The Effects of Complex Lactobacillus on Bowel Function in Nursing Home Elderly

Yu-Lai Liu¹, Shwu-Huey Yang², Chien-Hsun Huang³, Chin-Hsiao Tseng⁴,⁵,⁶

Abstract

Background: Lactobacillus is a gut microflora in humans that plays a helpful role in disease prevention and health maintenance. We evaluated whether a designed complex compound of lactobacillus, including *Lactobacillus bifidus*, *Lactobacillus acidophilus*, and *Bacillus subtilis natto*, given in a total amount of $10^8$ colony-forming units (CFU) daily, might improve the bowel function in nursing home elderly.

Methods: We conducted a randomized, double-blind, cross-over, placebo-controlled study among 38 nursing-home residents who were ≥ 65 years old at a community hospital in central Taiwan. The participants were randomized into either an experimental group who received the complex lactobacillus compound (6 g/day); or a placebo group who received glucose polymer (3 g/day). The 10-week study consisted of an initial period of 4 weeks, a 2-week wash-out period and followed by a final period of 4 weeks. We collected data on daily activities, bowel movements, and amount of enemas used. Participants did not change their diets or activity, and usual medications.

Results: Stool frequency at week 1 was significantly increased and enema use was significantly decreased at week 2 in the experimental group ($p < 0.01$). However, there was no significant difference in the amount or color of stool between these experiment and placebo groups. This study showed that adding complex lactobacillus compound into the diet improved bowel function among subjects, but these effects did not maintain after 2 weeks intervention.

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Conclusion: Providing 6 g complex lactobacillus compound per day improved fecal output frequency at week 1 and reduced the use of enemas at week 2 in nursing home for elderly. However, these effects were not observed with prolonged use. (Taiwan Geriatr Gerontol 2010; 5(2): 105-116)

Key words: complex lactobacillus, long-term care, elderly, bowel function, constipation

INTRODUCTION

To utilize probiotics in health care began in the 20th century [1]. Probiotics are live microbial feeding supplements that beneficially affect the host animal by improving its gut microbial balance [2]. The possible mechanisms include the synthesis of antimicrobial substances [3], competition for nutrients required for growth of pathogens [4], competitive inhibition of adhesion of pathogens [5], modification of toxins or toxin receptors [6], and stimulation of nonspecific and specific immune responses to pathogens [6,7].

The impact on the patients’ life quality may include bowel function [8]. For patients who are incontinent, an increase in fecal frequency may be unpleasant and may require intensive nursing, whereas a reduction in fecal consistency may increase the risk of infection and poor hygiene. Self-report constipation increases with age but not many studies focus on elderly residents in nursing home [9]. Therefore, we designed a study to explore the effects of a complex lactobacillus product on the bowel function in elderly institutionalized residents.

SUBJECTS AND METHODS

Subjects and study design

We recruited 43 elderly subjects (≧65 years) who had poor bowel function from a nursing home at a community hospital in central Taiwan. Exclusion criteria included current use of antibiotics or corticosteroids. The subjects’ vital signs were monitored as routine. We did not change their usual medication, dietary pattern, or physical activity during the study period.

The study was approved by the National Taiwan University Hospital Research Ethics Committee. Informed consent was obtained from study subjects or their family members in advance.

This was a randomized, double-blind, placebo-control, cross-over 10 weeks study which included 2 weeks of washout period. Subjects were randomized into two
groups, an experimental group and a control group. We recorded all subjects’ stool condition and the kind and amount of stool softeners used each week and anthropometric data in week 0, week 4 and week 10. Dietary and activity information were obtained before and after intervention. Most of the data were collected by nurses in the nursing home during study period, who were taught to record the stool hardness by its moisture on appearance, the weight of stool in standardized operation, the type of stool softeners used, the frequency of enemas used, and the frequency of bowel movements by handing regularly except the dietary information. The study dietitian recorded and analyzed the dietary component.

