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Relevance of patch testing in allergic contact dermatitis to cosmetics among patients attending outpatient department at a tertiary care center in North Kerala

Dr. Zarina Usman

Assistant Professor, Department of Dermatology, KMCT Medical College, Manassery, Mukkam, Pin code: 673602, Kerala, India.

Corresponding author email: drzarinausman@gmail.com

Dr. Rajiv Sridharan

Professor and HOD Dermatology, Government Medical College Kannur Pariyaram, Kerala, India

Dr Bifi Joy, MD

Professor, Government Medical College, Kannur, Kerala, India.

Dr Anoop Thyvalappil, MD

Professor, Government Medical College, Kannur, Kerala, India.

Abstract---Purpose: The incidence of dermatitis due to cosmetics is increasing because of the greater product use. Identification of causative allergen(s) in patients with cosmetic dermatitis is important. It can lead to patient awareness in cosmetic product selection and decrease in the incidences of allergic contact dermatitis. The aim of the study was to assess the clinical profile of allergic contact dermatitis to cosmetics and investigate the role of patch testing in evaluation of allergic contact dermatitis to cosmetics. Patients and method: It was a prospective, interventional study, which included 40 patients with a suspected allergic contact dermatitis to cosmetics. Patch testing was performed utilizing the 'Indian Standard Series and Standard Cosmetic and Fragrance Series' approved by 'Contact and Occupational Dermatoses Forum of India'. The reactions were recorded according to International Contact Dermatitis Research Group recommendations. Result: Out of total 40 cases that were recruited in the study with a provisional diagnosis of ACD to various cosmetic ingredients, 67.5% tested positive for one or more allergens. The clinical relevance of patch testing in suspected cases of cosmetic sensitivity was found to be statistically significant ($p < 0.027$).

Conclusion: The study found clinical relevance of patch testing in suspected cases of cosmetic sensitivity to be statistically significant ($p < 0.027$). This proves the efficacy of patch testing in identifying the offending allergen. This is important in the cases of contact sensitivity, as avoidance of the same and related agents will prevent future recurrences, which are often of a higher clinical intensity.

Keywords---Allergic contact dermatitis, cosmetics, patch testing.

Introduction

Allergic contact dermatitis (ACD) is a delayed-type hypersensitivity response presented with a pruritic, eczematous reaction of skin which is usually well demarcated and localized to the site of contact with the allergen. The pathogenesis of ACD involves an initial sensitization phase when the patient first comes in contact with the chemical, the subsequent re-exposure of the skin leads to the presentation of the responsible allergen to an already primed T-cell milieu, leading to the release of numerous cytokines and chemotactic factors and resulting in the clinical picture of eczema.¹ The acute phase of ACD is characterized by development of erythematous, indurated scaly plaques, with severe cases demonstrating vesiculation and bullae at the exposed sites. Affected sites often mimic the pattern of exposure and provide insight into allergen source and elicitor of disease. Repeated or continuous exposure results in chronic disease, which is characterized by lichenified, erythematous plaque with variable hyperkeratosis, scaling and fissuring.²

In the recent years, India has witnessed a tremendous hike in the process of urbanization and a shift towards westernized lifestyle, leading to a significantly greater chance of exposure to cement and various new cosmetic allergens. Cosmetics are defined as articles intended to be rubbed, poured, or sprayed on, introduced into, or otherwise applied to normal or previously altered (scar, birth mark) human skin or any other part thereof, for cleansing, beautifying, promoting attractiveness or altering the appearance and are not intended to alter or interfere with physiological competence of human skin or body.³

Adverse cutaneous reactions due to cosmetics are because of the presence of four classes of ingredients; preservatives, emulsifiers, fragrances, and coloring agents. The incidence of dermatitis from cosmetics depends upon the degree of sensitivity, influenced by amount, potency and persistence of allergen, duration of exposure and its irritant properties.⁴ Identification of causative allergen(s) in patients with cosmetic dermatitis is important because once the allergen(s) to which the patient is sensitive is/are identified, the patient can be instructed to avoid all the products containing the offending allergen(s).

