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Original Article

The Safety of Lactobacillus Plantarum Extract Used as a Possible Adjuvant Treatment of Breast Cancer

Baramee Boonlert, MD[1]
Achara Fongcome, MD[2]
Napaporn Virarach, BSN[3]

[1] *Department of Surgery, Lamphun Hospital, Thailand*
[2] *Department of Medicine, Lamphun Hospital, Thailand*
[3] *Chemotherapy Unit, Lamphun Hospital, Thailand*

Abstract

Objective: *Lactobacillus plantarum* is one of the most interesting strains of probiotics with potential anticancer effects. However, few clinical studies have been done to demonstrate this. The objective of the present study was to evaluate clinical safety of *Lactobacillus plantarum* extract used as an adjuvant treatment for breast cancer.

Materials and Methods: This study was a prospective, randomized, double-blind, and placebo-controlled study of early-stage breast cancer patients who underwent surgical removal of tumor and given conventional chemotherapy. The treatment group received products containing *L. plantarum* extract, and the placebo group received only a placebo for the duration of six months. Evaluated clinical parameters include body weight, symptoms resulting from side effects from chemotherapy, quality of life and laboratory tests.

Results: There were 56 patients in the study, of whom 27 were randomly assigned to a treatment group and 29 to the placebo group. A significant difference in the WBC count between the two groups was found in the second month after chemotherapy ($P = 0.04$). The mean white blood cell (WBC) count in the treatment group was 7,641 cells/mm^3 and 5,108 cells/mm^3 in placebo group, respectively. The mean bodyweight in the placebo group decreased in the second month to an extent more than in the treatment group, and continue to decrease in the sixth month while in the treatment group the mean bodyweight increased.

Conclusions: The present study demonstrated that *L. plantarum* extract can be used safely as a possible adjuvant therapy for breast cancer patients. There was a trend towards better clinical and laboratory profiles in the treatment group, but mostly without statistical significance. Only the WBC count at the second month of chemotherapy showed a significant difference.

Keywords: Efficacy of *Lactobacillus plantarum* extract, Breast cancer

Introduction

Cancer is the second leading cause of mortality in the world, and the first leading cause of death in Thailand since 2000. Breast cancer is the most common malignancy among woman and an important cause of cancer related morbidity and mortality worldwide. Although the advancement in screening and treatment of breast cancer have decreased its mortality steadily, however, the clinical management of breast cancer using conventional chemotherapeutic agents are harmful to normal host cells. These cytotoxic drugs are associated with various types of life-threatening side-effects and adverse clinical outcomes.

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Corresponding author: Baramee Boonlert, Department of Surgery, Lamphun Hospital, Lamphun province 51000; Telephone: +66 89 191 7884; Email: pom029@hotmail.com

The term probiotics is defined by the Food Agricultural Organization (FAO) and the World Health Organization (WHO) as live microorganisms. When probiotics is administered in adequate amounts, it may provide healthful benefits to the host.[1] Probiotics can be found in a large quantity in fermented food and yogurt. Most of the probiotics consists of lactic acid producing, non-pathogenic bacteria, such as *Lactobacillus, Streptococcus, Bifidobacterium, Enterococcus* or non-pathogenic yeast. Gastrointestinal (GI) tracts of humans and animals contain a complex community of bacteria, which has an active interaction with host cells. These microorganisms are helpful in physiologic activities such as digestion, metabolism of bile acids, synthesis of vitamins B and K, and play a crucial role in the development of homeostasis of the innate and adaptive immune system.

