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Abstract

Background: Current frequency and features for positivity to textile dye mix (TDM) in Spain are unknown.

Objectives: To study the frequency, clinical features and simultaneous positivity between TDM, para-phenylenediamine (PPD) and specific disperse dyes.

Materials and Methods: We analysed all consecutive patients patch-tested with TDM from the Spanish Contact Dermatitis Registry (REIDAC), from 1 January 2019 to 31 December 2022. Within this group, we studied all selected patients patch-tested with a textile dye series.

Results: Out of 6128 patients analysed, 3.3% were positive to the TDM and in 34% of them, the sensitisation was considered currently relevant. TDM positivity was associated with working as a hairdresser/beautician and scalp, neck/trunk and arm/forearm dermatitis. From TDM-positive patients, 57% were positive to PPD. One hundred and sixty-four patients were patch-tested with the textile dye series. Disperse Orange 3 was the most frequent positive dye (16%). One of every six cases positive to any dye from the textile dye series would have been missed if patch-tested with the TDM alone.

Conclusions: Positivity to TDM is common in Spain and often associated with PPD sensitisation. TDM is a valuable marker of disperse dyes allergy that should be part of the Spanish and European standard series.

KEYWORDS

contact dermatitis, disperse dyes, patch tests, Spain, standard series, textile dye mix, textile dye series

1 | INTRODUCTION

Disperse dyes (DDs), used for dyeing synthetic fabrics (polyester, acetate, nylon, or their blend with other fibre types), are considered to be the most important and common allergens in textile allergic contact dermatitis (ACD).^{1,2} Most are azo dyes, which are cheap and easy to apply.²

Textile dye mix (TDM) 6.6% pet. was added to the European baseline series in 2015,³ and to the Spanish baseline series in January 2022.⁴ The mix contains eight DDs, namely Disperse Blue 35 (DB 135) (CAS no. 12222-75-2), Disperse Blue 106 (DB 106) (CAS no. 12223-01-7), Disperse Blue 124 (DB 124) (CAS no. 61951-51-7), Disperse Orange 1 (DO 1) (CAS no. 2581-69-3), Disperse Orange 3 (DO 3) (CAS no. 730-40-5), Disperse Red 1 (DR 1) (CAS no. 2872-52-8), Disperse Red 17 (DR 17) (CAS no. 3179-89-3), and Disperse Yellow 3 (DY 3) (CAS no. 2832-40-8).

Contact allergy to TDM is widespread in Europe^{2,5-11} and clinical relevance of positive reactions ranges widely.^{9,11} Data concerning both frequency of positivity and relevance, as well as variables linked to positivity, is scarce within the Spanish population.

Simultaneous contact allergy to para-phenylenediamine (PPD) and DDs is common.^{12,13} Although it was in the past, nowadays PPD is not considered to be a good screening allergen for textile dye dermatitis or allergy to DDs.

The objectives of this study were to analyse the frequency and relevance of positive patch tests to TDM, associated characteristics, and simultaneous positivity to TDM, PPD and individual DDs in Spain.

2 | MATERIALS AND METHODS

The Spanish Contact Dermatitis Registry (REIDAC) prospectively recruits all consecutive patients patch-tested in participating centres in Spain. In this study, we included patients from 1 January 2019 to 31 December 2022. We analysed all consecutive patients patch-tested with TDM (6.6% pet.), PPD (1% pet.) and True-test PPD (90 µg/cm²), as part of the Spanish baseline series and/or the extension/recommended additions to the European baseline series.^{14,15}

We also carried out an analysis of all selected patients patch-tested with a textile dye series based on the Textile Colours and Finish series[®] (Chemotechnique Diagnostics, Vellinge, Sweden) when textile ACD was suspected. This series was simultaneously patch-tested with the baseline series and included, among others, TDM (6.6% pet.), DB 35 (1.0% pet.), DB 106 (0.3% pet.), DB 124 (0.3% pet.), DO 1 (1.0% pet.), DO 3 (1.0% pet.), DR 1 (1.0% pet.), DR 17 (1.0% pet.), DY 3 (1.0% pet.), and Disperse Blue (DB) mix 106/124 (1% pet.).

