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Short Communication

Are Over-the-Counter Acne Drugs Considered Safe?

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ABSTRACT

This descriptive observational study was conducted in 30 community pharmacies in Chidambaram, Tamil Nadu, to assess the dispensing of over-the-counter (OTC) acne medications. The most frequently dispensed preparations were hydroquinone + mometasone furoate + tretinoin (40%), followed by salicylic acid + betamethasone (26%). Among the observed combinations, only nicotinamide, salicylic acid, benzoyl peroxide, adapalene, and clindamycin are considered first-line agents in acne management. At the same time, drugs such as hydroquinone, mometasone furoate, tretinoin, and betamethasone are scheduled H drugs requiring physician supervision. The findings highlight the need for a regulated OTC drug list and the removal of inappropriate combination products to ensure safer and more effective acne treatment.

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INTRODUCTION

Over-the-counter drugs, or non-prescription drugs, are those medications sold without a prescription by the retail pharmacy [1]. In India, according to the Drugs and Cosmetics Act 1940, all kinds of drugs are categorized into schedules. The schedules are named with alphabetic letters such as A, B, C, C_1, D, E_1, F, F_1, F_2, F_3, FF, G, H, H_1, J, K, M, M_1, M_2, M_3, N, O, P, P_1, Q, R, R_1, S, T, U, U_1, V, W, X, and Y. Among these, Schedule H, H_1, and X drugs should only be dispensed under the prescription of a registered medical practitioner [2]. And schedule G drugs, especially antihistamines, should only be taken under medical supervision. But there is no such schedule for OTC drugs. It leads to the misuse of some drugs [3].

Acne vulgaris is the most common disease that affects the adolescent (72.3%) and adult (27%) age groups in India [4,5]. It resulted in the pilosebaceous unit over the skin and was characterized by the presence of comedones, papules, pustules, and nodules on the face, chest, and occasionally back. It developed for various reasons, mainly due to hormonal imbalance, sunlight exposure, and endocrine disorders [6]. Treatment regimens include benzyl peroxide, topical retinoids, topical antimicrobials, oral antibiotics, oral isotretinoin, and oral corticosteroids [7]

Nowadays, the usage of OTC drugs for acne is a most familiar habit among teens. Due to their

Table 1: List of combinations of OTC acne drugs

Composition of drugs	Number of pharmacies	Percentage
Clindamycin (1.00% w/w)and Nicotinamide 4.0%	3	10%
Hydroquinone (2.0% w/w),Tretinoin (0.025%w/w) and Mometasone furoate 0.1%w/w	12	40%
Salicylic acid (3.0%)and Betamethasone (0.1%)	8	26.6%
Clindamycin (1.0%) and Tretinoin (0.025%)	2	6.67%
Adapalene (0.1%w/w)&Clindamycin (1%w/w)	3	10%
Tretinoin (0.05%w/w)	1	3.34%
Clindamycin (1.00%w/w	1	3.34%

unawareness of them, they use multiple topical agents with a lot of unwanted combination drugs prior to the treatment at clinics or hospitals. Sometimes, this leads to worsening their skin problems. Herein, we identify the OTC acne drugs and their composition.

METHODOLOGY

A descriptive observational study using an unstructured observation method was conducted in community pharmacies located in Chidambaram, Tamil Nadu. A census sampling method was employed, resulting in a sample size of thirty (n=30) pharmacies included in this study. This study was conducted during the period of November 2023 to April 2024 (6 months). The information regarding the first-line OTC acne drugs and their composition is recorded in the data collection form, and it was solely based on observational data. Microsoft Excel analyzed the collected data.

RESULTS

This study reveals that the community pharmacy dispenses six different kinds of combination non-prescription drugs to treat acne vulgaris, as shown in Table 1. Among these combination drugs, the majority of the pharmacies (N=30) sold hydroquinone 2.0% w/w, tretinoin 0.025% w/w, and mometasone furoate 0.1%w/w (40%, 12/30), followed by salicylic acid (3.0% w/w) and betamethasone 0.1% w/w (26.6%, 8/30) as a first-line agent for acne vulgaris. But this drug does not serve as an OTC drug, and it comes under the Schedule H drugs. Corticosteroids are not recommended for acne treatment in the long term. On the other hand, this combination seems to be unwanted and irrational.

DISCUSSION

In India, after the implementation of the Drug and Cosmetic Acts and Rules of 1940, the initial alignment of the entire pharma market began. During that era, schedules were established for each class of medication. From this Schedule H, H_1, and X drugs should be dispensed only under the prescription made by a registered medical practitioner. But till now, there is no specific schedule for OTC drugs. This leads to a great thread, such as drug misuse and some health difficulties.

Acne vulgaris is a very common skin disorder with a high incidence rate worldwide. As per the standard treatment guidelines for acne vulgaris by the Indian Association of Dermatologists, Venereologists, and Leprologists, the topical treatment consists of benzoyl peroxide, retinoids, azelaic acid, and antibiotic creams such as clindamycin. And the systemic treatment consists of azithromycin, doxycycline, minocycline, tetracyclines, oral retinoids (isotretinoin), and hormonal therapy (oral contraceptives and anti-androgens). Other treatments include chemical peels, lasers, light therapy, fillers, and subcision. Simultaneously, corticosteroids are not recommended for the treatment of acne vulgaris.

