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Original article

An observational study on adverse reactions of cosmetics: The need of practice the Cosmetovigilance system

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ABSTRACT

Introduction: Cosmetovigilance is public health surveillance on cosmetic products with a public health objective. Since the radical development in beautifying products in Saudi Arabia, the Saudi Food and Drug Authority takes the responsibility of regulating cosmetic products and issuing guidelines to ensure its safety. Despite this, there exists a lacuna of Re published reports on cosmetics-related adverse reactions in the Saudi population. We aimed to assess self-reported adverse reactions in the general public of the Eastern Province, Saudi Arabia.

Materials and Method: A cross-sectional study was conducted for three months. The questionnaire for data collection was adopted and modified from previous studies for the cosmetic utilization behaviors and adverse reactions.

Results: Among the 425 participants, 50.6% reported that they had at least one adverse reaction in the past two years. Redness of the skin (19%), pimples (15%), and itching (13%) were the commonly reported adverse reactions. The majority of the adverse reactions were reported with hair care (29%) and skincare products (25%). The majority [n = 181 (84.2%)] of the participants with managed the ARs by the cessation of the product use. The univariate analysis found that gender, age, allergic to medications and food, family history of allergy, mixing cosmetics, and frequent switching of cosmetic brands were associated with adverse events. However, the adjusted analysis found that allergic to medication (adjusted OR: 3.9), family history of allergy (adjusted OR: 1.91), and mixing cosmetics (adjusted OR: 1.70) were significantly associated with cosmetics-related adverse reactions.

Conclusion: Cosmetovigilance is a model of safety monitoring of cosmetics. It can be considered as a one of the element in public health activities. Pharmacists should be more vigil on this issue in the near future. To strengthen the findings further, a national wide prevalence study can be conducted prospectively and analyses causality and report to the pharmacovigilance system of the country.

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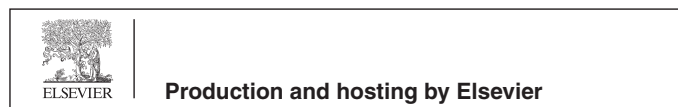
1. Introduction

Cosmetic is the primary aspect of the human daily lifestyle in all generations and is spread among the people for numerous uses and purposes (Saudi Food and Drug Authority, 2008). According to the US Food and Drug Administration (FDA), cosmetics are defined as

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“articles for beautification, cleansing or altering physical appearance” (U.S. Food and Drug Administration, 2018). Whereas Saudi FDA define the cosmetics as ‘any product contains one or more substance intended to use 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 good condition, to change or improve appearance, or to change or improve the smell of the body.” (Saudi Food and Drug Authority, 2008). Similarly, the requirements of cosmetics are different in US and Saudi Arabia: some personal care products are considered as OTC drug in US where as it is under cosmetics in Kingdome and other courtiers (Saudi Food and Drug Authority, 2008). (U.S. Food and Drug Administration, 2018).

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The majority of cosmetic consumers are focused on short-term outcomes of the cosmetics on appearance rather than the long-term consequences on the whole body. It is believed that such products have a reasonable degree of safety and tolerability (Kwa et al., 2017). In recent years, more attention has been given for testing and monitoring of the possible harmful effects of cosmetics. The studies revealed that exposure to various chemical substances present in cosmetics poses a health risk (Alani et al., 2013; Draelos, 2015). 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 (Alani et al., 2013; Draelos, 2015). Headache, dizziness, tiredness, and nausea were the frequently reported adverse reactions associated with prolonged exposure to heavy makeup (Al-Fawaz, 2016; Husain, 2019; Orton and Wilkinson, 2004). Cosmetovigilance is a public health surveillance on cosmetic products with public health objectives (Vigan and Castelain, 2014). In US and Canada, manufacturers, health care providers and consumers are encouraged to report cosmetics-related ADRs to the FDA or Health Canada, respectively (FDA, 2020a; MedEffect Canada, 2020). Whereas in the European Union, Post Launch Monitoring and Colipa guidelines targeted to harmonize the causality assessment of adverse effects of cosmetic products (European Commission, 2013; Zweers et al., 2012).

