CLINICAL EFFICACY OF PROBIOTIC LYSATE DEL-IMMUNEV® FOR THE TREATMENT OF GASTROINTESTINAL MANIFESTATIONS ASSOCIATED WITH FOOD ALLERGY IN PRESCHOOL CHILDREN

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Introduction:
Probiotic lysates are cellular structures that can be administered therapeutically without any of the potential adverse side effects associated live microbial cultures. Both in vitro and in vivo studies have demonstrated a high therapeutic potential for probiotic lysates, which are particularly oriented towards immune system regulation. The objective of the present study was to determine the effectiveness of the lysate of Lactobacillus rhamnosus V, in preschool children with gastrointestinal manifestations associated with food allergy.

Methods:
55 patients aged from 2 to 6 years with a demonstrated history of food allergies were recruited for this open-label investigation. Subjects were randomized into two groups; the primary group (n=30) who as part of a complex therapy received 1 capsule of Del-Immune V® daily (30 minutes prior to food) and; the control group (n=25) who received standard therapy without the inclusion of Del-Immune V®. Gastrointestinal, respiratory and skin clinical manifestations were evaluated using questionnaires and the SCORAD (SCORing AD) index at baseline and 2 months. Paraclinical evaluations included serum total Immunoglobulin E (IgE), serum eosinophilic cationic protein (ECP), salivary secretory IgA (sIgA) and stool culture at baseline and 2 months. Obtained data was statistically evaluated using the t-Student criterion, and a value of p < 0.05 was considered as statistically significant.

Results:
The primary group showed a statistically significant (p < 0.05) reduction in the frequency and severity of skin and respiratory syndromes associated with food allergy. The beginning score on the SCORAD index averaged 32 ± 2.3 points, and following treatment with Del-Immune V®, values reduced to 10 ± 1.2 points, compared with 22 ± 2.1 points in the control group.
Serum levels of ECP reduced from 78.5 ± 0.6 ng/ml at baseline to 28.6 ± 1.5 ng/ml following 2 months supplementation of Del-Immune V® and to 46.2 ± 2.8 ng/ml in control. In subjects taking Del-Immune V®, concentrations of salivary sIgA increased by 251% from baseline (94.6 ± 1.07) to reach 236.2 ± 5.3 mg/l. In the comparison group, concentrations of salivary sIgA increased from 91.3 ± 1.01 mg/l at baseline to 148.8 ± 5.1 mg/l. These diagnostic findings indicate a more intense activation of endogenous immune protective factors following Del-Immune V® supplementation.
Findings indicate Del-Immune V® has a positive impact on the microbiota profile, evidenced by a significant increase in Bifidobacteria and Lactobacilli counts and significant reduction on the colonization of pathogens as Staphylococcus aureus, Candida spp., Citrobacter spp., Proteus spp., Klebsiella spp. and Enterobacter spp.
Assessment of the frequency and duration of acute respiratory disease (ARVI) demonstrated a 2-fold reduction in the frequency (2.3 ± 0.32 vs. 4.3 ± 0.54 episodes, p < 0.05) and the duration of ARVI episodes (4.1 ± 0.15 vs. 9.2 ± 0.51 days, p < 0.05) in the Del-Immune V® group.

Discussion:
Results support previous data regarding the therapeutic potency and bifidogenic activity of probiotic lysates and allows us to recommend the inclusion of Del-Immune V® as a part of an integrated therapy for preschool children who present with gastro-intestinal, respiratory and skin manifestations associated with food allergy.

Keywords: Live cells, Probiotic lysate, L.rhamnosus V, Del-ImmuneV®, Food allergy, Open-label investigation, Therapeutic pothency, Immune regulation, Bifidogenic activity, Probiotic
Citation: