

Patch testing with a textile dye mix with and without Disperse Orange 3

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The authors declare no conflicts of interest

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Abstract

Background: The textile dye mix (TDM) 6.6% pet. contains Disperse Blue (DB) 35, D Yellow 3, D Orange 1 and 3, D Red 1 and 17, and DB 106 and 124. The most frequent allergen in TDM-positive patients is D Orange 3 (DO 3). Around 85% PPD-allergic dermatitis patients have shown positive patch-test reactions to DO 3. There has been a discussion to exclude DO 3 from TDM 6.6% because frequent, strong reactions to TDM 6.6% and PPD.

Objectives: To study if DO 3 can be omitted from a TDM.

Methods: Patch tests were performed on 2250 dermatitis patients with TDM 6.6%, TDM 5.6% pet., TDM 7.0% pet., and PPD 1.0% pet.; 122 patients were also tested to DO 3 1.0% pet.

Results: In 2250 tested, contact allergy prevalence to TDM 6.6% was 2.4%, to TDM 5.6% 1.8%, and to TDM 7.0% 2.0%. Of the 54 TDM 6.6%-positive patients, 55.6% reacted to PPD. Among PPD-allergic women 42.2% and among men 50% reacted to TDM 6.6%. Of 17 DO 3-positive patients, 94.1% showed a positive reaction to PPD.

Conclusion: Results indicate that DO 3 can probably be omitted from TDM, but patch testing to TDM 6.6%, TDM 7.0%, DO 3 1.0%, and PPD 1.0% simultaneously is needed to finally decide whether it is possible or not.

Key words: Patch testing; disperse dyes; DO 3; contact allergy; *p*-phenylenediamine; textile dye mix; simultaneous reactivity; baseline series.

1. Introduction

Disperse dyes (DDs), used for coloring synthetic textile materials based on fibers such as polyester, acrylic, acetate and polyamide, are well-known contact sensitizers, and from 2015 eight DDs are included in a textile dye mix (TDM) 6.6% pet. in the European baseline patch test series (1). The 8 dyes are Disperse Blue (DB) 35, Disperse (D) Yellow 3, D Orange 1 and 3, and D Red 1 and 17, all at 1.0%, and DB 106 and 124, each at 0.3%. The share of positive reactions to this mix is around 3-4%. Earlier patch test studies have shown around 60%

simultaneous positivity to *p*-phenylenediamine (PPD) and black rubber mix in patients with contact allergy to TDM 6.6% pet. (2,3). The most frequent dye allergen in TDM-positive patients has been Disperse Orange 3 (DO 3). Around 80-85% of PPD-allergic dermatitis patients have shown positive patch-test reactions to DO 3 (4,5,6) and over 90% of patients positive to DO 3 react to PPD (2,3). There has therefore been discussed to exclude DO 3 from TDM 6.6%, partly because of frequent, strong positive reactions to both TDM 6.6% pet. and PPD (2,3).

During 2011 members of the Swedish Contact Dermatitis Research Group provisionally included a textile dye mix at 2 concentrations, that is, at 6.6% and 8.0% pet. (all 8 ingredients tested at 1.0%), in the baseline series of each center, and dermatitis patients were tested to both simultaneously (2). Results showed no significant difference in the detection rate, even if TDM 8.0% numerically detected more positive patients.

Our aim in the present study was to patch test consecutive dermatitis patients with TDM 6.6% pet. simultaneously with 2 other textile dye mixes containing the 7 DDs present in TDM 6.6% but excluding DO 3. One of the 2 textile dye mixes contained 5 DDs at 1.0% each and Disperse Blue (DB) 124 and DB 106 at 0.3% each, in this contact point called TDM 5.6%. The other contained all 7 DDs at 1.0% each, respectively, in this contact point called TDM 7.0%. The purpose was to see which of the DO 3-lacking mixes detected most allergic patients if the original TDM 6.6% will be deleted from the baseline series. A second objective was added after the study had started, namely, to see how many PPD-allergic dermatitis patients showed positive patch-test reactions to DO 3.

