

Contact Allergy to Textile Dyes

Prevalence analysis of patch test data from the baseline series in the Swedish database EpiReg

PM 7/16



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Article number: 511 229.

Preface

On behalf of the Swedish Government, the Swedish Chemicals Agency has developed an action plan for a non-toxic everyday environment. The action plan highlights textiles as a prioritised group of consumer articles in the work towards a non-toxic everyday environment. As part of our work on the action plan, the Swedish Chemicals Agency develops proposals for risk minimising measures of hazardous chemicals within the European Union. The purpose of the present study is to gain more knowledge on the prevalence of contact allergy to skin sensitising substances in textiles in Sweden, using textile dyes as a marker. This PM is intended as a knowledge base for future risk management on skin sensitising substances in textile articles.

Clinical patch test data from patients with signs of contact allergy is, on a voluntary basis registered in a database, which is a part of the Swedish Contact Dermatitis Research Group. Hence, the Swedish Chemicals Agency commissioned the contact person of the register, Professor Senior Consultant Magnus Lindberg at Region Örebro County, Örebro University Hospital to perform a compilation and analysis of such data in order to estimate the prevalence of contact allergy to textile dyes among the Swedish population during 2015 and to conclude on the results in the present study.

The Swedish Chemicals Agency would like to thank Professor Senior Consultant Magnus Lindberg at Region Örebro County, Örebro University Hospital.

The conclusions and recommendations presented in the study are those of the author and do not necessarily reflect the view of the Swedish Chemicals Agency.

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Summary

The Swedish Chemicals Agency has made a risk management option analysis of possible regulatory actions within the REACH Regulation, to protect vulnerable people from contact allergy to allergens in textiles. In order to assess whether there are sufficient grounds to develop a proposal for risk minimising measures, further information on the prevalence of contact allergy to skin sensitising substances in textiles is needed.

Since 2015, a mix of textile dyes is included in the Swedish¹ and European² baseline series of epicutaneous tests which is routinely used to diagnose contact allergies. The mix can be used as a marker of contact allergy to allergenic textile dyes. This means that since 2015 dermatitis patients are routinely tested for certain textile dyes. In Sweden, the following information is reported and compiled annually in the database EpiReg of the Swedish Contact Dermatitis Research Group: the result of the patch test with the base line series, age, sex, year and clinic. The participating clinics that provide data to be registered in the database are doing so voluntarily.

Magnus Lindberg, MD, PhD, Professor, Senior Consultant, at Region Örebro County, Örebro University Hospital, and manager of the EpiReg database was given the task to compile and analyse available data on contact allergy to the textile dye mix reported to the EpiReg database from 2015 and onward. The assignment also included if possible to estimate the overall prevalence of contact allergy to textile dyes in Sweden.

The information reported to the EpiReg database showed that 3.12% of the dermatology patients that had been tested for the Swedish baseline series had a contact allergy to the textile dye mix. In order to estimate the overall prevalence in the Swedish population and to analyse the total costs for the society more data is needed to complement EpiReg, i.e. information about the use of different dyes, how often persons have allergic problems with textiles, and the relevance of positive tests for textile dyes.

¹ <http://ssdv.se/svenska-saellskapet-foer-arbets-och-miljoedermatologi-ssamd/riktlinjer-och-testserier-for-utredning-av-hudallergi/svensk-basserie-2016>

² <http://www.chemotechnique.se/products/series/european-baseline-series/>

Sammanfattning

Kemikalieinspektionen har gjort en riskhanteringsanalys som identifierar möjliga åtgärder inom ramen för Reach-förordningen för att skydda känsliga personer från kontaktallergi av allergiframkallande ämnen i textil. För att bedöma om det finns tillräcklig grund för att vidta regulatoriska åtgärder samt för att kunna ta fram ett åtgärdsförslag krävs dock ytterligare information om förekomst av kontaktallergi mot farliga ämnen i textilier.

Från och med 2015 ingår en mix av textilfärgämnen i den svenska³ och den europeiska⁴ basserien för epikutantester som rutinmässigt används för att diagnostisera kontaktallergi. Mixen kan användas som en markör för kontaktallergi mot allergiframkallande ämnen i textilier. Det innebär att sedan drygt ett år tillbaka testas patienter med misstänkt kontaktallergi rutinmässigt för vissa textilämnena. I Sverige rapporteras och sammanställs årligen följande uppgifter i databasen EpiReg av Svenska Kontaktdermatitgruppen: resultatet av epikutantest med basserie, ålder, kön, år och klinik. Registret baseras på att de deltagande klinikerna på frivilligbasis skickar in resultatet av sin testning i form av kopior på testprotokollen för året.

