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The usage of cosmetics and adverse events among female nurses: need for a cosmetovigilance system

Short Title: Usage of cosmetics and adverse

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ABSTRACT
Objectives: Cosmetics are known to cause adverse events in their users, although there is limited information on this topic both globally and in Türkiye. This study was carried out to assess the usage of cosmetics, patterns and characteristics of adverse cosmetic events (ACEs) among female nurses.
Materials and Methods: A cross-sectional study was conducted from February to April 2022 among registered female nurses with at least one year of work experience in a tertiary care hospital in Adana, Türkiye. The validated questionnaire (Cronbach alpha value: 0.800) was used for data collection which includes, 13 questions with three main sections. The first part comprised of demographic variables and cosmetic uses, second part addressed ACE and final section consisted of consultation types and reporting methods for adverse events adopted after experiencing ACE.
Results: Of the total 158 participants, 144 were included in this study, making a 91.1% response rate. All the female nurses reported the use of cosmetics and 26.4% (n=38) reported the experience of one or more cosmetic ACEs. Itching, burning, and eczema were the most frequently observed ACE. A higher proportion of ACEs was related to face care products (18.4%) and deodorants (13.1%). More than half (57.9%) of the nurses did not adopt any consultation after experiencing ACE. Moreover, the majority of the participants (47.4%) did not report ACE to concerned healthcare authorities.
Conclusion: A considerable proportion of the participants reported ACEs. Under-reporting of ACE was also highlighted in this study. The current study also emphasized the need for a robust cosmetovigilance system.
Keywords: Cosmetics, adverse event, cosmetovigilance.

INTRODUCTION

Cosmetics are major components of daily life for people of all generations and are used for a variety of purposes. [1] The United States Food and Drug Administration (FDA) defines a cosmetic as "a substance that is applied to the body of a person with the intention of cleansing, beautifying, enhancing attractiveness, or changing appearance".[2] However, in terms of legal definitions of drugs and cosmetics, the use of color additives and other ingredient restrictions as well as registration procedures are different for cosmetics in the United States and other countries.[3] According to the Turkish Medicines and Medical Devices Agency and European Union (EU), a cosmetic is any substance or mixture that is applied to the skin, hair, external genital organs, lips, teeth, and mucous membranes of the oral cavity with the sole or primary intention of cleaning, perfuming, altering appearance, protection, maintaining good condition, or removing body odors. [4]

According to the World Health Organization (WHO), an adverse cosmetic drug reaction is an unintended and harmful reaction to a cosmetic that normally happens following a proper application of a cosmetic, whereas an adverse cosmetic event (ACE) is a hypothetically anticipated noxious injury linked to the use of cosmetics.[5,6] The global cosmetic market has grown in recent years which is driven by consumer demands that are increasingly concerned about their appearance.[6] Most cosmetic users are more concerned regarding the immediate effects on appearance than the long-term effects on the entire body.[1,5] Cosmetic products are thought to be reasonably safe and tolerable.[1,3] However, It is well known that cosmetics use can sometimes cause adverse reactions. [3,5,6] Numerous studies have documented severe ACEs, including eczema, blistering, breathing difficulties, hair loss, unconsciousness, dizziness, skin burns, nausea, and vomiting. [5] Similarly, the most frequently reported adverse effects linked to prolonged exposure to heavy makeup were headache, fatigue, dizziness, and nausea.[7] Previous studies reported a range of reactions to cosmetics, from mild hypersensitivity to severe anaphylactic reactions or even lethal intoxication. These reactions may occur immediately or after using cosmetics for an extended period. [1,8,9] It is suggested that more emphasis should be needed on testing and monitoring the potentially harmful effects of cosmetics. [8,9]

