

Letter to the Editor

The concentration of para-phenylenediamine (PPD) for routine patch testing in a standard series needs to be redefined

Dear Sir,

PPD is undoubtedly an important allergen, in terms of potency, exposure and frequency of sensitization. However, active sensitization caused by patch testing with PPD, particularly in concentrations >1% (1) is known as a risk, albeit an 'extremely low one' (2). Recently, the frequency of this side-effect has been discussed controversial in the literature (3, 4). The German Contact Dermatitis Group (DKG) has conducted a prospective study on late patch test reactions to PPD and epoxy resin in 1411 patients (5). An interim analysis revealed that 45 (3.2%) reacted to PPD during D1-D3, 18 (1.3%) showed late reactions at readings D7-D21, i.e. 29% of all PPD allergies diagnosed were late reactions.

In our study 7 patients were re-tested with PPD, 5 (71%) reacted within 3 days, proving active sensitization and assuming that the majority of the late reactions had become positive due to patch test sensitization.

This would mean that, in view of ~400.000 patch tests per year in Germany (6), about 3700 patients would be sensitized by patch testing.

Based on the results and in careful consideration of its diagnostic value for routine patch testing *versus* the risk of active sensitization, the DKG could no longer support the use of PPD in its present concentration in the German standard series. Until further studies can confirm or refute our results, its use is recommended only for patch tests in patients with suspected PPD allergy.

Since patch test preparations are by law defined as medical drugs new data and insights in risks imposed the need for action upon the pharmaceutical industries for safety reasons. Thus, Hermal had to take immediate action prior to publication of the data and removed PPD from its standard series in Germany as well as the 'European' standard series. Because the data from the underlying study still await publication the scientific background of our decision was not transparent. We regret that this has provoked confusion and an ongoing discussion and want to make clear that it has never been the intention of the group to

dictate or enforce the removal of PPD from the 'European' standard series.

Dermatologists may still use PPD 1% pet. routinely as part of the 'European' standard series until a definitive evidence-based decision by European groups has been made to which after their publication the German data may contribute.

The DKG will launch dose-finding studies on PPD in sensitized individuals followed by prospective monitoring for late patch test reactions to provide data for a safer PPD-concentration for standard patch testing. We would like to invite European colleagues to participate in this process.

However, for the time being we are convinced that the concern raised by active sensitization dominates the eventual concern of missing an existing PPD-sensitization in the standard patch test, which can be counterbalanced by taking a concise history regarding the exposure to PPD followed by aimed testing.

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