

Factors Associated with the Inappropriate Use of Topical Corticosteroids among Out-Patient Dermatology Patients: A Cross-Sectional Study*

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ABSTRACT

Topical corticosteroids (TC) are among the most commonly prescribed topical agents and are used to treat various dermatoses. This study aimed to determine the prevalence, factors associated and reasons patients inappropriately use TC. Incidence of AE and risk of the development of AE due to inappropriate TC. Out-patient dermatology patients in a tertiary hospital in the Philippines were screened for TC use and interviewed using a questionnaire. Descriptive analysis and logistic regression to determine odds ratios were done. Out of 801 patients recruited, 260 (32%) used TC. Among those who used TC, 147 (56.53%) inappropriately used TC. Among the factors associated with inappropriate use of TC were: 1) Diagnosis of dermatitis as primary dermatosis (OR = 2.82, 95% CI 0.497, 1.276), 2) Lack of awareness of the FDA advisory (OR = 2.1, 95% CI 1.245, 3.601), 3) Lack of knowledge that TC cannot be applied for prolonged periods (OR = 5.5, 95% CI 3.201, 9.334), and 4) Lack of knowledge that TC use can result into AE (OR = 4.5, 95% CI 2.637, 7.657). Relatives and friends as source of information (OR=437, 95% CI 25.997, >1000), procurement (OR=60, 95% CI 3.081, >1000) and instruction (OR=337, 95% CI 19.827, >1000) were highly associated with inappropriate use. Twenty-two percent of those who inappropriately used TC self-medicated upon recommendation by

family and friends. Hypopigmentation was the most common AE. There is a 3.8 times (OR= 3.8, 95% CI: 1.918, 7.662) likelihood for a person who has inappropriately used TC to have an AE as compared to a person who has appropriately used TC. There is a need to educate the general public regarding proper TC use. Patient encounters at the clinic may be a good opportunity to reinforce guidelines on the use of TC.

Keywords: adverse effects, corticosteroids, Philippines

INTRODUCTION

Topical corticosteroids (TC) are among the most commonly prescribed topical agents.¹ They are utilized in the treatment of numerous cutaneous pathologies, such as atopic dermatitis, dyshidrotic eczema, nummular eczema, seborrheic dermatitis, irritant contact dermatitis, allergic contact dermatitis (acute phase), lichen simplex chronicus, insect bites, lupus erythematosus, psoriasis and lichen planus. TCs are known for both their antiproliferative effect, mediated by reduction of keratinocyte size and proliferation, and their vasoconstrictive effect on dermal capillaries. Vasoconstriction assays of TC are employed in predicting the clinical activity of these compounds,

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providing a basis for tiered classification schemes according to potency. There are two most cited classification systems – the United States' classification system (Group I-VII) and France's classification systems (ultra high, high, moderate, and low potency TC), which were further condensed by the World Health Organization into a single system.^{1,2,3,4} (Table 1) Other factors that can affect the potency of TCs include drug-related factors such as concentration/potency, total amount, duration, vehicle, concomitant use of occlusive dressings and intrinsic characteristics of the agent may contribute to potency variation. Patient-related factors are particularly important, including age, surface area, location of body surface, presence or absence of inflammation, integrity of skin.^{1,2} Notably, skin thickness differs in various body surfaces, increasing in thickness as follows: mucous membrane, scrotum, eyelids, face, chest and back, upper arms and legs, lower arms and legs, dorsa of hands and feet, palmar and plantar skin, and nails.⁵ Guidelines for appropriate TC use include the following: 1) dosing should not exceed twice daily; 2) application is limited to 1-2 weeks after which steroid holiday or pulse therapy can be done; and 3) high potency TC should be used only for short term flare control and on thick skin such as the palms and soles, moderate potency TC are limited to the trunk and extremities and low potency TC are applied on the face, neck, axilla and intertriginous areas.⁶ Steroid holiday or pulse therapy serves to decrease the incidence of tachyphylaxis, where the skin develops tolerance to the vasoconstrictive action of TC. Vasoconstriction usually occurs after 4 days of therapy, mandating a discontinuance of the drug after 4-7 days before it is restarted.⁷ Despite being effective, TCs are known to have adverse effects ranging from cutaneous reactions such as telangiectasia, skin atrophy, impaired wound healing, hirsutism, hypopigmentation, rosacea/perioral dermatitis, tinea incognito, acne flares, photosensitivity, purpura and xerosis. In

Ethiopia, Bilal et al. (2018) reported that most common adverse effects are allergic reactions (23.4%).⁸

There are currently no studies documenting the inappropriate use of topical corticosteroids in the Philippines, as of the authors' knowledge. Factors related to TC abuse include medical practice wise (misdiagnosis, poor doctor-patient communication, improperly filled prescriptions), pharmaceutical practice-wise (source of prescription, easy accessibility), media-wise (internet and social media consults, advertisements), and patient/consumer-wise (poor patient-doctor communication, poor patient education, usage of TC, economics).⁹ Other studies have been done in tertiary hospitals and centers^{9,10,11}, community pharmacies and cosmetic shops¹². Data collection was from 3 to 5 months^{9,10,11,12}. In our local pharmacies, TCs are touted to be as prescription-only drugs.¹³ However, there are anecdotal experiences of consumers availing of these drugs without prescriptions. In several online stores, consumers can procure Elica (mometasone furoate 0.1%, a class II potency), Cosmetique (betamethasone + erythromycin and hydrocortisone + erythromycin, a combination of TC and antibiotic), and LS BL cream (clobetasol propionate 0.05% + ketoconazole), among others, without a prescription.^{14,15} This unrestricted access puts uninformed patients at risk of adverse events, such as that of a locally reported case in 2019 of staphylococcal scalded skin syndrome.¹⁶ The infection was reportedly associated with topical-steroid induced iatrogenic Cushing syndrome, where LS BL cream was applied 3 times a day for 10 weeks. The patient unfortunately expired, prompting the Food and Drug Administration (FDA) to release an advisory reminding the public that pharmacies are not allowed to dispense TCs without a prescription, that these drugs have multiple side effects especially those related to the development of Cushing syndrome, and that the

purchase of medications in non-FDA-approved online stores are not recommended.¹⁷ In a subsequent FDA Advisory No. 2019-143, the agency stated that "... betamethasone 17-valerate and clobetasol propionate are not allowed to be part of cosmetic products as these are classified as drug products in the Philippines..." further emphasizing that the prolonged use of TC may cause adverse effects.¹⁸

