



Original Research Article

Patch testing in suspected cosmetic-induced facial dermatosis: A tertiary care hospital-based prospective, observational study

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Abstract

Introduction: Patch testing is a valuable tool for determining the culprit allergens—chemical combinations of different ingredients, and confirming the existence of an allergy. Studies on patch testing using cosmetic and standard battery series are scarce in the Indian subcontinent. In this study, we attempt to investigate the frequent allergens in cosmetics that cause cosmetic facial dermatitis.

Aim and Scope: A prospective, observational study was conducted at a tertiary care hospital.

Material and Methods: All patients with a possible clinical diagnosis of cosmetic-induced contact facial dermatitis were subjected to a patch test with 52 allergens from the Indian cosmetic series and Indian standard battery series and their personal cosmetic products on the upper back area. Patients were followed up after 48 and 72 hours to read the patch test findings.

The patch test reaction was noted per the International Contact Dermatitis Research Group Scoring System.

Results: A total of 97 patients with an average age of 26 years were included in the research.

Female: male ratio was 3.3:1. The most common clinical presentation was itching (88.7%), followed by erythema (63.9%). The whole face was the most common site (49.5%), and face cream was the most common allergic cosmetic (24.7%). The most common patch chemicals identified in the present study were paraphenyline diamine (17.5%) followed by thiomersal (13.4%). Patch test positive for at least one allergic chemical was found in 79% of the study participants.

Conclusion: This study adds to the evidence pool of suspected allergens and the likelihood of allergic contact dermatitis due to cosmetics. Hence, this evidence can be used by clinicians to manage their cases better.

Keywords: Patch test, Cosmetic facial dermatoses, contact facial dermatitis, cosmetic dermatitis, cosmetic series, Indian standard battery series.

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1. Introduction

Cosmetics and products for skin care are essential for everyday grooming. As per the Food and Drug Administration, the definition of a “cosmetic” is something that is meant to be sprinkled, splashed, messaged, sprayed, applied, injected into, or put in any other way into the human body to clean, beautify, enhance attractiveness, or change appearance.¹ According to research, a man uses up to six personal products with up to 85 ingredients per day, and a

woman uses 12 self-care products with up to 168 elements per day on average.² Most of these products are synthetic, with ingredients that have the capacity to result in skin hypersensitivity, thus leading to a raised frequency of cosmetic-induced dermatitis.³ Data implies that 1-5.4% of the general population have skin hypersensitivity to a cosmetic or its ingredients.³⁻⁵

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Severe adverse effects due to the use of cosmetics are rare.³ However, over 10% of individuals may experience mild to moderate side effects like dryness, prickling, and itching.⁴ The most commonly detected allergens in the cosmetic products are fragrances and preservatives.⁶ Other significant ones include UV filters, lanolin and its derivatives, para phenylene diamine, tosylamide formaldehyde resin in nail polish, and copolypropyl betaine.¹

Complemented by meticulous history and in-depth examination, the Patch test is the most reliable method for detecting allergic contact dermatitis (ACD). It is essential to include patients' cosmetics, along with the allergens, for patch tests. Usage tests and repeated open application tests (ROAT) help to detect cosmetic-induced dermatitis.⁷ A patch test validates the existence of an allergic hypersensitivity reaction and determines the culprit allergens, that are primarily the chemical blends of different elements in a cosmetic.^{4,8,9} Nearly 70–80% of contact dermatitis cases can be resolved via patch testing using a standard battery series; however, this method may miss the remaining 20–30% of allergies associated with cosmetics.¹⁰

Research supporting the usage of cosmetic and standard series for patch testing in patients with ACD to cosmetics is limited in the Indian subcontinent.¹¹ Thus, we made an effort to investigate the common allergens in cosmetics that may cause ACD.