2. Patients, Materials and Methods

2.1 Study population

From January 1, 2015 until December 31, 2017, 2250 patients, 710 males (mean age 46.1 years, range 14-92) and 1540 females (mean age 46.1 years, range 14-92) were tested to TDM 6.6%, TDM 5.6% pet., TDM 7.0% pet., and PPD 1.0% pet. In addition, 122 patients, 83 women and 39 men, were also tested to the textile or textile dye mix series, both containing DO 3 1.0% pet.

2.2 Substances and patch testing

TDM 6.6%, PPD 1.0%, and DO 3 1.0% were all bought from Chemotechnique Diagnostics (Vellinge, Sweden). The two mixes without DO 3 were prepared at the Malmö department from the 7 separate dye preparations, which were bought from Chemotechnique Diagnostics.

Finn Chambers (8 mm diameter; Epitest, Tuusula, Finland) and (SmartPractice, Phoenix, Arizona) on Scanpor tape (Norgesplaster, Vennesla, Norway) were used. The dose for the petrolatum preparations was 20 mg for a Finn Chamber (7). The test chambers were left on the back for 2 days and readings were taken following the guidelines of the International Contact Dermatitis Research Group (8,9). Reading days were day 3–4 (reading 1) and day 7 (reading 2). A dermatologist read all patch tests on both days.

2.3 Statistics

McNemar's two-sided test was used to compare the proportions of contact sensitization to TDM 5.6% and TDM 7.0%. A *P*-value of <.05 was considered to be significant.

3. Results

Of 2250 tested patients, 54 (2.4%) had a positive reaction to TDM 6.6%, 41 (1.8%) to TDM 5.6%, and 46 (2.0%) to TDM 7.0% (Table 1). Two patients were exclusively positive to TDM 5.6% and 7 patients exclusively positive to TDM 7.0%. The difference between the outcome for the 2 DO 3- deficient mixes was not significant (*P*=.18). Fifty-nine (2.6%) had a positive reaction to PPD 1.0%. Of the 54 TDM 6.6%-positive patients, 30 also reacted to PPD, ie 55.6% (Table 1, Fig. 1a). Nineteen of 45 (42.2%) PPD-allergic women and 7/14 (50%) PPD-allergic men also reacted to TDM 6.6% (Fig. 1b). Seventeen individuals were positive to DO 3 (Fig. 1c). In 16/17 (94.1%) a positive reaction to PPD was seen, and in 15/17 (88.2%) a simultaneous positive reaction to TDM 6.6% was noted (Fig. 1c). We did not detect any patients with a late reaction to any of the tested preparations that could be a sign of patch test sensitization.

4. Discussion

The question whether to remove DO 3 from TDM 6.6% has been discussed in several scientific articles (2,3). One prerequisite for this is that the detection of DO 3-contact allergy must not be jeopardized. This could be accomplished by testing only to PPD at first, if all DO 3- positive patients are detected by PPD positivity. To investigate this more carefully, one should have tested DO 3 and PPD simultaneously in the same patients. However, in the present study we did not patch test all patients to DO 3 at the same time but only tested DO 3 if the patient had reacted to any of the 3 TDM mixes first. Even then, 94.1% of the DO 3- positive individuals had a simultaneous positive reaction to PPD (Fig. 1c). Furthermore, in this study all male and female patients who were TDM 6.6%-positive and simultaneously DO 3-positive (15/15) were detected by testing to PPD 1.0%, a cross-reacting substance (Fig. 1c).

Females had positive reactions to TDM 5.6% and/or 7.0% 1.7 times more often than males (Table 1). However, when TDM 6.6% is concerned, the mix with DO 3, the figure is 3.2 times more. This could be due to females more often being allergic to PPD.

