Patch testing with a textile dye mix – a multicentre study

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Summary

Background. Disperse dyes are well-known contact sensitizers. However, they are not included in the majority of commercially available baseline patch test series.

Objectives. To investigate the outcome of patch testing with a textile dye mix (TDM) consisting of eight disperse dyes at dermatology clinics in various countries.

Patients/materials/methods. Two thousand nine hundred and seven consecutive dermatitis patients at 12 dermatology clinics representing nine countries were tested with a TDM at 6.6%, consisting of 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%, provisionally included in the baseline series. Eighty-seven per cent of the patients allergic to the TDM were also tested with the eight separate dyes.

Results. Contact allergy to TDM was found in 108 patients (3.7%). The frequency of contact allergy varied from 2.1% to 6.9% in different centres. 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 have explained or contributed to the dermatitis in approximately one-third of the patients for whom clinical relevance of the TDM contact allergy was recorded.

Conclusions. The TDM should be considered for inclusion in the European baseline series.

Key words: contact allergy; disperse dyes; Disperse Orange 3; patch testing; *p*-phenylenediamine; simultaneous reactivity; textile dye mix.

Disperse dyes (DDs) are used for the colouring of synthetic textile fibres. They are the most common contact sensitizers among textile dyes. The true frequency of contact allergy to DDs in the general population in various countries is unknown, owing to the lack of comparable epidemiological studies. DDs are not included in the majority of commercially available baseline patch test series, but several DDs have been used for patch testing in various studies, in order to identify patients with contact

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allergy to these textile dyes (1–3). In a recently published study from the United States, the authors concluded that supplementing the baseline series with a textile series would increase the rate of detection of patients with textile dye allergies (4). To save space and time, mixes of DDs have been used in several studies (3, 5–9). The frequency of contact allergy found in these studies has raised the question of whether a textile dye mix (TDM) should be included in the baseline series (10). Unfortunately, the frequency of allergic patients in most of the studies cannot be compared, because of different inclusion criteria and different composition of the mixes. In a previous study performed in Belgium and Sweden, consecutive patients were patch tested with a TDM consisting of eight DDs at a concentration 6.6%; 4.2% of the Belgian patients and 2.1% of the Swedish patients were allergic to the mix (11).

The present study investigated the outcome of patch testing with this TDM containing the eight DDs at the same concentration, 6.6%, in dermatology clinics from the European Environmental Contact Dermatitis Research Group (EECDRG). The results will contribute to the decision on whether a mix of DDs qualifies for inclusion in the European baseline series.

Materials and Methods

Study population

Twelve patch testing clinics representing nine countries participated in the study from January to June 2011. In these clinics, 2907 consecutively patch tested dermatitis patients, 943 males (mean age 47.7 years, range 8–90 years) and 1964 females (mean age 45.7 years, range 4–92 years), took part, distributed by the 12 clinics as summarized in Table 1.

Substances

The eight dyes included in the TDM 6.6% petrolatum (pet.) – Disperse Blue 35, Disperse Yellow 3, Disperse Orange 1 and 3, and Disperse Red 1 and 17, all 1.0% wt/wt (pet.), and Disperse Blue 106 and Disperse Blue 124, each 0.3% wt/wt (pet.) – were bought from Chemotechnique Diagnostics (Vellinge, Sweden). Disperse Blue 106 and Disperse Blue 124 were both included in the TDM at a concentration of 0.3%, because of their strong allergenic potential (12). The TDM and the separate dye preparations used for patch testing at the participating clinics were prepared from the same batches at the department in Malmö.