2. Materials and Methods

This prospective, observational research was conducted at a tertiary care hospital between May 2018 and November 2019. The primary objective of the research was to determine the patch test allergen positivity among patients with suspected cosmetic-induced facial contact dermatitis, and the secondary objectives of the study were to identify the frequently used products and the most common clinical signs and symptoms among these cosmetic-induced facial ACD patients. The study began after receiving ethical permission from the institution's ethics committee (IEC no: 745/15.1.19). All participants submitted their written informed consent.

2.1. Sample size calculation

A convenient sampling method was used. Consecutive patients meeting the inclusion criteria during the study period were enrolled.

Patients with possible clinical signs and symptoms of cosmetic-induced facial contact dermatitis were the study population for the present research. The diagnosis was based on clinical signs and symptoms such as itching, redness, dryness, scaling, and hyperpigmentation over the face after applying cosmetic products over the head and neck. Those who provided informed consent and agreed to participate in the patch tests and the routine follow-ups were included in the research. Patients with systemic allergic disease, connective tissue illness, those on systemic steroids such as

oral prednisolone (20 mg or more) or any other immunosuppressive medication, or history of application of topical steroids within the past two weeks were excluded from the research. All participants were advised to avoid consuming first-generation antihistamines for 72 hours and second-generation antihistamines for 7 days of the patch testing procedure.

2.2. Study procedure

The patch test was conducted in the well-exposed upper back area under aseptic conditions. All patients were treated with patch tests applying 32 allergens from the Indian cosmetic series and 20 known allergens from the Indian standard battery series, which were obtained from Systopic Pharmaceutical Ltd. and approved by the Contact and Occupational Forum of India (CODFI). (**Table 1** and **Figure 1**). Additionally, a patch test was carried out on the patient's suspected personal cosmetics. Each Allergen was mounted on Finn chambers; these are small occlusive aluminum discs mounted on a non-occlusive adhesive base and placed on the patient's upper back. (**Figure 1a**). Indelible ink or fluorescent markers were used to mark the test locations. The patients were advised not to bathe or exercise and to stay in a cooler area until the patch test allergens were removed. The patients were instructed to revisit after 48 and 72 hours, noting the patch test results. If any doubtful, suspicious reactions occurred, the patients were asked to follow up on the fifth day. Recording of patch test reaction was conducted as per the International Contact Dermatitis Research Group Scoring System: - (adverse), ?+ (doubtful reaction), + (weak positive reaction), ++ (strong positive reaction), +++ (extreme positive reaction), IR- Irritant reaction, NT- Not tested. (**Figure 1b,c,d**)

2.3. Statistical analysis

All the data were entered into an Excel spreadsheet and analyzed using SPSS version 26 software. The qualitative data were presented as numbers and percentages, whereas the quantitative data were presented as mean, standard deviation, and range.

3. Results

The present study comprised 97 patients. (**Figure 2, Figure 3**) The median age at presentation was 26 years (13–48 years). Most study participants (60.8%) were 21–30 years old. The majority of the patients were female (77%) and female to the male-patient ratio of 3.3:1. The study comprised students (40.2%), working professionals, and homemakers. Personal and family history of atopy was found in 18.6% and 22.7% of the participants, respectively.

Itching was the most frequent clinical presentation (88.7%), followed by erythema (63.9%).

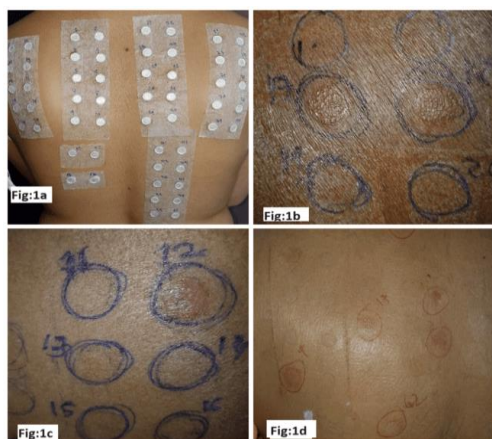


Figure 1: **a:** Shows total of 52 allergens along with patients won suspected cosmetics were put on the back of the patient; **b:** Shows patch tests positive for two allergens; **c:** Shows patch tests positive for a single allergen; **d:** Patch tests positive for multiple allergens.