Professor och överläkare Magnus Lindberg vid Region Örebro län, Örebro universitetssjukhus, som är kontaktperson för databasen fick i uppdrag är att ta fram underlag som ska kunna användas för att bedöma förekomsten av kontaktallergi mot allergiframkallande ämnen i textil i Sverige år 2015. Bedömningen baserar sig på en sammanställning och analys av data i EpiReg från patienter med misstänkt kontaktallergi som testas kliniskt för textilfärgmixen i den svenska basserien.

Information i EpiReg visade att 3,12% av patienterna som testats för svenska basserien hade en kontaktallergi mot textilfärgmixen. Underlaget i EpiReg är dock inte tillräckligt för en tillförlitlig bedömning av hur vanligt förekommande det är med kontaktallergi mot textilfärger i normalbefolkningen och inte heller för att bedöma vilka kostnader det innebär för samhället. För en sådan bedömning krävs ytterligare kunskap om användning av textilfärgämnen och en bättre förståelse för vad positiva provsvar för textilfärgmixen har för betydelse för uppkomsten av allergiska reaktioner.

³ <http://ssdv.se/svenska-saellskapet-foer-arbets-och-miljoedermatologi-ssamd/riktlinjer-och-testserier-for-utredning-av-hudallergi/svensk-basserie-2016>

⁴ <http://www.chemotechnique.se/products/series/european-baseline-series/>

1 Background

Textile dyes has probably been used since mankind started using textiles. The types and sources of these dyes have changed over time. Simplified, modern textiles can be of natural origin such as wool and cotton or synthetic such as nylon and polyester. Different dyes have properties suitable for a specific textile fiber used in a product. The production steps for dyeing textiles will thus differ depending on the textile and the dye used (1). The most used dyes belongs to the chemical classes of azo or anthraquinone dyes (2). The possibility of allergic reactions to textile dyes was discussed already in the 19:th century (3). Allergic contact dermatitis to azo dyes used in nylon stockings was first described in 1947 (4). In 2000 more than 70 dyes had been described as allergens (2). In a European multicenter (6 clinics) patch test study with a textile dye mix (TDM) composed of eight disperse dyes; Disperse Blue 35, Disperse Yellow 3, Disperse Orange 1 and 3, and Disperse Red 1 and 17, all at 1.0%, and Disperse Blue 106 and Disperse Blue 124, each at 0.3%, it was found that 3.7% (2.1% - 6.9%) of the tested patients were positive to the TDM. Simultaneous reactivity to p-phenylenediamine was found in 57 of the TDM-positive patients (53%). The most frequent dye allergen among the TDM-positive patients was Disperse Orange 3. The contact allergy could explain or contribute to the dermatitis in approximately one-third of the patients (5).

Contact allergy is a reaction pattern. No one is born with a contact allergy. To establish a contact allergy there has to be skin exposure, often frequently and over longer time periods (6). To develop allergic contact dermatitis (symptoms, disease) there needs to be a re-exposure to the allergen in a person previously sensitized for that allergen. Contact allergy is a delayed-type of hypersensitivity (Type IV) and is considered to be lifelong. If contact allergy is suspected in a patient with dermatitis, an epicutaneous patch test is performed (6). The principal for a patch test is to apply allergens on the skin surface to provoke the immune system (compare with a tuberculin test). Today, a patch test work up mostly includes a standard base line series with the most common allergens. The test is applied for 48 hours and evaluated at day 3 and day 6-7 after the application.

The Swedish base line series for patch testing comprises the 30 most common allergens found in the population. This base line series is used in all patients that undergo patch testing in Sweden on the indication of suspected contact allergic eczema. The Swedish contact dermatitis research group (SCDRG), (Svenska kontaktdermatitgruppen, SKGD), evaluates the included chemicals yearly and do compare with international test series, especially the European. This enables a regular update of the baseline series. Based on an increasing knowledge about textile dyes as possible causes of contact allergy, a textile dye mix was added to the Swedish test series in 2015 (1, 7). This textile dye mix is a composition with 8 different dyes (Disperse Blue 35, Disperse Yellow 3, Disperse Orange 1 and 3, and Disperse Red 1 and 17, all at 1.0%, and Disperse Blue 106 and Disperse Blue 124,) and is based on chemical analysis of and clinical patch test studies with different dyes (1, 7, 8). It has been suggested that Disperse Orange 3, can be omitted, owing to its frequent cross-reactivity with PPD (7).

