secondary education level. A total of 23 different brands containing 8 different corticosteroids, alone or in various combinations with antibacterials, antifungal, or antipruritic agents were identified.

Among the different brands Panderm/Pandem plus were the most commonly abused by the study patients. Duration of the drug used range from 1 week to 2 years. Majority of the patients (55%) used steroidal drug with twice daily application. In this study population steroids were most commonly recommended by pharmacists of medical shops (41%) followed by unqualified medical practitioners (23.6%).

Clobetasol propionate (49%) was the commonly abused drug followed by betamethasone dipropionate(27.7%). Most commonly identified adverse effect was tinea incognito (54.8%), followed by facial erythema (11.5%), acneform eruptions (11%) and hypertrichosis was least common adverse effect. Patients' educational status did not seem to play a role in abuse of corticosteroids. This study is highly significant. ($\chi 2$: 108.285, $P<0.001$).

IV. Discussion

This questionnaire based, cross-sectional, observational study on steroid abuse recorded a total of 600 patients with adverse effects. The incidence of patients having adverse effects was 3.96% which is relatively low compared to other studies[1–3] and could possibly be because this study excluded patients who had features suggestive of steroid abuse but were not able to give the details of the topical agent they had used. The results may not exactly represent the real magnitude of the problem as most of the people who use corticosteroids may not take consultation from a dermatologist or ignore seeking consultation for adverse effects.

In this study, males, 359/600; (59.8%) outnumbered females 241/600; (40.2%), in contrast to some studies [1–3] in Which female preponderance was seen. The most common age group affected was 15–30 years 294 (49%) as in some other studies. [1–3]This is predictable, as this age group is very conscious about their cosmetic appearance and also more likely to resort to self-medication.

In this study, topical corticosteroids (TCS) were majority times advised by pharmacists 245 (40.8%) and quacks (unqualified medical practitioners) 142 (23.7%). This result probably calls for a strict regulation regarding the sale of these products with a prescription from qualified persons only. Pharmacists and quacks were often the first points of contact for most of the patients. It is crucial to sensitize these people about the possible complications of these drugs and the extent of the problem the society is facing because of irrational and unregulated use of these drugs.

Majority of the patients with TCS abuse belonged to urban residency 371 (61.8%), this is due to a majority of the quacks/ unqualified practitioners / rural medical practitioners are practicing freely in the urban

areas and prescribing all type of drugs. Here the patients are unable to identify who is qualified doctor, who is not, because of less stringent laws against illegal practitioners and the sale of TCS over counter drugs.

In this study, all the patients with different educational levels were suffered from adverse effects of TCS abuse. This is due to lack of medical education, lack of awareness of TCS usage, and difficulty in identifying qualified doctors among the practitioners as the number of illegal practitioners are increasing in number day by day.

In this study, 29 among 600 patients (4.8%) used injectable steroids in addition to topical steroid agents. Clobetasol propionate 0.05% was the most commonly (294/600; 49%) abused TCS. This observation is similar to a study done by AlDhalimi and Aljawahiry [2,4] but in contrast to some other studies, [1–3] in which betamethasone valerate 0.1% was the main TC abused.

TCS is frequently misused as fairness creams due to their potent bleaching action and antiinflammatory action in different dermatoses. [1–3,5] However, in this study, the main reason for using TCS was Tinea infection in 329 (63%) patients. The other reasons were skin lightening 66 (11%), Pyoderma 47(7.8%) and melasma 42% (7%).

A total of 667 adverse effects were noted in 600 patients. Tinea incognito was found to be the most common adverse effect (329 (54.8%)). In another study by Al Dhalimi and Aljawahiry,[2] only (4/140; 2.9%) patients presented with tinea incognito while Dey [3] reported 56 (14.77%) patients with it. TCS by suppressing the normal cutaneous immune response, enhance fungal infections.[6] The clinical manifestation can mimic many other dermatoses. Pyoderma associated with TC abuse seen in 59 (9.8%) patients. It is caused by decreasing cutaneous immunity.