Patch testing

The test preparation with the TDM 6.6% pet. was provisionally included in the baseline series of the 12 participating EECDRG clinics. Patch testing and reading of the patch tests were performed according to the routines of the participating clinics, with Finn Chambers® (diameter, 8 mm; Epitest Ltd, Tuusula, Finland) on Scanpor® tape (Norgesplaster A/S, Vennesla, Norway) in 10 clinics, and IQ chambers™ ($9 \times 9\ mm^2$; Chemotechnique Diagnostics) and IQ Ultra® ($8 \times 8\ mm^2$; Chemotechnique Diagnostics) (13) in two clinics. The dose for the pet. preparations was 20 mg for a Finn Chamber® (13). The test chambers were left on the back for 2 days, and readings were performed according to the guidelines of the International Contact Dermatitis Research Group (14). Reading were performed on D2–D4 (reading 1). In six clinics (1654 patients), readings were also performed on D6–D8 (reading 2). Any positive reaction, either on D2–D4 or D6–D8, was registered as a positive reaction in the present study. The patients with positive reactions (+, ++, +++) to at least one of the TDM, *p*-phenylenediamine (PPD) 1.0% wt/wt (pet.), *N*-isopropyl-*N*′-phenyl-1,4-phenylenediamine (IPPD) 0.1% wt/wt (pet.) or benzocaine 5.0% wt/wt (pet.) at the first patch test reading were tested with the eight individual DDs at the same concentration as in the TDM, and also with Disperse Blue 106 and Disperse Blue 124 at 1.0% (Disperse Blue 106 and Disperse Blue 124 were tested at two concentrations – 0.3% and 1.0%). In one clinic (332 patients), black rubber mix (BRM) 0.6% wt/wt (pet.), consisting of three components [*N*,*N*′-diphenyl-1,4-phenylenediamine, *N*-cyclohexyl-*N*′-phenyl-1,4-phenylenediamine, and IPPD, at 0.2% wt/wt (pet.) each], was tested instead of IPPD alone. An individual test protocol was filled in for each patient with patch test reactions (allergic, doubtful, or irritant) to at least one of the following test preparations: the TDM, any of its eight ingredients, PPD, IPPD/BRM, or benzocaine. It was emphasized that all patch test reactions without an obvious morphology of an allergic or irritant nature were to be classified as doubtful. In 10 of the 12 patch testing centres, the sites of dermatitis and an assessment of clinical relevance of the contact allergy to the TDM were registered in the test protocol. This assessment was performed by the test-reading dermatologist together with the patient.

Statistical analysis

Fisher's exact test was used to investigate any sex differences in the frequencies of positive reactions and differences in frequencies related to the test units used (Finn Chambers® as compared with IQ chambers™/IQ Ultra®). Frequencies of contact allergy to the TDM, PPD, IPPD, benzocaine and the TDM alone, without

Table 1. Positive reactions to the textile dye mix (TDM), *p*-phenylenediamine (PPD), *N*-isopropyl-N′-phenyl-1,4-phenylenediamine (IPPD) and benzocaine when they were tested simultaneously in 2907 patients in 12 dermatology clinics: simultaneous positive reactions to TDM and PPD in TDM-positive patients and in PPD-positive patients, to TDM and IPPD in IPPD-positive patients, and to TDM and benzocaine in benzocaine-positive patients; positive reactions to the TDM in the patients reacting to the TDM but not to PPD, IPPD, or benzocaine

