

Clinical Profile and Allergens in Pigmented Cosmetic Dermatitis and Allergic Contact Dermatitis to Cosmetics in India

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Background: Pigmented cosmetic dermatitis (PCD) is frequently encountered in dark-skinned individuals as gradual hyperpigmentation on the face without preceding erythema or itching. Little is known about the allergen profile in PCD.

Objectives: The aim of the study was to describe the clinical profile and common allergens in PCD and allergic contact dermatitis (ACD) to cosmetics in Delhi.

Methods: Records of patients suspected of PCD and ACD to cosmetics were analyzed. All patients were patch tested with the Indian standard series, Indian cosmetic and fragrance series, and personal cosmetics and, in relevant cases, hairdresser series.

Results: One hundred six patients were analyzed. Patch test was positive in 77 cases (72.6%). Cetrimonium, gallate mix, thiomerosal, and skin lightening creams were more frequently positive in cases of PCD ($P = 0.019-0.003$), whereas *p*-phenylenediamine, toluene-2,5 diamine sulfate, *p*-aminophenol, *m*-aminophenol, and nitro-*p*-phenylenediamine were predominantly positive in ACD to cosmetics ($P < 0.001$).

Conclusions: Preservatives, antioxidants, and skin lightening creams seem to play a role in causation of PCD, whereas hair dye allergens cause ACD to cosmetics in India.

Cosmetics include a wide range of personal care products, the constituents of which vary with time and geographical area. Pooled data of 7 studies from Europe and the United States, comprising 30,207 patients including general and patch-tested populations, revealed a prevalence of 9.8% of allergic contact dermatitis (ACD) to cosmetics.¹ Apart from ACD to cosmetics, pigmented cosmetic dermatitis (PCD) is frequently observed in Asians. Lately, we have observed the use of skin lightening agents by a fairly large number of patients. These are available as over-the-counter preparations, and herbal and ayurvedic products, the ingredients of which are seldom known. However, large-scale studies of patch test findings in PCD are lacking. We undertook this study to describe the

clinical and patch test profiles of patients presenting with hyperpigmentation or dermatitis suspected to be due to cosmetics.

MATERIALS AND METHODS

This was a retrospective analysis of records of the patients suspected of PCD and ACD to cosmetics from January 2015 to October 2017 at the contact dermatitis clinic in our center in New Delhi, India. These included all consecutive cases presenting with dermatitis or pigmentation affecting sites of application of 1 or more cosmetics and a temporal correlation with use of such agents and onset of dermatitis. Information regarding all the cosmetics used, duration of use, frequency of application, and precipitation or exacerbation of the dermatitis on cosmetic use was noted.

Patch test findings were noted from the records. All patients were patch tested with the Indian cosmetic and fragrance series and relevant allergens from the Indian standard series (Chemotechnique Diagnostics, Sweden) approved by the Contact and Occupational Dermatoses Forum of India. A total of 56 allergens were used. An extended hairdressing series (Chemotechnique Diagnostics) of 30 allergens was applied in cases suspected of contact dermatitis to dyes or those who showed a positive patch test to PPD in cosmetic series. In addition, all the cosmetic products and skin lightening creams used by the patients before onset of dermatitis were tested. Patients' material was tested "as is" except shampoos, soaps, and shaving products, which were diluted to 1:10 in distilled water. Reactions were

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The authors have no funding or conflicts of interest to declare.

This study is attributed to the Department of Dermatology and Venereology, All India Institute of Medical Sciences, Ansari Nagar, New Delhi, India.

This study was awarded the "Howard-Maibach" Travel Grant Award at the Annual Meeting of the American Contact Dermatitis Society, held in San Diego on February 15, 2018.

DOI: 10.1097/DER.0000000000000407

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evaluated initially at 48 hours (D2) and again at 96 and 144 hours (D4 and D6, respectively) after patch test. Recording of patch test reactions was performed according to the International Contact Dermatitis Research Group guidelines.² On the basis of patch test results, the causal relationships between specific cosmetic products and current dermatitis were assessed and relevance was determined accordingly. Repeated open application tests and usage tests were carried out in cases where patch testing was negative or doubtful, and the index of suspicion for a particular cosmetic was strong.

