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The Role of Patch Testing with Indian Cosmetic Series in Patients with Facial Pigmented Contact Dermatitis in India

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Abstract

Background:

Pigmented contact dermatitis (PCD) is a non-eczematoid variant of contact dermatitis, mainly characterised by hyperpigmentation. It occurs due to contact with a low amount of allergen over a long duration of time. PCD is frequently seen in Indians but is often misdiagnosed or underdiagnosed because of the asymptomatic nature of the entity. The aetiology and the allergens implicated in PCD in the Indian subcontinent is still an enigma because of the limited studies done.

Materials and Methods:

This was an institution-based cross-sectional study, done at a tertiary hospital. Patch testing with Indian Cosmetic Series was conducted in a standardised method. Readings were taken at 48 hrs/72 hrs and on the 7th day [Figure [2a](#) and [b](#)]. The International Contact Dermatitis Research Group (ICDRG) scoring system was used to grade the readings.

Results:

Out of the 38 biopsy proven cases of PCD, 18 (47%) showed lichenoid features, 17 (45%) showed spongiotic features, 3 (8%) showed a mixed lichenoid and spongiotic pattern. Among total 1216 (32 patches × 38 patients) patch applied, 42 (3.4%) showed positivity in 30 patients. Among allergen categories, colorant (PPD) was found to be most common (37%) followed by fragrances (18%), preservatives (15%), anti-microbial (11%) and emulsifier and anti-oxidants (each 8%).

Conclusion:

It is important to identify the allergens implicated in PCD to help in better management of the condition. Patch testing proves to be a non invasive, low cost method and its role is indispensable in identifying the correct allergen.

KEY WORDS: *Facial melanosis, Indian cosmetic series, lichen planus pigmentosus, patch testin, pigmented contact dermatosis*

Introduction

Facial hypermelanosis is a clinical feature of diverse group of disorders. Amongst the multitude of causes, one of them is pigmented contact dermatitis (PCD) which is a non-eczematoid variant of contact dermatitis (CD), characterised clinically by hyperpigmentation with little or no sign of dermatitis.[1] The term PCD was first used by Osmundsen.[1] There are certain known culprits of PCD like optical whiteners, azo dyes, chemicals used in fragrances etc.[2] Riehl's Melanosis is considered a variant of PCD. This is a form of photo allergic dermatitis mostly over face induced by fragrances or essential oil used in cosmetics.[3]

Even though PCD is quite common in our country, there is paucity of data on its occurrence and aetiopathology among Indian patients. Since the cultural practises are different in Indian subcontinent from other parts and that drug and cosmetics acts are not as stringent as in the Western countries leading to low-quality and hyper-allergic products widely prevalent in the Indian market, we need our indigenous data for effective control of this condition. In view of the above, we have done patch testing with cosmetic series for better understanding of the prevalence and aetiology of PCD and the relevance of patch test amongst Indian patients.

Materials and Methods

This was an institution-based cross-sectional study, done at a tertiary hospital of Kolkata, West Bengal after obtaining clearance from the institutional ethics committee. Patients with facial hypermelanosis, attending the Dermatology OPD for the first time were examined by two independent observers. All patients who presented with CD on face with minimal or no inflammatory component and more of pigmentary features, with history of contact with cosmetics as probable source of allergens were clinically considered as a case of PCD after examination by two independent observers. On histopathology, PCD is characterised by basal liquefied degeneration and lichenoid tissue reaction, rarely spongiosis or acanthosis. All patients with biopsy confirmed PCD were enrolled in the study after informed written consent. Patients with congenital hypermelanosis, melasma, systemic illness, and doubtful diagnosis where both observers gave a different diagnosis and unwilling to sign consent were excluded from the study.

The epidemiological data of the patients were recorded, along with the sites effected. Special emphasis was given to the type of cosmetic used, the name, frequency, and duration of use. Patch testing with Indian Cosmetic Series (Systopic laboratories, New Delhi) was conducted in a standardised method [Figure 1a and b].

