

Patch test in Chinese in Shanghai with cosmetic allergy to cosmetic series and products

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Abstract

Background: There are increasing cosmetic adverse reactions in China, mostly cosmetic contact dermatitis, with the development of its cosmetics industry.

Aims: To identify the allergens and cosmetics products responsible for cosmetic allergic contact dermatitis (CACD) in Shanghai.

Methods: Five hundred and sixty patients, including 342 suspected CACD patients from dermatological clinic and 218 cosmetics consumers with an allergic history, were patch tested with a cosmetic series (C-1000 series). And 154 patients patched with possible culprit cosmetics.

Results: Two hundred and forty-six subjects showed positive reaction to C-1000 series. Clinic patients had much higher positive rate than that of cosmetics consumers. Leading allergens were methylisothiazolinone (MI), methylisothiazolinone + methylchloro-isothiazolinone (MCI/MI), thimerosal, and the positive rates were significantly higher in patients than in cosmetic consumers ($P < .001$ for all). MCI/MI elicited positive patch test reactions in 73.5% of MI-positive patients. Of those patched with cosmetic products, 19 patients had 31 positive reactions, including 22 skin care products and 5 color decorating.

Conclusions: Preservatives, especially MI, MCI/MI, and thimerosal, were the most common cosmetic allergens, and skin care products occupied the most allergic reaction of CACD. Patch testing is highly recommended for suspected CACD patients. Future comparative investigation with large sample size should benefit cosmetovigilance surveillance.

KEYWORDS

allergy, contact dermatitis, cosmetic, patch test, preservative

1 | INTRODUCTION

Cosmetics consumption has rapidly increased in China with the development of its cosmetic industry, resulting in an increased occurrence of cosmetics allergic contact dermatitis (CACD), adverse cosmetics reaction surveillance and reporting. At least 1%-3% of

female population is allergic to cosmetics.¹ The prevalence of CACD probably is even higher in China, since some patients with mild signs of CACD stop application instead of seeking medical consultation. Hence, it is essential to investigate prevalence of Chinese skin reaction to common cosmetics allergens and strengthen cosmetovigilance in China.

Patch testing is a vital method for CACD diagnosis. Patch testing with standard series detects the reliable allergens in nearly 70%-80% case of contact dermatitis.¹ To the best of our knowledge, there is no large size study of cosmetics allergen series patch testing of CACD in China. In order to identify the relevant allergens and clarify the prevalence, we reviewed the cases of suspected CACD from our dermatological clinic and consumer tests in Shanghai.

2 | METHODS

2.1 | Subjects

This retrospective study was conducted from January 2013 to December 2017. A total of 560 subjects were patch tested, of which 342 were patients with symptoms indicative of CACD from Dermatology Clinic of Shanghai Skin Disease Hospital; the other 218 were cosmetics consumers in Shanghai with a history of cosmetic adverse reaction, who were screened from 6079 consumers by questionnaire. The questionnaire consists of 8 questions related to cosmetics application and 14 questions about history of cosmetics adverse reaction. The 218 respondents, who declared had cosmetics-related skin disease before by questionnaire, were recruited as cosmetics consumers with a history of cosmetic adverse reaction.

2.2 | Methods

All subjects were patch tested with cosmetic series of allergens (C-1000, Chemotechnique Diagnostics). A total of 56 allergens were included in the series (Table 2). When possible, patients who could supply the suspected cosmetics were also patch tested with their personal products.

Finn chambers (Epitest) with allergens were patched on the back and adhered with Scanpor tape (Alpharma). Strips were removed after 48 hours, and the results recorded at 48, 72 (if available for subjects), and 96 hours according to the standard scoring system recommended by the International Contact Dermatitis Research

Group (ICDRG).² Only reactions graded as +, ++, or +++ were classified as positive.

2.3 | Data analysis

Categorical variables were expressed as frequency (percentage). Continuous variables were expressed as mean $\pm$ standard deviation (SD). Chi-squared test was applied for categorical variables. Two-sided *P* values of $<.05$ were considered to be statistically significant. Calculations were performed with SPSS version 18 (SPSS).