Figure 2: **a:** Shows a case of pigmentary contact dermatitis; **b:** Shows a case of sunscreen allergy; **c:** Shows a case of shaving cream allergy; **d:** Shows a case of bindi allergy.



Figure 3: **a:** Shows a case of eye makeup allergic dermatitis, figure3b: Shows a case of lipstick allergic dermatitis, figure3c: shows the case of hair dye allergy, figure3d: shows a case of face cream allergic contact dermatitis.

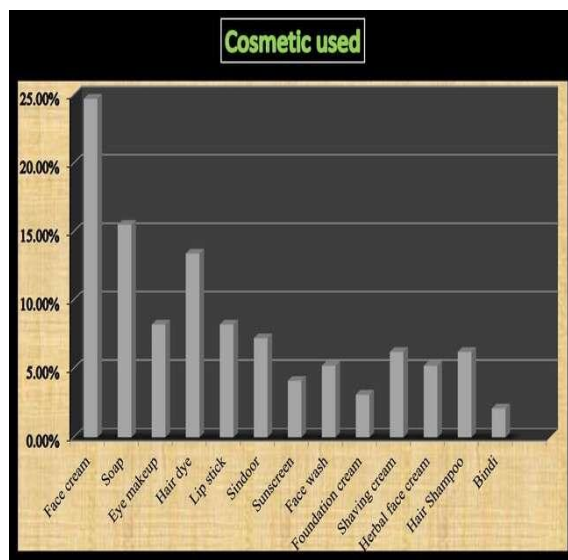


Figure 4: Frequency distribution of different cosmetics used in the study population

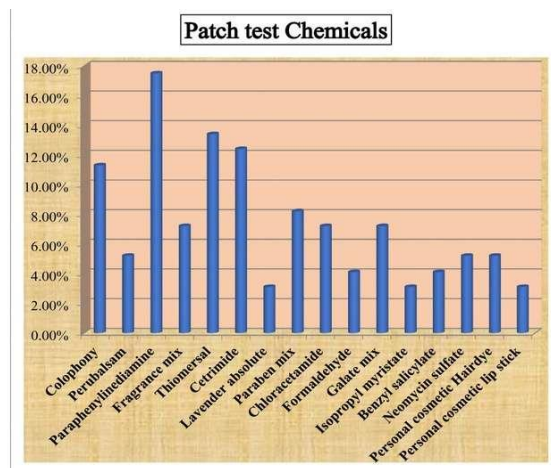


Figure 5: Frequency distribution of different allergic chemicals found positive in the patch test

A history of photosensitivity was found in 17% of patients. The duration of symptoms at presentation varied from one week to four months, with a median duration of two months. Most patients (76.3%) presented with 1-3 months' duration. Major sites of involvement were the whole face (49.5%) and scalp with hairline (12.4%).

The most common allergic cosmetic product was the face cream (24.7%) (**Figure 4**). Patch test positive for at least one allergic chemical was found in 79% of the study participants. Patch test positivity was found in 1.47% of the total number of patches applied in patients (77 positive patches out of 5238). The most common chemicals identified in the patch were para phenylene diamine (17.5%), thiomersal (13.4%), and cetrimide (12.4%) (**Figure 5**). Thirty-nine patients (60%) were positive out of 65 patients patch tested with personal cosmetics products, reinforcing the evidence of ACD due to personal cosmetics.

Herbal face cream users most commonly had isopropyl myristate and gallate mix positivity (**Figure 2**), whereas Peru balsam and thioacetamide were the main antigens in sunscreen users (60%) (**Figure 2b**). Galate mix was positive in all patients using shaving cream (**Figure 2c**). Paraphenyline diamine was found positive in all patients (100%) using bindi (**Figure 2d**) and 92.3% of patients using hair dye (**Figure 3c**). Thiomersal was positive in 83% of sindoor users and 37.5% of eye makeup users (**Figure 3a**). Colophony was the significant antigen among eye makeup users (**Figure 3a**). Lavender absolute was found positive in 38% of lipstick users (**Figure 3b**). Major antigens in face cream are paraben mix, formaldehyde, benzyl salicylate, and neomycin sulfate (**Figure 3d**).