Any disequilibrium in both composition and quantity of the gut microbiota can generate a condition known as dysbiosis. Dysbiosis could be linked to human pathology that includes metabolic disorders such as obesity, types 2 diabetes, autoimmune disease, asthma, inflammatory bowel disease, irritable bowel syndrome and cancer.[2-6] Furthermore, probiotics has been proven to be able to revert intestinal dysbiosis, which may play a role in the development of several diseases including cancer.[7] Numerous clinical studies have suggested that probiotics may have various benefits in cancer treatment including the reduction of serious side-effects associated with anticancer therapy,[8-11] improvement of efficacy of some anti-neoplastic drugs[12] and immunotherapies,[13] reduction of post-operative complications[14] and prevention the recurrence of cancer.[15]

Probiotics are mostly considered safe, affordable, and important microbes, which may have anti-carcinogenic activities in some cancers.[16] Dead probiotics and their metabolic products may provide similar beneficial effects in the prevention and treatment of cancer compared to live probiotics.[17-18] Molecules and metabolites such as lipopolysaccharide, exopolysaccharide extracted from various specific strains of probiotics could play an important role in prevent and treatment of colon cancer.[19-22]

In vitro and *in vivo* studies have provided some evidence that many specific strains of probiotics may display activity against breast cancer.[23-27] *Lactobacillus plantarum* is one of the most interesting strain of probiotics.[28] *Lactobacillus plantarum* may have anti-cancer property via multiple mechanisms of action such as inflammatory suppression via cytokines, induced apoptosis of tumor cell, activating T cell mediated and enhancing NK cell activity.[28-31] However, only a few clinical trials have been conducted in breast cancer patients. The objective of the present study was to determine the safety of using *Lactobacillus plantarum* as a probiotic supplement and possibly adjuvant treatment in breast cancer.

Patients and Methods

The present study was a prospective, randomized, double-blind, and placebo-controlled study. Early-staged breast cancer patients (Stages 1 to 3 by the American Joint Committee on Cancer (AJCC) TNM system) aged between 21 to 65 years with ECOG performance status 0 to 1 who had undergone surgical treatment and planned to receive further conventional chemotherapy at the Chemotherapy Unit, Lamphun Hospital, were recruited into the study. All patients provided written informed consent before participating.

All patients were enrolled by the investigator and assigned to a placebo group and treatment group by simple randomization, according to the randomization number obtained through a computer-generated randomization table. Information obtained from the patient included age, tumor stage, number of positive lymph nodes, and hormonal receptor status. The study products were pre-packaged by the sponsor as per the randomization codes and dispensed accordingly. Placebo and probiotics were prepared and labelled 'A' or 'B'. The capsules and their content were visually identical in both groups. Only a nurse not directly involved in the trial was able to break the treatment codes.

Chemotherapeutic regimens were standard anthracycline and cyclophosphamide (AC) or 5-FU with an anthracycline and cyclophosphamide (FAC), or with added taxane (AC-T) for more advanced stage cancers.

All patients received 5 capsules of products containing *L. plantarum* extract or placebo to be taken 4 times a day for a period of 6 months, covering the whole duration of chemotherapy. Patients underwent evaluation of clinical symptoms and signs and routine laboratory tests at every 3 weeks. Clinical parameters included body weight, symptoms of side effects from chemotherapy, and basic laboratory tests such as complete blood counts. Quality of life questionnaires such as WHOQOL-BREF-THAI and PHQ-9 were administered at the first month and 6 months later.

The preparation of the *L. plantarum* extract capsules began with inactive ingredients in powder form: turmeric (10%), lemon grass (10%), maize (10%), soybean (25%), ginkgo seed (25%) and Indian gooseberry (10%). All the ingredients were mixed thoroughly. Water was then added to the mixture, at up to 900 mL/kg of the mixed powder. The mixture was then sterilized by an autoclave. *Lactobacillus plantarum* was cultured overnight in 100 mL of the mixture mentioned above, then transferred into 800 mL of the residual mixture and subsequently fermented for one week. The bacterial extract was prepared from the *L. plantarum* cultured on solid medium plate for two days. Bacterial cells were scrapped and put into liquid detergent and incubated for 12 hours. Sodium chloride was added and was extracted with ethanol. Ten grams of this precipitate was added in the fermented *L. plantarum* mixture previously prepared and then sterilized once again by autoclave. Finally, the mixture was heat dried in an oven and packed in capsules. Each capsule contained 3 mg of *L. plantarum* extract.