3 | RESULTS

3.1 | Subjects information

Of 560 patients tested with cosmetic series, the mean $\pm$ SD age was 34.6 ± 13.8 (range, 15-83) years, and 37 were men and 523 were women. Among them, 342 were suspected CACD patients with the mean $\pm$ SD age of 34.8 ± 11.4 (range, 15-73) years, in which 11 were men and 331 were women. The remaining 218 were cosmetics consumers with allergic history (26 men and 192 women with the mean $\pm$ SD age of 47.3 ± 13.9 (range, 21-83) years.

3.2 | Patch testing of C-1000 cosmetic series

Of all subjects, 246 (43.9%) had positive reactions, in which females predominated (45.5%, 238/523). Positivity rate of the patients (59.9%, 205/342) was significantly higher than that of the cosmetics consumers (18.8%, 41/218) ($P < .001$) (Table 1).

The top five allergens were similar for the total subjects and CACD patients, that is, methylisothiazolinone (MI), methylisothiazolinone + methylchloro isothiazolinone (MCI/MI), thimerosal, shellac, and oleamidopropyl dimethylamine. The leading positive allergens for cosmetics consumers were thimerosal, MCI/MI, shellac, quaternium-15, dodecyl gallate, DMDM hydantoin, diazolidinyl urea, and sorbitan sesquioleate (the latter 4 allergens occupied same positive rate) (Table 2).

	Total subjects (n = 560) n (%)	Patients (n = 342) n (%)	Cosmetics consumers (n = 218) n (%)	P value (Patients vs Cosmetics consumers)
Total	246 (43.9)	205 (59.9)	41 (18.8)	.0*
Female	238 (45.5)	199 (60.1)	39 (20.3)	.0*
Male	8 (21.6)	6 (54.5)	2 (7.7)	.0*
P value (Female vs Male)	.0 [#]	.8	.2	

TABLE 1 Positive rate of different gender and groups

*Positive rate was significant difference between patients and consumers.

[#]Positive rate was significant difference between female and male.

The positive rate of 9 allergens was significantly higher in CACD patients than in cosmetic consumers, namely MI, MCI/MI, thimerosal, shellac, oleamidopropyl dimethylamine, drometrizole, iodopropynyl butylcarbamate, paraben mix, and methenamine ($P < .001$ for all, Table 2). MCI/MI elicited positive patch test reactions in 73.5% (75/102) of MI-positive patients. However, cross-reactivity was not observed in cosmetics consumers.

3.3 | Patch testing of possible culprit products

Among the 342 patients with suspected CACD, 154 patients offered a total of 653 cosmetics products. Nineteen patients (12.3%) revealed 31 positive reactions. Of these, skin care products accounted for 71.0%, followed by color decorating products and unspecified products. Rinse-off products, sunscreen, and detergent (in 1% concentration) showed no positive result in patch testing. In terms of form classification, cream/lotion, toner/spray and mask were the top 3 ranking product categories (Table 3).

4 | DISCUSSION

As recently reported, cosmetic contact dermatitis accounted for 2%-4% cases in Dermatology Clinics.³ Furthermore, the frequency of sensitization is probably much higher.⁴ As the second largest cosmetics market in the world, China has an extensive cosmetics consumer group. Diagnosis and treatment of CACD is a matter of great clinical, regulatory and toxicologic significance.

Patch testing is a gold standard aid in the diagnosis of allergic contact dermatitis. Patch testing with cosmetic series allergens and suspected products has been suggested to identify the relevant allergens in patients of suspected CACD who had disease history, relevant symptoms and clinical examination based on a standard textbook.⁵ CACD was confirmed if patients of suspected CACD had positive patch testing results with cosmetic series allergens or/and suspected cosmetics. Once the allergens have been confirmed, patients should be educated to avoid exposure to preventing reoccurrence of CACD.

There is a statistically significant predominance allergy in females (45.5%) as compared with males (21.6%, $P = .005$), probably explained by higher exposure and frequent use of cosmetics, and more concerned about facial skin conditions in females. The results are in line with those of prior retrospective observational studies that women were more inclined to keep a watchful eye on their skin and prone to yield higher rates of sensitization to cosmetic allergens.³

In our study, five of the top 10 allergens with positive reading are preservatives --critical ingredients in cosmetics to prevent biological degradation and microorganisms contamination. Abundant evidence documents that preservatives, especially MI, MCI/MI, thimerosal, and methylidibromo glutaronitrile, are common cosmetics allergens identified, while paraben mixture demonstrates a much lower prevalence.⁶

