

Research Article

# Prevalence of Topical Corticosteroids Related Adverse Drug Events and Associated Factors in Selected Community Pharmacies and Cosmetic Shops of Addis Ababa, Ethiopia

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## Abstract

**Introduction:** Inappropriate use of topical corticosteroids was found to cause different dermatological complications. Despite its complex adverse effects, misuse of topical corticosteroids has been a common practice throughout the world. The objective of this study was to assess the prevalence of misuse of topical corticosteroids and its associated factors in selected community pharmacies and cosmetics shops of Addis Ababa.

**Methods:** A cross-sectional study design was conducted from February to April in twelve community pharmacies and six cosmetics shops in Addis Ababa. A convenience sampling method using semi-structured interviews was used to collect topical corticosteroids use pattern and related adverse events. Descriptive statistics were used to summarize the nature and frequency of cosmetic use while binary and multinomial logistic regression was employed to test associated factors. Statistical significance was set at  $p < 0.05$ .

**Result:** From a total of 286 participants, more than two third obtained the topical corticosteroids as over the counter. Among these, majority (59.8%) used for beautification purpose. More than half of the users faced adverse drug events and the most common affected site was face. Educational status was found to be associated with OTC use of corticosteroids. Age, reading of label, frequency of application, recommendation by friends and, mixing with other cosmetics and water have shown statistically significant association with occurrence of adverse drug events.

**Conclusion:** Majority of the topical corticosteroids were obtained without prescription for the purpose of beautification rather than treatment. A higher proportion of cosmetic users reported to have experienced at least one adverse event. There needs to consider safety concerns related to topical corticosteroids use in the city.

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## 1. Introduction

Topical corticosteroids (TCs) are group of drugs which has anti-inflammatory, immunosuppressive, anti-proliferative and vasoconstrictive effects [1]. Corticosteroids work by binding to a specific receptor in the cellular cytoplasm and modulating the transcription of multiple genes that lead to the suppression of the production of inflammatory substances such as; prostaglandins and leukotrienes as well as by inhibiting the recruitment of inflammatory cells into the skin [1, 2].

Since their introduction in the early 1950's, TCs have become the cornerstone of treatment mainly; for non-infective dermatologic disorders associated with inflammation [3–5]. These disorders include a wide variety of dermatoses, such as atopic dermatitis, eczema, contact dermatitis, psoriasis, seborrheic dermatitis, vitiligo, lichen scleroses and intertrigo [6, 7].

Topical corticosteroids are the first-line therapy for the treatment of atopic dermatitis according to various independently published international guidelines from both dermatology and allergy groups worldwide [8, 10, 11]. Other studies have also documented that these agents have a positive impact on the quality of life of patients [12, 13]. Topical corticosteroids have been shown to be a safe treatment options both in short-term daily use and long-term intermittent application [14]. They are, specifically, recommended when patients have failed to respond to consistent eczema skin care regimen, including the regular use of moisturizers (emollients), appropriate antibacterial measures, and trying to eliminate any possible allergens that may be contributing to the underlying conditions [8].

The potency of TCs has been assessed by measuring their vasoconstrictive effect on the skin. Based on their potency, British National Formulary (BNF) divides the topical corticosteroids into four groups, whereas American system divides them into seven classes, where class I represents super potent or ultra-potent drugs and class VII the least potent. Previous studies indicated significantly increased proportion of dermatological visits related to a number of local and systemic adverse effects from misuse of TC over the face, ranging from dermatitis and skin rashes to the development of diabetes mellitus, hypertension and renal problems [15, 16]. The quick amelioration of signs and symptoms of many facial dermatoses, the easy access of TC by the people and their use as a cosmetics agent are the most important reasons for irrational use of these groups of drugs [17, 18].

Despite the occurrence of complex adverse effects, misuse of TCs has become a common practice in the community. This study was conducted to assess the pattern of misuse on TCs and factors associated to this practice in selected community pharmacies and cosmetic shops of Addis Ababa.

## 2. Methods

### 2.1. Description of the study area and settings

Addis Ababa is the capital city of Ethiopia with a total population of 3,384,569 with annual growth rate of 3.8% as reported on the 2007 census conducted by the central statistical agency of Ethiopia [19]. According to the 2008 Ethiopian health and health related indicators report, there were 378 pharmacies, 273 drug stores and 1 rural drug vender in the city [20].