The diagnosis of ACD is made by Patch Testing. Patch test was first employed in 1847 by Staedler by blotting paper method to test idiosyncrasy.⁵ Patch testing relies on the observation that primed antigen specific T lymphocytes will be present throughout the body, hence; allergen in the patch test can be applied to normal skin. The test relies on the allergen being absorbed in sufficient quantity to

induce a reproducible inflammation of the skin at the site of application in sensitized subjects. A positive reaction to a correctly prepared and applied patch test confirms the person has allergic contact sensitivity, although this does not necessarily mean that the substance is the cause of the presenting clinical dermatitis, and its relevance should always be carefully considered.¹ Clinically relevant positive patch test results helps in specific diagnosis and earlier intervention. This helps in improving the dermatology specific quality of life⁶ and reduces the cost of therapy in patients with severe ACD.⁷ Patch test procedure can also be used before recommending alternative medicaments, skin care products, cosmetics, gloves, etc. in a particular patient. The present study was intended to assess the clinical profile of ACD to cosmetics and to investigate the role of patch testing in evaluation of ACD cosmetics.

Materials and Method

The study was conducted over the period of one year, from January 2014 to January 2015 at 'Department of Dermatology, Venereology and Leprology' in Pariyaram Medical College, Kerala, India.

The sample size was 40.

Inclusion criteria

- Patients diagnosed clinically with contact dermatitis due to the cosmetics and/or personal care products
- Willingness of the patients for patch testing

Exclusion Criteria

- Patients with active skin lesions of ACD or other skin diseases at the sites of ACD
- Contact Dermatitis involving the test site
- Patients who are not willing to enroll into the study
- Patients who have been taking systemic steroid or immunosuppressive in the last two weeks, and those who have been taking antihistamines in the last one week
- Pregnant women

Patients attending outpatient department, who were clinically diagnosed as ACD to cosmetics and personal care products and who met the fixed criteria were selected. After explaining about the study in detail, including the procedure of patch testing, informed consent was taken from all the participants. Detailed medical, family, and occupational history was recorded.

Patch testing was performed utilizing the 'Indian Standard Series and Standard Cosmetic and Fragrance Series' approved by 'Contact and Occupational Dermatoses Forum of India'. The allergen test patches were applied to upper back as per standard procedure and labelled. Patients were reviewed after 48 hours (hrs.) of application of test patches and patch test reading was taken half an hour after removal of patches, reading was repeated after 96 hrs. The reactions were recorded according to 'International Contact Dermatitis Research Group' recommendations.

Results

The data was statistically analyzed by using SPSS software.

Among total 40 patients, males constituted 62% while females were 38%. All the subjects fall between the age group of 14-71 years, with majority of the subjects belonging to the age group 41-50 years (30%). Of the 40 participants 17.5% were housewives, followed by the groups constituting students, drivers, salesman and various other professionals.

Of the total number of cases, 47.5% had a history of atopy, 25% had a family history of atopy and 37.5% had a history of similar illnesses. The most frequent presenting complaints were itching (67.5%) and burning sensation (30%); 2.5% participants were asymptomatic. Common presenting clinical features reported were hyperpigmentation (60%), papules and plaques (55%) and erythema (37.5%) and scaling (37.5%). Uncommon presentations were vesicles (15%), hypopigmentation (7.5%) and pustules (2%).

The clinical features observed in participants were redness (57.5%), hyperpigmentation (40%), scaling (35%), vesiculation (17.5%), hypopigmentation (10%) and severe allergic reaction such as pustulation (5%). The most involved body site was the face (60%), followed by trunk (30%), upper limb and axilla (30%) and scalp (25%); the least involved body site was neck (22.5%), lower limb and groin (15%). There were no cases of any lesions over the lip in the studied sample.

Patch test results:

Out of 40 patients patch tested, 67.5% patients were patch test positive, while 33.5% were patch test negative. Single antigen positivity was seen in 32.5% study population, 22.5% were positive for two antigens and 12.5% were positive for multiple antigens. Total positivity in males was 72% and in females was 60%. The proportion of cases with positive patch test result was not significantly different between males and females.