Our study showed that MI and MCI/MI were the leading positive allergens in patch testing, consistent with other reports. MI demonstrated the highest prevalence of allergy of 4.5% followed closely by MCI/MI with 4.1%.⁷ In a European study of 3434 patients from 11 hospitals, the MI prevalence was 6%.⁸

Methylisothiazolinone and MCI/MI, both isothiazolinones, are popular preservatives. One study predicted that 23% preservatives comprise isothiazolinones.⁹ Prevalence of isothiazolinones allergy showed unprecedented increase since approved for use in cosmetics, household and industrial products.¹⁰⁻¹⁵ In view of the utilization of MCI/MI resulting outbreak in early 1980s, stricter regulations were applied to reduce the risk of sensitization, and hence, the maximum concentration was restricted to 15 p.p.m.¹⁶ Currently, it remains the most prevailing allergen in patients, responsible for 19% of positive results.³ MI alone was introduced for cosmetic use in 2005,⁷ first reported contact allergy related to cosmetics products in 2010^{16,17} and included in their baseline series in 2013 by the American Society of Contact Dermatitis.¹⁸ MI was regarded as less effective than MCI/MI resulting in lower sensitizing capacity, with a prevalence of 1.5% in Europe.¹⁸ In fact, the allergy rates of MI and MCI/MI are related with their market prevalence. In a study containing 2028 patients, the prevalence of MI and MCI/MI sensitization showed a sharp rise from 2.3% in 2012 to 6.9% in 2014 and from 4.8% in 2010 to 9% in 2013, respectively.¹⁹ On the contrary, frequencies of MI and MCI/MI sensitization displayed no marked increase from 2009 to 2013 in Singapore because of wildly popularity use of Japanese cosmetics products, in which MCI/MI was prohibited in leave-on products.

As a result, it is necessary to highlight the types and concentrations of preservatives usage in further research.^{3,6,7} MCI/MI was allowed in rinse-off products at a maximum concentration of 15 p.p.m for products placed on the market after 16 July 2015. Moreover, Member states of the European Union banned MI use in leave-on products from January 2017.⁸ In China, MI and MCI/MI could be present up to 100 and 15 p.p.m respectively, either in leave-on or rinse-off cosmetics before December 2016. But MCI/MI was no longer used in leave-on products from then on. Considering the high prevalence of MI and MCI/MI, we suggest the rules should be placed in line with those in Europe.

It is not surprising that MCI/MI occupied an allergy rate of 73.5% in MI-positive patients here, which had been confirmed by several investigations with the rate of cross-reactivity from 40% to 70%.^{6,8,16,18,19} Therefore, if reaction to isothiazolinones is questioned, both MI and MCI/MI should be patch tested. If allergy to either one occurs, the other one should be taken into account.

It is interesting that the positive rates of MI and MCI/MI of patients in our study are much higher than previous reports of China and abroad. Since more than 60% of our patch testing was performed on patients with suspected CACD in a dermatological clinic, the results were highly correlated with cosmetics allergy, thus the reason of higher rates than general eczema patients.²⁰ On the basis of our clinical practice, history of cosmetic exposure and related medical history has great significance for patch testing and CACD

TABLE 2 Allergens of cosmetic series ranked by relative frequency of positive reactions, stratified by group, between patients and cosmetics consumers