"Cosmetovigilance" is a term used to describe the processes involved in gathering, analyzing, and monitoring of spontaneous reports related to unfavorable events noticed during, or after usual or reasonably anticipated usage of cosmetics". [3,10] Cosmetovigilance is crucial for better health surveillance of cosmetic products. [10] The French health products safety agency established cosmetovigilance as a component of the pharmacovigilance system for cosmetics.[11] Today, addressing the safety of cosmetic products is acknowledged on a global scale as a concept of public health. Türkiye started a cosmetovigilance regulation system in 2012.[12,13] These guidelines recommended the reporting of any undesirable effects related to cosmetics.[14] In Türkiye, the implementation may be poor, but regulations are harmonised with the EU regulations. Despite the regulations, consumers may still experience ACEs from using cosmetic products. [1,3,14] The number of reported ACEs is relatively low due to self-diagnosis, self-medication, and lack of medical consultation. [1,5,7] Moreover, ACEs are still underreported and miscalculated. [5] Nurses fulfill many important roles in the provision of cosmetic services. [15] They play a critical role in pharmacovigilance activities and adverse drug events reporting. [16] Cosmetic use and its adverse effects may vary and depend on an employee's background characteristics, including income level, education, informational access, and other factors. [6] Additionally, females are more likely effected due to more use of cosmetics than males. [17,18] It is important to understand the pattern and characteristics of ACEs in among all stakeholders including health professionals. Only one review article was found which highlighted the cosmetic safety with context to Turkish cosmetovigilance regulation [14]. However, no research on cosmetic use and ACEs has been done in the Turkish population or among any group of healthcare professionals. Therefore, this study was conducted to assess the usage of cosmetics, patterns, and characteristics of ACEs among female nurses in Türkiye.

MATERIALS AND METHODS

Study design and population

A cross-sectional study was conducted among the registered female nurses working in a tertiary care hospital in the Adana Province of Türkiye between February to April 2022. Full-time registered female nurses with at least one year of work experience were included in this study. Nursing students on a traineeship and part-time registered nurses, who had less than < 1 year of work experience and were unwilling to participate were excluded.

Sample size

According to hospital data, 326 nurses (both male and female) worked in a selected healthcare setting and 218 of them were female nurses. To determine the appropriate sample size for a proportional or descriptive study, we entered this data into the Epi Info™ software (Centers for Disease Control and Prevention, Epi Info™). 140 participants were required as a minimum, taking into account a 50% predicted frequency of the outcome factor in the population, a 95% confidence interval, and a design effect of 1

[*https://www.openepi.com/SampleSize/SSPropor.htm*]. A convenient sampling technique was used, and the sample size was increased to 158 participants to ensure reliability and compensate for any missing data or non-response rate.

Data collection method and tool

The authors chose some sections of a previously used questionnaire among the general public by Malaysian researchers with their permission.[5] The questionnaire was also adapted and modified from earlier studies on cosmetic usage patterns and adverse events.[1,6,7] The developed questionnaire was translated from English into Turkish (Türkiye's official language) using one-way direct translation rather than the back-translation method. This approach was used because it reduces time and cost.[5,19] The translations were carried out by two competent and experienced researchers who were fluent in both reading and writing Turkish and English. Minor changes were suggested after the instrument underwent face and content validity testing. The final instrument was then modified as per their recommendations. A pilot study was carried out with a sample of 20 nurses. The purpose of the pilot study was to assess the study tool's applicability and clarity as well as to detect any potential issues that might arise during data collection. The study's findings were satisfactory, and minor modifications were made. Following the pilot, the reliability coefficient (Cronbach alpha value: 0.800 and Cronbach alpha based on standardized items:0.896) was also determined. The pilot sample was excluded from the final study sample. The respondents were able to finish the questionnaire in an average of 5 minutes.

The final questionnaire had 13 questions and three main sections (**Supplementary file 1**): the first part asked about general demographic data and cosmetic use; the second part addressed the ACEs. The final section consisted of consultation types and reporting methods adopted after experiencing ACE**.** The first section consisted of 5 questions and the participants were requested to declare about age, working experience, cosmetic use (yes/no), factors consider while purchasing/using cosmetics, and recommendation/advice sources. The second part included 6 questions regarding ACEs (yes/no), frequency, types, symptoms of ACEs, affected body area, and type of cosmetic product. The final section consisted of 2 questions about the type of consultation adopted (such as medical specialists, pharmacists, general practitioners, beauticians, and others) and reporting method for ACE. Two trained researchers collected the data prospectively by distributing a Turkish version questionnaire. The respondents were informed about the purpose of the study and data confidentiality, and informed consent (oral and written) on their willingness to participate in the study was obtained. The purpose of the study and the confidentiality of the data was explained to the respondents, and their verbal and written informed consent was obtained.

