

Efficacy of heat-killed *Lactobacillus casei* DKGF7 in old patients with irritable bowel syndrome

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Background/Aims: Increasing evidence has shown that supplementation with pre- and pro-biotics appears to have positive effects on irritable bowel syndrome (IBS). There is a considerable amount of data demonstrating the ability of non-viable bacteria, called paraprobiotics, as an immunomodulator in the intestinal environment of hosts. Heat-killed treatment is the most widely used method for inactivating probiotic bacteria. In a previous study, heat-killed *Lactobacillus casei* DKGF7 showed good effects in the IBS animal model. This study was designed to evaluate the beneficial effects of heat killed *L. casei* DKGF7 in old patients with IBS.

Methods: Sixty-two elderly IBS patients (aged ≥ 60 years) were randomly assigned to two groups and took either the placebo or paraprobiotics containing heat-killed *L. casei* DKGF7 once a day for 4 weeks. Patients recorded subject global assessment (SGA), visual analogue scale (VAS), and Bristol stool chart. Patients with SGA ≥ 2 were considered weekly responders and who weekly respond for more than 2 of the 4 weeks were considered overall responders. Patients with decrease in VAS more than 30% were also considered responders.

Results: There was no statistically significant difference between the responder rates assessed by SGA (Overall responder: Control 25.8% vs. Paraprobiotics 29.0%, $p=0.776$), (Weakly responder: Control 38.7% vs. Paraprobiotics 41.9%, $p=0.796$). There were also no significant differences in abdominal pain, gas, bloating and happiness assessed by VAS ($p=0.611$, $p=1.000$, $p=0.799$ and $p=0.168$, respectively). There were no adverse events in both groups.

Conclusions: In contrast to the previous animal study, heat-killed *L. casei* DKGF7 did not show no significant beneficial effects on symptom improvement in older patients with IBS. Given the good effects in the IBS animal model, further large study with a different population are required in the future.

Overall responder rates for overall IBS symptom improvement assessed by SGA

| | Placebo | Paraprobiotics | P value |
|-------------------|-----------|----------------|---------|
| Overall responder | 8 (25.8) | 9 (29.0) | 0.776 |
| Weakly responder | 12 (38.7) | 13 (41.9) | 0.796 |

Overall responder rates for improvement of symptoms assessed by VAS

| | Placebo | Paraprobiotics | P |
|----------------|-----------|----------------|-------|
| Abdominal pain | 16 (51.6) | 14 (45.2) | 0.611 |
| Gas | 17 (54.8) | 17 (54.8) | 1.000 |
| Bloating | 16 (51.6) | 17 (54.8) | 0.799 |
| Happiness | 12 (38.7) | 7 (22.6) | 0.168 |