

Use of Topical Steroids in Dermatology: A Questionnaire Based Study

Abstract

Context: Topical steroids, the most widely prescribed drugs in dermatology are being increasingly misused. **Aims:** This study was conducted to assess knowledge and practices regarding the use of topical steroids and to analyze prescriptions containing topical steroids. **Subjects and Methods:** Following approval from the institutional ethics committee, participants were recruited as per the selection criteria and divided into those treated in the institution and those having outside prescription. They were administered a pre-validated questionnaire to assess knowledge and practices regarding the use of topical steroids. **Statistical Analysis Used:** Comparison of awareness between two patient categories was done using Chi-square test. Prescription variables were analyzed using descriptive statistics. Significance of *P* value was set at 0.05. **Results:** Out of 400 patients, 167 had external prescriptions whereas 233 were institutional patients. Only 5.5% of all patients knew about the type of drug prescribed whereas 31.25% were aware of the indication. A total of 33.75% of the patients knew topical steroids required a prescription and 5.6% said they were aware that topical steroid use was associated with side effects. Side effects were reported by 96 patients. Awareness regarding knowledge, indication, and need for prescription were significantly better in institutional patients whereas knowledge about side effects was lacking in both groups. Psoriasis was the most common indication overall whereas tinea was the most common indication (51.5%) among externally prescribed. **Conclusions:** Although this study showed that institutional patients had comparatively better knowledge than community-treated patients, there is a need to create more awareness among patients overall and implement measures to stop irrational prescribing practices in the community.

Keywords: Awareness, fixed-dose combination, steroid abuse, topical steroids

Introduction

Topical steroids are the most commonly prescribed drugs in dermatology. They are indicated in a variety of conditions such as psoriasis, atopic dermatitis, seborrheic dermatitis, intertrigo, eczema, and lichen simplex chronicus due to their anti-inflammatory, immunosuppressive, and anti-mitogenic effects.^[1] Long-term use of topical steroids is associated with numerous side effects which are both topical and systemic. Locally, they cause atrophic changes in the skin such as striae, telangiectasia, stellate pseudoscars, hypopigmentation, fragile skin, ulceration, purpura, impaired wound healing, and facial hypertrichosis.^[2] Moreover, topical steroids can increase local susceptibility to bacterial, fungal, and viral infections. To minimize the side effects of topical steroids; potency, delivery vehicle, frequency of administration, and site

of application should be considered before prescribing.^[3] Topical steroids are misused for skin infections, acne, and also as fairness creams. Young adults procure topical steroids over the counter and use them for a subjective feeling of better appearance. A study reported that more than half of the prescriptions of topical steroids were delivered for fungal infection. Availability over the counter, self-medication by patients, affordability, and poor health infrastructure make topical steroids one of the most commonly misused medications among the masses. The misuse is so rampant that a major proportion of dermatology-related clinical visits by patients is for complaints concerning the adverse effects related to excessive usage of topical steroids.^[4]

There is a need to assess the practices regarding the use of topical steroids. Studies concerning steroid abuse have been

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reported from multiple countries including China,^[5] Iraq,^[6] and the USA^[7] but the evidence is limited from Indian studies.^[8] Owing to the growing menace of topical steroid abuse, there is a need to assess the awareness among masses regarding knowledge pertaining to the use of topical steroids. There have been no studies in India assessing the knowledge of the people regarding topical steroid use. Moreover, across the world too, very few studies have been conducted pertaining to this aspect.^[9-11]

This study was conceptualized to assess knowledge and practices regarding the use of topical steroids and to analyze the prescription containing topical steroids in patients visiting dermatology clinic. The study also compared the awareness and practices of patients being prescribed topical steroids within the dermatology out-patient department (OPD) of the tertiary care hospital, to those reporting to the OPD with steroids prescribed from outside.

