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Insight of Saudi Users of Cosmetic Regarding Cosmetovigilance: A Survey of Knowledge, Attitude and Practice



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Fatimah Alosyli¹, Lana Aljebrin¹, Noura Alnowaiser¹, Yara Alodhilah¹, Nada Ibrahim¹, Mohammed Saif Anaam¹, Maryam Farooqui¹, Saud Alsahali^{1,*}, Abir Elghazaly¹, Yasser Almogbel¹ and Ali Alsuhibani^{1,2}

¹Department of Pharmacy Practice, College of Pharmacy, Qassim University, Buraidah 51452, Qassim, Saudi Arabia ²Department of Pharmacotherapy and Outcomes Sciences, School of Pharmacy, Virginia Commonwealth University, Richmond, VA, USA

Abstract:

Background: The term "Cosmetovigilance" was first introduced as a new term for addressing the safety of cosmetic products. There is still significant variability across the community regarding knowledge as well as legislation about cosmeceuticals.

Methods: An organized set of 38 questions addressing demographics, knowledge, practices, attitudes, and perceptions toward cosmetics along with additional 10 questions about reporting cosmetic adverse drug reactions were used to conduct a cross-sectional study. Using a convenience sample of 601 cosmetics consumers in Saudi Arabia, a Microsoft form was used to administer the questionnaire. The data analysis was performed using a statistical package for social science analysis (SPSS).

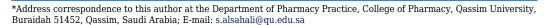
Results: The overall percentage of participants who answered the questions related to the knowledge was 89.6% (539/601). The association between knowledge score and demographic characteristics was explored. None of the demographic variables showed a significant association with knowledge (p > 0.05). Regarding attitudes, significant associations were found with age, marital status, income, and nationality (p < 0.001). Out of the 323 participants who completed the additional part of the questionnaire, 150 (46.4%) experienced cosmetic-related side effects, but only 1.3% reported the incidence of these effects. The occurrence of adverse effects connected to cosmetics is more common in women, younger age groups, and people who have ever experienced allergies (p < 0.001).

Conclusion: Our findings support the huge need for continued efforts to fully increase consumers' awareness of regulatory oversight and the importance of reporting adverse events to completely ensure the safety of cosmetic products in Saudi Arabia.

Keywords: Cosmetovigilance, Cosmetic adverse drug reaction, Cross-sectional, Quantitative, Knowledge, Questionnaire.

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1. INTRODUCTION

Cosmetics have been a major part of human daily life for all generations and are used for a variety of purposes. According to the Saudi Food and Drug Authority, a cosmetic product is "any product that contains one or more substances intended to be used on the outer parts of the human body (skin, hair, nails, lips, and the outer parts of the genital), teeth, and the mucous lining of the oral cavity for cleaning purposes, perfuming, to protect or keep the body in good condition, to change or improve appearance, or to change or improve the smell of the body". Recently, it has been recognized that one of the most important aspects of cosmetics is the side effects associated with their use [1, 2].

Relevant research mentions that most cosmetic users pay more attention to the immediate benefits of their looks than to the long-term negative effects on the entire body. Some consumers expect that the cosmetics don't have any bad effects on the body and are highly safe. Also, many consumers may not read the labels to identify the substances and ingredients of the product used [3,4].

Cosmetics could cause many adverse events, but they also help people feel beautiful [5]. Some forms of unexpected reactions associated with cosmetics are sensitivity or allergy to the ingredients, such as preservatives, fragrances, color additives, microbial contamination and misuse due to improper labeling of the product [6]. Also, it is suggested that the use of some ingredients and their cumulative effects on the product is one of the causes of unwanted cosmetic-related events [7]. The adverse events resulting from cosmetics use could occur immediately after application or after long-term use, depending on the nature of the ingredients causing these events. A study conducted among 425 participants to assess adverse reactions to cosmetics, in Dammam, Saudi Arabia, reported 50.6% of the participants experienced at least one adverse reaction in the previous two years [3].

A series of studies have been conducted in different countries to assess the use of cosmetic products and related adverse reactions. These studies stressed the need to implement a cosmetovigilance system to study consumer safety data with the cooperation of several scientific experts, health and governmental authorities, and manufacturers in order to decrease the risk of negative effects on cosmetics consumers [8-16].

The Saudi Food and Drug Authority has the responsibility of regulating cosmetic products in the Saudi market and issuing regulatory guidelines to ensure their safety. The SFDA established an electronic system to control the production, importation, and marketing of cosmetic items. In addition, the SFDA established a call center for inquiries regarding the safety of cosmetics, pharmaceuticals, and food [17].

