

CONTACT ALLERGY TO PRESERVATIVES IN COSMETICS AND RELATIONSHIP TO THE DEGREE OF FORMALDEHYDE ALLERGY

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Synopsis

In 6200 patch test series performed because of the tentative diagnosis "contact dermatitis" we found 497 (8.0%) positive patch test reactions to potential ingredients of cosmetics, 221 (3.6%) of them at all relevant and only 8 (0.1%) due to formaldehyde releasers (FR).

Test series with different formaldehyde concentrations and FR in 140 patients suffering from proven allergy to formaldehyde revealed:

The potential hazard of allergic side effects varies among the different FR and is correlated with the degree of formaldehyde sensitivity.

Riassunto

Nel tentativo di giungere ad una diagnosi certa si sono eseguiti 6.200 patch test predittivi.

497 (8%) delle risposte positive sono da addebitarsi a ingredienti cosmetici.

La reattività è molto evidente in 221 (3,6 %) patch test e soltanto 8 (0,1 %) risposte positive sono attribuibili a composti donatori di formaldeide. È stato, inoltre, rilevato che il grado di positività riscontrata per la presenza dei donatori di formaldeide è direttamente correlabile al grado di sensibilizzazione alla formaldeide dei soggetti esaminati.

Cosmetic-related allergies are the subject of numerous publications. So will only briefly present our epidemiological data, which is limited to emulsifiers and preservatives, and draw attention to possible correlations with the formaldehyde allergy.

7254 patients were patch tested because of a tentative diagnosis of "contact dermatitis or eczema", 5470 with the GDR-standard series, containing wool alcohols and parabens, and 620 with a special series (emulsifiers and preservatives); altogether 6200 patients were tested with potential ingredients of cosmetics.

In table 1 the statistical results from our computer stored data are summarized. The relevance was determined on the basis of case history and medical examination. This table shows two things: first the well known fact that side effects from additives are much more frequent in therapeutic preparations, applied to damaged skin and probably containing other powerful sensitizers, than in cosmetics. The relation 221:45, that is about 5:1, agreed with

other published experiences in this field.

Secondly we can see that the ranking list of such allergens depends on the frequency of performed tests and on the duration and amount of exposure. Parabens have for many years been the basic preservatives in nearly all vehicles of the oil in water-type, produced in the GDR.

Piasolan®, an imidazolidinyl urea like Germall®, has been used for about 10 years, Bronopol® and Kathon CG® since 1985. The "other preservatives" include sorbic acid, gallates and benzalconium chloride, up to now (1989) no Kathon CG®. From the 8 cosmetic-related allergies to formaldehyde releasers (FR) only 5 also showed a formaldehyde allergy. As these substances are no part of the standard series, a lot of sensitizations may have been undetected. On the other hand, formaldehyde has unquestionably been the major allergen in the GDR for many years, especially in young women, that is in persons who normally use a lot of cosmetics. So we considered whether cosmetic intolerance might be related to formaldehyde allergy.

Table I

POSITIVE PATCH TESTS

Emulsifiers Preservatives	total	relevant at all	cosmetic related
Wool alcohols	156	99	12
Other emulsifiers	27	18	5
Parabens	155	83	15
Formaldehyde-releaser	46	14	8
Other preservatives	13	7	5
Total	497	221	45
% of 6200 test series	8.0	3.6	0.7

In cooperation with Rothe and Zschunke from the Central Institute of Occupational Medicine in Berlin we tested this series (upper line) and in our department, moreover, these additional formaldehyde concentrations. In 20 patients, most of them with minor symptoms or a family history of atopy, repeated control tests revealed slight irritant reactions to the 1% and 0.7% preparations. It should be kept in mind that these generally recommended concentrations might give rise to false positive reactions in several cases. The vehicle of the FR (ungt. emuls. aquos.) is the o/w-emulsion of our pharmacopoeia and the basic vehicle in this type of cosmetic.

In the remaining 140 subjects, suffering from proven allergy to formaldehyde, confirmed by repeated patch testing and additionally by the case history and clinical pattern, we obtained these results:

Two aspects are of cosmetical interest.

1.: The potential hazard varies distinctly among the different FR. It is low for Bronopol®, somewhat higher for Germall® and Piasolan®, respectively, and clearly higher in Dowicil 200®. Grotan BK®, a biocide in cutting fluids, is the strongest allergen and clearly releases the most formaldehyde. Among these 3 preservatives the

amount of free formaldehyde in fresh and 3 month stored preparations, respectively, decreased from Dowicil 200®, set as 100%, to about 50% in Germall 115® and 20% in Bronopol®, as described by HABEL. This is the same order as in most other published ranking lists of contact allergies to cosmetics, for instance those by FISHER, DE GROOT or EIERMANN. Though only a part of the allergies to such preservatives is coupled with a formaldehyde allergy, their sensitizing potency is obviously related to the amount of released formaldehyde.

2.: The frequency of positive tests due to FR is significantly correlated with the degree of hypersensitivity to formaldehyde ($p < 0.01$).

Hence it follows that especially in persons with highly marked hypersensitivity to formaldehyde FR in cosmetics are capable of provoking relapses of allergic dermatitis. But even these positive patch test reactions do not automatically imply an intolerance of cosmetics. Only 5 of the 66 allergic women, tested in Dresden, had a confirmed case history of contact dermatitis from skin care products containing FR. None had problems with rinse off products. So we believe, that patients with formaldehyde allergy, provided it is not an extreme one, need not com-

Table II

SUBSTANCES, CONCENTRATIONS AND VEHICLES USED IN PATCH TESTING:

Formaldehyde 0.7%, 0.35%, 0.2%, 0.05% w.
(additional in 86 patients from Dresden formaldehyde 1% pet., 1% and 0.1% w.)

Piasolan 2%, Dowicil 200 and Germall 115 1%,

Bronopol 0.25% in ungt.emuls.aquos.

Grotan BK 1% w.

pletely avoid cosmetics preserved by such chemicals. But to prevent adverse effects from possibly incorporated FR, they should perform a repeated open application test before using a new, unknown cosmetic.

Table III

Reactivity to FR	Degree of hypersensitivity to formaldehyde (%w)				Positive reactions
	0.7	0.35	0.2	0.05	
Bronopol		1	1	3	5
Germall 115		2	5	2	9
Piasolan		2	7	4	13
Dowicil 200	1	4	16	14	35
Grotan BK	3	14	42	19	78
FR negative	17	23	11	0	-
No. of subjects	21	40	59	20	140

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