It is important to separate prevalence's in a patch test population with eczema from prevalence's in the general population. Population based prevalence studies performed in North America or Europe between 1966 and 2007 were review in 2007. It was found that the median prevalence of contact allergy to at least 1 allergen was 21.2% (range 12.5-40.6%) in the general population and the weighted average prevalence was 19.5% based on data collected on all age groups (9). In Denmark the C-DUR procedure was used in 2007 to

estimate the 10-year prevalence of contact allergy (10). It was estimated that the prevalence of contact allergy ranged between 7.3% and 12.9% for adult Danes older than 18 years.

In a European multi-center study, contact allergy to at least one allergen of the European baseline series was diagnosed in more than one-quarter of the general European population (11). In the same population the prevalence of para-phenylenediamine contact allergy was 0.8% (95% confidence interval 0.6-1.0%), with no statistically significant association with gender or hair dye use.

The prevalence of textile dye contact allergy in the general population is not known.

Back in 2008 a Swedish patch test register was established (12). Dermatological clinics participate on a voluntary base and the number of clinics participating has increased to nearly 20 in 2016 geographically covering all of Sweden. This national coverage enables monitoring trends in contact allergy prevalence's. In the registry, the SCDRG collects data on results of patch testing (test reactions, age and sex of the patients). It has not yet been possible to establish a satisfactory reporting of clinical relevance for the test results.

2 Material and Methods

Patch test data of the textile dye mix for 2015 was extracted from the EpiReg registry. For further analysis, the following parameters were used: age, sex, clinic, test substance (allergen) and outcome of the test. Patch tests were applied for 48 hours (removed by the patient on day 2). Most tests were then read on day 3 and day 5-7 after starting the exposure to the test substances. Tests were read and scored in accordance to recommendations from the ICDRG (International Contact Dermatitis Research Group) (6). Test reactions with the scoring +, ++, and +++ were considered as positive.

Morphology of test reactions.

IR = irritant morphology

+? = doubtful, erythema without infiltration and papules or vesicles

+ = erythema, edema, possible papules, covering the whole test area

++ = erythema, edema, papules, possible vesicles, covering the whole test area

+++ = erythema, edema, papules, vesicles, possible bullae, covering the whole test area

Crude prevalence and prevalence stratified for sex and age (under 40 years and 40 years and older) were calculated.

The allergens tested are given in Table 1.

Statistical analysis (Statistica 13, Dell Inc.) was performed to compare women to men, variation between clinics and correlation between the textile dye mix and para-phenylenediamine.

The reporting of clinical relevance for the positive test reactions was insufficient and did not allow for more advanced analyses.

3 Results

In total, for year 2015 the register contained results of 2533 patch tests (females 1784; Males 747) performed at 15 dermatology departments in Sweden. Mean age was 43.5 years (SD 18.0). There was a significant age difference between sexes (Females 43,5 (SD 18.0); Males 46.8 (SD 52.4); $p=0.02$). It was estimated that the participating clinics represents 30 – 50 % of the patch tests with the Swedish baseline series performed in Sweden 2015.

The number of tests per clinic and sex is given in table 2. The prevalence for positive patch tests for textile dye mix is also found in table 2 as well as the number of positive tests for p-phenylenediamine base and PPDA mix. Total prevalence for textile dye mix allergy in 2015 was 3.12 % (Females 3.31%; Males 2.68 %). Between clinics there was a variance in positive tests from 0 % to 6.16 %. Of the 79 positive TDM reactions 42 were +, 19 were ++ and 18 were +++.

Prevalence's stratified for age (< 40; > 40) and sex is given in table 3. In this material, no statistical difference was found between females and males or between age groups.

Compiling the test results it was found that the number of +? or doubtful reactions was quite high, see Table 4. There was a significant difference between +? and doubtful reactions between TDM and p-phenylenediamine. There was also a good correlation between positive TDM reactions and simultaneous reaction to p-phenylenediamine ($P<0.05$). Of patients tested positive for TDM (79 persons), 33 did also react to p-phenylenediamine, table 5.

In the EpiReg database we record the outcome of testing with the Swedish base line series. However, there is problem with recording of test result relevance. In the present compilation of TDM test results, decision on clinical relevance of the positive test was recorded in only 31 patients out of the 79 with positive tests (38,8 %). Of these 7 were classified as present relevance, 3 as earlier relevance and 21 as unclear/unknown relevance. In theory, clinical relevance implies that results of an investigation, in our case a patch test result; explain the symptoms/the disease. In the case of patch testing relevance can be difficult to determine without further testing, exposure evaluation or follow up with time (6).