Numerous studies have examined the knowledge, attitudes, and practices of skincare among women across different ages and socioeconomic statuses. A study at Najran University by Amar *et al.* [18] focused on women's knowledge and attitudes toward cosmetic use, revealing

that education levels significantly influence their purchasing behaviors, with many women reading ingredient lists before buying products. However, some do not verify whether products are approved by their country's Ministry of Health. Additionally, a study conducted in Thailand [19] indicated that gender and education affect adolescents' skincare practices; while most are aware of the harmful effects of sunlight, few apply sunscreen regularly. Given that this area remains underexplored among the Saudi population, the present study aims to assess the extent of knowledge, attitude, perception, and practice of safe cosmetic use among the Saudi population. The need for more indicators of perception and practice in the cosmetovigilance detection process for patients' safety and to provide inside buildings in the Saudi cosmetovigilance system compared to standard designed equivalent systems is essential.

2. MATERIALS AND METHODS

2.1. Study Design and Setting

A descriptive cross-sectional study was conducted using an online survey among the Saudi Arabia general population. The data collection was carried out over a period of three months, from December 2022 to February 2023.

2.2. Inclusion and Exclusion Criteria

Residents of Saudi Arabia were included in the study irrespective of their nationality, gender, or age. We included 18- and older-age groups, which allowed us to evaluate the variability of consumption patterns across age. Also, people who have a habit of using any category of cosmetic products and who can read or write in Arabic were included in the study. The participants in this study had to meet a number of requirements in order to be qualified to take part, including being a resident of Saudi Arabia, a cosmetic product consumer, being at least 18 years old and could read and write in Arabic or English.

2.3. Development of Questionnaire

A structured online survey was obtained from a previous study conducted in Malaysia [20]. The permission to reuse the survey was obtained from the author of the Malaysian study. The questionnaire originally was based on previous published studies [9, 10, 21-23]. Slight modifications were made to meet the needs of the current work and seek further validation from experts in the field. The questionnaire contained 38 questions related to participants' demographics, knowledge of and attitudes toward cosmetic safety, perceptions of cosmetics, and practices related to cosmetics. Also, after a search in the literature [3], we added 10 additional questions about experienced cosmetic-related adverse reactions and the participants could select more than one adverse reaction. These additional questions are optional part at the end of the survey and not mandatory to be answered by the participants. After 9 questions about demographics, there were 12 questions about knowledge of cosmetic safety, 5 questions about attitudes toward cosmetic safety, 4

questions about perceptions of cosmetics, and 8 questions about practices related to cosmetics. The demographic section of the survey asked participants to provide information about their gender, age, marital status, nationality, income range, location, level of education, occupation, and the store where they frequently purchase cosmetics by selecting from a list of options. For the knowledge section of the questionnaire, there were two possible answers: "Yes" and "No," and for the attitude, perception, and practice sections, there was a five-point Likert scale. The responses in knowledge section of the questionnaire consisted of "yes" and "no", and during data analysis, it was scored using "1" for a correct answer and "0" for an incorrect answer. The total score for the knowledge ranged from 0 to 12, indicating better knowledge for a higher score. Regarding the answers to the attitude, perception, and practice parts, a Likert scale ranging from 1-5 was used to describe the responses; strongly agree got the highest score of five (5) points, followed by four (4) points, three (3) points, two (2) points, and one (1) point for strongly disagree. Then, the total score for those sections was calculated.

2.4. Questionnaire Validation and Reliability Test

The first draft was presented to a panel of three local experts in questionnaire design. These experts independently examined the content, question format, sequencing, and overall clarity of the questionnaire. Some minor modifications were made to enhance its suitability to the local context. To assess the face validity of the questionnaire, the time taken to complete the questionnaire and participants' comprehension difficulties, it was administered to 10 participants. No comments or feedback were provided by the participants, and the time needed to complete the survey was estimated at 8-10 minutes. Following the content and face validity assessments mentioned above, the instrument was subsequently administered to 15 participants to test its reliability. The internal consistency of the questionnaire was measured using Cronbach's alpha test. The obtained values were 0.70, 0.74, and 0.67 for the knowledge, attitude, and perception subsections, respectively. The translation was completed independently by two qualified and experienced individuals with strong English language skills and Arabic as their first language.