Data Analysis

Categorical variables were expressed as frequency (percentage). Continuous variables were expressed as mean $\pm$ standard deviation (SD). χ^2 Test was applied for categorical variables. For statistical analyses of PCD versus ACD, odds ratios were calculated. Two-sided *P* values of less than 0.05 were considered to be statistically significant. Calculations were performed with SPSS version 22 (SPSS, Chicago, IL).

RESULTS

Clinical Details

There were 106 patients, with females outnumbering males (females, 77; males, 29). The mean $\pm$ SD age was 43.4 ± 1.2 years (range, 15–69 years). Most patients were in the age group of 30 to 44 years (*n* = 41, 44.1%), followed by 37, 17, and 11 patients in the age groups of 45 to 59, 15 to 29, and older than 60 years, respectively. Disease duration ranged from 2 days to 15 years (mean $\pm$ SD, 3.16 ± 3.3 years).

Acute dermatitis in the form of crusted oozy plaques was seen in 15 cases, subacute dermatitis with erythematous scaly plaques was seen in 17 cases, and hyperpigmented macules were seen in 74 cases. Clinically, a diagnosis of PCD was considered in most cases (*n* = 74, 69.8%); and CD, in the rest of the cases (*n* = 32, 30.2%). Pigmented cosmetic dermatitis was seen as noneczematous dermatitis in the form of mottled brownish coalescing macules on the cheeks (*n* = 68), forehead (*n* = 14), neck (*n* = 19), and ear lobes (*n* = 6) and along the hairline (*n* = 6). A history of application of a new cosmetic agent preceding the onset of this pigmentation and, in some cases, erythema made us suspect a cosmetic causation. Atopy was present in 11.3% of the patients (*n* = 12). Mild-moderate itching was noted in 37.7% of the patients (*n* = 40).

There was involvement of 1 site in 62 patients, 2 sites in 38 patients, and 3 sites in 5 patients. The most commonly involved site was the face (*n* = 92), followed by the neck (*n* = 26), scalp (along the hairline) (*n* = 8), upper back (*n* = 7), fingers (*n* = 6), ear lobes (*n* = 6), arm (*n* = 6), forearm (*n* = 1), and lips (*n* = 1). There was no history of photosensitivity in any patient.

The most frequently used cosmetics were hair dyes (*n* = 139 products), followed by herbal mehendis/henna (*n* = 108), skin lightening creams (*n* = 108), soaps and cleansers (*n* = 113), hair oils (*n* = 76), moisturizers (*n* = 83), shampoos and conditioners (*n* = 52), foundation creams (*n* = 15), sunscreens (*n* = 42), lipsticks (*n* = 18), shaving creams

(*n* = 16), sindoor/bindis (*n* = 16), antiaging creams (*n* = 13), deodorants (*n* = 8), nail polish (*n* = 3), sandalwood (*n* = 3), and lemon juice (*n* = 1).

Patch Test Results

A total of 267 positive patch test reactions were seen in 89 patients. Of these, 77 patients showed 244 reactions relevant to the patients' current cosmetic dermatitis. Fifteen patients reacted to a single allergen, 18 patients reacted to 2 allergens, 19 patients reacted to 3 allergens, and 25 patients reacted to more than 3 allergens. Whereas 175 reactions were seen with the patch test series allergens, 92 were with the patients' own products. A repeated open application test was performed in 18 patients, which revealed a positive reaction to skin lightening creams in 4 patients at 1 week (Tables 1, 2).

Overall, patch test was positive in 52 cases suspected of PCD and 25 cases suspected of ACD.