In the Middle East, beauty and personal care trade is growing twice as fast as any other part of the world (Eye of Riyadh, 2018). Economic and cultural changes in the Kingdom of Saudi Arabia has an effect on cosmetic use habit. Fragrances, haircare, cosmetics, skincare, and men's grooming are the key categories of cosmetics that grows the beauty and personal care market in the Kingdom (Chęś, 2016; Husain, 2019). The beauty industry in Saudi Arabia has been valued at a staggering US\$5.7 billion in 2019 and estimated to grow up to \$6.9 billion in 2021 (Chęś, 2016; Maisey, 2018; Statista Research Department, 2018). Since the radical development in beautifying products in the Kingdom, the Saudi FDA (SFDA) takes the responsibility of regulating cosmetic products and issuing guidelines to ensure its safety. In order to regulate manufacturing, importation, and marketing of cosmetic products, SFDA implemented an electronic system called eCosma (<https://ecosma.sfda.gov.sa>). Furthermore, SFDA assigned a unified call center number to enquire about the safety of food, drugs, and cosmetics (Saudi Food and Drug Authority, 2008). Despite all these efforts, 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 of the Dammam metropolitan region.

2. Materials and methods

2.1. Study design and settings

A cross-sectional study was conducted, from January to March 2019, among the general population living in the metropolitan area in the Eastern Province of Saudi Arabia. The metropolitan area is formed by three main neighboring cities: Dammam, Dhahran, and Khobar. Study questionnaires were distributed in public as well as working places such as schools, colleges, hospitals, companies, and shopping malls. Participants were requested to read the information about the study and to agree with the informed consent before proceeding to items in the questionnaire.

2.2. Study population and sampling

Sample size calculation was done by using OpenEpi (Version 3). A population size of 700,000 was considered (Bilal et al., 2017).

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 362, which we approximated to 400.

Residents of Dammam metropolitan region were included in the study irrespective of their nationality and gender or age. Persons who have a habit of using any categories of cosmetic products and who read/write either English or Arabic were included in the study. Pediatric populations where considered if their legal guardians can fill the data collection tool. Persons with hearing and sight problems were excluded from the study. Similarly, persons on permanent cosmetic methods like plastic surgery, tattoos, fillers, and Botox were also excluded from the study.

2.3. Data collection

The questionnaire for data collection was adopted and modified from previous studies for the cosmetic utilization behaviors and adverse reactions (Bilal et al., 2017; Di Giovanni et al., 2006; Meharie et al., 2014; Sautebin, 2008). US FDA *Med watch* ADR reporting forms for the consumers were used as the primary reference for the development of AR section. The questionnaire was translated into Arabic; a back-translation method was used to confirm the phase validity of the original questionnaire. Moreover, expert opinion was considered for further editing after translation.

The questionnaire had three main parts: first part was about general socio-demographic information, second part addressed the cosmetics utilization pattern. 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 AR 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. The information on the brand or the details of the cosmetics that caused them the reactions were not obtained.

Three trained pharmacy students who speak both Arabic and English distributed the questionnaire. 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. Considering the sample size of 400, we targeted for distributing 1000 questionnaires.

2.4. Statistical analysis

Data management and analysis were carried out using SPSS Statistics (Version 24.0. Armonk, NY: IBM Corp.). 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.

2.5. Operational definitions

Adverse Reactions are defined as harmful/ noxious outcomes that probably related to the cosmetic use in view of the participants.

Cosmetics are defined as any articles used for beautification, cleansing, and personal care, including skincare, hair care, nail care, personal care, makeups, and perfumes.

