Assessment of the allergen composition in diagnostic and therapeutic mite allergen preparations

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Background

The quality of allergen products is a prerequisite for successful diagnosis and therapy of allergic diseases. However, commercially available pharmaceutical allergen preparations have been shown to vary significantly with respect to the presence of major and minor allergens. In the presented approach the allergen composition of diagnostic and therapeutic allergen products was extensively assessed by mass spectrometry (MS) using the mite species *D. pteronyssinus* and *D. farinae* as example.

Methods

Skin-Prick-Test-solutions, production batches of allergen extracts used for allergoid production, and production batches of aluminium hydroxide-adsorbed extracts of both mite species (Allergopharma) were investigated (three batches each). In parallel, current in house reference preparations (IHRPs) were analysed. The presence of major mite allergens was investigated by allergen-specific monoclonal antibodies. To determine the allergen composition comprehensively, samples were subjected to trypic digestion and resulting peptides analysed by tandem mass spectrometry (LC-MS/MS).

Results

Current IHRs, three batches of each Skin-Prick-Test-solution, of each allergen extract and of each aluminium hydroxide-adsorbed allergen extract were analysed (Fig. 1 & Fig. 2). The major mite allergens (group 1 and group 2 allergens) were detected in all samples of the respective species both, by monoclonal antibodies and by MS (Fig. 3). In addition, MS analysis allowed identification of 13 and 12 additional allergen groups in the *D. pteronyssinus* and *D. farinae* allergen preparations, respectively (Fig. 4). While Casset et al., 2012 were able to detect the “intermediate” relevant allergens of group 5, 7, and 21 in only two of 13 commercial extracts, these allergens were identified by MS in all analysed Allergopharma extracts and products.

Conclusion

The investigated diagnostic and therapeutic mite products were found to be comparable regarding allergen composition. In addition to all major allergens, they contain all “intermediate” relevant allergens, and the majority of minor allergens. Thus all important mite allergens are present in the investigated allergen preparations.

Reference(s)


Conflict of Interest: The authors are employees of Allergopharma GmbH & Co. KG.