



ORIGINAL ARTICLE

Analysis of factors influencing skin reactions to sunscreens, skin whitening products, and deodorants: Results from a large-scale patch test dataset in China

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Abstract

Background: Cosmetic products are widely used in daily life and can cause skin reactions. However, to date, few studies have investigated the prevalence and associated factors of skin reactions to different types of cosmetic products using patch test results.

Objectives: To investigate the frequency and associated factors of skin reactions to sunscreens, skin whitening products, and deodorants using patch test results in China.

Methods: This cross-sectional analysis used data collected during 2004–2017 at the Shanghai Skin Disease Hospital, China. Skin reactions were measured using patch tests following internationally standardized protocols.

Results: In total, 151 280 patch tests comprising 16 477 cosmetic products conducted in 4029 healthy volunteers were analyzed. The frequencies of skin reactions to different cosmetic products were 1.07%, 1.28%, and 4.41% for sunscreens, skin whitening products, and deodorants, respectively. With increasing age, a higher frequency of reactions to sunscreens in women ($p < 0.001$) and a lower frequency of reactions to skin whitening products in men ($p < 0.05$) were observed. In addition, men were more likely to develop skin reactions to deodorants compared to women ($p < 0.05$). Skin reactions were more frequent in winter ($p < 0.05$), which was true for different types of cosmetic products.

Conclusions: The frequency of patch testing for different cosmetic products was 1.07–4.41%. The effects of age, sex, and season vary among the different types of cosmetic products. We hope that these findings can offer guidance for a healthy skincare concept.

KEYWORDS

associated factors, deodorants, patch test, skin reactions, skin whitening products, sunscreens

1 | INTRODUCTION

Cosmetic products are widely used in daily life and are a common cause of skin reactions.^{1,2} A survey conducted in the US in 2004 indicated that women used, on average, 12 cosmetic products per day, as compared with men, who used 6 products.³ In 2015, the average French woman used 16 cosmetic products daily versus the average French man who used 8 products.⁴ The increasing use of cosmetic products is associated with an increase in the incidence of skin reactions to cosmetic products. For example, in the UK, the prevalence of adverse skin reactions to cosmetic products increased from 12% in 1979⁵ to 18.5% in 2001,⁶ which indicates that one out of six consumers experienced some sort of adverse skin reaction to cosmetics. Given the widespread use of cosmetic products and the high prevalence of skin reactions to these products, guidance on a healthy skincare concept is of great concern.

We have provided solid evidence that season, sex, and age can affect patch test reactions with cosmetic products.⁷ However, the occurrence of skin reactions depends on the composition and concentration of the ingredients present in cosmetic products and thus may vary among different functional product categories.⁸ In general, sunscreens work by absorbing or blocking UV irradiation through chemical and physical UV filters⁹; the active ingredients in skin whitening products aim to reduce the concentration of melanin¹⁰; a large amount of fragrance and antimicrobial agents are added to deodorants to counteract the underarm odor and decrease the number of bacteria that produce volatile odoriferous substances.^{11,12} Considering the potential skin reaction of these cosmetics, the given cosmetic products (not ingredients), including sunscreens, skin whitening products, and deodorants, need to be tested for safety evaluation before being sent to the market according to current regulations in China.¹³ To better understand the factors that potentially affect skin reactions caused by different types of cosmetic products, 151 280 safety assessment patch test data using the different types of cosmetic products were analyzed. This paper is the first to present different types of cosmetic product data and the second in a series of papers on this large patch testing study conducted in China.

2 | MATERIALS AND METHODS

2.1 | Study sample

Our dataset included 151 280 patch test results, which were generated by patch testing a total of 16 477 cosmetic products in 4029 healthy volunteers at the Shanghai Skin Disease Hospital,

China from 2004 to 2017. The criteria for participant recruitment have been published previously.⁷ Briefly, the criteria for excluding the participants were self-reported sensitive skin, pregnant and lactating women, skin cancer history, chronic skin diseases, and other chronic diseases. The participants were told not to use drugs or undergo any treatments before the study. To control for bias, individuals who participated in any other clinical testing or with damaged skin in or around the test sites were also excluded. All participants signed informed consent before the study, which was approved by the local ethics committee at the Shanghai Skin Disease Hospital, China.