2.5. Sample Size Determination and Sampling Technique and Questionnaire Administration

As of March 2022, the total population of Saudi Arabia was 35.84 million, according to global media insight. The population of individuals aged 18 and older was 25,308,476. Sample size calculation was performed using Raosoft software, considering a 95% confidence level, a 5% margin of error, and a 50% response distribution. Consequently, the estimated minimum sample size required for this study was 385 participants. To recruit participants, a convenience sampling method was employed. Invitations were sent to the participants through WhatsApp, WhatsApp groups, and Facebook,

along with a link to the online survey. The invitation included a message providing a brief explanation of the study's aims, granted confidentiality, and assured participants that their personal data would be used solely for scientific purposes. Multiple reminders were sent to encourage potential participants to fill out the survey. The duplicate responses were avoided by allowing only one response from the same device. The consent to participate in the study was assumed once the participants responded to the online questionnaire.

2.6. Ethical Consideration

The Deanship of Scientific Research at Qassim University's committee on health research ethics provided (ethical approval 22-17-01).

2.7. Data Collection

The questionnaire was developed as a multi-section online Microsoft form and was available in Arabic. All data were gathered in the form of responses on a Microsoft form, which were later transformed into the data analysis program.

2.8. Data Analysis

Data was analyzed using Statistical Package for Social Sciences software (SPSS, version 28, SPSS, Chicago, IL, USA). Descriptive statistics (i.e., frequencies, percentages, means or medians) were used to describe the responses of the participants to the knowledge, attitude and perception statements. Inferential statistics were used to establish the difference in means of knowledge, attitude and perception scores between demographic groups. The Kolmogorov-Smirnov (K-S test) was used to test for the normal distribution of the continuous variables before conducting inferential statistical tests. Mann-Whitney U test and the Kruskal-Wallis test were used to examine the difference in medians of the continuous variables between the targeted groups. Pearson's Chi-square or Fisher's exact test was used to examine the association between categorical variables. A multivariate analysis using logistic regression was also used to control for confounding variables and understand interactions between variables. A *p*-value of <0.05 was considered statistically significant.

3. RESULTS

3.1. Sociodemographic Characteristics of Respondents

The demographic features of survey participants are summarized in Table 1. The survey received 601 responses; most of them were female (67%) and Saudi citizens (94%), with 34% of the respondents ranging in age from 18 to 25 years. The majority of respondents (69%) hold a graduate degree. Residents of urban areas make up nearly all survey participants (95.2%). 35% had incomes greater than 10,000 SR, while only 14% earned more than 5000 SR or less than 10,000 SR. Most of the survey respondents (65%) buy their cosmetics products from the pharmacy, and 40% buy those products either online or from malls.

Table 1. Demographic characteristics of the study participants (N = 601).

Characteristic	N (%)
Gender	-
Females	400 (67%)
Males	201 (33%)
Age (years)	-
18-25	204 (34%)
26-36	137 (22.7%)
37-47	131 (21.8%)
48-58	102 (17%)
>58	27 (4.5%)
Marital status	-
Single	279 (46%)
Married	322 (54%)
Nationality	-
Saudi	565 (94%)
Non-Saudi	36 (6.0%)
Occupation	-
Unemployed	128 (21%)
Student	162 (27%)
Employee in the private sector	77 (13%)
Employee in government sector	234 (39%)
Location	-
Urban	572 (95.2%)
Rural	29 (4.8%)
Education	-
Elementary level	5 (0.9%)
Intermediate level	8 (1.3%)
Secondary level	102 (17%)
Bachelor's or diploma level	415 (69%)
Master level and higher	71 (11.8%)
Monthly income in riyal	-
No source of income	87 (14%)
Less than 1000 SAR	102 (17%)
From SAR 1000 to 5000	116 (19%)
From 5000 to 10,000	83 (14%)
More than 10,000	213 (35%)
Place to buy cosmetic products	-
pharmacy	392 (65%)
online	241 (40%)
malls	238 (40%)
Others	34 (5.7%)

3.2. Knowledge of Cosmetic Safety

To evaluate their knowledge of cosmetic safety, participants were asked twelve questions. The study found that a majority of participants (96%) were aware that they could report cosmetic adverse events to the Saudi Food

and Drug Administration. In addition, 98% of participants recognized the importance of regulatory oversight for cosmetic products. Overall, the study found that most participants answered the questions correctly. Table 2 contains the detailed results.

Table 2. Participants' responses to the questions regarding knowledge of cosmetic safety (N = 601).

