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COMPARATIVE STUDY OF FORMALDEHYDE 2% IN AQUEOUS SOLUTION VS TRUE TEST IN DETECTING FORMALDEHYDE SENSITIZATION.

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COMPARATIVE STUDY OF FORMALDEHYDE 2% IN AQUEOUS SOLUTION VS TRUE TEST IN DETECTING FORMALDEHYDE SENSITIZATION.

The optimal Formaldehyde (FA) concentration for patch testing that allow to identify true FA sensitization has been studied and discussed over time. Several studies support that FA 2% aqueous solution (aq.) was the most effective concentration identifying true formaldehyde sensitization, without causing too many irritant reactions ¹. Thus, in 2016 the Spanish baseline series was updated by the “Grupo Español de Investigación de Dermatitis de Contacto y Alergia Cutánea” (GEIDAC) and test concentration of FA was modified from 1% to 2% aq. ².

Several parameters may affect the results, too, including technical methods such as diagnostic patch testing support material ³⁻⁴.

We present a prospective multicenter Spanish study that compares agreement and diagnostic accuracy of positive patch test reactions to FA 2% aq. to FA in TRUE test.

METHODS

Six specialized Contact Dermatitis Clinics within Departments of Dermatology throughout Spain were involved in the study. In 2017 for 12 months, 1136 patients were patch tested with the Spanish baseline series with two 2 patch test support materials: FA at 180 µg/cm² (146 µg) in TRUE test (SmartPractice, Phoenix, Arizona) and FA 2% aq. (Chemotechnique Diagnostics, Vellinge, Sweden or AllergEAZE by, SmartPractice Phoenix, Arizona) occluded for 2 days. Readings were performed at D2 and D4, according to International Contact Dermatitis Research Group (ICDRG) and European Society of Contact Dermatitis Society (ESCD) recommendations. Reactions +/- were not included.

RESULTS

Fifty-two patients reacted positively to FA 2% aq. (4.57%), only 13 patients (1.14%) reacted to FA in TRUE test and all of them showed a positive reaction to FA 2% aq.

In the 39 patients that reacted positively to FA 2% aq. but not to TRUE test, only 3 cases were assessed as irritant reactions. From 21 patients it was possible to establish either present relevance (15 patients) or past relevance (6 patients) and 15 patients presented unknown relevance. Five patients from this subgroup with discordant data showed sensitization to FA releasers, too.

The assessment of present and past relevance of the positive reactions helped to define if discordant reactions were false positive or negative reactions. Cohen's Kappa test showed a moderate concordance [0.49 ($P < .001$)] between the clinical relevance of positive reactions to FA 2% aq. and FA in TRUE test. The unknown relevance distribution was not statistically different in both tests ($P > .1$). In addition, the concomitant reactions to FA releasers in five patients with a positive reaction to FA 2% aq. but negative reaction to FA in True test support true FA sensitization.

DISCUSSION

Based on the presented data, TRUE test is a highly specific patch testing preparation (100% specificity), but with very low sensitive power (33% sensitivity) to detect FA sensitization compared with FA 2% aq. The TRUE test is an easy, rapid way to perform patch test, that guarantee a fixed amount of the applied contact allergen, but if we consider FA 2% aq. the Gold standard for detection of FA sensitizations, it is advisable to carry out an additional patch test with FA 2% aq. in patients with exposure to FA who continue to have to dermatitis despite of a negative reaction to FA in the TRUE test.

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