							Simultaneous positive patch test reactions				
	Total tested	Females (%)	TDM-positive (%)	PPD-positive (%)	IPPD-positive	Benzocaine-positive	TDM + PPD /TDM-positive	TDM + PPD/ PPD-positive	TDM + IPPD/ IPPD-positive	TDM + benzocaine/ benzocaine-positive	Solely TDM/ TDM-positive (%)
Barcelona, Spain	136	84 (61.8)	6 (4.4)	2 (1.5)	0	0	2/6	2/2	0/0	0/0	4/6 (66.7)
Bari, Italy	542	386 (71.2)	19 (3.5)	14 (2.6)	0	0	13/19	13/14	0/0	0/0	6/19 (31.6)
Basel, Switzerland	145	91 (62.8)	3 (2.1)	2 (1.4)	0	1	2/3	2/2	0/0	1/1	1/3 (33.3)
Coimbra, Portugal	160	112 (70.0)	11 (6.9)	9 (5.6)	1	1	8/11	8/9	1/1	1/1	3/11 (27.3)
Copenhagen (Bispebjerg), Denmark	293	194 (66.2)	10 (3.4)	3 (1.0)	2	0	2/10	2/3	0/2	0/0	8/10 (80.0)
Copenhagen (Gentofte), Denmark	586	424 (72.4)	13 (2.2)	14 (2.4)	5	0	6/13	6/14	1/5	0/0	5/13 (38.5)
Heidelberg, Germany	51	28 (54.9)	2 (3.9)	2 (3.9)	0	1	0/2	0/2	0/0	0/1	2/2 (100.0)
Leuven, Belgium	245	164 (66.9)	16 (6.5)	11 (4.5)	0	3	9/16	9/11	0/0	3/3	6/16 (37.5)
Malmö, Sweden	332	221 (66.6)	13 (3.9)	12 (3.6)	2*	2	9/13	9/12	1/2*	0/2	4/13 (30.8)
Odense, Denmark	256	153 (59.8)	7 (2.7)	0	1	0	0/7	0/0	1/1	0/0	6/7 (85.7)
San Francisco, USA	50	35 (70.0)	2 (4.0)	1 (2.0)	0	0	1/2	1/1	0/0	0/0	1/2 (50.0)
Strasbourg, France	111	72 (64.9)	6 (5.4)	5 (4.5)	1	0	5/6	5/5	1/1	0/0	0/6 (0)
Total	**2907**	**1964 (67.6)**	**108 (3.7)**	**75 (2.6)**	**12 (0.4)**	**8 (0.3)**	**57/108 (52.8)**	**57/75 (76.0)**	**5/12 (41.7)**	**5/8 (62.5)**	**46/108 (42.6)**

*Patch tested with black rubber mix, consisting of *N*,*N*′-diphenyl-1,4-phenylenediamine, *N*-cyclohexyl-N′-phenyl-1,4-phenylenediamine, and IPPD.

any simultaneous contact allergy to PPD and/or IPPD and/or benzocaine, were compared between the Nordic test clinics (Denmark and Sweden) and the non-Nordic clinics. The body site distribution of the dermatitis in the TDM-positive patients with clinically relevant dermatitis was compared with the sites of the dermatitis in the TDM-positive patients not considered to have textile-related skin problems. We regarded a two-sided p-value of < 0.05 as statistically significant.

Results

The results are summarized in Table 1. In the 6-month period, 2907 patients were patch tested, and contact allergy to the TDM was found in 108 patients (3.7%). Six of the patients had positive test reactions to the TDM first seen at the D6–D8 reading. The frequency of contact allergy varied from 2.1% to 6.9% in different centres (Fig. 1). Sixty-nine per cent of the test reactions were strong (++/+++). Furthermore, 38 doubtful (1.3%) and eight (0.3%) irritant reactions to the TDM were reported. More women reacted to the TDM (4.2% versus 2.7% of the men, $p = 0.036$).

Contact allergy to PPD was found in 75 patients (2.6%; 3.2% of females and 1.4% of males; $p = 0.004$). Simultaneous reactivity to PPD was found in 57 of the TDM-positive patients (53%), and simultaneous reactivity to TDM was found in 76% of the PPD-positive patients (Table 1). Moreover, 42.6% of the TDM-positive patients did not react to PPD, IPPD/BRM, or benzocaine. Table 2 shows the number of positive reactors, contact allergy rates and statistical differences (Fisher's exact rest, two-sided) for the TDM, PPD, IPPD, benzocaine and the TDM without any simultaneous contact allergy to PPD, IPPD and benzocaine for the Nordic centres (Denmark and Sweden) and the non-Nordic centres. The contact allergy frequencies were statistically significantly higher for the TDM and PPD in the non-Nordic centres, whereas a statistically significantly higher contact allergy frequency for IPPD was found for the Nordic centres, independently of whether the BRM-positive patients in Malmö were included or not. The frequency of TDM contact allergy without any simultaneous contact allergy to the sensitizers in Table 2 was the same, 1.6%, in the Nordic and non-Nordic centres.