No.	Allergens	Total subjects (%)	Patients (%)	Cosmetics consumers (%)	P value (Patients vs Cosmetics consumer)
54	Methylisothiazolinone (0.2% aq)	18.4	29.8	0.5	.0*
35	Methylisothiazolinone + methylchloro- isothiazolinone (0.02% aq)	16.8	25.8	2.8	.0*
13	Thimerosal (0.1% pet)	6.8	8.8	3.7	.0*
51	Shellac (20.0% alc)	4.8	6.4	2.3	.0*
56	Oleamidopropyl dimethylamine (20.0% alc)	3.6	5.6	0.5	.0*
45	Methyldibromo glutaronitrile (0.5% pet)	2.7	3.8	0.9	.1
37	Drometizole (1.0% pet)	2.5	3.8	0.5	.0*
39	Dodecyl gallate (0.25% pet)	2.5	3.2	1.4	.3
33	Cocamidopropylbetaine (1.0% aq)	2.3	3.2	0.9	.1
47	Iodopropynyl butylcarbamate (0.2% pet)	2.1	3.5	0.0	.0*
8	Octyl gallate (0.25% pet)	2.0	2.9	0.5	.1
20	Hexahydro-1,3,5-tris-(2-hydroxyethyl) triazine (1.0% aq)	2.0	2.6	0.9	1.0
17	Paraben mix (16.0% pet)	1.6	2.6	0.0	.0*
50	Peppermint oil (2.0% pet)	1.6	2.3	0.5	.2
40	Quaternium-15 (1.0% pet)	1.4	1.2	1.8	.7
44	DMDM hydantoin (2.0% aq)	1.4	1.5	1.4	1.0
15	Methenamine (2.0% pet)	1.3	2.1	0.0	.0*
42	Diazolidinyl urea (2.0% pet)	1.3	1.2	1.4	1.0
5	Sorbitan oleate (5.0% pet)	1.1	1.5	0.5	.4
30	Benzyl salicylate (10.0% pet)	1.1	1.2	0.9	1.0
55	Musk mix (3.0% pet)	1.1	1.8	0.0	.1
2	Amerchol L 101 (50.0% pet)	0.9	1.2	0.5	0.7
26	Sorbitan sesquioleate (20.0% pet)	0.9	0.6	1.4	.4
49	Lauryl glucoside (3.0% pet)	0.9	1.2	0.5	.7
23	Hydroabietyl alcohol (10.0% pet)	0.7	1.2	0.0	.2

(Continues)

TABLE 2 (Continued)

No.	Allergens	Total subjects (%)	Patients (%)	Cosmetics consumers (%)	P value (Patients vs Cosmetics consumer)
32	Sodium-2-pyridinethiol-1-oxide (0.1% aq)	0.7	1.2	0.0	.2
53	Turpentine peroxides (0.4% pet)	0.7	1.2	0.0	.2
4	Polysorbate 80 (5.0% pet)	0.5	0.3	0.9	.6
14	Imidazolidinyl urea (2.0% pet)	0.5	0.9	0.0	.3
18	Phenyl mercuric acetate (0.01% aq)	0.5	0.9	0.0	.3
25	Benzophenone-3 (10.0% pet)	0.5	0.6	0.5	1.0
43	Tocopherol (100%)	0.5	0.6	0.5	1.0
48	3-(Dimethylamino)-1-propylamine (1.0% aq)	0.5	0.9	0.0	.3
11	p-Chloro-m-cresol (PCMC) (1.0% pet)	0.4	0.3	0.5	1.00
22	Ethylenediamine dihydrochloride (1.0% pet)	0.4	0.3	0.5	1.0
36	t-Butyl hydroquinone (1.0% pet)	0.4	0.3	0.5	1.0
41	2-Phenoxyethanol (1.0% pet)	0.4	0.6	0.0	.5
46	Tea Tree Oil oxidized (5.0% pet)	0.4	0.6	0.0	.5
52	Tocopheryl acetate (10.0% pet)	0.4	0.3	0.5	1.0
1	Isopropyl Myristate (20.0% pet)	0.2	0.0	0.5	.4
6	BHA (2.0% pet)	0.2	0.0	0.5	.4
9	Triclosan (2.0% pet)	0.2	0.3	0.0	1.0
16	Chlorhexidine digluconate (0.5% aq)	0.2	0.3	0.0	1.0
19	Chloroacetamide (0.2% pet)	0.2	0.3	0.0	1.0
21	Clioquinol (5.0% pet)	0.2	0.0	0.5	.4
24	Phenyl salicylate (1.0% pet)	0.2	0.3	0.0	1.0
27	Propylene glycol (5.0% pet)	0.2	0.3	0.0	1.0
28	Stearyl alcohol (30.0% pet)	0.2	0.0	0.5	.4
34	Benzyl alcohol (10.0% sof)	0.2	0.3	0.0	1.0
38	Propyl gallate (1.0% pet)	0.2	0.0	0.5	.4
3	Triethanolamine (2.0% pet)	0.0	0.0	0.0	1.0

(Continues)

TABLE 2 (Continued)

No.	Allergens	Total subjects (%)	Patients (%)	Cosmetics consumers (%)	P value (Patients vs Cosmetics consumer)
7	BHT (2.0% pet)	0.0	0.0	0.0	1.0
10	Sorbic acid (2.0% pet)	0.0	0.0	0.0	1.0
12	Chloroxylenol (PCMX) (0.5% pet)	0.0	0.0	0.0	1.0
29	Cetyl alcohol (5.0% pet)	0.	0.0	0.0	1.0
31	2-Bromo-2-nitropropane-1,3-diol (0.25% pet)	0.0	0.0	0.0	1.0

*Positive rate was significant difference between patients and consumers.