**Products**

Complex lactobacillus, the study’s product ingredients: *Lactobacilli* MRS Broth (DIFCO 0881, Proteose Peptone no. 3, 17.84%; beef extract, 17.84%; yeast extract, 8.92%; dextrose, 20 g; polysorbate 20 (Tween), 1.78%; ammonium citrate, 3.57%; sodium acetate \((\text{CH}_3\text{COONa})\), 8.92%; magnesium sulfate \((\text{MgSO}_4)\), 1.78%; manganese sulfate monohydrate \((\text{MnSO}_4\cdot\text{H}_2\text{O})\), 0.09%; and potassium hydrogen phosphate \((\text{K}_2\text{HPO}_4)\), 3.57%. Two grams per complex lactobacillus sachet and each gram of the combination product contained \(10^8\) colony-forming units (CFU) of *Bifidobacteria, Acidophilus*, and *Bacillus subtilis* (*natto*) with 0.8 kcal per gram. The placebo ingredient: glucose polymer, corn starch, with 3.8 kcal per gram (Yi-Fu Industrial Corp. Ltd., Taiwan). The placebo is similar in color and appearance to complex lactobacilli.

Packaging and storage: The Complex lactobacillus and sugar polymer were both provided as powder and packaged with aluminum foil. They were stored at room temperature below 28°C.

Study compounds were given before subjects drank water or got the tube-feeding diet. The nurses mixed one package of complex lactobacillus (Zen-u Biotechnology Co., Ltd., Taiwan) or placebo powder with water or tube-feeding diet per day over the first 4 weeks of intervention period. Three packages per day and each package contained 2 g of complex lactobacillus or 1 g of placebo.

**Data collection**

The information of stool condition included the frequency and the volume, color, and stool hardness of natural defecation and diarrhea. The stool softeners, such as Dulcolax (Boehringer Ingelheim GmbH, Germany), magnesium oxide (MgO), and/or Chinese herbs used
by the subjects were recorded. Anthropometric data included height, weight, and body mass index (BMI, or kg/m\(^2\)). The BMI was calculated by a general equation based on the height in meters and weight in kilograms. White blood cell, neutrophil, lymphocyte and monocyte were analyzed for immunity function by the Department of Laboratory of National Taiwan University Hospital Yun-Lin Branch, Yun-Lin, Taiwan

**Diet and activity records**

Dietary information, including: dietary energy, protein, carbohydrate, fat and fiber was analyzed by Nutrients analysis software (Kitchen Business Cooperation, Taiwan). The data bank of the software was established from the database for food composition in Taiwan [10]. We also recorded the activity level and medication use of each subject. Daily activities such as controlling a wheelchair and walking were recorded and expressed as minutes per day. Subjects did not change their diet, daily activity, or usual medication during the study period.

**Statistical analysis**

All values are expressed as mean ± SEM or percentage. Statistical analysis was performed using one-way ANOVA and post hoc test by Duncan’s multiple-range test, Student’s t-test and paired t-test analysis by SAS version 9.0 statistical software. \(p<0.05\) was considered statistically significant.

**RESULTS**

**Subjects’ characteristics**

One subject left the study when she was discharged and 4 subjects withdrew from the study due to hyperglycemic hyperosmolar syndrome. A total of 38 subjects (16 men and 22 women) completed this study. Their age ranged from 65 to 94 years, with a mean of 80.1 ± 1.4 years (79.8 ± 2.3 years for male and 80.2 ± 1.7 years for female patients, \(p>0.05\)) (Table 1). The activity levels among the subjects ranged from 3 minutes/day to 60 minutes/day.

