Use of Over-the-Counter Topical Medications in Dermatophytosis: A Cross-Sectional, Single-Center, Pilot Study from a Tertiary Care Hospital

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Abstract

Background: Dermatophytosis is a common, superficial fungal infection of the skin. In developing countries like India, casual attitude toward seeking medical attention and lax drug control policies lead to indiscriminate use of irrational over-the-counter (OTC) medications. Studies on OTC topical medication abuse in dermatophytosis are lacking despite its frequent occurrence. Aims: To assess the magnitude of OTC topical medication use in dermatophytosis by studying the demographic variables, source of prescription, and their adverse effects. Materials and Methods: This cross-sectional, observational, questionnaire-based pilot study was carried out in a tertiary care center. One hundred consecutive, mycologically confirmed dermatophytosis patients were questioned about the use of OTC medications and examined for adverse effects of the preparations used. Results were documented in a predesigned pro forma and the data were expressed in terms of means and proportions. Results: The study population consisted of 75 males and 25 females. Tinea cruris was the most common pattern observed. Only 32% of the patients consulted a dermatologist on developing a rash, whereas the majority (68%) used medicines suggested by others. Clobetasol-based preparations were commonly misused, and 63.23% of the study population experienced adverse effects. Furthermore, majority (89%) of the study population were unaware of steroids and their adverse effects. Conclusions: The growing threat of OTC drug abuse in India is evident from this study. Stringent drug control policies and awareness of adverse effects of OTC topical medication abuse are truly the need of the hour to control this menace.

Keywords: Dermatophytosis, drug abuse, over-the-counter topical medication

INTRODUCTION

Dermatophytosis is one of the most prevalent public health problems in developing countries like India. Once an easily curable infection, its treatment has now become challenging, which is attributable to changing climatic conditions, westernization, casual health-seeking attitude, and lax drug control policies in India facilitating over-the-counter (OTC) topical medication abuse. Indiscriminate use of irrational topical fixed drug combinations (FDCs) alters the clinical presentation, evokes an irritant response, and contributes to resilience of fungi, resulting in recurrences, chronicity, and probably resistance to antifungal agents.

Commonly available OTC topical medications for “itchy skin rash” include FDC creams containing steroid, antibiotic, and antifungal agents. Preparations containing irritants such as dithranol, salicylic acid, and herbal ingredients are also frequently used by patients who do not wish to visit the doctor and indulge in self-medication due to easy availability of such medications. The anti-inflammatory properties of these preparations may give quick symptomatic relief to a patient, but they serve as an important cause of persistence and spread of fungal infection in the community.

Despite the extensiveness of their use in India, comprehensive studies on OTC topical medication abuse in dermatophytosis are lacking. We aim to ascertain the growing menace of OTC drug abuse and its implications in dermatophytosis.

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Materials and Methods

This was a cross-sectional, questionnaire-based, pilot study conducted in the dermatology outpatient department (OPD) at a tertiary care center. The study was approved by the Institutional Ethical Committee. After obtaining informed consent, 100 consecutive mycologically proven patients with dermatophytosis of all ages and both sexes were recruited. Patients with tinea unguium, illiterate patients, and those unwilling for participation were excluded.

Skin scrapings from all patients were subjected to 10% potassium hydroxide (KOH) mount and examined under a microscope for fungal hyphae, the presence of which was considered positive for dermatophyte infection. In doubtful and KOH mount-negative cases, skin scrapings were cultured in Sabouraud’s dextrose agar with chloramphenicol and cycloheximide for dermatophytes. A standard validated questionnaire eliciting clinico-demographic variables, characteristics of OTC topical medication use, source of prescription, and their adverse effects was administered to all eligible patients. Patients were then examined by a single observer to determine the pattern of presentation and adverse effects of medications used.

Results

Our study population consisted of 75 males and 25 females. The mean age of the study population was 31.9 years, ranging from 4 to 72 years. The mean duration of dermatophytosis in our study population was 2.6 months, and 45% of the cases had the disease ranging from 1 to 6 months’ duration. Clinical examination of the study population revealed tinea cruris as the most common presentation (44%), followed by tinea corporis (10%), tinea faciei (5%), and an overlap of these in the others [Table 1].

Surprisingly, only 32% of the study population consulted a dermatologist on developing a rash, whereas the majority (68%) used OTC topical medications recommended by pharmacists and friends/relatives, general practitioners, and practitioners of alternative systems of medicine [Table 2].