4 Discussion

The present study is based on the EpiReg database where outcome of patch testing with the Swedish base line series is recorded. EpiReg is part of the Swedish Contact Dermatitis Research Group. In this report we present data on the patch testing with a Textile dye mix introduced in the Swedish base line series in 2015 (7).

The participating clinics differed in sizes and represent both academic clinics, county clinics and private practitioners. We found a crude prevalence of 3.12 % (of 2531 tests) with a variation from 0 % to 6.16 % between clinics. This is a result in accordance with previously published data on testing with the same textile dye mix (5, 8). Azo dyes are based on aromatic amines and as such they can cross react with substances with similar structures. A cross reaction between p-phenylenediamine and disperse dyes, especially Orange-3 (included in the TDM) is known (1, 7). P-phenylenediamine has earlier also been used/seen as a marker for textile dye allergy. The clinical importance of such a cross reactivity is not clear (7). In contact allergy two separate phenomenon can be identified; simultaneous reactions and cross reactivity. Simultaneous reactions mean that the sensitization for an allergen can occur with

one product and then there is a reaction to the allergen in another product (c.f. black henna tattoos and hair dyeing or textile dyes). Cross reactions imply a similarity in the chemical structure with a sensitization to one allergen and a subsequent reaction to another allergen (c.f. p-phenylenediamine and disperse dyes). Sensitization to p-phenylenediamine can occur with products containing the allergen and that are used for other things than textile dyeing, e.g. for coloring hair and in so called “Tourist tattoos or black henna tattoos”. As a consequence, a person sensitized to the allergen in other products can also react to textile dyes and react with a positive reaction to the TDM (5) which in turn can cause concern when discussing relevance of a test result.

We pooled the test reactions +, ++, and +++ as positive. The grading of the test reactions is morphological and does not give us any information on variations in symptoms or on needs for medical care or costs for the individual nor the society. Patch testing can be seen as a biological provocation test and the strength of a reaction to a specific allergen in one individual varies over time and is influenced by factors in the individual and in the environment.

We found that reactions to the dye mixed often were reported as doubtful reactions. It is probably a result of difficulties to recognize test reactions when using a test preparation, such as the dye mix, that colors the skin. This result points at a need for education and quality assessment in reading patch tests.

Patch testing involves several moments that has to be standardized and the assessment of relevance is a difficult part. The EpiReg database has not yet reached a good standard for registration of patch test relevance. For 2015 only 38.8 % of the positive dye tests were judged for relevance. Of these 38.8 % positive tests (31 patients) only 10 patients were considered to have present or past relevance. The lack of registered relevance does point at a moment for major improvement of EpiReg.

Most patch test reports are based on testing selected populations, such as eczema patients. How common are contact allergy in the general population? There are only few published studies that address this question. A prevalence of around 20 % for at least 1 allergy was reported in 2007 by Thyssens et al. in a review and around 10% calculated from retrospective data (9, 10). In a prospective European multicenter patch test study Diepgen et al found that 27 % of the general European population had at least 1 allergy to the allergens in the European base line series. Contact allergy was significantly more common among women. Diepgen et al. (13) also reported a prevalence of 0.8 % to p-phenylenediamine in the general European population. Population based prevalence's for allergy to textile dyes are, however, missing. From published data it is not possible to determine the population prevalence. To be able to estimate such prevalence's we need better data, preferably population based patch test studies. To calculate possible problems in the general population due to textile dyes we would also need: i) information on the use of different dyes, ii) how often persons have problems with textiles, iii) the relevance of positive tests for textile dyes.

5 Conclusions

Compiling data from the EpiReg database concerning allergy to TDM 2015, we found:

- The prevalence for TDM contact allergy in Swedish patch test clinics was in accordance with previously published data for Northern Europe including the Malmö clinic (5). The present report does not include data from that multi-center study.
- The cross-reactivity between TDM and p-phenylenediamine was confirmed.
- The test readings revealed a high frequency of doubtful reactions for TDM tests indicating a need for quality work on reading of patch tests.
- The evaluation and documentation of relevance of positive patch test reactions must be improved.
- The prevalence of TDM allergy in the general population cannot be calculated on previously published data nor the data in the present report.

Acknowledgements

This report was written on the behalf of the Swedish Contact Dermatitis Research Group (SCDRG) and the participating clinics.

