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Misuse of Topical Corticosteroids in Dermatological Disorders in Tribhuvan University Teaching Hospital

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ABSTRACT

Background: Topical corticosteroids are one of the most commonly used drugs in dermatology. Their improper use lead to serious adverse effects. However, it's commonly misused by patients and chemists in Nepal. The main objective of the study was to determine the pattern of misuse of topical corticosteroids, its adverse effects, and factors associated with its misuse.

Methods: This was a hospital-based, descriptive study conducted in a tertiary center of Nepal for three months. Patients meeting the inclusion criteria were enrolled in this study. Purposive sampling technique was used. Ethical approval was taken prior to study. Informed consent was taken from patients and interviewed using semi-structured questionnaire. The data was analyzed using Microsoft Excel and SPSS software.

Results: Two hundred sixteen patients comprised the study population where males (54.5%) outnumbered females. The mean age was 28.72 years with 21-30 years as the most frequent range. Beclomethasone dipropionate (27.3 %) and clobetasol propionate (26.9%) were the most commonly misused drugs. The most common purposes for the application of these drugs were fungal infections (66%), pigmentary disorders (15%), such as fairness cream, acne, etc. Over-the-counter sale of topical corticosteroids (62%) was significantly higher than other forms of prescription. Aggravation of fungal infections (61.6%), acneiform eruptions, striae, and steroid induced dermatoses were common adverse effects.

Conclusions: Topical corticosteroids are common misused drug with high over the counter sales. It is advised that drug authority should take necessary actions for its unethical use. Besides, awareness programs should be conducted for its rational use in public.

Keywords: Dermatological disorders; misuse; over the counter drugs; steroids; topical corticosteroids

INTRODUCTION

Topical corticosteroids (TC) initially started as compound F, are the most commonly used drugs in dermatology because of their potent anti-inflammatory and immunosuppressive properties.¹ However, these drugs produce adverse effects and are highly susceptible to be misused by patients and health professionals. Thus, TCs are a boon and banes in dermatological practice.²

Although the ethical use and sale of drugs are clearly focused in the Drug Act of Nepal 1973, its rationale use is still not achieved. Thus, there is unrestricted availability of TCs as over-the-counter (OTC) and are highly misused.^{3,4}

In spite of being a burning issue of misuse of TC, only few

studies have been conducted on its misuse.⁵⁻⁸ The aim of the study was to determine the commonly misused TCs, causes of misuse, their frequency of misuse, the reasons behind their misuses and find out the adverse effects associated with TCs use. This research would help determine scenario and challenges of misuse of topical corticosteroids for their safe, effective, and optimal benefits, thus later would help to develop a guideline or protocol for their rational and ethical use.⁹

METHODS

A prospective descriptive study was conducted in the outpatient department (OPD) of dermatology, Tribhuvan University Teaching Hospital, Nepal in the period of 1st October 2016 to 31st December 2016. Ethical approval was taken from the Institutional Review Board, Approval

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No. 145(6-11-E)/073/074. Non-probability purposive sampling technique was used for selecting the study population. ‘Universal sampling’ technique was used to determine the sample size for this study. Total number of patients visiting the dermatology outpatient department from the period of 1st October 2016 to 1st December 2016 and conformed as cases presenting misuse of TCs were taken as a sample population for this study. During the study period, total number of selected study population were 216 patients. Those patients visiting the OPD and clinically confirmed as cases with misuse of TCs were selected as study population. “Misuse of TCs” was defined and included following: use in dermatological disorders where TCs were not indicated, using different potency than indicated, using for a longer period of time, frequency of use than indicated and self-medication.

After selection of study population, the selected population were further filtered by employing inclusion and exclusion criteria. The inclusion criteria were all patients with confirmed misuse of TC, willing for informed consent. Exclusion criteria were those patients with preexisting comorbidities that could cause changes similar to TC’s side effect and cases where topical application in use cannot be confirmed as a corticosteroid. After taking informed consent, they were interviewed by investigators using semi-structured questionnaires designed by investigators themselves containing demographic and clinical variables in a preformed proforma approved by the institutional review board. The preformed proforma contained demographic variables including age, sex, occupation, educational status and clinical variables like use of TC in dermatological conditions, brand name, dose, strength, frequency, duration, prescribed by, potency of drug, adverse effects encountered etc. (See Proforma) Pretesting was done in the first ten subjects for any correction of the variables needed or missing in proforma. All the information regarding age, gender, education, occupation etc. were recorded in preformed proforma. Statistical analysis of data was performed using the software SPSS version 20.

