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The Use of Topical Clobetasol among the Women in Hail Region, Saudi Arabia: A Cross-sectional Study on Knowledge and Practice

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Authors' contributions

This work was carried out in collaboration among all authors. Author MA designed the study, performed the statistical analysis, wrote the protocol and wrote the first draft of the manuscript. Authors SP and MIMI designed the study and managed the analyses. Author PRS managed the literature searches and performed the statistical analysis. All authors read and approved the final manuscript.

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ABSTRACT

Aims: The current study aimed to evaluate female consumers' knowledge and practice about harmful effects of topical clobetasol applied on the face for cosmetic purposes.

Study Design: Cross-sectional study.

Place and Duration of Study: Randomly selected community pharmacies, well known cosmetic shops and shopping malls of Hail region, Saudi Arabia from March 2018 to June 2018.

Methodology: We included 391 participants who only used 'clobetasol' as a topical steroid at the time of interview, responses were collected as per the study tool and analyzed using SPSS for Windows, Version 16.0. Chicago, SPSS Inc..

Results: Relatives (28.1%), friends (25.6%) and community pharmacists (15.6%) contributed significantly towards using topical clobetasol cream. In 86.2% of the cases, the pharmacists who dispensed clobetasol did not inform the consumer about the harmful effects. Purchasing the cream without prescription (P = 0.025) was significantly associated with age. In the study, 41.9 % of the females experienced adverse effects, with the commonest one being hair growth on face (23%) followed by dermatrophy (14.8%); with a significant association with frequency of use (p<0.001). **Conclusion:** There was haphazard use of topical clobetasol by females and they were unaware of the adverse effects. Over-the-counter availability of topical clobetasol, lack of knowledge about harmful effects, and lack of counseling on its safety profile by community pharmacists and other healthcare professionals are mainly responsible for its misuse and harmful consequences.

Keywords: Adverse effects; clobetasol; consumers; corticosteroids; Saudi Arabia; topical.

1. INTRODUCTION

Corticosteroids are naturally synthesized in the body by the adrenal cortex and synthetic forms are commercially available in multiple dosage forms and are intended for various purposes ranging from topical inflammation to life-threatening anaphylaxis. Topical corticosteroids (TCs) were introduced into dermatological therapy by Sulzberger and Witten about 67 years ago [1]. Topical corticosteroids (TCs) are one of the most extensively used therapeutic modalities in modern dermatological practice [2]. They provide quick relief and symptom suppression.

Meanwhile, the misuse of TCs has also increased especially application on the face which has increased the incidence of various adverse effects such as atrophy, irritant dermatitis. acne. purpura. hypertrichosis. dyspigmentation [3,4], leading to a significant proportion of visits to dermatologists [5,6]. In several countries, potent TCs are easily available over-the-counter (OTC) at a low price, and hence misuse has been noticed among the general population, leading to many adverse effects [7,8]. However, TCs such as Dermovate (Clobetasol propionate 0.05%) is a prescription only potent topical cream in Saudi Arabia [9].

There are various factors, beyond quick symptom relief, that can lure consumers towards haphazard use of corticosteroids. Some of these include eye-catching posters, advertisement on television and other electronic media, easy availability, and desire for becoming fairer than before, and at the same time they experience numerous adverse effects [4]. Misuse of TCs for cosmetic purposes such as, face peeling or whitening the body is an alarming problem in Saudi Arabia, especially in women [10]. Availability of TCs over the counter and their sale without prescription are the major causes of their

misuse and adverse effects. Use of OTC medicines is a global problem including in Saudi Arabia. Use of OTC TCs is common especially among young females [11,12]. This existing scenario underscores the need for understanding the consumers' knowledge and practice regarding use of clobetasol, and suggesting possible interventions.

Hence, the present study was conducted with the aim to evaluate female consumers' knowledge and practice about harmful effects of topical application of Dermovate (Clobetasol Propionate) on the face for cosmetic purpose.

2. MATERIALS AND METHODS

2.1 Study Design

Cross-sectional descriptive study was carried out to evaluate the knowledge and practice among Saudi Arabian females regarding topical clobetasol preparations, such as Dermovate.

2.2 Study Setting

This study was undertaken at randomly selected community pharmacies, well known cosmetic shops and malls in Hail region, Saudi Arabia from March 2018 to June 2018.

2.3 Study Population, Sample Size and Sampling Procedure

Study population were the adolescent and adult females living in Hail region, who have been using clobetasol cream on the face for at least one month. The participants were sampled among those using only clobetasol as topical steroid.

Inclusion criteria: Those that use only clobetasol as topical steroid were included in the study.