Additionally, this study hopes to identify the possible factors associated with inappropriate TC use. In India, a third world country like the Philippines¹⁹, the reasons for inappropriate TC use range from the problems in the health system such as unavailability of dermatologists in their area, inadequate execution of laws, to lack of education of not only patients but undergraduate medical students or general practitioners as well.²⁰ By identifying then addressing these factors, adverse effects of inappropriate TC use will be prevented, ineffective and costly treatment will be avoided, and delay in diagnosis due to masking of steroids will be prevented. Moreover, this study will also contribute in improving patient care and active merchant surveillance. In a prevalence study by Sinha et al. addressing inappropriate TC use, treatment was focused not only on cessation of usage but also on tapering of TCs with less potent steroids. Patients presenting with stinging, pruritus and photosensitivity were given emollients and sunscreens.²¹ With that, the objectives includes: (1) to determine the prevalence of inappropriate use of topical corticosteroids by patients in an Out Patient Department (OPD), Department of Dermatology, tertiary hospital in Metro Manila. (2) to determine the association of inappropriate use of topical corticosteroids by patients and the following factors: clinicoepidemiologic factors (age, location, sex, educational attainment, employment status, civil status, primary dermatosis), accessibility factors (source of information of the product, source of the product

procurement, source of instructions on application), awareness factors (FDA advisory on TC use, prolonged TC use, adverse effects due to TC use) (3) to identify the reasons patients inappropriately use topical corticosteroids (4) to determine the incidence of adverse effects among patients with appropriate and inappropriate use of topical corticosteroids (5) to determine the association of appropriate and inappropriate use of topical corticosteroids to adverse effects.

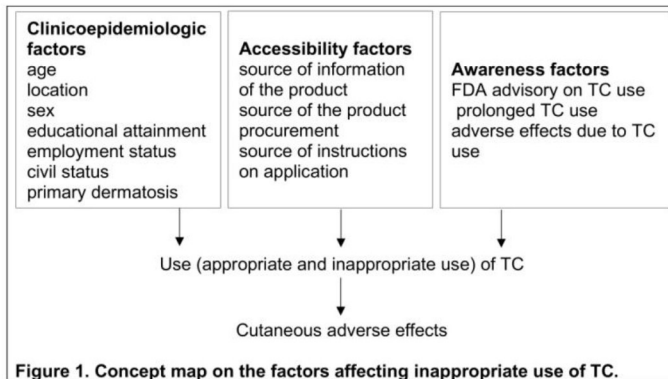
Materials and Methods

Study Design

This study is a prospective, cross-sectional observational study on the use of TCs of patients using an interview semi-structured questionnaire in the Dermatology OPD of a tertiary hospital in the Philippines for 5 months (September 2021-January 2022) utilizing both telemedicine and face-to-face (FTF) consults via convenience non-probability sampling.

The conceptual framework (*figure 1*) presented the clinicoepidemiological characteristics of those with inappropriate TC use was hypothesized to be in the age range of 19 to 29, single, females who were students who reached any college level or finished with a college degree.^{9,10,11,12} In terms of location, a higher occurrence of inappropriate use may be seen among those residing outside of Metro Manila possibly due to less strict regulations as compared to those from Metro Manila. In terms of accessibility factors, majority of inappropriate users may have sourced information from relatives and friends, while appropriate users are hypothesized to have received information from doctors. In terms of procurement, inappropriate users may have probably purchased the items from online stores, or received from relatives and friends. In terms of awareness factors, both user types may vary on awareness of corresponding FDA advisories on

TCs and the associated adverse effects.²² The incidence of adverse effects is expected to occur more with those who used TC inappropriately.



Operational Definition of Variables

I. Factors associated with TC use

a. Dependent Variable

- i. **TC use** pertains to the behavior of application of TC for the dermatoses for which the patient is currently seeking consult, (a) **Inappropriate use** – use of TC that is self-prescribed (regardless of duration of usage) OR prescribed by a doctor but used longer than prescribed or used for more than 2 weeks without follow-up consult (b) **Appropriate use** – use of TC which is use of TCs not falling under inappropriate use criteria.

b. Independent Variables

- i. **TCs** are topical forms of corticosteroids in pure or with combination will be classified based on TC, percentage and vehicle into the following: (1) ultrapotent (ie. clobetasol propionate, halobetasol propionate), (2) high (ie betamethasone propionate, mometasone furoate), (3) moderate (ie. triamcinolone acetonide) and (4) low potency (ie. hydrocortisone acetate, desonide), as well as brand. Drug factors such as frequency of application, longest continuous duration

of application, applied with occlusion and patient factors such as primary area (mucous membrane, scrotum, eyelids, face, chest or back, upper arms and legs, lower arms and legs, dorsa of hands and feet, palmar and plantar skin, nails and others) and surface area applied using palm method.

ii. Clinicoepidemiologic factors include (a)

- Age** – It will be categorized into the following: 0 to 9 years, 10 to 19 years, 20 to 29 years, 30 to 39 years, 40 to 49 years, 50 to 59 years, above 60 years.
- (b) **Sex**– It will be categorized into (1) male and (2) female.
- (c) **Location**– The primary address of the patient will be categorized into (1) within Metro Manila and (2) outside Metro Manila.
- (d) **Educational attainment** – it will be categorized into (1) no formal education or stopped at any grade school level, (2) stopped at any high school level (3) reached any college level or finished with a college degree.
- (e) **Employment status**– it will be categorized into (1) unemployed, (2) student, (3) employed.
- (f) **Civil status**– it will be categorized into (1) single/separated/widowed and (2) married/ live-in.
- (g) **Primary dermatosis**– it will be categorized into (1) infectious dermatoses (fungal, bacterial, viral, arthropod) (2) dermatitis (3) pigmentary dermatoses (4) acneiform and (5) others.

- iii. **Accessibility factors** include (a) **source of information of the TC**– these will be categorized into (1) advertisement (online, radio, TV, others) (2) relatives and friends, (3) prescribed by doctor (for current disease, for previous disease) (4) prescribed by dermatologist (for current

disease, for previous disease) (5) suggested by paramedical (nurse, pharmacist) (6) Others. (b) **Source of the TC procurement-** these will be categorized into (1) pharmacy (prescription-only, over-the-counter), (2) in stores, (3) online (4) relatives and friends (5) doctors (6) others. (c) **Source of instructions on application of TC-** these will be categorized into (1) label on box/container (2) relatives and friends (3) prescribed by non-dermatologist (4) prescribed by dermatologist (5) suggested by paramedical (nurse, pharmacist) (6) others.

iv. Awareness factors include (a) **FDA advisory on TC-** This pertains to the awareness of the patients on the existence of the FDA advisory on TC use (FDA Advisory 2019-388: Incorrect use of anti-fungal corticosteroid combination therapy). (b) **TC use should not be used for prolonged periods-** This pertains to the awareness of the TC cannot be used for prolonged periods. (c) **TC use can result into adverse effects-** This pertains to the awareness of the patients on the possibility of adverse effects with TC use. These will be categorized into yes or no.