The comparisons of clinical and laboratory characteristics and outcomes between the two groups were done separately at several time points during the trial. Unpaired t-tests, Wilcoxon rank-sum test, and Chi-square tests were used as appropriate. *P*-values of 0.05 or less were considered statistically significant. The data were analyzed by using STATA statistical software version 15.1.

Results

From January 2017 to February 2019, 65 patients were enrolled into the study, but only 56 patients had complete data for evaluation. Although the calculated sample size was planned for 100 patients, the study had to be completed within two years. Due to this schedule restriction, only 65 patients were obtained. Nine subjects were excluded (5 in treatment arm and 4 in the placebo arm) because of product discontinuation by these patients within 2 weeks after enrolment into the study. Some of these patients complained of taking too many pills, causing difficulty of ingestion. Others experienced some adverse side effects allegedly from the medication, such as the loss of appetite, nausea, and vomiting. The flow diagram showing randomization and follow-up of the trial is shown in Figure 1. Patient's baseline characteristics are summarized in Table 1.

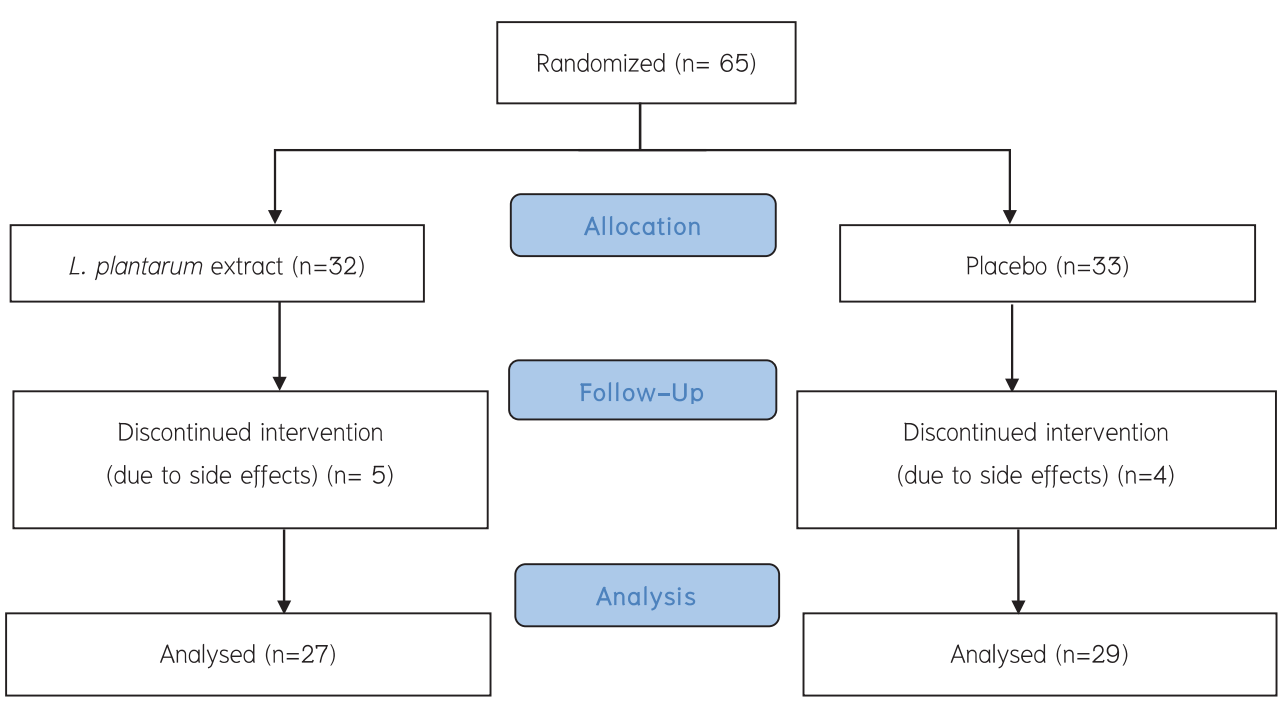

Figure 1 Flow diagram of the clinical trial

Table 1 Baseline characteristics of patients

Characteristic	*L. plantarum* (N = 27)	Placebo (N=29)	*p*-value
Age (years): mean (SD)	51.1 (9.5)	52.3 (10.9)	0.670
Weight (kg): mean (SD)	56.2 (10.9)	54.5 (9.2)	0.540
Underlying disease: number (%)	14 (52)	13 (45)	0.599
Stage 1: number (%)	14 (52)	15 (52)	0.093
Stage 2: number (%)	4 (15)	0	0.093
Stage 3: number (%)	9 (33)	13 (45)	0.093
Chemotherapy: number (%)			0.757
FAC/AC	11 (41)	13 (45)	
AC-T	16 (59)	16 (55)	
Alternative medicine: number (%)			0.279
Yes	22 (81)	25 (86)	
No	3 (11)	1 (3)	
ECOG status: mean (SD)	0.8 (0.4)	0.4 (0.2)	0.498
PHQ-9: mean (SD)	1.1 (1.1)	0.6 (0.7)	0.609
WHOQOL-BREF-THAI: mean (SD)	95.8 (11.2)	89.1 (20.8)	0.147

SD: standard deviation; stage refers to breast cancer staging (see text); chemotherapy regimen is as in text; ECOG, PHQ-9, WHOQOL-BREF-THAI are quality of life measures (see text)

