Article

Lacticaseibacillus paracasei GM-080 Ameliorates Allergic Airway Inflammation in Children with Allergic Rhinitis: From an Animal Model to a Double-Blind, Randomized, Placebo-Controlled Trial

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Abstract: *Background:* Probiotics may facilitate the clinical management of allergic diseases. However, their effects on allergic rhinitis (AR) remain unclear. We examined the efficacy and safety of *Lacticaseibacillus paracasei* GM-080 in a mouse model of airway hyper-responsiveness (AHR) and in children with perennial AR (PAR) by using a double-blind, prospective, randomized, placebo-controlled design. *Methods:* The production of interferon (IFN)-γ and interleukin (IL)-12 was measured by using an enzyme-linked immunosorbent assay. GM-080 safety was evaluated via the whole-genome sequencing (WGS) of virulence genes. An ovalbumin (OVA)-induced AHR mouse model was constructed, and lung inflammation was evaluated by measuring the infiltrating leukocyte content of bronchoalveolar lavage fluid. A clinical trial was conducted with 122 children with PAR who were randomized to receive different doses of GM-080 or the placebo for 3 months, and their AHR symptom severity scores, total nasal symptom scores (TNSSs), and Investigator Global Assessment Scale scores were examined. *Results:* Among the tested *L. paracasei* strains, GM-080 induced the highest IFN-γ and IL-12 levels in mouse splenocytes. WGS analysis revealed the absence of virulence factors or antibiotic-resistance genes in GM-080. The oral administration of GM-080 at 1×10^7 colony forming units (CFU)/mouse/day for 8 weeks alleviated OVA-induced AHR and reduced airway inflammation in mice. In children with PAR, the oral consumption of GM-080 at 2×10^9 CFU/day for 3 months ameliorated sneezing and improved Investigator Global Assessment Scale scores significantly. GM-080 consumption led to a nonsignificant decrease in TNSS and also nonsignificantly reduced IgE but increased INF-γ levels. *Conclusion:* GM-080 may be used as a nutrient supplement to alleviate airway allergic inflammation.

Keywords: allergic airway inflammation; animal model; allergic rhinitis; clinical trial; probiotics