### 2.2. Study design

A cross-sectional study design was conducted from February to April 2017 in selected community pharmacies and cosmetics shops of Addis Ababa.

### 2.3. Source and study population

The source population included all TC users who visited community pharmacies and cosmetics shops in Addis Ababa city administration whereas; the study population included all customers who came to purchase TC with or without prescription during the study period.

### 2.4. Sampling procedure and Sample size calculations

Because TCs were out of stock in the market during the stated period, convenience sampling method was used to select Pharmacies and cosmetics shops. All customers who came to buy TCs with or without prescription in the selected community pharmacies were asked for consent and were made to fill out the questionnaires. Those sent by other TC users were not asked since true information could not be obtained from them. And in cosmetic shops, customers who came to purchase TCs which are

not allowed (intermittent to super potent TCs) to be sold in cosmetic shops were asked to fill out the questionnaire.

The minimum number of sample required for this study was determined by using single population proportion formula considering the following assumptions:

$$n = \frac{(Z\alpha/2)^2 P (1 - P)}{(E)^2}$$

Where,

n= the required sample size

P=the prevalence of misuse of topical corticosteroids (p=0.79)

Z= Z score at 95% confidence interval=1.96

E = the margin of error=0.05

Accordingly, the sample size will be:

$$n = \frac{(1.96)^2 \times 0.79(1 - 0.79)}{(0.05)^2} = 255$$

Assuming 10% non-response rate, the total sample size was 286.

## 2.5. Inclusion and Exclusion Criteria

Topical corticosteroid users in selected community pharmacy and cosmetics shop aged 18 or above were included in the study whilst, Consumers of other cosmetics products, those aged below 18 and, those sent by other TC users were excluded from the study.

## 2.6. Data collection methods and quality assurance

Quantitative data collection method was employed and, a structured questionnaire was used to determine the prevalence of TC misuse. The data collection questionnaire was designed in English and transcribed to Amharic (the national working language of the country). Training was given to data collectors and supervisors. Pre-test was done two days before the start of actual data collection at one of the study areas. Based on the findings from the pre- test, the questionnaire was revised and adopted.

## 2.7. Data entry and analysis

Descriptive statistics were used to summarize the nature and frequency of cosmetic use. Bivariate logistic regression analyses were applied to investigate the determinants

of cosmetic use associated with adverse events. All explanatory variables associated with the outcome variable in the bivariate analysis with  $p < 0.20$  were included in the multivariate logistic regression model. SPSS version 20 for Windows was used for the data entry and analysis. Statistical significance was set at  $p < 0.05$ .

## 2.8. Operational Definitions

**Misuse:** The use of TCs out of the intended purpose (Treatment).

**Topical corticosteroids:** Any preparation that contains one or a combination of TCs in the form of cream, ointment or lotion to be applied on the skin.

**Cosmetic shops:** Shops in which all kinds of cosmetics products are sold.

**Cosmetics:** TCs used for beautification purpose.

**Community Pharmacies:** drug retail outlets including drug stores and pharmacies not owned by health facilities.

**OTC use:** use of TCs without appropriate prescription paper.

## 2.9. Ethical consideration

The Institutional Ethical Review Board of the School of Pharmacy, Addis Ababa University, gave permission to conduct the study. An official letter of cooperation was also written from the Department of Pharmaceutics and Social Pharmacy and, the study was conducted after securing permission from the selected community pharmacies and cosmetics shops. Moreover, verbal consent was sought from every participant after explaining about the nature of the study, objective, and expected duration of the interview. Every subject was informed that participation in the study was fully voluntary. To assure anonymity, the name and address of the study participants were not recorded on the questionnaires and all the information gathered was kept confidential.

## 3. Results

### Findings from Selected cosmetic shops and Community Pharmacies

Among the 286 study participants approached in the study sites, 211(73.8%) were female. One hundred thirty three (46.5%) of the participants were in the age group 18-28. More than half of TC users were single (54.5%). Majority of the participants had a higher educational background (56.6%) (Table 1).

Variables	Frequency	Percent
Gender		
Male	75	26.2
Female	211	73.8
Age (Yrs.)		
18-28	133	46.5
29-39	104	36.4
>40	49	17.1
Marital Status		
Single	156	54.5
Married	130	45.5
Educational Status		
1-12 grade	124	43.4
Higher Education	162	56.6
Occupation		
Student	31	10.8
Government Employee	40	14.0
Unemployed	17	5.9
Non-Governmental Employee	58	20.3
Private Work	140	49.0

TABLE 1: Socio-Demographic Characteristics of Topical Corticosteroid Users in Selected Community Pharmacies and Cosmetics Shops of Addis Ababa, Ethiopia.

