

Article

Efficacy of *Lactobacillus* Administration in School-Age Children with Asthma: A Randomized, Placebo-Controlled Trial

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Abstract: Probiotics may have immunomodulatory effects. However, these effects in asthma remain unclear and warrant clinical trials. Here, we evaluated the effects of *Lactobacillus paracasei* (LP), *Lactobacillus fermentum* (LF), and their combination (LP + LF) on the clinical severity, immune biomarkers, and quality of life in children with asthma. This double-blind, prospective, randomized, placebo-controlled trial included 160 children with asthma aged 6–18 years (trial number: NCT01635738), randomized to receive LP, LF, LP + LF, or a placebo for 3 months. Their Global Initiative for Asthma–based asthma severity, Childhood Asthma Control Test (C-ACT) scores, Pediatric Asthma Severity Scores, Pediatric Asthma Quality of Life Questionnaire scores, peak expiratory flow rates (PEFRs), medication use, the levels of immune biomarkers (immunoglobulin E (IgE), interferon γ , interleukin 4, and tumor necrosis factor α) at different visits, and the associated changes were evaluated. Compared with the placebo group by generalized estimating equation model, children receiving LP, LF, and LP + LF had lower asthma severity ($p = 0.024$, 0.038 , and 0.007 , respectively) but higher C-ACT scores ($p = 0.005$, < 0.001 , and < 0.001 , respectively). The LP + LF group demonstrated increased PEFR ($p < 0.01$) and decreased IgE levels ($p < 0.05$). LP, LF, or their combination (LP + LF) can aid clinical improvement in children with asthma.

Keywords: *Lactobacillus*; probiotics; asthma; Childhood Asthma Control Test; peak expiratory flow rate; immunoglobulin E

1. Introduction

Asthma, a chronic complex disease of the airways, is characterized by reversible airflow obstruction, bronchial hyperresponsiveness, and underlying inflammation [1]. The prevalence of asthma has increased in the past decades. A potential mechanism underlying this high prevalence is the microbial hypothesis [2], which argues that less microbial exposure upregulates the cytokine production of T-helper cell type 2 (Th2), leading to an increase in allergic diseases. According to this hypothesis, probiotic administration is an alternative treatment for atopic disease, which when administered in adequate amounts, can confer a health benefit to the host [3]. The researchers found that probiotics have some health effects in atopic disease patients through immunity balancing of T-helper cell type 1 (Th1) and Th2, particularly in those with atopic dermatitis (AD). However, relevant studies focusing on asthma patients are limited.