

## Original Research Article

# Over the counter medication: a study among dermatology outpatients

Ramadevi Birudala<sup>1</sup>, Shruthi Hassan Nagaraj<sup>2\*</sup>, Kousar Begum Bannala<sup>1</sup>,  
Vijayarangam ShivaKumar<sup>1</sup>

Department of Dermatology, Venereology and Leprosy, <sup>1</sup>P.E.S. Institute of Medical Sciences and Research, Kuppam, Andhra Pradesh, <sup>2</sup>Karwar Institute of Medical Sciences, Karwar, Karnataka, India

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**\*Correspondence:**

Dr. Shruthi Hassan Nagaraj,

E-mail: [dr.shruthiharish@gmail.com](mailto:dr.shruthiharish@gmail.com)

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### ABSTRACT

**Background:** Over-the-counter (OTC) medicine or non-prescription medicine refer to medicine that you can buy without a prescription from a health care professional. The prevalence, clinical patterns and causative agents of cutaneous drug reactions vary among different populations. The most widely used over the counter medication in dermatological practice are topical steroids. The main objective is to know awareness among the people about over the counter medication and clinical analysis of effects caused by them, to find the most commonly used OTC medication.

**Methods:** Prospective questionnaire based study comprising of 453 cases of cutaneous effects due to over the counter medication was carried out for a period of 1 year. Diagnosis was made mainly based on clinical features.

**Results:** Super potent and high potent steroids were the most common OTC medication used which caused nodulocystic acne in 51.6% patients, atrophy in 3.97% patients, tinea incognito in 23.8% patients. Irritant contact dermatitis (due to hydroquinone, cotrimoxazole, neomycin) was seen in 18.5% patients. Fixed drug eruption was seen in 1.32% patients, cushingoid features in 0.66% patient.

**Conclusions:** Indiscriminate abuse of steroids by people due to lack of awareness should be stopped. This misuse and damage have serious effect on the quality of life of the patients in general and the skin of the face in particular. Management is difficult and necessitates psychological counselling as well as physical soothing of the sensitive skin. For the safety of people Indian association of Dermatology, Venereology and Leprology (IADV) also started IADV Task force Against Topical Steroid Abuse (ITATSA).

**Keywords:** Over the counter medication, Nodulocystic acne, Misuse, IADV, Topical steroid dependant face

### INTRODUCTION

Over-the-counter (OTC) medicine or non-prescription medicine refer to medicine that anyone can buy without a prescription from a health care professional.<sup>1</sup> According to the Food and Drug Administration, there are more than 300,000 over-the-counter drug products on the market, a number that continues to grow as an increasing number of medications move from prescription to over the

counter status.<sup>2</sup> The prevalence, clinical patterns and causative agents of cutaneous drug reactions vary among different populations.<sup>3</sup>

The most widely used over the counter medication in dermatological practice are topical steroids. In the Indian market, at least 18 different corticosteroid molecules, ranging in potency and activity from mild to super potent are available for topical use on skin. These are marketed

under a variety of brand names by thousands of pharmaceutical companies.<sup>4</sup>

The study was done to assess the side effects of medication i.e. both topical and oral medication taken over the counter, to know awareness among the people about over the counter medication and to find the most commonly used OTC medication. There are only few studies available which have highlighted the severity of this problem in India. These studies have tried to bring to the notice of regulatory authorities about the damage caused by the free availability of these creams.

**METHODS**

Cross sectional observational study comprising of 453 cases of cutaneous effects after using over the counter medication was carried out for a period of 1 year i.e., February 2017 to January 2018. The study was conducted at a tertiary care hospital in Chittoor District of Andhra Pradesh State. All the patients who attended DVL department and who has given the history of using non prescriptive medicine for more than one month were included. The patients who have used the prescriptive medicine for more than the time advised by doctor and the patients using non prescriptive medicine for less than one month were excluded. A questionnaire was given regarding medication (type, duration, indication for usage). Diagnosis was made mainly based on clinical features. Those not willing to answer the questionnaire were excluded from the study. Consent was taken from all the patients. The institutional ethical committee clearance was taken before starting the study.