3. Results

3.1. Characteristics of the study participants

A total of 1000 data collection forms were distributed to the general public, and 473 were returned. Four hundred twenty-five 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. The male–female ratio was 1:3. The age ranged from 10 to 67 years, with more than two-third below the age of 30 years. More than one-half of our study participants had university-level education (245; 57.65%). The average monthly income of the majority (252; 59.29%) was less than 5000 Saudi riyals. Nearly 20% (n = 83) and 10% (n = 43) of participants had a history of food and drug allergy, respectively.

3.2. Types of cosmetics: Usage by gender

Makeup products [n = 1313 (24.56%)] and personal care products [n = 1255 (22.43%)] were the frequently used cosmetics by the study population. Makeup [n = 1300 (28.61%)] and Skincare [n = 993 (22.5%)], were the favorite choice for females whereas personal care products [n = 318 (47.16%)] and haircare products [207 (25.5)] were preferred by men. Details of preference for cosmetics between the gender were given in Fig. 1.

3.3. Cosmetic utilization behaviors

Cosmetic usage behavior is given in Table 2. Nearly one-half of participants [n = 199 (47%)] used 3–5 cosmetics per day. A large proportion of participants [n = 224 (53%)] utilized cosmetic products more than once a day. Nearly 31% (n = 131) and 23% (n = 93) were mix cosmetics either each other or with water, respectively. In addition, 48% (n = 206) of the consumers share make-ups with family members or friends. Local shop [n = 227 (26.40%)] and pharmacy [n = 262(26.28%)] were the preferable spot of purchase. Quality [287 (31.43%)] and brand [203 (22.23%)] were the top preferable motive for deciding the cosmetics. A large number of respondents store their products in room cabinet [n = 363 (54.50%)].

3.4. Safety measures on cosmetic habits

Of the total 425 participants, 38% (n = 163) of them read instructions label before the use of cosmetics, and a quarter of participants [n = 103 (24%)] perform allergy testing prior to cosmetics use (Table 3). A large proportion of respondents, 69% (n = 293),

circumspect to check the expiry date of products; while in contrast, 43% (n = 182) used the cosmetic products until it finishes. 41.4% (n = 176) of participants stated that they change the cosmetics brand of sporadically.

3.5. Adverse reactions of cosmetics

Of the total 425 participants involved in the study, 50.6% (n = 215) developed one or more adverse reactions related to cosmetics usage at least once in the last two years; therefore, the two-year prevalence of AR in our study was 50.5%. A total of 562 adverse reactions were reported among 215 participants giving an average of 2.6 (range1-6) per person. Redness of the skin (n = 107), pimples (n = 87) and itching (n = 75) were the topmost reported ARs by the participants. Fig. 2 enlists the pattern of AR in the study participants.

A major proportion of the ARs were related with hair care [n = 151 (27%)] and skincare product [n = 136 (24%)], respectively. The details are given in Fig. 3.

3.6. Management of adverse effects of the cosmetics

The majority [n = 181 (84.2%)] of the participants with ARs managed the ARs by the cessation of the product use. Several participants had consulted physician [n = 65 (30.9%)] or taken medication [n = 22 (10.2%)] to managing adverse effects of cosmetics. Gender-wise comparison is given in Fig. 4.

3.7. Predictors of cosmetic adverse events

The univariate analysis found that gender, age, allergic to medications and food, family history of allergy, mixing cosmetics, and frequent switching of cosmetic brands were associated with adverse events (Table 4). However, the adjusted analysis found that allergic to medication (adjusted OR: 3.9), family history of allergy (adjusted OR: 1.91), and mixing cosmetics (adjusted OR: 1.70) were significantly associated with cosmetics-related adverse reactions.

4. Discussions

Cosmetovigilance is a growing area under pharmacovigilance an one of the in Saudi Arabia. This study analyses the cosmetic utilization pattern and related ARs by using self reported survey. Longitudinal monitoring of the safety of drugs is practiced in countries like Netherlands (Härmark et al., 2011).

Table 1
Demographic details of the study participants.