In a study from Sweden in 2011 with a similar design as the present one, the same high number of concomitant reactions to PPD was seen with all but one out of 28 patients allergic to DO 3 (27/28=96.4%)(2). Another study within the European Environmental Contact Dermatitis Research Group showed similar results. Forty-three of 44 TDM-positive patients (97.7%) who were allergic to DO 3 also reacted to PPD (3). The authors in both studies concluded that DO 3 may perhaps be excluded from the mix in the future but this would need further studies (2,3).

If DO 3 is excluded from the textile dye mix, and a patient reacts to PPD, which may indicate textile dye allergy, the patient should be questioned about skin problems from textiles and if these are/were present, DO 3 should be patch tested on its own, preferably included in a textile series. The patient information leaflet on PPD allergy must in that case be updated with accurate information.

In this study we used 2 mixes without DO 3 and found that both mixes detected less positive patients than the original TDM 6.6%, but the difference in detection rate between the 2 mixes without DO 3 was statistically not significant. TDM 7.0% detected numerically more positive reactors than TDM 5.6%, which is why we think the former should be incorporated into baseline series instead of the old TDM 6.6%, but only if it is shown that virtually all patients with contact allergy to DO 3 are detected by PPD 1.0%. To investigate this, two studies have been initiated, in which simultaneous patch testing to TDM 6.6%, TDM 7.0%, DO 3 1.0%, and PPD 1.0% will take place in consecutively patch-tested dermatitis patients. One study will be conducted within the Swedish Contact Dermatitis Research Group and the other within the International Contact Dermatitis Research Group.

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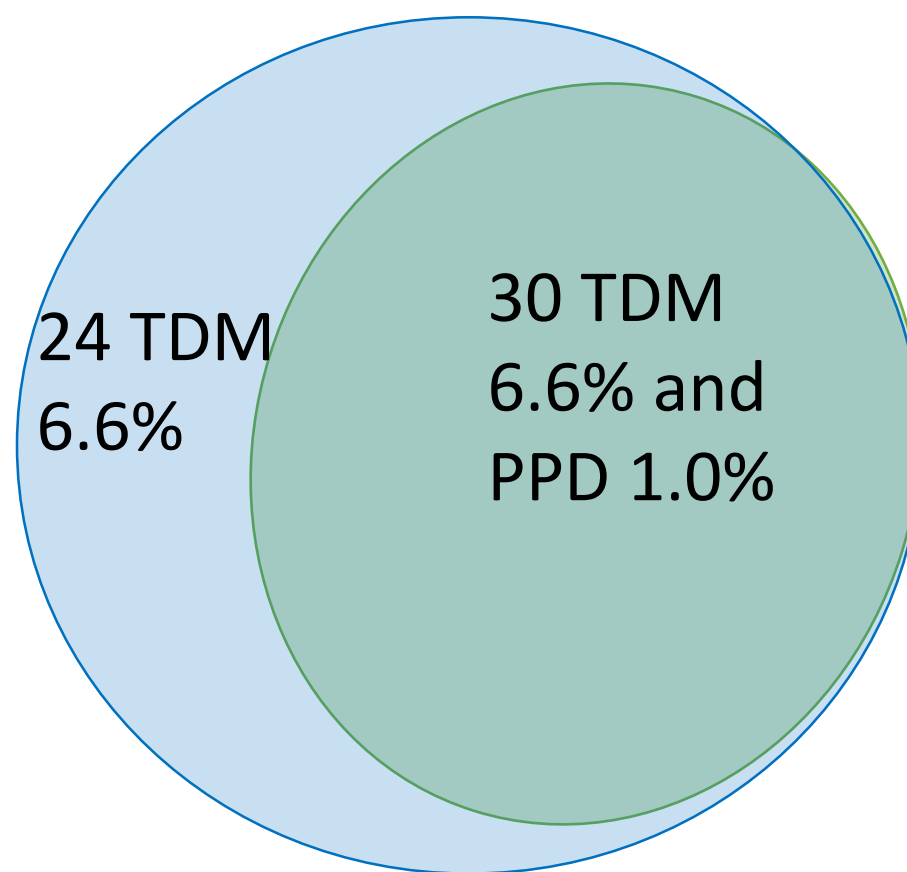
Figure 1. Proportions of positive patch test reactions to textile dye mix (TDM) 6.6%, *p*-phenylenediamine (PPD) 1.0%, and Disperse Orange (DO) 3 1.0% in 2250 dermatitis patients, presented as area-proportional Euler diagrams. **(A)** Concomitant and solitary positive reactions to TDM 6.6% or PPD 1.0% on either D3/4 or D7. **(B)** Concomitant and solitary positive reactions to PPD 1.0% or TDM 6.6% on either D3/4 or D7. **(C)** Concomitant and solitary positive reactions to PPD 1.0%, TDM 6.6%, or DO 3 1.0% on either D3/4 or D7.