The allergen positivity was maximum in individuals >50 years of age (100%), 58.3% of cases were positive between the age group of 41-50 years, 66.7% were positive between age group 31-40 years and 50% were positive in cases <30 years of age in the studied sample.

Percentage of positivity of various allergens: Paraphenylenediamine (PPD) was the most common positive allergen (35%), followed by fragrance mix and other allergens as shown in chart 1.

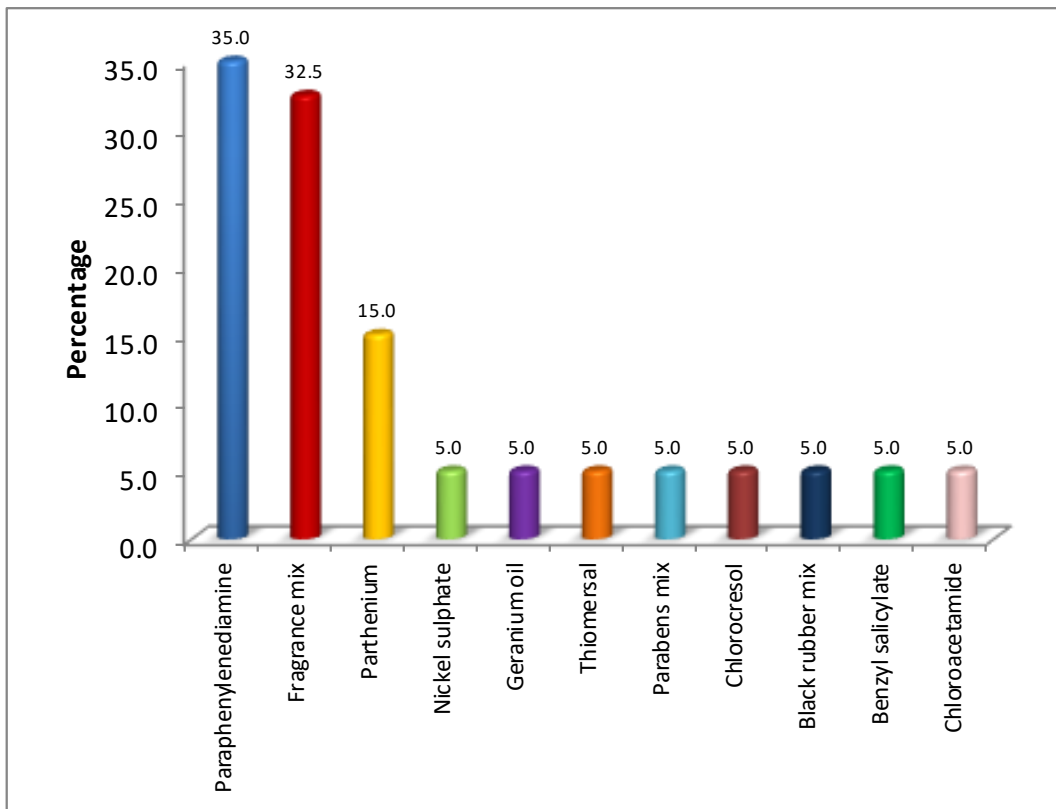


Chart1. Allergen positivity

Reaction pattern of Allergens: Out of the total 2080 allergens tested (40 cases X 52 allergens), positive reaction was observed in 59 allergens (2.84%) and doubtful reactions were observed in 25 allergens (1.2%).