Readings were taken at 48 hrs/72 hrs and on the 7th day [Figure 2a and b]. The International Contact Dermatitis Research Group (ICDRG) scoring system was used to grade the readings, the interpretation of which is shown in Table 1. In case of PCD apart from papule or erythema, there may be brown pigmentation on patch testing which is also considered positive. Angry back was also recorded. Relevance of the positive test was calculated as per no relevance/past relevance/present relevance on the basis of the detailed history and examination of the cosmetics used.

Results

All patients clinically suspected of PCD were subjected to histopathological examination (HPE) of skin. Among all biopsies, 18 (47%) showed lichenoid features, 17 (45%) showed spongiotic features and 3 (8%) showed a mixed lichenoid and spongiotic pattern. All patients of biopsy confirmed PCD were included after ruling out other causes of facial hypermelanosis like melasma, ochronosis, berloque dermatitis etc.

Out of 38 biopsy-proven cases of PCD, 14 (37%) were males and 24 (63%) were females (M:F 1:1.7). Most patients belonged to the 4th decade with mean age being 39.7 years, the youngest patient was 16 years and oldest was 60 years old. 60.5% (24) belonged to urban locality and 50% (19) were housewives.

89.5% (34) patients had insidious onset of disease and most (53%, $n = 20$) have been suffering from it for the last 1–2 years. A total of 50% ($n = 19$) of the patients were asymptomatic whereas the others complained of itching (47%) and mild burning (3%). A total of 60% ($n = 23$) gave history of prior

photosensitivity. No significant history of prior drug intake was found except two patients, one was on L-thyroxin and one on levocetirizine prior to onset.

The most common site of involvement was the forehead (76%) followed by medial cheek (71%). Nose was the least common site of involvement (40%).

The cosmetics used by patients has been summarised in [Table 2](#). Hair dye was the most common (74%) cosmetic followed by fairness cream (42%) [Figures 3–8].

Patch test results Among total 1216 (32 patches × 38 patients) patch applied, 42 (3.4%) showed positivity in 30 patients. Patch testing with Indian Cosmetic Series and paraphenylenediamine (PPD) was done to all study patients. A total of 30 (79%) patients showed positive testing and among positive results, 27 (71%) showed present relevance and only 3 (8%) were of no relevance.

Among allergen categories, colorant (PPD) was found to be most common (37%) followed by fragrances (18%), preservatives (15%), anti-microbial (11%) and emulsifier and anti-oxidants (each 8%).

Among hair dye users ($n = 28$), present relevance with PPD was found in 14 (50%) cases, with BHA in 2 (7%) cases, with BHT and polyoxyethylene sorbitol oleate one (4%) for each were found relevant. In 12 (43%) cases, patch test was of no relevance or negative.

Among night cream or moisturiser users ($n = 10$), one case (10%) for each was positive relevantly with Musk mix, Sorbitan sesquio, vanillin, and propylene glycol. Rest 7 (70%) cases patch testing was either negative or of no relevance.

Among cold cream users ($n = 7$), one case was positive relevantly with jasmine absolute (14%), and one with sorbitan sesquio and vanillin (14%). The rest 5 (72%) were either negative or of no relevance.

Among Fairness cream users ($n = 16$), 2 (12.5%) were relevantly positive with Lavender absolute. One (6%) case for each was positive for Musk mix, Cetyl alcohol, Thimerosal, Sorbic acid, Germall 11 and benzyl salicylate. For the remaining 8 (50%) cases, patch testing was either negative or of no relevance.

Among fragrance users ($n = 5$), only one case was positive relevantly with benzyl salicylate (20%); for the rest four (80%) cases patch testing was either negative or of no relevance.

Among antiseptic lotion and cream users ($n = 7$), cetrimide was found positive with present relevance in three (43%) cases and rest four (57%) cases patch testing was either negative or of no relevance.

There were two ($n = 2$) cases who used after shave and one (50%) of them was found positive with musk mix with present relevance. Among users of make-up, lip color, kumkum and bindi, no relevant result was shown in patch testing. All above under this heading is being summarised in [Table 3](#).

Among 14 significant positivity of PPD, only 5 (36%) showed strong positivity (++) in patch testing and the rest nine showed weak positivity (+). Among three significant positivity with cetrimide, two (66%) were strongly positive and one (33%) was weakly positive. All other patch-positive allergens were weakly positive (+). None showed (+++) or ulcer on reading. (Doubtful positivity i.e., (±) and (?) reading on 72 hr or 7th day reading were not considered).