Most of these acne drugs fall under Schedule

H, which requires a prescription before dispensing, except for benzoyl peroxide. Unfortunately, most of the community pharmacies sold these acne drugs as non-prescription drugs. At the worst, topical corticosteroid drugs are dispensed as a first-line treatment. In India, due to poor law implementation and patient awareness, non-prescription drugs are constantly being misused.

Ankita Srivastava and Shristi Shrestha, *et al*, highlighted that the increasing misuse of topical corticosteroids represents a significant concern in dermatology outpatient departments [8, 9]. The non-prescription dispensing of over-the-counter corticosteroid formulations has been linked to several adverse outcomes. In particular, their inappropriate use in acne management has been identified as a major factor contributing to the aggravation and worsening of the disease condition.

This problem can be addressed through the awareness created by clinical pharmacists. They should explain to patients the harmful effects of using over-the-counter (OTC) topical corticosteroids. Patients can be advised to bring their medications for review, allowing pharmacists to analyze their composition and provide appropriate care. From a retail dispensing perspective, manufacturers should include clear warning notices on product labels. Altogether, these measures can help prevent the misuse of topical corticosteroids.

CONCLUSION

Inappropriate dispensing of medication, particularly corticosteroids, has always been a noticeable problem in retail pharmacies. The outcomes, such as corticosteroid misuse, drug resistance, and treatment failure rates, have been increasing recently. Formulating an OTC drug list may solve this entire situation. Concurrently removing the unwanted combination products from the pharma market helps to provide a better treatment option for people. Even though the retail pharmacist takes a step up towards safe dispensing of drugs with prescriptions, and has great concern for Schedule H drugs, especially corticosteroids. Adults need to have awareness regarding the OTC acne medication before using it. Implementing a clinical pharmacist medication review process will help prevent the misuse of topical corticosteroids.

CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

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None

ABBREVIATION:

OTC – Over the Counter

SUMMARY

This study investigated the dispensing practices of over-the-counter (OTC) acne medications in 30 community pharmacies in Chidambaram, Tamil Nadu. The most commonly dispensed preparations were hydroquinone + mometasone furoate + tretinoin (40%) and salicylic acid + betamethasone (26%). While agents like benzoyl peroxide, adapalene, clindamycin, nicotinamide, and salicylic acid are recognized as first-line acne treatments, several of the dispensed products, particularly corticosteroid-containing combinations, fall under Schedule H and require medical supervision. Their inappropriate availability as OTC drugs highlights a concerning trend of irrational use, misuse, and potential harm. The findings emphasize the urgent need to establish a regulated OTC drug list, eliminate irrational combinations, and strengthen the role of pharmacists in patient education and safe dispensing practices to ensure effective and safe acne management.

REFERENCES

1. Marathe PA, Kamat SK, Tripathi RK, Raut SB, Khatri NP. Over-the-counter medicines: global perspective and Indian scenario. J Postgrad Med. 2020;66(1):28-34. Doi:10.4103/jpgm.JPGM_381_19. PMID:31898596; PMCID:PMC6970327.
2. The Drugs and Cosmetics Act, 1940 and Rules, 1945 [Internet]. New Delhi: Central Drugs Standard Control Organization; 2016 [cited 2019 Jun 11]. Available from: https://cdsco.gov.in/opencms/opencms/en/Acts-Rules/
3. Abraham O, Chmielinski J. Adolescents' misuse of over-the-counter medications: the need for pharmacist-led intervention. Innov Pharm. 2018;9(3):1-7. Doi:10.24926/iip.v9i3.979. PMID:34007709; PMCID:PMC6302752.
4. Sharma RK, Dogra S, Singh A, Kanwar AJ. Epidemiological patterns of acne vulgaris among adolescents in North India: a cross-sectional study and brief review of the literature. Indian J Paediatr Dermatol. 2017;18(3):196-201. Doi:10.4103/ijpd.IJPD_82_16.
5. Budamakuntla L, Parasramani S, Dhoot D, Deshmukh G, Barkate H. Acne in Indian population: an epidemiological study evaluating multiple factors. IP Indian J Clin Exp

Dermatol. 2020;6(3):237-42. doi.org/10.18231/j.ijced.2020.048

6. Trivedi NR, Cong Z, Nelson AM, Albert AJ, Rosamilia LL, Sivarajah S, et al. Peroxisome proliferator-activated receptors increase human sebum production. J Invest Dermatol. 2006;126(9):2002-9.
7. Sacchidan S, editor. IADVL textbook of dermatology. 5th ed. New Delhi: Bhalani Publishing House; 2021.
8. Srivastava A. A clinicoepidemiological study of topical corticosteroid misuse at a tertiary care center. J Dermatolog Treat. 2019;30(7):685-90. Doi:10.1080/09546634.2018.1544703. PMID:30394142.
9. Shrestha S, Joshi S, Bhandari S. Prevalence of misuse of topical corticosteroid among dermatology outpatients. JNMA J Nepal Med Assoc. 2020;58(231):834-8. Doi:10.31729/jnma.5271. PMID:34506417; PMCID:PMC7775011.

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