The allergens were commercially obtained from Chemotechnique® (Chemotechnique Diagnostics, Vellinge, Sweden), allergEAZE® (SmartPractice, Calgary, Canada) and True-test® (SmartPractice, Hillerød, Denmark), based on availability at each centre. Patch tests were performed following the European Society of Contact Dermatitis (ESCD) guidelines. Depending on the centre, readings were performed on day (D)2 and D4, and occasionally on D7; reactions documented as (+), (++) or (+++) were considered to be positive.¹⁶ Relevance was considered after the evaluation of the patient's history of possible exposure to every allergen and clinical examination. Current relevance was presumed when sensitisation could explain or contribute to the dermatitis.

As previously described,⁴ from January 2019 to June 2022 data was collected using the OpenClinica platform (OpenClinica LLC and collaborators, Waltham, MA, USA, RRID: SCR_019223). From July 2022 to December 2022, data was collected using the REDCap electronic data capture tools hosted at Academia Española de Dermatología y Venereología. Positive (+, ++, +++), irritant and doubtful (?+) reactions were collected, as well as relevance (current, past, unknown, cross-reaction), age, sex, occupation-related dermatitis, atopic dermatitis, site(s) affected, and occupations. Univariate analyses were performed to study whether these variables were linked to TDM positivity.

Continuous variables (age) are reported as means (standard deviations), and categorical variables are reported as numbers (proportions). Factors associated with sensitisation are expressed as odds ratios (OR) with 95% confidence intervals (95% CI). Significance was calculated with Fisher's exact test. Results were considered significant when the *p*-value was 0.05 or lower. For data analysis, the statistical package Stata 16 (StataCorp. 2019. Stata Statistical Software: Release 16. College Station, TX: StataCorp LLC, RRID: SCR_012763) was used.

3 | RESULTS

3.1 | Sensitisation and relevance

A total of 6128 patients were consecutively patch-tested with TDM and included in this analysis (Table 1). The MOAHLFA index of the whole population was as follows: male, 31%; occupational, 12%; atopy, 19%; hand, 23%; leg, 5%; face, 18%; age >40, 69%.

The frequency of global positivity to TDM was 3.3% (200/6128) (Table 1). 34.5% of the cases (*n* = 69) were linked to current relevance. Allergy to TDM varied from 3.4% in 2019–2020 to 4.1% in 2021 and 2.6% in 2022; this variation was non-significant (*p* = 0.22). Proportions of weak (+), moderate (++) and strong (+++) positives were 25.5% (51/200), 38.0% (76/200) and 36.5% (73/200), respectively (Table 2). Within the whole population, we observed a 0.2% (15/6128) doubtful and 0.1% (4/6128) irritant reactions. We did not observe any late reactions (data not shown in Table 2).

The frequency of sensitisation to PPD was 3.4% (209/6099) (Table 2). This percentage was 3.3% in the group of patients patch-tested with PPD in petrolatum and 3.6% in the group patch-tested with True-test PPD. Analyses showed no significant differences between neither TDM (*p* = 0.8) nor DO 3 (*p* = 0.2) positivity frequency between both groups. PPD allergy was significantly more common in women when compared to men, both in the overall population (4% vs. 2.2%, *p* < 0.01) and in the subgroup of patients with current relevance (2.4% vs. 0.9%, *p* < 0.01).

A total of 164 selected patients with suspected textile ACD were patch-tested with the textile dye series (Table 2), with the following sensitisation frequencies: DB 35 (0%), DB 106 (6.2%), DB 124 (4.3%), DO 1 (6.8%), DO 3 (15.9%), DR 1 (2.5%), DR 17 (2.5%), DY 3 (4.3%) and DB mix 106/124 (4.9%).

3.2 | Factors associated with sensitisation to TDM

Factors associated with TDM positivity are presented in Table 1. Considering all TDM-positive patients, we found that working as a hairdresser/beautician (OR: 2.4; 95% CI: 1.1–5.0; *p* = 0.03), scalp dermatitis (OR: 4.0; 95% CI: 2.3–7.1; *p* < 0.01), simultaneous scalp and extra-scalp dermatitis (OR: 4.5; 95% CI: 2.6–7.7; *p* < 0.01), neck/trunk dermatitis (OR: 1.6; 95% CI: 1.1–2.5; *p* = 0.03), and arm/forearm dermatitis (OR: 1.9; 95% CI: 1.1–3.3; *p* = 0.03), were significantly associated with TDM positivity, opposite to hand dermatitis (OR: 0.7; 95% CI: 0.5–0.9; *p* = 0.02).