Variables	Male [n = 109]	Female [n = 316]	Total [n = 425]
Age (in years)			
Under or equal to 18	15 (13.8%)	111 (35.1%)	126 (29.6%)
19–29	38 (34.9%)	128 (40.5%)	166 (39.1%)
30–40	33 (30.3%)	51 (16.1%)	84 (19.8%)
Above or equal 41	23 (21.1%)	26 (8.2%)	49 (11.5%)
Education level			
Intermediate or lower	6 (5.5%)	14 (4.4%)	20 (4.7%)
Secondary	25 (22.9%)	135 (42.7%)	160 (37.6%)
University	78 (71.6%)	167 (52.8%)	245 (57.6%)
Monthly Income			
Less than 5000 SR	36 (33%)	216 (68.4%)	252 (59.3%)
5000 – 10,000 SR	30 (27.5%)	58 (18.4%)	88 (20.7%)
>10,000 SR	43 (39.4%)	42 (13.3%)	85 (20%)
Allergic to any medication	12 (11%)	31 (9.8%)	43 (10.1%)
Allergic to food	22 (20.2%)	61 (19.3%)	83 (19.5%)
Family history of allergy	34 (31.2%)	150 (47.5%)	184 (43.3%)

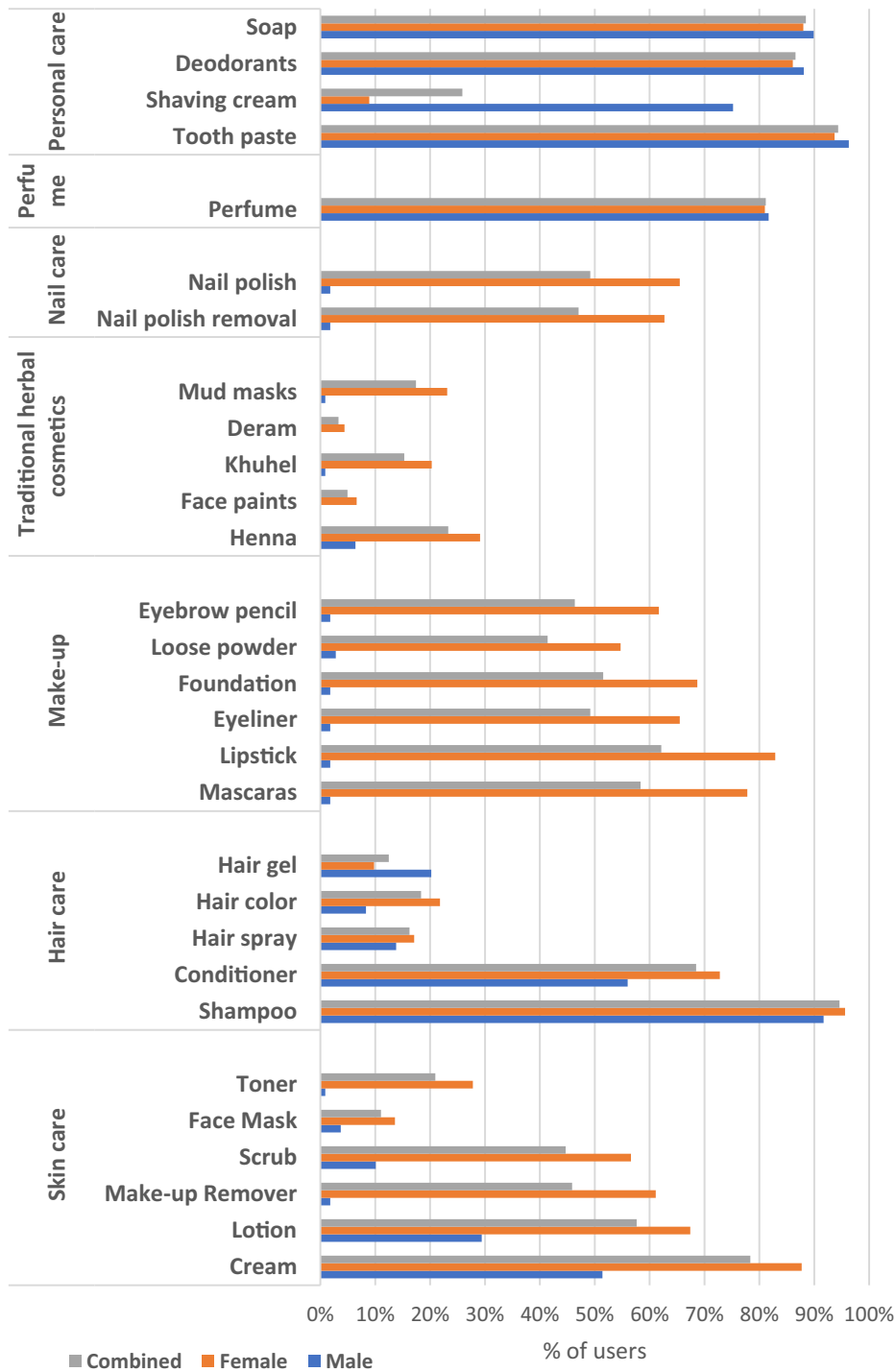


Fig. 1. Types of cosmetics: usage by gender.

One-half of our study participants reported the occurrence of AR to cosmetics in the past two years. The proportion was much higher than that reported with the previous studies (Getachew and Tewelde, 2018; Huf et al., 2013). 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 non-medicated cosmetic as well as methodological and cultural difference in the study and studied population. In contrast, study from Ethiopia had reported a much higher incidence of 64% (Bilal et al., 2017). In the present study, similar to other studies (Bilal et al., 2017; Di Giovanni et al., 2006), 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 addition, the gender-specific difference in the psychological factors that affect cosmetics use and ARs (Bilal et al., 2017; Korichi et al., 2008). Younger age participants were reported more ARs, and this finding could be highly attributed to a high rate of consumption and more awareness in the younger age group. Moreover, this age group is sprite and have a robust desire for self-care and beautification. A similar trend was observed in previous studies (Bilal et al., 2017; Norudin, M., Desnika, MA., Rafi, 2010).

Table 2
Cosmetic use behavior.

