

SIGNIFICANT IMPROVEMENT OF ALLERGY SYMPTOMS AFTER PROBIOTIC FOOD SUPPLEMENTATION MEASURED IN AN ALLERGEN EXPOSURE CHAMBER

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Introduction

The prevalence of allergic diseases is steadily increasing. This disease has a high socioeconomic impact for the patients, but also for the whole society. Over the last few years, a high number of articles were published in the field of microbiome research, investigating the effects of the loss of microbial diversity linked to different diseases, also shown for the development of allergies. Besides allergen immunotherapy, which is the only causative treatment to date, there are additional strategies to relieve symptoms of allergic patients, e.g. the modification of the patient's microbiome respectively the increase of microbial stimuli from beneficial bacterial strains.

Studies suggest that certain strains of probiotic bacteria can improve allergy symptoms like rhinitis or rhinoconjunctivitis, however, these studies vary in quality, and standardisation is rare. A certified allergen exposure chamber (AEC) is a highly standardised platform to perform clinical studies with allergic patients and reliably generate allergic symptoms. Type and amount of pollen as well as duration of exposure are standardised, leading to study results that are reproducible and better comparable than natural exposures, which vary. We therefore successfully initiated the first study with patients suffering from allergic rhinoconjunctivitis due to birch pollen, investigating the effects of the intake of a probiotic/prebiotic food supplement via a controlled provocation in an allergen exposure chamber before (baseline) and after (final) intake of a probiotic food supplement.

Methods

Thirty Patients with diagnosed rhinoconjunctivitis (confirmed by prick test or allergen-specific IgE measurement in serum and with clinical history of at least two symptoms of an allergic rhinoconjunctivitis) gave written informed consent and were included in the study. The study was conducted outside the birch pollen season at the ECARF Institute (Berlin, Germany) in a standardised allergen exposure chamber.^{1,2,3}

At baseline visit (V1), the patients were exposed to 8.000 birch pollen/m³ for 120 minutes at 21 °C and 55% relative air humidity. Symptom Scores (Total Nasal Symptom Score (TNSS), Total Eye Symptom Score (TESS), Total Bronchial Symptom Score (TBSS), Total Other Symptom Score (TOSS), and resulting Total Symptom Score (TSS)) were assessed every 10 min by the patients during the exposure. Amongst others PNIF and PEF was measured every 30 min during exposure, as well as spirometry was performed before and after the exposure.

After a 4-month intake period of the probiotic/prebiotic food supplement, consisting of a combination of *Lactobacillus acidophilus* NCFM, *Bifidobacterium lactis* BL-04 and Fructo Oligosaccharides (FOS)^{4,5}, the patients were exposed for a second time (V3, final visit) with the same conditions and measurements as during V1. A safety call was performed 24 h after both exposures (V2 and V4). 27 patients completed the study and were included in the preliminary data analysis.

Results

1. Development of the different Symptom Scores at V1 and V3 during 120 min of birch pollen exposure:

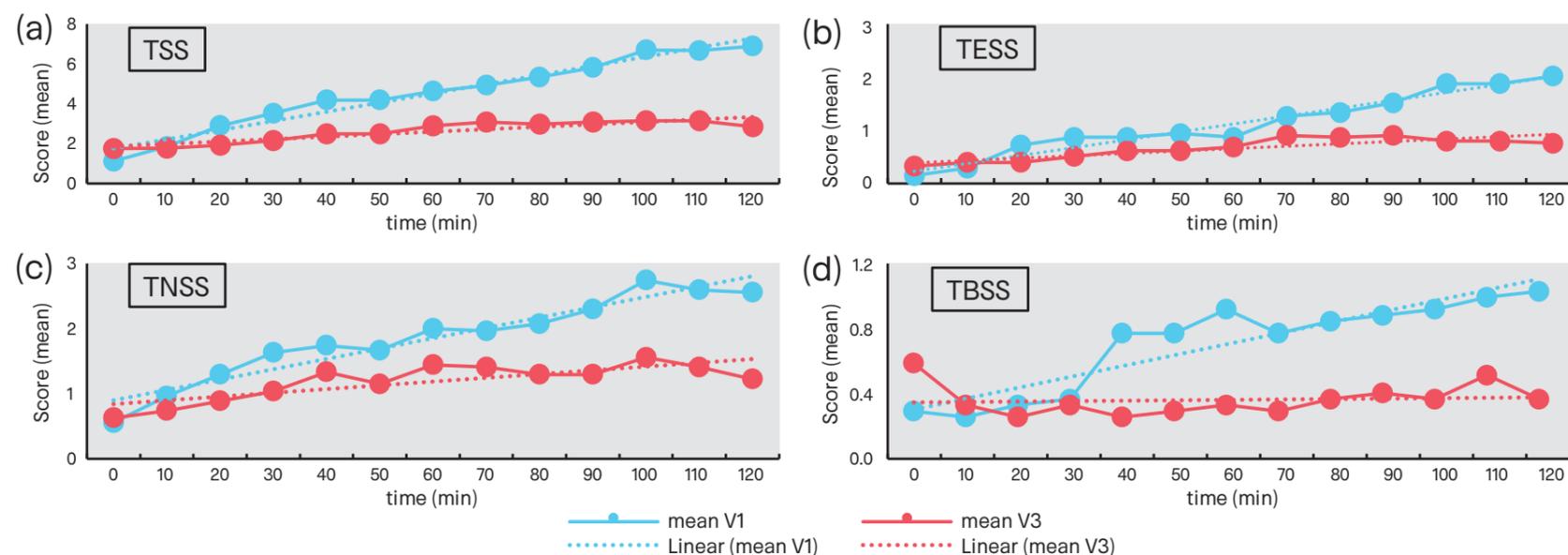


Figure 1: In total, we observed significant and clinically relevant improvement of medium effect size (d) at 120 min exposure. Reduction of Total Symptom Score (TSS) of 2.85 at V3 versus 6.89 at V1 ($d=-0.74$, $p<0.009$), Total Nasal Symptom Score (TNSS) of 1.22 at V3 versus 2.56 at V1 ($d=-0.66$, $p<0.02$), Total Eye Symptom Score (TESS) of 0.78 at V3 versus 2.07 at V1 ($d=-0.68$, $p<0.02$), and Total Bronchial Score (TBSS) of 0.37 at V3 versus 1.04 at V1 ($d=-0.46$, $p<0.10$) between baseline (V1) and final exposure (V3) after intake of the probiotic/prebiotic food supplement.

2. Other measured parameters: TOSS (Total Other Symptom Score, itching palate and/or skin) was also shown to be significantly different ($p<0.02$) before and after the treatment. There were no significant differences observed for PNIF and PEF as well as spirometry did not show a difference between V1 and V3. However, since there were no obstructions measured before and after exposure at V1, we did not expect to see differences at V3. Furthermore, the probiotic/prebiotic food supplement showed a good safety and tolerability profile.

Conclusions

For the very first time in a highly standardised allergen exposure chamber setting, we investigated the effects of a probiotic food supplement in the context of birch pollen allergy. The probiotic/prebiotic combination led to robust and relevant treatment effects shown by the reduction in Total Symptom Score (TSS) analysed after an intake period of only 4 months. Nasal and conjunctival symptoms were significantly reduced at the final exposure. In addition, the probiotic food supplement showed an excellent tolerability profile.

References:

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