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Are all new allergens in TRUE Test® essential for a baseline set?

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The prevalence of contact allergy to specific allergens differs among countries, as a result of social and environmental characteristics. Patch testing is the gold standard in the diagnosis of contact dermatitis to identify the culprit substance. TRUE Test® is a ready-to-use patch test system commercialized since 1985, and is used worldwide. As TRUE Test® does not cover several allergens recommended for the (European) baseline series, clinicians have to test additional allergens separately. Recently, TRUE Test® added five new allergens. The newly included allergens are gold sodium thiosulfate, bacitracin, parthenolide, Disperse Blue 106, and 2-bromo-2-nitropropane-1,3-diol (bronopol). The aim of our study was to evaluate the relevance of these new allergens as a part of our baseline series.

We included all patients from seven allergy departments in Spain who had been referred for patch testing with the 34-allergen TRUE Test®, including the five new allergens, and six additional allergens to cover the recommended standard panel, during 1 year. Readings were performed on day (D)2 and D4, according to ICDGR recommendations. Results were analysed as positive versus negative, and the clinical relevance of positive results was evaluated.

One thousand and forty-six patients were included. Of these, 66 patients (6.3%) had a positive result with one or more of the five new allergens. Many positive results were obtained with gold sodium thiosulfate (3.2% of the total sample). Readings were +++ in 8 patients, ++ in 11 patients, and + in 14 patients, respectively, and were irritant in 6 patients. The positive results were considered to be relevant in only 4 of 33 patients (12%). Disperse Blue 106 was positive in 6 patients (0.57% of the total sample): +++ in 1 patient, ++ in 1 patient, and + in 4 patients. In 3 patients, this was considered to be clinically relevant. Bacitracin was positive in 5 patients (0.46%), including 3 patients with a +++ reading and 2 patients with a + reading. In 4 cases, this was considered to be clinically relevant. Only 4 patients (0.38%) had a positive reading with 2-bromo-2-nitropropane-1,3-diol (1 ++ and 3 +). This was considered to be relevant in only 1 patient. Parthenolide was positive in only 1 patient (0.09% of the total sample).

We found a lower prevalence of positive patch test results than previously published: gold sodium thiosulfate, 8.6–10.2%; Disperse Blue 106, 1.9–3%; 2-bromo-2-nitropropane-1,3-diol, 3.4%; bacitracin, 7.9–9.2%; and parthenolide, 0.1–3.1% (1–4). A recent study showed an even lower prevalence of positive results for 2-bromo-2-nitropropane-1,3-diol (5). The inclusion of a sensitizer in a baseline series has been proposed only when routine testing shows a relative frequency of contact allergy exceeding 0.5–1% of patients (6). Given that the prevalence of positive results was very low, we think that parthenolide and 2-bromo-2-nitropropane-1,3-diol should not be included in our baseline series. Moreover, sesquiterpene lactone mix (which is usually tested in our baseline series) has shown better results for screening than parthenolide alone in some previous studies (7). Besides the prevalence, clinical relevance is also very

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important when inclusion of a new substance in the baseline series is considered (6). In our experience, as well as previously reported (2), gold sodium thiosulfate has triggered sometimes strong and persistent reactions, and a positive test result has been considered to be clinically irrelevant in most patients. This was the reason for its exclusion from standard series some years ago, and for recommending that it should be tested only when allergy is suspected (1, 2, 6). Nevertheless, bacitracin is a sensitizer that is clinically relevant in almost every patient in our data. It is also important to include in standard series those substances that are difficult to suspect as a cause of dermatitis by means of clinical history. Disperse Blue 106 has been shown to be a good marker of disperse dye allergy; only 50% of sensitized subjects had a concomitant positive test result with *p*-phenylenediamine; the prevalence of sensitization is high enough for it to be included in standard series, and it is usually relevant (3, 8, 9). In spite of Disperse Blue 106 being considered to be a strong sensitizer, in a large, multicentre study only 1 patient reported a late reaction that should be interpreted as active sensitization (8).

In conclusion, on the basis of own results, only Disperse Blue 106 and bacitracin should be considered for inclusion in our baseline series.

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