2.2 | Patch test to measure skin reactions to cosmetic products

Traditionally, skin reactions to cosmetic products have been assessed by a questionnaire that is subjective, inaccurate, and usually overestimated the prevalence.^{2,6,14} In our study, single occlusive patch tests were carried out according to a standard protocol that was written in the Chinese Cosmetic Regulation [2015].^{13,15} Patch testing-based methods provide means of objective evaluation of skin reactions to cosmetics. A total of 16 477 cosmetics (including sunscreens, skin whitening products, deodorants, and few products with unknown functions) were tested during the study period (February 2004– December 2017). As reported previously,⁷ patch testing was performed on the volunteers' upper back. Patches (Finn Chambers, SmartPractice, Phoenix, USA) were occluded for 24 h, and readings were taken at 0.5, 24, and 48 h after patch removal. The patch test reactions were read according to the International Contact Dermatitis Research Group criteria.¹⁶ In our study, a score of 0 meant no reaction, and the others were defined as a reaction. For the subsequent data analysis, the cosmetic test products were divided into the following three categories based on their function: sunscreens, skin whitening products, and deodorants (Figure 1). Cosmetic products with unknown functions were excluded.

2.3 | Statistical analysis

Baseline characteristics were presented as means (standard deviation) for quantitative variants and numbers (percentages, %) for categorical variants. *p* values of logistic regression, or odds ratio (OR) and 95% confidence intervals (95% CI), were reported as parameters of association between age, sex, and season with skin reactions to cosmetic products. A multivariable regression model was used to estimate independently adjusted statistics. The significance threshold

FIGURE 1 Details of skin reaction classification to cosmetic products according to functions

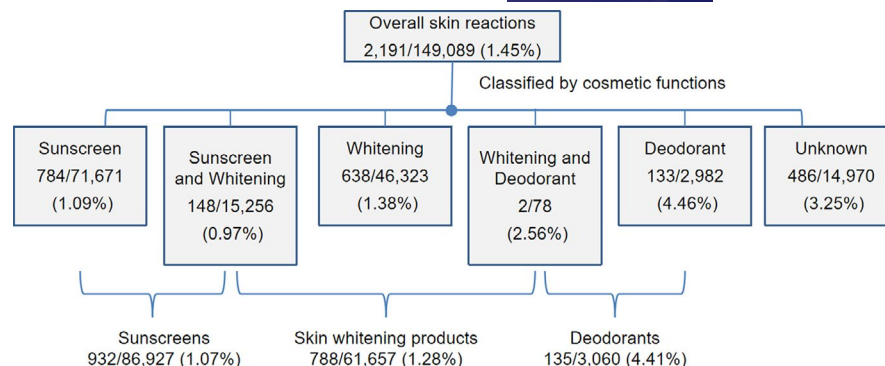


TABLE 1 Baseline characteristics of the study population

	Subjects (N = 4029)
Age, mean (SD), years	46.74 (11.05)
Female sex, n (%)	2895 (71.85%)
Relative humidity, mean (SD),%	71.09 (13.00)
Air temperature, mean (SD),°C	18.45 (8.82)
Season	
Spring, n (%)	948 (23.53%)
Summer, n (%)	1297 (32.19%)
Autumn, n (%)	897 (22.26%)
Winter, n (%)	887 (22.02%)

was adjusted with Bonferroni correction for the stratified analysis. All analyses were performed using R software (version 3.5.1, <https://www.r-project.org/>).

3 | RESULTS

The dataset included 151 280 patch test results, which were generated by patch testing a total of 16 477 pre-marketing cosmetics in 4029 healthy volunteers. The age of the volunteers ranged from 18 to 64 years, with 2895 women (71.85%) and 1134 men (28.15%) (Table 1).

The overall reaction rate of the epicutaneous patch test reactions to cosmetic products was 1.45% (2191/151 280). Next, the tested products were divided into the following three major categories: sunscreens, skin whitening products, and deodorants. The order of reaction rates of skin reactions to different cosmetic products from low to high was sunscreens (1.07%, 932/86 927), followed by skin whitening products (1.28%, 788/61 657) and deodorants (4.41%, 135/3060) (Figure 1).

