Effect of Malunggay *(Moringa oleifera)* Capsules on Lipid and Glucose Levels

Mark Anthony S. Sandoval[1,2] and Cecilia A. Jimeno[1,3]

[1]*Section of Endocrinology, Diabetes and Metabolism, Department of Medicine, College of Medicine and Philippine General Hospital, University of the Philippines Manila*
[2]*Department of Physiology, College of Medicine, University of the Philippines Manila*
[3]*Department of Pharmacology, College of Medicine, University of the Philippines Manila*

ABSTRACT

Objectives. To determine the effect of malunggay leaf capsules on LDL (primary efficacy outcome measure); weight, BMI, FBS, serum glucose 2 hours after a 75 g oral glucose load, cholesterol, HDL and triglycerides (secondary efficacy outcome measures); creatinine, ALT and CBC (secondary safety outcome measures); and to determine if these are associated with adverse events.

Study design. randomized controlled trial

Participants. Seventy nine Filipinos, 18-55 years old with LDL >2.6 mmol/L (100 mg/dL) but of low cardiovascular risk were randomized into malunggay and placebo groups.

Intervention. Malunggay capsules for 30 days versus placebo

Results. 33 and 35 participants in the malunggay and placebo groups, respectively, completed the treatment. There was a reduction of 13.76 mg/dL in the LDL of the malunggay group, compared to a 19.28 mg/dL reduction in the placebo group (p=0.564).

Conclusion. Malunggay leaf capsules given for 30 days among adults with serum LDL >2.6 mmol/L (100 mg/dL) but with low cardiovascular risk decreased LDL levels to the same degree as placebo. There were no significant differences in the change in the secondary efficacy and safety outcome measures, and in the occurrence of adverse events.

Key Words: Moringa oleifera, malunggay, LDL, cholesterol, dyslipidemia, lipid profile, glucose

Introduction

Moringa oleifera Lam., locally known as "malunggay," is widely consumed as a vegetable in the Philippines. The leaves are usually added in common viands, and the fruits or pods are eaten as a vegetable dish. It is known as horse radish tree or drumstick tree in other English-speaking countries.

Corresponding author: Mark Anthony S. Sandoval, MD
Section of Endocrinology, Diabetes and Metabolism
Medical Research Laboratory
Philippine General Hospital
Taft Avenue, Ermita, Manila 1000 Philippines
Telephone: 0916-5921818
E-mail: markanthony_sandoval@yahoo.com

There are popular but yet unproven claims that malunggay is used for the treatment of high cholesterol and diabetes mellitus. There are, however, several animal studies that have shown positive effects.

Mehta et al. in 2003 have shown that the administration for 120 days of *M. oleifera* fruit, like lovastatin, was able to lower the serum cholesterol, phospholipids, triglyceride, very low density lipoprotein (VLDL), low density lipoprotein (LDL), cholesterol ratio and atherogenic index, and was able to increase the high density lipoprotein (HDL) ratio compared to the corresponding control groups in rabbits. One proposed mechanism of action is that *M. oleifera* promotes gastrointestinal excretion of cholesterol as *M. oleifera*-treated rabbits had higher levels of cholesterol in their feces.[1]

The crude extract of the leaves of *M. oleifera* has also been shown to possess hypocholesterolemic effects in high-fat diet fed wistar rats. If given for 30 days, the extract was able to decrease the high-fat diet-induced increases in serum cholesterol levels by 14.35%.[2]

The leaves of *M. oleifera* have also been shown to decrease cholesterol levels by 50% in hypercholesterol-fed rabbits after 12 weeks of treatment.[3]

Aside from cholesterol levels, *M. oleifera* has been demonstrated to improve glucose tolerance among rats. It was demonstrated that *M. oleifera* leaves significantly improved glucose tolerance after a 2-g/kg glucose administration in nondiabetic rats and in rats induced to develop diabetes.[4]

At least four human clinical studies have been carried out already in the Philippines but these investigated the effects of malunggay on breastmilk volume, prolactin levels, and weight gain of infants of mothers given malunggay.[5,6,7,8] None of these studies dealt with the effects on cholesterol levels. A total of 126 Filipino mothers have been included in these four studies. Malunggay was given at a dose ranging from 250 mg of the leaves twice a day to as much as 700 mg three times a day. Duration of administration of malunggay ranged from as short as 3 days to as long as 4 months. Only the study by Co et al. in 2002, which administered 250 mg of the malunggay capsule 3x a day for 14 days, reported an adverse event.[8] There was one subject in the malunggay-treated group who reported developing tinnitus but this was

said to be not directly related to the administration of malunggay.[8] All the three other studies did not demonstrate the occurrence of any adverse effects. The monitoring of adverse events in these studies was performed by asking for the development of any abnormal symptoms, and did not include the performance of any laboratory test.