RESULTS

A total of 216 patients showing misuse of TCs were selected for the study during the study. Out of them, 118 patients (54.6%) were males whereas 98 patients (46.4%) were females. The mean age of the patients were 28.72 years. The ages of the patients ranged from 0.5 to 65 years. The patients in the age group of 21-30 years had a high frequency (41.2%) of misuse of TCs than other groups (Table 1).

Table 1. Gender and age-wise distribution of patients.

Gender	Number	Percent	
Male	98	45.4	
Female	118	54.6	
Total	216	100.0	
Age group	<10 yrs.	04	1.9
	10-20 yrs.	31	14.4
	21-30 yrs.	89	41.2
	31-40 yrs.	51	23.6
	41-50 yrs.	32	14.8
	51-60 yrs.	08	3.7
	>60 yrs.	01	0.4
Total	216	100	

According to the data of the patient’s education profile, 6.9% were completely illiterate and remaining had different educational status (Table 2).

Table 2. Education level of patients.

Education level	Frequency (n)	Percentage (%)
Post graduate	05	2.3
Graduate	50	23.1
Undergraduate	113	52.3
Under SLC	33	15.4
Illiterate	15	6.9
Total	216	100.0

Based on the US classification of TC,¹⁰ it was found that TCs of class 1 i.e. super-potent (52.8%) were most frequently used by the patients, followed by class 5 TCs (29.2%), class 4 (9.7%), class 2 TCs (6.5%) and class 7 (1.8%). (Figure 1)

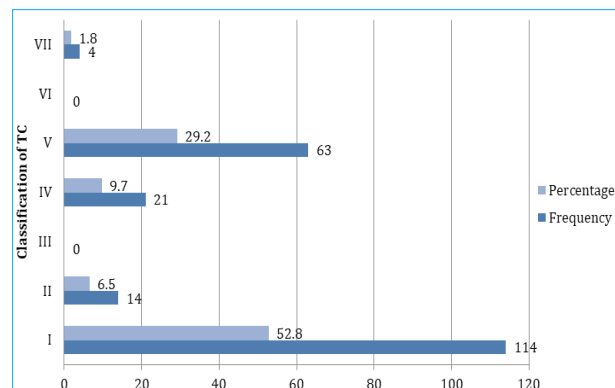


Figure 1. Classification of TCs according to frequency of use.

Among the various TCs, the most commonly misused drugs were beclomethasone dipropionate (27.3%) and

clobetasol propionate (26.9%). It was also observed that 41 patients (19%) had used more than one TCs drugs. Other misused TCs drug were: mometasone furoate (10.2%), betamethasone valerate (7.4%), halobetasol propionate (7.4%) and hydrocortisone (1.8%). (Figure 2)

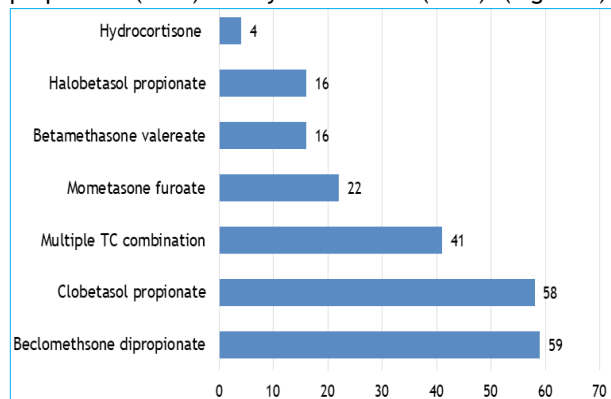


Figure 2. Frequency of commonly misused TCs.

Altogether, 14 different brands of TCs drugs were found to be misused by the patients which included: Cloben-G, Sonaderm, Ultrasol, Elocon, Betnovate, Momate, Coster, Candid-B, Cloderm, Halobet, Metasone, Betacream, Beclotime and Castor-NF. It was found that 56 out of 216 patients (25.9%) had misused Cloben-G while 54 patients (25.0%) had misused Sonaderm brand. A total of 41 patients (19%) had used multiple brands of TCs drugs having different same or different potency.