### 3.1. Extent of over the counter use of Topical corticosteroids

More than two third (68.5%) of the participants utilized TCs as over the counter (OTC) and majority (60%) used the TCs for beautification purpose. Most of the participants (44.1%) in the study area selected the TCs by consulting a health professional while about one third of the participants selected TCs by asking a friend. Many of the participants (73.4%) claimed to read information that is written on the container and 138 (48.3%) have reported that they read this information always when purchasing cosmetics. Expiry date is the most commonly read information reported by 131 (45.8%) subjects (Table 2).

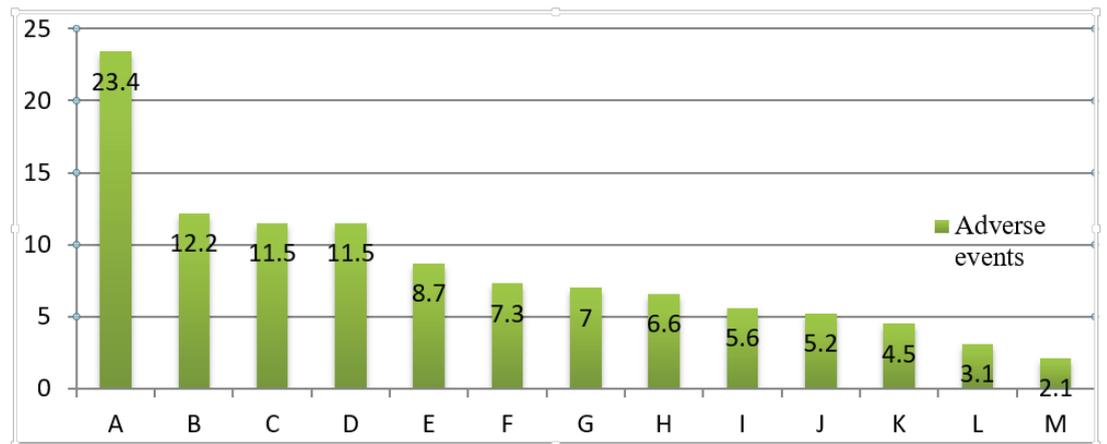
Characteristics	Number	Percent
Type of prescription		
OTC	196	68.5
Prescribed	90	31.5
Purpose of use		
Treatment	107	37.4
Beautification	171	59.8
Duration of application		
Less than 1 month	94	32.9
1-6 month	81	28.3
Greater than 6 month	111	38.8
Frequency of application		
Once	194	67.8
Twice	74	25.9
Three and Greater than three times	18	6.3
Do you read information's on the container		
Yes	210	73.4
No	76	26.6
How do you use different cosmetics		
Use each alone	210	73.4
Use different types by mixing	40	14.0
Use by mixing with water	36	12.6

TABLE 2: Pattern of topical corticosteroids utilization in selected community pharmacies and cosmetics shops in Addis Ababa, February 2017.

### 3.2. Adverse effects and actions taken

One hundred fifty (52.4%) of the participants faced any sort of adverse drug event (ADE) and, the most commonly affected site was face (45%) followed by arm pit and hair (17.1%). Twenty nine (19.3%) of those who faced the ADEs stopped using TCs for some time and started back again when symptoms disappeared. Only 39 (13.6%) of the study participants consulted health professionals.

Allergic reactions were the most common problems faced by the users, followed by development of hair on face, sore on skin and face, Acne, discoloration on face and skin, hair brittleness and breakage (Figure 1).



**Figure 1:** Common ADR seen in TC users in selected pharmacies and cosmetic shops of Addis Ababa, February 2017.

*A-allergic reaction, B-development of hair on the face, C-sore on skin and face, D -acne, E- discoloration on face and skin, F-hair brittleness and breakage, G-photosensitization, H-feasibility of blood vessels, I-hyperpigmentation, J-skin thinning, K-stinging and darkening of the arm pit, L-contact dermatitis, M-hypopigmentation*

### 3.3. Factors associated with OTC use of TC

A logistic regression analysis was used to determine association between patients' socio-demographic variables and OTC utilization of TCs. Significant association was detected between OTC use and education. Participants who were in grades 1-12 (lower level education) had two times used TCs as OTC than those who were in higher education with AOR=2.67, 95%CI (1.49-4.79). However other socio-demographic variables like age, gender, marital status, and occupation did not show a statistically significant association (Table 3).