Subjects and Methods

This was an observational, cross-sectional study conducted in the dermatology OPD in a tertiary care hospital. It was initiated after obtaining permission from the institutional ethics committee (EC/148/2016) in January 2017 and was registered in the clinical trials registry of India. (CTRI No: CTRI/2017/12/010733) The study has been performed in accordance with Indian Good Clinical Practices and the Indian Council of Medical Research guidelines. Patients of either gender between the age group of 18 to 65 years, visiting dermatology OPD of tertiary care hospital receiving topical steroids continuously or intermittently for a period of at least 1 week or more were included after obtaining written informed consent. They were enrolled in the study over a period of 12 months from February 2017 to January 2018. The patients were enrolled as they attended the dermatology clinic (convenient sample) and formal sample size calculation was not done. The patients were divided on the basis of their initial prescription of topical steroids into institutionally prescribed (those who were initiated on topical steroid treatment in the tertiary care OPD) and externally prescribed (those reporting to the OPD with topical steroids initiated from outside) steroids. A pre-validated questionnaire was administered to the patients. The questionnaire contained 19 questions divided in two domains *viz* knowledge (type of drug prescribed, indication, side effects, and need for prescription) and practices domain (duration and pattern of use, type of prescriber, frequency of application, quantity of application, relief of symptoms, relapse, abrupt stoppage of drug, use of old prescriptions, over the counter purchase, side effects, and instructions regarding application). Demographic details, type of steroid received, duration prescribed, frequency, indication, and duration were noted down from the prescriptions. Side effects occurring due to the topical steroids were also asked and recorded.

Validation of the questionnaire was performed before administering the questionnaire to the participants. Face validity and content validity was done by ten experts. Face validity was done to assess the clarity of the wording, layout and style, and readability of the questions. For content validity, the experts were asked to rate the questions as essential, useful and nonessential. Content validity ratio [CVR] was calculated based on the ratings by the formula $CVR = (n - N/2) \div N/2$ [where “n” = Number of experts who found the question essential/useful and “N” = Total number of experts]. Test to check internal consistency for reliability was done.

Chi-square test was used to compare attributes such as knowledge of the drug, indications, need for a prescription, awareness about side effects, abrupt stoppage of topical steroids, use of old prescriptions, over the counter purchase of topical steroids, and side effects between externally prescribed and institutional patients. The prescription analysis data was analyzed using descriptive statistics. Level of significance was set at $P < 0.05$. Data analysis was done using SPSS for Windows, Version 16.0. Chicago, SPSS Inc.

Results

A total of 400 patients were included in the study. Mean age of patients was 36.64 ± 12.73 years. The total number of male patients was 243 whereas females were 157. Out of 400, 167 patients were prescribed topical steroids from outside whereas 233 comprised the institutional patients. There were 20 questions in the questionnaire; out of which 19, with a CVR greater than or equal to 0.8 were retained. Internal consistency for the reliability value of Cronbach’s alpha for the questionnaire was calculated to be 0.71.

Table 1 depicts responses to the knowledge domain of the questionnaire. Out of 400 patients, 5.5% of patients knew about the type of drug prescribed. When asked about the indication for prescription, 68.75% were not aware of the same. Knowledge regarding side effects of topical steroids was found to be lacking with only 5.6% people knowing that steroids use was associated with side effects. Moreover, 66.25% of the patients did not know that procuring topical steroids required a prescription. The comparison between two patient groups showed that the knowledge regarding the type of drug, indications, and need for prescription was significantly better in the institutional patients as compared to the externally prescribed group ($P < 0.05$). However, awareness regarding side effects was missing in both groups.

Out of all 400 patients, 77.25% patients reported relief. The earliest symptom to be relieved was itching followed by redness. In acute conditions, duration of symptom relief was observed to be within 3 days. Chronic conditions such as psoriasis required 2 weeks to 3 months. The findings related to practices domain have been presented

in Table 2. Symptom relapse after stopping the medication was observed in 32% of patients. Around 52% of patients receiving steroids for tinea reported relapse of symptoms immediately after stopping the use of the steroid. Out of 400 patients, 96 patients reported experiencing side effects following application of topical steroids and 71% (68/96) were from the externally prescribed group. The most common side effects i.e., exacerbation of lesions; was reported by patients using topical steroids for tinea. Other side effects were hypopigmentation, atrophy, acne, and steroid-dependent red face syndrome. Fifty-nine patients reported that they were provided inadequate instructions regarding the application of topical steroids. Out of these, 7 were not given clear instructions regarding the frequency of application and 52 were not told about the quantity and manner in which topical steroids were to be applied.

The data of both groups for the variables duration and frequency has been represented in a combined manner. Out of 400 patients, 135 had been using topical steroids for more than 6 months. The results for the duration of use have been given in Figure 1.

