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Cosmetic products utilization and its adverse reactions among patients attending dermatology outpatient department in a tertiary care hospital: Gearing up Cosmetovigilance

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ABSTRACT

Introduction: In recent years, more attention has been given for testing and monitoring of the possible harmful effects of cosmetics because few studies revealed that exposure to various chemical substances present in cosmetics poses a health risk. Cosmetovigilance is a public health surveillance mainly encourages to report cosmetics-related ADRs.

Methodology: A cross-sectional study conducted in dermatology outpatient department of a tertiary care hospital from March- June of 2023 which included 173 participants. The questionnaire for data collection was adopted. Participants were also asked to provide the nature and type of reaction, onset of the reaction, cosmetics suspected to cause the reaction and how they managed to the reaction.

Results: Among the 173 participants, 48.9 % reported that they had at least one adverse reaction in the past two years. Redness of the skin (21%), pimples (25%), and itching (19%) were the commonly reported adverse reactions. The majority (64.2%) of the participants with managed the adverse reactions by the cessation of the product use. However, the adjusted analysis found that allergic to medication (adjusted OR: 3.6), family history of allergy (adjusted OR: 0.91), and mixing cosmetics (adjusted OR: 2.0) were significantly associated with cosmetics-related adverse reactions

Statistical analysis: Descriptive statistics (frequency and percentage) were used to summarize demographic characteristics, the pattern of cosmetic use, and adverse events. Logistic regression model was used to assess the determinants of the occurrence of cosmetics-related adverse events among the respondents.

Conclusion: Cosmetovigilance is a model of safety monitoring of cosmetics and can be considered as a one of the element in public health activities. Approaches to address adverse reactions may include awareness creation programs and promoting the concept of cosmetovigilance among cosmetic sellers, users, and other stakeholders.

Keywords*: Cosmetovigilance, adverse reactions, cosmetics,allergy.*

INTRODUCTION

Cosmetics is defined by their intended use as a material rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body for cleansing, beautifying, promoting attractiveness, or altering the appearance. g, promoting attractiveness, or altering the appearance.[1] Among the products included in this definition are skin moisturizers, perfumes, lipsticks, fingernail polishes, eye and facial makeup preparations, cleansing shampoos, permanent waves, hair colors, medicated soaps and deodorants, as well as any substance intended for use as a component of a cosmetic product.1 However, little is known about these products' related adverse events.[1,2]

The majority of cosmetic consumers are focused on short-term outcomes of the cosmetics on appearance rather than the longterm consequences on the whole body. It is believed that such products have a reasonable degree of safety and tolerability. In recent years, more attention has been given for testing and monitoring of the possible harmful effects of cosmetics. [3]The studies revealed that exposure to various chemical substances present in cosmetics poses a health risk. It can vary from mild hypersensitivity response to severe anaphylactic reaction or even a lethal intoxication. It may occur immediately or after the prolonged use of cosmetics. It has been suggested that the presence of multiple ingredients and their cumulative effects in the cosmetic products are the top causes of toxicity exposure to consumers. cosmetics regulatory authorities tried to minimize the unwanted reactions of cosmetics, by setting criteria for safety, efficacy, and quality of cosmetics . [4,5]Headache, dizziness, tiredness, and nausea were the frequently reported adverse reactions associated with prolonged exposure to heavy makeup Nevertheless, selling products without the authorities' approval, lack of population awareness about proper use of cosmetics and lack of proper adverse effect reporting systems are still prevailing factors particularly in developing countries.[5] Cosmetovigilance is a public health surveillance on cosmetic products with public health objectives In US and Canada, manufactures, health care providers and consumers are encouraged to report cosmetics-related ADRs to the FDA. there exists a lacuna of research on cosmetics utilization patterns and cosmetics-related adverse reactions in the Saudi population. Hence this pilot study was aimed to assess cosmetics utilization patterns and self-reported adverse reactions in the general public.[5,6]

MATERIALS & METHODS:

Study design: Cross-sectional study

Study type: Observational study

Study duration : 6 months from January 2023 – June 2023

Sample size: 173 participants
Participants were requested to read the information about the study and to agree with the informed consent
Ethics committee approval : Approved

Sample size calculation: Previous literature shows the prevalence of adverse effects of cosmetics was varied from 8 to 38%. With 95% confidence limit and 5% margin of error, the sample size required for estimating the prevalence of 38% was 173.