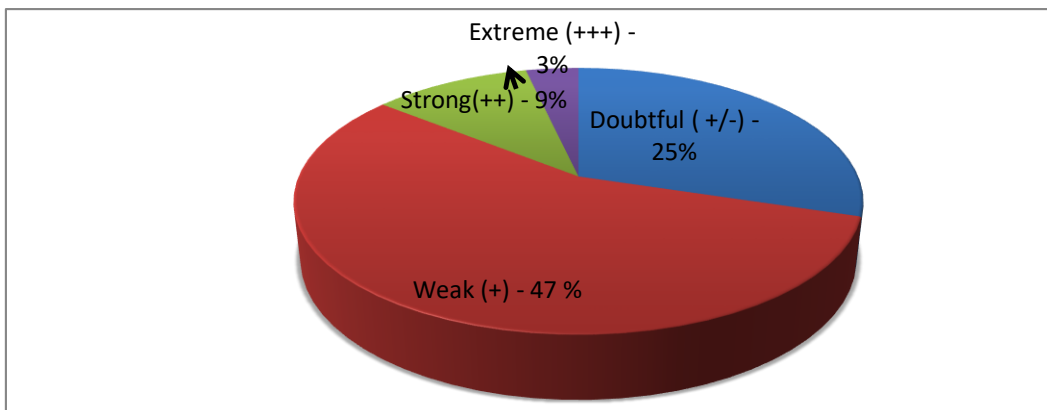


Chart 2: Reaction pattern of allergens

Association between PPD positivity and history of use of hair cosmetics: Out of the total 40 cases studied, 20 cases (50%) gave history of hair cosmetic use in the form of hair dye, and the patch test positivity for PPD in these patients were 80%. Patch test positivity among non-users of hair dye (50%) was 55%. There was no significant association found between the history of use of hair dye and patch test positivity for PPD (using chi-square test of significance, $p = 0.091$).

Association between recently used body creams or lotions and selected allergens: Among the 13 cases that were positive for fragrance mix, 53.8% had a positive history of recent use of body creams or lotion. Among the negative cases (27), only 14.8% had a positive history of recent use of body creams or lotions. Similarly, among the two cases that were positive for geranium oil, both (100%) had a positive history of use of body creams or lotions, and among the negative cases (38) only 23.7% had a positive history of recent use of body creams and lotions. There was statistically significant association between fragrance mix ($p = 0.010$), geranium oil (using chi-square test of significance, $p = 0.018$) positivity and history of use of body creams or lotions.

On similar comparison no significant association between the recent use of perfumes, sprays or colognes and fragrance mix or geranium oil positivity was found. Also no statistical association between allergen positivity and history of atopy was found.

Based on Patients

Table 1: Causative classes of allergens in patients with positive patch test reactions

| Allergen groups | Count | Percent |
|--|-------|---------|
| Dyes, pigments, and resins | 16 | 40.0 |
| Fragrances | 13 | 32.5 |
| Preservatives and antimicrobials | 8 | 20.0 |
| Vehicles, cosmetic excipients, and emulsifiers | 3 | 7.5 |
| UV filters and antioxidants | 3 | 7.5 |
| Miscellaneous | 7 | 17.5 |

Table 2: Causative classes of allergens in the total positive patch test reactions

| Allergen groups | Count | Percent |
|---|-------|---------|
| Dyes, pigments, and resins | 17 | 28.8 |
| Fragrances | 15 | 25.4 |
| Preservatives & antimicrobials | 12 | 20.3 |
| Vehicles, cosmetic excipients & emulsifiers | 4 | 6.8 |
| UV filters & antioxidants | 4 | 6.8 |
| Miscellaneous | 7 | 11.9 |
| Total | 59 | 100.0 |

Out of total 40 cases, 67.5% tested positive for one or more allergens. The clinical relevance of patch testing in suspected cases of cosmetic sensitivity was found to be statistically significant ($p < 0.027$) and with 95% confidence interval. This percentage may vary from 53 to 82%.

Table 3: Clinical relevance of patch test result

| Allergen Positivity | Count | Percent | 95% CI | P |
|---------------------|-------|---------|---------|-------|
| No | 13 | 32.5 | 53 – 82 | 0.027 |
| Yes | 27 | 67.5 | | |

Discussion

In our study, a total of 40 patients suspected to be suffering from ACD were evaluated and patch testing with standard allergens was performed to identify the culprit allergen, to confirm the diagnosis and to estimate the clinical relevance.

