

Difficulties in avoiding exposure to allergens in cosmetics

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The aim of the study is to describe the ability of patients with allergic contact dermatitis to avoid exposure to allergens in cosmetics. The study is a questionnaire survey among 382 patients with contact allergy to preservatives and fragrances, included from 3 dermatological clinics. The questionnaire included questions about the level of difficulty in reading labels of ingredients on cosmetics and about patients' strategies to avoid substances they were allergic to. It also included questions about eczema severity as well as about educational level. 46% of the patients found it difficult or extremely difficult to read the ingredient labelling of cosmetics, and this finding was significantly related to low educational level. Patients allergic to formaldehyde and methyl dibromoglutaronitrile experienced the worst difficulties, while patients with fragrance allergy found ingredient label reading easier than patients with preservative allergy. Reading of ingredient labels is a major problem for patients with contact allergy to allergens in consumer products. It is a general problem for all patients and not restricted to a small group with multiple allergies.

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Elimination of the allergen is an effective remedy in the treatment and prevention of allergic contact dermatitis. Compliance with avoidance of contact allergens for patients with contact allergy is of major importance for the prognosis of allergic contact dermatitis (1, 2). Consequently, when sensitization to ingredients in consumer products is diagnosed, the patients are instructed to avoid allergen exposure by careful reading of ingredient labels. For cosmetic products, the labelling should be in accordance with the International Nomenclature of Cosmetic Ingredients (INCI), which is used throughout all the EU member states as a means of informing the consumers (3).

Theoretically, reading of labels should make it possible for the patients to avoid relevant allergens. However, compliance is often not satisfactory, and an explanation for this could be patients' lack of capability to read ingredient labels and in this way avoid exposure to relevant allergens. A previous qualitative study has indicated that patients find ingredient labels very difficult to read and that the degree of difficulties is increasing with low social status (4).

Few data are available about the ability of the patients to take necessary precautions to avoid exposure to substances in cosmetics and toiletries and this is the focus of the present study.

Subjects and Methods

The study is a postal questionnaire survey among patients with allergic contact dermatitis to fragrances and preservatives. Questions were inspired by sociological theory (5) and were either previously used in other studies or formulated based on interviews with patients with allergic contact dermatitis (4, 6).

A preliminary questionnaire, which consisted of 95 questions, was tested in a pilot group of 10 patients. The relevance and understanding of each question in the completed questionnaire were discussed with the participants. Categories were added or removed, ambiguous questions were omitted or changed, which left 83 questions in the final questionnaire.

The patients were generally taught to read INCI names on the labelling. The presence of perfume

was recognized by the patient in the ingredient label by the word 'perfume' or in some cases by the name of specific fragrances.

The questionnaire included questions about degree of difficulty in reading the labels of ingredient, the quality of ingredient labels, and patients strategies to avoid ingredients that they are allergic to.

The degree of difficulty in reading the labels of ingredients was assessed by the patients on a 100-mm visual analogue scale (VAS) with numbers from 0 to 10; 0 meaning extremely easy and 10 meaning extremely difficult. The exact wording of the question was 'How do you experience reading the ingredient labels on cosmetics? Mark the number that corresponds to the degree of difficulty'.

With regard to evaluation of the quality of the ingredient labellings the patients were asked to consider the following statements: 'Ingredient labellings are easy to separate from other text', 'The size of letters is appropriate', 'Ingredient names are easy to read', and 'Labels of ingredients are accurate'. Response categories were 'Agree', 'Disagree', and 'No opinion'.

Furthermore, the questionnaire included questions about education, which was classified according to its level on completion (7).

Questionnaires were posted in the summer of 2004, and non-responders received 2 reminders with an interval of 2 weeks.

Participants

Patients were recruited from out-patient dermatological clinics in 3 centres in different parts of Denmark in the period 1 July 2000 to 30 June 2003.

Inclusion criteria were as follows – age 18–65 years and contact allergy identified as a positive patch test to 1 or more of following preservatives and fragrances: formaldehyde, quaternium-15, methyl-dibromo glutaronitrile (MDBGN), methyl-isothiazolinone/methylchlorisothiazolinone, parabens, balsam of Peru, and fragrance mix I. All patients with positive reactions were included. Exclusion criteria were atopic dermatitis and not Danish speaking. Permission was obtained from The Danish Data Protection Agency.

Statistical analysis

Comparison of 2 proportions was performed using chi-squared test and where appropriate Fisher's exact test, using 0.05 as the level of significance.

Multivariate analysis was performed as binary logistic regression with difficulties in reading ingredient labelling as response variable (VAS 7.5–10 as difficult or extremely difficult; versus

<7.5). Explanatory variables were educational level, types, and number of allergies. Associations were expressed as odds ratios with 95% confidence intervals. Statistical significance was defined as $P < 0.05$. SPSS version 14.0 was used.

Results

The overall response rate was 79%, as 485 patients were available for the study, and a total of 382 patients (109 men and 273 women) responded to the questionnaire. 10 patients (2%) could not be traced, 7 patients (1%) declined to participate for various reasons and 86 patients (18%) did not respond.

