

## Original Research Article

**Abuse of Topical Corticosteroids : An Observational Study in a Tertiary Care Teaching Hospital , Andhra Pradesh, India****Dr Ramya Rachamanti<sup>1\*</sup> , Dr Supriya Sanke<sup>2</sup>, Dr Solomon Raju Kankipati<sup>3</sup>**

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**ABSTRACT**

**Background:** Topical corticosteroids (TCs) are one of dermatology's most commonly used drugs. The clinical effects of TCs are maintained through their anti-inflammatory, vasoconstrictive, anti-proliferative, immunosuppressive and sex hormone-like effects.<sup>2,3</sup> There were fewer studies on the abuse of TC from developing countries like India, especially in Andhra Pradesh<sup>4,5,6</sup>. So, this study was conducted to assess the magnitude of abuse of topical corticosteroids, their reasons, and various complications due to it. **Objectives:** To know the prevalence of topical corticosteroid abuse, to know the reasons, pattern, adverse effects and formulation used among cases with TC abuse and to compare clinic-demographic profile among cases and controls. **Methodology:** The current study was done in the outpatient unit of the dermatology department. This is a type of cross-sectional, observational study done from September 2022 to November 2022. Patients aged above 18 years, males and females, presenting with some complaints to the dermatology unit, suspected of TC abuse and who are willing to participate and provided consent were included in the study. **Results:** TC abuse was seen among 26% of patients. Most of the patients were aged 21-30 years. 63% of patients were females, and 67% of patients reported the most common area of usage as the face. Most of the patients reported cosmetic reasons for topical corticosteroid abuse. 13.4% of patients reported intermittent usage. The most common adverse effect due to topical corticosteroid abuse seen was Tinea incognito. **Conclusion:** It is the need of the hour to increase public awareness and educate the prescribers on corticosteroids. One major step would be to regulate the manufacture and OTC sale of topical steroids. We highly

recommend topical steroids and their combinations to be sold as “prescription-only” medications.

**Keywords:** Topical corticosteroids, abuse, Over the counter drugs, Tinea incognito, Clobetasol, intermittent usage

## INTRODUCTION

Topical corticosteroids (TCs) are one of dermatology’s most commonly used drugs. Sulzberger and Witten published 1<sup>st</sup> report on the utilization of compound F or hydrocortisone.<sup>1</sup> Later, many compounds were introduced by structural modifications of the parent compound hydrocortisone. The clinical effects of TCs are maintained through their anti-inflammatory, vasoconstrictive, anti-proliferative, immunosuppressive and sex hormone-like effects.<sup>2,3</sup> TCs are commonly used for allergies, atopic dermatitis, psoriasis, and vitiligo. They were used for some non-diagnosed skin conditions and also by some physicians without establishing an accurate diagnosis. Lack of proper health infrastructure, specialist services, increased self-medication practice, affordability, and more access to over-the-counter (OTC) medications caused widespread abuse of TCs. Side effects have become the main concern due to the widespread abuse of TCs. Inappropriate usage of TCs can cause local side effects like tinea-incognito, peri-oral dermatitis, steroid rosacea, impetigo incognito, hypertrichosis, acneiform eruption, steroid acne, skin atrophy, secondary bacterial, fungal infections, pigmentary disorders.

There were fewer studies on the abuse of TC from developing countries like India, especially in Andhra Pradesh<sup>4,5,6</sup>. Thorough assessment and proper counselling of steroid abusers and general physicians, including paramedical staff against the use of TC is the need of the hour. But the information or existing literature is insufficient to draw conclusions on preventing steroid abuse. So, this study was conducted to assess the magnitude of abuse of topical corticosteroids, their reasons, and various complications due to it.