Among the cosmetic allergen categories, the most common to show positive patch tests were preservatives (*n* = 71, 46.7%), followed by hair dye components (*n* = 47, 31%), fragrance components (*n* = 25, 16.4%), emulsifiers/surfactants (*n* = 5, 3.2%), and vehicle components (*n* = 2, 1.3%) (Table 1). The most frequently positive allergen was PPD (*n* = 27), followed by cetrimonium bromide (*n* = 21), thimerosal (*n* = 17), gallate mix (*n* = 13), fragrance mix I (*n* = 9), Peru Balsam (*n* = 8), *p*-aminophenol (*n* = 7), benzyl salicylate (*n* = 6), nitro-PPD (*n* = 5), toluene-2,5-diamine sulfate (*n* = 5), methylisothiazolinone/methylchlorisothiazolinone (MI/MCI) (*n* = 5), *m*-aminophenol (*n* = 3), hydroquinone (*n* = 2), and colophony (*n* = 2). Among the patients' products, most commonly, positive reactions were seen with hair care products, including dyes (*n* = 53) and herbal mehendis (*n* = 10), skin lightening creams (*n* = 10), shampoos and conditioners (*n* = 5), and hair oils (*n* = 5) (Table 2). A total of 42 sunscreen cream brands were tested, of which 2 cases tested positive with 1 cream each and benzyl salicylate (*n* = 2).

The demographic, clinical, and patch test profiles in PCD and ACD to cosmetics are summarized in Table 3. Pigmented cosmetic dermatitis was associated with statistically significant patch test positivity to cetrimonium bromide (*P* = 0.003), gallate mix (*P* = 0.008), thimerosal (*P* = 0.019), and skin lightening creams (*P* = 0.003) (Fig. 1). Allergic contact dermatitis to cosmetics was associated with patch test positivity to hair dye allergens, namely, PPD (*P* < 0.001), *p*-aminophenol (*P* < 0.001), nitro-PPD (*P* = 0.002), *m*-aminophenol (*P* = 0.029), and toluene-2,5-diamine sulfate (*P* = 0.033) (Fig. 2).

Most of our cases (*n* = 82, 77.3%) belonged to darker phototype V, and fewer were of phototype IV (*n* = 24, 22.6%). Patch test was positive in 58 cases (70%) with phototype V and 19 cases (82%) with phototype IV (*P* = 0.257).

DISCUSSION

With the increasing use of cosmetics and routinely performed diagnostic patch testing, there has been a rise in the prevalence of contact dermatitis to cosmetics. In a questionnaire-based survey of 360 female customers of beauty salons in Israel in 2009, 11 patients

TABLE 1. Patch Test Results in All the Patients Suspected of Cosmetic Contact Dermatitis

Type of Allergens	Positive Patch Test, n	Relevant Reactions, n
Preservatives	77	71
•Cetrimonium bromide (0.5% pet)	21	21
•Thimerosal (0.1% pet)	23	17
•Gallate mix (1.5% pet)	13	13
•MI/MCI (0.02% aq)	5	5
• <i>p</i> -Chloro- <i>m</i> -cresol (1% pet)	4	4
•Paraben mix (16% pet)	2	2
•Benzyl alcohol (10% pet)	2	2
•Hydroquinone (1% pet)	2	2
• <i>t</i> -Butyl hydroquinone (1% pet)	1	1
•Diazolidinyl urea (0.2% aq)	1	1
•Quaternium-15 (1% pet)	1	1
•Captan (0.5% pet)	1	1
•Chloroacetamide (0.2% pet)	1	1
Hair dye components	47	47
•PPD (1% pet)	27	27
• <i>p</i> -Aminophenol (1% pet)	7	7
•2-Nitro-PPD (1% pet)	5	5
•Toluene-2,5-diamine sulfate (1% pet)	5	5
• <i>m</i> -Aminophenol (1% pet)	3	3
Fragrance components	25	25
•Fragrance mix I (8% pet)	9	9
•Peru Balsam (25% pet)	8	8
•Benzyl salicylate (10% pet)	6	6
•Vanillin (10% pet)	1	1
•Jasmine synthetic (2% pet)	1	1
Emulsifiers/surfactants	5	5
•Stearyl alcohol (30% pet)	1	1
•Cetyl alcohol (5% pet)	1	1
•Oleamidopropyl dimethylamine (0.1% aq)	1	1
•Methenamine (2% pet)	1	1
•Ammonium thioglycolate (2.5% aq)	1	1
Vehicle components	2	2
•Colophony (20% pet)	2	2
Others	19	2
•Nickel(II) sulfate hexahydrate (5% pet)	6	0
•Potassium dichromate (0.5% pet)	6	2
•2-Mercaptobenzothiazole (2% pet)	2	0
•Neomycin sulfate (20% pet)	2	0
•Thiuram mix (1% pet)	1	0
•Nitrofurazone (1% pet)	1	0
•Chloroxylenol (PCMX) (0.5% pet)	1	0
Total	175	152

aq, aqueous; pet, petrolatum.

