Patch Testing In Cosmetic Dermatoses: A Report From South India

A Nath, D Mohan Thappa

Citation

Abstract
Thirty five patients with cosmetic dermatoses were patch tested in this study. Out of 35 patients, 23 were female and 12 were male, with a female to male ratio of 1.9:1. Mean age of patients was 42 years. Kumkum was the incriminated cosmetic in 24 patients, sticker bindi in 5 patients, kumkum and sticker bindi both in 1 patient, hair dye in 3 patients, Fair & Lovely and aftershave lotion in 1 patient each. Out of 2380 patches applied, positive reactions were seen in 57 patches. Twenty eight out of 35 patients had positive (allergic) patch test reaction. Thimerosal showed positive reaction in 27 patients (27/35), gallate mix in 15 patients (15/35), paraphenylenediamine in five patients (5/35), nickel sulphate in two patients, and parabens, Kathon CG, benzotriazol, tertiary-butyl hydroquinone, quaternium-15, balsam of Peru, potassium dichromate and cobalt chloride in one patient each.

INTRODUCTION
Adverse cutaneous reactions due to cosmetics are because of the presence of four classes of ingredients – preservatives, emulsifiers, fragrances, and coloring agents. Serious adverse effects caused by cosmetics are infrequent compared to their widespread use. However, mild reactions such as itching, prickling, and dryness can occur in more than 10% of the adult population. Most individuals who experience a cutaneous reaction to cosmetic usually have a mild reaction and simply change to another product, and only rarely is a reaction reported. Since the clinical features of cosmetic dermatitis are more often mild or covert, patch testing should be done to confirm the diagnosis. The aim of our study was to identify the allergens by patch testing in patients with dermatoses due to cosmetics.

MATERIALS AND METHODS
This was a descriptive study conducted in the dermatology department in JIPMER, Pondicherry (India) from August 2004 to June 2006. Patients with dermatoses due to the use of cosmetics and personal care products were included in the study. Patch testing was performed with the cosmetic allergens procured from Systopic® Pharmaceutical Ltd., India and the Indian Stanard series of allergens approved by Contact and Occupational Dermatoses Forum of India (CODFI). In patients with acute dermatitis, patch testing was postponed till the acute dermatitis subsided. Reading was done at 48 hours and 96 hours. In case of doubtful reactions, patients were advised to return on day 7. The grading system as followed by the North American Contact Dermatitis Group was used. Ethical committee approval was obtained.

RESULTS
Thirty five patients with dermatoses due to cosmetics and personal care products were patch tested in our study. Twenty three were female and 12 were male. Female to male ratio was 1.9:1. Mean age of patients was 42 years. Frequency of positive patch test reaction was higher in females (82.6%) than in males (75%), but it was not statistically not significant (P=0.66 by Fisher's Exact test).

Twenty four out of 35 patients (68.6%) had dermatoses due to kumkum; sticker bindi was the responsible cosmetic in five patients (14.3%); dermatosis due to both kumkum and sticker bindi was seen in one patient. Three cases (8.5%) of contact dermatitis due to hair dye; one due to Fair & Lovely; and one due to aftershave lotion were also seen.

A total of 2380 patches were applied, and positive reactions were seen in 57 patches (2.4% of the patches applied). Overall, out of 57 patches which showed positive reactions, preservatives showed positive reaction in 30 patches (30/57, 52.6%), antioxidants in 15 patches (26.3%),
paraphenylenediamine in 5 patches (8.8%), fragrance in one (1.7%), and miscellaneous allergens in six patches.

Twenty eight out of 35 patients (80%) had positive (allergic) patch test reaction. Twelve out of 28 patients (42.9%) had positive reaction to one allergen, and 16 patients (57.1%) had positive patch test reactions to two or more allergens. No irritant reactions were recorded. Thimerosal showed positive reaction in 27 patients (27/35, 77.1%), gallate mix in 15 patients (15/35, 42.8%), paraphenylenediamine in five patients (5/35, 14.2%), nickel sulphate in two patients, and one each had positive reaction to parabens, Kathon CG, benzotriazol, tertiary-butyl hydroquinone, quaternium-15, balsam of Peru, potassium dichromate, and cobalt chloride (Table 1).