Questions	Correct N (%)	Incorrect N (%)
Not all natural or organic cosmetics are completely safe, as some may still contain synthetic chemicals	515 (86%)	86 (14%)
Organic ingredients in cosmetic products can be toxic or allergenic	511 (85%)	90 (15%)
Some products may serve the dual purpose of being both cosmetics and drugs.	513 (85%)	88 (15%)
Cosmetics should be avoided in areas that are infected or inflamed.	577 (96%)	24 (4.0%)

(Table 4) contd.....

Questions		Incorrect N (%)
Cosmetics should not be shared with others.	476 (79%)	125 (21%)
The most frequently encountered adverse cosmetic reactions and intolerances include irritation, a burning sensation, and mild itching in the area where the cosmetic was applied.	579 (96%)	22 (3.7%)
The effectiveness of counterfeit or fake cosmetic products is the same as that of the original products.	500 (83%)	101 (17%)
FDA (U.S Food and Drug Administration) lacks the authority to require companies to conduct safety testing on their products before they are launched.	543 (90%)	58 (10%)
Regulation of cosmetic products is essential.	591 (98%)	10 (2%)
The Saudi Food and Drug Administration (SFDA) is tasked with overseeing the regulation of cosmetic products.	564 (94%)	37 (6.2%)
A list of cosmetic products that have been withdrawn from the market can be found on the SFDA website.	518 (86%)	83 (14%)
Any adverse cosmetic event can be reported to the SFDA.	575 (96%)	26 (4%)

Note: Data are Presented as Number (%), SFDA: Saudi Food and Drug Authority.

Table 3. Means and medians of knowledge, attitude, and perception scores.

Variables	Mean	SD	Median	Min-Max
Knowledge score	8.7	1.3	9	0-12
Attitude score	17.9	3.9	18	5–25
Perception score	14.1	2.7	14	4-20

Abbreviation: SD: standard deviation.

Table 4. Differences in total knowledge scores. (N = 601).

Characteristic	Mean (SD)	Median (Min-Max)	p Value
Gender	-	-	<0.001 *
Females	8.7 ± 1.2	9 (0-12)	-
Males	8.6 ± 1.3	9 (5-12)	-
Age	-	-	0.2
18-25	8.7 ± 1.1	9 (5-12)	-
26-36	8.7 ± 1.4	9 (0-12)	-
37-47	8.5 ± 1.2	9 (5-12)	-
48-58	8.6 ± 1.2	9 (5-11)	-
>58	9.2 ± 1.6	9 (6-12)	-
Marital status	-	-	0.9
Single	8.7 ± 1.3	9 (0-12)	-
Married	8.7 ± 1.2	9 (5-12)	-
Location	-	-	0.9
Urban	8.7 ± 1.2	9 (0-12)	-
Rural	8.8 ± 1.1	9 (7-11)	-
Nationality	-	-	0.5
Saudi	8.7 ± 1.2	9 (0-12)	-
Non-Saudi	8.6 ± 1	9 (7-11)	-
Education	-	-	0.5
Elementary/intermediate/Secondary	8.6 ± 1.3	9 (0-12)	-
Graduate/postgraduate	8.7 ± 1.2	9 (6-12)	-
Income range	-	-	0.6
No source of income	8.8 ± 1.2	9 (6-12)	-
Less than 1000 SAR	8.6 ± 1.3	9 (0-11)	-
From SAR 1000 to 5000	8.6± 1.2	9 (5-12)	-
From 5000 to 10,000	8.6 ± 1.3	9 (5-12)	-
More than 10,000	8.7 ± 1.2	8 (5-12)	-

Note: Data are expressed as mean (SD), median, Min-Max; \mathbf{Y} : Mann Whitney u test, \mathbf{S} : Kruskal Wallis test, $\mathbf{v} < 0.05$ was significant.

As shown in Table 3, the mean (standard deviation) for the total knowledge score was 8.7~(1.3), with a median of 9 and a range from 0 to 12. The mean (SD) for attitude scores was 17.9~(3.9), with a median of 18 and a range from 5 to 25. Lastly, the mean (SD) for the total perception score was 14.1~(2.7), with a median of 14 and a range from 4 to 20).

In Table 4, the total knowledge score was analyzed by Mann Whitney U test or Kruskal Wallis test based on demographic characteristics. None of the demographic variables showed a significant association with the knowledge score (p > 0.05).