(3.1%) had patch test–proven contact dermatitis to cosmetics.³ Prevalence of patch test positivity to cosmetic series varies with geographical areas. In our study, the patch test was positive in 72.6%, increasing from the previous report of 59.2% in 2000.⁴ A similar patch test positivity rate of 68.4% was reported by the Mayo Clinic Contact Dermatitis Group in a larger sample size of 945 patients, who were tested with personal care products and an extended cosmetic series.⁵

Dermatitis has been reported as a predominant manifestation of CD to cosmetics.⁶ However, hyperpigmentation was reported as a presenting feature in 8 of 49 cases suspected of cosmetic sensitivity in India.⁷ A study of kumkum-induced (which is a red pigment used by Hindu women to make a round mark on the forehead) cosmetic dermatoses from South India found PCD to be more common (35 cases) than ACD (11 cases).⁸

Pigmented cosmetic dermatitis, a manifestation of CD to cosmetics in Asians, is seen as asymptomatic blotchy or reticulate slate-gray and brown hyperpigmentation usually involving the face in middle-aged women along with a positive patch test reaction. This pattern was originally described as pigmented contact dermatitis, with Tinopal, an optical whitener, and then, textile dyes were incriminated.^{9,10} Subsequently, a series of cases, with cosmetics as incriminated agents, have been described from Japan, Israel, and India (Table 4).^{3,8,11}

Patch test results showed that the causative allergen was more apparent in cases of ACD to cosmetics, whereas allergens could be revealed only on patch testing in cases with PCD. A significant difference in the allergen profile in the 2 groups suggests that particular allergens, namely, cetrimonium, gallate mix, and thimerosal, may play an important role in causation of PCD (Table 3).

Preservatives have been found to cause epidemics of ACD. Among the top 20 allergens listed by the 2009–2010 patch test results by the North American Contact Dermatitis Group (NACDG), 6 were preservatives: quaternium-15, formaldehyde, iodopropynyl butylcarbamate, methylidibromo glutaronitrile, MI/MCI, and diazolidinyl urea.¹² A

TABLE 2. Patch Test Results to Patients' Products

Patients' Products	No. Products Tested	No. Positive Patch Tests
Hair dyes	139	53
Natural henna/mehendis	108	10
Soaps/cleansers	113	1
Skin lightening creams	108	10
Moisturizers	83	1
Sunscreens	42	2
Shampoos/conditioners	52	5
Hair oils	76	5
Bindi	4	0
Sindoor	12	1
Lipsticks	18	0
Mascara/eye kajal	3	0
Antiaging creams	13	1
Foundation	15	0
Shaving products	16	2
Deodorant	8	0
Topical steroids	4	0
Lemon juice	1	0
Nail polish	3	1
Sandalwood/chandan	3	0
Aloe vera	8	0
Total	829	92

TABLE 3. Comparative Demographic, Clinical, and Allergen Profiles in Cases Suspected of PCD and ACD

Characteristics	PCD	Cosmetic ACD	Total	P*
No. cases	74	32	106	
Age, mean $\pm$ SD, y	42.07 $\pm$ 1.45	46.7 $\pm$ 1.95	43.4 $\pm$ 1.18	0.076
Disease duration, mean $\pm$ SD, y	3.3 $\pm$ 3.5	2.84 $\pm$ 3.02	3.16 $\pm$ 3.3	0.512
Itching	9	31	40	<0.001
Atopy	4	8	12	0.076
Patch test positive	52 (72.8%)	25 (81.5%)	77 (72.6%)	0.361
Main allergens implicated				
Cetrimonium bromide (0.5% pet)	20	1	21	0.003
Gallate mix (1.5% pet)	13	0	13	0.008
Thimerosal (0.1% pet)	16	1	17	0.019
PPD (1% pet)	8	19	27	<0.001
Toluene-2,5-diamine sulfate (1% pet)	1	4	5	0.033
<i>p</i> -Aminophenol (1% pet)	0	7	7	0.000
<i>m</i> -Aminophenol (1% pet)	0	3	3	0.029
2-Nitro-PPD (1% pet)	0	5	5	0.002
Fragrance mix I (8% pet)	5	4	9	0.456
Peru Balsam (25% pet)	5	3	8	0.703
Benzyl salicylate (10% pet)	6	0	6	0.173
Skin lightening cream	14	0	14	0.003

