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TOLERABILITY AND EFFICACY OF HDM INJECTIVE IMMUNOTHERAPY WITH MONOMERIC ALLERGOID: 2-YEARS-FOLLOW UP

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Background. Subcutaneous immunotherapy (SCIT) is an effective treatment for respiratory allergy and carbamylated monomeric allergoids, by virtue of their reduced IgE-binding activity, resulted clinically safe by sublingual administration. We investigated the tolerability and efficacy of house dust mites (HDM) carbamylated allergoid administered by injective route in patients with respiratory allergy.

Method. This prospective open-label non-randomized controlled study was conducted since November 2009 to November 2011. A preparation of 0.70 mL of 10 BU/mL containing modified extract with 50% *Dermatophagoides pteronyssinus* and 50% *Dermatophagoides farinae* was delivered monthly for 2 years, following a 5-week build-up induction phase (0.10-0.20-0.30-0.50-0.70 mL), to 11 monosensitized patients (53% males, mean age 29.1 ± 10.7) suffering from rhinitis due to HDM; 11 patients with similar baseline characteristics were observed as controls. All patients were allowed to assume drug therapy for their condition on demand. Immediate adverse reactions (AR) to treatment were recorder by doctors at each visit; patients were instructed to report late AR by phone or during the subsequent visit for the whole study duration. Visual analogue score (VAS) was assessed each month since November to February for 2 years.

Drug consumption was calculated for the same period. Patients' and physicians' judgements (unsatisfactory, mild, good, optimal) on efficacy and tolerability were collected at the end of the study.

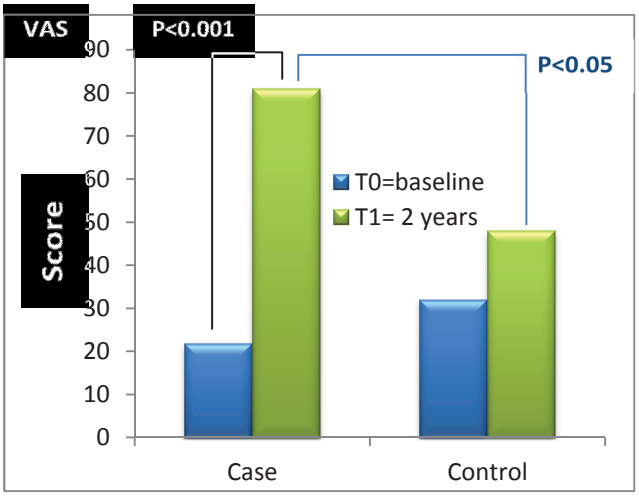

Figure 1: Efficacy Results

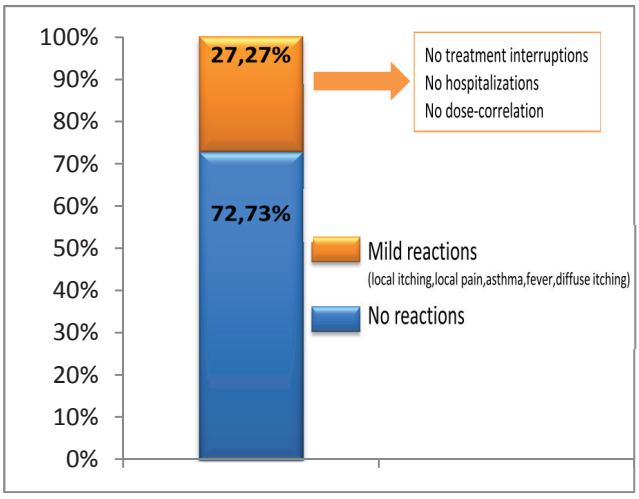

Figure 2: Safety Results

Results. Four patients from control group withdrew during the second year for uncontrolled disease. All patients receiving SCIT concluded the study and no AR occurred in 8 patients (72.73%); 3 patients (27.27%) referred mild AR (local itching; local pain, asthma, fever, diffuse itching) not requiring interruption; no severe AR occurred. Both groups showed a progressive improvement in mean monthly VAS ($p<0.001$) with significant difference in favour of the SCIT group ($p<0.05$). Drug intake was significantly lower in patients receiving SCIT ($p<0.05$) in both years. The number of doctors and patients with optimal or good judgment of the treatment efficacy and tolerability was largely superior for SCIT.

Conclusion. Preliminary experiences suggest that the traditional safety of monomeric allergoid seems confirmed also through injective route; this treatment was associated with improved health condition and lower drug usage, being favourably judged by both patients and physicians.