**METHODS:** The current study was done in the outpatient unit of dermatology department. It is an Observational, Case-control study. The study is case-control, as a comparison between cases and controls. Cases are patients with TC abuse. Controls are patients without TC abuse. The study is observational, as no therapy was given to any study patients, as a part of the study. It was conducted from March 2022 to November 2022 at government medical college, Ongole, Andhra Pradesh, India. Patients coming to dermatology OPD of with some complaints, suspected of TC abuse were taken as the study sample. We used convenience sampling method to detect eligible patients. As per the study done by Srivatsava<sup>7</sup> et al., the prevalence of topical corticosteroid abuse was 3.76%. Using Epi Info Software, the sample size was calculated as per the population survey model:  $N = Z^2 PQ / E^2$ , where, N-sample size, Population proportion: 3.76%, considering error as 5% and confidence level as 99%, 97 was found to be the minimum sample size. So, we included 100 patients, considering 3% of losses to follow up. All 100 patients provided informed consent for the study. The data of all 100 patients was complete.

**Inclusion criteria:**

Male and female patients aged above 18 years, presenting with some complaints to the dermatology unit, suspected of TC abuse and who provided consent for the study were included.

**Exclusion criteria:**

Pregnant and lactating women, patients who use systemic corticosteroid therapy- as per oral history, patients with incomplete data and with acute serious illnesses- severe liver or renal, cardiac disorders interfering with data collection, patients using TCs with dermatologists' prescriptions for genuine causes were excluded from the study.

**Ethical considerations:** Permission from the Institutional ethical committee attached to GMC, Ongole before conducting the study. Every patient was explained the whole process and advantages of availing their data for the study. Patients were also told that their information will be kept confidential. After he/she accepts, an informed consent form was given in the local language or understandable language and the person was asked to sign it or put a thumb impression. They were assured that their doubts if any to be clarified at any time.

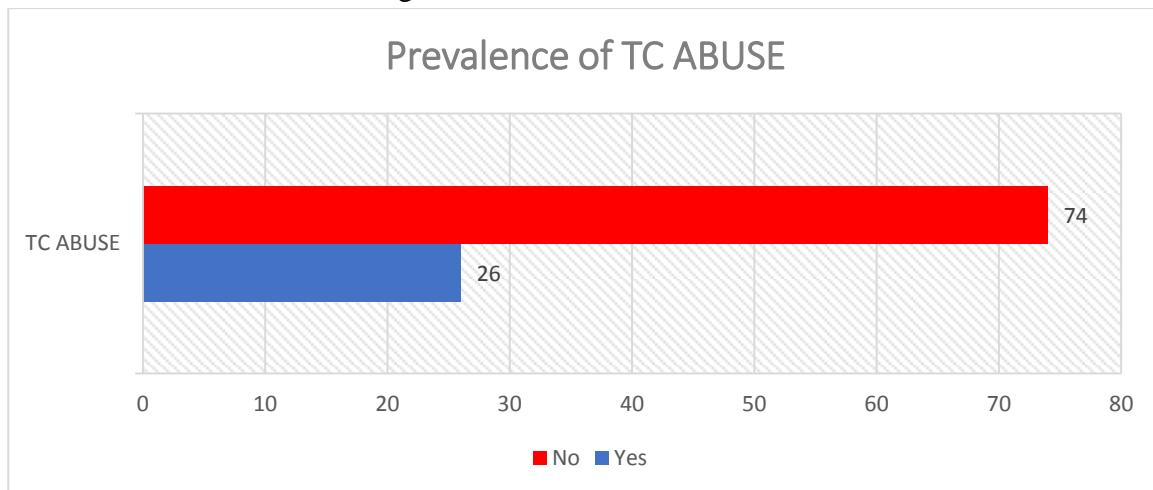
**Study Procedure:** After getting approval from the institutional ethics committee, this study was conducted. Assurance was provided regarding the maintenance of confidentiality for each patient. A thorough history of every patient was taken. Demographics like age, gender and adverse effects were recorded. Details like an indication of topical steroid usage, the formulation used, duration of application, and source of acquiring medication were recorded. Clinical examination findings were noted. Patients were counselled on the rational use of topical steroids. Data was entered in a case record form designed for the study and it was subjected to statistical analysis.