Considering all TDM-positives linked to current relevance, we found that working as a hairdresser/beautician (OR: 5.0; 95% CI: 1.2–20.3; *p* = 0.02), simultaneous scalp and extra-scalp dermatitis (OR: 7.9; 95% CI: 3.5–17.9; *p* < 0.01), neck/trunk dermatitis (OR: 2.6; 95% CI: 1.3–5.2; *p* = 0.01), and arm/forearm dermatitis (OR: 3.0; 95% CI: 1.2–7.2; *p* = 0.02), were significantly associated with TDM positivity, opposite to hand dermatitis (OR: 0.5; 95% CI: 0.3–0.96; *p* = 0.04) and face dermatitis (OR: 0.4; 95% CI: 0.2–0.9; *p* = 0.02).

3.3 | Simultaneous sensitisation

Information on simultaneous positivity between the TDM and PPD was available in 197/200 patients allergic to the TDM and 206/209 patients allergic to the PPD. From TDM-positives, 56.9% (112/197) were also positive to PPD (Figure 1), whereas from PPD-positives, 54.4% (112/206) were also positive to TDM.

Information on simultaneous positivity between the TDM, PPD and DO 3 was available in 161/164 patients who underwent concomitant patch-testing with the three allergens (Figure 2). From TDM-positives, 57.1% (24/42) were also positive to DO 3, whereas from DO 3-positives, 92.3% (24/26) were also positive to TDM. From PPD-positives, 80% (20/25) were also positive to DO 3, whereas from DO 3-positives, 76.9% (20/26) were also positive to PPD.

TABLE 1 Clinical-demographic characteristics of the population and odds ratio for textile dye mix (TDM) positivity.

	TDM all (%)	TDM-negative (%)	TDM-positive, any relevance (%)	OR (95% CI)	TDM-positive, current relevance (%)	OR (95% CI)
Demographics						
TOTAL ^a	6109 (100)	5909 (96.7)	200 (3.3)		69 (1.1)	
Female sex	4219 (69)	4082 (69)	137 (69)	1.0 (0.7–1.3)	45 (65)	0.8 (0.5–1.4)
Occupational dermatitis	562 (10)	538 (9)	24 (12)	1.4 (0.9–2.1)	10 (15)	1.7 (0.9–3.4)
Atopic dermatitis	1072 (18)	1034 (18)	38 (19)	1.1 (0.8–1.6)	12 (17)	1.0 (0.5–1.8)
Hand dermatitis	1848 (30)	1803 (31)	45 (23)	0.7 (0.5–0.9)	13 (19)	0.5 (0.3–1.0)
Leg dermatitis	334 (6)	325 (6)	9 (5)	0.8 (0.4–1.6)	3 (4)	0.8 (0.2–2.5)
Face dermatitis	1341 (22)	1305 (22)	36 (18)	0.8 (0.5–1.1)	7 (10)	0.4 (0.2–0.9)
Age ≥40 years	4120 (68)	3983 (68)	137 (69)	1.0 (0.8–1.4)	50 (72)	1.3 (0.7–2.1)
Age (years), mean (SD)	48.4	48.4 (18.6)	48 (17.6)		50.3 (16.4)	
Location						
Scalp ^b	201 (3)	183 (3)	18 (9)	4.0 (2.3–7.1)	2 (3)	1.5 (0.3–6.7)
Scalp + extra-scalp ^b	213 (4)	192 (3)	21 (11)	4.5 (2.6–7.7)	11 (16)	7.9 (3.5–17.9)
Face	1290 (21)	1256 (21)	34 (17)	1.1 (0.7–1.7)	6 (9)	0.7 (0.3–1.7)
Neck/trunk ^b	1157 (19)	1113 (19)	44 (22)	1.6 (1.1–2.5)	21 (30)	2.6 (1.3–5.2)
Arm/forearm ^b	389 (6)	372 (6)	17 (9)	1.9 (1.1–3.3)	8 (12)	3.0 (1.2–7.2)
Hand ^c	1839 (30)	1795 (31)	44 (22)	1	13 (19)	1
Thigh/knee	144 (2)	142 (2)	2 (1)	0.6 (0.1–2.4)	2 (3)	1.9 (0.4–8.7)
Leg	333 (5)	324 (6)	9 (5)	1.1 (0.6–2.3)	3 (4)	1.3 (0.4–4.5)
Foot	156 (3)	151 (3)	5 (3)	1.4 (0.5–3.5)	2 (3)	1.8 (0.4–8.2)
Mucous membranes (oral, anogenital)	343 (6)	338 (6)	5 (3)	0.6 (0.2–1.5)	1 (1)	0.4 (0.1–3.1)
Main occupation						
Health professional ^c	470 (8)	455 (8)	15 (8)	1	3 (4)	1
Clerical support worker	693 (12)	673 (12)	20 (10)	0.9 (0.5–1.8)	3 (4)	0.7 (0.1–3.4)
Service and sales worker	305 (5)	292 (5)	13 (7)	1.4 (0.6–2.9)	2 (3)	1.0 (0.2–6.3)
Hairdresser/beautician	195 (3)	181 (3)	14 (7)	2.4 (1.1–5.0)	6 (9)	5.0 (1.2–20.3)
Food processing and related trades worker	155 (3)	148 (3)	7 (4)	1.4 (0.6–3.6)	2 (3)	2.1 (0.3–12.4)
Cleaners and helpers, general	339 (6)	327 (6)	12 (6)	1.1 (0.5–2.4)	4 (6)	1.9 (0.4–8.4)
Housewife/-man	519 (9)	502 (9)	17 (9)	1.0 (0.5–2.1)	6 (9)	1.8 (0.5–7.3)
Student/pupil	630 (11)	612 (11)	18 (9)	0.9 (0.4–1.8)	1 (1)	0.3 (0–2.4)
Old age pensioner	1072 (18)	1044 (18)	28 (14)	0.8 (0.4–1.5)	12 (18)	1.7 (0.5–6.2)
Unemployed	207 (3)	197 (3)	10 (5)	1.5 (0.7–3.5)	5 (7)	3.9 (0.9–16.2)
Others	1406 (23)	1363 (24)	43 (22)	1.0 (0.5–1.7)	24 (35)	2.7 (0.8–8.9)