Ethical consideration

The study's approval was given by the University Ethics Committee for Non-Invasive Clinical Research (Meeting number= 119 and date of approval February 04, 2022; **Supplementary file 2**).

Statistical analysis

Statistical Package for Social Sciences (SPSS) version 25 was used to tabulate and analyze the data gathered for this study. Descriptive statistics were used to determine the frequency and percentage of all sections.

RESULTS

In the current study, a total of 158 female nurses were invited to participate. Sixteen (n=14; 8.8%) were excluded due to less than 1 year of working experience (n=9; 5.7%) and lack of time (n=5; 3.1%). Finally, a total of 144 nurses were included (response rate of 91.1%). The mean age of nurses was 33.99 years (range 20-64 years) with a standard deviation of 7.870. We found that most younger age participants (20-30 years) reported the usage of cosmetics. The majority of the participants had working experience of 1-5 years (n=56; 38.9%) followed by 11-15 years (n=15; 35.4%) (Table 1**)**. All the female nurses reported the usage of cosmetics. The majority of the participants consider the safety and quality (27.1%), expiry date (11.8%), and Manufacturer/brand (11.1 %) before purchasing or applying cosmetics. Thirty-one (21.5%) respondents also reported a combination of factors while 17.4% of the participants consider nothing before purchasing or using cosmetics. The participants reported that they give importance to the advice of friends/relatives (31.3%), cosmetologists (26.4%), and pharmacy/pharmacists (11.8%) during the selection of cosmetics (Table 1**)**.

Table 1. Sociodemographic, cosmetic usage, factors, and advice considered by the participants (n=144).

Variables	Frequency	Percentage
Age		
20-30	60	41.7
31-40	51	35.4
41-50	31	21.5
51-60	1	0.7
More than 61 years	1	0.7

Experience		
1-5 years	56	38.9
6-10 years	13	9
11-15 years	51	35.4
16-20 years	7	4.9
More than 20 years	17	11.8
Cosmetic use		
Yes	144	100
No	0	0
Factors considered when purchasing/applying cosmetics		
Safety and Quality	39	27.1
Expiration date	17	11.8
Manufacturer/brand	16	11.1
Price	15	10.4
Packaging	1	0.7
Expiration date + Manufacturer/brand	4	2.8
Expiration date + Safety and Quality	3	2.1
Expiration date + Price	3	2.1
Manufacturer/Brand + Packaging	2	1.4
Expiration date + Safety and quality+ Manufacturer/brand	5	3.5
Safety and quality + Manufacturer/brand + Price	1	0.7
Expiration date+ Safety and quality+ Price	1	0.7
Expiration date+ Safety and quality+ Manufacturer/brand+ Price + Packaging	12	8.3
None	25	17.4
Whose advice do you give importance while selecting a cosmetic?		
Friends/relatives	45	31.3
Cosmetologist	38	26.4
Pharmacy/Pharmacist	17	11.8
Beauty center/Beautician	16	11.1
Doctor	14	9.7
Pharmacy/Pharmacist + Doctor	2	1.4
Cosmetologist + Pharmacy/Pharmacist	2	1.4
Cosmetologist +Doctor	1	0.7
Cosmetologist + Beauty center/Beautician	1	0.7
Pharmacy/Pharmacist + Friends/relatives	1	0.7
Pharmacy/Pharmacist + Friends/relatives+ Beauty center/Beautician	1	0.7
Cosmetologist + Pharmacy/Pharmacist + Doctor	1	0.7
Cosmetologist + Pharmacy/Pharmacist + Friends/relatives+ Beauty center/Beautician+ Doctor	1	0.7
None	4	2.8

Out of the total 144 respondents, 26.4% (n=38) reported the experience of one or more ACEs. Most of the ACEs were cutaneous (n=35; 92.1%) followed by systemic + cutaneous (n=2; 5.3%) and systemic (n=1: 2.6%). Itching, burning, and eczema were the most frequently observed cutaneous cosmetic ADRs. Headache was the most common ACE among the systemic category (Table 2).