**DISCUSSION**

The incidence of dermatitis due to cosmetics is increasing because of greater products use. Identification of the causative allergen(s) in patients with cosmetic dermatitis is important because once the allergen(s) to which the patient is sensitive is/are identified, he/she can be instructed to check the manufacturer's list of ingredients before buying any cosmetic product and avoid all the products containing the offending allergen(s). The standard series and cosmetic series can detect more than 80% of the allergens responsible for the dermatoses.

Frequency of positive patch test reactions in patients with cosmetic dermatitis ranges from 32.8% to 81.3% in various studies. In our study, a rather high percentage (80%) of patients had positive reaction in patch test. Frequency of positive patch reactions was more common in females in Lindberg et al's study. However, in our study, positive reactions were marginally more common in females, but statistically insignificant. It is generally accepted that the leading cause of allergic contact dermatitis associated with cosmetics is from fragrance, followed by preservatives and paraphenylenediamine in hair dyes. In India, Dogra et al. patch tested 200 females with cosmetic dermatitis and found paraphenylenediamine (PPD) to be the commonest (35%) cosmetic allergen, followed by balsam of Peru (22.5%), parabens (19.25%). However, a number of other studies have found preservatives to be the commonest class of allergens. de Groot et al. patch tested 119 patients with cosmetic dermatitis – the most common allergens in his cosmetic series were Kathon CG (MCI/MI) (35% of patients), thimerosal (26.2%), triethanolamine (8.7%), and octyl gallate (7.5%). In our study, preservatives were most frequently implicated cosmetic allergens, followed by antioxidants, and paraphenylenediamine. Among the preservatives, thimerosal

<table>
<thead>
<tr>
<th>Class of ingredients (N=number of patches)</th>
<th>No. of patients with positive reaction</th>
<th>Percentage (out of 35 patients patch tested)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Preservatives</strong> (N=30)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Thimerosal</td>
<td>27</td>
<td>77.1%</td>
</tr>
<tr>
<td>Kathon CG</td>
<td>1</td>
<td>2.8%</td>
</tr>
<tr>
<td>Parabens</td>
<td>1</td>
<td>2.8%</td>
</tr>
<tr>
<td>Quaternium-15</td>
<td>1</td>
<td>2.8%</td>
</tr>
<tr>
<td><strong>Antioxidants</strong> (N=15)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gallate mix</td>
<td>15</td>
<td>42.8%</td>
</tr>
<tr>
<td><strong>Paraphenylenediamine</strong> (N=5)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ni<strong>ckel sulphate</strong></td>
<td>2</td>
<td>5.7%</td>
</tr>
<tr>
<td>Benzotriazol</td>
<td>1</td>
<td>2.8%</td>
</tr>
<tr>
<td>Tertiary-butyl hydroquinone</td>
<td>1</td>
<td>2.8%</td>
</tr>
<tr>
<td>Potassium dichromate</td>
<td>1</td>
<td>2.8%</td>
</tr>
<tr>
<td>Cobalt chloride</td>
<td>1</td>
<td>2.8%</td>
</tr>
</tbody>
</table>

Out of 27 patients with positive reaction to thimerosal, 25 patients (92.6%) showed 3+ reaction, one patient (3.7%) showed 2+ reaction, and one patient showed 1+ reaction. Frequency of positive reaction to thimerosal was higher in females (18/23, 78.3%) than in males (9/12, 75%), but was not statistically significant (P = 1 by Fisher's Exact Test). Out of 15 patients with positive reaction to gallate mix, nine had 1+ reaction, and six had ‘±’ (doubtful) reaction. Out of five patients with positive reaction to PPD, four showed 2+ reaction, and one showed 1+ reaction. Nickel sulphate showed 2+ reaction in one patient and 1+ reaction in one patient. Parabens, Kathon CG, benzotriazol, tertiary-butyl hydroquinone, quaternium-15, balsam of Peru, potassium dichromate, cobalt chloride showed 1+ reaction in one patient each.