**Statistical analysis:** The data collected was entered in MS Excel 2019 and analysis was carried out using Microsoft excel and statistical software called Epi info version 7.2.5 free version. Frequencies and percentages were used. Mean and SD was also used. Comparison between categorical variables between cases and controls was done using the chi-square test. Comparison between numerical variables was done using the student's T test. P value less than 0.05 is considered significant.

**RESULTS:**

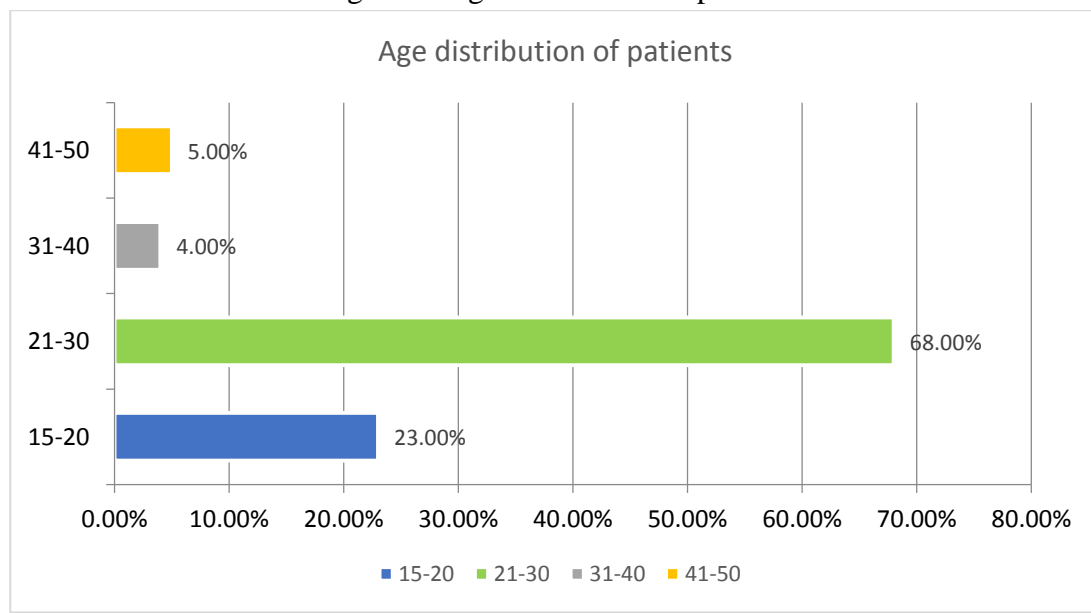
**Prevalence of TC abuse:** TC abuse was seen among 26% of patients. These 26 patients were cases and 74 patients were controls. TC abuse was confirmed as per the oral history and the creams, and the medications the patients showed to us.

Figure 1: Prevalence of TC abuse



**Age-** Most of the patients (68%) were aged 21-30 years. 23% of patients were aged 19-20 years. 4% of patients were aged 31-40 years. 5% of patients were aged 41-50 years. The patient's age ranged from 19 to 50 years. There is no significant difference in the mean age between cases and controls, as per T test ( $P=0.8$ ). The mean age of cases was 25.3 years and the mean age among controls was 25.0 years.