Table 2. ACEs and types (n=38).

Questions	**Frequency**	**Percentage**
ACEs experienced		
Yes	38	26.4
No	106	73.6
Number of ACEs (n=38)		
1	20	52.6
2	14	36.8

3	3	7.9
4	0	0
More than 4	1	2.6
Types of ACEs		
Cutaneous (Skin)		
Itching	8	21
Burning	7	18.4
Eczema	2	5.2
Redness	2	5.2
Itching + Eczema	6	15.8
Itching + Burning	8	21
Itching + Burning + Eczema	2	5.2
Systemic		
Headache	1	2.6
Cutaneous + Systemic		
Itching + Burning +Nausea+ Dizziness + shortness of breath	1	2.6
Itching + Burning+ headache	1	2.6
Total	**38**	**100**

ACEs: adverse cosmetic events

In this study, messy faces, armpits, hands, neck, scalp, and eye (ocular mucosa) were the most commonly affected body sites by ACEs (Figure 1).

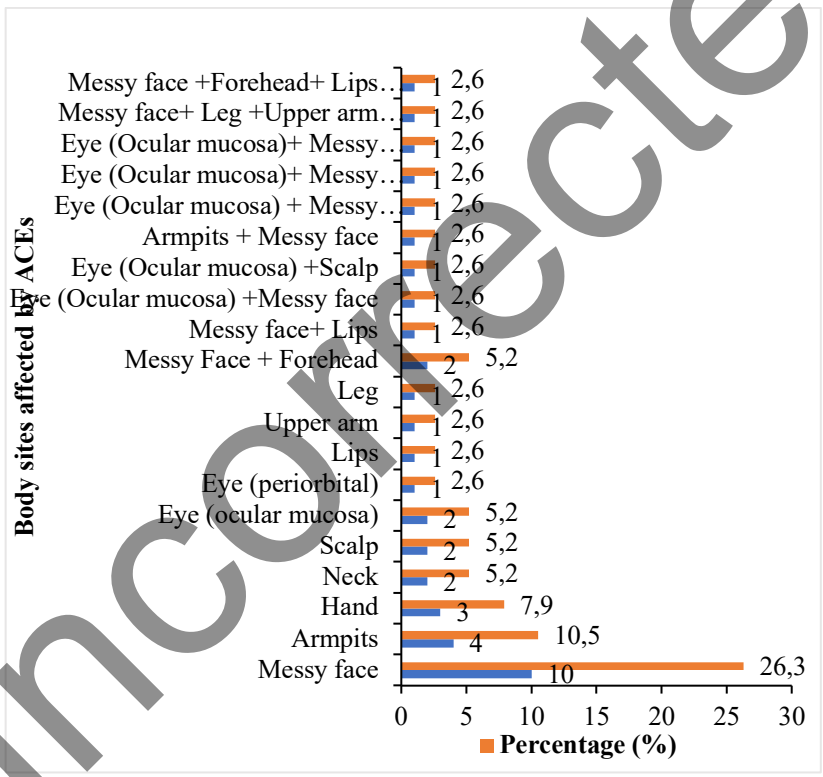

Figure 1: Body sites affected by ACEs (n=38)

A higher proportion of ACEs was related to face care products (18.4%), Deodorants (13.1%), body care products (10.5%), Eye makeup (7.9%), and face makeup (5.2%) (Table 3).

Table 3. ACEs observed with cosmetic class (n=38)

Cosmetic class	Number of ACEs observed	Percentage
Face care products	7	18.4
Deodorants	5	13.1
Body care products	4	10.5
Eye makeup	3	7.9
Face Makeup	2	5.2
Hair care products	2	5.2
Cleaning product	2	5.2
Depilatory (hair removal) product	2	5.2
Face care products+ Face makeup	2	5.2
Face care products + Body care products	1	2.6
Face care products+ Cleaning product	1	2.6
Eye makeup+ Cleaning product	1	2.6
Hair care products+ Eye care products	1	2.6
Cleaning product + Depilatory (hair removal) product	1	2.6
Body care products+ Eye makeup+ Face makeup	1	2.6
Body care products+ Cleaning product+ Eye care products	1	2.6
Eye makeup+ Face makeup Depilatory (hair removal) product+ After sun products	1	2.6
Face care products+ Body care products+ Eye makeup+ Face makeup+ Hair care products+ Cleaning product	1	2.6
Total	**38**	**100**