**Table 1** The characteristics of study subjects at baseline

<table>
<thead>
<tr>
<th>Variable</th>
<th>Male (n=16)</th>
<th>Female (n=22)</th>
<th>(p)-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>79.8±2.3</td>
<td>80.2±1.7</td>
<td>0.8521</td>
</tr>
<tr>
<td>Boyd height (cm)</td>
<td>163.5±1.7</td>
<td>151.2±1.5*</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Body weight (kg)</td>
<td>51.7±1.9</td>
<td>49.2±1.8</td>
<td>0.3398</td>
</tr>
<tr>
<td>Body mass index (kg/m(^2))</td>
<td>19.4±0.7</td>
<td>21.5±0.7*</td>
<td>0.0498</td>
</tr>
<tr>
<td>Length of stay (days)</td>
<td>563±130</td>
<td>893±130</td>
<td>0.0874</td>
</tr>
</tbody>
</table>

Data are expressed as mean ± SEM. *\(p<0.05\) by Student’s t-test.
Dietary status

The subjects’ calorie intake ranged from 1,419 kcal/day to 2,050 kcal/day. The calorie intake before the study was 1,685 ± 32 kcal/day. There were no nutrients intake difference among underweight \((\text{BMI} < 18.5 \text{ kg/m}^2)\), normal \((18.5 \text{ kg/m}^2 \leq \text{BMI} < 23.9 \text{ kg/m}^2)\) and overweight \((\text{BMI} \geq 24 \text{ kg/m}^2)\) groups at baseline (Table 2). The average calorie intake for the placebo group before the study was 1,696 ± 28 kcal/day, and 1,704 ± 35 kcal/day for the experimental group. After the study, the calorie intake was 1,715 ± 36 kcal/day for the placebo group, and 1,658 ± 34 kcal/day for the experimental group. No statistically significant differences in dietary data or immunity function was found while comparing the experimental group and the placebo group for either the data at baseline or at week 4 (Student’s \(t\)-test) or while comparing within groups for either the baseline data or the data at week 4 (paired-\(t\)-test) (Table 3).

Table 2  The characteristics of subjects by subgroups of body mass index

<table>
<thead>
<tr>
<th>Body mass index (kg/m(^2))</th>
<th>Group A (&lt; 18.5 \text{ (n=9)})</th>
<th>Group B (18.5 \sim 23.9 \text{ (n=23)})</th>
<th>Group C (\geq 24 \text{ (n=6)})</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>79.9 ± 1.4</td>
<td>80.4 ± 2.2</td>
<td>78.8 ± 1.4</td>
</tr>
<tr>
<td>Anthropometric data</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Body height (cm)</td>
<td>161.7 ± 2.4</td>
<td>155.9 ± 2.0</td>
<td>150.1 ± 2.7</td>
</tr>
<tr>
<td>Body weight (kg)</td>
<td>43.4 ± 1.5</td>
<td>51.0 ± 1.6(^b)</td>
<td>58.0 ± 2.0(^a)</td>
</tr>
<tr>
<td>Body mass index (kg/m(^2))</td>
<td>16.5 ± 0.4</td>
<td>20.9 ± 0.4(^b)</td>
<td>25.6 ± 0.4(^a)</td>
</tr>
<tr>
<td>Triceps skinfold (cm)</td>
<td>14.5 ± 1.3</td>
<td>17.6 ± 1.0(^b)</td>
<td>23.9 ± 4.1(^a)</td>
</tr>
<tr>
<td>Mid arm circumference (cm)</td>
<td>21.8 ± 0.8(^b)</td>
<td>24.9 ± 0.7(^a)</td>
<td>27.0 ± 0.7(^a)</td>
</tr>
<tr>
<td>Dietary data</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Energy (kcal/day)</td>
<td>1657 ± 81</td>
<td>1685 ± 40</td>
<td>1731 ± 78</td>
</tr>
<tr>
<td>Protein (g/day)</td>
<td>57.6 ± 3.8</td>
<td>59.2 ± 5.3</td>
<td>60.7 ± 5.2</td>
</tr>
<tr>
<td>Fat (g/day)</td>
<td>57 ± 2</td>
<td>67 ± 8</td>
<td>62 ± 6</td>
</tr>
<tr>
<td>Carbohydrate (g/day)</td>
<td>236 ± 28</td>
<td>211 ± 10</td>
<td>205 ± 17</td>
</tr>
<tr>
<td>Fiber (g/day)</td>
<td>9.9 ± 2.9</td>
<td>10.2 ± 1.5</td>
<td>16.8 ± 2.7</td>
</tr>
<tr>
<td>Fluid (mL/day)</td>
<td>2441 ± 208</td>
<td>2669 ± 99</td>
<td>2181 ± 251</td>
</tr>
<tr>
<td>Stool amount / week</td>
<td>1257.1 ± 288.4</td>
<td>1222.4 ± 131.1</td>
<td>884.4 ± 68.0</td>
</tr>
<tr>
<td>Baseline</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Placebo group</td>
<td>1257.1 ± 288.4</td>
<td>1222.4 ± 131.1</td>
<td>884.4 ± 68.0</td>
</tr>
<tr>
<td>Experimental group</td>
<td>1087.5 ± 185.1</td>
<td>977.9 ± 126.2</td>
<td>1187.5 ± 293.9</td>
</tr>
<tr>
<td>Week 4</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Placebo group</td>
<td>1378.6 ± 332.9</td>
<td>956.6 ± 91.7(^*)</td>
<td>937.5 ± 102.7</td>
</tr>
<tr>
<td>Experimental group</td>
<td>1341.1 ± 298.0</td>
<td>994.7 ± 70.3</td>
<td>896.9 ± 147.7</td>
</tr>
</tbody>
</table>