Note: Statistically significant (p -value ≤ 0.05) variables highlighted in bold. Those linked to positive TDM are highlighted in red, whereas those linked to negative TDM are highlighted in green.

^aProportions related to the whole population. Data shown refers to patients patch-tested with TDM with available information on results (n : 6109).

^bScalp: localised dermatitis on any area of the scalp; scalp + extra-scalp: localised dermatitis simultaneously on any area of the scalp plus any area other than the scalp; neck/trunk: localised dermatitis on the neck and/or the trunk; arm/forearm: localised dermatitis on the arm and/or the forearm.

^cReference category (OR: 1).

Information on simultaneous positivity between the TDM, when patch tested as part of the baseline series, and allergens of the textile dye series, was available in 160/164 patients who underwent concomitant patch-testing with both. 26.3% (42/160) of the patients

were allergic to the TDM, whereas 25.6% (41/160) were allergic to any of its eight separate dyes and 26.3% (42/160) to any allergen of the textile dye series. Comparing the latter with all TDM positives, TDM's sensitivity was 83.3% (35/41).

TABLE 2 Frequency of positivity to the textile dye mix (TDM), para-phenylenediamine (PPD), and eight disperse dyes of the TDM and disperse blue mix 106/124, and its clinical relevance.

	Reaction						Relevance															
	Positive																					
	Tested	Any (%)	+	(%)	++	(%)	+++	(%)	Irritant	(%)	Doubtful ?+	(%)	Current	(%)	Past	(%)	Unknown	(%)	Cross-reaction	(%)	Irritant	(%)
TDM	6128	200 (3.3)	51 (0.8)	76 (1.2)	73 (1.2)	4 (0.1)	15 (0.2)	69 (34.5)	11 (5.5)	54 (27)	62 (31)	3 (1.5)	1 (0.5)									
PPD, all	6099	209 (3.4)	48 (0.8)	87 (1.4)	74 (1.2)	1 (0)	18 (0.3)	116 (55.5)	50 (23.9)	35 (16.8)	8 (3.8)	0 (0)	0 (0)									
PPD, petrolatum	3055	100 (3.3)	17 (0.6)	37 (1.2)	46 (1.5)	0 (0)	5 (0.2)	59 (59)	20 (20)	18 (18)	0 (0)	3 (3)	0 (0)									