*A $P < 0.05$ was considered significant.

high positivity rate was seen with preservatives (46.7%) in our series too. However, the allergens as well as the clinical pattern of CD were different from the reports in western literature. Cetrimonium, thimerosal, gallate mix, and MI/MCI were the most frequent allergens in our series, and the predominant clinical pattern was PCD. Interestingly, recent studies from India have also shown high patch test positivity to these allergens.¹³ Cetrimonium is an antiseptic and a surfactant used widely in hair conditioning products. In our study, patients who were patch test positive with cetrimonium were using various facial cosmetics, including creams and face cleansers, and hair conditioning agents. Gallate mix consists of dodecyl gallate, octyl gallate, and propyl gallate. These antioxidants are frequently used as preservatives in lipsticks, cleansers, skin lightening creams,

conditioners, and makeup products. In a systematic review, 74 cases of ACD to gallates were found in the literature.¹⁴ Affected cases showed dermatitis as a predominant clinical manifestation. Cosmetics were implicated in most cases, with lipsticks as a causative agent in 27%.¹⁴ In our cases, skin lightening creams seem to be common offending agents, and the pattern seen was PCD. The relevance of thimerosal allergy is often unclear. In a meta-analysis of 14 studies involving TRUE Test (Thin-layer Rapid Use Epicutaneous patch Test) allergens, thimerosal was the second most prevalent allergen but was mostly not relevant.¹⁵ Thimerosal was labeled as the Nonallergen of the Year 2002 by the American Society of Contact Dermatitis.¹⁶ However, recent reports implicating thimerosal as a relevant allergen have emerged, indicating that important sources of thimerosal exposure remain.¹⁷ In our patients with a positive patch test to “Fair n Lovely” skin lightening cream, thimerosal was



Figure 1. A, Pigmented cosmetic dermatitis on the face with ill-defined brownish macules. Patch test positive to (B) thimerosal (0.1% pet) and (C) depigmenting cream “as is” (Fair n Lovely).



Figure 2. Allergic contact dermatitis to hair dyes with lichenoid plaques (A) along the hairline on the preauricular area with a positive patch test (B) to *p*-phenylenediamine (1% petrolatum) and toluene-2,5-diamine sulfate (1% petrolatum).

TABLE 4. Summary of Reports of Patch Testing in PCD

Serial No.	Author(s), Year, Place	Study Sample	Clinical Details	Allergen(s)
1.	Tratner et al, ³ 1999, Israel	29 (26 Jewish, 8 Yemenis, 5 Moroccans, 5 Indians, 8 others)	Hyperpigmentation (face, 18; neck, 12; upper back, 10; chest, 6; upper extremities, 7; lower extremities, 2)	Perfume mix (n = 6), nickel (n = 3), fragrance mix (n = 4), formaldehyde (n = 2), potassium dichromate (n = 1), colophony (n = 1), Amerchol L-101 (n = 1), Grotan BK (n = 1), amyl cinnamic aldehyde (n = 1), formaldehyde (n = 1), evernic acid (n = 1), Kathon CG (n = 1), 4-tert-butylcatechol (n = 1), moisturizing cream with sandalwood oil (n = 1) Thimerosal (n = 18), gallate mix (n = 12), kumkum (n = 7), PPD (n = 1), MI/MCI (n = 1), benzotriazol (n = 1), tert-butyl hydroquinone (n = 1), parabens (n = 1) Nickel (n = 8), cobalt (n = 2), fragrance mix II (n = 3), ashy dermatosis (n = 8), LPP (n = 4), PCD (n = 4), PIH (n = 1)
2.	Nath and Thappa, ⁸ 2006, India	46	PCD (n = 35), ACD (n = 11)	
3.	Tientavorn et al, ¹¹ 2014, Thailand	40; ashy dermatosis (n = 20), LPP (n = 11), PCD (n = 10), PIH (n = 2)	Slate-gray hyperpigmentation (60.47%) and erythematous patches (34.88%) on sun-exposed areas in 63.83%, covered areas in 25.53%, generalized 10.64%	
4.	Sharma et al. 2018, India (current study)	106 (PCD 74, ACD 32)	Mottled brownish hyperpigmentation (cheeks, 68; neck, 19; forehead, 14; along the hairline, 6; ear lobes, 6)	PCD: cetrimonium bromide (n = 20), gallate mix (n = 13), thimerosal (n = 16), skin lightening creams (n = 14); ACD: PPD (n = 19), p-aminophenol (n = 7), nitro-PPD (n = 5), fragrance mix (n = 4), toluene-2,5 diamine sulfate (n = 4)