Values are presented as the means ± SEM

\(^a, b, c\)  Values sharing differently superscript letters in the same row are significant from one to another by one-way ANOVA and post hoc test by Duncan’s multiple-range test at \(p < 0.05\).

\(^*\)  \(p < 0.05\) compared with baseline data by paired \(t\)-test
### Anthropometric data

The subjects’ body height ranged from 135 cm to 171 cm, with a mean ± SEM of 156.4 ± 0.1 cm. The mean height for men was 163.5 ± 1.7 cm, and 151.2 ±1.5 cm for women. There was gender difference on body height (Table 1). Men had significantly lower BMI than women, but the mean BMI values were within normal in either sex.

### Disease and drug use

The primary disease among these subjects was stroke, which affected 34.2% of the subjects. Pneumonia was the second-most common condition, affecting 28.9% of the subjects. Twenty-three subjects (60.6%) had constipation and utilized stool softeners, 17 subjects used MgO, 2 subjects used Dulcolax, and 4 subjects used both of the two stool softeners.

### Effects of Lactobacillus complex on bowel function

#### Comparison of the difference in stool amount

There was no significant difference in stool amount among the underweight, normal or overweight residents at baseline (Table 2). Statistically significant decrease in stool amount was noted for normal weight group after placebo treatment.
Stool amount did not change significantly after treatment in the experimental group ($p > 0.05$) but did change significantly after treatment in the placebo group ($p < 0.05$) (Table 4). Stool frequency was significantly increased after 1 week treatment in the experimental group ($p < 0.05$) and significantly reduced the use of enemas at week 2 in nursing home for elderly ($p < 0.05$) (Table 4).

Although we divided subjects into 3 groups by their BMI, the stool amount was not significantly different between placebo and experimental group either at baseline or after the study period, except for normal weight placebo group after the study period (Table 2).

According to the stool quantity at baseline, subjects were divided into 4 groups: 300 g, 200 g, 75 g and 25 g.

