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## A possible immuno-modulatory effect of probiotic and sublingual immunotherapy in allergic subjects: A safety profile

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**Introduction & aim:** Gastrointestinal microflora promotes immune regulation and potentially antiallergenic processes. Lactobacillus rhamnosus has proved safe at an early age and effective in treatment of allergic inflammation and food allergy. Probiotic bacteria, which affect the host b improving microbial balance, may mediate anti-allergic effects by stimulating production TGF ß, Th1-cytokines and IgG antibodies. Moreover, probiotic may act synergistically to improve the clinical efficacy of sublingual allergen immunotherapy. It was shown that lung function improved in patients receiving SLIT and probiotic. Another study showed that sublingual administration of B. bifidum together with recombinant Bet v 1 enhanced tolerance induction in BALB/c mice. A recent study with a mouse model of allergic asthma showed that oral administration of L. gasseri attenuated allergen-induced airway inflammation and induced a reduction in IL 17-mediated immune response13. The purpose of this study was to investigate the role of SLIT and probiotic association on allergy symptoms.

**Methods:** Treatment groups received oral administration of Bifidobacterium lactis (>1×109) and Lactobacillus rhamnosus (>1×109) in water for 8 weeks (Kallergen TH, Allergy Therapeutics, Milan, Italy) daily started from 14 d before the first ORALVAC oral administration with pollen extract (day 0) and continued for 4 months. The patients were enrolled in three groups (1, SLIT; 2 probiotic; and 3, SLIT-probiotic). IgE-specific antibodies for RAs, rPhl p 1, rPhl p 2, nPhl p 4, rPhl p 5, rPhl 6, rPhl p 7, rPhl 11, rPhl 12 were evaluated using the immuno-enzymatic CAP system (Thermo Fisher Diagnostics, Uppsala, Sweden) following the manufacturer's instructions. The results were expressed in classes of positive results from 0 to 6, where class 0 corresponds to <0.1 kUA/l; class 1, 0.1-0.7 kUA/l; class 2, 0.7-3.5 kUA/l; class 3, 3.5-17.5 kUA/l; class 4, 17.5-50 kUA/l; class 5, 50-100 kUA/l; and class 6, >100 kUA/l.

**Results:** No relevant local or systemic symptoms were registered in the three groups of patients in the study. This confirms the optimal safety profile of Kallergen Th<sup>\*</sup> and ORALVAC PLUS<sup>\*</sup>, in mono- or combined therapy.

**Conclusions:** In conclusion, these preliminary data suggest that: high-dose pre-seasonal or perennial SLIT protocol is safe and well-tolerated when administered in association with probiotics. As previous studies seem to suggest, whether SLIT and co-treatment by probiotics promotes a better tolerance induction towards environmental allergens, it is currently under investigation.

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