Regarding the pattern of use, 292 (of 400) patients said they use steroids continuously and 108 patients reported

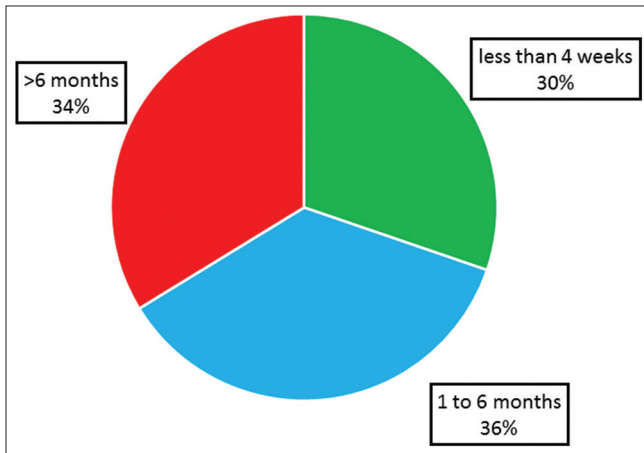


Figure 1: Duration of use of topical steroids

intermittent use of steroids. Among the externally prescribed patients, only 43.1% (72/167) had been prescribed by dermatologists. The distribution regarding prescribers has been given in Figure 2.

Among the 400 patients, 159 reported once-daily application, 224 reported twice daily application whereas the remaining 17 reported thrice daily application of topical steroids. The quantification of drug applied was difficult to perform as the finger-tip unit was not used in clinical practice by prescribers. Hence, it could not be evaluated.

Clobetasol was the most common steroid prescribed accounting for 50.75% of the prescriptions, followed by mometasone (25%), fluticasone (13.75%), betamethasone (5%), halobetasol (3.75%), beclomethasone (1.25%), and fluocinolone (0.75%).

Psoriasis was the most common indication for which steroid was prescribed followed by tinea. All the patients who were prescribed steroids for tinea belonged to the externally prescribed group. The distribution of indications has been represented in Figure 3. Other indications included acne (4), melasma (3), scabies (1), alopecia (1), and acanthosis (1) in the externally prescribed group and contact dermatitis (4), Prurigo nodularis (2), and atopic dermatitis (2) in the institutional group.

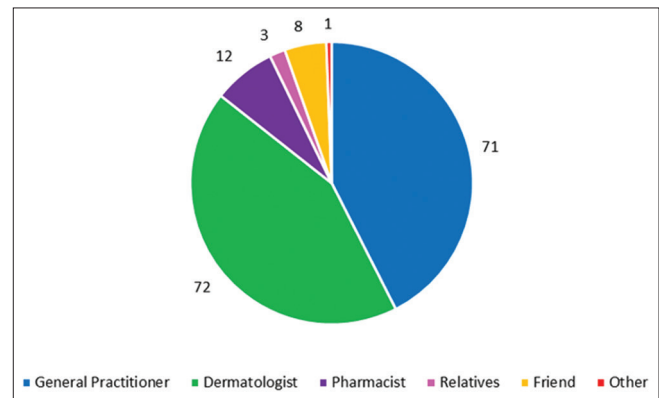


Figure 2: Type of prescriber

Table 1: Analysis of favourable responses to the knowledge domain of the questionnaire

| Patient groups | Type of drug prescribed | Indication | Side effects | Need for prescription |
|--------------------------------|-------------------------|------------|--------------|-----------------------|
| Institutional prescribed (233) | 20 | 101 | 16 | 105 |
| Externally prescribed (167) | 2 | 24 | 7 | 30 |
| <i>P</i> | <0.001* | <0.001* | >0.05 | <0.001* |

Statistical analysis was done using Chi-square test, *P*<0.05 was considered significant*

Table 2: Analysis of favourable responses to practices domain of the questionnaire

| Patient groups | Relief of Symptoms | Abrupt Stoppage of Medication | Relapse of Symptoms | Over the Counter purchase | Use of old prescriptions | Side effects |
|--------------------------------|--------------------|-------------------------------|---------------------|---------------------------|--------------------------|--------------|
| Institutional prescribed (233) | 20 | 101 | 16 | 105 | 29 | 28 |
| Externally prescribed (167) | 2 | 24 | 7 | 30 | 21 | 68 |
| <i>P</i> | <0.001* | <0.001* | >0.05 | <0.001* | 0.96 | <0.001* |

Statistical analysis was done using Chi-square test, *P*<0.05 was considered significant*

Out of 400 patients, 191 received steroid fixed-dose combinations (FDC) [Figure 4]. The most commonly prescribed formulations of topical steroids were creams in 310 patients followed by ointments (80) and lotions (10). Ultrahigh potency steroids were prescribed to 234 patients, moderate-to-potent steroids to 146 patients whereas 20 patients received low-potency steroids.