Of the TDM-positive patients patch tested with the ingredients, 65 of 94 (69%) were allergic to at least one separate ingredient when it was tested at the same concentration as used in the TDM. The most frequent single dye allergen was Disperse Orange 3, followed by Disperse Orange 1 (Fig. 2). All but 1 patient allergic to Disperse Orange 3 also reacted to PPD, whereas only a few patients allergic to Disperse Blue 106 and/or Disperse Blue 124 also reacted to PPD (Fig. 2).

The distribution of the dermatitis was registered in 95 of 108 TDM-positive patients. The hands and face were the most common sites of dermatitis in these patients. The contact allergy to the DDs (immunologically acquired delayed hypersensitivity) could explain or contribute to the dermatitis in 29 of the 93 TDM-positive patients (31%) for whom an assessment of clinical relevance was performed. Dermatitis on the neck and on the trunk was statistically significantly more common in those 29 patients than in the 64 patients not considered to have a textile-related dermatitis. The body site distribution of the dermatitis in these two groups of TDM-positive patients is shown in Table 3. Allergic reactions to Disperse Orange 3 were found in 12 of the 29 patients with clinically relevant TDM contact allergy, all of whom were simultaneously allergic to PPD. Of the remaining 17 patients, 12 reacted to at least one ingredient, 6 of them to Disperse Blue 106 and/or Disperse Blue 124. None of these 6 patients reacted to Disperse Orange 3 or PPD.

Discussion

In the present study, the frequency of patients with contact allergy to the TDM at 12 dermatology departments in nine countries was evaluated (Table 1). Here, 3.7% of the patients were allergic to the TDM 6.6% pet., whereas, in the aforementioned study, performed in Malmö and in Leuven from 2006 to 2008, 2.6% of the patients were allergic to the TDM patch tested at the same concentration (11). Contact allergy to the TDM was twice as common in Leuven as in Malmö in that study, and was almost twice as common in our present study. Interestingly, the same relationships were found when the contact allergy rates for the Nordic centres (Denmark and Sweden) and those for the non-Nordic centres (Table 2) were compared. The frequency of TDM-positive patients varied considerably, from $\sim 2\%$ in Basel, Gentofte in Copenhagen, and Odense, to $> 6\%$ in Leuven and Coimbra (Table 1). In Basel, IQ Ultra® was used, whereas the remaining four clinics used Finn Chambers®; Leuven and Coimbra, which had the highest frequencies, used Finn Chambers®. No statistically significant difference in the frequency of allergic reactions to TDM was found between the patients patch tested with Finn Chambers® and those tested with the IQ test units.

In the entire study, 68% of the patch tested patients were females, and they were more often allergic, both to the TDM and to PPD, than the males. Leuven and Coimbra had a higher proportion of women in the patch tested population than Basel and Odense, and Leuven