II. Reason includes the reasons for TC use and the causes that led to TC use.

III. Adverse effects (AE) pertains to the unwanted or harmful reaction experienced following the administration of a drug or combination of the drug that manifests cutaneous noted to be present upon patient examination (hypopigmentation, striae, skin atrophy, allergic contact dermatitis, tinea incognito, acne flares, telangiectasia, xerosis, photosensitivity, purpura and others).

Patient Recruitment

Inclusion criteria of the study were patients who sought consult in the Dermatology OPD, while for patients who are incapacitated or those unable to give consent due to developmental, physical or mental inability to comprehend, the caregiver/legally authorized representative (LAR) may answer the survey. Minors may also give assent. Exclusion criteria included those who previously answered the survey but were unreachable by audio call for interview during the research period. Withdrawal criteria of the study included those who withdrew from the study and were unable to complete the interview.

Sample size computed was 255 and this was based on the following assumptions: prevalence of inappropriate use of TCs of 79%⁸, Z score of 1.96 and margin of error of 0.05. Assuming a 10% non-response rate, the total sample size was 286.

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

where, n= the required sample size, P=the prevalence of inappropriate use of TCs, Z= Z score at 95% confidence interval=1.96, E = the margin of error=0.05

Materials and Procedures

After their dermatologic consultation, patient's consent to participate in the study was obtained via FTF or text message. They were then interviewed by the investigators using a pre-tested semi-structured questionnaire (*Figure 2*) to collect quantitative and qualitative data. De-identification was done. In place of patient's names, each patient was assigned a 4-digit ID number by the investigator. The investigator then confirmed TC use by either of the following: (1) name of the product, (2) prescription, (3) seeing the used product, or (4) photos or packets of community-available products (printed and online) (*Figure 3*).

For any adverse effects on the skin, the patient or caregiver/LAR was asked if there was presence of adverse effects and was shown photos of the different cutaneous adverse effects. If the patient presents with adverse effects located on the applied area, identification of the adverse effect and photo documentation of the affected body part was done with the consent/assent for the photograph. At the end of the interview, the patient was advised to discontinue or taper the use (if applicable) of the corresponding TC. Patient education was given regarding the development of possible adverse effects, the need to regularly seek consult for usage, the appropriate duration of use, and the need for follow-up with their dermatologist. If with adverse effects, they were also referred or treated accordingly. Permission to conduct this study was approved by the Research Ethical Board.

Demographic Characteristics (DK) of patient

DK1. Gender: ☐ Male ☐ Female
 DK2. Age of the patient (in year): _____
 DK3. Date of Birth (Month/Day/Year): _____

DK4. Address/Residence (Household): _____
 DK5. Educational Attainment: ☐ College/Vocational ☐ High School ☐ Elementary/No formal education
 DK6. Employment Status: ☐ Unemployed ☐ Student ☐ Employed
 DK7. Civil Status (Marital Status): ☐ Single/Separated ☐ Divorced ☐ Married ☐ Widowed

DK8. Disposition/Physician's Recommendation (Based from Medical History Chart, on applied area): _____

Confirmation of screening (CS)

CS1. Confirmation of topical corticosteroids and its combination: ☐ Yes ☐ No
 CS2. Use of topical corticosteroids: ☐ Misuse ☐ Self prescribed ☐ Prescribed but used longer than prescribed or chronic use (more than 2 weeks) with no follow-up ☐ Proper use

History of Topical Corticosteroids (HC)

HC1. Topical corticosteroid used (with %): _____
 HC2. Frequency of application (How often): _____
 HC3. Longest continuous duration of application: _____
 HC4. Drug in Combination (if any, with %): _____
 HC5. Applied with occlusion (if any, how): _____
 HC6. Area applied: _____
 HC7. Surface area: _____
 HC8. Mucous membrane: _____

Access (A)

A1. How did you learn of the topical corticosteroid? ☐ Advertisement ☐ Online ☐ Radio ☐ TV ☐ Others: _____
 A2. Where did you get the topical corticosteroid? ☐ Prescription only ☐ Over the counter ☐ Internet ☐ Informal (e.g., friends, family, etc.) ☐ Others: _____

Awareness (AW)

AW1. Did you know that the FDA (Food and Drug Administration) has released an advisory (2023-388) on October 26, 2023 on to avoid using (anti-fungal corticosteroid) products without proper consultation from a dermatologist, to buy medicines in FDA-licensed drug stores and avoid buying online? ☐ Yes (Ch) ☐ No (Hnd)
 AW2. Did you know that you cannot apply topical corticosteroids for prolonged periods? ☐ Yes (Ch) ☐ No (Hnd)
 AW3. Did you know it can result into side effects/adverse drug? ☐ Yes (Ch) ☐ No (Hnd)

Rationale of use (R)

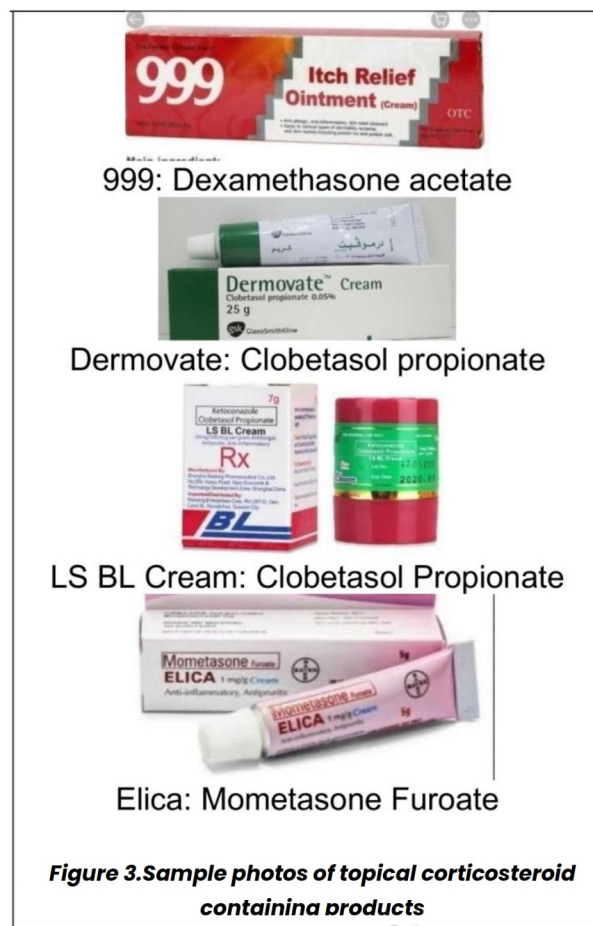
R1. Reason for use of Topical Corticosteroids and its combination (Do/Don't and body planning part): _____