Figure 2: Age distribution of patients



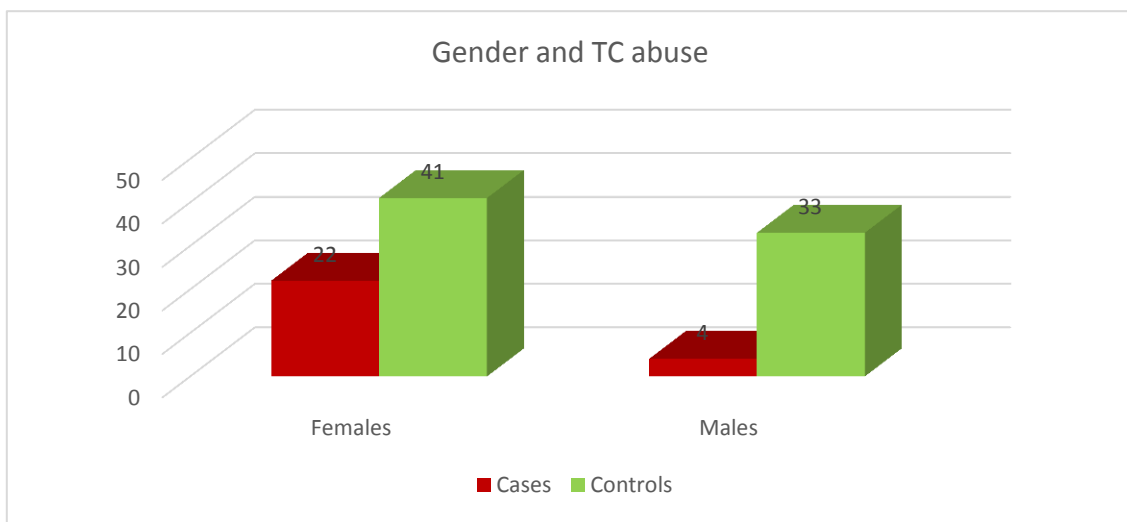
**Gender:** Overall 63% of patients were females. There is a significant association between gender and group. TC abuse was more commonly seen among females compared to males, as per the chi-square analysis ( $p=0.03$ ).

Table 2: Association between gender among cases and controls

| GENDER       | Group |          | Total |
|--------------|-------|----------|-------|
|              | Cases | Controls |       |
| Females      | 22    | 41       | 63    |
| Males        | 4     | 33       | 37    |
| <b>TOTAL</b> | 26    | 74       | 100   |

| STATISTICAL TESTS | Chi-square | 2-tailed p |
|-------------------|------------|------------|
| Chi-square        | 7.0425     | .00796     |

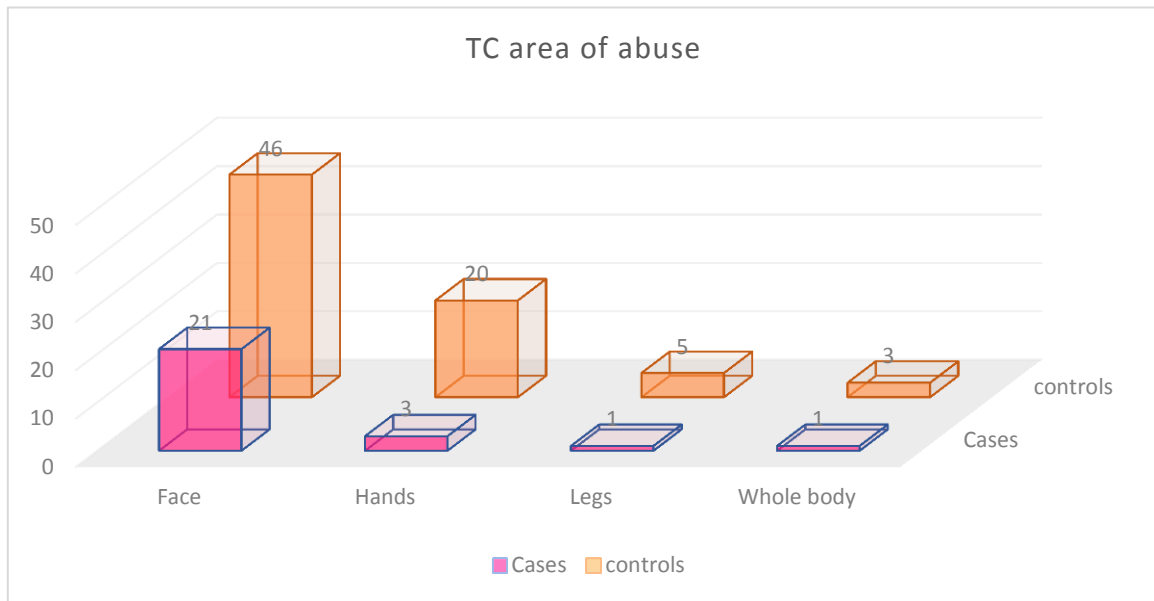
Figure 3: Association between gender and TC abuse