The mean age among responders was 48 years (range 19–65 years). Non-responders were slightly younger (mean age 46 years, range 20–65 years) but not statistically significantly. No significant differences between responders and non-responders was found regarding distribution of sex, allergies, and recruitment centres.

In total, 170 patients (46%) found it difficult or extremely difficult to read the ingredient labels of cosmetics and toiletries defined as the upper quartile of the VAS (7.5–10). The distribution of sex, age, eruptions, education, and types of allergies according to degree of difficulties in reading the ingredient labels is given in Table 1.

Finding reading of ingredient labelling difficult or extremely difficult was independent of sex and age but significantly related to the educational level. More patients with lower educational level found it difficult or extremely difficult to read the ingredient labelling than those with long or medium further education. This finding was confirmed by the multivariate logistic regression analysis with difficulties in reading ingredient labels as response variable (Table 2). Fewer patients with fragrance allergy found it difficult or extremely difficult to read the label of ingredients compared with those with both fragrance and preservative allergy (Table 2); this effect disappeared in the multivariate analysis, when other variables were entered. No statistically significant interactions was detected although noted between fragrance mix allergy and the other variables in the equation. With respect to the different kinds of preservative allergy, significantly more patients with contact allergy to formaldehyde and MDBGN experienced major difficulties in reading ingredient labels than those with contact allergy to the other preservatives (Table 2). Among patients with quaternium-15 allergy, a majority [14/23 (60%)] found major difficulties in reading the ingredient labels. However, these 14 were also allergic to formaldehyde, and the relationship to difficulties

Table 1. Level of difficulty in reading label of ingredients in relation to sex, age, frequency of eruptions, education, types of allergies, and specification of allergies. Univariate analysis using chi-squared test and where appropriate Fisher's exact test^a

Variable	VAS <7.5, n = 205 (%)	VAS 7.5–10, n = 170 (%)	Total, n = 375 (%)	P-value ^b
Sex ^c				0.406
Males	61 (58)	44 (42)	105 (100)	
Females	144 (53)	126 (47)	270 (100)	
Age (years) ^c				0.504
19–35	29 (54)	25 (46)	54 (100)	
36–50	83 (59)	59 (41)	142 (100)	
51–65	93 (52)	86 (48)	179 (100)	
Eruptions				0.442
Constant/frequent	115 (53)	103 (47)	218 (100)	
All others	88 (57)	67 (43)	155 (100)	
Missing values	2		2	
Education				0.019
Medium/long further education	49 (67)	24 (33)	73 (100)	
All others	155 (52)	144 (48)	299 (100)	
Missing values	1	2	3	
Types of allergies ^c				0.0001
Preservatives and fragrances	19 (40)	28 (60)	47 (100)	
Only preservatives	67 (46)	79 (54)	146 (100)	
Only fragrances	119 (65)	63 (35)	182 (100)	
Specification of allergies (positive to) ^c				
Formaldehyde	22 (39)	35 (61)	57 (100)	0.008
Methylisothiazolinone/methylchloroisothiazolinone	28 (54)	24 (46)	52 (100)	0.8
Methyldibromo glutaronitrile	40 (42)	55 (58)	95 (100)	0.004
Parabens	4 (57)	3 (43)	7 (100)	1.00 ^d
Quaternium-15	9 (39)	14 (61)	23 (100)	0.122
Balsam of Peru	49 (62)	30 (38)	79 (100)	0.139
Fragrance mix I	118 (62)	74 (38)	192 (100)	0.007

VAS, visual analogue scale.

^aThis Table is based on 375 patients as 7 patients did not answer the question about level of difficulty in reading labels of ingredients on cosmetics. Using VAS, the upper quartile is defined as those who find it most difficult to read labels (VAS 7.5–10).

^bChi-squared test for equal distribution between patients finding it most difficult to read labels on cosmetics (VAS 7.5–10) and patients finding it less difficult (VAS 0–7).

^cData were obtained from the patients files.

^dFisher's exact test.

in reading the labels was not significant in the multivariate analysis.

275 patients (72%) had 1 allergy and 107 patients (28%) had 2–4 allergies among the 7 target allergens. Only 5.5% were allergic to more than 2 of these allergens. In the multivariate regression analysis, no significant relationship between having difficulties in reading labels and having multiple allergies (more than 1 allergy) was found (Table 2).

In qualifying which aspects of ingredient labeling was difficult, most patients found that reading the chemical names was difficult, a majority also found the size of the letters problematic and half of the responders did not trust the correctness of the ingredient labelling (Table 3).

Most patients [303/375 (79%)] always or frequently try to read the label of ingredients of cosmetic to determine whether a cosmetic product contains substances they are allergic to and fewer test the product [142/367 (37%)] and/or consult the shop assistant [121/367 (32%)]. Of the 233 patients allergic to fragrance mix and/or balsam

of Peru, 44% of patients always or frequently smell to the product, before buying or using it, to avoid contact allergens.