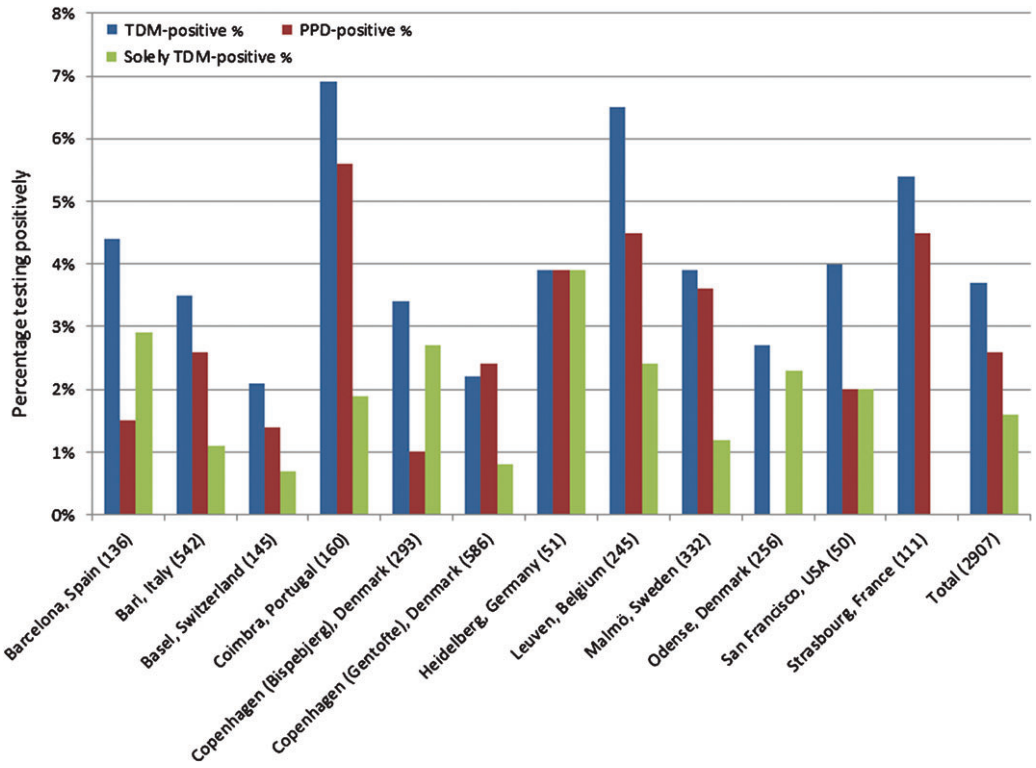

Fig. 1. The proportions of positive reactions (%) to the textile dye mix (TDM), *p*-phenylenediamine (PPD), and to the TDM in the patients solely reacting to the mix but not to PPD, *N*-isopropyl-*N*′-phenyl-1,4-phenylenediamine, or benzocaine. The number of patients patch tested at each clinic is shown in paremtheses.

Table 2. The number of positive reactors, contact allergy rates and statistical differences (Fisher's exact test, two-sided) for Nordic (Denmark and Sweden) centres and non-Nordic centres for textile dye mix (TDM), *p*-phenylenediamine (PPD), *N*-isopropyl-*N*′-phenyl-1,4-phenylenediamine (IPPD) benzocaine and TDM without any simultaneous contact allergy to any one of PPD, IPPD, and benzocaine

	Nordic countries n = 1467		Non-nordic countries n = 1440		
Test preparation	No. of positive reactions	%	No. of positive reactions	%	*p*-value
TDM	43	2.9	65	4.5	0.006
PPD	29	2.0	40	3.2	0.011
IPPD	10	0.7	2	0.1	0.021
	(8)*	(0.7)	–	–	(0.024)
Benzocaine	2	0.1	6	0.4	0.105
Solely TDM†	23	1.6	23	1.6	>0.3

*Black rubber mix reactions in Malmö are excluded.
†TDM contact allergy without any simultaneous contact allergy to any one of PPD, IPPD, and benzocaine.

and Coimbra had the highest frequencies of TDM-positive patients, with Basel and Odense having a much lower frequency of TDM-positive patients (Table 1; Fig. 1). In contrast, the pattern of a high frequency of women reacting to both the TDM and PPD was not seen in Bari and at the department of Gentofte in Copenhagen, where ~ 72% of the patch tested patients were women. In Bari, 3.5% of the patients were allergic to the TDM. At Gentofte, only 2.2% of the patch tested patients (all women) reacted to the TDM, and 2.4% reacted to PPD (Table 1). In all other departments, there were more patients (males and females) reacting to the TDM than to PPD. For Barcelona and Bispebjerg in Copenhagen, the frequency of contact allergy to the TDM was at least three times higher than the frequency of contact allergy to PPD.