**Complaint:** All patients (100%) presented with rash in our study.

**Area of rash:** Among 100 patients included, 67% had the rash on the face. 23% had a rash on their hands. 6% of patients had rash on the legs. 4% had rash on the whole body. There is no significant difference in area of rash between cases and controls, as per chi-square analysis (chi-square value=0.32, p value=0.35)

Figure 4: Area of rash



**Indication of Topical Corticosteroid usage among cases:**

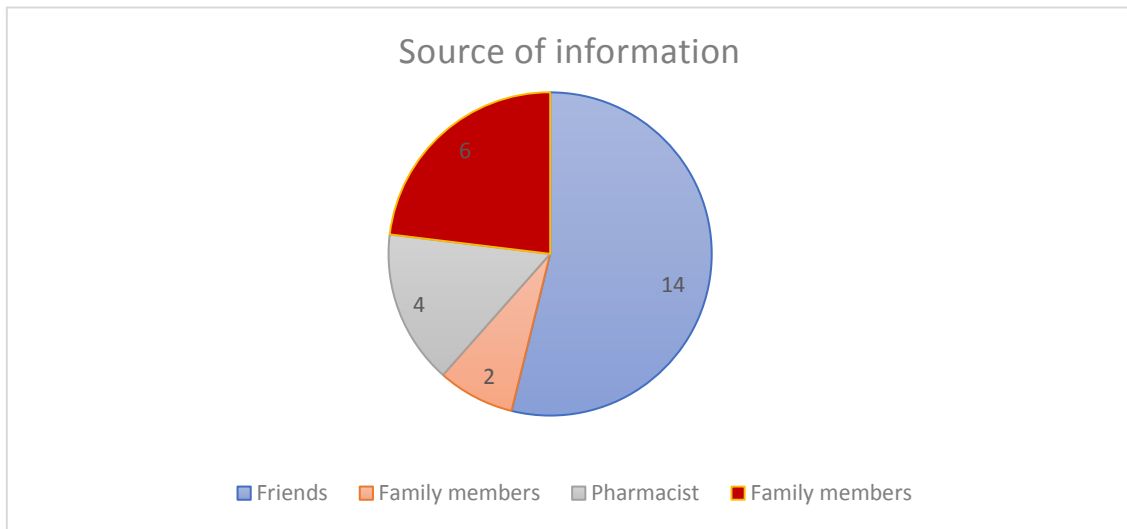
46% of patients reported acne as the main reason for topical corticosteroid usage. 6% reported tinea corporis for TC usage. 15% of patients reported hyperpigmentation and itching as reasons each.

Table 3: Reason for topical corticosteroid usage

| INDICATION                 | Frequency | Percent |
|----------------------------|-----------|---------|
| Acne                       | 12        | 46.1%   |
| Tinea corporis             | 6         | 23.07%  |
| Cosmetic-hyperpigmentation | 4         | 15.38%  |
| Itching                    | 4         | 15.38%  |
| Total                      | 26        | 100.00% |

**Source of information for using TCs:** 14 patients reported that they heard of using TCs from their friends- most common. 4 patients reported that they heard of using TCs from pharmacists. 2 patients reported that they heard of using TCs from family members.