PPD, True-test	3044	109 (3.6)	31 (1)	50 (1.6)	28 (0.9)	1 (0)	13 (0.4)	57 (52.3)	30 (27.5)	17 (15.6)	0 (0)	5 (4.6)	0 (0)									
Disperse Blue 106, True-test	3044	22 (0.7)	14 (0.5)	7 (0.2)	1 (0)	0 (0)	2 (0.1)	10 (45.4)	2 (9.1)	7 (31.8)	3 (13.6)	0 (0)	0 (0)									
Disperse Blue 35 ^a	163	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)									
Disperse Blue 106 ^a	164	10 (6.2)	3 (1.8)	6 (3.7)	1 (0.6)	0 (0)	2 (1.2)	5 (50)	0 (0)	4 (40)	1 (10)	0 (0)	0 (0)									
Disperse Blue 124 ^a	163	7 (4.3)	1 (0.6)	5 (3.1)	1 (0.6)	0 (0)	0 (0)	3 (42.9)	0 (0)	3 (42.9)	1 (14.3)	0 (0)	0 (0)									
Disperse Orange 1 ^a	163	11 (6.8)	0 (0)	4 (2.5)	7 (4.3)	0 (0)	0 (0)	6 (54.6)	0 (0)	4 (36.4)	1 (9.1)	0 (0)	0 (0)									
Disperse Orange 3 ^a	164	26 (15.9)	0 (0)	16 (9.8)	10 (6.1)	0 (0)	0 (0)	14 (53.9)	1 (3.9)	5 (19.2)	6 (23.1)	0 (0)	0 (0)									
Disperse Red 1 ^a	164	4 (2.5)	1 (0.6)	0 (0)	3 (1.8)	0 (0)	1 (0.6)	3 (75)	0 (0)	1 (25)	0 (0)	0 (0)	0 (0)									
Disperse Red 17 ^a	164	4 (2.4)	1 (0.6)	1 (0.6)	2 (1.2)	0 (0)	1 (0.6)	3 (75)	0 (0)	1 (25)	0 (0)	0 (0)	0 (0)									
Disperse Yellow 3 ^a	164	7 (4.3)	1 (0.6)	3 (1.8)	3 (1.8)	0 (0)	0 (0)	3 (42.9)	0 (0)	4 (57.1)	0 (0)	0 (0)	0 (0)									
Disperse Blue mix 106/124 ^a	162	8 (4.9)	2 (1.2)	4 (2.5)	2 (1.2)	0 (0)	0 (0)	5 (62.5)	0 (0)	2 (25)	1 (12.5)	0 (0)	0 (0)									

^aTested as part of the textile dye series.

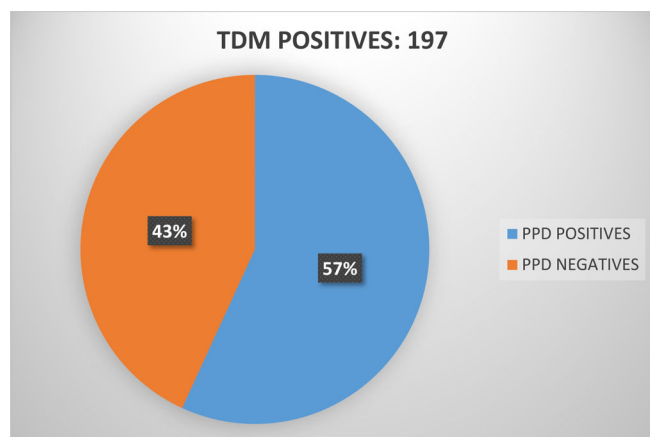


FIGURE 1 Simultaneous positivity to para-phenylenediamine (PPD) in 197 patients with positive patch test reactions to textile dye mix (TDM) when tested with both in the baseline series.

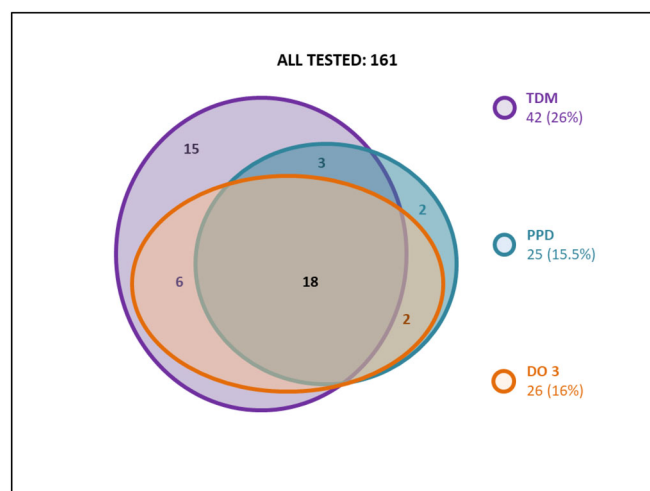


FIGURE 2 Simultaneous positivity to the textile dye mix (TDM), para-phenylenediamine (PPD) and Disperse Orange 3 (DO 3) in 161 selected patients patch-tested with the textile dye series. TDM and PPD patch-tested as part of the baseline series. DO 3 patch-tested as part of the textile dye series.