A total of 33 different commercially available OTC preparations were used. For the ease of analysis, we classified the OTC topical medications into steroid-based preparations, antifungals, and miscellaneous agents. Steroid-based OTC medications were most popular among our study group and majority (77.94%) of the patients used steroid-based preparations, followed by preparations containing salicylic acid, lactic acid, dithranol, coal tar, urea, etc., (14.7%) and some used topical antifungal agents (7.35%) [Figure 1]. Furthermore, about one-third of this group admitted using more than one preparation for their disease. Among the steroid-based preparations, clobetasol propionate was commonly used followed by betamethasone valerate, beclomethasone dipropionate, and fluticasone. Among the topical antifungal agents, miconazole was most commonly used followed by clotrimazole [Table 3].

| Clinico-epidemiological variables | n |
|-----------------------------------|---|
| Age (years)                       |   |
| 0-10                              | 2 |
| 11-18                             | 10|
| 19-45                             | 74|
| 46-75                             | 14|
| Educational qualification         |   |
| Primary                           | 5 |
| 12th pass                         | 28|
| Matriculation                     | 37|
| Graduate                          | 18|
| Postgraduate and above            | 12|
| Duration of disease               |   |
| <2 weeks                          | 14|
| Up to 1 month                     | 27|
| 1-6 months                        | 45|
| 7 months-1 year                   | 7 |
| >1 year                           | 7 |
| Clinical presentation             |   |
| Tinea cruris                      | 44|
| Tinea corporis                    | 10|
| Tinea faciei                      | 5 |
| Tinea pedis                       | 1 |
| Overlap                           | 40|

Table 2: Source of over-the-counter medication prescription

| Source                              | n (%) |
|-------------------------------------|-------|
| Friends/relatives                   | 20 (29.4) |
| Pharmacist                          | 21 (30.88) |
| Nurse                               | 3 (4.4) |
| Ayurvedic/homeopathic doctor        | 4 (5.88) |
| General practitioner                | 13 (19.11) |
| Other specialists                   | 6 (8.82) |
| Media                               | 1 (1.47) |

Brand names of commonly misused steroid-based preparations were Quadiderm, Fourderm, Betnovate, Panderm, and Candid B, which could be procured OTC without prescription. Irritant preparations like Derobin, Zalim, Sapat, and Salex L were infrequently used.

About 63.23% of the patients using these OTC preparations reported adverse effects on questioning. More than half of these patients (55.81%) had multiple adverse effects. The common adverse effects observed in our study included burning sensation (44.18%), atrophy (30.23%), striae (16.27%), hypopigmentation (23.25%), worsening of rash (30.23%), and contact dermatitis (16.27%) [Table 4].

Furthermore, in our survey, majority (89%) of the patients had never heard of steroids and were not aware of the adverse effects of steroids.
Dermatophytosis is a widely prevalent superficial mycosis in India with a recent upsurge in its incidence and a myriad of atypical presentations due to a complex interplay of agent factors (true resistance, parasitism of vellus hair), host factors (changing clothing habits, ping pong effect within the family, untreated sanctuary sites, casual health-seeking attitude, lack of adherence to standard therapy), and social factors (hesitation to seek medical advice due to involvement of groins, gluteal region, or the inframammary regions). The rampant inappropriate use of topical steroids. About 12% of the patients admitted using of TC and dermatophytosis was the leading cause of steroid abuse (38.4%). Betamethasone valerate-based medications were most commonly used with friends/relatives as the common source of prescription (33.2%). Furthermore, a case series of tinea incognito resulting from misuse of potent TCs has been reported by Sheth et al.[9] The rampant inappropriate use of steroids has been emphasized time and again.

This study aimed at assessing all types of OTC topical medication abuse by study population in dermatophytosis.
In the present study, tinea cruris was the most common clinical presentation (44%), differing from a recent study which reported tinea faciei as the predominant type.[7] This difference could be because of the male predominance who wore occlusive clothing for prolonged periods.

The casual health-seeking attitude of Indian patients is reflected in this study with only one-third (32%) of the patients consulting the dermatologist on developing a skin rash. The data are comparable to the previous studies wherein dermatologists were approached by 14%–40% of patients.[10,11] The major source of advice for the use of OTC medicines were pharmacists (30.8%) and friends/relatives (29.4%). Pharmacists have been a major source of prescription (20%–78%) in the earlier studies also.[7,8] Hence, educating pharmacists and general practitioners about the adverse effects of irrational use of OTC medications is crucial.

In this study, 68% of patients used 33 different commercially available OTC medications. TCs were commonly used, and clobetasol-based preparations were predominant unlike other previous Indian studies wherein betamethasone was the most frequently used OTC preparation.[7,8] Burning sensation was the most common adverse effect experienced by the patients, and clinically, atrophy, striae, eczematous changes, hypopigmentation, and widespread bizarre lesions were most frequently encountered [Figures 2 and 3]. Burning sensation was more common in patients who used irritants such as salicylic acid, coal tar, and dithranol, indicating irritant contact dermatitis [Figure 4]. In a developing country such as ours, with literacy levels something that we cannot be proud of, it does not come as a surprise that most of the patients (89%) had neither heard of steroids nor were aware of their adverse effects.

The growing threat of OTC medication misuse in India is evident from this study. In this direction the Indian Association of Dermatologists, Venereologists and Leprologists has already started a nationwide campaign against topical steroid abuse.[12] It is critical for the drug regulatory agency to keep a check on the availability of rational topical formulations only, minimizing the number of OTC topical preparations and sale of others solely on valid prescriptions.

**Conclusion**

Health education to create public awareness about irrational drug abuse and its adverse effects is truly the need of the hour. In addition, combined efforts from the drug manufacturer, doctors, and pharmacists supported by stringent drug control policies are of paramount importance in overcoming this hurdle.

**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 his/her/their images and other 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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Conflicts of interest
There are no conflicts of interest.

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