Discussion

PCD is presently an emerging skin condition particularly in India and other third-world countries because of unsupervised marketing of cosmetic and skin care products where detailed labelling of components is not legally mandatory.

PCD, a manifestation of CD to cosmetics in Asians, presents as asymptomatic blotchy or reticulate slate-gray to brown pigmentation. It usually involves the face of middle-aged women along with a positive patch test reaction. PCD was first described with tinopal, an optical whitener.[1] Later, studies from Japan and Israel incriminated various cosmetics as a cause of PCD.[4,5] There is very limited data available regarding PCD and the relevance of patch test for Indian skin; moreover, the data of patch testing positivity with cosmetic series varies with geographical location.[6]

With increasing use of cosmetics and use of routine diagnostic patch test, the prevalence of CD to cosmetics is on a rise. In a study conducted in the year 2000, the prevalence of patch test positivity was 59.2%, followed by 72.6% in an Indian study conducted in 2018 and our study in 2019 reports a prevalence of 78.9%.[\[6,7\]](#)

In our study, most PCD patients were users of hair cosmetics (74%) and 50% of them tested positive with PPD. In our study, PPD was the most common allergen implicated followed by fragrances and preservatives. This is in contrast to the Western world, where fragrances are the major allergens. A large scale study by a North American CD group showed that a difference in ethnicity influenced patch testing. [\[8\]](#) Higher rates of patch test reactions were seen to PPD in blacks, whereas whites had an increase in positive reactions to fragrances and formaldehyde.[\[8\]](#) Strict legislations in Europe and USA prohibits the use of PPD on the basis of the Consumer Product Safety Commission which recognises only 5 allergens as “strong sensitizers” including PPD.[\[6\]](#) Unfortunately, such stringent laws are lacking in India leading to the rampant use of such allergens in various cosmetics and even in “herbal” hair dyes.

The second most common offending cosmetic was fairness creams (42%); a similar observation was made in other studies.[\[6,9\]](#) The most common allergen identified in our study was lavender absolute (12.5%) followed by others like sorbitol, thiomersal etc. This is in contrast to the study done by Kumar *et al.* and Sharma *et al.* where they found propyl gallate and thiomersal, respectively, to be the most common allergen.[\[6,9\]](#) Due to the stigma associated with dark skin tone, India is a mine of fairness products. Our study is one of the first to report lavender absolute as the most common allergen in fairness creams. This may be explained by new fairness creams coming in the market each day giving rise to newer allergens.

Fragrances were not a very common allergen amongst our study group and the rate of patch test positivity with fragrances was low (20%). Similar low positivity has been reported in other studies.[\[6\]](#) This may be explained by Indian standard series and Indian cosmetic series not including FM2 and its constituents yet.

PCD and its allergens are continuously evolving, earlier studies report Kumkum as the most common cause of PCD in Indian patients but this stands in contrast to our study and other recent Indian studies. [\[6,10\]](#)

The results of patch test as reported in various studies have been summarized in [Table 4](#).

Limitation The number of the antigen used in the present study is a little less than the Indian Cosmetic and Fragrance Series (CODFI) series as at the time of conducting the study, a few antigens were not available in Eastern India as the lone supplier of the patch tests battery in this part failed to provide those antigens.

Conclusion

Pigmented contact dermatitis is a widely prevalent form of facial dermatitis in the Indian subcontinent, but it is often missed or underreported because of its fairly asymptomatic nature. It is important to identify the allergens implicated in PCD to help in better management and generate consciousness amongst patients and doctors. Patch testing proves to be a non invasive, low cost method and its role is indispensable in identifying the correct allergen.

The trend of allergens in PCD is undergoing a shift in India with a change in the behaviour of consumers regarding the type of cosmetics, with Kumkum as the commonest allergen in older days to hair cosmetics now. Fairness creams always manage to find a place amongst the top allergens in Indian PCD patients given their rampant use. Patch test helps us to establish a definite correlation between PCD and the given cosmetic product, thus helping us generate awareness and educate the masses against their use.