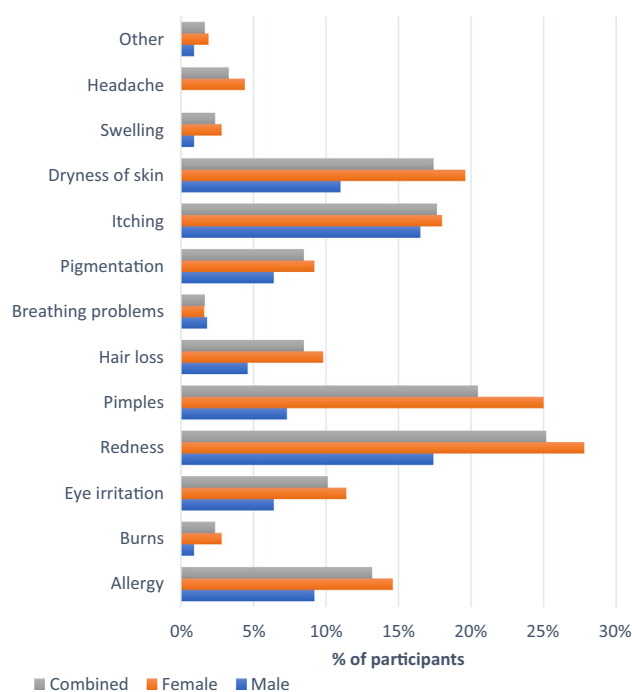
	Male [n = 109]	Female [n = 316]	Total [n = 425]
Number of cosmetics used per day.:			
≤ 2	46 (42.2%)	107 (33.9%)	153 (36%)
3–5	55 (50.5%)	144 (45.6%)	199 (46.8%)
6–10	8 (7.3%)	38 (12%)	46 (10.8%)
>10.	0 (0%)	27 (8.5%)	27 (6.4%)
Cosmetics utilization per day			
1	46 (42.2%)	178 (56.3%)	224 (52.7%)
2	46 (42.2%)	79 (25%)	125 (29.4%)
3	12 (11%)	43 (13.6%)	55 (12.9%)
≥4	5 (4.6%)	16 (5.1%)	21 (4.9%)
Mixing cosmetics each other's	14 (12.8%)	117 (37%)	131 (30.8%)
Sharing the Cosmetics.	33 (30.3%)	173 (54.7%)	206 (48.5%)
Store cosmetics ¹ :			
Room cabinet.	81 (74.3%)	282 (89.2%)	363 (84.5%)
Bathroom.	67 (61.5%)	62 (19.6%)	129 (30.3%)
Car.	21 (19.3%)	2 (0.6%)	23 (5.5%)
Handbags.	7 (6.4%)	108 (34.2%)	115 (27.2%)
Other.	7 (6.4%)	29 (9.2%)	36 (8.5%)
Criteria for selecting cosmetics ¹ :			
Brand.	36 (33.0%)	167 (52.8%)	203 (47.8%)
Advertisements.	15 (13.8%)	54 (17.1%)	69 (16.2%)
Quality.	70 (64.2%)	217 (68.7%)	287 (67.5%)
Cost.	50 (45.9%)	120 (38.0%)	170 (40.1%)
Recommendation	32 (29.4%)	152 (48.1%)	184 (43.3%)
Mode of purchasing ¹ : Shop	47 (43.1%)	196 (62.0%)	243 (57.2%)
Online shopping.	17 (15.6%)	99 (31.3%)	116 (27.3%)
Pharmacy	71 (65.1%)	155 (49.1%)	226 (53.3%)

¹ Number exceed the total due to multiple factors allowed

Table 3
Safety measures on cosmetic habits.

	Male [n = 109]	Female [n = 316]	Total [n = 425]
Duration of cosmetics use:			
≤6 months.	22 (20.2%)	27 (8.5%)	49 (11.53%)
6–12 months.	10 (9.2%)	53 (16.8%)	63 (14.82%)
≥2years.	6 (5.5%)	22 (7.0%)	28 (6.59%)
Until its finishes	56 (51.4%)	126 (39.9%)	182 (42.82%)
Till its expiry date.	15 (13.8%)	88 (27.8%)	103 (24.24%)
Change the cosmetic brand:			
Yes.	26 (23.9%)	103 (32.6%)	129 (30.35%)
Sometimes.	39 (35.8%)	137 (43.4%)	176 (41.41%)
No.	44 (40.4%)	76 (24.1%)	120 (28.24%)
Check the expiry of cosmetics:			
Yes.	74 (67.9%)	219 (69.3%)	293 (68.94%)
No.	35 (32.1%)	97 (30.7%)	132 (31.06%)
Read the instruction	36 (33%)	127 (40.2%)	163 (38.4%)
Sometimes.	39 (35.8%)	111 (35.1%)	150 (35.3%)
No.	34 (31.2%)	78 (24.7%)	112 (26.4%)
Testing for allergy	17 (15.6%)	86 (27.2%)	103 (24.2%)

In line with other studies (Bilal et al., 2017; Dibaba et al., 2013; Getachew and Tewelde, 2018; Mehari et al., 2014), hair care and skincare 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 (Huf et al., 2013). It is well documented that these products contain many chemical additives in order to improve performance, effectiveness, and viability of the cosmetics (Alani et al., 2013; Juhász and Marmur, 2014). Exposure to various chemical substances present in cosmetics poses a health risk that varies from a mild hypersensitivity response to a lethal intoxication (Dhavalshankh and Dhavalshankh, 2012; Zainy, 2017). Correspondingly, toxicological studies on cosmetics in Saudi Arabia has been reported the presence of heavy metals and other components more than an approved limit (Al-Saleh et al., 2012, 2009; AlQuadeib et al.,

**Fig. 2.** Adverse reactions of cosmetics.

2018; Zainy, 2017). Also, misbranded and spurious cosmetics are not uncommon in the beautifying market (Dhavalshankh and Dhavalshankh, 2012).