Adverse Effect (AE)

AE1. Did you have any adverse effect? ☐ Yes ☐ No
 AE2. If yes, what cutaneous adverse effect happened? ☐ Itching/Pruritus ☐ Skin atrophy ☐ Hypopigmentation ☐ Telangiectasia ☐ Acne flares ☐ Photosensitivity ☐ Purpura ☐ Xerosis ☐ Allergic contact dermatitis ☐ Striae ☐ Others: _____

AE3. Photographed File name (ID number_ASRX, ie. 001_ASR1): _____

Figure 2. Data collection form



Statistical Analysis

Data from FTF and telemedicine consults were collected. The data was inputted into the Microsoft Excel 2016 for storage. Missing data was excluded. The data was processed using SAS Enterprise Guide for descriptive and inferential statistics. Descriptive statistics was used to identify the prevalence of inappropriate use of TC, the frequency of the drug and patient factors, factors influencing behavior, and adverse effects. Moreover, the frequency of the product per brand and where it was procured was also obtained. Logistic regression was used to determine the factors (clinicoepidemiologic, access, awareness) that influence inappropriate TC use, and the association of inappropriate TC use to AEs. Statistical significance was set at <0.05.

RESULTS

Eight hundred one patients were interviewed, 56.53% (147 out of 260 TC users) of whom inappropriately used TC (Figure 4). These patients used TCs once a day (n=74) to twice a day (n=65) for 1 day to 2 weeks (n=74) without occlusion (n=140). Among patients who inappropriately used TC, clobetasol propionate,

and ultra high potency TC in combination with ketoconazole (LS BL cream) were the most commonly used combination (Table 2), usually procured over-the-counter in pharmacies (Table 3). For patient factors, TCs were commonly applied on lower arms and legs, upper arms and legs and face, on around <1-1% body surface area for inappropriate use. (Table 2).

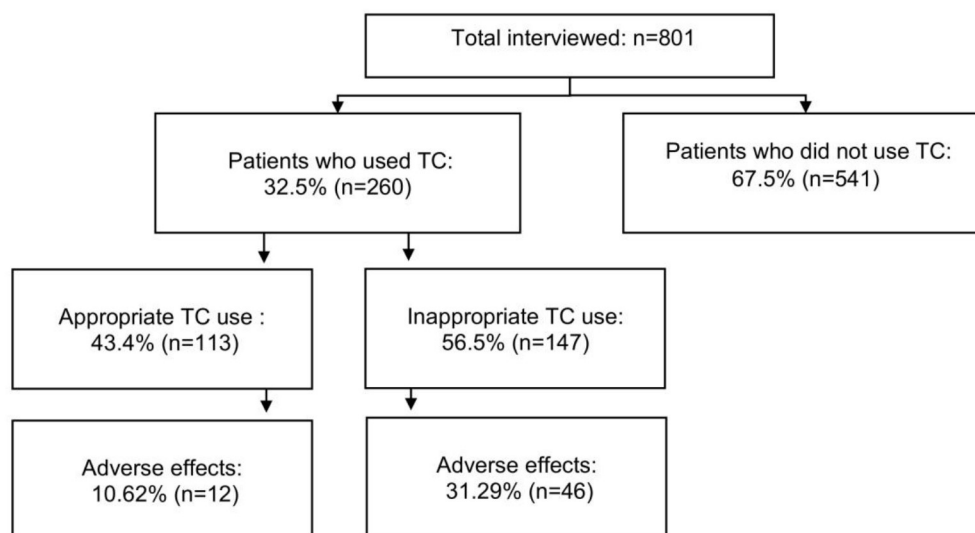


Figure 4. Prevalence of use of TC and Incidence of AE among patients who inappropriately use TC

Factors Associated with Inappropriate Topical Corticosteroid Use by Patients

Clinicoepidemiologic factors were not associated with inappropriate use of TC except for the primary dermatosis. Accessibility and awareness factors were associated with inappropriate TC use. The odds that a person experienced dermatitis inappropriately used TC was 2.82 (95% CI: 1.7, 4.7) times more likely than a person with other dermatoses. A person with acneiform dermatosis inappropriately used TC 82.6% (95% CI: .1, .4) less often than a person with other dermatosis (Table 4).

In terms of accessibility, as compared to a person whose source of information were dermatologists, the odds that a person whose source of information of the product were relatives and friends was 437 (95% CI: 25.9, >1000) times more likely to inappropriately use TC. While the odds that a person whose source of information was advertisement was 74 (95% CI: 3.9, >1000) times more likely and paramedical was 41 (95% CI: 1.9, 902.2) times more likely to inappropriately use TC as compared to a person whose source of information of the product were dermatologists. The source of information prescribed by doctors (dermatologist and non dermatologist) were not significantly associated with inappropriate use (Table 4).

For the source of product procurement, the odds that a person whose source of TC were relatives/friends inappropriately used TC was 60 (95% CI: 3.1, >1000) times more likely as compared to a person whose source of TC were doctors. Those who procured from the pharmacy (over the counter) were 24.6 (95% CI: 8.7, 69.8) times more likely to inappropriately use TC. Those who procured from stores were 10.6 (95% CI: 2.3, 49.6) times more likely and those who procured online were 9.8 (95% CI: 1.4, 70.7) times more likely to inappropriately use TC as compared to those whose source of TC were doctors (*Table 4*).

The odds that a person whose source of instructions on application of TC were from relatives/friends is 337 (95% CI: 19.8, >1000) times more likely to inappropriately use TC as compared to a person whose source of instructions on application of TC were dermatologists. The odds that a person whose source of instructions on application of TC was only from his knowledge (others) is 193 (95% CI: 11.1, >1000) times more likely to inappropriately use TC as compared to a person whose source of instructions on application of TC were dermatologists. The odds that a person whose source of instructions on application of TC were only on label on box/container is 43 (95% CI: 1.98, 945.9) times more likely to inappropriately use TC as compared to a person whose source of instructions on application of TC were dermatologists. The odds that a person whose source of instructions on application of TC were from paramedical suggestions is 37 (95% CI: 1.6, 858.5) times more likely to inappropriately use TC as compared to a person whose source of instructions on application of TC were dermatologists (*Table 4*).