Discussion

Steroid abuse has become a growing concern amounting to a large proportion of dermatology clinic visits. The analysis of the questionnaire in this study revealed a lack of knowledge in terms of the type of drug being used by the patients and the indication for using the same. Only 5.5% of patients were aware that they were using a topical steroid. Moreover, more than half of the patients were not even aware of the indication for which they were being prescribed the medication. Less than 6% knew that steroid use is associated with side effects. The steroids in some cases had been either self-prescribed or prescribed by friends or family. The practices followed regarding the use of steroids highlighted the extent of misuse in the community. The glaring finding was that tinea was a common indication for using topical steroids in the community. Despite the heavy patient load, institutional practices were found to be better than those of the externally prescribed patients.

A major concern for dermatologists in recent years has been unscrupulous selling by chemists without prescriptions. Our study revealed that more than one-third of the patients had obtained topical steroids without a prescription while close to one-eighth had reused old prescriptions. Over the counter use of topical steroids was significantly higher in the externally prescribed patients, compared to the institutionally prescribed patients since they were not aware of the need for a prescription to procure steroids. Sinha *et al.* reported that 80% of people had obtained steroids over the counter while only 4% had consulted dermatologists.^[12] Balasubramanian *et al.* also reported a high prevalence of over the counter use of topical steroids.^[13]

Out of all the topical steroids, only clobetasol propionate, clobetasone 17-butyrate, fluticasone propionate, and

mometasone furoate were included in Schedule H. The remaining have not been mentioned. A note at the bottom of this list states that topically applied drugs do not come under the category of Schedule H. This creates confusion leading to difficulty in interpretation of the data from Schedule H.^[14] Therefore, there is a need to have better clarity on the prescription category of topical steroids in Schedule H.

Topical steroids or steroid-containing antifungal creams are commonly misused for fungal infections particularly in developing countries like India owing to their unregulated sales. Topical steroids may alleviate the symptoms such as itching but do not eliminate the fungus from the skin surface and also leads to antifungal drug resistance.^[15] In our study, among the externally prescribed, the commonest indication for the use of topical steroids was tinea. These patients reported relapse of lesions after few days of steroid application which occurs due to continuous fungal proliferation. Besides, some patients developed tinea incognito and acne. Mahar *et al.*^[16] also reported fungal infections to be the most common cause for the use of topical steroids followed by acne and skin lightening.

The most commonly prescribed steroid in our study was clobetasol (ultrahigh potency) followed by mometasone cream (moderate potency). A study revealed that four of the five top-selling creams across all segments in India contained clobetasol propionate.^[17] Our study showed that more than half the patients had been using ultrahigh potency steroids whereas the rest used moderate-to-high potency steroids. More than half of the externally prescribed patients received ultrahigh potency steroids for tinea. In the study by Mishra *et al.*,^[18] patients prescribed potent steroids by non-dermatologists suffered more adverse reactions than those prescribed by dermatologists. The authors attributed this to the lack of knowledge about potency and indications for using steroids, on the part of non-dermatologists. In our study, it was observed that of all the patients prescribed topical steroids for tinea, 60% had been prescribed by general practitioners. This shows that probably these physicians were prescribing steroids even in case of unclear diagnosis, contributing to the steroid