Cosmetics are reported to cause a wide array of adverse reactions, including pigment disorders, irritant, contact urticaria, photosensitization, damage of hair and nails, and acneiform eruptions (Pereira and Pereira, 2018). Similarly, in line with previous studies (Bilal et al., 2017; Di Giovanni et al., 2006), our study

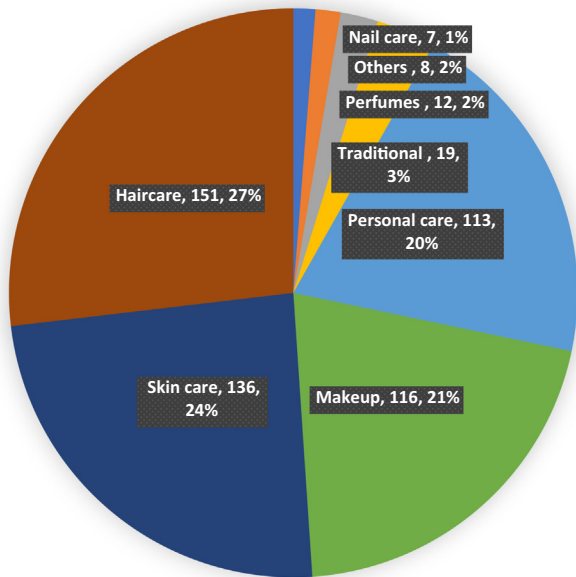


Fig. 3. Pattern of product-related ARs.

sample had experienced various ARs: redness (20%) and pimples (15%) were the topmost ARs. Sites of cosmetic application were the utmost affected by cosmetics-related AR. Again, this finding is supported by literature (Dibaba et al., 2013; Getachew and Tewelde, 2018). One percent of participants reported systemic effects like breathing problems as an AR caused by perfume, deodorant, soap, hair spray, and hair coloring products. Likewise, headache was also reported with certain products such as cream, toner, foundation, deodorant, and soap. However the causal relationship between the reported AR and cosmetics use is not assessed in the study.

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 (Bilal et al., 2017; Di Giovanni et al., 2006; Dibaba et al., 2013; Norudin, M.,

Desnika, MA., Rafi, 2010), which highlight the serious nature of the reactions. Allergic to medication and family history of allergy were significantly associated with cosmetic related ARs. In line with previous reports, mixing cosmetics, and changing the brands of cosmetic products were recognized as important predictors for experiencing an adverse event. This could be partly explained by the interaction between cosmetic products or the synergistic effect of the products to each other (Bilal et al., 2017; Dibaba et al., 2013; Norudin, M., Desnika, MA., Rafi, 2010).

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. 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 (St. Sauver et al., 2013). Studies also reported that products labeled as hypoallergenic also contained recognized allergens or irritants (FDA, 2020b; Hamann et al., 2015; Lazzarini et al., 2018). 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 (Ashique and Chandrasekhar, 2017). The role of pharmacist in Public engagements are well documented (Allison et al., 2017). 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 therapeutics (Ashique and Chandrasekhar, 2017).