In terms of awareness factors, the odds that a person who was not aware on FDA advisory on TC inappropriately used TC was 2.1 (95% CI: 1.2, 3.6) times more likely as compared to a person who

was aware on FDA advisory on TC. The odds that a person who was not aware that TC cannot be applied for prolonged periods inappropriately used TC was 5.5 (95% CI: 3.2, 9.3) times more likely as compared to a person who was aware that TC cannot be applied for prolonged periods. The odds that a person who was not aware that TC use can result to AE inappropriately used TC was 4.5 (95% CI: 2.6, 7.7) times more likely as compared to a person who was aware that TC use can result to AE (*Table 4*).

Reasons Patients Inappropriately Used Topical Corticosteroids

The reasons patients inappropriately used TC were the following: suggestion of family, friends, pharmacists and even celebrities (n=32) to use the medication since it has been effective in their experience and the treatment needed for their disease (n=28). Other reasons for TC use include effect of medication (n=20) on decreasing pruritus, erythema and improving hair growth, unable to consult (n=17), general sentiment of wanting to get better (n=16), effectiveness of medication (n=10) as it has previously treated disease, due to being advised by the doctors (n=7), financial constraints (n=7), worsening disease (n=7) where in there is recurrence or rebound effect after application and lastly, convenience (n=3). (*Table 5*)

Incidence of Adverse Effects Among those who Use Topical Corticosteroids

The incidence of AE among all patients who used TC is at 22.3% (n=58 out of 260) (*Figure 4*). Hypopigmentation (n=16), skin atrophy (n=8), striae (n=7) and allergic contact dermatitis (n=7) were the most common AE (*Figure 5*) among those who used TC (*Table 6*). Among those who inappropriately used TC, hypopigmentation was the most common adverse effect (*Table 6*).



Figure 5. Photos of cutaneous adverse reactions documented in the study

Association of Inappropriate Topical Corticosteroid Use with Incidence of Adverse Effects

The odds that a person inappropriately used TC had an AE was 3.8 (95% CI: 1.9, 7.7) times more likely as compared to a person who had appropriately used TC (Table 7). This was reflected in the incidence of AE that slightly higher among patients who inappropriately use TC at 31.29% (n=46 out of 147) (Figure 4) as compared to those who appropriately use TC at 10.62% (n=12 out of 113) (Figure 4).

DISCUSSION

For the first objective, the overall prevalence of inappropriate TC use in our study was as high as 18.35% (147 out of 801) while in other studies from India and Ethiopia had ranged from 3.76% to 11.77%^{10,20}. It can be considered that this is possibly an effect of the pandemic due to the limited access to FTF consults.

In a study by Lao et al (2018), 64% of patients practice self-medication with topical agents and the most common agents used were combinations of corticosteroids, antibiotics and antifungals at 31% and pure corticosteroids at 11%²³.

In our study, 51% applied pure corticosteroids while 39% were in combination with ketoconazole as the most commonly used combination for patients who have inappropriately used TC. Similarly, the most common inappropriately used TC included clobetasol propionate (50%)²⁰ which is an ultra-high potency applied once a day (52-67.8%)^{8,10,20,24} for 1 day to 2 weeks as compared to others studies for less than a month up to a year^{8,10,20,24}. The lower extremities was the most common site of application followed by the face covering <1-1% body surface area while other studies state the face^{8,20,24} as the most common location covering up to around 9% of the

body surface area.²¹ The combination of clobetasol and ketoconazole- LS BL Cream was the most common brand used by patients who inappropriately used TC. This was commonly procured over-the counter in pharmacies (n=41), stores (n=8) and relative and friends (n=6). The next brands were unrecalled (n=25) procured from the pharmacy (n=14) and doctors (n=22) then followed by Dermovate and Elica commonly procured over-the counter and prescription in pharmacies (n=10).

For the second objective, the clinicoepidemiologic characteristics in our study was similar to previous studies from India and Ethiopia. Of those who inappropriately used TC, majority belonged to 20 to 29 years old age group^{8,10,20,24} who were single^{8,10,20,24} female^{8,10,24} college graduates²⁰. Though in our study, those employed living in the metropolitan area were the majority who inappropriately used TC as compared to other literature presented that majority of the employment status were of students^{10,20,24}. The clinicoepidemiologic factors²² in our study were not significantly associated with inappropriate TC use. Notably, Bilal stated a significant association was established between over-the-counter use (inappropriate use) and educational attainment, with an increasing use among those of higher educational background⁸. This is probably due to the ability to purchase of the group in our study as they are employed with college graduates who are single who also gave the reason that they were unable to consult due to the pandemic and work. The only significantly associated clinicoepidemiologic factor is the type of dermatoses, specifically dermatitis type of diagnosis. This is possibly explained by TC as the treatment used for dermatitis cases such as seborrheic dermatitis, atopic dermatitis, hand dermatitis to name a few. In other studies, users consume these TCs predominantly for dermatophytosis treatment.^{10,20}

In the United Kingdom (UK), there are three main sources of drugs namely prescription-only medicines, over-the-counter drugs under the supervision of a pharmacist, and widely-available drugs in shops and hotels.²⁵ On the other hand In India, majority of inappropriate users were able to procure TCs through over-the- counter means, as well as from other family members or peers^{10,20,24}. Accessibility to the drug is a concern as the source of information, procurement and instruction consistently show relatives and friends as to have a significant association with inappropriate use of TC as compared to the source from doctors or dermatologists. The suggestion of family, friends, pharmacists and endorsers is also the most common reason for inappropriate TC use as the medication was effective in their experience. Thus, it is crucial to note that the family often functions as a body of self-perpetuated knowledge²⁶. This was consistent with other significant associations in the study including the pharmacy (over the counter) and paramedical (nurses and pharmacist) as a source of accessibility as compared to doctors or dermatologists. Another study also states that the major factor responsible for topical corticosteroid abuse in India is the fact that topical corticosteroids are available over-the-counter²⁰. The vital part of having over-the-counter is dependent on the pharmacist's knowledge of the indications and contraindications and ability to appropriately prescribe. If there is a lapse in the consumers and pharmacist knowledge, topical corticosteroids should be kept as a Prescription-only medication.