3.1 | Age

According to the results of multivariable logistic regression model, skin reactions to sunscreens significantly increased with age

(adjusted OR, aOR, 1.01; 95% CI, 1.01–1.02; $p < 0.001$; Table 2). Further stratified analyses showed that this association was significant, especially in women (aOR, 1.02; 95% CI, 1.01–1.02; $p < 0.001$; Table 3), but not in men ($p = 0.11$). In contrast, no significant associations were observed between age and overall skin reactions to skin whitening products or deodorants ($p > 0.05$, Table 2). Furthermore, stratified analyses showed that skin reactions to skin whitening products significantly decreased with age in men (aOR, 0.99; 95% CI, 0.98–1; $p = 0.02$; Table 4), but not in women ($p > 0.05$). Skin reactions to deodorants were independent of age in both women and men (Table 5, $p > 0.05$).

3.2 | Sex

The sex differences were analyzed using the multivariable logistic regression model. After adjusting for age and season factors, it was found that men were more likely to develop skin reactions to deodorants than women (aOR, 0.68; 95% CI, 0.48–0.98; $p = 0.04$; Table 2). However, after stratification by age groups, men and women were equally likely to develop skin reactions to sunscreens, skin whitening products, and deodorants ($p > 0.05$, Table 6).

3.3 | Season

The risk of developing a skin reaction to sunscreens was significantly lower in spring (aOR, 0.47; 95% CI, 0.39–0.57; $p < 0.001$), summer (aOR, 0.62; 95% CI, 0.53–0.73; $p < 0.001$), and autumn (aOR, 0.44; 95% CI, 0.36–0.53; $p < 0.001$) than that in winter. Similarly, for skin whitening products, the risk of having a test reaction was lower in spring (aOR, 0.58; 95% CI, 0.47–0.72; $p < 0.001$) and summer (aOR, 0.82; 95% CI, 0.68–1; $p = 0.04$), compared with that in winter. In addition, the risk of having a skin reaction to deodorants was lower in spring (aOR, 0.4; 95% CI, 0.2–0.76; $p = 0.01$) than that in winter (Table 2).

4 | DISCUSSION

This is an unprecedented large-scale study using patch test measurements to investigate skin reactions to different types of cosmetic

TABLE 2 Associated Factors of Skin Reaction to Sunscreens, Skin Whitening Products, and Deodorants

	Sunscreens N = 932/86 927 (1.07%)					Skin whitening products N = 788/61 657 (1.28%)	
	Case/Total (%)	Crude OR [95% CI]	<i>p</i> value	Adjusted OR ^a [95% CI]	Adjusted <i>p</i> value	Case/Total (%)	Crude OR [95% CI]
Age	/	1.01 [1.01–1.02]	< .001	1.01 [1.01–1.02]	< .001	/	1 [0.99–1]
Sex							
Men	250/24 837 (1.01%)	1[ref]	/	1[ref]	/	278/19 846 (1.4%)	1[ref]
Women	682/62 090 (1.1%)	1.09 [0.95–1.27]	0.24	1.09 [0.94–1.26]	0.26	510/41 811 (1.22%)	0.87 [0.75–1.01]
Season ^b							
Winter	341/19947 (1.71%)	1[ref]	/	1[ref]	/	181/11 142 (1.62%)	1[ref]
Spring	174/21 528 (0.81%)	0.47 [0.39–0.56]	< .001	0.47 [0.39–0.57]	< .001	174/18 349 (0.95%)	0.58 [0.47–0.71]
Summer	265/25 164 (1.05%)	0.61 [0.52–0.72]	< .001	0.62 [0.53–0.73]	< .001	253/18 852 (1.34%)	0.82 [0.68–1]
Autumn	152/20 288 (0.75%)	0.43 [0.36–0.52]	< .001	0.44 [0.36–0.53]	< .001	180/13 314 (1.35%)	0.83 [0.67–1.02]

Note: Abbreviations: 95% CI: 95% confidence interval; OR, odds ratio; ref, reference.

^aAdjusted statistic was calculated by multivariable logistic regression to adjust for age, sex and season. Significant *p* values are bolded (< 0.05).