### 3.4. Factors associated with adverse effects of TC

A statically significant association was detected between adverse events and age. Those participants in the age group 29-39 reported more adverse events than those in the age group 18-28 and greater than 40. With AOR=2.45, 95% CI (1.11-5.39). A significant association was also observed between frequency of application and adverse events. Participants who applied a TC once and twice per day have a lesser probability of reporting ADEs as compared to those who applied more than twice with

Variables	OTC Use		COR	AOR
	Yes	No		
Age				
18-28	92	41	1.19[0.59-2.38]	1.35[0.62-2.94]
29-39	72	32	1.18[0.58-2.45]	1.31[0.62-2.77]
Greater than 40	32	17	1.00	1.00
Gender				
Female	145	66	1.03[0.58-1.82]	0.97[0.53-1.75]
Male	51	24	1.00	1.00
Educational Status				
1-12	98	267	2.46[1.44-4.20]*	2.67[1.49-4.79]*
Higher Education	98	64	1.00	1.00
Marital Status				
Single	100	56	0.63[0.38-1.05]	0.69[0.39-1.24]
Married	96	34	1.00	1.00
Occupation				
Student	23	8	1.27[0.52-3.07]	0.96[0.36-2.54]
Governmental Employee	25	15	0.73[0.355-1.53]	0.79[0.37-1.68]
Unemployed	11	6	0.81[0.28-2.34]	0.54[0.17-1.65]
Non-governmental work	40	18	0.98[0.50-1.91]	1.07[0.53-2.16]
Private	97	43	1.00	1.00

TABLE 3: Factors affecting OTC utilization of TCs in selected pharmacies and cosmetic shops of Addis Ababa, February 2017.

AOR=0.16, 95% CI(0.44-0.69) and AOR= 0.15, 95%CI(0.39-0.63) respectively. The probability of ADE were three and five times higher for those who selected their TC by asking their friends and who looks appearance and aroma respectively as compared to those who used cost and affordability as a selection criteria (AOR= 3.32, 95% CI (1.64-6.75)); (AOR=5.21, 95%CI (1.48-14.33)) respectively. Occurrence of ADEs was three times higher for those who used their TC by mixing with other agents (AOR= 3.58,

95% CI (2.2-7.83)). In addition, the occurrence of ADE were also two times higher for those TCS users who mixed their cosmetics with water (AOR=2.56, 95%CI (1.55-4.32)).

#### 4. Discussion

The number of participants who reported to have experienced adverse cosmetic events was higher as compared to figures documented in other parts of Ethiopia [21, 22] and in other countries such as the Netherlands [23], UK [24], Nepal [25], and Rio de Janeiro [26]. However, a higher figure had also been reported in a study by Bilal et al. among residents of Jigjiga town in the same country [27]. This can be explained, partly, by the little priority given to cosmetic use safety evaluations and laboratory assessments in Ethiopia [28, 29]. In addition, most cosmetics outlets lack proper channels of supply where most of these products are smuggled by non-professional and uneducated sellers. This, in turn, may result in poor storage of the products, product exposure to sunlight and inappropriate handling of products as compared to cosmetics obtained from drug retail outlets [22].

This study also has shown that more number of female was found to use TCs than male. Similar findings were obtained inside the country [30, 31]. This practice is again reported in the rest of the world such as; South Africa, India, Pakistan and Iraq [32-34]. Higher prevalence of TCs use among the females might be attributed to their considerable interest to feel clean and attractive, increasing sexual stamina, feeling good and sexually active as well as countering sexual risks as reported in some studies [35, 36]. Other studies have also documented that females reported skin diseases, emotional distress and associated contact dermatitis more often compared to males [37-39].

Even though an earlier study indicated that there were OTC uses of TCs [31], the higher figure in this study may indicate the degree to how much the professionals were not following the ethics and rules that govern the pharmaceutical sector. This problem had been reflected in the significant number of TC users reporting an ADE. The fact that those in grades 1-12 (lower level education) had a two times higher probability of using TC as OTC indicates that there needs to do an educational campaign on this group of users.