Other significantly associated accessibility factors to inappropriately use TC as compared to the source from doctors or dermatologists include advertisement as a source of information, stores and online as a source of procurement and their own knowledge and labels as the source of instruction. For advertisements, stores, online and to their own knowledge which were seen as a

source in health care information in the decision to self-medicate. Online stores are also associated with inappropriate TC use and this is driven by the reasons of convenience. As label on the box/container as a source of instruction is associated with inappropriate use, a way to address the knowledge of the consumers includes the example of the Swedish National Board of Health and Welfare on labelling instructions (including purpose of the drug, recommended dosage, frequency, period, and warnings).²⁶

The lack of awareness in regard to the FDA advisory is associated with inappropriate TC use. The FDA has made efforts through posting advisories such as the FDA advisory 2019-388 on the incorrect use of anti-fungal corticosteroid combination therapy¹⁷ which reflects that those who are not aware on FDA advisory inappropriately uses TC 2.1 times more likely as compared to a person who is aware on FDA advisory. This shows that the role of regulation may be vital to decreasing inappropriate use of TC. The FDA is able to do surveillance as they are able to release other advisories on other TC but release of these advisories may not be reaching some of the consumers as they are only online and tighter regulations may be needed. In terms of awareness on the use and adverse effects of TC, 73.5% who inappropriately applied TC were not aware that it should not be applied for prolonged periods but even more (76.19%) were not aware that TC use can result into adverse effects. Being unaware of this, patients were at a 4-5 fold risk of inappropriately using TC as compared to TC users who were aware. Similarly in India, Mahar noted that 96.8% of patients using TCs were unaware about the adverse effects, Awareness may be increased through agency advisories and established guidelines on judicious TC use and AEs that may result from inappropriate use. Awareness of consumers is critical in the addressing inappropriate TC use.

For the third objective, majority of the patient's reason for inappropriate use of TC was due to the suggestion of family, friends, pharmacists and even celebrities to use the medication since it has been effective in their experience consistent with the majority of the source of accessibility, followed by the treatment needed for their disease. An anecdote states that the use of clobetasol and ketoconazole for seborrheic dermatitis on the face has been used in their community as it has been effective. The effect of the medication such as decreasing pruritus, erythema and improving hair growth was also a reason for use of TC. Other reasons for TC use include general sentiment of wanting to get better, unable to consult due to the pandemic and work, effectiveness of medication as it has previously treated their disease. But at the same time, some experience worsening disease which prompted them to continue the use of TC wherein there could be recurrence or rebound effect after application. Financial constraints with the belief that the medication is the first aid since consulting would mean additional costs such as transportation and additional tests. This is where the benefit to making only topical hydrocortisone 1% an over-the-counter drug include consumers savings in time costs (travel, waiting, and consultation time) and consumer savings in money costs (travelling expenses and prescription charges)²⁵. Some considered convenience of using the medications especially those available online or in stores without having to consult. This was supported by the odds that a person whose source of TC were online would inappropriately used TC 9.8 times more likely as compared to a person whose source of TC were doctors. The reasons for other studies was different namely from the purpose of fair complexion, beautification purposes to dermatologists not being available which are not mentioned in our study.

For the last objectives, the incidence of AE among all patients who used TC is at 22.3% (n=58 out of 260) (Table 7). Hypopigmentation, striae and skin atrophy were the most common adverse effects since the primary type of dermatosis associated was dermatitis. While other literature cites Allergic reactions: (23.4%)⁸ and Tinea incognito: 171 (52.77%)²⁰ to be the most common side effects since the most common dermatosis seen were fungal infections. The inappropriate TC use should be prevented as there was a 3.8 times likelihood to develop adverse effects as compared to a person who has appropriately used TC. Similarly, Bilal et al. (2018) has established a three- to five-fold risk of AEs for those who sourced out information regarding TCs through peers⁸ Hence, the factors associated with inappropriate TC use should be addressed to decrease the likelihood of adverse effects from occurring.

In summary, 56.53% inappropriately used TC and this was associated with a diagnosis of dermatitis, lack of knowledge regarding its adverse effects especially after prolonged use, and self-medication upon recommendation of family and friends. Revealing that accessibility and awareness factors were both associated with behavior of use of TC. Hypopigmentation was the most common AE documented. There is 3.8 times likelihood for a person who has inappropriately used TC to have an AE as compared to a person who has appropriately used TC.

CONCLUSION

Based on our results on awareness, there may be lapse in the consumers and pharmacist knowledge on TC use. Hence it is advisable to document this and possibly keep topical corticosteroids as a prescription-only medication. As the most common type are the ultrapotent class of TC, FDA should find other avenues to disseminate information for consumers and have tighter regulations by continuously monitoring

online shops, stores and pharmacies. Advertisements/ labels should include proper information as it is a source of information that is associated with inappropriate TC use.

There is a need to create awareness and educate consumers on TC use. We can remind patients to inform their family and friends as it appears to be a major factor in the inappropriate use of TC. For all cases, especially dermatitis type of cases, as doctors we should ensure to explain the TC use. In conclusion, as a dermatologist, there is a need to educate the general public regarding proper TC use. Patient encounters at the clinic may be a good opportunity to reinforce guidelines on the use of TC.

LIMITATIONS AND RECOMMENDATIONS

It should be noted that the prevalence was based on patients at the out-patient dermatology clinic in a tertiary hospital. With that, it may or may not accurately reflect the community data especially for those who consult are those probably with adverse effects or with no resolution with the use of TCs. It may not get the prevalence of those who used TCs with resolution of cutaneous problems. This study limits the questionnaire to patients and will not include other contributing factors such as pharmacist, and doctors or medical student's knowledge of prescribing TC. Selection bias was dependent on the availability of the patient. To address this, the patients who were unavailable were contacted again during the data collection period. Information bias may be present because the informed consent/assent form contained the mention of TC and the questionnaire contained AE. To prevent this, the patients were initially asked if they applied any medication and if they could name the medication and reasons of use remained to be an open-ended question. Another recommendation would include documentation of systemic side effects such as cushingoid features (Hirsutism, Buffalo hump) and cataracts.