^bSeason: winter: Jan-Feb-Mar; spring: Apr-May-Jun; summer: Jul-Aug-Sep; autumn: Oct-Nov-Dec.

products and their associated factors in the general population of China. Data for this study were obtained from patch tests with pre-marketing cosmetic products rather than data from the questionnaire survey used in previous studies. Therefore, this study provides a unique value by adopting objective patch tests using real-world cosmetic products.

In this study, the skin reaction frequency of patch testing for cosmetic products was 1.45% in the general population. In a survey in 1977, comprising 30 000 American consumers, 700 reactions (2.3%) of cosmetic products occurred in a year.¹⁷ A questionnaire-based survey in 1988 reported that 12.2% of people from the Netherlands experienced adverse reactions to cosmetic products in the preceding 5 years.² The frequencies, which were higher than that in our study, reported by questionnaires may be personal concerns or subjective symptoms only but not the actual skin reaction. Skin reactions to cosmetic products are likely to be very rare at the individual level if consumers do not change cosmetics very frequently. It is worth noting that the reactions are usually mild in the study. In addition, it was shown that the reaction rate of deodorants was up to 4.41%, which is three times higher than that of sunscreens (1.07%) and skin whitening products (1.28%). This observation is in agreement with a questionnaire-based study that reported the prevalence of skin reaction to deodorants to be 30.6% and to sunscreens to be 10.1%.¹⁸ These results indicate that people with sensitive skin should be more cautious when using deodorants, especially during winter.

We found that the risk of skin reactions to sunscreens increased with age, especially in women. This may be explained by the increased exposure to cosmetic allergens (e.g. benzophenones, dibenzoylmethane¹⁹) with increasing age in women, whereas repetitive cutaneous exposure is necessary to develop a delayed-type

hypersensitivity reaction to contact allergen.²⁰ This suggests that older people should be more careful about skin reactions when using sunscreens, especially during winter. Interestingly, the frequency of skin reactions to skin whitening products decreased with age in men. Several factors may explain this observation. Although Asian women are keen on whitening products for all age ranges, Asian men avoid repetitive cutaneous exposure to skin whitening products with increasing age as they rarely use them. As demonstrated in previous studies, there is a waning response to new/previous allergens with increasing age.^{20–22}

No sex differences in skin reactions to different types of cosmetic products, except for deodorants, were found. For deodorants, the overall reaction rate was significantly higher in men than in women, but this was not true in the subsequent stratification analysis. We believe that the statistical power of this result is low because the sample size was too small. Many experimental investigations have found that there is no sex difference in skin sensibility^{23–25} and skin barrier function.²⁶ Therefore, there is no reliable biological evidence to support the existence of a significant sex difference in skin reactions to cosmetics.

There is a potential for bias from the frequency estimation because all pre-marketing cosmetics had not yet been in contact with the general population. However, we believe that such a study design should not impact the relationship between skin reaction to cosmetics and age, sex, and season.

Overall, we provide concrete evidence, based on a large-scale dataset of 151 280 patch test results, that skin reaction to sunscreens, skin whitening products, and deodorants, with a general frequency of 1.07%–4.41%, were associated with age and season, but not with sex. We hope that these findings can offer guidance for a healthy skincare concept.

Deodorants N = 135/3060 (4.41%)							
p value	Adjusted OR [95% CI]	Adjusted p value	Case/Total(%)	Crude OR [95% CI]	p value	Adjusted OR [95% CI]	Adjusted p value
0.45	1 [0.99–1]	0.54	/	1 [0.98–1.02]	0.82	1 [0.99–1.02]	0.72
/	1[ref]	/	53/935 (5.67%)	1[ref]	/	1[ref]	/
0.06	0.88 [0.76–1.02]	0.1	82/2125 (3.86%)	0.67 [0.47–0.96]	0.03	0.68 [0.48–0.98]	0.04
/	1[ref]	/	32/595 (5.38%)	1[ref]	/	1[ref]	/
< .001	0.58 [0.47–0.72]	< .001	13/596 (2.18%)	0.39 [0.2–0.74]	0.01	0.4 [0.2–0.76]	0.01
0.048	0.82 [0.68–1]	0.04	53/1069 (4.96%)	0.92 [0.59–1.45]	0.71	0.92 [0.59–1.46]	0.72
0.08	0.83 [0.68–1.03]	0.09	37/800 (4.62%)	0.85 [0.53–1.39]	0.52	0.86 [0.53–1.4]	0.53