Table 1: Indian standard battery series

Serial Number	Allergen	Batch Number
1	Vaseline	01C10
2	Wool Alcohol (Lanolin)	02C10
3	Perubalsam	03C10
4	Formaldehyde	04C10
5	Mercaptobenzothiazole	05C10
6	Pottassium bichromate	07C10
7	Nickel sulphate	08C10
8	Cobalt sulphate	09C10
9	Colophony	10C10
10	Epoxy resins	11C10
11	Parabens mix	12C10
12	Paraphenylenediamine	14C10
13	Parthenium	17C10
14	Neomycin sulphate	18C10
15	Benzocaine	52C10
16	Chlorocresol	61C10
17	Fragrance mix	62C10
18	Thiuram mix	63C10
19	Nitrofurazon	64C10
20	Black rubber mix	65C10

Table 2: Cosmetic series and fragrance series

1	Vaseline	01C10
2	Ethylenediamine	13C10
3	Benzyl alcohol	67C10
4	Benzyl salicylate	68C10
5	Bronopol	69C10
6	Butyl Hydr. (BHA)	70C10
7	Butyl Hydr. (BHT)	71C10
8	Cetyl alcohol	72C10
9	Chloroacetamide	73C10
10	Geranium oil	74C10
11	2-Hydr-4Meth.Berhbenz	75C10
12	2(2-Hydr-5-Meth Benzotriazole	76C10
13	Imidazolidinylurea (Germall 115)	77C10
14	Isopropyl Myristate	78C10

15	Jassmine absolute	79C10
16	Lavender absolute	80C10
17	Musk mix	81C10
18	Phenyl salicylate	82C10
19	Polyoxyethyleneso oleate (Tween-80)	83C10
20	Rose oil	84C10
21	Sorbitan sesquio (ARLACEL-83)	85C10
22	Thiomersal	86C10
23	Triclosan	87C10
24	Triethanolamine	88C10
25	Vanillin	89C10
26	Cetrimide	90C10
27	Hexamine	91C10
28	Chlorhexidine Diglucuronate	92C10
29	Diazolidinylurea (Germail LL)	93C10
30	Propylene Glycol	94C10
31	Kathon CG	95C10
32	Sorbic acid	102C10

4. Discussion

Our study had 97 participants, compared to 58 and 50 participants in studies by Garg et al. and Rastogi et al., respectively.

Most patients (60.8%) were aged between 21–30 years. Our finding was in line with a previous study in which the majority of patients with cosmetic-induced dermatoses were 21-40 years of age.^{12,13} Female predominance was seen in the current research, similar to previous studies.^{12,13} Most of the study participants in our study were students. In earlier studies, the majority of patients were housewives.¹³ Personal and family history of atopy were assessed in the present study, which was lacking in most previous studies.

Similar to the present research, itching was the most typical symptom, and erythema was the most common clinical finding in studies by Rastogi et al. and Garg et al.^{12,13} However, the prevalence of the above symptoms was slightly higher in the present study due to the predominance of acute and subacute cases. In our research, the site that was most involved was the entire face, whereas the head and neck area were the most frequently involved in the research by Rastogi et al.¹³ In earlier studies, face cream, soap, and hair dye were reported to be the three most common allergic cosmetics.^{12,13} The current study findings had a similar outcome. In a few other studies, products for skin care, such as moisturizing lotions, cleansing lotions, creams, and milk, were found to be responsible for the majority of cosmetic contact allergies.^{12,13,14} Patch test positivity for at least one allergic chemical was found in 79% of our study participants, in contrast to 60% of patients in a study by Rastogi et al.¹³ Patch test positivity was found in 1.47% (77 positive patches out of 5238) of the total number of patches applied in patients. In contrast to our findings, 1.7% (27 out of 1600) patch tests from the cosmetic series and 3.5% (35 out of 1000) from

