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The efficacy and safety of heat-killed *Lactobacillus paracasei* for treatment of perennial allergic rhinitis induced by house-dust mite

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Live *Lactobacillus paracasi* 33 (LP33) may effectively improve the quality of life for patients with perennial allergic rhinitis. It has been demonstrated that heat-killed lactic acid bacteria (LAB) suppress specific immunoglobulin E synthesis and stimulate interleukin-12 production in animals. The aim of this study was, therefore, to evaluate the efficacy of heat-killed LP33 in the treatment of allergic rhinitis induced by house-dust-mite in human subjects. A total of 90 patients were enrolled in a randomized, double blind, placebo-controlled trial and assigned to three treatment groups. Patients in groups A and B received two capsules per day of live or heat-killed LAB (5×10^9 colony-forming units/capsule), respectively, over a period of 30 days while those in Group C received placebo capsules. A modified questionnaire on pediatric rhinoconjunctivitis-related quality of life was administered to all subjects or their parents during each clinical visit. The overall quality of life score decreased for groups A and B, as compared with the placebo group, in terms of both frequency (9.47 ± 2.89, 6.30 ± 2.19, vs. -3.47 ± 1.53, respectively; $p < 0.0001$) and level of bother (5.91 ± 3.21, 6.04 ± 2.44, vs. -2.80 ± 1.64, respectively; $p = 0.004$) after the 30-day treatment. The efficacy of the heat-killed LP33 was not inferior to the live variant. No obvious side effects were reported for either active treatment group during the study period. Our results suggest that heat-killed LP33 can effectively improve the overall quality of life for patients with allergic rhinitis, and that it may be efficacious as an alternative treatment.

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Certain strains of lactic acid bacteria (LAB) can stimulate the production of immunoglobulin A (IgA) (1–3), and increase the number of IgA-secreting cells (2), types I and II interferons and interleukin-12 (IL-12) and interleukin-18 (IL-18) production (3). Interaction of gram-positive cell-wall components (peptidoglycans and lipoteichoic acid) with surface receptors (CD14 and Toll-like receptor 2) of mononuclear phagocytes may inhibit T-helper subset 2 cell-skewed immune responsiveness, suppress immunoglobulin E (IgE) synthesis (4), and stabilize of the mucosa barrier (5). Dose-dependent effects for heat-killed forms of food-borne bacteria and enhancement of innate immunity and stimulation of lymphoid follicles of Peyer's patch of the small intestine have also been demonstrated (6). Further studies have demonstrated that non-viable LAB preparations can effectively enhance immunity (6) and stimulation of IL-12 production in mice and human (7–9). It is clear, however, that the extent and quality of LAB-induced immunoregulation is strain dependent (6, 10).

Heat treatment may affect bacterial cell-wall composition and alter: (i) frequency of interaction between bacterial ligands and monocyte