TABLE 3 Associations between age and skin reaction to deodorants stratified by sex

Deodorants	Crude OR [95% CI]	p value	Adjusted OR [95% CI] ^a	Adjusted p value
Age associations in women	1 [0.98–1.03]	0.73	1.01 [0.98–1.03]	0.62
Age associations in men	1 [0.97–1.02]	0.86	0.99 [0.97–1.02]	0.60

Note: Abbreviations: 95% CI: 95% confidence interval; OR, odds ratio.

^aAdjusted statistic was calculated by multivariable logistic regression to adjust for season. Significant p values are bolded (Cutoff of p values was adjusted by applying a Bonferroni correction, $p < 0.05/2$).

TABLE 4 Associations between age and skin reaction to sunscreens stratified by sex

Sunscreens	Crude OR [95% CI]	p value	Adjusted OR [95% CI] ^a	Adjusted p value
Age associations in women	1.02 [1.01–1.02]	< .001	1.02 [1.01–1.02]	< .001
Age associations in men	1.01 [1–1.02]	0.11	1.01 [1–1.02]	0.29

Note: Abbreviations: 95% CI: 95% confidence interval; OR, odds ratio.

^aAdjusted statistic was calculated by multivariable logistic regression to adjust for season. Significant p values are bolded (Cutoff of p values was adjusted by applying a Bonferroni correction, $p < 0.05/2$).

TABLE 5 Associations between age and skin reaction to skin whitening products stratified by sex

Skin whitening products	Crude OR [95% CI]	p value	Adjusted OR [95% CI] ^a	Adjusted p value
Age associations in women	1.01 [1–1.02]	0.19	1.01 [1–1.02]	0.21
Age associations in men	0.99 [0.98–1]	0.03	0.99 [0.98–1]	0.02

Note: Abbreviations: 95% CI: 95% confidence interval; OR, odds ratio.

^aAdjusted statistic was calculated by multivariable logistic regression to adjust for season. Significant p values are bolded (Cutoff of p values was adjusted by applying a Bonferroni correction, $p < 0.05/2$).

TABLE 6 Associations between sex and skin reaction to sunscreens, skin whitening products and deodorants stratified by age groups

Age group	Sex	Sunscreens		Skin whitening products		Deodorants	
		Case/Total (rate %)	Adjusted p^a	Case/Total (rate %)	Adjusted p	Case/Total (rate %)	Adjusted p
<35	Women	64/8891(0.72%)	0.69	53/4601(1.15%)	0.08	6/210(2.86%)	0.15
	Men	41/5597(0.73%)		73/4231(1.73%)		11/205(5.37%)	
[35, 45)	Women	93/9679(0.96%)	0.84	59/6569(0.9%)	0.07	14/368(3.8%)	0.83
	Men	42/4037(1.04%)		41/3080(1.33%)		7/160(4.38%)	
[45, 55)	Women	276/23572(1.17%)	0.45	200/15393(1.3%)	0.69	35/835(4.19%)	0.052
	Men	88/8143(1.08%)		89/6542(1.36%)		25/360(6.94%)	
≥55	Women	249/19948(1.25%)	0.20	198/15248(1.3%)	0.69	27/712(3.79%)	0.62
	Men	79/7060(1.12%)		75/5993(1.25%)		10/210(4.76%)	

^aAdjusted statistic was calculated by multivariable logistic regression to adjust for season. Significant p values are bolded (Cutoff of p values was adjusted by applying a Bonferroni correction, $p < 0.05/4$).

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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CONFLICT OF INTEREST

All the listed authors have nothing to disclose.

AUTHOR CONTRIBUTIONS

Ying Zou and Sijia Wang conceived and planned the study, interpreted the data, and revised the manuscript. Bingjie Li analyzed the data and drafted the manuscript. Ying Cheng, Yimei Tan take responsibility for data collection and data interpretation. Fudi Wang,

Weiyi Hu, and Xuemin Wang have involved in the data collection and data interpretation. Wei Liu and Jean Krutmann interpreted the data and revised the manuscript.

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