

Patch testing with own cosmetics – a prospective study of testing and reporting of adverse effects to the Swedish Medical Products Agency

Monica Tammela¹, Magnus Lindberg², Marlène Isaksson³, Annica Inerot⁴, Jana Rudel⁵ and Berit Berne^{6,1}

¹Department of Cosmetics, Medical Products Agency, SE-751 03 Uppsala, Sweden, ²Department of Dermatology, Örebro University Hospital and School of Health and Medical Sciences, SE-701 85 Örebro University, Örebro, Sweden, ³Department of Occupational and Environmental Dermatology, Skåne University Hospital, SE-205 02 Malmö, Sweden, ⁴Department of Dermatology, Sahlgrenska University Hospital, SE-413 45 Gothenburg, Sweden, ⁵Department of Dermatology, Ryhov County Hospital, SE-551 85 Jönköping, Sweden, and ⁶Department of Medical Sciences, Dermatology and Venereology, Uppsala University, SE-751 85 Uppsala, Sweden

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Summary

Background. The Swedish Medical Products Agency (MPA) provides a voluntary reporting system for adverse reactions to cosmetics. However, the reporting is sparse, and the products involved are sometimes difficult to identify.

Objectives. To investigate how often patients referred for patch testing were tested with the cosmetic products that they had been using themselves, and to improve the reporting to the MPA by the use of photographic documentation of product labels.

Patients and methods. Consecutive patients at five dermatology departments who were patch tested with their own cosmetics were included. Reports including protocols of positive patch test results for the patients' own cosmetics and photographs/photocopies of product labels were sent to the MPA.

Results. Three hundred and sixteen of 948 patients (33%) were tested with their own cosmetics, and 15% of these tested positive with one or more products. The number of reports was more than three times higher than in corresponding periods in earlier years. For 79% of the products, photographs/photocopies of the containers were submitted, and for 30%, batch numbers were submitted.

Conclusions. For a substantial number of patients, their own cosmetics were suspected of causing adverse reactions and were therefore tested. During the study, the number of reports to the MPA tripled, and the relevant products were easier to identify.

Key words: adverse cosmetic reactions; cosmetovigilance; patch testing; reporting system.

In Sweden, adverse reactions to cosmetics can be reported to the Medical Products Agency (MPA) similarly to the way in which medicinal products are reported (1). This is a voluntary system, and 40–50 reports are received each year, most of them based on positive patch test results.

The reports are few in number in relation to the expected number of adverse effects of cosmetics as judged by the presence of self-reported reactions in Sweden; 18% for women and 6% for men (2). In a more recent epidemiological study in the UK, 23% of women and 14% of men had experienced an adverse reaction to cosmetics during a period of 1 year (3). In addition to the underreporting of adverse reactions, the MPA sometimes has problems in identifying the specific products involved using the current system. An improvement in the reporting system, regarding both the number of reports and the information necessary to identify the products, would be desirable.

Correspondence: Monica Tammela, Department of Cosmetics, Medical Products Agency, P.O. Box 26, SE-751 03 Uppsala, Sweden. Tel: +46 (0) 18174870; Fax: +46 (0) 18548566. E-mail: monica.tammela@mpa.se

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Table 1. Categories and number of products causing positive patch test reactions

Product category	Concentration	Number of positive test reactions
Skin creams, lotions, gels, oils	as is	17
Soap and other cleansing products	as is, semi-open, or 5%	11
Shampoo and hairstyling products	as is, semi-open, or 5%	7
Nail products	as is, 50%, 25%, 10%, or 0.1%	6
Mascara	as is	5
Make-up for skin	as is	3
Lipstick	as is	3
Sunscreen products	as is	3
Perfume products	as is	2
Anti-wrinkle products	as is	2
Depilatories	as is	1
Deodorants, antiperspirants	as is	1
Self-tanning products	as is	1
Total		62

In the current study, we collected information on the extent to which patients investigated for suspected contact allergy were patch-tested with their own cosmetic products. The reporting to the MPA of suspected adverse reactions was made in an improved way with more extensive identification of the products.

Patients and Methods

The study was performed in accordance with the Declaration of Helsinki.

In this article, the term cosmetics is used for the whole group of products used for external care of the body (4) (Table 1).

Five dermatology departments in different parts of Sweden participated in this prospective study during a period of 6 months in 2008–2009. All consecutive patients who were patch-tested with their own cosmetics were included.