The collected data was entered into MS excel 2007 software and further analysed using SPSS 20. For descriptive analysis, the categorical variables were analysed by using percentages.

**RESULTS**

In the present study females were most commonly involved and the most frequently involved age group is 21-30 years (228 patients i.e., 50.3%) followed by 11-20 years (126 patients i.e., 27.8%), 31-40 years (90 patients i.e., 19.9%) and greater than 40 years (9 patients i.e., 1.99%). In the present study out of 453 patients, 291 were of female sex, 162 were of male sex. The most common complaints for which patients approached pharmacists were acne (180 patients i.e., 39.7%) and groin rash (108 patients i.e., 23.8 %). The other reasons were dark spots and hyperpigmentation, used as fairness cream. Complaints for which patients used OTC medication were shown in Table 1.

The common side effects found in the study were acne in 234 patients (51.6%), aggravation of existing skin problem, alteration of fungal infection in 108 patients (23.8%), irritant contact dermatitis showing erythema and burning in 84 patients (18.5%), atrophy and

hypopigmentation in 18 patients (3.97%), fixed drug eruption and cushingoid features in 6 (1.32%) and 3 (0.66%) patients respectively in Table 2.

**Table 1: Complaints for which patients used OTC medication.**

Complaints	Number	%
Fairness cream	72	15.9
Dark spots and hyperpigmentation	84	18.5
Acne and scars	180	39.7
Groin rash	108	23.8
Body pains	9	1.99
<b>Total</b>	<b>453</b>	<b>100</b>



**Figure 1 (A and B): Aggravation of acne.**



**Figure 2: Steroid induced acne, (A) 40 year old female. (B and C) 18 year old male.**



**Figure 3: TSDF-semi permanent or permanent damage to skin.**

**Table 2: Effects of OTC medication.**

Complaints	Number	%
Acneiform eruptions	234	51.6
Hypopigmentation and atrophy	18	3.97
Erythema and burning	84	18.5
Tinea incognito	108	23.8
FDE	6	1.32
Cushingoid features	3	0.66
Total	453	100



**Figure 4: Pigmentation with hypertrichosis.**



**Figure 5: Tinea incognito.**



**Figure 6: Erythema with burning after using triple combination.**



**Figure 7: Striae.**

**Table 3: Most commonly used OTC medication.**

OTC medication	Number	%
Betamethasone valerate	174	38.4
Clobetasol propionate	186	41.1
Triple combination	84	18.5
NSAIDS	6	1.32
Oral steroid	3	0.66
Total	453	100

Table 3 shows most commonly used OTC medication in the dermatology outpatients. Most commonly used drugs are super potent and high potent topical steroids like clobetasol propionate in 186 patients (41.1%) and Betamethasone valerate in 174 patients (38.4%) followed by triple combination i.e., combination of hydroquinone, potent steroid and tretinoin in 84 patients (18.5%). The other less commonly used OTC was NSAIDS and oral steroids.

**DISCUSSION**

Topical corticosteroids are the most widely used therapeutic agents in modern dermatologic therapy. However they are considered as double edged sword drugs i.e., invaluable but need careful handling by the provider and the recipient for safe and effective use.<sup>5</sup> Because of their property of producing bleaching and anti-inflammatory effect, they have been misused frequently.<sup>6</sup> The main reason for such misuse in our country is its free availability as an OTC medication. They are misused for varied indications such as acne, pigmentation, fungal infection, pruritus, and many a times as a cosmetic or a skin cream for any type of rash. Misuse results in cutaneous damage characterised by erythema, monomorphic acne, steroid atrophy, steroid rosacea, striae telangiectasia.