TABLE 3 Cosmetic products category causing allergic contact dermatitis in patients

Cosmetic products category	n (%)
Skin care products	22 (71.0)
Cream/lotion	8 (25.8)
Toner/spray	7 (22.6)
Cosmetic raw liquid	1 (3.2)
Mask	6 (19.4)
Color decorating products	5 (16.1)
Lipstick/lip balm	2 (6.5)
Eyeliner	1 (3.2)
Foundation	1 (3.2)
Loose powder	1 (3.2)
Unspecified/else	4 (12.9)
Homemade preparation	1 (3.2)
Chinese herb product	1 (3.2)
Foot mask	1 (3.2)
Unspecified product	1 (3.2)
Total	31 (100)

diagnosis. The high rate indicated the importance of medical history inquiry for patch testing.

Nine allergens showed significant higher positive rate in patients than in cosmetic consumers ($P < .001$ for all). It is not surprising that 7 of them are preservatives, including MI, MCI/MI, and thimerosal. This can be attributed to the wide use of cosmetic products containing preservatives. Preservatives have been confirmed to a common cause of allergens to cosmetics in the present study. Their high prevalence of preservatives emphasizes the importance of clinical patch testing and market supervision of cosmetics in China.

Thimerosal, an organic compound preservative, ranked number 3 here. Thimerosal is wildly used in ophthalmologic and OTC preparations, contact lens solutions, vaccines, antitoxins, desensitization solutions, and for intradermal tests. In China, thimerosal is allowed for use only in eye products with a maximum concentration of

0.007%. The prevalence of thimerosal allergy showed 6.7% to 9.9% in Korea,²¹ 11.7% of children and 37.6% of adolescents in Poland, 10.8% to 19.4% in China,^{22,23} 3.2% in Turkey, 13.6% in America, and 15.5% in India. The differences probably result from exposure frequency and population diversity of these regions.

Shellac is used widely as a colorant in cosmetic industry, especially in eyeliners and mascaras.²⁴⁻²⁶ A study in Beijing in 2011 showed shellac was the second leading allergen and recommended as an additional candidate for patch testing in patients with suspected CACD.²² Our analysis demonstrated similar results. Thus, shellac should also be included for routine candidates for patch testing of suspected CACD in China.

For the lack of awareness of patch test for CACD, less than half of patients provided relevant cosmetics. The leading responsible cosmetics for CACD in current study are skin care products (cream/ lotion, toner/spray, and mask) and color decorating products. The results were in concordance with previous studies.^{1,2} Data from Euromonitor reveal that total retail sales of skin care products in China reached RMB169.1 billion in 2016, achieving year-on-year growth of 5%, which contributes to sensitization.

Another problem revealed in our investigation is perception deficiency of cosmetics ingredients caution. Ingredient labeling was required on cosmetics products from November 2009 in China. However, documenting cosmetic ingredients remains difficult in dermatological clinics, also patients discard the package label. And, there is no systematic publication resource to obtain ingredients of cosmetics in China. Significant growth of online shopping channels in recent years, purchase from beauty salon or e-commerce also contributed to missing information.

To summarize, our study showed that the allergy rate of MI and MCI/MI is high in Chinese CACD patients. The present legal restrictions on use of isothiazolinones in cosmetics should be reconsidered. Patch testing with cosmetic series allergens and personal cosmetics products are recommended to boost the detection of relevant allergens in patients suspected CACD. Our study represents the population in Shanghai only, and future surveillance should benefit cosmetovigilance and market surveillance in China.

ACKNOWLEDGMENTS

We thank Drs. Ninan Sun and Mrs Lijie Yang from Shanghai Skin Disease Hospital for assistance in data collection. We also thank all the patients for their participation in this study.

CONFLICT OF INTEREST

All authors declare no conflicts of interest.

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How to cite this article: Qin O, Cheng Y, Hu W, et al. Patch test in Chinese in Shanghai with cosmetic allergy to cosmetic series and products. *J Cosmet Dermatol*. 2019;00:1-7. <https://doi.org/10.1111/jocd.13249>