4 | DISCUSSION

We found a high 3.3% frequency of positivity to TDM in our population, which was similar to the results in a previous study analysing a partial 2019–2020 sample of the present population, supporting the inclusion of the TDM in the 2022 update of the Spanish baseline series.⁴

European studies have evaluated the frequency of allergy to TDM in consecutive patients. Prevalence ranges from 0.4% to 6.9%, with an average of 2%–3%,^{2,5–12} which is similar to ours. In a nationwide study conducted in Italy from 2018 to 2019, Stingeni et al.¹¹ found a lower prevalence of 1.5%, supporting a decreasing trend of contact sensitisation to DDs in Italy. A study run by the International Contact Dermatitis Research Group (ICDRG)¹² found that prevalence

in 2013 was significantly lower in a group of four European clinics from Belgium, Germany, Denmark, and Sweden, when compared to a group of five from America and Asia.

Most common positive specific DDs vary across studies, DB 106 and 124, and DO 1 and 3 being the most frequent.^{6,7,10,11,13} In our study, DO 3 (15.9%), DO 1 (6.8%) and DB 106 (6.2%) were the most common in those patients patch-tested with the textile dye series (Table 2). Of note, nearly half of all the patients of the study (3044/6128: 49.7%) were patch-tested with DB 106 as part of the True-test. From these, only 0.7% (22/3088) was positive. Therefore, DB 106 does not look like a good marker of textile allergy in our population.

We found an overall high 3.4% frequency of sensitisation to PPD. This frequency was similar when patch-tested in petrolatum (3.3%) versus as part of the True-test (3.6%). Allergy to PPD was significantly more common in women, probably because of a higher exposure to the allergen in hair dyes.

About one in three TDM-positive cases in our population were linked to current relevance, although this proportion might be higher, since also one in three TDM-positive cases were considered due to cross-reactivity, and thus not currently relevant. Other studies have shown mixed findings. In the aforementioned study conducted by the ICDRG,¹² Isaksson et al. found a clinical relevance of 21%, and a lower 12.5% in a more recent research of the Swedish Contact Dermatitis Research Group (SCDRG).⁹ Ryberg et al. observed a clinical relevance of 31% in a study run by the European Environmental Contact Dermatitis Research Group (EECDRG),⁶ and a 37.5% in a work of the SCDRG.⁷ In contrast, Stingeni et al.¹¹ observed a higher clinical relevance of 70%. Concerning studies in selected patients with suspected textile ACD, Nijman et al.¹⁷ observed that most cases were linked to clinical relevance in a Dutch sample, as well as Wentworth et al.¹⁰ in an American group.

Patch testing with the TDM usually results in moderate/strong (+/+ +++) reactions.^{2,6,7,11,12} We also documented a high 74.5% (149/200) proportion of moderate/strong (+/+ +++) positives in our population. Additionally, we found a low proportion of doubtful (0.2%) and irritant (0.1%) reactions, as previously reported.^{6,7,12}

Several studies have analysed the features associated with TDM allergy. The role of sex is unclear, with some studies pointing to female sex as an associated factor,^{18,19} whereas others point to male sex^{11,20} or as in our study, do not find a relation.^{7,9,12} Age over 40 or increasing age is linked in various studies,^{18–20} opposite to our results lacking any association with age. Stingeni et al.¹¹ did not find significant differences concerning atopic dermatitis, aligned with us, but opposite to the studies by Lisi et al.¹⁸ and Ryberg et al.¹⁹ Along with our research, the vast majority of reported cases are non-occupational.^{11,18,20} In our study, only 12% were occupational. TDM allergy was most common in hairdressers/beauticians (14/200: 7.2%), and this was the only occupation linked to a higher risk for TDM allergy, both in the overall population and when current relevance was presumed. This is likely related to exposure of hairdressers/beauticians to PPD and cross-reactivity between TDM and PPD.