Exclusion criteria: The subjects using any other corticosteroids along with clobetasol were excluded from the study. Three hundred and ninety one women participated. Consecutive sampling method was adopted to approach the study participants. As study participants were women, female interviewer collected the data. The interviewer interacted with each woman in the study settings after meeting the inclusion criteria. Written consents were taken and the interview was performed according to the questionnaire.

2.4 Instrument and Instrumentation

The questionnaire was self-designed based on the objectives of the study after extensive literature review. The questionnaire consisted of three parts with mixed type of questions. Part A represented demographic characteristics of the participants (i.e. age, educational status, marital status and occupation), Part B (consisted of three items with nominal values) determined the knowledge of participants about clobetasol and Part C (consisted of six items with nominal as well as ordinal values) was related to the practice of using clobetasol. Face and content validities were determined by sending the instrument to carefully selected experts from the Department of Clinical Pharmacy, University of Hail. The study was piloted among 20 similar participants. Based on the pilot study findings, modifications were performed in a few ambiguous questions. The reliability of the tool measured using Cronbach's alpha was 0.8. The data was collected by a trained female interviewer using the survey tool.

The participants were interviewed as per the questionnaire to gather the required data.

2.5 Data Collection and Analyses

The coded data from each questionnaire were entered in SPSS 16.0 for window (SPSS Inc. Released 2007. SPSS for Windows, Version 16.0. Chicago, SPSS Inc.) and analyses were carried out. Descriptive statistics was used to describe the findings. Chi-square test was used to see the associations between categorical variables. A priori alpha value of less than 0.05 was considered significant.

3. RESULTS

Three hundred and ninety-one women participated in this study. Majority (78%, n=305) of the participants were within the age range of 15 to 35 years. The use of clobetasol cream was very common among educated young females at higher secondary school and bachelor levels. The use of clobetasol was commoner among unmarried females (54.2%, n=212). Other demographic details were as depicted in Table 1.

Relatives, friends and community pharmacists played the most influential role towards promoting the use of clobetasol cream (Fig. 1). About three-fourth of the females were not aware about the harmful effects of clobetasol cream. Among the remaining (24.6%) who had some idea, only 1.6% were able to mention harmful effects such as skin inflammation, hyperpigmentation and thinning of skin.

Table 1. Demographic characteristics of the study respondents (n=391)

Variables		Number	Percentage (%)
Age (yrs)	<15	11	2.8
	15-25	203	51.9
	26-35	102	26.1
	>35	75	19.1
Educational status	No formal education	9	2.2
	Primary level	13	3.3
	Secondary level	22	5.6
	Higher secondary	99	25.3
	Bachelor	235	60.1
	Master	13	3.3
Marital status	Unmarried	212	54.2
	Married	179	45.8
Occupation	Students	107	27.4
	Government job	100	25.6
	Private	55	14.1
	House wife	129	33.0

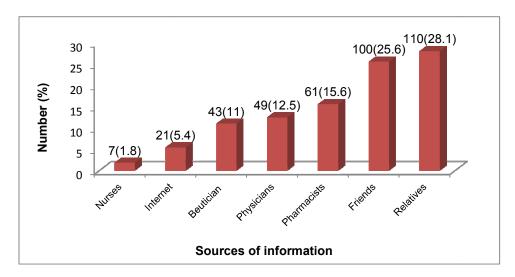


Fig. 1. Sources of information about clobetasol cream

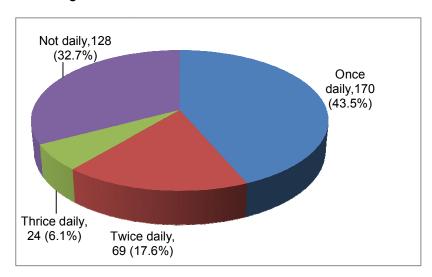


Fig. 2. Frequency of using clobetasol cream

More than 75% of the users mentioned that they purchased clobetasol cream without a valid prescription. Moreover, in 337 (86.2%) of the cases, the pharmacist who dispensed clobetasol cream did not inform the consumer about its harmful or adverse effects (Table 2).

Purchasing clobetasol cream without prescription (P=0.025) was significantly associated with age. Similarly, reading leaflet before use was significantly associated with marital status of the participants (P=0.031). Sharing the cream with others was significantly associated with occupation (P=0.001).

Majority (73%) of the users had been using clobetasol cream for one month or more, and the

remaining one-fourth used for last one or two weeks. Among the users, 43% used once daily (Fig. 2). Frequency of using the cream was also significantly associated with age (P = 0.005), education (P < 0.001), marital status (P = 0.028) and occupation (P = 0.009) of the participants.