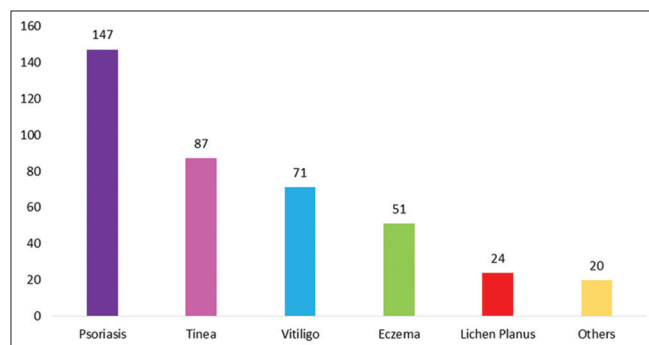


Figure 3: Indications for prescription of topical steroids

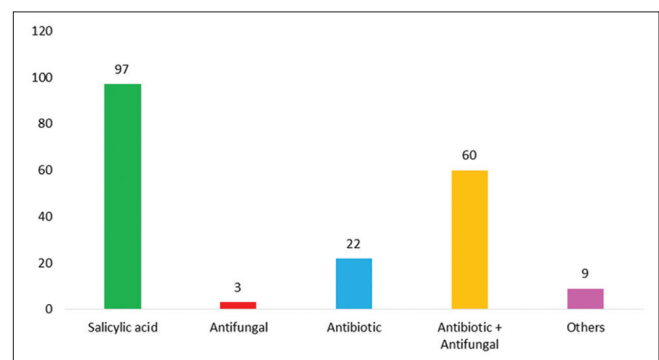


Figure 4: Fixed-dose combinations containing topical steroids

misuse. Nagesh *et al.*,^[8] reported that almost half the patients in their study were advised to use topical steroids by pharmacists, friends, and relatives. The authors claimed that most of the time, general practitioners and doctors from alternative medicine had prescribed these medicines. Our observations are in accordance with these findings.

Our study also showed ultrahigh potency steroids being prescribed by general practitioners, for conditions like tinea. Recently, there has also been a misleading trend to use steroids of mid and strong potency for beautification and in the form of fairness creams. Studies have reported irrational use of steroids for fairness and melasma,^[19-22] although lesser use for these indications was observed in our study.

According to a study, the total annual sale of steroid creams in India is USD\$329 million. Furthermore, 87% of the topical steroid sales were in the form of FDC's. Of these, 70% FDCs contained a topical steroid and antifungal.^[17] Our study supports these findings as we observed that 47.75% of prescriptions contained FDCs. According to our study, the most common FDC used was salicylic acid with steroid, which is a rational indication for use. The most common FDC according to Verma *et al.* is clobetasol propionate, ornidazole, ofloxacin, and terbinafine,^[14] which was same as the most common antimicrobial-steroid combination used in our study. The Drug Controller General of India (DCGI) and Ministry of Health and Family Welfare of the Government of India had issued through a gazette notification in 2016, that certain fixed-dose combinations (FDC) of topical steroids along with antibiotics drugs had no therapeutic justification and prohibited their manufacture with immediate effect.^[23] As per the recent Central Drugs Standard Control Organization (CDSCO) notification of 2018, among 328 FDCs which have been banned by the DCGI, there are 12 topical steroid FDCs along with antibiotics which have been banned.^[24] We found that one of these (clobetasol propionate, ornidazole, ofloxacin, and terbinafine) was commonly used by externally prescribed patients in our study for tinea. Institutional prescribing practices were found to be better as none of the patients was given topical steroids or FDCs for tinea or in absence of valid indications.

In our study, 24% of the patients reported adverse effects due to steroids. The institutional patients reported significantly lesser side effects compared to the externally prescribed group. The study by Nagesh *et al.*,^[8] reported side effects in more than half the patients using topical steroids. The knowledge regarding side effects associated with the use of steroids was lacking in both the groups of patients in our study. Our study revealed the practice of abrupt stoppage of steroids by patients after their symptoms got relieved. The practice was significantly higher in the externally prescribed patients. These observations highlight

the need to improve awareness of patients, as it is one of the important contributing reasons for steroid misuse.

The misuse of topical steroids in the community is increasing and steps need to be taken at every level to curb the problem. The precautions to be taken while using steroids and practices of using steroids were poor among externally prescribed patients as compared to institutional patients. The fact that 57% of externally prescribed prescriptions were by non-dermatologists might have contributed to the inadequate information being given to the patients. The comparison of prevailing in-house practices with prescriptions from the community helped us to give specific recommendations to our dermatology department.

There have been efforts at a national level by Indian Association of Dermatologists, Venereologists and Leprologists (IADVL). A Taskforce Against Topical Steroid Abuse (ITATSA) by IADVL has submitted an online petition to the Ministry of Health and Family Welfare, Government of India, and CDSCO to look into the issues related to the indiscriminate over the counter sale of topical steroids in India.^[24]

Conclusions

The present study highlights the extent of misuse of topical steroids in the community especially with respect to fungal infections and also indicates an overall lack of awareness about the type of drug and side effects.

Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent forms. In the form, the patient(s) has/have given his/her/their consent for their clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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