3.3. Attitude towards Cosmetic Safety

There were 5 attitude questions that asked about various aspects of consumer behavior related to cosmetic products. The analysis showed that 22% and 58%, respectively, of the participants agreed and strongly agreed with the statement that they check the expiration date of cosmetics before purchasing them. Additionally, 40% of participants either agreed or strongly agreed with the statement that they consistently check the list of cosmetic products that have been withdrawn by the authorities. A smaller proportion of participants, 15% and 10.2%, respectively, agreed and strongly agreed with the statement that the notification number for cosmetic

products begins with the code MAL. However, this is actually an incorrect statement, and only 16.5% strongly disagreed with it. On the other hand, approximately 75% agreed or strongly agreed with the statement, "I never purchase new cosmetic products without being informed about the ingredients." (See supplementary 1).

Table 5 shows that there is a significant association between age, marital status, income range, and nationality with the total attitude score (p < 0.001), while there is no significant association between gender, location, or educational level with the total attitude score (p > 0.05).

3.4. Perceptions toward Cosmetic Products

The data show that 40.4% and 32.6% of the participants strongly agreed and agreed, respectively, with the statement that 'the price of cosmetic products does not indicate their efficacy.' Regarding the statement 'Cosmetics speed up skin aging,' only 29.4% of participants either strongly agreed or agreed with this statement. For the statement 'Cosmetics can cause acne,' 62% either strongly agreed or agreed. Finally, 44.3% either strongly agreed or agreed with the statement that 'cosmetic products have at least one toxic ingredient for the human body,' while 40% were neutral (See supplementary 2).

Table 5. Differences in total attitude scores. (N = 601).

Characteristic	Mean (SD)	Median (Min-Max)	p Value
Gender	-	-	0.1
Females	17.7 ± 4	18 (8-25)	-
Males	17.7 ± 3.7	19 (5-25)	-
Age	-	-	<0.001 *
18-25	16.5 ± 4	17 (5-25)	-
26-36	17.8 ± 3.7	18 (9-25)	-
37-47	18.8 ± 3.5	19 (8-25)	-
48-58	19.3 ± 3.5	20 (10-25)	-
>58	18.2 ± 3.3	18 (12-23)	-
Marital status	-	-	<0.001 *
Single	16.7 ± 4	17 (5-25)	-
Married	18.8 ± 3.5	19 (8-25)	-
Location	-	-	0.2
Urban	17.9 ± 3.9	18 (5-25)	-
Rural	17.1 ± 3.9	18 (8-24)	-
Nationality	-	-	<0.001 *
Saudi	17.7 ± 3.9	18 (5-25)	-
Non-Saudi	19.9 ± 3	20 (13-25)	-
Education	-	-	0.5
Elementary/intermediate/Secondary	17.6 ± 4	18 (8-25)	-
Graduate/postgraduate	17.9 ± 3.8	18 (5-25)	-
Income range	-	-	<0.001 *
No source of income	17.9 ± 3.8	18 (9-25)	-
Less than 1000 SAR	16.5 ± 3.9	17 (8-25)	-
From SAR 1000 to 5000	17.7 ± 4.2	19 (8-25)	-
From 5000 to 10,000	19.2 ± 3.9	20 (5-25)	-
More than 10,000	18 ± 3.5	18 (10-25)	-

Note: Data are expressed as mean (SD), median, Min-Max; \mathbf{Y} : Mann Whitney u test, \mathbf{S} : Kruskal Wallis test, * p < 0.05 was significant.

Table 6. The characteristics of cosmetics related side effects (N = 323).

Characteristic	N (%)
Do you experience side effect?	-
Yes	150 (46.4%)
No	173 (53.6%)
Which is the form of the side effect	-
Blister/acne	76 (50.7%)
Burning feeling	51 (34%)
Itching	61 (40.7%)
Eczema	8 (5.3%)
Skin Discoloration	26 (17.3%)
Skin rash	23 (15.3%)
Others	12 (8%)
Do you report the incidence of cosmetics side effect *	2 (1.3%)
Do you have any type of allergy	47 (31.3%)
Drug allergy	15 (35%)
Food allergy	15 (33.3%)
Family history of allergy	17 (37.2)
How do you think reliable information about cosmetics/care is obtained	-
Pharmacy	29 (8.7%)
SFDA	60 (18.1%)
The cosmetics company	17 (5.1%)
Official websites	10 (3%)
General physicians, dermatologists, cosmetics experts	41 (12.3%)
Previous reviews & family and friends	18 (5.4%)
Social media	13 (3.9%)
Reading and searching about cosmetics	50 (15%)
Skincare websites	9 (2.7%)
Do not know	12 (3.6%)
Others	9 (2.7%)

3.5. Practices toward Cosmetic Products

In this section, the study participants responded to 8 questions related to their cosmetic practices. Over one-third of the participants (34.5%) reported consistently cleaning their cosmetic equipment after use, while only 1.3% stated that they never cleaned their cosmetic equipment after use. More than half of the participants (52%) reported that they always store their cosmetic products properly before and after use, and 27.3% reported doing so often, while 5.8% either never or rarely do so (See supplementary 3).