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Appendix

Table 1. World Health Organization (WHO) Classification of Topical Corticosteroids³ – classification of potency of topical corticosteroids

United Kingdom and France's Classification	United States' classification	
Ultra high potency TCs	Group I	- clobetasol propionate cream (0.05%) - diflorasone diacetate ointment (0.05%) - halobetasol propionate ointment (0.05%) ^a - halobetasol propionate cream (0.05%) ^{a,b} - halobetasol propionate lotion (0.05%) ^b
High potency TCs	Group II	- amcinonide ointment (0.1%) - betamethasone dipropionate ointment (0.05%) - desoximetasone (cream or ointment) (0.025%) - fluocinonide (cream, ointment, or gel) (0.05%) - halcinonide cream (0.1%)
	Group III	- netamethasone dipropionate cream (0.05%) - betamethasone valerate ointment (0.1%) - diflorasone diacetate cream (0.05%) - triamcinolone acetonide ointment (0.1%) - mometasone furoate ointment (0.1%) ^{a,b} - fluticasone propionate ointment (0.005%) ^a
Moderate potency TCs	Group IV	- desoximetasone cream (0.05%) - fluocinonide acetonide ointment (0.025%) - fluocinolone acetonide cream (0.02%) ^a - hydrocortisone valerate ointment (0.2%) - triamcinolone acetonide cream (0.1%) - betamethasone valerate foam (0.12%) ^a - clocortolone pivalate cream (0.1%) ^a - flurandrenolide ointment (0.05%) ^a
	Group V	- betamethasone dipropionate lotion (0.02%) - betamethasone valerate cream (0.1%) - fluocinonide acetonide cream (0.025%) - hydrocortisone butyrate cream (0.1%) - hydrocortisone valerate cream (0.2%) - triamcinolone acetonide lotion (0.1%) - triamcinolone acetonide cream (0.1%) - prednicarbate cream (0.1%) ^a
Low potency TCs	Group VI	- betamethasone valerate lotion (0.05%) - desonide cream (0.05%)

		• fluocinonide acetone solution (0.01%) • alclometasone dipropionate ointment (0.05%) ^a • alclometasone dipropionate cream (0.05%) ^a
	Group VII	• dexamethasone sodium phosphate cream (0.1%) • hydrocortisone acetate cream (1%) • methylprednisolone acetate cream (0.25%) • topicals with flumethasone and prednisolone ^a

^a Del Rosso, J., & Friedlander, S. F. (2005). Corticosteroids: Options in the era of steroid-sparing therapy.²

^b Horn, E., Domm, S., Katz, H., Lebwohl, M., Mrowietz, U., & Kragballe, K. (2010). TCs in psoriasis: strategies for improving safety.⁴

Table 2. Frequency of drug and patient factors with its corresponding TC use.

Variable Category	Appropriate use of TC (%) n=113	Inappropriate use of TC (%) n=147
Drug factors		
TC		
clobetasol propionate 0.05%	47.79	61.22
mometasone furoate 0.1%	13.27	10.88
betamethasone dipropionate 0.05%	9.73	6.8
hydrocortisone 1%	7.08	6.12
betamethasone valerate 0.05%	7.08	4.08
Others	15.04	10.88
Combination		
None	89.38	51.02
Ketoconazole	0	39.46
Petroleum Jelly	1.77	2.04
Gentamycin	1.77	1.36
Calcipotriol	1.77	1.36
Isoconazole nitrate	1.77	1.36
others	3.54	3.4
Vehicle		
cream	45.13	64.63
ointment	43.36	32.65
lotion	10.62	2.04
solution	0.88	0
gel	0	0.68
Potency		
Ultra high potency topical corticosteroids	53.1	64.63
High potency topical corticosteroids	23.01	19.05
Moderate potency topical corticosteroids	12.39	8.84
Low potency topical corticosteroids	11.5	7.48
Brand		
Unrecalled	53.1	17.01
LS BL Cream (Shanghai Baolong Pharmaceutical)	0	39.46
Dermovate (GSK)	14.16	10.2
Elica (Bayer)	6.19	8.84
Frostlike (Tianjin Pacific pharmaceutical Ltd.)	1.77	4.76
Others	24.78	19.73
Frequency (per day)		
once a day	18.58	46.94
twice a day	75.22	44.22
more than twice a day	3.54	5.44
Duration		
1 day to 2 weeks	76.99	50.34
3 weeks to 1 month	13.27	15.65
6 weeks to 3 months	6.19	12.24
4 months to 6 months	0.88	5.44
7 months to 9 months	0	0.68
10 months to 1 year	0.88	7.48
More than 1 year	1.77	8.16
Occlusion		
NO	92.92	95.24
YES	7.08	4.76
Patient factors		
Area applied		
Lower arms and legs	22.12	21.77
Face	18.58	20.41
Upper arms and legs	15.04	21.09
Chest or back	22.12	14.29
Dorsa of hands and feet	7.96	9.52
Others	14.16	12.93
Surface area		
<1% to 1%	37.17	40.82
2% to 4.5%	23.89	23.13
5% to 9%	15.93	9.52
10% to 18%	4.42	8.16
19% to 36%	4.42	6.8
37% to 72%	9.73	4.08
73% to 95%	4.42	7.48

Table 3. Frequency of brands of TC and where it was procured

Brand (Company)	Source of product procurement (number)						
	Pharmacy (Prescription only)	Pharmacy (OTC)	Stores	Online	Relative and friend	Doctor	Others
Unrecalled	40	14	1	2	5	22	1
LS BL Cream (Shanghai Baolong Pharmaceutical)	1	41	8	2	6	0	0
Dermovate (GSK)	16	10	0	1	2	0	2
Elica (Bayer)	8	8	0	0	1	3	0
Frostlike (Tianjin Pacific pharmaceutical ltd.)	1	1	4	2	0	1	0
Betnovate (GSK)	4	2	0	0	0	1	0
Daivobet (Leo Pharmacy)	2	2	0	0	0	2	0
Glevate (Glenmark)	0	0	0	0	0	3	2
Halovate (Glenmark)	1	2	0	0	0	1	0
Travacort (Leo Pharmacy)	3	1	0	0	0	0	0
Others	15	6	2	1	1	6	0

