Comparison of molecular singleplex and multiplex analysis in the diagnosis of house dust mite allergy

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Background

It is well known from the literature that molecular diagnosis with the four routinely available allergens (rDer p 1, 2, 10, and 23) does not detect all house dust mite allergic patients.

Research questions

1) How reliable is molecular house dust mite allergy diagnosis?

2) Can additional allergens (rDer p 5, 7 and 11) using the newly available multiplex assay ALEX® increase sensitivity?

3) Are multiplex assays (ISAC® and ALEX®) comparable to molecular singleplex analysis (ImmunoCAP®)?

Methods

Two hundred fifty house dust mite allergic patients (53% females, mean age 27 ±15 years) defined by clear clinical symptoms and IgE reactivity to *Dermatophagoides pteronyssinus* (D.p.) extracts >0.35kUA/l were explored for IgE reactivity to D.p. molecular allergens: rDer p 1, 2, 10 and 23 using the singleplex assay ImmunoCAP®, nDer p 1, rDer p 2 and 10 using the multiplex assay ISAC® and rDer p 1, 2, 5, 7, 10, 11 and 23 using the multiplex assay ALEX® Allergy Explorer.

Results I – Qualitative and quantitative results of molecular diagnosis

There was no difference between the three test systems regarding positivity to the individual allergens or their specific IgE levels.

Results II – Correlation of the test systems

Pearson's r	CAP® vs. ALEX®	CAP® vs. ISAC®	ALEX® vs. ISAC®
Der p 1	0.903	0.901	0.828
Der p 2	0.829	0.910	0.807
Der p 10	0.977	0.998	0.969
Der p 23	0.803	-	-

All three test systems correlated well with Pearson´s correlation coefficients ranging between 0.803 and 0.998, p<.001.

Results III – ImmunoCAP® vs. ISAC® vs. ALEX®

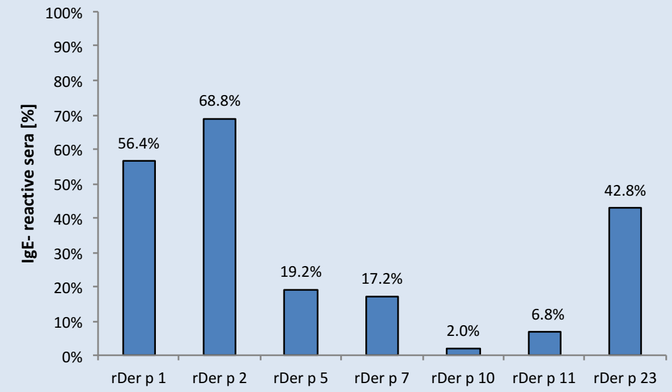
method	overall sensitivity
CAP® D.p. extract	100%
CAP® molecular	90.8%
ISAC®	86.4%
ALEX®	85.6%

Results of molecular diagnosis were comparable between all test systems. Differences in overall sensitivity rates between ImmunoCAP® analysis with molecular allergens, ISAC® and ALEX® were not statistically significant.

Nevertheless, sensitivity of the molecular allergy diagnosis was significantly lower compared to the conventional extract based diagnosis.

After exclusion of sera with IgE-levels against D.p. extracts lower than 1 kU/l, the sensitivity of the molecular approach was markedly higher (ImmunoCAP® 95.3%, ISAC® 92.5%, ALEX® 93.4%), but still statistically lower compared to the extract based diagnosis.

Results IV – Sensitization profiles (ALEX®)



The additional allergens rDer p 5, 7 and 11 are only minor allergens.

1 out of 250 patients was monosensitised to rDer p 5, whereas no patients were monosensitised to rDer p 7 or 11.

Conclusion

1) To date, neither multiplex assays nor molecular singleplex analysis can reliably replace extract based IgE diagosis of house dust mite allergy. Depending on the system, 9.2 to 14.4% of the patients could not be correctly diagnosed.

1) Adding rDer p 5, 7 and 11 using the newly available multiplex assay ALEX® did not increase the overall sensitivity.

2) All three test systems showed similar results in the molecular diagnosis of house dust mite allergy.

In relation to this presentation, I declare that there are no conflicts of interest.