Table 1. Number of tested patients and number of positive patients tested to textile dye mix (TDM) 6.6%, TDM 5.6% and TDM 7.0%.

No tested 2250	N pos. patients to TDM 6.6%		N pos. patients to TDM 5.6%		N pos. patients to TDM 7.0%	
	54, 30/54 are PPD 1.0% positive (55.6%)		41		46	
No of females and males	41 females	13 males	26 females	15 males	29 females	17 males

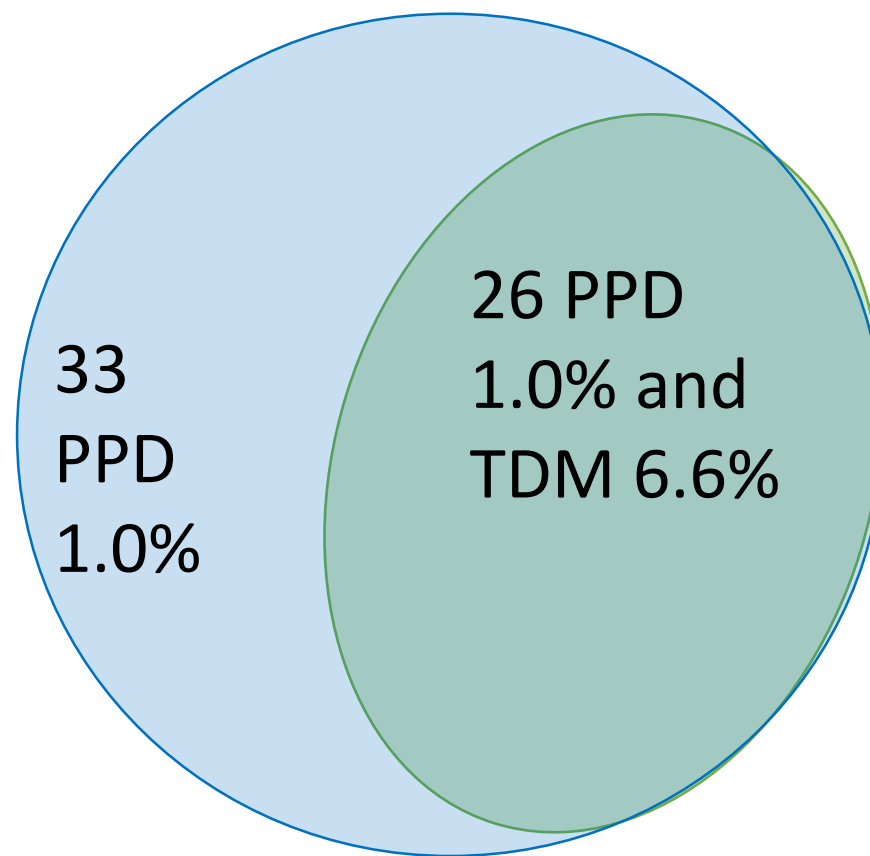
PPD, *p*-phenylenediamine

TDM 6.6%
positive
N=54



30/54 TDM 6.6% positives are PPD 1.0% positive (55.6%)