Regarding the practice of keeping cosmetic products away from children, 68% of the participants always follow this practice, 18% often follow it, and 4.1% never or rarely do so. More than half (57%) of the participants reported never using similar cosmetic products on other parts of their body, while 16% reported that they rarely use similar products. Additionally, about two-thirds of the participants never apply cosmetic products on cuts and abrasions; 20.8% of participants either rarely or sometimes apply cosmetic products on cuts and abrasions, while the remaining (7.2%) do so often or always.

Only 46% of participants buy cosmetic products from authorized dealers or sellers, while 28% do so often. The remaining participants either follow the practice

sometimes (13%), rarely (4.2%), or never (8.2%). Regarding the statement, "I have purchased many cosmetic products, but I rarely use them" 27% of respondents reported doing so, while 23% stated they bought products but never used them. The remaining 50% reported that they sometimes, often, or always do so.

3.6. Additional Part in the Questionnaire

More than half of the participants, 323 (53.8%), agreed to continue the questionnaire and answer the following additional questions, while the remaining terminated the questionnaire.

As shown in Table 6, 46.4% of the participants who completed the questionnaire experienced cosmetic-related side effects, but only 1.3% reported the incidence of these effects. One patient reported it to the pharmacy, while the other reported it to the company producing the cosmetic agent by submitting a complaint.

Blisters and acne were the most common form of cosmetics-related side effects, occurring in 50.7% of cases, followed by itching at 40.7%. Eczema was the least common form of cosmetics-related side effects, occurring in only 5.3% of cases.

Of the participants who completed the questionnaire, 31.3% reported having a previous history of allergy (drug, food, or genetic). When seeking reliable information about

Total Characteristic Experienced Side Effects (N = 150)Not Experienced Side Effects (N = 173)p Gender <0.001 * Females 124 (55.9%) 98 (44.1%) 222 75 (74.3%) 101 Males 26 (25.7%) <0.001 * Age (years) 18-25 60 (52.2%) 55 (47.8%) 115 -83 26-36 42 (50.6%) 41 (49.4%) -39 (62.9%) 37-47 23 (37.1%) 62 -48-58 23 (41.1%) 33 (58.9%) 56 -2 (28.6%) 5 (71.4%) 7 ->58 History of previous allergy 15 (100.0%) 15 <0.001 * Food allergy 0 (0.0%) Drug allergy 15 (100.0%) 0 (0.0%) 15 < 0.001 * Family history of allergy 17 (100.0%) 0 (0.0%) 17 <0.001 *

Table 7. The association between the participant's characteristics and the incidence of cosmetics related side effects (N = 323).

Note: Data are expressed as the number and percentage, the p-value was calculated using a chi-square test or Fischer exact test, * p < 0.05 was significant.

cosmetics, 18% of the participants sought information from the Saudi Food and Drug Administration, while 15% obtained reliable information by reading and researching about cosmetics. 12.3% obtained their information from healthcare professionals and cosmetics experts, and 8.7% obtained their information while purchasing cosmetic products at the pharmacy. However, 3.6% of the participants did not know how to obtain reliable information regarding cosmetics.

Univariate analysis revealed significant associations between gender, age, allergic reactions to medications and food, and genetic allergies with cosmetic side effects (p < 0.001). The female sex and the presence of any history of allergy were found to be associated with an increased incidence of cosmetics-related side effects. Furthermore, these side effects were observed to occur more frequently in younger age groups. Detailed information can be found in Table 7. A multivariate analysis using logistic regression was conducted to control for confounding variables, understand interactions between variables, and improve predictive power. The analysis indicated a significant association only between gender and the occurrence of cosmetic side effects (adjusted odds ratio (aOR) 4.84, 95% confidence interval (CI) 2.48-9.48).