The treatment and placebo groups were similar with regards to age, body weight, clinical staging of cancer, ECOG status, depression score, and quality of life by WHOQOL-BREF-THAI at the first visit. All patients received concurrent chemotherapy. There were some baseline laboratory test differences between the two groups, with the mean hematocrit and platelet count in the placebo group being slightly higher than those of the treatment group ($p = 0.013$ and $p = 0.03$, respectively); but the other laboratory values were not significantly different (Table 2).

Table 2 Baseline laboratory test results

Laboratory value	*L. plantarum* (N = 27)	Placebo (N = 29)	*p*-value
Hemoglobin (g/dL): mean (SD)	11.8 (1.3)	12.3 (1.0)	0.149
Hematocrit (%): mean (SD)	35.5 (3.2)	37.7 (2.9)	0.013
WBC (cells/mm^3): mean (SD)	7,124 (2,406)	7,033 (2,381)	0.891
Platelets (cells/mm^3): mean (SD)	285,560 (88,808)	332,348 (61,190)	0.028

SD: standard deviation; WBC: white blood cell count

At the second month after beginning of treatment (third visit), there were significant differences in the WBC count between two groups ($p = 0.04$). The mean WBC count in the treatment group was increased from 7,124 cells/mm^3 to 7,640 cells/mm^3, while the mean WBC count in placebo group was decreased from 7,034 cells/mm^3 to 5,108 cells/mm^3 (Table 3).

Table 3 Clinical and laboratory test results at the second month (third visit)

Value	*L. plantarum* (N = 27)	Placebo (N = 29)	*p*-value
Weight (kg): mean (SD)	56.1 (21.4)	53.4 (8.4)	0.362
Number of adverse symptoms from chemotherapy: mean (SD)	3.6 (1.0)	3.8 (1.7)	0.521
Hemoglobin (g/dL): mean (SD)	11.1 (1.3)	10.9 (1.4)	0.747
Hematocrit (%): mean (SD)	33.7 (3.8)	33.8 (4.1)	0.940
WBC (cells/mm^3): mean (SD)	7,640 (3,060)	5,108 (1,971)	0.046
Platelets (cells/mm^3): mean (SD)	365,143 (120,981)	397,640 (167,675)	0.340

SD: standard deviation; WBC: white blood cell count

The mean body weight of patients in both groups decreased in the second month compared to baseline (56.2 kg to 56.1 kg in treatment group and 54.5 kg to 53.4 kg in placebo group). At the sixth month, the mean body weight in the treatment group was increased compared to baseline (56.2 kg to 58.6 kg in treatment group) while the body weight in the placebo group continue to slightly decrease (54.5 kg to 54.4 kg). However, these changes were not significantly different between the two groups (Table 4).