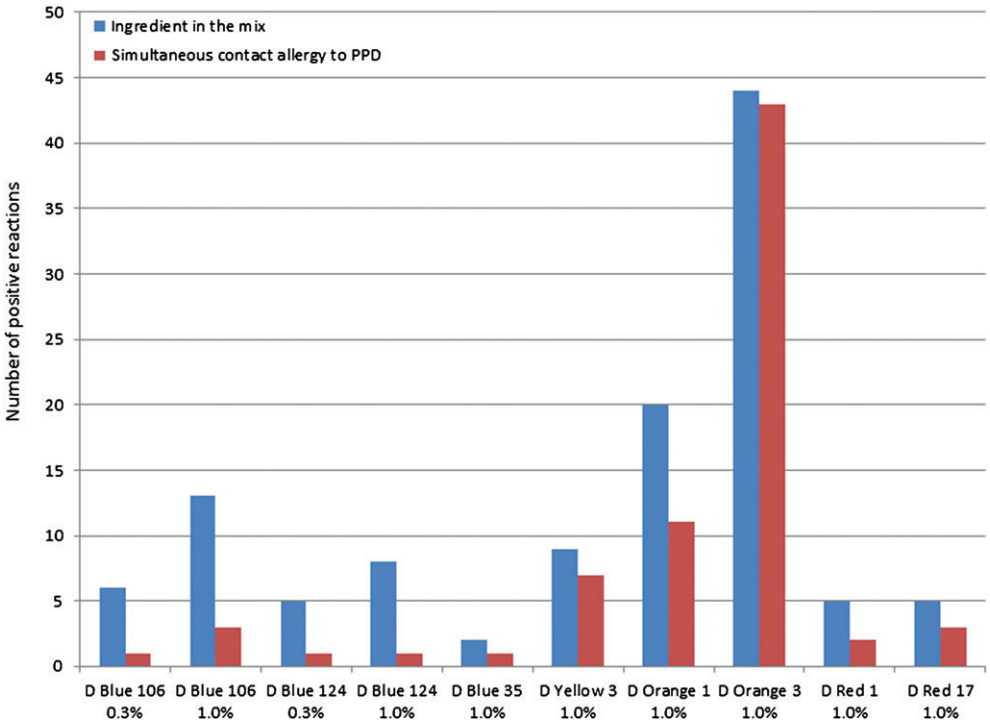

Fig. 2. The number of positive reactions to the eight disperse dye ingredients in the textile dye mix in the 94 mix-positive patients when patch tested with the ingredients, and simultaneous contact allergy to *p*-phenylenediamine (PPD) in the patients reacting to each dye included in the mix.

Table 3. The body site distribution of the dermatitis in the textile dye mix (TDM)-positive patients with clinically relevant contact allergy to the TDM as compared with the sites of dermatitis in the TDM-positive patients for whom no correlation was found between the TDM contact allergy and the skin problems

	Clinically relevant n = 29		Not clinically relevant n = 64		
Site of dermatitis	No. of reactions	%	No. of reactions	%	*p*-value
Hands	13	44.8	26	40.6	> 0.3
Arms	4	13.8	10	15.6	> 0.3
Trunk	7	24.1	5	7.8	0.044
Neck	6	20.7	0	–	< 0.001
Face	7	24.1	17	26.6	> 0.3
Scalp	3	10.3	9	14.1	> 0.3
Legs	7	24.1	8	12.5	0.223
Feet	4	13.8	2	3.1	0.073

The European baseline series includes PPD, but also IPPD and benzocaine, which are para-substituted amino-benzene substances and thus chemically related. Here, simultaneous contact allergy to the TDM and to PPD, IPPD/BRM and/or benzocaine was found in 57% of the patch tested patients (Table 1). Some patients who were allergic to the TDM may initially have been sensitized to PPD or to related substances and then reacted to DDs because of cross-reactivity, or they may have been sensitized by exposure to a common metabolite, rather than DDs in textiles. Another explanation for the simultaneous contact allergy to the TDM, PPD and IPPD/BRM could be a common impurity present in all of the patch test preparations. PPD has long been considered to be a screening allergen for textile dye dermatitis, but is now considered to be a better screening agent for contact allergy to hair dyes than for allergy to DDs (15). However, in a previous study (16), a significant association was