Discussion

This study is the first to scientifically evaluate difficulties in reading ingredient labels on cosmetics among patients with allergic contact dermatitis. The present data from a population of patients with allergic contact dermatitis to fragrances and preservatives show that 46% of the patients found it difficult or extremely difficult to read the ingredient labels of cosmetics and toiletries. The difficulties were unrelated to sex and age, but a strong relationship was found between low educational level and high degree of difficulties in reading the labels. Considering the length of the chemical names of the allergens, this is not surprising, but important for the clinician to remember when advising the patient because different strategies may be successful for patients with different educational levels. In a recent study of the prognosis

Table 2. Multivariate logistic regression analysis with degree of difficulties in reading ingredient labels [dichotomized as very difficult (VAS 7.5–10) versus less difficult (VAS <7.5) as response variable and different explanatory variables tested in 4 different models

Explanatory variables	Odds ratio	95% confidence interval	P-value
Model 1			
Age 19–35 (years)	1 (reference)		
Age 36–50 (years)	0.83	0.43–1.56	0.565
Age 51–65 (years)	1.05	0.56–1.96	0.878
Sex: female/male	1.23	0.77–1.98	0.382
Educational level: lower/medium–high	1.85	1.08–3.18	0.026
Model 2^a			
Allergy to both (reference)	1 (reference)		
Allergy to preservatives, only	0.78	0.39–1.56	0.490
Allergy to fragrances, only	0.35	0.17–0.68	0.002
Model 3^a			
Methylchloroisothiazolinone/methylisothiazolinone	1.11	0.58–2.15	0.737
Methyldibromo glutaronitrile	2.01	1.10–3.68	0.022
Paraben mix	1.33	0.28–6.37	0.722
Quaternium-15	1.45	0.57–3.72	0.439
Balsam of Peru	0.86	0.48–1.53	0.608
Fragrance mix	0.85	0.50–1.44	0.547
Formaldehyde	2.09	1.05–4.17	0.035
Model 4^a			
Monoallergy	1 (reference)		
Multiple allergies	0.77	0.48–1.22	0.266

VAS, visual analogue scale.

^aControlled for sex, age, and educational level.

Table 3. Patients' perceptions regarding ingredient labelling on cosmetics

Quality of ingredient labelling	Agree, n (%)	Disagree, n (%)	No opinion, n (%)
Difficult to separate from other text (n = 374)	173 (45)	107 (28)	94 (25)
Size of letters inappropriate (n = 379)	257 (67)	72 (19)	50 (13)
Ingredient names difficult to read (n = 378)	287 (75)	34 (9)	57 (15)
Labels of ingredients inaccurate (n = 377)	185 (48)	14 (4)	178 (47)

for occupational hand eczema, low socioeconomic status was reported as a risk factor for prolonged sick leave and loss of job (8). Difficulty in reading the ingredient labels is just one of the factors making patients with eczema and low educational level a vulnerable group.

Fewer patients with fragrance allergy found it difficult to read an ingredient label, which is probably explained by the fact that in this group, 44% of patients also smell the product before buying. However, still 38% of patients with perfume allergy found label reading difficult.

Patients with allergies to preservatives experienced major difficulties with ingredient label reading, and among these patients especially those allergic to formaldehyde and MDBGN had trouble. With respect to formaldehyde allergy, also the names of synonyms and formaldehyde releasers need to be taken into account, and this makes

avoidance of this allergen especially difficult. Benefits from special care taking of patients with formaldehyde allergy have previously been reported (1, 9). With respect to MDBGN, an allergen often causing hand eczema and no longer recommended for use in cosmetics (10), it is probably the long chemical name that makes it difficult.

The Scientific Committee on Consumer Products advisory to the EU Commission has previously expressed their concern regarding very long and difficult INCI names assigned to well-known allergens. They have suggested that more easily recognized INCI names may be of assistance to the consumer (11). No regulatory initiatives has been taken yet.

Naturally, in cases of more than 1 allergy, the matter of reading the ingredient labels is further complicated. However, in our data, we do not find that this group differs significantly from patients with only 1 allergy with respect to difficulties in label reading. Reading and understanding the ingredient labels is a general problem and not constricted to the relatively smaller group with multiple contact allergens.

It is notable that just about half of the responders do not trust the accuracy of the labels of ingredients. One explanation is that patients experience eczema eruptions even if they make an effort to avoid contact with allergens by reading the labels of ingredient on cosmetics; another that the information on labels of products and from manufacturers may not be reliable (12).

Conclusions

Although it is widely accepted that reading ingredient labels may cause difficulties for many patients, it is remarkable that 46% of patient with contact allergies experienced major difficulties. More difficulties were experienced by patients with low educational level, indicating that different management strategies should be preferred by different patient groups. Patients allergic to formaldehyde had severe problems, which may be because of the necessity of also being aware of the formaldehyde releasers, and patients with MDBGN allergy also had severe problems, probably because of the very long and difficult name of the allergen. Patients with fragrance allergy had fewer problems with label reading than those with preservative allergy, but still 38% of patients allergic to fragrances had severe difficulties with label reading. The problem with ingredient label reading is common, not restricted to any specific groups, and general for all patients with contact allergy to allergens in consumer product.

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