ACEs: adverse cosmetic events

In the current study, more than half (n=22; 57.9%) of the nurses did not adopt any consultation with a medical specialist, pharmacist, general practitioner, or beautician. However, 42.1% (n=16) consulted with professionals regarding ACEs. Medical specialists (15.8%) followed by the pharmacist (7.9%), general practitioners (5.2%), and beauticians (2.6%) were the commonly chosen consultations by participants. A combination of Medical specialist+ General practitioner (7.9%) and Medical specialist+ General practitioner+ Beautician (2.6%) was also sought for consultation by the participants (Figure 2).

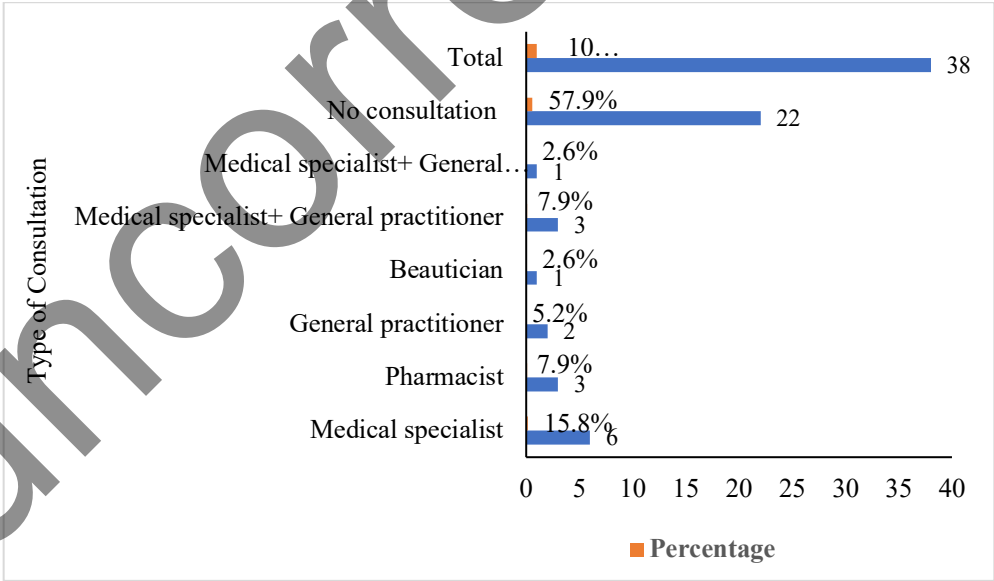

Figure 2: Type of consultation adopted after experiencing ACEs (n=38).

Surprisingly, of the total 38 participants, nearly half (n=18; 47.4%) didn't report the ACEs to the concerned authority. However, 28.9% (n=11) reported the ADR to a hospital, and only 10.5% and 7.9% forwarded the ACEs report to TUFAM (National Turkish pharmacovigilance center) and beauty center respectively (Figure 3).