Regarding the indication of TCs, a majority (65.7%) had used for fungal infections, 33 patients (15.3%) for pigmentation disorders, 24 patients (11.1%) for acne and 17 patients (7.9%) used it for allergic reaction. (Figure 3) It was found that female patient used TCs mostly for pigment disorders and acne. It was found that, those who used TCs in fungal infections used for the period of more than one year.

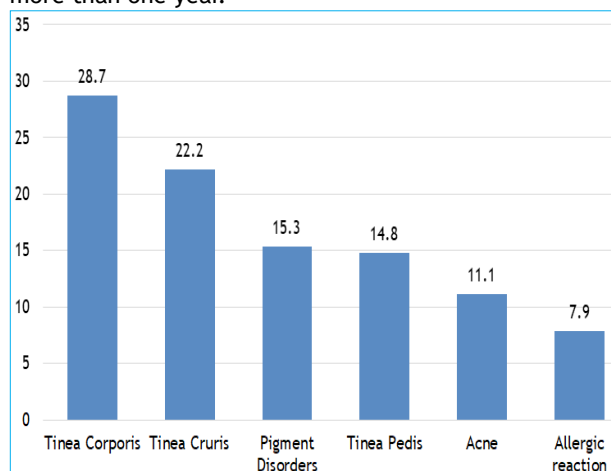


Figure 3. Causes of misuse of TCs (percentage).

Regarding the source of prescription of TCs, a substantial bulk of patients (134 patients i.e. 62%) consulted from a chemist store, whereas 18 were prescribed by registered physicians. Out of these, 17 patients were prescribed by medical officers (MBBS) and a single patient was prescribed by a dermatologist. Healthcare paramedics were responsible for 7.4% of misuse of TCs whereas recommendations from friends/family accounted for 16% of the total misuses. Self-medication practice was seen in 13 patients (6.2%).

The common adverse effects of TCs in our patient included aggravation of dermatophytoses and acne, tinea incognito, steroid induced dermatoses like burning sensation, dryness, erythema, telangiectasia, hypo-hyperpigmentation. Altogether, 133 (61.6% of cases) were diagnosed with aggravation of fungal infections, whereas about 30% had with tinea incognito. Similarly, other problems included aggravation of facial acne (24% of the cases), hypopigmentation (23.6% of the cases), hyperpigmentation (11.6% of the cases). (Table 3)

Table 3. Dermatological abnormalities seen in patients.

Dermatological abnormalities seen in patients	Responses		Percent of Cases (N=216)
	Number	Percent	
Hyperpigmentation	25	6.9	11.6
Hypopigmentation	51	14.2	23.6
Tinea incognito	66	18.3	30.6
Aggravation of tinea	133	37	61.6
Steroid induced dermatoses	33	9.2	15.3
Facial acne aggravation	52	14.4	24.1
Total	360	100.0	

DISCUSSION

Despite being the most useful drug in dermatology, TCs are also known to produce various serious adverse effects both locally and systemically if misused.¹¹ According to various studies, misuse of TCs is increasing day by day in almost every country and is a possible cause for the increased incidence of antimicrobial of resistance.^{4, 5, 12} The misuse of TCs locally causes harmful effects on the epidermis and dermis of skin. Local adverse effects are more frequently seen than systemic effects.¹¹

This study showed the mean age of the patients was 28.72 years, with the most common age group being 21-30 years (41.2%). Other studies from Nepal and India showed that majority of patients were in the age group of 21-30 years, whereas studies from Iraq showed 10-19 age group.^{5-8, 13} This study showed male dominance in

misusing TCS than females. If pigmented disorder were considered, women accounted significantly in misusing TC probably as skin lightening fairness cream which is similar to other studies.^{6,7}

More than half of the total patients (53.7%) who misused TCs were from Terai region of Nepal. This is probably due to widespread practice of visiting the community drug store instead of visiting dermatologists. It might also reflect a lack of adequate dermatologists in Terai region.

Almost two-third of total patients who were misusing TCs were not graduated. The result from this study also indicated that patients who are not educationally qualified has more tendency to misuse the TCs in comparison to educated ones.