Declaration of patient consent The authors certify that they have obtained all appropriate patient consent forms. In the form, the patients have given their consent for their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

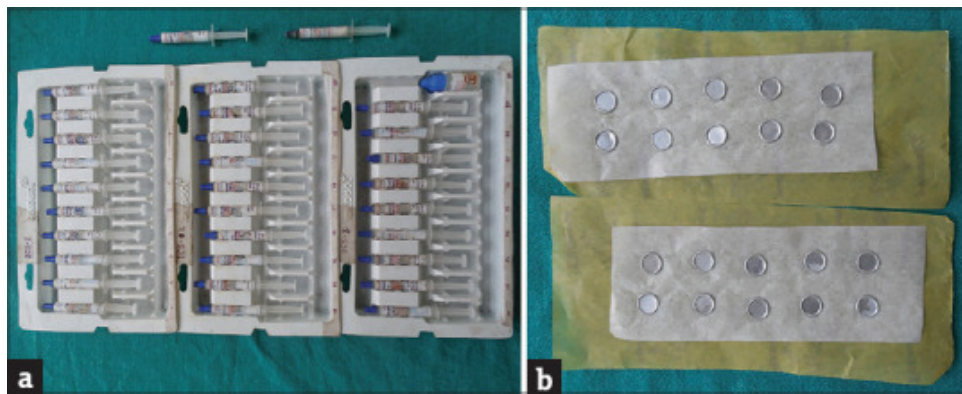
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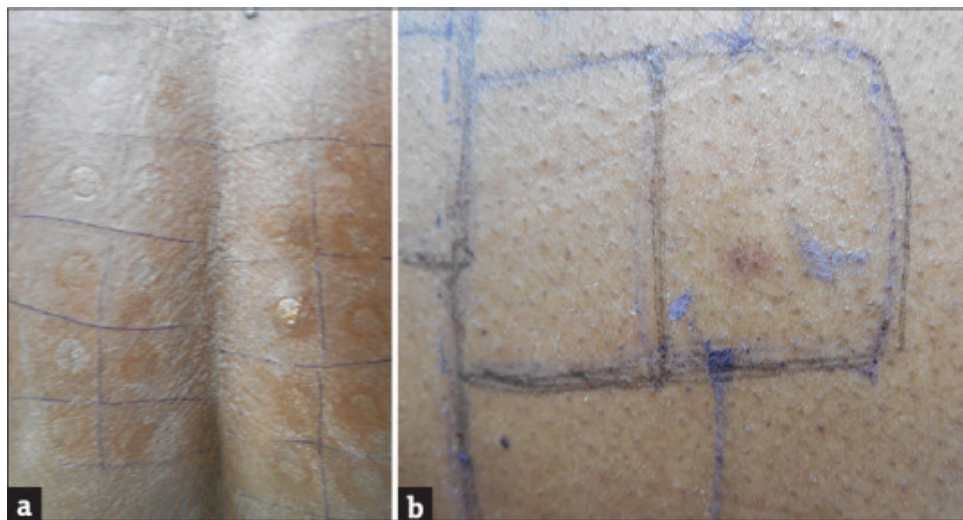
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Figures and Tables

Figure 1

(a) Patch testing kit (Indian Cosmetic Series, Systopic lab.). (b) Aluminium Finn chambers

Figure 2

(a) Patch testing showing strong reaction to cetrimide. (b) Patch testing showing erythema on day 7

Table 1

Grading and interpretation of patch test readings

Symbol	Morphology	Interpretation
-	No reaction	No reaction
?	Faint macular erythema only	Doubtful reaction
+	Erythema, infiltration and possibly papules	Weak positive reaction
++	Erythema, infiltration, papules and vesicles	Strong positive reaction
+++	Bullous reaction	Extreme positive reaction
IR	Irritant reaction of different type	Irritant reaction
NT	Not tested	Not tested