LPP, lichen planus pigmentosus; PIH, postinflammatory hyperpigmentation.

the most common allergen (4/10), followed by cetrimonium (2) and gallate mix (2). Mercury in the range of 0.102 to 0.775 µg/g was found in this cream, with some samples containing mercury greater than the Food and Drug Administration permissible limit of 1 ppm.¹⁸ In India, stigma related to dark skin color unfortunately still exists, making the use of skin lightening agents rampant. This is reflected by the fact that skin lightening creams were the second most commonly used agents (n = 108), next only to hair coloring products (n = 139). Facial dermatitis with a positive patch test reaction with 3-*o*-ethyl-L-ascorbic acid in skin lightening creams was recently reported.¹⁹

Methylisothiazolinone/methylchlorisothiazolinone was the fourth most common preservative, showing a positive patch test in our cases. A dramatic rise in rate of sensitization to MI/MCI was seen from 2.2% to 3.6% in North America from 2000 to 2010 and from 4.8% to 11.2% in Bangkok from 2009 to 2011.^{12,20} In a recent multicenter study representing 9 countries involving 3865 patients, contact allergy to MI alone without any simultaneous contact allergy to 200 ppm of MI/MCI was diagnosed in 93 patients (32.7%, 2.4% of all tested patients).²¹ However, MI alone is not yet available for testing in India, because of which a number of potential positive reactions may be missed.

The rate of positive reactions with fragrances was low (16.4%). Among 4232 individuals patch tested by the NACDG from 2011 to 2012, a total of 12.1% tested positive for fragrance mix (FM)1 and 5.2% for FM2.²² Approximately 33% of fragrance allergy may be missed if FM1 alone is used for patch testing.²³ FM2 and its constituents are not a part of currently used Indian Standard Series and Indian cosmetic and fragrance series.

Next to preservatives, common allergens found positive in our study were hair dye related, namely, PPD, nitro-PPD, and *p*-aminophenol. A difference in ethnicity was shown to influence patch test results in a study by the NACDG involving 19,457 patients.²⁴ Higher rates of patch test reactions were seen to PPD in blacks, whereas whites had an increase in positive reactions to fragrances, formaldehyde, and some formaldehyde releasers ($P < 0.001$).²⁴ To date, there are only 5 allergens, including PPD, that are recognized by the Consumer Product Safety Commission (formerly designated by the Food and Drug Administration) as “strong sensitizers.”²⁵ Legislation in Europe and the United States prohibits the use of such allergens. Such a system is unfortunately yet to be implemented in India.

Propylene glycol, a common ingredient in many cosmetics, was recently named the American Contact Dermatitis Society's Allergen of the Year 2018. However, in our study, there were no cases with a positive patch test reaction to this allergen.²⁶

CONCLUSIONS

The trend of contact dermatitis to cosmetics in India is undergoing a shift. Pigmented cosmetic dermatitis constituted most cases in our study. Milder or no itching, predominant hyperpigmentation, and rare frank dermatitis are clinical features that distinguish PCD from ACD to cosmetics. Patch testing with the cosmetic

series and patients' cosmetics, besides the standard series, is of utmost importance. Newer allergens, namely, cetrimonium, gallate mix, and thimerosal, are predominant causative agents in PCD, compared with PPD in ACD to cosmetics. Fairness creams were not uncommon culprits in PCD and should always be patch tested. High index of suspicion along with patch testing is an important step in diagnosing PCD and ACD to cosmetics.

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