**Figure 1**

Table 1: Causative (classes of) ingredients in patients with positive patch test reaction.
was the most common allergen to show positive reaction (27 cases). Antioxidant group had only gallate mix, which showed positive reaction in 15 cases.

While patch testing with cosmetic allergens, 44% of doubtful reactions are clinically relevant, 1+ and 2+ reactions have 80% relevance. Stronger reactions were associated with greater relevance. Held et al. reported that doubtful reactions were relevant to the presenting dermatitis only in 29%. In our study, thimerosal mostly produced 3+ reactions (25/27); gallate mix showed 1+ and doubtful ('±') reactions only. Thimerosal is a commonly used preservative – in vaccines, eye medications, contact lens solutions, solutions for intracutaneous skin testing, immunoglobulin preparations, and cosmetics. Vaccination can be the cause of sensitization in early childhood. Therefore, interpretation of positive patch test reaction to thimerosal should be done carefully. In our study, 77.1% of patients patch tested showed positive reaction to thimerosal, which was significantly higher than that reported in other studies. However, the observed high frequency of positive reactions to thimerosal can not be equated with clinical relevance in the dermatitis as false positive reactions can occur due to earlier sensitization from unrelated sources like vaccines or eye drops. Cosmetic products (Kumkum, sticker bindi, hair dye, Fair & Lovely and aftershave lotion) which were responsible for the dermatitis in our study are not known to contain thimerosal. Suneja et al. reported positive reaction to thimerosal to be relevant only in four out of 50 patients. Wantke et al. observed high incidence of positive patch test reactions to thimerosal on routine patch testing, which could not be clinically correlated. It is reported that high frequency of positive reactions to thimerosal is primarily due to the widespread use of vaccines containing thimerosal as a preservative and at present thimerosal sensitization is clinically relevant only in patients with allergic contact conjunctivitis. Thimerosal is also more likely to cross-react with neomycin and tixocortol pivalate.

Kumar and Paulose reported 40% of their cosmetic dermatitis patient demonstrating positive reaction to gallate mix (one patient had 3+ reaction, two patients had 2+ reactions, and 17 patients had mild reaction (1+) in patch test). Out 35 patients patch tested in our study, positive reactions to gallate mix was seen in 15 patients (15/35, 42.8%) – nine had 1+ reaction, and six had doubtful ('±') reaction. High positivity to gallate mix is probably due to the presence of propyl gallate. Fisher states that the use of liposome containing creams may unleash a rise in propyl gallate allergy.

PPD is the most common allergen associated with allergic contact dermatitis to permanent hair dye. Three patients with ACD due to hair dye were patch tested in our study. Two had 2+ reaction to PPD, all three had positive reaction to thimerosal (two 3+ reactions, and one 2+ reaction), one patient had 1+ reaction to quaternium-15. Quaternium-15 is widely used as preservative in shampoos and conditioners, eye makeup, foundation makeup, shaving products, bath gel, liquid soaps and dusting powder, and skin moisturizers. Hence, sensitization might have occurred earlier and may not have relevance in hair dye dermatitis.

CONCLUSIONS

To conclude, thimerosal was the most common allergen to show positive patch test reaction in our study, followed by gallate mix and paraphenylenediamine. Thimerosal showed strong reaction in most patients. The common allergens showing positive reaction in our study were different from those reported in other studies. Therefore, it is recommended that similar studies be conducted periodically in order to observe the diverse variations in allergens responsible for the hypersensitivity to cosmetic products.

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