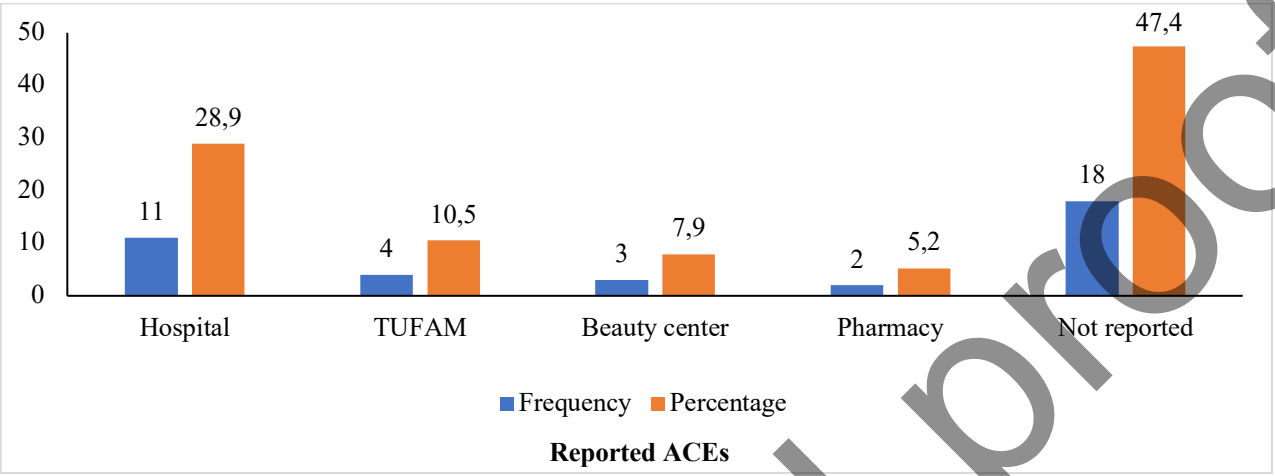

Figure 3: Reporting of ACEs (n=38)

DISCUSSION

Cosmetovigilance is a developing pharmacovigilance field both globally and in Türkiye. This is the first study in Türkiye to use a self-reported survey to analyze the cosmetic use pattern and associated ACEs among female nurses. In this study, all the participants reported the usage of cosmetics (100%). A study conducted in Ethiopia reported that a higher proportion (80.1%) of the participants utilized at least one cosmetic item. [6] Additionally, we found that most younger age participants reported the usage of cosmetics, and this finding could be attributed to the younger age group's high consumption rate. A similar pattern was also reported in previous studies. [1,6]

In our study, more than one-fourth proportion of the sample (26.4%) reported the occurrence of ACEs. The proportion was higher than in a study conducted in Ethiopia (19%). [6] However, a higher rate of ACEs was reported in Malaysia (29.0%) [5], Brazil (38%) [20], and Saudi Arabia (50.6%).[1] The variation may result from differences in the frequency, cosmetic types, duration of the study, and sample, as well as cultural and methodological differences between the population of the study.

The finding revealed that the skin was the most affected region due to ACEs. These findings were consistent with previously published studies conducted in different countries. [3,5,21] In the current study, itching followed by burning, eczema, and redness were the most commonly observed cutaneous ACEs. A similar finding was also reported by Lucca et al and Hadi et al.[1,5] However, the frequency of redness and eczema were frequently reported in Lucca et al [1] and Hadi et al [5] studies, respectively. Similarly, headache, dizziness, and shortness of breath were also observed in our study. These findings also align with previous studies. [1,5] Therefore, a climatic difference did not play a role in this matter, as the manifestations of similarities in Türkiye were nearly identical to those found in previous studies conducted in various countries.

The face was the most affected body site by ACEs in this study. Previous studies also documented similar findings.[5,6] Furthermore, the findings of this study revealed that a higher proportion of ACEs was related to face care products and deodorants. Similarly, previous studies also reported that the majority of ACE occurs as a result of products intended for use on the face. [1,3,5] According to a Brazilian study, the most common cause of ACEs was soap, shampoo, and deodorants. [20] Another study found that face lotion and hair cosmetics were the most commonly reported causes of ACEs. [6] Additionally, it has been reported that the type of cosmetic products may also have an impact on the adjacent site. [5] It is widely known that these products contain a variety of chemical additives to enhance the functionality, potency, and sustainability of cosmetics.[1,8,22] Exposure to the different chemicals found in cosmetics poses a health risk that can range from a mild hypersensitivity reaction to a lethal intoxication. [23] Moreover, misbranded and spurious cosmetics are common. [1,23]

In the current study, more than half (57.9%) of the respondents did not adopt any consultation after experiencing ACEs. A similar finding was also reported in a Malaysian study. [5] The number of nurses who attempted to consult health professionals (HCPs: medical practitioners, pharmacists, and general practitioners) was 29.9% in our study. The low number of respondents who sought consultation demonstrated that they are misjudging the occurrence of