Age and gender profile

In our study, majority of the patients belonged to age group between 41-50 years, constituting 30% of the studied sample. This was slightly higher than that reported from previous studies. In the study pediatric population (<18 years) constituted only 2.5% (single participant) of the total sample, this finding stays consistent with the fact that cosmetic sensitivity is relatively less common in the pediatric population due to less frequent exposure, although hetero transfer from parents and care givers is known to occur.¹³ Age has little influence on capacity for sensitization, however; due to the accumulation of allergies acquired over a lifetime, the number of positive patch-test reactions tends to increase with age. Occupational or cosmetic allergies are more likely to occur in young adults whereas elderly people are more liable to medicament and 'historic' sensitivities.¹⁴ This contrasts with the study conducted by Roul S et al, who reported a peak incidence of contact sensitivity in early childhood.¹⁵

Males outnumbered females in our study with a male to female ratio of 1.6:1, this contrasted with various studies namely Vij A *et al* and De Groot *et al* which depicted a moderate female preponderance possibly because of higher incidence of use of cosmetics among females.^{8,20} Nath et al also reported similar results with female to male ratio of 1.9:1.¹¹ The higher prevalence among males in our study was possibly because of the larger number of cases of ACD to hair dye and relatively lesser use of cosmetics among the female population in this part of the state.

Occupational profile

Cosmetic sensitivity may be influenced by various external parameters such as occupation and outdoor activities. In our study majority of the participants were housewives (17.5%), followed students, drivers, salesmen and various other skilled professionals. Dogra A *et al* reported higher cases of cosmetic sensitivity among working women specially beauticians, nurses, and Para-medical workers.¹²

Clinical profile

In our study, the most frequent presenting complaint was itching (67.5%) followed by burning sensation (30%). This was concurrent with the literature that highlights itching to be more frequent in cases of ACD than burning and stinging sensation, which was more frequently observed in irritant contact dermatitis.^{16, 17} The clinical presentation showed redness being the most common presenting feature (57.5%), followed by hyperpigmentation (40%) and scaling (35%). Less common features included vesiculation (17.5%) and hypopigmentation (10%) and acute eczematous reaction (5%). This stands discordant with literature that reports eczematous lesions to be the most frequent presenting feature in ACD. This variation might be due to the delay in early presentation to health care setting, partial subsidence of the lesions following withdrawal of the offending agent as identified by the patients and over the counter medication.

In majority of the cases (60%), lesions were localized to face, since most of the cases had ACD to hair dye. Other common sites for ACD lesions were trunk (30%) and upper limb and axilla (30%), accounting to the use of various fragrance products and body cosmetics. Scalp involvement was observed in 25% of the cases. The least involved body sites were neck (22.5%), lower limb and groin (15%), concordant with relatively lesser cosmetic exposure along these body sites. There were no cases of any lesions over the lip, this was probably due to infrequent use of such cosmetics in the studied population.

Patch test result

Patch testing is the current evidence-based approach for identifying the sensitizing allergen. The total number of positive cases in our study was 67.5%, which was concordant with various studies that showed the frequency of positive patch test reactions in patients with cosmetic dermatitis to range from 32.8% to 81.3%.^{11,18}

In our study the total positivity in males was 72% and in females was 60%. However, the proportion of cases with positive result for patch test was not significantly different between males and females (p value = 0.433). This contrasted with the study by Nath et al that observed a marginally higher incidence of positivity in females¹¹ and the NACDG analysis, which reported patch test positivity of 24% in females and 18% in males.¹⁹

Our study results showed maximum positivity for single antigen at 32.5%, 22.5% were positive for 2 antigens whereas 12.5% were positive for multiple antigens. This was dissimilar to the study by Dogra A et al which showed multiple sensitivities in most of the cases.¹² In our study the allergen positivity was maximum in individuals > 50 years of age (100%), this accounts for the higher exposure of allergens (hair dye and fragrances) and impaired skin barrier integrity-repair function in this age group.