Table 4 Clinical and laboratory test results at the sixth month (final visit)

Value	*L. plantarum* (N = 27)	Placebo (N = 29)	*p*-value
Weight (kg): mean (SD)	58.6 (12.8)	54.4 (8.5)	0.290
Hemoglobin (g/dL): mean (SD)	11.3 (1.4)	11.5 (1.2)	0.718
Hematocrit (%): mean (SD)	34.7 (4.1)	35.5 (3.2)	0.383
WBC (cells/mm^3): mean (SD)	7,181 (3,258)	6,889 (2,158)	0.693
Platelets (cells/mm^3): mean (SD)	377,778 (111,755)	435,517 (85,843)	0.034
ECOG status: mean (SD)	0.04	0.00	0.228
PHQ-9: mean (SD)	1.1 (1.1)	0.6 (0.7)	0.180
WHOQOL-BREF-THAI: mean (SD)	92.1 (23.4)	86.2 (26.6)	0.412

SD: standard deviation; WBC: white cell count; ECOG, PHQ-9, WHOQOL-BREF-THAI are quality of life measures (see text)

Other clinical and laboratory measures, including adverse symptoms from chemotherapy, values of the hemoglobin, hematocrit and platelet counts were similar in both groups at all visits. There were no statistically significant differences in terms of ECOG status, depression score, and quality of life by the WHOQOL-BREF-THAI questionnaire between two groups at the sixth month of visit.

Discussion

In a previous study, polynucleotide extracted from *L. plantarum* was demonstrated to have efficacy and safety as adjuvant treatment in HIV infected patients.[32-33] Thus, we conducted a similar study of *L. plantarum* extract in breast cancer patients. Although probiotics can be used safely in the general population,

in immunocompromised patients such as cancer patients receiving chemotherapy, probiotics may cause opportunistic infections.[9] Therefore, the use of dead probiotics would be safer in this group of patients.

The result of the present study demonstrated that at the third visit of follow up, or about two months after chemotherapy, when most patients were experiencing the side effects of chemotherapy, the clinical and laboratory profile of treatment group tended to be slightly better than those of the placebo group. This included body weight reduction, the reduction of hemoglobin and hematocrit levels, and the platelet count from baseline, and the number of chemotherapy adverse events, but none of these differences were statistically significant. Only the difference in the WBC count was of borderline significance.

We could not exactly explain why the platelet count increased in both groups at the second and sixth month, while the RBC and WBC counts decreased. We hypothesized that the increase in platelet counts was the result of reactive thrombocytosis from iron deficiency anemia caused by occult GI hemorrhage, which is a side effect of several chemotherapeutic drugs used in our protocol.[34-36] Of course, all of these minor differences could have been due to chance variation.

From several in vitro studies, several mechanisms of action of *L. plantarum* may be beneficial in cancer treatment. *L. plantarum* seems to demonstrate some chemopreventive efficacy in a rat model of breast cancer.[30] The oral supplement of a selenium nanoparticle enriched with *L. plantarum* may increase IFN-γ, TNF-α, IL-2 levels and increase NK cell activity in breast cancer-bearing mice.[29] One major limitation of the present study was that our current institution could not carry out any of the laboratory tests mentioned in these studies, and thus any biological link between these hypothetical mechanisms and the observed clinical and laboratory effects could not be directly verified.

Other limitations of the present study included the small sample size, the small effect differences, and the use of multiple statistical comparisons, which meant that any borderline significant results were likely to be due to chance. Finally, the study could not address the issue of cancer-adjuvant effects of *L. plantarum* as no cancer-related outcomes were obtained in the present study.

Conclusions

The present study showed that *L. plantarum* extract can probably be used safely as a possible adjuvant therapy in breast cancer. There seemed to be slightly better clinical and laboratory profiles in the treatment group as compared with the placebo group, but without statistical significance. Only one difference in the WBC counts at one time point seemed to be of borderline significance. Perhaps future studies including a larger number of patients performed in institutions with more detailed laboratory testing could be done to confirm and extend the findings of the present study.

Acknowledgement

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Conflicts of Interest

The authors declare no conflicts of interest.

