Effect of multi-strain probiotics (multi-strain microbial cell preparation) on glycemic control and other diabetes-related outcomes in people with type 2 diabetes: a randomized controlled trial

ABSTRACT

Aim: Evidence of a possible connection between gut microbiota and several physiological processes linked to type 2 diabetes is increasing. However, the effect of multi-strain probiotics in people with type 2 diabetes remains unclear. This study investigated the effect of multi-strain microbial cell preparation also refers to multi-strain probiotics on glycemic control and other diabetes-related outcomes in people with type 2 diabetes. Design: A randomized, double-blind, parallel-group, controlled clinical trial. Setting: Diabetes clinic of a teaching hospital in Kuala Lumpur, Malaysia. Participants: A total of 136 participants with type 2 diabetes, aged 30-70 years, were recruited and randomly assigned to receive either probiotics (n = 68) or placebo (n = 68) for 12 weeks. Outcomes: Primary outcomes were glycemic control-related parameters, and secondary outcomes were anthropomorphic variables, lipid profile, blood pressure and high-sensitivity C-reactive protein. The Lactobacillus and Bifidobacterium quantities were measured before and after intervention as an indicator of successful passage of the supplement through gastrointestinal tract. Statistical analysis: Intention-to-treat (ITT) analysis was performed on all participants, while per-protocol (PP) analysis was performed on those participants who had successfully completed the trial with good compliance rate. Results: With respect to primary outcomes, glycated hemoglobin decreased by 0.14 % in the probiotics and increased by 0.02 % in the placebo group in PP analysis (p < 0.05, small effect size of 0.050), while these changes were not significant in ITT analysis. Fasting insulin increased by 1.8 µU/mL in placebo group and decreased by 2.9 µU/mL in probiotics group in PP analysis. These changes were significant between groups at both analyses (p < 0.05, medium effect size of 0.062 in PP analysis and small effect size of 0.033 in ITT analysis). Secondary outcomes did not change significantly. Probiotics successfully passed through the gastrointestinal tract. Conclusion: Probiotics modestly improved HbA1c and fasting insulin in people with type 2 diabetes.

Keyword: Blood pressure; Glycated hemoglobin; Glycemic control; High-sensitivity C-reactive protein; Homeostasis model assessment-estimated insulin resistance; Lipid profile; Type 2 diabetes mellitus