Reaction pattern of allergens

Out of the total 2080 allergens tested (40 cases X 52 allergens), positive reaction was observed with 59 allergens (2.84%). This finding was concordant with previous studies. Rook in 1998 observed that 1-3% of the population to be allergic to a cosmetic or their ingredients. However, higher percentages of positive patches (11.54%) with cosmetic ingredients and cosmetics products were reported by another study conducted by Dogra A et al in 1994.¹²

Table 4: Comparison of positive allergen patches

| Studies | Positive patches | Percentage |
|----------------------------------|------------------|------------|
| Our study | 59/2080 | 2.84% |
| Nath et al ¹¹ | 57/2380 | 2.4% |
| Dogra et al ⁴ (2003) | 69/2065 | 3.3% |
| Dogra et al ¹² (1994) | 382/4410 | 11.54% |
| De Groot (1987) ²⁰ | 67/1781 | 3.4% |

Positivity of various allergens

It is generally accepted that the leading cause of ACD associated with cosmetics is from fragrance, followed by preservatives and PPD in hair dyes.^{11, 18} Nath et al observed that preservatives were most frequently implicated cosmetic allergens, with Thiomersal showing maximum positivity, followed by antioxidants with Gallate mix and PPD.¹¹ Dogra A et al (1994), reported PPD to be the most common positive allergen (35%) followed by Balsam of Peru (22.5%) and Parabens (19.25%).¹² Sarma N et al observed Paraben to be the most common allergen, followed by Fragrance mix in cosmetics.¹³

Table 5: Causative classes of allergens in patients with positive patch test reactions

| Allergen groups | Count | Percent |
|---|-------|---------|
| Dyes, pigments, and resins | 16 | 40.0 |
| Fragrances | 13 | 32.5 |
| Preservatives & antimicrobials | 8 | 20.0 |
| Vehicles, cosmetic excipients & emulsifiers | 3 | 7.5 |
| UV filters & antioxidants | 3 | 7.5 |
| Miscellaneous | 7 | 17.5 |

Our study observed maximum positivity with dyes, pigments, and resins, which constituted 40% (16 cases) and PPD was the most frequent allergen from this group with positivity in (35%) of cases, which was consistent with the study by Dogra A et al (1994).¹² In contrast to this, Hsu T S et al in their study reported a much lower percentage of PPD positivity constituting only 2.26%.²¹

The second most common positive allergen in our study was Fragrance mix (32.5%). This was significantly higher than that observed in a Danish study from 1997/98, wherein perfume sensitization was reported in 4.5% of the tested

population and, two German studies which showed a prevalence of fragrance mix sensitization in 11.4% and 15.9%, respectively.²²The main causes of primary sensitization to fragrance chemicals are cosmetic products, particularly deodorants and fine perfumes, however; multiple sources of exposure have been seen.

In our study higher positivity for PPD in males accounted for higher exposure to hair dyes and higher Fragrance mix positivity in females accounted for the higher exposure to fragrance products such as perfumes, and various fragrances incorporated in face and body cosmetics. Geranium oil positivity in 13.3% of female patients could be explained similarly.

Parthenium positivity was significant in the study population (20%), although this was an incidental finding, it denoted increasing sensitivity of individuals in this part of the state to Parthenium, which may be implicated in various other unrelated dermatosis in these individuals, stressing the need to keep this diagnosis in mind while confronting various unresponsive or refractory dermatosis.

Nickel sulphate positivity was observed in 13.3% of females in our study, accounting for the higher exposure to nickel coated jewelries, articles, and pigments in certain cosmetics. Prolonged period of skin contact with nickel ions released from such materials may cause sensitization. Nickel sensitivity is more common among females and incidence rates is about 10% and it is increasing.²³

Association between PPD positivity and history of use of hair cosmetics

In our study, statistical test for association failed to prove a significant correlation between the use of hair dye and PPD positivity ($p = 0.091$). However, an unexpected PPD positivity of 55% was observed among cases who denied exposure to any form of hair dye, hence, proving sensitization from sources other than hair dye. The clinical relevance between frequency of PPD positivity and dermatitis cannot be equated as false positive reactions can occur due to earlier sensitization from unrelated exposure. Sources of PPD exposure include photographic developers, lithography, photocopying, oils, greases, gasoline etc. In the study by Nath et al¹¹, three patients with ACD due to hair dye, only two had 2+ reaction to PPD, statistical correlation was not assessed.

PPD is also known to cause irritant reactions under a covered patch test.¹² Irritant reactions were observed in three cases of PPD positivity in our study.