**Table 4** The bowel function of subjects

<table>
<thead>
<tr>
<th>Placebo group</th>
<th>Experimental group</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Baseline</td>
</tr>
<tr>
<td>Stool amount  (g/week)</td>
<td>1181±93</td>
</tr>
<tr>
<td>Enemas (times/week)</td>
<td>0.4±0.1</td>
</tr>
<tr>
<td>Handing (times/week)</td>
<td>0.2±0.1</td>
</tr>
<tr>
<td>Diarrhea (times/week)</td>
<td>2.3±0.4</td>
</tr>
<tr>
<td>Normal stool (times/week)</td>
<td>2.9±0.5</td>
</tr>
<tr>
<td>Stool frequency (times/week)</td>
<td>6.2±0.8</td>
</tr>
<tr>
<td>Stool weight / stool frequency</td>
<td></td>
</tr>
<tr>
<td>300 g (times/week)</td>
<td>2.2±1.3</td>
</tr>
<tr>
<td>200 g (times/week)</td>
<td>2.5±2.1</td>
</tr>
<tr>
<td>75 g (times/week)</td>
<td>1.0±1.3</td>
</tr>
<tr>
<td>25 g (times/week)</td>
<td>0.3±0.8</td>
</tr>
</tbody>
</table>

Data are presented as mean ± SEM;  
* $p < 0.05$ compared with baseline data by paired t-test;  
† $p < 0.05$ compared with week 1 data by paired t-test;  
‡ $p < 0.05$ compared with week 2 data by paired t-test;  
§ $p < 0.05$ compared with week 3 data by paired t-test
Comparison of difference in stool weight

Subjects with 300 g stool weight at baseline

After the complex lactobacillus intervention, the stool frequency of subjects with 300 g stool did not change during the study period. The frequency was significantly higher at week 2 ($p < 0.05$) in the placebo group but not in the experiment group. The complex lactobacillus did not enhance bowel function with 300 g of stool weight (Table 4).

Subjects with 200 g stool weight

In the experimental group, no significant differences were observed in each time interval. In the placebo group, the stool frequency of subjects with 200 g of stool weight was significantly lesser at week 1 than at baseline ($p < 0.05$) (Table 4).

Subjects with 75 g stool weight

In the experimental group, the stool frequency of subjects with 75 g stool was significantly decreased at week 1 ($p < 0.05$), but no difference was found at weeks 2, 3, or 4. In the placebo group, no significant difference was found in each time interval. There was no bowel function improvement after the complex lactobacillus intervention. However, more observation in the future is required for its long-term benefit (Table 4).

Subjects with 25 g stool weight

There were no difference in each time interval between experimental group and placebo group with 25 g stool weight subjects except a statistically significant reduction in stool frequency at week 4 ($p < 0.05$) (Table 4) was observed which comparing week 4 to week 1 in the experimental group and placebo group.

The bowel function

After the complex lactobacillus intervention, the frequency of enemas used at week 1 was increased significantly compared to baseline ($p < 0.05$), the frequency of enema use at week 2 was significantly decreased ($p < 0.05$) but not in week 3 and week 4. There was some effect of complex lactobacillus on bowel movements in the initial period but did not continue for week 2, 3, 4. However, the frequency of enema use was significantly reduced at week 2 in the experiment group ($p < 0.05$). In the placebo group, the frequencies of enemas used at weeks 2 were significantly greater than that of the baseline ($p < 0.05$) (Table 4).

The frequency of digital exam to induce defecation was not significantly different between the placebo and the experimental groups.
Comparison of difference in immunity function

The number of white blood cell, neutrophil, lymphocyte and monocyte were counted for immunity function. There were no differences between the two groups by Student’s $t$-test and within each group by paired-$t$ test (Table 3).

DISCUSSION

Our results showed that providing 6 g/day complex lactobacillus product to nursing home elderly with poor bowel function could significantly improve their stool frequency at week 1 and decrease enema use at week 2.

The physiologic condition, immune function and complexity of disease of the elderly are totally different from younger adults [10]. Generally, most of the previous studies of Lactobacillii focus on younger adults. But this study was conducted in elderly subjects in institution whose mean age was 80 years old.

Bifidobacteria is a microorganism that coexists with mammals. It can be consumed in regular food and/or as supplements. The side effects of Bifidobacteria include infection, and thus it should be cautiously used in subjects with decreased immune function [11, 12]. In our study the markers for immunity function did not change after treatment.