Figure 5: Area of TC abuse



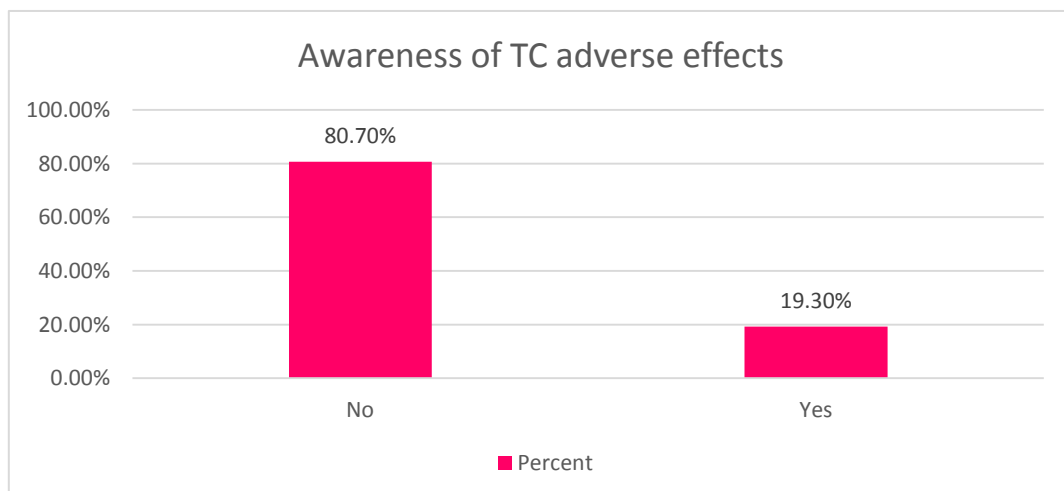
**Pattern of usage:** Most of the cases were using TCs intermittently (regular use- daily at least one application for the last 6 months)

Table 4: Pattern of usage of TCs

| REGULAR OR INTERMITTENT | Frequency | Percentage |
|-------------------------|-----------|------------|
| Regular                 | 22        | 84.6%      |
| Intermittent            | 4         | 13.4%      |
| Total                   | 26        | 100.00%    |

**Awareness of adverse effects of corticosteroids:** Awareness of the adverse effects of corticosteroids is seen only among 19.3% of patients. 80.7% of patients don't know the adverse effects caused by corticosteroids.

Figure 6: Awareness of TC adverse effects



**Adverse effects of TC abuse:** 42.3% had tinea incognito due to TC abuse- most common. 11.5% of patients included had enlarged blood vessels due to TC abuse.

Table 4: Adverse effects due to CS abuse

| ADVERSE EFFECTS        | Frequency | Percent |
|------------------------|-----------|---------|
| Enlarged blood vessels | 3         | 11.5%   |
| Tinea incognito        | 11        | 42.3%   |
| Hypopigmentation       | 4         | 13.4%   |
| Increased acne         | 6         | 23.0%   |
| Skin atrophy           | 2         | 7.69%   |
| Total                  | 26        | 100.00% |

**Formulation used:** 3.8% of patients used monotherapy of topical corticosteroids. 96.2% of patients used combinational topical corticosteroids. Most common used combination contains Clobetasole Propionate+ Ofloxacin+ Ornidazole + Terbinafine HCl.

Table 5: Formulation used

| FORMULATION  | Frequency | Percent |
|--|-----------|---------|
| Betamethasone valerate   | 1         | 3.80%   |
| Betamethasone valerate + clioquinol                                | 1         | 3.8%    |
| Betamethasone valerate +neomycin sulphate                          | 6         | 23.0%   |
| Clobetasole+Gentamycin Sulphate + Miconazole + clioquinol          | 3         | 11.5%   |
| Clobetasole Propionate+ Ofloxacin+ Ornidazole +<br>Terbinafine HCl | 15        | 57.6%   |
| Total  | 26        | 100.00% |

**DISCUSSION:** The current study included 100 patients. Most of the patients were aged 21- to 30 years and most of the patients were females.