The frequency of use had also shown a statistically significant association with the occurrence of ADE. Similar findings were reported inside the country where higher frequency of use increased the occurrence of the ADE [27]. This study has clearly

<b>Adverse effects</b>				
<b>Variables</b>	<b>Yes</b>	<b>No</b>	<b>COR</b>	<b>AOR</b>
Age (Yrs.)				
18-28	66	67	1.21[0.62-2.33]	1.46[0.65-3.27]
29-39	62	42	1.81[0.91-3.59]	2.45[1.11-5.39]*
>40	22	27	1.00	1.00
Sex				
Male	43	32	1.00	1.00
Female	107	104	0.76[0.45-1.30]	0.71[0.38-1.32]
Educational Status				
Grades 1-12	24	39	1.40[0.879-2.25]	0.93[0.50-1.72]
Higher Education	32	29	1.00	1.00
Marital Status				
Single	76	80	0.71[0.45-1.14]	0.66[0.37-1.18]
Married	74	56	1.00	1.00
Occupation				
Student	15	16	0.96[0.44-2.10]	0.59[0.22-1.54]
Governmental Employee	26	14	1.91[0.92-3.96]	1.99[0.84-4.70]
Unemployed	12	5	2.47[0.826-7.37]	1.76[0.45-6.78]
Non-governmental work	28	30	0.96[0.521-1.77]	0.75[0.36-1.56]
Private	69	71	1.00	1.00
Duration of application				
Less than a month	50	44	1.28[0.74-2.23]	1.02[0.52-1.98]
1-6 months	48	33	1.65[0.92-2.945]	1.29[0.66-2.53]
Greater than 6 months	52	59	1.00	1.00
Frequency of application				
Once	97	97	0.28[0.91-0.89]*	0.16[0.44-0.69]*
Twice	39	35	0.31[0.09-1.05]	0.15[0.39-0.63]*
3 or more times	14	4	1.00	1.00
Selection of TCS				
Recommended by friends	51	27	3.10 [1.36-6.98]*	3.32[1.64-6.75]*
Looking appearance and aroma	15	5	4.92 [1.46-16.53]*	5.21[1.48-14.33]*
Recommended by health professionals	59	60	1.61 [0.75-3.43]	1.34[0.82-3.11]
Recommended by shop owners	11	21	0.861 [0.32-2.30]	1.12[0.45-2.2]
Low cost	14	23	1.00	1.00
Use of different cosmetics				
Using TCS without mixing with other cosmetics	99	116	1.00	1.00
Using TCS by mixing with other cosmetics	30	9	3.90[1.77-8.61]*	3.58[2.2-7.83]
Using TCS by mixing with water	21	11	2.23 [1.02-4.866]	2.56 [1.55-4.32]

\*Statistically significant association at 95% CI

TABLE 4: Factors affecting adverse effects of TC in selected pharmacies and cosmetic shops of Addis Ababa, February 2017.

shown that the participants who selected their TCs by friends as well as by looking appearance and aroma were at a higher risk to develop an ADE. This underscores the importance of consulting health professionals while selecting the TCs for use. Likewise, a three and two times increase in ADE was reported by TC users who applied through mixing it with other cosmetics and water. This could be explained by presence of interaction between cosmetic products or a synergistic effect of the products to each other. similar studies also reported that mixing of cosmetics with other substances like water and saliva increase the ADE [21, 27].

This study has tried to catch those users who visited both community pharmacies and cosmetics shops for obtaining their TC. However, some of the adverse events reported by the study participants might have not, necessarily, been caused by the cosmetic product they used. There needs further investigation for causality assessment which was beyond the scope of this study.

## 5. Conclusion

The result of this study has revealed that most TCs were being utilized without a prescription. Besides, many participants have reported to purchase TCs for beautification purpose rather than treatment. Significant number of users had experienced adverse events in which frequency of application, the way of selection and mixing the TC with other cosmetics and substances were important predictors for such events. There needs a due consideration on cosmetic use-related safety concerns through awareness creation programs and promoting the concept of cosmetovigilance among cosmetic sellers, users, and other stakeholders.

## 6. List of Abbreviations

ADR:	Adverse drug reaction
AOR:	Adjusted odds ratio
BNF:	British National Formulary
COR:	Crudes odds ratio
CSA:	Central Statistical Agency of Ethiopia
FMHACA:	Food Medicine and Healthcare administration and control authority
OTC:	Over the counter
SPSS:	Statistical package for the social science program
TC:	Topical corticosteroids

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