Dermatitis location is variable with some studies showing that leg,²⁰ neck,^{6,12} trunk,^{6,12,20} and generalised²⁰ dermatitis are significantly more common in patients with suspected textile ACD, whereas face¹⁸ and hand¹⁸ dermatitis are less common. In our study, the neck/trunk and hands were the most frequent locations of the dermatitis. We found that isolated scalp, combination of scalp and extra-scalp, neck/trunk, and arm/forearm dermatitis, were significantly associated with TDM allergy. Considering only those cases linked to current relevance, positivity was significantly associated with combination of scalp and extra-scalp, neck/trunk, and arm/forearm dermatitis. Interestingly, isolated scalp dermatitis was linked to TDM allergy in the overall population but not in those cases linked to current relevance, in which it was only when accompanied by extra-scalp dermatitis. This is probably related to cross reactivity between TDM and PPD. On the one hand, in TDM-positive patients who develop isolated scalp dermatitis, sensitisation is likely due to cross-reactivity to PPD, which acts as the prime sensitizer in hair dyes. This is the reason why dermatitis affects only the scalp. On the other hand, in TDM-positive patients who develop both scalp and extra-scalp dermatitis, sensitisation may arise from exposure to textiles and/or PPD in hair dyes, whichever acting as the prime sensitizer, and dermatitis develops as a consequence of exposure to both PPD and textile dyes. In those cases, TDM allergy is likely to be considered currently relevant. Textile ACD most commonly affects the upper extremities, trunk, face, buttocks and the folds.^{2,3} Due to this distribution pattern, potential textile ACD should be investigated in adults with recalcitrant atopic dermatitis,²¹ especially when scalp dermatitis is present.

In our work, around 57% of TDM-positive patients were also positive to PPD, whereas around 54% of PPD-positive patients were also positive to TDM. Apart from that, 80% of PPD-positive patients were also positive to DO 3, whereas 77% of DO 3-positive patients were also positive to PPD. The research of Stingeni et al.¹¹ is the only one with a low proportion of concomitant positivity between TDM and PPD (28.5%). The vast majority of studies show that, similar to our results, simultaneous positivity between TDM and PPD is common, as it is between DO 3 and PPD, and vice versa.^{6-9,11,12,17} In the study of Isaksson et al.,¹² 61% of TDM-allergic patients were also allergic to PPD and 75% to any separate DDs, DO 3 being the most frequent. In the two cited works by Ryberg et al.,^{6,7} 53%–58% of TDM positive patients were allergic to PPD. In both, all but one DO 3 sensitised patients reacted to PPD. The author raised the hypothesis whether DO 3 could hence be excluded from the TDM, so that people allergic to PPD would avoid reactions to TDM due to cross reactivity. This was further analysed by Stenton et al.⁸ and confirmed by Isaksson et al.,⁹ who suggested replacing the conventional TDM 6.6% in the Swedish baseline series for a new TDM 7.0% containing DB 106 1% and DB 124 1%, and excluding DO 3. In our population, roughly one in every four DO 3 positive cases would be missed if patients were patch-tested with the PPD alone, so our results do not support removal of DO 3 from the TDM. However, as part of the textile dye series, DO 3 was only patch tested when textile ACD was suspected, thus

not simultaneously to PPD and TDM in the larger population. Therefore, it is difficult to draw firm conclusions regarding the possible exclusion of DO 3 from the TDM.

We observed 8 cases of positivity to the DB mix 106/124, far less than the total 17 cases of sensitisation to DB 106 (10) and 124 (7) when tested separately. Therefore, we think that the DB mix 106/124 should not be tested as a substitute of its separate allergens. Apart from that, there were four patients sensitised to a total of five allergens included in the textile dye series other than those of the TDM, namely Basic Red 46 (2), Direct Orange 34 (1), Disperse Blue 153 (1), and Reactive Blue 21 (1). Two of these patients were also positive to the TDM, whereas the other two were negative. From the latter, one was sensitised to DR 1 and DR 17, whereas the other one was negative to the eight DDs of the TDM. More research is needed to know whether these other dyes should be included in the TDM in Spain and other countries. Carlsson et al.¹ showed that DO 3 was the only allergen of the TDM commonly used in synthetic garments on the Swedish market, whereas Malinauskiene et al.²² observed that the eight DDs of the TDM are very rarely used in textiles worldwide. Chromatography techniques have shown that individual textile dyes, and thus patch tests preparations, may contain impurities, dye precursors, dye metabolites or other chemicals, such as arylamines and halogenated dinitrobenzenes, which might be responsible for the positive reactions to the TDM or specific DDs, due to concomitant sensitisation or cross-reactivity.^{1,5,22}