Table 4. Logistic regression of factors vs appropriate and inappropriate TC use

Variable Category	Total (n)	No use of TC (frequency, % n=541)	Appropriate use of TC (frequency, % n=113)	Inappropriate use of TC (frequency, % n=147)	Odds Ratio* (CI)
Clinicoepidemiologic factors					
Age					
50 to 59 years	68	43 (7.95%)	10 (8.85%)	15 (10.20%)	1.296 (.5, 3.6)
above 60 years.	93	58 (10.72%)	15 (13.27%)	20 (13.61%)	1.281 (.5, 3.4)
10 to 19 years	91	59 (10.91%)	13 (11.50%)	19 (12.93%)	1.196 (4, 3.2)
40 to 49 years	91	58 (10.72%)	17 (15.04%)	16 (10.88%)	1.025 (.4, 2.8)
0 to 9 years	37	26 (4.81%)	4 (3.54%)	7 (4.76%)	1
30 to 39 years	137	91 (16.82%)	22 (19.47%)	24 (16.33%)	0.98 (.4, 2.5)
20 to 29 years	284	206 (38.08%)	32 (28.32%)	46 (31.29%)	0.829 (.3, 2.0)
Sex					
Female	491	330 (61%)	71 (62.83%)	90 (61.22%)	1.01 (.7, 1.5)
Male	310	211 (39%)	42 (37.17%)	57 (38.78%)	1
Location					
Outside Metro Manila	266	177 (32.72%)	38 (33.63%)	51 (34.69%)	1.093 (.7, 1.6)
Within Metro Manila	535	364 (67.28%)	75 (66.37%)	96 (65.31%)	1
Educational attainment					
High school level	176	113 (20.89%)	24 (21.24%)	39 (26.53%)	1.208 (.7, 2.2)
No formal education/ grade school	103	70 (12.94%)	13 (11.50%)	20 (13.61%)	1
College level	522	358 (66.17%)	76 (67.26%)	88 (59.86%)	0.86 (.5, 1.5)
Employment status					
Unemployed	255	161 (29.76%)	44 (38.94%)	50 (34.01%)	1
Student	198	137 (25.32%)	23 (20.35%)	38 (25.85%)	0.893 (.5, 1.4)
Employed	348	243 (44.92%)	46 (40.71%)	59 (40.14%)	0.782 (.5, 1.2)
Civil status					
Married/ live-in.	233	145 (26.8%)	43 (38.05%)	45 (30.61%)	1
Single/separated/widowed	568	396 (73.2%)	70 (61.95%)	102 (69.39%)	0.83 (.6, 1.2)
Primary Dermatitis					
Dermatitis	140	49 (9.06%)	47 (41.59%)	44 (29.93%)	2.82* (1.7, 4.7)
Others	285	179 (33.09%)	49 (43.36%)	57 (38.78%)	1
Infectious	184	142 (26.25%)	6 (5.31%)	36 (24.49%)	796 (.5, 1.3)
Pigmentary	38	27 (4.99%)	9 (7.96%)	2 (1.36%)	.233 (.1, 1.0)
Acneiform	154	144 (26.62%)	2 (1.77%)	8 (5.44%)	.174* (.1, .4)

Accessibility factors					
Source of information					
Relatives and friends	79	<Not Applicable>	0	79 (53.74%)	437.795* (25.9, >1000)
Advertisement	13		0	13 (8.84%)	74.342* (3.9, >1000)
Suggested by paramedical	7		0	7 (4.76%)	41.301* (1.9, 902.2)
Others	1		0	1 (0.68%)	8.27 (.1, 777.6)
Prescribed by non dermatologist	24		13 (11.5%)	11 (7.48%)	2.346 (.97, 5.7)
Prescribed by dermatologist	136		100 (88.5%)	36 (24.49%)	1
Source of the product procurement					
Relatives and friends	15	<Not Applicable>	0	15 (10.2%)	60.843* (3.1, >1000)
Pharmacy, over-the-counter	87		6 (5.31%)	81 (55.1)	24.613* (8.7, 69.8)
In stores	15		2 (1.77%)	13 (8.84%)	10.6* (2.3, 49.6)
Online	8		1 (0.88%)	7 (4.76%)	9.815* (1.4, 70.7)
Doctors	39		26 (23.01%)	13 (8.84%)	1
Others	5		4 (3.54%)	1 (0.68%)	0.654 (.1, 5.5)
Pharmacy, Prescription-only	91		74 (65.49%)	17 (11.56%)	0.461 (.2, 1.1)
Source of instructions on application of TC					
Relatives and friends	58	<Not Applicable>	0	58 (39.46%)	337.481* (19.8, >1000)
Others	33		0	33 (22.45%)	193.233* (11.1, >1000)
Label on box/container	7		0	7 (4.76%)	43.26* (1.98, 945.9)
Suggested by paramedical (nurse, pharmacist)	6		0	6 (4.08%)	37.492* (1.6, 858.5)
Prescribed by non-dermatologist	23		14 (12.39%)	9 (6.12%)	1.89 (.8, 4.7)
Prescribed by dermatologist	133		99 (87.61%)	34 (23.13%)	1
Awareness factors					
FDA advisory on TC					
No	178	<Not Applicable>	67 (59.29%)	111 (75.51%)	2.117* (1.2, 3.6)
Yes	82		46 (40.71%)	36 (24.49%)	1
Awareness that TC cannot be applied for prolonged periods					
No	146	<Not Applicable>	38 (33.63%)	108 (73.47%)	5.466* (3.2, 9.3)
Yes	114		75 (66.37%)	39 (26.53%)	1
TC use can result into adverse effects					
No	159	<Not Applicable>	47 (41.59%)	112 (76.19%)	4.494* (2.6, 7.7)
Yes	101		66 (58.41%)	35 (23.81%)	1

*significantly affects the behavior of inappropriate use of TC

Table 5. Purpose and reason for use of TC of appropriate and inappropriate use

Reason for use of TC	Appropriate use of TC (frequency)	Inappropriate use of TC (frequency)
Advised by others (non-doctors)	0	32
Treatment of disease	48	28
Effects of medication	11	20
Unable to consult	2	17
General sentiment of wanting to get better	7	16
Effectiveness of medication	0	10
Prescribed or advised by doctor	44	7
Financial constraints	0	7
Worsening disease	0	7
Convenience	1	3

Table 6. Frequency of Cutaneous Adverse Effects

Cutaneous Adverse effects	Use of TC	Appropriate use of TC	Inappropriate use of TC
Hypopigmentation	16	5	11
Skin atrophy	8	2	6
Striae	7	0	7
Allergic contact dermatitis	7	2	5
Tinea incognito	6	1	5
Acne flares	5	0	5
Others: worsening of infection	3	1	3
Telangiectasia	2	0	2
Xerosis	2	1	2

Table 7. Logistic regression of behavior of use of TC vs Presence of AE

Behavior of use of TC	With AE (frequency)	Without AE (frequency)	Odds Ratio*	Odds Ratio CI
Appropriate use	12	101	1	
Inappropriate use	46	101	3.833*	1.9, 7.7

*significant