4. DISCUSSION

The results indicate that the majority of participants have sufficient knowledge of cosmetic safety. However, no significant association between males and females in terms of knowledge score and other demographic data, which is in contrast to studies conducted on Malaysians [20], where knowledge was higher among women than men, and the study that was held in Delhi [22].

The study showed a higher prevalence of cosmetics use and reported side effects in females than in males, which is in line with the results of previous studies [9, 24]. It is possible that one reason for the difference in adverse reactions to cosmetics between men and women is that

women tend to use cosmetics at a higher rate and in greater quantities than men. Additionally, there may be psychological differences between men and women that influence their use of cosmetics and their reactions to them [24]. A local study on females by Almousa A.H. et al. found that most participants had lack of awareness about cosmetics' side effects, especially younger age [25]. Also, Alghamdi H.S et al. reported in their survey, the majority of young female students at Albaha University regularly use cosmetics, indicating a high prevalence of use and just 8% of them are well-versed on the dangers associated with makeup [26]. Their respondents' knowledge of the health risks associated with cosmetic usage was found to be inadequate, necessitating a special focus on safety issues related to cosmetic use through awareness campaigns [26]

In our study, the highest score for poor knowledge was if cosmetics can be shared with others (21%), which is one of the biggest reasons that they may transmit infection and cause allergies in some people. Alshehrei F.M et al's. investigation found that almost 50 samples collected from the Mecca region, Saudi Arabia, were contaminated with microorganisms. High-quality brands are less contaminated than low-quality brands; this might be due to the product's contents, how preservatives are applied, or the conditions of transit and storage [27]. Based on these findings, the public and health authorities should focus on educating people about the dangers of sharing cosmetics and the need for interventions that increase awareness or capture the attention of specific populations.

The study also revealed that educational background did not have an impact on participants' product preferences. This is in contrast with results obtained by Helali R.G *et al.* who observed that the use of cosmetics among females at Universities in Saudi Arabia has demonstrated that education level is a significant predictor of the response to commercials on purchasing behavior [18].

The total attitude score is influenced by some

demographic factors (age, marital status, nationality, and income range). Most participants strongly agreed with never buying new cosmetic products without being informed about the ingredients, always verifying the expiry date before purchasing cosmetic products (50.1% and 58%, respectively), and agreed (25.1% and 22%, respectively), which indicates that people read about the ingredients and know that one of the biggest causes of adverse drug reactions may be an inconspicuous ingredient in some products. This is in line with a local study by Almousa A.H. et al., which found that most participants of all ages, regardless of nationality or employment, use cosmetics products and that the majority had a positive attitude toward cosmetics. On the other hand, cosmetics consumers, particularly women under the age of 20, indicated a lack of understanding of negative effects of cosmetics [25].

The responses to the statements related to perception towards cosmetic products were good in general, especially to the question of whether the price indicates the quality of the product, so 40.4% strongly agreed. This indicates an awareness of the importance of ingredients and not the price, either in terms of "cosmetics speed up skin aging" or "Cosmetic products contain at least one ingredient that is toxic to the human body." The most considerable results were neutral (35% and 40%), and here, we need to raise awareness about the fact that the frequent use of cosmetics has an adverse effect on the skin. However, most of the respondents (40%) agreed that "cosmetics can cause acne," indicating their knowledge of its effect on the skin as acne and not as aging skin.

Awareness should be raised regarding the practice of using cosmetics. In "I clean cosmetic equipment after use," the answer was always only 34.5%, which may be the first reason for ADR, not the ingredients. The reason is that equipment may be exposed to microbes in the air. Some of the components of the tools may be affected. Also, in poor storage, only 52.1% are the ones who store them well, and the third reason may be "use cosmetic products more frequently than recommended each day," which gives the opposite effect, and the highest results were rare at 29%. Another reason is that cosmetics are purchased from unlicensed sellers, they have 8.2%, and the highest value was that (46%), bought from licensees.

The importance of raising awareness about ADR reports to the SFDA is that the report informs the implementing agencies for occupational health and safety (the SFDA and local authorities) about serious incidents and cases of illness and the handling of the reported product.

To achieve the best possible results when using cosmetics products, acquiring knowledge and training in modern cosmetic practices, techniques, and applications is strongly advised. By doing so, individuals can better understand how to use products efficiently and effectively, leading to a more successful outcome. Therefore, it is highly recommended to seek instructions [28, 29].