This study was proposed to fill the knowledge gap regarding the metabolic effect, specifically on the lipid profile and glucose levels, of the widely cultivated and easily available malunggay in humans. Since clinical studies did not find any significant adverse effects in lactating women, it would be acceptable to perform a phase II clinical trial involving humans with dyslipidemia.

This study compared malunggay with placebo, but did not compare it with statins, the standard drugs for the treatment of dyslipidemia. Since it would be unethical to withhold statin therapy in patients for whom it *is recommended* (i.e., those with high cardiovascular risk), this study included dyslipidemic patients with low cardiovascular risk in whom statin therapy only *may be recommended* (i.e., no established atherosclerosis but have LDL >100 mg/dL or total cholesterol >190 mg/dL and at least three cardiovascular risk factors) or *not recommended* (i.e., those with LDL >100 mg/dL or total cholesterol >190 mg/dL but who have less than three cardiovascular risk factors). These cut-off values were based on the Clinical Practice Guidelines for the Management of Dyslipidemia in the Philippines published in 2005.[9]

Research Question

What is the effect of malunggay leaf capsules on the fasting LDL cholesterol levels of adult Filipinos with baseline serum LDL >100 mg/dL and low cardiovascular risk?

Objectives

General Objective

To determine the effect of malunggay leaf capsules on the fasting levels of LDL cholesterol among adult Filipinos with baseline serum LDL >2.6 mmol/L (>100 mg/dL) and low cardiovascular risk.

Specific Objectives

Primary Efficacy Outcome Measure

1. To determine if there are any significant differences in the change in mean fasting LDL levels from baseline and after a 30-day treatment period between the malunggay and placebo groups.

Secondary Efficacy Outcome Measures

2. To determine if there are any significant differences in the change in mean weight, body mass index (BMI), fasting blood sugar, serum glucose 2 hours after a 75-gram oral glucose load, HDL and triglycerides from baseline and after a 30-day treatment period between the malunggay and placebo groups.

Secondary Safety Outcome Measures

3. To determine if there are any significant differences in the change in the results of complete blood count, creatinine and alanine aminotransferase (ALT) from baseline and after the 30-day treatment period in the malunggay and placebo groups.
4. To determine whether there are any significant differences in the occurrence of adverse events by symptom questioning between the malunggay and placebo groups.

Methods

Sample Size

In order to detect a decrease of 0.22 mmol/L (5.79 mg/dL) in the LDL cholesterol in the subjects to be given malunggay versus a 0.02 mmol/L (0.77 mg/dL) rise in the LDL cholesterol levels (standard deviation 0.35 mmol/L) in those given placebo with study power (β) of 0.80 and level of significance (α) of 0.05, the minimum sample size for each treatment arm would be 33 subjects to reject the null hypothesis.

These expected results were taken from the hypocholesterolemic effects of a dietary fiber supplement as studied by Hunninghake et al.[10] This study involved a similar subject population with this investigation. It is assumed that if ever malunggay would have an effect on cholesterol levels, it would at least be because of its fiber content. There are no clinical studies on the effects of malunggay on cholesterol levels from which expected results can be taken.

To allow for 20% drop-out rate, the final sample size per group was [33 x 1.2] = 39.6 or 40 subjects.

Screening of Subjects

This study was carried out at the Philippine General Hospital–Medical Research Laboratory.

The targeted population for screening consisted of Filipinos, either male or nonpregnant female, aged 18 to 55 years old with no known diabetes, coronary artery disease, cerebrovascular disease nor peripheral arterial disease. They were selected by purposive sampling by announcements and invitations in the workplace and in the community.

Potential participants were screened by the clinical investigator with a medical interview, physical examination, and laboratory testing for fasting blood sugar (FBS) and lipid profile.

Inclusion and exclusion criteria

Participants were eligible for inclusion in this study if they have the following characteristics:

1. 18 to 55 years old
2. Fasting serum LDL >2.6 mmol/L (>100 mg/dL)

3. No known history of diabetes mellitus, coronary artery disease, cerebrovascular disease, nor peripheral arterial disease.
4. Gave informed consent for inclusion in the study.