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Table 1

The allergens used for patch testing in this report

MIX	Test substance	Short name	Test konc	Vehikel
	p-phenylenediamine base	PPD	1.0 %	Petrolatum
	Black rubber mix	PPDA-mix	0.1 %	Petrolatum
Textile dye mix	Mix of allergens below		6.6 %	Petrolatum
	Disperse Blue 35	DB 35	1.0 %	Petrolatum
	Disperse Yellow 3	DY 3	1.0 %	Petrolatum
	Disperse Orange 1 and 3	DO 1 and DO 3	1.0 %	Petrolatum
	Disperse Red 1 and 17	DR 1 and DR 17	1.0 %	Petrolatum
	Disperse Blue 106	DB 106	0.3 %	Petrolatum
	Disperse Blue 124	DB 124	0.3 %	Petrolatum

Table 2

Number of positive tests by clinic and sex. Prevalence for TDM

Sex: 1= females; 2= males, TDM= textile dye mix

Clinic	sex	number of tested	TDM %	TDM	p-phen. diamine	PPDA mix
1	1	109	0,92	1	3	1
	2	35	5,71	2	0	0
	Total	144	2,08	3	3	1
2	1	140	5,00	7	2	2
	2	48	0,00	0	0	0
	Total	188	3,72	7	2	2
3	1	287	3,14	9	9	1
	2	122	0,00	0	1	0
	Total	409	2,20	9	10	1
4	1	481	3,33	16	12	2
	2	228	3,95	9	10	2
	Total	709	3,53	25	22	4
5	1	119	4,20	5	6	0
	2	63	1,59	1	1	1
	Total	182	3,30	6	7	1
6	1	14	0,00	0	0	0
	2	8	0,00	0	0	0
	Total	22	0,00	0	0	0
7	1	86	1,16	1	4	1
	2	28	3,57	1	0	0
	Total	114	1,75	2	4	1
8	1	53	0,00	0	1	0
	2	27	3,70	1	0	0
	Total	80	1,25	1	1	0
9	1	72	0,00	0	3	0
	2	35	0,00	0	0	0
	Total	107	0,00	0	3	0

10	1	106	7,55	8	9	2
	2	40	2,50	1	0	0
	Total	146	6,16	9	9	2
11	1	15	0,00	0	0	0
	2	1	0,00	0	0	0
	Total	16	0,00	0	0	0
12	1	142	5,63	8	11	0
	2	51	5,88	3	0	1
	Total	193	5,70	11	11	1
13	1	121	3,31	4	3	1
	2	47	2,13	1	1	1
	Total	168	2,98	5	4	2
14	1	37	0,00	0	0	0
	2	14	7,14	1	1	0
	Total	51	1,96	1	1	0
ALL	1	1784	3,31	59		
	2	747	2,68	20		
	Total	2531	3,12	79	77	15

Table 3

Prevalence and number of positive tests by age group and sex

n = number of positiv patch tests

Sex	Age year	Number of tested	Textile dye mix	p-phenylendiamine	PPDA mix
F	<40	791	2.9 % (n=23)	3.5 % (n=28)	0.6 % (n=5)
F	≥40	994	3.7 % (n=37)	3.6 % (n=36)	0.5 % (n=5)
Total		1785	3.4 % (n=60)	3.6 % (n=64)	0.6 % (n=10)
M	<40	319	1.9 % (n=6)	1.6 % (n=5)	0.3 % (n=1)
M	≥40	429	1.3 % (n=14)	2.1 % (n=9)	0.9 % (n=4)
Total		748	2.7 % (n=20)	1.9 % (n=14)	0.7 % (n=5)
Column Total		2533	3.2 % (n=80)	3,1 % (n=78)	0.6 % (n=15)
Ingen skillnad mellan grupper analyserat med Chi-square					

Table 4

Test results noted as +? or unclear reaction

a= p=0.0001 compared to p-phenylenediamine

Compared to total number of tested persons n=2533.

Textile dye mix	p-phenylendiamin	PPDA mix
n=76 ^a	n=26	n=8
3.0 %	1.0 %	0.3 %

Ratio compared to positive reactions

Textile dye mix	p-phenylendiamin	PPDA mix
76:80 = 0.95	26; 78 = 0.33	8:15 = 0.53

Chi square TDM p-phen p=0.0001

Table 5

Number and per centage of patients with multiple positive reactions

TDM= textile dye mix

Total number of positive reactions to TDM = 80

TDM and p-phenyldiamine	TDM and PPDA mix	TDM and p-phenylen and PPDA mix
32	7	1
40 % (32/80)	8.8 % (7/80)	1,2 % (1/80)

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