ETAD

Final Report on the Project
"Prospective investigation on frequency and spectrum of contact allergy to textile dyes"

Project Coordination:

Prof. [redacted], Institute for Medical Informatics, Biometry und Epidemiology, Erlangen, Germany

Prof. [redacted], IVDK-Center, Göttingen University, Germany

Dr. [redacted], ETAD (the Ecological and Toxicological Association of Dyes and Organic Pigments Manufacturers), Switzerland

Summary

A two-year monitoring of cases of allergic contact dermatitis reported to 15 dermatological centers, all members of the German Information Network of Departments of Dermatology, was performed. Aim of the study was to ascertain the relevance of dyes used in textiles as cause of allergic contact dermatitis and, if necessary, to clarify the precise identity of any suspected dye. With no reported cases ascribable to the presence of dyes, the study confirmed previous ETAD results which indicated the negligible relevance of textile dyes as responsible of allergic skin reactions.

Introduction

The topic of contact allergy to textiles components has been followed closely by ETAD since 1996, being even the subject of specifically developed guidelines[a, b]. Reviewing the existing information, it became evident that a structured approach was necessary to clarify and quantify the consumer exposure to dyes classified as skin sensitizers, and derive a realistic risk assessment for them.

A specific project in collaboration with Prof. [redacted] and Prof. [redacted] was started in 2000 with the main goal of better understanding the actual relevance of textile dyes for allergic contact dermatitis, including the question whether patch test positive dyes were actually contained in the garments the patient had been exposed to. The study contacted 200 physicians worldwide and received inputs from USA, Canada, Belgium, UK and Portugal. The results of the study were published in form of various articles[c, d, e] and showed a low clinical relevance of positive patch tests, as well as a decisive role of perspiration fastness in the observed allergic reactions. Furthermore, the incidence rate of actual textile dyes-related contact dermatitis appeared to be extremely low.

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[a] ETAD, *Risk Assessment of Contact Sensitizing Disperse Dyes in Representative Textiles*, ETAD Project G1033/1041, **1996**

[b] ETAD, *Extractability of Dyestuffs from textiles over a normal life time of use*, ETAD Project G 1033, **1997**

[c] Hatch K. L., Motschi H., Maibach H. I.,*Textile-Dye and Colored-Textile Allergic Contact Dermatitis*, Exog. Dermatol 2, **2003**, 206-209.

[d] Hatch K. L., Motschi H., Maibach H. I., *Identifying the Source of Textile Dye Allergic Contact Dermatitis*, Exog. Dermatol 2, **2003**, 240-245.

[e] Kimber I., Maibach H. I., Motschi H., *Thresholds of contact sensitization from disperse dyes in textiles*, Contact Dermatitis 52, **2005**, 295.

The presentation of the study results to the German authorities in 2005 triggered the idea of a common project between ETAD and IVDK (the German Information Network of Departments of Dermatology) as continuation and further evolution of the screening, and the study outlined in next chapter was agreed upon.

Fig. 1. ***Flow chart of the study protocol***

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Short description of the project

The collaboration began in 2009 as a multicenter 2-years study coordinated, for the diagnostic part, by Prof. [redacted] (Erlangen) and Prof. [redacted] (Göttingen) and, for the analytical part, by Dr. [redacted] (ETAD).

The study consisted of two steps:

- Collection of cases with detailed case description, followed by patch tests with both a textile allergen series and a piece of suspected garment(s), in order to have evidence of an actual possible connection between the allergic reaction and the presence of dye(s);
- Analysis of suspected garments as regards fiber composition, color fastness to perspiration as well as analysis of acetone extracts for presence of textile dyes. In case of detection of new suspect disperse dyes, an addition patch test to be performed with them.

A flow chart of the study steps is presented in Figure 1.

The screening of suspected garments was performed by IVDK and the ESSCA networks, which comprise some 70 centers in 11 European Countries (a comprehensive list of participating dermatologists can be found in Annex I). ETAD agreed to sponsor and organize the analytical part of the project, carried on by an external qualified laboratory.

Results and Conclusions

In spring 2011, the project was formally terminated. Despite the remarkable commitment of all collecting partners, no case came through the first step of the protocol and was considered eligible for the second step. Even taking into account the restrictive inclusion/exclusion criteria in the case selection, the complete lack of reports seems to reflect the very low incidence rate already concluded by the precedent ETAD project.

Nevertheless, the study protocol in the framework of the project can still be used as a guideline for diagnostic work-up of the rare eligible patients there may be in the future. Discussing about this possibility, ETAD expressed its willingness to further support IVDK by the analytical part of the protocol in case such cases would appear.

The detailed study protocol can be requested at info@etad.com.

Annex 1: List of participating dermatologists:

Department	*Contact*
Bayreuth	[redacted]
Berlin	[redacted]
Bern	[redacted]
Bochum	[redacted]
Dresden	[redacted]
Erlangen	[redacted]
Essen	[redacted]
Graz	[redacted]
Hamburg	[redacted]
Hannover	[redacted]
Heidelberg/AKS	[redacted]
Jena	[redacted]
Magdeburg	[redacted]
München/LMU	[redacted]
Osnabrück	[redacted]