Participants were not eligible for inclusion in this study if they had *any* of the following characteristics:

1. Serum LDL <2.6 mmol/L (<100 mg/dL)
2. Fasting blood sugar of 7.0 mmol/L (126 mg/dL) or greater
3. Known diabetes mellitus, coronary artery disease, cerebrovascular disease or peripheral arterial disease.
4. Taking any medication for diabetes or dyslipidemia
5. Taking malunggay capsule at least 6 weeks before the start of randomization
6. Participation in any other clinical trial
7. Known to have liver disease or kidney disease
8. Pregnancy
9. Did not give informed consent for inclusion in the study

Pregnant women were excluded not because malunggay might be harmful (malunggay is actually being used among pregnant and lactating mothers), but because of the following reasons: weight gain is inevitable during pregnancy, and also because pregnancy is an insulin resistance state. Thus, weight, fasting blood glucose and serum glucose 2 hours after a 75-gram oral glucose load will definitely rise regardless of the treatment allocation.

Randomization

Once enrolled in the study after consideration of the inclusion and exclusion criteria, the participants were randomized into any of two groups:

1. Placebo
2. Malunggay capsule

The dosing for the malunggay capsules (350 mg/capsule, 2 capsules 3x a day, or 2100 mg/day) was based on the highest dose already previously used in augmenting breastmilk production that did not show any side effects.[5] It is not known whether the same dose will have effects on the lipid profile and glucose levels.

Participants were randomized using calculator-generated random numbers.

Treatment allocation was not known to the participants and clinical investigator. It is only the research assistant dispensing the capsules who was aware of the treatment group assignments.

Blinding

This was a double-blind, placebo-controlled study with the participants and clinical investigator unaware of the participants' group allocation. Placebo capsules were manufactured by the Department of Industrial Pharmacy, College of Pharmacy, UP Manila.

Provision for Dropouts

All participants randomized were analyzed in their respective groups even if they dropped out from the study for whatever reason. A dropout rate of <20% was allowable for this study.

Had there been participants who voluntarily withdrew (and who were supposed to be considered dropouts) due to unacceptable adverse events would still have been included in the analysis in their respective groups.

Malunggay preparation

A commercially available preparation of malunggay leaves (Carica brand Malunggay Capsules, Carica Herbal Health Products, Inc., BFAD LTO No. RDII-RIV-F-2149) was administered to the participants randomized to receive the treatment: 350 mg capsule, 2 capsules 3x a day (2100 mg per day). These were taken for 30 days. This brand was chosen because it was more affordable than other brands and because it was present in 350 mg per capsule preparation since the others were prepared as 250 mg capsules. Confirming the botanical nature of the contents of the commercially prepared malunggay leaf capsules was beyond the scope of this study.

Participants randomized in the placebo group were made to take the same number and frequency of placebo capsules.

Study Flow/Experimental Procedure

The following parameters were taken at baseline prior to the start of the treatment period: weight, height, body mass index, fasting blood glucose, fasting serum LDL, HDL and triglycerides, serum glucose 2 hours after 75 gram oral glucose load, complete blood count, serum creatinine and ALT.

Participants were advised a low fat diet. They were given pamphlets on low fat diets prepared by the Dietary Department of the Philippine General Hospital, and these were verbally discussed with them by the investigator upon randomization. They were advised to maintain their usual level of physical activity.

Upon randomization, the participants were given their 30 days' supply of either malunggay capsules or placebo.

After the 30-day treatment period, the same parameters taken at baseline were measured again.

When the participants returned after the 30-day treatment period, the clinical investigator administered a checklist containing various symptoms that they may have experienced during the treatment period. All adverse events, minor and serious, were reported. It was the prerogative of the participants whether to continue with the study or not should they have found unacceptable any adverse event.

Indemnification Policy

Based on previous studies, there have been no serious adverse events reported in relation to malunggay intake at the doses used for breastmilk augmentation. However, had a participant experienced an adverse event associated with the treatment, he or she would have been treated accordingly, either as an outpatient or inpatient, depending on the nature of the adverse event.

Statistical analysis

Baseline characteristics of the participants in the two groups were compared to verify similarity prior to the start of the treatment interventions: age, sex distribution, height, weight, BMI, fasting blood sugar, serum glucose 2 hours after a 75-gram oral glucose load, CBC, creatinine and ALT.

Test for normality of the two groups was performed first. The variables satisfied the test for normality. The variances of the two groups were also found to be equal. Statistical analysis was performed using the t-test for continuous data. The test for two proportions was used for the analysis of adverse event occurrence. All p-values <0.05 were considered significant.

Ethical considerations

This protocol has been given technical and ethical approval by the Expanded Hospital Research Office (EHRO) of the Philippine General Hospital.