Inclusion criteria:

- Patients of any age & gender
- Persons who have a habit of using any categories of cosmetic products and who read/ write either English was included in the study

Exclusion criteria

- Pediatric populations
- Persons with hearing and sight problems
- persons on permanent cosmetic methods like plastic surgery, tattoos, fillers, and Botox

Data collection:

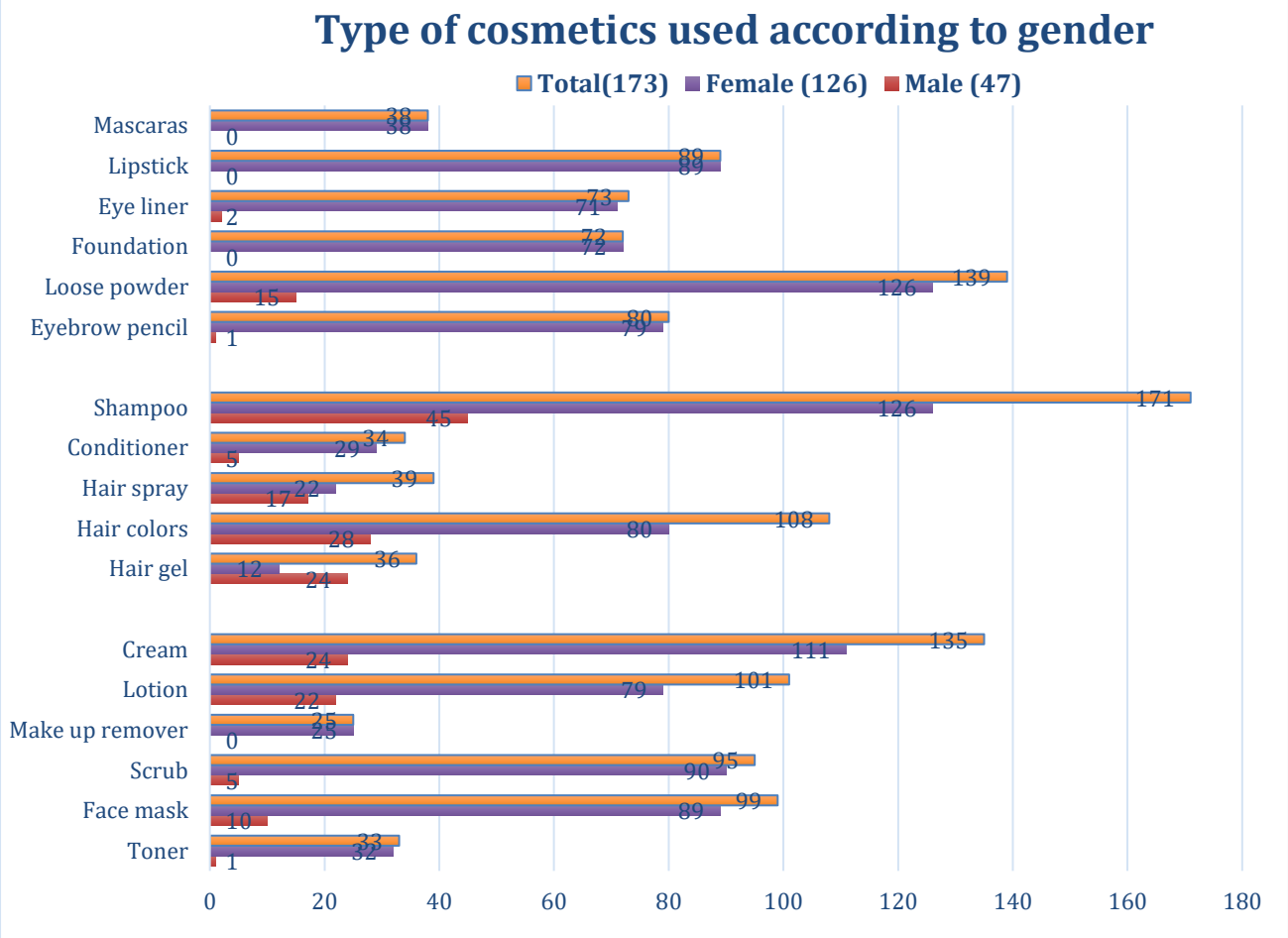
The questionnaire for data collection was adopted and modified from previous studies for the cosmetic utilization behaviors and adverse reactions. The questionnaire had three main parts: first part was about general socio-demographic information, second part addressed the cosmetics utilization pattern.[10] The last part dealt with the participant's experience of cosmetics-related adverse reactions for the last two years The types of cosmetics have been divided into skin care, hair care, make-up, personal care, nail care, perfumes and traditional care products. In the adverse reactions section, participants were asked to provide the nature and type of reaction, onset of the reaction, cosmetics suspected to cause the reaction and how they managed to the reaction .Participants were informed about the purpose of the study and data confidentiality, and informed consent on their willingness to participate in the study was obtained. The information on the brand or the details of the cosmetics that caused them the reactions were not obtained.[11]