ACEs. Studies revealed that consumers underreport ACEs even though they may have suffered severe harm in some cases. [3,5,21,24] Prior studies highlighted the possibility of more serious reactions involving internal body systems, such as cancer. [25,26] Previous studies also recommended the identification of cosmetics' harmful ingredients to avoid harmful effects and protect consumers. [26,27] Therefore, it is suggested that the manufacturer should conduct a safety evaluation of their products before they are marketed. [3,5,28,29] Furthermore, dermatologists and primary care physicians are reported to be the first points of contact for the general public with skin complaints. [1] A pharmacist's role in public engagements is well also documented. [30] Therefore, there is a need for effective communication, counseling sessions, and education among cosmetic consumers and healthcare professionals to avoid the potential risk of ACEs.

In this study, we also observed that despite experiencing ACEs due to cosmetics, the majority of the participants (47.4%) did not report it to the concerned healthcare authority. Globally, the reported number of ACEs is very low. [31,32] Under-reporting of ACEs is also highlighted in the literature. [3,5,33,34] Additionally, the absence of formal and trustworthy monitoring systems (referred to as "cosmetovigilance") may also contribute to the underestimation of such harmful effects and under-reporting. [34] The United States Food and Drug Administration launched a "MedWatch Online Voluntary Reporting Form" for cosmetic-related complaints and adverse reactions.[35] Türkiye started the cosmetovigilance program under the umbrella of the pharmacovigilance system in 2012. [12,13] Turkish Medicines and Medical Devices Agency developed an online form for consumers, patients, and healthcare professionals to report cosmetic-related undesirable effects. [36] However, our study reported low reporting rates of cosmetic ADRs in Türkiye as well as previously reported in a global context.[3,10,25,34] Therefore, to address a lower reporting rate, awareness-raising campaigns and the promotion of cosmetovigilance among cosmetic users, retailers, healthcare professionals, and other stakeholders are needed.

Study limitations

This study may have some limitations, which readers should consider when interpreting the evidence. Firstly, the current study utilized a self-report questionnaire to gather information on cosmetic use and the associated ACEs. As a result, there is a chance of recall bias, which may lead to underestimation. Second, this study did not include participants' medical illnesses or medication history. Similarly, some of the ACEs reported by study participants may not have been caused by cosmetics. It could have been evaluated using proper further causality analysis studies, which was not possible in our study scope. Third, the current findings may not be generalizable, especially since our study was based on a sample of female nurses recruited from a single hospital in Türkiye. Further research with larger samples and validated scales is required to confirm our findings, as the findings among female nurses may not be representative of all practices across the country. Fourth, this is a cross-sectional study that collects data on all variables at a single point in time, therefore, no causal relationship can be inferred. Finally, we did not use advanced statistics to draw more statistical relations about the variables in the study. However, as part of our study objectives, we used descriptive statistics to reach a more accurate conclusion.

Despite these limitations, there had some strengths in this study. This is the first study to assess cosmetic use, pattern, and characteristics of ACEs among female nurses in our healthcare setting as well as in Türkiye. Socio-cultural factors also have a significant impact, which varies from country to country. Furthermore, this study provides baseline local data, and the findings may be useful for cosmetic users, clinical settings, healthcare professionals, and policymakers.

CONCLUSION

A considerable proportion of the participants reported ACEs. The most commonly affected skin area was the face and itching followed by burning and eczema were the frequently reported ACEs. Most of the respondents did not adopt any consultation from qualified HCPs after experiencing ACEs. Under-reporting of ACEs was also highlighted in this study. Cosmetovigilance is a new model of cosmetic safety monitoring that can be considered one of the main components of public health activities. Therefore, some of the measures to strengthen the implementation of cosmetovigilance include the distribution of informational leaflets, awareness sessions, media campaigns, and the offering of direct information facilities to consumers and HCPs. Similarly, prompt detection and management of ACEs may be helpful to enhance the financial aspects of therapeutics. Furthermore, in the future, a nationwide prospective prevalence study based on causality analyses should be conducted in different populations to further validate existing data and also to strengthen the cosmetovigilance system in Türkiye as well as gobally.

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