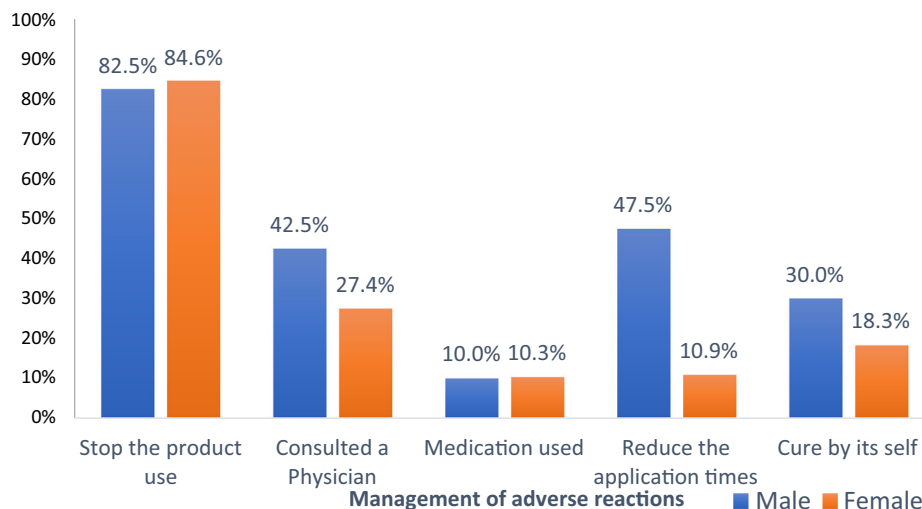


Fig. 4. Management of ARs.

Table 4
Predictors of ARs.

Variables	n (%)	p-value ¹	Adjusted OR ² (95% CI)
Gender	Male.	40 (36.7%)	0.001*
	Female.	175 (55.4%)	1.61 (0.97, 2.67)
Age	less than19	81 (64.3%)	0.003*
	19–29	73 (44%)	0.95 (0.47, 1.92)
	30–40	40 (47.6%)	1.26 (0.58, 2.71)
	>40	21 (42.9%)	Ref
Do you allergic to any medication?	No	180 (47.1%)	0.000*
	Yes	35 (81.4%)	3.9 (1.66, 9.17)*
Do you allergic to any type of food?	No	161 (47.1%)	0.003*
	Yes	54 (65.1%)	1.29 (0.73, 2.26)
Family history of allergy	No.	99 (41.1%)	0.000*
	Yes.	116 (63%)	1.91 (1.24, 2.95)*
Number of cosmetics / days	Less than or equal 2.	69 (45.1%)	0.275
	3–5.	108 (54.3%)	–
	6–10.	22 (47.8%)	–
	>10	16 (59.3%)	–
Frequency of cosmetics/ day	1	108 (48.2%)	0.134
	2	64 (51.2%)	–
	3	35 (63.6%)	–
	>3	8 (38.1%)	–
Mixing Cosmetics	No.	133 (45.2%)	0.001*
	Yes.	82 (62.6%)	1.70 (1.07, 2.68)*
Sharing cosmetics	No	108 (49.3%)	0.588
	Yes.	107 (51.9%)	–
Read the label of instruction	Yes.	81 (49.7%)	0.113
	Sometimes.	85 (56.7%)	–
	No.	49 (43.8%)	–
Changing cosmetic brand frequently	Yes.	77 (59.7%)	0.023*
	Sometimes.	87 (49.4%)	1.59 (0.92, 2.75)
	No.	51 (42.5%)	1.19 (0.71, 2.0)
			Ref

¹ Chi-square test was carried out; ²Adjusted odds ratio was estimated using multiple logistic regression; *statistically significant at 5% level.

5. 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.

CRedit authorship contribution statement

Jisha M. Lucca: Conceptualization, Data curation, Investigation, Methodology, Resources, Supervision, Visualization, Writing - original draft, Writing - review & editing. **Royes Joseph:** Formal analysis, Investigation, Methodology, Project administration, Resources, Software, Validation, Writing - review & editing. **Zainab Hussain Al Kubaish:** Data curation, Formal analysis, Investigation, Project administration, Resources, Writing - original draft, Writing -

review & editing. **Sarah Mohammad Al-Maskeen:** Data curation, Formal analysis, Investigation, Project administration, Resources, Writing - original draft, Writing - review & editing. **Zainab Ali Alo-kaili:** Data curation, Formal analysis, Investigation, Project administration, Resources, Writing - original draft, Writing - review & editing.

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