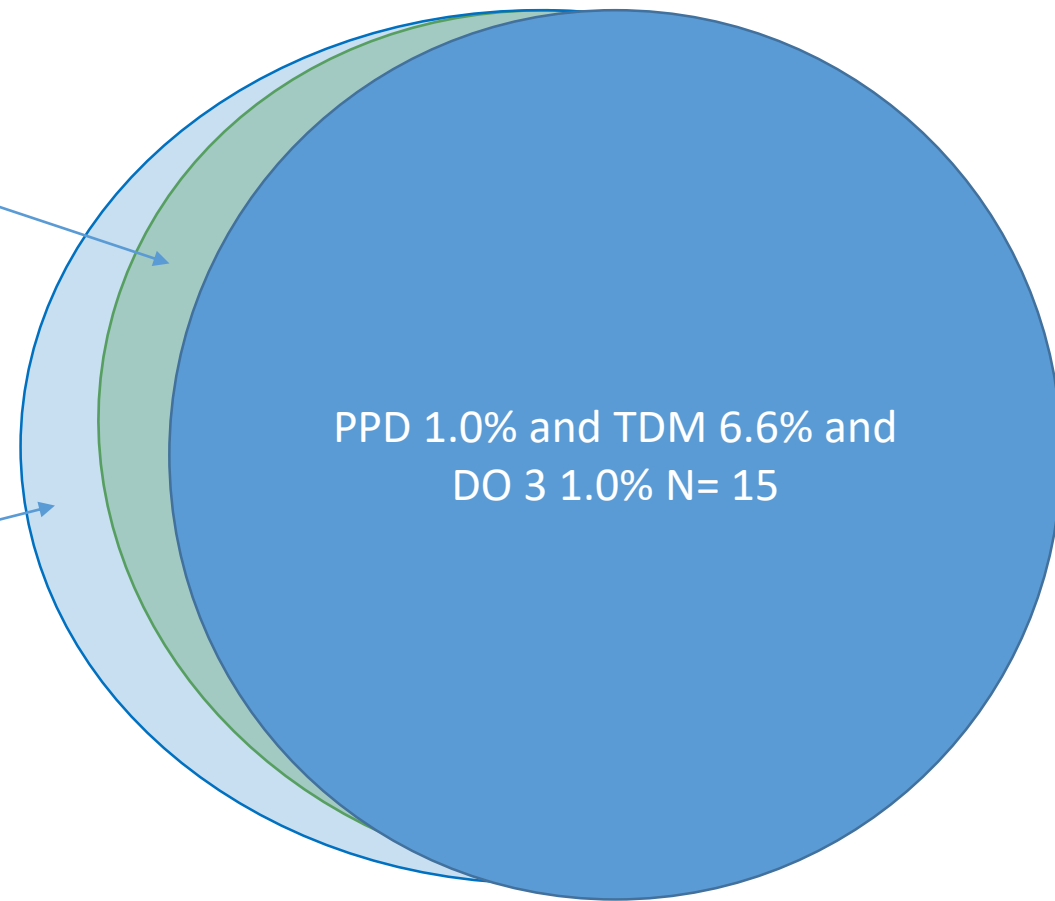
PPD 1.0% positive
N=59, 45 females,
14 males



19/45 (42.2%) females and 7/14 males (50.0%)
of PPD 1.0% positives are TDM 6.6% positive

PPD 1.0% and
DO 3 1.0%
N=1

DO 3 1.0%
N=1



PPD 1.0% and TDM 6.6% and
DO 3 1.0% N= 15

17 individuals positive to DO 3 1.0%. 16/17 also positive to PPD 1.0% (94.1%).
15/17 also positive to TDM 6.6% (88.2%).