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บทคัดย่อ

ความปลอดภัยของสารสกัดจากเชื้อแบคทีเรียไม่ก่อโรค (*Lactobacillus plantarum*) ที่นำมาใช้ร่วมในการรักษาผู้ป่วยโรคมะเร็งเต้านม

บารมี บุญเลิศ, พ.บ.[1], อัจฉรา ฟองคำ, พ.บ.[2], นภาภรณ์ วิระราช, พย.บ.[3]

[1] กลุ่มงานศัลยกรรม โรงพยาบาลลำพูน

[2] กลุ่มงานอายุรกรรม โรงพยาบาลลำพูน

[3] หน่วยงานคลินิกเคมีบำบัด โรงพยาบาลลำพูน

ความเป็นมา: เชื้อแบคทีเรีย *Lactobacillus plantarum* เป็นเชื้อโปรไบโอติก ที่มีผลการวิจัยพบว่ามีกลไกหลากหลายในการต่อต้านเซลมะเร็งในห้องปฏิบัติการ แต่ยังมีการศึกษาในผู้ป่วยน้อย

วัตถุประสงค์: เพื่อทำการศึกษาความปลอดภัยของสารสกัดจากเชื้อแบคทีเรียไม่ก่อโรค (*Lactobacillus plantarum*) นำมาใช้ร่วมในการรักษาผู้ป่วยโรคมะเร็งเต้านม

วิธีการศึกษา: เป็นการศึกษาแบบ prospective, randomized, double-blind, placebo-controlled ในผู้ป่วยโรคมะเร็งระยะแรกจำนวน 56 ราย ซึ่งได้รับการผ่าตัดเรียบร้อย และเตรียมที่จะได้รับยาเคมีบำบัดสูตรมาตรฐาน ผู้ป่วยจำนวน 27 ราย ได้รับการสุ่มเป็นกลุ่มทดลอง และ 29 รายเป็นกลุ่มควบคุม ผู้ป่วยในกลุ่มทดลองจะได้รับยาแคบซูลที่บรรจุสารสกัดจากเชื้อ *Lactobacillus plantarum* ในขณะที่อีกกลุ่มจะได้รับยาหลอกเป็นระยะเวลา 6 เดือน โดยมีการเก็บข้อมูลทางคลินิก เช่น น้ำหนักตัว, ดัชนีคุณภาพชีวิต, อาการแพ้ยาเคมีบำบัด และค่าทางห้องปฏิบัติการ

ผลการศึกษา: พบว่าค่าเฉลี่ยของระดับเม็ดเลือดขาวของกลุ่มทดลอง 7,640.5 cell/ mm^3 และ 5,107.6 cell/ mm^3 ในกลุ่มควบคุม มีความแตกต่างกันอย่างมีนัยสำคัญทางสถิติ ($P = 0.04$) ในเดือนที่สองของการวิจัย ค่าเฉลี่ยของน้ำหนักตัวของผู้ป่วยในกลุ่มควบคุมจะลดลงมากกว่ากลุ่มทดลองในเดือนที่สองของการวิจัยเช่นเดียวกัน แต่ไม่มีนัยสำคัญทางสถิติ และยังคงลดลงในเดือนที่ 6 ในขณะที่กลุ่มทดลองมีค่าเฉลี่ยของน้ำหนักตัวที่เพิ่มขึ้น

สรุปผลการศึกษา: การศึกษานี้แสดงให้เห็นว่า สารสกัดจากเชื้อ *Lactobacillus plantarum* สามารถนำมาใช้ในการรักษาร่วมกับการรักษามาตรฐานในการรักษาโรคมะเร็งเต้านมได้อย่างปลอดภัย ผลการศึกษายังพบว่ามีตัวแปรทางด้านคลินิกหลายตัวที่ในกลุ่มทดลองจะมีผลดีกว่าในกลุ่มควบคุม แต่มีเพียงค่าเฉลี่ยของเม็ดเลือดขาวเพียงตัวแปรเดียวที่แสดงให้เห็นความแตกต่างอย่างมีนัยสำคัญทางสถิติ