Statistical analysis:
Descriptive statistics (frequency and percentage) were used to summarize demographic characteristics, the pattern of cosmetic use, and adverse events. Logistic regression model was used to assess the determinants of the occurrence of cosmetics-related adverse events among the respondents. Variables that found significant in the univariate analysis were entered into multivariable logistic regression. Adjusted odds ratio (AOR) and its 95% confidence interval (CI) were used to show the strength of association and statistical significance of predictors

RESULTS:
Study participant's characteristics: A total of 300 data collection forms were distributed and 173 participants were included in the study after refining the completeness of the data. The demographic details of the study participants were given in Table 1.

Table 1: Demographic details of participants

Variables		Male (47)	Female(126)
Age in years	19-29 30- 50 >51	19 20 8	46 58 22
Education level	Intermediary or lower Secondary University	6 16 25	12 53 61
Monthly income			
Allergic history to food, drugs		16	33
Family history of allergy		4	9



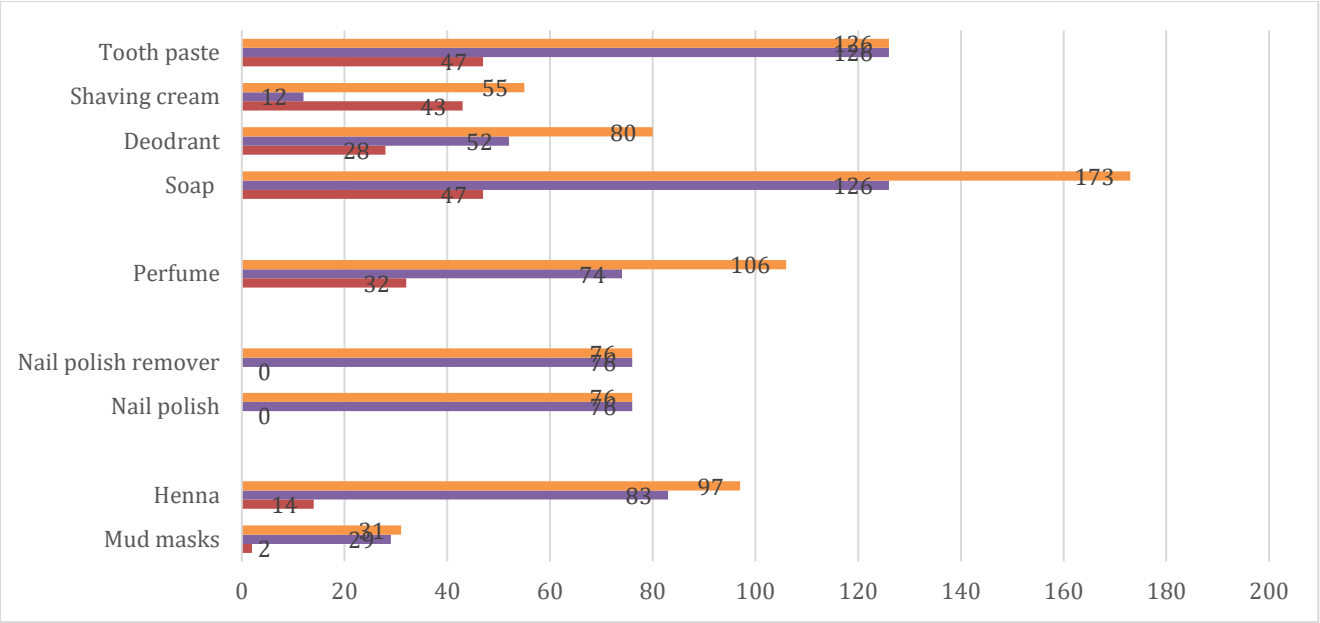


Figure 1: Type of cosmetics : Usage by gender

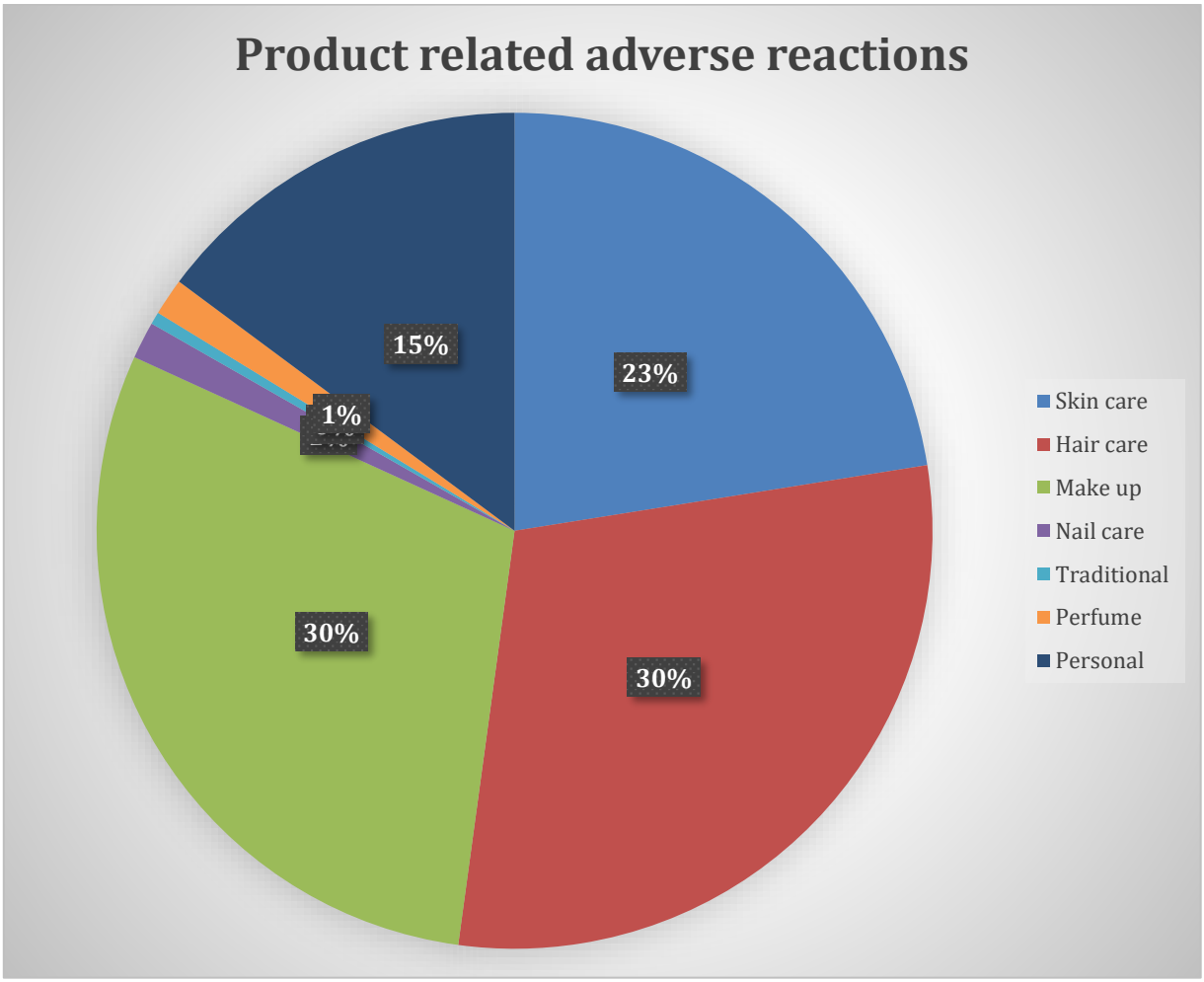


Figure 2: Various products related adverse reactions

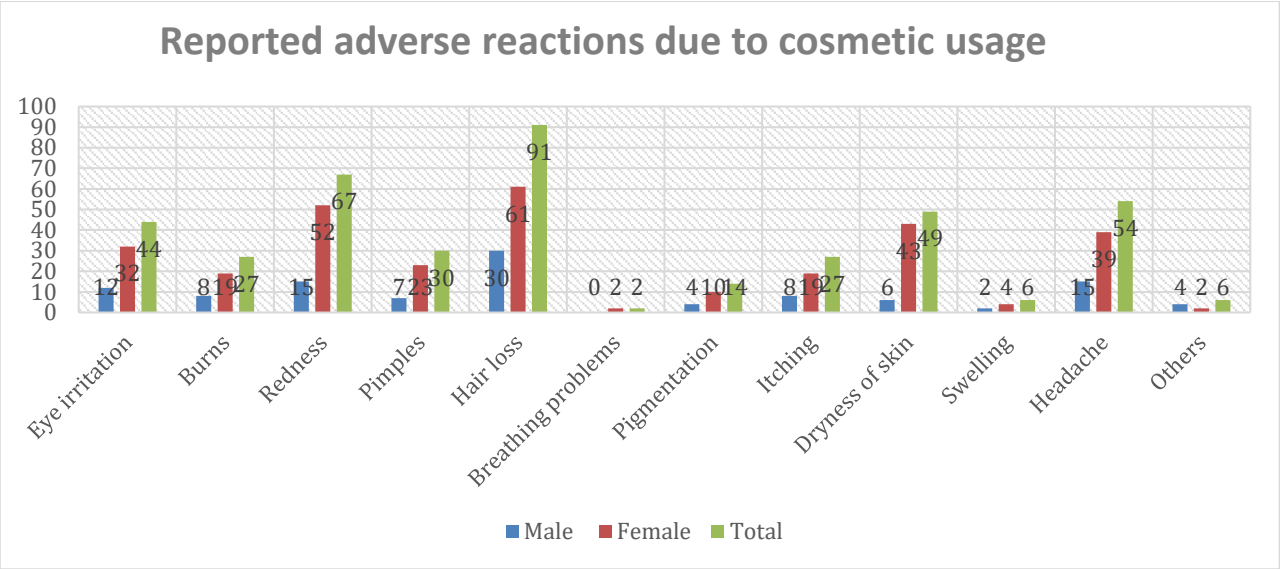


Figure 3: Reported adverse reactions

	Male (47)	Female(126)	Total(173)
Duration of cosmetic use: • <6 months • 6-24 months • >2years • Until it finishes • Till its expiry date	 9 3 1 20 14	 26 15 22 43 20	 35 18 23 63 34
Change of cosmetic brand: • Yes • Sometimes • No	 10 30 7	 51 61 14	 61 91 21
Check for expiry date of cosmetics: • Yes • No	 26 21	 98 28	 124 49
Read the instruction: • Yes • Sometimes • No	 21 16 10	 78 33 15	 99 49 25
Testing for allergy	0	13	13

Table 2: Safety measures of cosmetic use

DISCUSSION

Cosmetovigilance is a growing area under pharmacovigilance. This study analyses the cosmetic utilization pattern and related ARs by using self reported survey.