In this study, Rosacea due to TCS abuse was seen in 69 (11.5%) patients. Topical steroids increase the proliferation of Propionibacterium acnes, and Demodex folliculorum, leading to acne rosacea like condition within 6 months.[3] Mometasone furoate, known to be safe for use on the face, but it is a medium-potency steroid, and has resulted in "mometasone-induced steroid rosacea."[7]

The acneiform eruption was seen in 66 (11%) patients. TCS induce comedones formation by rendering follicular epithelium more responsive to comedogenesis[8] other studies by S Meena, LK Gupta Acneiform eruption was seen in 112 (30.27%) patients.[9] Corticosteroid-induced acne consists predominantly of inflammatory papules and pustules that are small and uniform in size, with few or no comedones. Anti-inflammatory effects of topical corticosteroids may initially suppress inflammatory papules and pustules and decrease erythema; however, patients may experience dramatic flare-ups when the topical agent is discontinued. [9]

In this study, atrophic striae were seen in 45 (7.5%) patients. Physiology of skin atrophy due to topical steroids – Topical corticosteroids cause the synthesis of lipocortin, which inhibits the activity of enzyme phospholipase A2. Phospholipase A2 acts on the cell membrane phospholipids, to release arachidonic acid, which causes the inflammation. The inhibition of phospholipase A2 results in the reduction of inflammation, mitotic activity, and protein synthesis.[10] Topical Steroid use causes the skin to go through three phases— preatrophy, atrophy, and finally tachyphylaxis. Atrophy causes a burning sensation, and further steroid use causes vasoconstriction and soothing of the burning. When topical steroids are withdrawn, vasodilation occurs, till the vessels become more dilated than their initial diameter, and this is known as a "trampoline-like effect." This happens due to the effect of steroids on nitric oxide in the endothelium. Release of endothelial nitric oxide stores results in "hyperdilation" of vessels.[10]

Pathogenesis of skin atrophy due to topical steroids Inhibitory effect on keratinocyte proliferation in the epidermis, Inhibition of collagen 1 and 3 synthesis in the dermis, Inhibition of fibroblasts and hyaluronan synthase 3 enzyme are resulting in the reduction of hyaluronic acid in the extracellular matrix leading to dermal atrophy.[10]Factors that increase chances of atrophy are Extremities of age, body site e.g., intertriginous areas, high-potency topical steroid, occlusion, and moisture.

Hypopigmentation was seen in 7.57% (28/370) patients in our study. The pigmentary alteration, particularly hypopigmentation with steroid, is frequently reported in many studies.[1–3]TC induced hypopigmentation is hypothesized to resulting from impaired melanocyte function.[11]

Topical steroid dependent / damaged face (TSDF) or red face syndrome is caused by unsupervised abuse /overuse of TC of any potency on the front over prolonged period.[12] In this study it was seen in 27 (9.73%) patients, whereas a study conducted by Anil Abraham and Gillian Roga TSDF was viewed in 36(9.73%) patients.[4]

In this study, telangiectasia was seen in 19 (3.2%) patients. Steroid-induced telangiectasia occurs due to stimulation of release of nitric oxide from dermal vessel endothelial cells leading to abnormal dilatation of capillaries.[10]In a study conducted by Meena et al.. telangiectasia was seen in 31 (8.38%) patients.

In this study, steroid-induced hypertrichosis was seen in 16 (2.7%) patients. Steroids promote villus hair growth by an unknown mechanism. Local and disseminated hypertrichosis due to TS is rare, seen commonly with systemic steroids. Even months after withdrawal of TS, the darker hairs may persist.[13] In a study conducted by Meena et al.. hypertrichosis was seen in 5 (1.35%) patients.

This study is highly significant.

V. Conclusion

In our study, the results indicate that, Irrespective of educational status, all groups of people in the society were affected by adverse effects of improper use of the steroids (both topical and systemic steroids). Patients wasted their money and time on these preparations, as these drugs increased the existing problem and added new problems to it, leading to psychological distress to the patients. In most cases, prolonged use of potent topical corticosteroids was advised by non-professional practitioners. Majority of the affected were young patients. The adverse effects were temporary to permanent and mild to profound. The results explain the lack of health awareness in the society, lack of strict regulations against illegal medical practitioners. So it is high time to create awareness among the patients as well as doctors and to make strict regulations regarding the proper usage of corticosteroids.

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