In our study, beclomethasone dipropionate was the most commonly misused TC. This finding is similar with study by Kumar A et al.⁷ whereas different from Dhalimi et al.¹³, Inkanti et al.¹⁴ and Parajuli et al.⁶ where clobetasol (Class I) and class IV TCs were more common. In a Korean study, betamethasone valerate and prednicarbate were the most commonly misused TCs.¹⁵ More than half of the study population (52.8%) had applied super potent TCs preparations. According to Kumar S et al.¹⁶, 98% of the TCs abused were superpotent TCs. Similarly, Saraswat A et al.¹⁷ found potent and superpotent TCs were more frequently abused even over the face.

Altogether, fourteen different brands of TCs drugs were found to be misused, whereas 'Cloben-G', a triple combination cream containing beclomethasone dipropionate 0.05%, clotrimazole and gentamicin followed 'Sonaderm-GM' (clobetasol propionate 0.05% w/v) were found to be highly misused. More than half of the patients either applied 'Cloben-G' or 'Sonaderm'. These two brands are the most misused brands which could be due to unethical marketing policies adopted and lack of strong drug regulatory body in controlling the OTC sale of those TCs. The variations in commonly misused TCs might be due to variation in site of application, indication, easy availability and cost effectiveness.

The most common reasons of patients using TCs were fungal infections, pigment disorders, fairness creams, acne, allergic disorders like dermatitis etc. Various studies in Nepal and abroad concluded that the main reason for using the TCs were treatment of melasma, as a fairness cream, antifungal treatment, eczema etc.⁵⁻⁸

The study revealed that only single patient was prescribed to use TCs by dermatologist. Thus, TC misuse

was significantly high among non-dermatologist. About 7.8% of the patients were prescribed by medical officers (MBBS). A large bulk of patients (92%) did not visit registered physicians and bought the TCs from chemist. These findings are similar with studies from Nepal, India and Korea. Registered physician's recommendation on TCs in our study was in very less i.e. 8.3% compared to 18% in Kumar A et al.⁷ and 59.3% in study by Saraswat et al.¹⁷ The Korean study revealed that the common way to obtain TCs was buying directly from pharmacist without any prescriptions.¹⁵ One of the studies found that in 85% of cases, the basis of prescribing TCs could not be established.¹⁶

This practice of using TCs by pharmacist is totally unethical because as per drug act of Nepal 2035 B.S. as TCs belongs to the class of prescription drugs and can only be dispensed by the pharmacists after getting written prescriptions from registered physicians.³ The main reason behind this practice is that regulatory authority/bodies of our country are not strong enough so that drug act and regulations are not properly maintained. TCs are rampantly being used as over the counter drugs all over the country therefore patients are directly purchasing highly potent TCs drugs from the community pharmacy.⁴

A large number of dermatological abnormalities such as perioral dermatitis, tinea incognito, infantile gluteal granuloma, acneiform eruptions, hypertrichosis, cutaneous atrophy, hyper/hypopigmentation, pyoderma etc. are associated with the misuse of TCs.¹⁸ Result shows that aggravation of fungal infection was the most common (61.6%) adverse effects. Other dermatological problems which were diagnosed in the patients misusing TCs were tinea incognito, hypopigmentation, hyperpigmentation, steroid induced dermatoses like striae, telangiectasia and facial acne aggravation. Condo A et al.¹⁹ on a review article mentioned that the common side effects observed in patients after misuse of TCs are atrophy, contact allergy, aggravation of fungal infection, acneiform eruptions, rosacea, perioral dermatitis, hyper/hypopigmentation and steroid addiction. Saraswat A et al.¹⁷ in a multicenter study on abuse of TCs on the face concluded that acne/exacerbation of acne was the most common adverse effect seen.

It was found that about ninety percent of the patients had basic information on frequency of TCs which is to be applied whereas eighty percent of the them had no information about the amount to be applied. Similarly, the majority of the patients (85.2%) had no information on the possible side effects of TCs. This could be one of the reasons behind misuse of TC in our community.

This study might not reflect the actual scenario of the misuse of TCs. As this study was conducted at a single tertiary dermatology center, it would be inappropriate to generalize the result in the entire population. The potential systemic adverse effects due to prolonged misuse of TCs was not seen in this study. Another limitation of this study is that the duration for this study was relatively short.

CONCLUSIONS

Topical corticosteroid therapy is fundamental in dermatological practice. Despite their effectiveness, their increasing misuse predisposes a patient to increase in morbidity with a number of adverse effects. It is extremely important that patients are correctly prescribed and OTC availability of TCs must be regulated. Thus, rational use of TCs can minimize the systemic and cutaneous side effects.

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