Considering available information of those cases that were simultaneously tested with both the TDM and its eight separate allergens as part of the textile dye series, in our study only 14.6% (6/41) of the cases would have been missed if patch-tested with the TDM alone. When compared to the entire textile dye series, this proportion would have been 16.7% (7/42). There is further evidence that the TDM is a useful marker of textile contact allergy. Linauskiene et al.⁵ showed that a group of 9 out of 10 TDM-positive Swedish patients reacted to textile extracts made from synthetic garments which did not contain pure DDs present in TDM 6.6%, probably because of the abovementioned unknown dye substances, DDs metabolites or impurities. However, Nijman et al.¹⁷ found that patch-testing the TDM alone in a Dutch group with suspected textile ACD would involve missing a substantial amount of dye positive and clinically relevant cases. We agree that both the TDM and a specific textile dye series should be patch-tested in clinical practice in case of suspected textile ACD.

5 | STRENGTHS AND LIMITATIONS

This research is a multicentre REIDAC study with a large sample of consecutive patients, which can be considered representative of the Spanish population attending reference hospitals for ACD. A limitation of the study is that relevance of positive cases was based on clinical history and not based on positivity to garments that could cause the dermatitis. Another limitation is the low number of patients tested with the specific textile dye series.

6 | CONCLUSIONS

At present, there is a high frequency of positivity to TDM in Spain. One in every three cases is linked to current relevance. In such cases, positivity is associated with working as a hairdresser/beautician and concurrent scalp and extra-scalp dermatitis, as well as neck/trunk and arm/forearm dermatitis. Simultaneous positivity between TDM and PPD is common, as well as between PPD and DO 3, but probably not common enough to exclude DO 3 from the TDM. Our findings support that TDM is a good marker of DDs sensitisation.

AUTHOR CONTRIBUTIONS

Carlos Pelayo Hernández Fernández: Conceptualization; investigation; writing – original draft; writing – review and editing; methodology; validation; visualization; supervision. **Leopoldo Borrego:** Conceptualization; investigation; funding acquisition; methodology; validation; visualization; writing – review and editing; project administration; data curation; supervision; resources. **Ana María Giménez Arnau:** Resources; writing – review and editing; methodology; investigation. **Violeta Zaragoza Ninet:** Writing – review and editing; methodology; investigation; resources. **Tatiana Sanz Sánchez:** Resources; writing – review and editing; methodology; investigation. **Francisco Javier Miquel Miquel:** Investigation; writing – review and editing; methodology; resources. **Ricardo González Pérez:** Resources; writing – review and editing; methodology; investigation. **Juan Francisco Silvestre Salvador:** Investigation; writing – review and editing; methodology; resources. **Susana Córdoba Guijarro:** Resources; writing – review and editing; methodology; investigation. **José Manuel Carrascosa Carrillo:** Investigation; writing – review and editing; methodology; resources. **María Elena Gatica Ortega:** Resources; writing – review and editing; methodology; investigation. **Inmaculada Ruiz González:** Investigation; writing – review and editing; methodology; resources. **Pedro Mercader García:** Resources; writing – review and editing; methodology; investigation. **Fátima Tous Romero:** Investigation; writing – review and editing; methodology; resources. **Esther Serra Baldrich:** Resources; writing – review and editing; methodology; investigation. **María Antonia Pastor-Nieto:** Investigation; writing – review and editing; methodology; resources. **Mercedes Rodríguez Serna:** Resources; writing – review and editing; methodology; investigation. **Javier Sánchez Pérez:** Investigation; writing – review and editing; methodology; resources. **Araceli Sánchez Gilo:** Resources; writing – review and editing; methodology; investigation. **Gemma Melé Ninot:** Investigation; methodology; writing – review and editing; resources. **Paloma Sánchez-Pedreño Guillén:** Methodology; writing – review and editing; investigation; resources. **Marina de Vega Martínez:** Software; formal analysis; methodology; investigation. **Miguel Ángel Gallego Descalzo:** Supervision; data curation; formal analysis; software; project administration; writing – review and editing; methodology; visualization; validation. **Ignacio García Doval:** Supervision; data curation; formal analysis; software; project administration; writing – review and editing; methodology; validation; visualization.

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CONFLICT OF INTEREST STATEMENT

The authors have no conflicts of interest to declare that are relevant to the content of this article.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

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