Bouvier et al. conducted a double-blind study on 70 healthy subjects for 11 days by providing the yogurt Bifidobacterium animalis strain DN-173 010 and intestinal transit time was observed to reduce by 20% , which was more effective in female subjects [13]. Bouvier et al. confirmed that probiotics may improve bowel movements [13]. Marteau et al. performed a randomized, double-blind, placebo-control study of healthy women, who consumed 3 different amount (375, 250, 125 mL) of yogurt with Bifidobacterium animalis strain DN-173 010 for 10 days [10]. They found that that Bifidobacterium animalis could effectively reduce transit time ($p < 0.05$). There was no significant effect on stool weight, bacteria CFU, bile salts quantity in feces [10,13]. Bifidobacterium yogurt initially increased the concentration of cholic acid in feces, and could shorten transit time [13]. Taking yogurt containing B. animalis DN-173 010 resulting in reduced bowel transit time was also observed by others ($p <0.001$) [14,15]. The effect was more significant at a higher dose (375 vs. 250 mL) ($p < 0.05$) [16]. Another large-scale, open and controlled study was conducted in 200 elderly subjects, whose age ranged from 50 to 75 years. The subjects were divided into 2 groups, depending on whether they had a normal transit time (40-50 h) or a slow transit time (> 50 h).
One hundred subjects were included in each group. The subjects were randomized to consume *Bifidobacterium* yogurt daily for 2 weeks [14]. The results indicated that consuming *Bifidobacterium* yogurt could reduce the fecal transit time with a dose-effect response.

The results of our study suggested that providing complex lactobacillus, *L. bifidus, L. acidophilus* and *B. subtilis natto* improved stool frequency at week 1 and reduced enema use at week 2 within experiment group and between groups in nursing home elderly. However, the effects of complex lactobacillus did not last long. Several studies have recently investigated probiotic adaptation in the highly competitive ecosystem of the gastrointestinal tract and showed possible physiological adaptation [19]. Therefore, the effect of adding lactobacillus supplements to the usual dietary pattern for the improvement of long-term bowel function requires more investigation. For this purpose, other materials and methods should be simultaneously applied, such as increasing the intake of dietary fiber, abdominal massage, or increased exercise.

In summary, providing 6 gram lactobacillus complex compound per day improved fecal output frequency at week 1 and reduced the use of enema at week 2 in nursing home for the elderly.

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REFERENCES


複合乳酸菌對護理之家老年人腸道功能之影響

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摘 要

背景：益生菌為人類腸道菌叢之一且有利於人體健康。本研究即探討給予長期照護住民複合乳酸菌（包含雙叉乳桿菌、嗜酸乳酸菌與納豆菌總數），對腸道功能之影響。

方法：研究採隨機、雙盲、交叉、安慰劑、對照試驗設計。受試者為護理之家65-94歲住民38名隨機分成兩組，經過兩週穩定期後，進入4週實驗期：實驗組每天攝食6公克複合乳酸菌，安慰劑組每天攝食3公克糖飴，經過2週排空期再交換進入4週第二次實驗期，結束實驗期後持續追蹤2週。研究期間受試者不改變飲食，活動習慣及用藥種類與份量。研究收集受試者每天活動量、住院天數、住院次數、72小時再住院人數、腸道症狀。

結果：實驗組在介入第1週排便次數顯著增加，第2週時灌腸次數顯著減少（p < 0.01）；兩組間糞便顏色沒有差異。研究顯示此複合乳酸菌在初期可促進長期照護住民老年人腸道功能，但效用無法持續維持。

結論：持續4週給予老年人本複合乳酸菌每天6克，可增加第1週排便次數，減少第2週灌腸次數，然而這些作用並無法持續。

（台灣老年醫學暨老年學雜誌 2010；5(2)：105-116）

關鍵詞：複合乳酸菌、長期照護、老人、腸道功能、便祕