For patch testing, the Swedish baseline series, consisting of 30 allergens, was used by all participating centres. In addition, patients were tested with different screening series and their own cosmetic products that they had brought with them, either 'as is' or diluted as appropriate, depending on the particular product. The test panels were applied on the upper back for 2 days. The test reactions were read twice (on days 3 and 7), and were determined as allergic, irritant, doubtful or negative according to established criteria recommended by the International Contact Dermatitis Research Group (5). The relevance

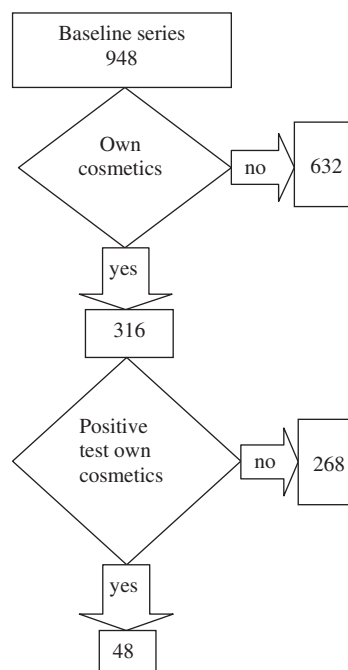
was estimated in connection with the second reading as current, previous, not relevant, or unknown. No patients were tested with separate raw materials from the cosmetic products involved or with a repeated open application test (6).

For all patients with positive patch test results for their own cosmetics, photocopies of medical records and test protocols and photographs or photocopies of the containers of the products involved were sent monthly as reports of suspected adverse reactions to the MPA. The product category, the name of the product and the manufacturer were specified in the test protocol. The photographs or photocopies should show the name of the product and the manufacturer, batch number, and listing of ingredients. Causality assessments were made at the MPA in accordance with the resolution of the Council of Europe on cosmetovigilance (7).

Test protocols for patients with negative results were collected with information limited to sex and age. The total number of patients patch-tested with the baseline test panel was also reported.

Results

For the number of patients tested, see Fig. 1. A total of 948 patients were patch-tested with the baseline series. Three hundred and sixteen (33%) of them were also tested with

**Fig. 1.** Number of patients patch-tested.

their own cosmetics. The proportion of patients tested with their own cosmetic products ranged between 21% and 53% in the various departments. Most patients (78%) were tested with one to five different products. Nineteen per cent were tested with 6–10 products, 3% were tested with 11–15 products, and 1 patient was tested with 18 products.

Forty eight of the 316 patients tested (15%) had one or more positive patch test reactions to their own cosmetics (62 different products), and these were reported as suspected adverse reactions to the MPA. These reports included 42 women and 6 men. The age of the women ranged from 16 to 79 years (mean 47 years), and that of the men from 25 to 60 years (mean 42 years). In this test-positive group, 75% were tested with 1–5 different products, 17% with 6–10 products, and 8% with 11–15 products.

The product categories and number of positive test reactions are shown in Table 1. As can be seen, most reactions were found for skin creams, followed by soap and other cleansing products.

A number of allergens that are commonly present in cosmetics were included in the baseline and different screening series. Seventeen patients had positive patch test results for 20 individual allergens. The most commonly found positive test reactions were for perfume compounds (10/20, 50%). Three (3/20, 15%) cases of allergic reactions to preservatives were found. The relationship between single allergen positivity and product category positivity is shown in Table 2.

According to the medical evaluation at the MPA, 47 patients had allergic contact dermatitis for 61 different products, and the causality was assessed as 'very likely' for 58 products and 'likely' for three products. For 1 patient, photo-allergic contact dermatitis was reported, and the causality in this case was assessed as 'very likely'.

For 49 products (79%), photographs or photocopies of the containers of the products were included in the report. Batch numbers were submitted for 19 (30%) of the products. For 34 products (55%), the submitted information about the product and its ingredients was sufficient, and it was not necessary to contact the manufacturer before finalizing the assessment.

Discussion

When considering cosmetic allergy, it is of foremost importance to extend the patch testing beyond the baseline series (8), preferably including the patients' own products (9). In this prospective study performed at five Swedish dermatology departments, one-third of the patients had their own cosmetics included in the patch testing. This is in line with a retrospective Danish study, in which, during a 2-year period, contact allergy to cosmetics was suspected and tested for in 35% of patients with contact dermatitis (10). However, the proportion of patients tested with their own cosmetics differed between our participating centres, between 21% and 53%. The departments were told to use their normal indications for testing,

Table 2. Relationship between single allergen positivity and product category positivity

Product category	Specific allergens/INCI name*						
	Perfumes ^a	Preservatives ^b	Surfactants ^c	Colophonium	Propolis	Propyl gallate*	PTGC ^d
Skin creams, lotions, gels, oils	3/17	1/17	1/17	1/17	1/17	—	—
Soap and other cleansing products	3/11	—	1/11	—	—	—	—
Shampoo and hairstyling products	1/7	—	1/7	—	—	—	—
Nail products	—	1/6	—	—	—	—	1/6
Mascara	—	—	—	—	—	—	—
Make-up for skin	—	—	—	—	—	—	—
Lipstick	—	—	—	—	—	1/3	—
Sunscreen products	1/2	—	—	—	—	—	—
Perfume products	—	—	—	—	—	—	—
Anti-wrinkle products	—	1/2	—	—	—	—	—
Depilatories	—	—	—	—	—	—	—
Deodorants, antiperspirants	2/1	—	—	—	—	—	—
Products for tanning without sun	—	—	—	—	—	—	—
Total	10	3	3	1	1	1	1

^aPerfume mix, *Myroxylon pereirae*, linalool, D-limonene.