Table 2

Cosmetics used by the patients

Cosmetics	No. of patients (n=38)	Percentage
Hair cosmetics (dye/coloring agent)	28	74%
Fairness Cream	16	42%
Night cream/moisturiser	10	26%
Lip color	9	24%
Cold cream	7	19%
Antiseptic lotion/cream	7	19%
Kumkum/Sindoor	6	16%
Fragrances	5	13%
Make up (foundation, primer, concealer etc)	4	10%
Bindi	3	8%
Aftershave	2	5%

Figure 3

PCD due to application of night cream

Figure 4

PCD due to fairness cream

Figure 5

PCD due to Sindoor

Figure 6

PCD prominent in mandibular area due to antiseptic lotion

Figure 7

PCD prominent on forehead due to use of hair dye

Figure 8

PCD prominent on malar and temple area owing to the use of fairness cream

Table 3

Patch testing (Indian cosmetic series, Systopic lab) results and its relevance

Name of the allergen	Number of positive patch tests	Strength of positivity +	++	+++	Cosmeceuticals used	Relevance of the positive patch test
Vaseline	0	-	-	-	-	0
Ethylenediamine 1%	0	-	-	-	-	0
Benzyl alcohol 1%	0	-	-	-	-	0
Benzyl salicylate 2%	1	1	0	0	Fairness cream	100%
Bronopol 0.30%	0	-	-	-	-	0
Butyl Hydr. 2% (BHA)	1	1	0	0	Hair dye	100%
Butyl Hydr. 2% (BHT)	0	-	-	-	-	0
Cetyl alcohol 5%	1	1	0	0	Fairness cream	100%
Chloracetamide 0.20%	0	-	-	-	-	0
Geranium oil	0	-	-	-	-	0
2 Hydr.-4-Meth.Benz	0	-	-	-	-	0
2 (2-Hydr.-5 Meth.)	0	-	-	-	-	0
Benztriazol 1%						
Imidazolidinyl urea	0	-	-	-	-	0
(Germall 115) 2%						
Isopropyl myristate 20%	0	-	-	-	-	0
Jasmine absolute	1	1	0	0	Cold cream	100%
Lavender absolute 2%	2	2	0	0	Fairness cream	100%
Musk mix. 5%	1	1	0	0	Night cream	100%
Phenyl salicylate 1%	0	-	-	-	-	0
Polyoxy ethylene sorbitol oleate 1%	1	1	0	0	Hair dye	100%
Rose oil 2%	0	-	-	-	-	0
Sorbitan sesquio (Arlacel 89) 2%	1	1	0	0	cold cream	100%
Thimerosal 0.10%	1	1	0	0	Fairness cream	100%
Triclosan 2%	0	-	-	-	-	0
Triethanolamine 2%	0	-	-	-	-	0
Vanillin 2%	1	1	0	0	Cold cream	100%
Cetrimide 0.50%	3	1	2	0	Antiseptic creams	100%
Hexamine 2%	0	-	-	-	-	0

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Table 4

Patch test reports in pigmented CD summarised

Author	Year	Country	Sample size	Top 5 Allergens positive in patch test
Trattner <i>et al.</i> [4]	1999	Israel	29	Perfume mix (<i>n</i> =6) Fragrance mix (<i>n</i> =4) Nickel (<i>n</i> =3) Formaldehyde (<i>n</i> =2) Potassium dichromate (<i>n</i> =1)
Nath and Thappa[10]	2007	India	35	Thiomersal (<i>n</i> =18) Gallate mix (<i>n</i> =12) Kumkum (<i>n</i> =7) PPD (<i>n</i> =1) MI/MCI (<i>n</i> =1)
Tienthavom <i>et al.</i> [5]	2014	Thailand	10	Nickel (<i>n</i> =8) Fragrance mix 2 (<i>n</i> =3) Cobalt (<i>n</i> =2)
Sharma <i>et al.</i> [6]	2018	India	74	Cetrimonium bromide (<i>n</i> =20) Thiomersal (<i>n</i> =16) Skin lightening creams (<i>n</i> =14) Gallate mix (<i>n</i> =13)
Our study	2019	India	38	PPD (<i>n</i> =14) Cetrimide (<i>n</i> =3) Lavender absolute (<i>n</i> =2) Musk mix (<i>n</i> =1) Thiomersal (<i>n</i> =1)

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