One-half of our study participants reported the occurrence of AR to cosmetics in the past 6 months. The proportion was much higher than that reported with the previous studies (Getachew and Tewelde, 2019; Lucca J M et al., 2013)[10, 11].The difference might be due to the difference in the pattern and type of cosmetic usage,long duration of the study, low priority on safety of nonmedicated cosmetic as well as methodological and cultural difference in the study and studied population.

In the present study, similar to other studies (Khan Z et al; Nayak M et al.,)[3,6] a higher proportion of ARs was reported among females. One of the reasons could be that the rate and number of cosmetics usages in female group is much higher than the male.

In our study age group between 30-50 year participants reported more ARs(45%) followed by Younger age (19-29 year)participants(37%), and this finding was in contrast with results observed in previous studies (Dhavalshankh A.G et al, Nayak M et al) where younger age participants reported more ARs which could be highly attributed to a high rate of consumption and more awareness, desire for self-care and beautification in the younger age group.[3,7]

In line with other studies, hair care(30%),Makeup(30%) and skincare(23%) products are found to be more associated with ARs. In contrast, a Brazilian study reported that soap, shampoo, and deodorants as the common culprit for ARs.[10]

The assessment on the management of adverse effects revealed that approximately 85% of the participant managed their ARs by the cessation of the products. Surprisingly 30% of the patients with cosmetic-related adverse events utilize the health care services. A similar finding was reported in previous literature (Getachew M et al.;Yazar S et al), which highlight the serious nature of the reactions. [1,10]

This study might have some limitations. Firstly, the present study used a self-report questionnaire to collect the data on cosmetic use and the related ARs. Therefore, there will be chance of bias created by the fact that people who had a reaction were more likely to respond to the questionnaire. Similarly, the study requested the participants to report the AR over period of two years, therefore could not exclude the possibility that findings might be affected by recall bias, and it may lead to underestimation as well. Secondly, participants' medical illnesses and medication history were also not within the scope of this study.[9]

Likewise, some of the adverse reactions stated by the study participants might not have been initiated by the cosmetic product. It could have been assessed by proper further causality assessment, which was beyond the scope of this study

Dermatologist and primary care physicians are the foremost reference for public with any skin complaints. A recent study reported that skin related issues are the most common reason for visits to primary care physicians.[12] Studies also reported that products labeled as hypoallergenic also contained recognized allergens or irritants. Therefore, there exists a responsibility by the consumer as well as their physician, and a special consideration has to be advised patients who are at risk of contact dermatitis and adverse skin reactions.[9,10] Considering as primary and easy contact by the public, pharmacist can crucially play a role to strengthen the Cosmetovigilance system of a country. Distributing educational leaflets on Cosmetovigilance , conducting awareness classes, mass media activities and direct information providing services to the health care providers and the consumers can be considered as some of the measured to improve the Cosmetovigilance. Similarly an early detection and management of AR of cosmetics may benefits the improve the economic aspects of therapeutic.

CONCLUSION

Cosmetovigilance is a new model of safety monitoring of cosmetics. A substantial percentage of study participants reported having had at least one adverse reaction. Therefore, better methodologies to address this issue might be considered in the future. Awareness creation programs and supporting the Cosmetovigilance model among cosmetic users, sellers, and other stakeholders may help to expand this. Correspondingly Cosmetovigilance can be considered as a one element in public health activities. Pharmacists should be more vigil on this issue in the near future. To strengthen the existing data, a national wide prevalence study can be considered can be prospectively and analyses causality and report to the Saudi Pharmacovigilance system.

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