Most commonly used over the counter medication is topical corticosteroids followed by triple combination under the trade names Lobate GM, Panderm, Fourderm, Betnovate, skin lite etc., Patients were using these

medications as a cosmetic for fairness and to remove pigmentation due to various reasons. The patients approached pharmacist mostly for acne, fairness, groin rash and body pains.<sup>7</sup> Many of them are using these creams mainly over the face causing topical steroid-dependent face (TSDf) and other parts of the body for any rashes causing their aggravation or altering the original condition (tinea incognito). TSDf is defined as the semi permanent or permanent damage to the skin of the face precipitated by the irrational, indiscriminate unsupervised use of topical corticosteroids.<sup>8</sup>

The common side effects found in our study were acne, pigmentation, atrophy and aggravation of existing skin problem (acne, fungal infection). These are similar to the findings by Saraswat et al.<sup>9</sup> The other side effects are redness, burning sensation due to triple combination, fixed drug eruption due to NSAIDs. Indian doctors are witnessing a pandemic of adverse effects induced by topical corticosteroids.

## CONCLUSION

According to Drugs and Cosmetics (D and C) Act 1940, the TCs fall under the category of schedule H drugs, meaning that they should be sold by retail shops only on the valid prescription of a qualified doctor. Lack of qualified doctors especially dermatologists, more so in rural areas, is also compounding the problem of irrational use of over the counter medication. Due to costs and the inconvenience of specialist consultations, patients with prescriptions often re-purchase and share drugs with friends and relatives with similar symptoms.

## Recommendations

Awareness programs must be conducted regarding OTC medication to the people and pharmacists as well. Indiscriminate abuse of steroids by people due to lack of awareness should be stopped. Restrict sales of topical corticosteroids strictly by prescription, because they should be used judiciously, for appropriate indications and duration. The government of India should also ensure that topical steroids, except for those with low potency, are regulated appropriately in terms of production and sales.

Various measures have been taken to stop steroid misuse. In 2006 proposal named “stop OTC supply of potent topical steroids” was submitted by Lahiri and Coondo to IADVL. A special Task Force titled IADVL Task force Against Topical Steroid Abuse (ITASTA) has recently been constituted. The theme of IADVL 2019 is “to fight against topical steroid misuse”.

## Limitations

The present study was limited only to the non-prescriptive medicine usage, if iatrogenic affects were also included overall steroid misuse can be understood better.

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## REFERENCES

1. Panda A, Pradhan S, Mohapatra G, Mohapatra J. Drug-related problems associated with self-medication and medication guided by prescription : A pharmacy-based survey. *Indian J Pharmacol*. 2016;48:515-21.
2. Brody JE. Over-the-Counter Medicines' Benefits and Dangers. *The New York Times*. 30.11.2015.
3. Choon S, Lai N. An epidemiological and clinical analysis of cutaneous adverse drug reactions seen in a tertiary hospital in Johor, Malaysia. *Indian J Dermatol Venereol Leprol*. 2012;78:734-9.
4. Mehta AB, Nadkarni NJ, Patil SP, Godse KV, Gautam M, Agarwal S. Topical corticosteroids in dermatology. *Indian J Dermatol Venereol Leprol*. 2016;82:371-8.
5. Mishra AK, Saraswat D. Topical corticosteroid abuse in dermatology. *IOSR journal of dental and medical sciences* 2016;15:110-4.
6. Nagesh TS, Akhilesh A. Topical steroid awareness and abuse: a prospective study among dermatology outpatients. *Indian J Dermatol*. 2016;61:618-21.
7. Kumar S, Goyal A, Gupta YK. Abuse of topical corticosteroids in India: Concerns and the way forward. *J Pharmacol Pharmacother*. 2016;7:1-5.
8. Lahiri K, Coondoo A. Topical steroid damaged/dependent face (TSDf): An entity of cutaneous pharmacodependence. *Indian J Dermatol*. 2016;61:265-72.
9. Saraswat A, Lahiri K, Chatterjee M, Barua S, Coondoo A, Mittal A, et al. Topical corticosteroid abuse on the face: A prospective, multicenter study of dermatology outpatients. *Indian J Dermatol Venereol Leprol*. 2011;77:160-6.

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