This study found 46.4% of the participants who

completed the additional part of the questionnaire experienced cosmetic-related side effects but only 1.3% reported the incidence of these effects. Shaaban H. *et al's*. study conducted in Saudi Arabia showed that in terms of self-reported adverse events, 16.1% of participants encountered them. Lotions and face creams were the most commonly reported cosmetic goods to produce side effects, followed by deodorant [30].

Overall, our findings support the need for continued efforts to increase consumer awareness of regulatory oversight and the importance of reporting adverse events to ensure the safety of cosmetic products in Saudi Arabia. This study highlights the importance of monitoring and regulating cosmetic products to ensure their safety. The recent increase in pigmented cosmetic dermatitis of the face and ocular discomfort among eye cosmetic users has been linked to the widespread usage of cosmetics and their potentially harmful effects. A cosmetovigilance program, as mentioned in many sources, may help to monitor the occurrence, acting as predictor of undesirable effects caused by cosmetic products. Also, it may help to assess the severity of the events and facilitate the work of regulators to issue any preventive actions related to adverse cosmetic events [3, 7].

5. IMPORTANCE OF THE CURRENT STUDY

The importance of our study lies in its contribution to enhancing public knowledge concerning cosmetic safety and the associated health risks. Given that cosmetics are widely used, particularly among women, understanding the potential adverse effects of these products is crucial for preventing negative health outcomes. This study underscores several critical areas related to cosmetic safety, including a general lack of consumer awareness regarding safe practices, particularly concerning the sharing of products and the presence of contaminants. By highlighting these knowledge gaps, our research lays the groundwork for educational campaigns that can significantly reduce the risk of infections and allergic reactions. Additionally, we identify specific risk factors contributing to adverse reactions, such as poor storage practices and misuse of products, which can inform targeted intervention strategies for health authorities. Furthermore, our findings advocate for stronger regulatory oversight of cosmetics by revealing a high prevalence of reported side effects and inadequate responses to them, thereby calling for enhanced monitoring systems to protect consumers. Lastly, this study provides a foundation for future research into cosmetic safety in Saudi Arabia by offering baseline data on participant knowledge and attitudes, which can guide investigations into demographic vulnerabilities and the long-term health impacts of cosmetic use.

6. LIMITATIONS

The current research faced several limitations. First, although the sample was considered adequate for making inferences, it only represented a small fraction of cosmetic users in Saudi Arabia. Additionally, the participants were selected using a convenience method, which could

introduce bias and restrict the sample's representation. Another limitation is the exclusion of participants under the age of 18, which may restrict the generalizability of the study's findings to a broader population. To enhance the external validity of the study, future researchers should consider incorporating individuals from diverse age groups, socioeconomic backgrounds, and locations. By including a more diverse sample, the results can be more applicable to a wider population, and the findings can be considered more reliable.

CONCLUSION

The study shows that Saudi Arabian cosmetics consumers have a good understanding of cosmetic safety, a positive attitude and a good perception of regulatory oversight. Many participants were aware of reporting adverse events to the Saudi Food and Drug Administration (SFDA), but a low percentage used the SFDA as a reliable source. The study emphasizes the importance of cosmovigilance in ensuring patient safety and improving public health outcomes, and the crucial role of regulatory authorities in monitoring cosmetic product safety. The findings support the need for increased consumer awareness and reporting of adverse events to ensure the safety of cosmetic products in Saudi Arabia.

AUTHORS' CONTRIBUTION

F.A., L.A., N.A., Y.A., N.I.: Study conception and design; S.A.: Data collection; Y.A.: Validation; M.A.: Analysis and interpretation of results; A.E., A.A.: draft manuscript.

LIST OF ABBREVIATIONS

SPSS = Statistical Package for Social Science Analysis

SFDA = Saudi Food and Drug Authority

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

The research ethics committee of Qassim University in Qassim, Saudi Arabia, approved the study. (Approval date: 18 December 2022, number of certifications of approval 22-17-01).

HUMAN AND ANIMAL RIGHTS

All human research procedures followed were in accordance with the ethical standards of the committee responsible for human experimentation (institutional and national), and with the Helsinki Declaration of 1975, as revised in 2013.

CONSENT FOR PUBLICATION

Informed consent was obtained from all participants.

STANDARDS OF REPORTING

STROBE guidelines were followed.

AVAILABILITY OF DATA AND MATERIALS

The data and supportive information are available within the article.

FUNDING

None.

CONFLICT OF INTEREST

The authors declare no conflict of interest, financial or otherwise.

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Declared none.

SUPPLEMENTARY MATERIALS

Supplementary material is available on the Publisher's website.

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