the Indian standard series were positive in a study by Rastogi et al.¹³

Paraphenyline diamine (PPD) was the most common patch test-positive allergen in the present study. This finding was similar to studies by Rastogi et al. and Dogra et al.^{13,14} Cetrimide was the most common allergen in a study by Garg et al., whereas de Groot et al. and Trattner et al. found Kathon CG as the most common allergen.^{15,16} In a survey by Nath and Thappa, the leading substances linked to allergies in cosmetics were preservatives, antioxidants, and paraphenylenediamine.¹⁷ Thiomersal was found positive in 12.4% of cases, wherein sindoor was the most common cosmetic product used. However, this finding was significantly lower than the findings by Nath et al.¹⁸ Nevertheless, as false positive reactions might result from prior hypersensitivity from other triggers, such as vaccinations and eye drops, the high frequency of positive responses to thimerosal that have been recorded cannot be equated with clinical importance in dermatitis. Wantke et al. found that in routine patch testing, thimerosal resulted in a high prevalence of positive results that were not clinically correlated.¹⁸ According to reports, the widespread use of vaccines containing preservatives like thimerosal is mostly to blame for the higher incidence of positive responses to the preservative. Clinically significant thimerosal sensitivity is peculiar to individuals suffering from allergic contact conjunctivitis.^{19,20} Moreover, thimerosal is more likely to cross-react with tixocortol pivalate and neomycin.²¹

Galate mix was found positive in all shaving cream users, 20% of herbal face cream users, and 33% of face cream and foundation cream users. Kumar and Paulose reported that 40% of cosmetic dermatitis patients reacted positively to gallate mix.²² Propyl gallate is most likely the cause of the high positivity to gallate mix.²² Fisher states that using liposome-containing creams may increase propyl gallate sensitivity.²³

When it comes to ACD and permanent hair coloring, PPD is the most prevalent allergen. In the current survey, it was positive in all patients using bindi and 92.3% of patients using hair dye. Shampoos, conditioners, shaving products, eye and foundation makeup, bath gel, liquid soaps, dusting powder, and skin moisturizers contain quaternion-15 as a preservative.²³ Therefore, sensitization is irrelevant to hair dye dermatitis and may have happened earlier.

Cetrimide was positive in 12.4% of patients, particularly among hair shampoo users. In contrast to our finding, 6% of patients were positive for cetrimide in a study by Rastogi et al., particularly among those using moisturizing face cream and aftershave lotion.¹³

The majority of patients use multiple cosmetics sequentially or concurrently. The lack of strict regulations about labeling the ingredients on cosmetics thus makes identifying the causative allergen a primary challenge in

cosmetic-induced dermatitis. In this investigation, patch testing established whether or not an ingredient caused contact hypersensitivity in the patient. Thus, we believe that a patch test helps with early allergen identification, and its removal from the patient's surroundings can avert the chronicity of the dermatitis.

Moreover, patch testing using standard series alone could fail to identify many crucial allergens related to cosmetics. Therefore, further tests utilizing sensitive personal cosmetic products and cosmetic series should be conducted to enhance the identification of pertinent allergens in individuals with a cosmetic allergy.

5. Conclusion

Facial cosmetic contact dermatitis should be suspected in patients with acute, sub-acute, or chronic dermatitis after applying cosmetic products. A patch test is the benchmark for identifying this dermatitis. Formal patch testing may not be feasible in cases where dermatologists practice individually without being affiliated with an institute and only see a few instances. So, this study adds to the pool of evidence of suspected allergens and the likelihood of ACD due to cosmetics. Hence, practicing dermatologists can use this evidence to manage their cases.

6. Source of Funding

None.

7. Conflict of Interest

None.

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