^b*Formaldehyde, *diazolidinyl urea.

^c*Cetearyl alcohol, *cocamide dea, *cocamidopropyl betaine.

^dTrimellitic anhydride/glycol copolymer.

and a variable degree of awareness of and interest in cosmetic dermatitis between the clinics cannot be excluded.

In the present study, 15% of the patients had one or more positive reactions to their own cosmetic products. Only a handful of studies have been published on patients tested with their own cosmetics, and, in a study published in 1999, the proportion of positive test reactions was 7.5% (10).

The main product categories that caused positive patch test results were different skin creams, (27%) and soap and other cleansing products (18%) (Table 1). This is in agreement with a retrospective study by the Information Network of Departments of Dermatology (11). The high proportion of positive test results for skin creams is similar to earlier Danish results (38%) (10), and is not surprising, as this product category is one of the most widely sold and used.

The test-positive patients were obviously using many different cosmetic products, as 8% of them were tested with 11–15 products. In the test-negative group, only 3% brought in more than 10 products. This implies that exposing the skin to many different cosmetics increases the risk of developing allergic contact dermatitis for such products.

Regarding testing with individual cosmetic allergens, a weighted prevalence rate of 9.8% of positive test results in patients referred for patch testing by a dermatologist has been identified (12). In a recent US-based study of 10 061 patients, 23.8% of the females and 17.8% of the males had at least one allergic patch test reaction associated with a cosmetic source (13). In our study, only 17 patients of the 316 who were tested with their own cosmetics showed positive patch test reactions to 20 individual cosmetic allergens. The discrepancy between the 62 recorded positive reactions to products (Table 1) and the 20 reactions to single allergens (Table 2) is attributable to the fact that the participating clinics were instructed to follow their usual testing procedures. Thus, the Swedish baseline series was used by all clinics, but the added screening series were different. Moreover, no patients in this study were tested with single allergens from the products giving positive test results. In our group, the majority (50%) of single allergens were related to perfume compounds. It has been estimated that between 1% and 4% of the general population is allergic to fragrances (14), and, in dermatitis patients seen by dermatologists, a prevalence of contact allergy to fragrances of between 5.0% and 12.6% has been reported (15). Second to fragrances, preservatives are the most common cosmetic allergens (16). However, in our small group, we only found a few reactions (3) related to preservatives, although the most common of these allergens are included in our baseline series.

In addition to the reports of adverse reactions submitted within the study, the MPA received 17 more reports, resulting in a total of 65 reports from October 2008 to March 2009. This is a considerably higher number of reports than during the corresponding 6-month periods of 2005–2008, when only about 20 reports were submitted. This supports the view that far from all adverse reactions are reported to the MPA, even when cosmetics are suspected and/or patch-tested.

An important aim of this study was to obtain more information about the products from the reporters, thereby simplifying the processing of the reports at the MPA. Similar problems with the recording of products have been discussed by Sportiello et al. (17). In our current study, the identification of the cosmetic products involved was easier to achieve at the MPA when photographs or photocopies were included than when only the names of the products were submitted. The batch numbers were less frequently submitted, as they were often difficult to find and read on the packaging. The processing within the MPA was faster because of the better identification of the products. These improvements resulted in faster and more reliable reporting to the companies responsible.

The high proportion (95%) of reports assigned the causality assessment 'very likely' is attributable to the fact that only patients with positive patch test results were reported in this study. Normally, this assessment is assigned less frequently, for example in 56–78% of the reports during the corresponding periods of 2005–2008.

The need for more careful and reliable control of undesirable effects of cosmetics has been alerted by the Council of Europe (7). In the current legislation within the EU, it is not mandatory for the authorities to collect information on adverse reactions to cosmetic products. In Sweden, a voluntary adverse reaction reporting system was introduced in 1989. During recent years, some other countries, for example France and Norway, have also set up their own reporting systems.

Today, manufacturers are already obliged to keep information about undesirable effects on human health in their documentation on individual cosmetic products, and this information must be accessible to the competent authority (18). This requirement is supplemented in new legislation, where special attention is given to the severe adverse effects. In the new EU Regulation on cosmetics, which will come into force in 2013, it will be mandatory for some stakeholders, that is, the manufacturers, distributors, and competent authorities, to report severe undesirable effects to each other (19).

A prerequisite for the reporting systems fulfilling their aims is that most of the adverse effects are

reported by healthcare personnel and consumers, either to the manufacturer or to the authorities. Our study shows that the reporting process can be promoted and improved.

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