Association between history of use of Body creams or lotions / Face cosmetics / Perfumes, sprays or colognes and Fragrance mix positivity

In our study statistical test for association proved significant correlation between the use of various body creams or lotions and Fragrance mix positivity ($p = 0.010$), but it failed to prove a significant correlation between the use of various face cosmetics and Fragrance mix positivity ($p = 0.217$). Similarly, no significant association was found between the history of use of perfumes, sprays or colognes and Fragrance mix positivity.

Fragrance mix is present in soaps, perfumes, toothpastes, colognes, after shave lotions, scents, food items like sweets, ice-cream, household products like room fresheners, insect repellents and in industrial products like metalworking fluids. Hence, sensitization may occur from multiple sources causing difficulty in asserting clinical relevance.

Association between history of use of Body-creams or lotions / Face cosmetics / Perfumes, sprays or colognes and Geranium oil positivity

In our study statistical test for association proved significant correlation between the use of various body-creams or lotions and geranium oil positivity ($p = 0.018$); but no significant association between the history of use of face cosmetics and geranium oil positivity ($p = 0.127$) was found.

Relationship with atopy

The relationship of atopy, particularly atopic dermatitis, as a predisposition to ACD has been a matter of much debate. There is down regulation of Th1 cells in atopy, which should mean a decreased tendency to develop allergic contact dermatitis. However, clinical studies have shown variable results.¹⁴ Recent studies have shown an equal or even higher occurrence of contact allergy in atopic when compared with non-atopic subjects.^{22, 24} A possible explanation to this increased risk of sensitization in subjects with atopic eczema can be explained by increased allergen penetration through damaged skin.

In the study by Sarma N et al prevalence of ACD was higher among atopics than among non-atopics (94.4% vs. 75%), however; relevance was less in atopics.¹³ In our series, the prevalence of atopy was similarly higher (68.4%) among the cases tested positive for one or more allergens, but this was not statistically significant as 31.6% of patients in the negative group were also atopic. A total of 10 (25%) cases had family history of atopy.

Clinical relevance of patch test result

In the study, out of total 40 participants 67.5% were tested positive for one or more allergens. The association between patch test positivity and clinical relevance was found to be statistically significant ($p < 0.027$). Thereby confirming the clinical relevance of patch testing in suspected cases of cosmetic contact dermatitis. In the twenty first century, prevalence rates of patch test proven ACD to cosmetics continue to rise worldwide.^{8, 9, 10}

In the modern society, with exceptionally faster rates of urbanization and westernization, there is over-zealous use of innumerable cosmetic agents by the population. Lack of stringent laws against standardization of these products further adds to the malady. Hence, our population is at an increased risk of contact sensitivity. Therefore, a high index of suspicion is critical to identify and possibly avoid the triggering factor. Dermatologists need to be aware of this scenario and are expected to include patch tests routinely in their diagnostic kits.

Conclusion

As per our study, majority of cases of cosmetic contact dermatitis belonged to age group between 41 to 50 years. Males constituted the majority (62%) of the study population as most cases recruited were those of suspected hair dye allergy. The allergen positivity was also more in males (72%). The most common allergen was PPD followed by Fragrance mix, this was consistent with certain previous studies. There was statistically significant association between both Fragrance mix and Geranium oil positivity and history of use of body creams or lotions.

The clinical relevance of patch testing in suspected cases of cosmetic sensitivity was found to be statistically significant ($p < 0.027$). This proves the efficacy of patch testing in identifying the offending allergen, which is of prime importance in cases of contact sensitivity, as avoidance of the same and related agents should be undertaken to prevent future recurrences, often of higher clinical intensity.



Figure 1: ACD to hair dye, sub-acute stage over moustache region



Figure 2: ACD to perfumes, axillae.



Figure 3: Photograph showing patch test units applied on the back



Figure 4: Patch test reading showing 2+ reaction to PPD (No 12)

Abbreviations:

ACD: Acute contact dermatitis

Hours: Hrs.

Paraphenylenediamine: PPD

Disclosure:

The author reports no conflicts of interest in this work.

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