seen in females regarding contact allergy to PPD and self-reported skin problems arising from synthetic textile materials. The results from Coimbra and Leuven, with high frequencies of patients allergic both to the TDM and to PPD in the present study, can perhaps be explained by the use of other textiles or by the more frequent use of hair dyes or temporary 'black henna' tattoos by these patients than by patients in other countries. No information was collected in the present study on the textile materials used, the frequency of hair-dyeing, or the types of hair dye used in the participating countries. The difference in rates of contact allergy to PPD between northern European countries and central–southern countries has been reported previously (17). In our study, both the frequency of contact allergy to PPD and the frequency of contact allergy to the TDM were statistically significantly higher in the non-Nordic countries than in the Nordic countries (Table 2), but, considering exclusively TDM-positive patients, there was no difference between the Nordic and non-Nordic clinics (1.6%). Thus, the higher frequency of patients allergic to the TDM in the non-Nordic countries can perhaps be explained by the higher frequency of contact allergy to PPD. In contrast to what was found for the TDM and PPD, the contact allergy rate was significantly higher in the Nordic countries for IPPD. These results may also reflect a difference in the populations studied at various centres, with occupational relevance being more common among patients in the Nordic countries.

Furthermore, women may have a tendency to wear more tight-fitting clothes, leading to increased friction and sweating, and possibly to a higher risk of contact allergy to the DDs used in the textiles. These circumstances may partly explain why women have a higher frequency of contact allergy to DDs. Approximately 43% of the patients allergic to the TDM were not allergic to PPD, IPPD, or benzocaine (Table 1), and 33 of them (72%) were females. These patients would not have been found if they had been patch tested with only the European baseline series, and not with the TDM. TDM-positive patients reacting to Disperse Blue 106 and Disperse Blue 124 less often reacted to PPD than the patients reacting to the remaining DDs in the TDM, as seen in Fig. 2. In the present study, all patients allergic to Disperse Orange 3 and considered to have a textile-related dermatitis also reacted to PPD, whereas the corresponding patients allergic to Disperse Blue 106 and/or Disperse Blue 124 reacted to the TDM but not to PPD. It is important to find these patients, especially as Disperse Blue 106 and Disperse Blue 124 are regarded as strong sensitizers (12, 18).

Of the TDM-positive patients, 69% were allergic to at least one ingredient when it was tested at the same concentration as used in the mix. One possible explanation for why the ingredient testing was negative in some TDM-positive patients could be that the penetration of the ingredients in the TDM into the skin was higher when they were tested together in a mix than when they were tested separately. Another explanation could be a compound allergy caused by additive or synergistic effects of the different substances, as has been shown when other mixes, such as fragrance mix, have been tested (19–21).

The most frequent single dye allergen in the TDM-positive patients in the present study was Disperse Orange 3, followed by Disperse Orange 1. In previous studies, Disperse Orange 1 was the most common allergen in the patients allergic to the mix (3, 11, 22). In several other studies, however, Disperse Blue 106 and Disperse Blue 124 have been described as common allergens (4), and many authors of studies on contact allergy to DDs have recommended them as screening allergens for textile dye dermatitis (8, 23). One possible reason for the difference between these results and those in our studies may be that Disperse Blue 106 and Disperse Blue 124 were tested at 0.3% each in the TDM in our present study, but at a higher concentration, 1% pet. each, in their studies (4, 8, 23).

Thus, ~ 70% of the patients were allergic to at least one ingredient when it was tested at the same concentration as used in the TDM, but a further 8 TDM-positive patients were allergic to Disperse Blue 106 and/or Disperse Blue 124 when these dyes were patch tested at a higher concentration, 1.0% pet. each. These results also raise the question of which is the optimal patch test concentration for the ingredients in the TDM. Generally, the higher the patch test concentration used, the more individual cases of contact allergy to the dyes will be detected. However, a higher patch test concentration creates a higher risk of adverse effects, including the risk of patch test sensitization. Furthermore, concerning Disperse Blue 106 and Disperse Blue 124, previous studies have indicated that all patch test preparations of Disperse Blue 124 contain Disperse Blue 106, and vice versa (24, 25). This must also be considered when deciding on the optimal concentrations for these two blue dyes to be used in a TDM.

The composition of the TDM was identical to that of a mix used earlier by Brandão in Almada, Portugal. This mix has also been used in previous studies performed by the Malmö department. In the present study 43 of the 44 TDM-positive patients who were allergic to Disperse Orange 3 also reacted to PPD in the baseline series (Fig. 2). Hence Disperse Orange 3 may, perhaps, be excluded from the mix in the future, but this would need further studies.