A higher proportion (58.1%; n=227) of the females did not experience any noticeable adverse effects. The remaining 41.9% of the females encountered adverse effects and the most common were hair growth on face (23%; n=89) followed by dermatrophy (14.8%; n=58) (Fig. 3). Adverse effects experienced during use of the cream was significantly associated with frequency of use (p<0.001).

4. DISCUSSION

The eve-catching posters, and advertisement on television allures people mainly females toward the indiscriminate use of the cream. The problem got worsened as the user had easy access to the product without relevant prescription that lead to adverse effects and sometimes dependence on such topical products. Topical corticosteroids have acquired a reputation as an anti-acne, antiblemish and fairness cream in the general population, not only among the dark people but also the fair ones who want to be fairer than they used to be [4]. The study clearly revealed the problem of topical steroid misuse on the face. The facial skin is more vulnerable to TCs because it is thinner than the skin of most other parts of the body. Furthermore, there is more blood supply to this region that results in increased percutaneous absorption of the drug.

Studies conducted in various countries including Saudi Arabia found out that TCs were used mostly by females [6,10,13]. Craving towards the use of TCs was profound among young females which was also reflected in the findings of other studies [6,10]. The main reason for using TCs was to have aesthetic effect [14]. Majority of the participants had higher secondary and graduate level of education as found in a previous study [15] (Table 1).

Although participants got motivated from various sources such as relatives, friends, pharmacists, physicians, nurses, beauticians, and internet; relatives and friends were the leading inspiration toward using TCs (Fig. 1). The findings agreed with the findings of Majed et al. [13]. The latter study found friends or relatives recommending in

about one-third cases, pharmacists (one-fifth) and internet (less than ten percent) which are even higher than that found in this study [13]. Study by Sendrasoa et al also supported the findings [14]. However, there was extreme lack of knowledge among the users about harmful effects of TCs. About three-fourth of the females were not aware of the harmful effects of clobetasol cream. A study conducted by Mahdy et al in the UAE found the same knowledge pattern among the users [15]. On the contrary, very few (1.6%) were able to mention some adverse effects about the topical use of TCs, which was less compared to a previous study (11.2%) [15].

The availability of TCs as OTC medicine was one of the major causes of their misuse [6,15]. Pharmacists can play an important role towards minimizing adverse drug reactions (ADRs) through promoting proper counseling, and improve the situation [16]. About 38% of the users referred to leaflet to obtain information, but it was only about 21% in a Nigerian study [17] (Table 2).

Once or twice daily use of clobetasol cream was common as reflected in a previous study [15] (Fig. 2). Study among university students found quite low (7.6%) incidence of adverse effects due to TCs. However, the incidence of adverse effects due to clobetasol cream was about 42% in this study probably due to diversity of respondents. Study showed hypertrichosis and dermatrophy as common adverse effects due to clobetasol [18,19,20] (Fig. 3).

This study was carried out in only one city of the Kingdom and generalization of the findings may require more extensive multicenter studies.

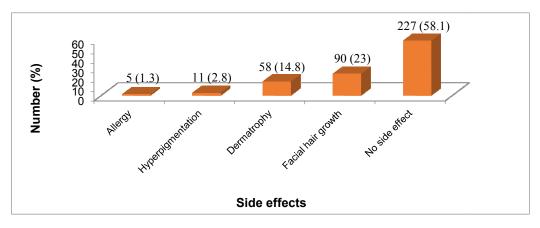


Fig. 3. Side effects experienced during use of clobetasol cream

Table 2. Practice of using clobetasol cream

Variable	Yes	No
	N (%)	N (%)
Purchasing easily without prescription	295 (75.4)	96 (24.6)
Pharmacist's counseling about side effects	54 (13.8)	337 (86.2)
Reading leaflet before use	150 (38.4)	241 (61.6)
Sharing clobetasol cream with others	142 (36.3)	249 (63.7)

5. CONCLUSION

The study revealed that indiscriminate use of topical clobetasol by females could lead to significant adverse effects. It also showed that topical clobetasol could be obtained without valid prescription and community pharmacists emphasized less on the safety profile of this medication.

6. RECOMMENDATIONS

Government to reinforce laws against improper dispensing drugs classified under Prescribed Order Medicines (POM) list in the Kingdom.

Authorities concerned to awaken professionalism in drug dispensing by educating relevant personnel.

Consumer education through the media and health professionals will be of high value.

Health education related to issues of drug misuse to be included in school curricula.

CONSENT AND ETHICAL APPROVAL

As per international standard, participant consent and ethical approval has been collected and preserved by the authors.

COMPETING INTERESTS

Authors have declared that no competing interests exist.

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