**Comparison with relevant studies:**

**Saini B et al.** in their study included 80 patients with TC abuse.

Age of the patients ranged from 15 to 50 years age group. The mean age of patients with TC misuse was  $24.08 \pm 7.931$  years. 43.8% of patients belonged to the age group 15-20 years, followed by 28.8% in the age group 21-25 age group, 13.8% of patients in 36-40 years age group, 10% of the patients in 26-30 age group, 2.55% of patients in 31-35 age group and 1.3% of patients in 45-50 age group. 76% of patients were females. Male: Female ratio is 1:3. Age and gender were almost similar to our study results.

The most common adverse drug reactions seen were burning and itching sensations, seen in 53% of patients. 44% had increased acne. Hypertrichosis was seen in 23% of patients, rosacea-like dermatitis was seen in 18% of patients, skin thinning was seen in 17% of patients. New emergence of acne was seen in 15% of patients, bruise and tear on the skin surface were seen in 15% of patients, hyperpigmentation was seen in 12% of patients, hypopigmentation was seen in 11% of patients, enlarged blood vessels on the skin were seen in 6% of patients, perioral dermatitis was seen in 5% of patients and stretch marks were seen in 2% of patients.<sup>8</sup> In the current study, the most common adverse drug reaction seen was tinea incognito. No single case of rosacea like eruption was seen in our study.

**Nagesh et al.** did a study among 1000 adults who came to dermatology OP with suspected TC abuse. 360 were males and 640 were females.<sup>9</sup> Female preponderance was similar to our study.

**Srivatsava et al.** did a study on 324 patients with topical corticosteroid abuse. The most commonly used steroid was clobetasol followed by mometasone and beclomethasone.<sup>7</sup> In our study, also the most common formulation used was Clobetasol.

**Saraswat A et al.**<sup>10</sup> study included 2926 patients with facial dermatosis. 433 patients had TC abuse. Among these 433 patients, 611 local adverse effects were found. Acne exacerbation was found to be the most common adverse effect seen, but in our study, Tinea incognito was most common adverse effect seen.

**Bilal et al.** did a study in Ethiopia and showed that 52.4% of 286 patients who used TCs had sources of information on TCs from pharmacies and cosmetic shops.<sup>11</sup> In our study, the commonest source of information was from friends.

**Thomas et al.** study included 723 patients and found that clobetasol was most commonly abused corticosteroid, seen in 58.2% of patients, similar to our study.

Pharmacists contributed to 78% of the sources on information for TC abuse. Around 58% of patients perceived TC abuse reactions as allergic reactions to food.<sup>12</sup>

Misuse of TC is mainly reported in South Africa, India, Pakistan and Iraq, showing that the main reason for misuse is related to skin colour<sup>13,14,15</sup>. Also, there were many recent cases of increased use of potent corticosteroids by self-application for long-term inflammatory skin diseases or diaper rash in Austria and Singapore.<sup>16</sup>

**Swaroop R<sup>17</sup> et al.**, wanted to evaluate corticosteroid abuse pattern on face. Their study included 100 patients. Results showed that females were more common compared to males, similar to our study. The most common age group involved was 21-30 years, similar to our study. The commonest used TC was betamethasone valerate. Most common indication for

applying steroids was acne, similar to our study. In 46% of patients, suggestion for the application of TC was given by friends. Common side effect seen was acneiform eruptions.

### **CONCLUSION:**

Females were more commonly abusing TCs. Misuse of TCs has been rapidly increasing recently. TCs were used as “steroid cocktails”, especially in dermatophytoses and allergic reactions which led to the emergence of resistance. Besides the usage of TC as a fairness cream, treatment for hyperpigmentation is very common that led to an increased occurrence of the topical steroid-damaged face (TSDF). Factors that led to this epidemic include and promotion of inappropriate drug dose combinations containing TCS, along with unregulated OTC supply and unrestricted sale of TCs, professional ignorance and public ignorance. So, it is the need of the hour to increase public awareness and educate the prescribers. One major step would be to regulate the manufacture and OTC of topical steroids. Finally, we recommend that topical steroids and their combinations should be sold as “prescription-only” drugs.

Small sample size is the limitation of this study.

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**Conflicts of interest:** There were no conflicts of interest

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