There are many possible explanations for the considerable differences in frequencies of contact allergy to the TDM between the various centres, including simultaneous reactions to PPD and the other para-substituted

amino compounds, differences in referrals of patients for patch testing, and differences in clothing habits. Another explanation may be differences in evaluation of the morphology of a test reaction. The irritant patch test reactions were all reported from two of the participating clinics, both using Finn Chambers®, the remaining 10 clinics not reporting irritant patch test reactions. The percentage of doubtful reactions varied from 0% to 3.6%. This variation implies that standardization is warranted not only for the dose of the patch test, but also for the morphology of irritant, doubtful and weak reactions (13). Moreover, although the majority of the patients with contact allergy to the TDM were detected at the first reading on D2–D4, a further 6 TDM-positive patients were found at the second reading on D6–D8. These results indicate the importance of a second late reading for the TDM, as for several other allergens (26–29).

One patient was reported with a late + reaction, first seen after the second reading on D6–D8. This patient was not tested with the ingredients in the mix. Late patch test reactions appearing > 10 days after the test application may indicate active sensitization. In a 4-year review of late reactions by Aalto-Korte et al., some DDs induced late reactions in even higher percentages of patients than PPD did, and the authors concluded that these textile colours were primary active sensitizers, and that concomitant late reactions to PPD may only represent cross-allergy (30). However, a late patch test reaction to Disperse Orange 1 has also been described in a patient previously shown to be allergic to DDs (31). The cause in that case may have been a delayed immune response, or the physicochemical features, metabolism or degradation of the substance, but the mechanism of these late patch test reactions is not completely known, and a retrospective evaluation of the consequences of alleged patch test sensitization indicated that the development of clinical allergic contact dermatitis following patch test sensitization is rare (32).

The hands and face were the commonest sites of involvement in all TDM-positive patients in the present study (Table 3). However, dermatitis on the trunk and on the neck was statistically significantly more common in the TDM-positive patients with clinically relevant contact allergy to the TDM than in the patients where no correlation was found between the TDM contact allergy and the skin problems. The results shown in Table 3 indicate differences in the distribution of the dermatitis, with dermatitis being more frequent on body sites where textile covers the skin in the patients with clinically relevant contact allergy. Unfortunately, no registration of the sites of dermatitis in the TDM-negative patients was performed.

However, some of the self-reported skin problems caused by textiles may also reflect irritant reactions to clothes and other textiles, rather than contact allergy to DDs (33, 34). Furthermore, in the present study, approximately 65–70% of the TDM-positive patients did not have any textile-related skin problems. This can perhaps be explained by the fact that, according to a study published in 2012, the eight DDs used in the mix seem to be rarely used in textiles today (35), but, in contrast to previous suppositions, they are still present in some European clothes (36). Additionally, it is also possible that many of the dyes detected but not chemically identified may be contact sensitizers that cross-react with the DDs in the TDM. Nevertheless, according to the assessment of clinical relevance, contact allergy to the TDM was related to textile dermatitis in > 30% of the TDM-positive patients in the present study.

Conclusions

Contact allergy to the TDM was common, as 3.7% of the patients were allergic to it, although the variation between the centres was more than threefold. The contact allergy was interpreted as clinically relevant in approximately one-third of the allergic patients. Patch testing solely with the baseline series (including PPD) would have missed almost one-half of the patients with contact allergy to the textile dyes. Indeed, the rate of contact allergy to the TDM was 1.6% in both the Nordic and non-Nordic countries, when those with simultaneous contact allergy to any one of PPD, IPPD and benzocaine were excluded. The European Society of Contact Dermatitis recommends a sensitizer for inclusion in the baseline series when routine testing of patients with suspected contact dermatitis results in a contact allergy rate exceeding 0.5–1.0% (10). Therefore, the inclusion of a TDM in the European baseline series should be considered (10).

Whether there are other better textile dye mixes with other concentrations and/or dyes included to enable better tracing of contact allergy today and in the near future should be a subject of concern and continuous exploration.

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