Results

There were 133 adult Filipinos who were screened. Of these, 79 fulfilled the inclusion and exclusion criteria, giving a positive screening rate of 59% (79/133). The other 54 were excluded because of a fasting LDL level of <2.6 mmol/L (<100 mg/dL). No participant was excluded because of a fasting blood sugar of 7.0 mmol/L (126 mg/dL) or higher.

Of the 79 who had been randomized to the treatment groups, 40 were allocated to the malunggay group while 39 were in the placebo group.

Of the 40 randomized into the malunggay group, 33 completed the 30-day treatment period and returned for follow-up. In the placebo group, 35 completed the study. The drop-outs were not due to any adverse event. Refer to Figure 1 for the schematic representation as to how participants were screened, randomized and able to complete the study.

Table 1 shows the baseline characteristics of the participants. Except for the difference in the white blood cell count, they appear comparable at baseline. There were no differences in age, weight, BMI, total cholesterol, LDL, HDL, triglycerides, FBS, serum glucose 2 hours after a 75-gram oral glucose load, complete blood count, ALT and creatinine.

For the primary outcome measure (Table 2), there was a mean decrease of 0.36 mmol/L (13.76 mg/dL) in the malunggay group versus a mean decrease of 0.50 mmol/L (19.28 mg/dL) in the placebo group. Even if the LDL decreased in the malunggay group after the study period, a similar decrease was noted in the placebo group and the changes in LDL between groups were not significantly different (p=0.564).

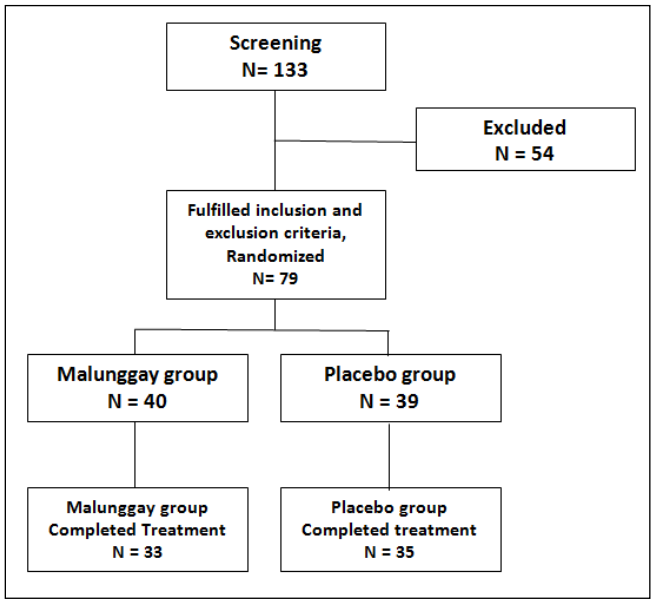

Figure 1. Summary of participants' screening, randomization and completion of study.

Table 1. Baseline characteristics of participants

Mean Values (SD), Proportion	Malunggay N=40	Placebo N=39	P
Age (y)	38.85 ± 9.58	36.97 ± 9.81	0.392
Males (%)	35.00%	38.46%	0.753
Weight (kg)	58.09 ± 11.56	61.87 ±12.69	0.169
Body Mass Index (kg/m2)	23.71 ± 9.20	24.86 ± 8.82	0.248
Total Cholesterol (mg/dL)	200.98 ± 30.84	207 ± 31.95	0.400
Presence of Cardiovascular Risk (CV) Factors *			0.689
No CV risk factor (%)	37.50%	35.90%	
With 1 CV risk factor (%)	50.00%	43.59%	
With 2 CV risk factors (%)	12.50%	20.51%	
With 3 CV risk factors (%)	0%	0%	
LDL (mg/dL)	133.65 ± 27.11	136.81 ± 25.30	0.595
HDL (mg/dL)	50.52 ± 11.95	54.42 ± 14.50	0.195
Triglycerides (mg/dL)	113.65 ± 44.09	106.31 ± 40.93	0.458
Fasting blood sugar (mg/dL)	76.69 ± 12.62	75.43 ± 14.01	0.675
Serum glucose 2hrs after 75g oral glucose (mg/dL)	91.05 ± 22.03	100.15 ± 28.43	0.115
Creatinine (umol/L)	64.00 ± 14.42	65.00 ± 18.44	0.790
ALT (U/L)	26.81 ± 21.55	25.15 ± 17.70	0.711
Hemoglobin (g/L)	136.20 ± 15.40	139.13 ± 16.04	0.413
Hematocrit (%)	0.42 ± 0.05	0.44 ±0.04	0.108
White Blood Cell Count ($x10^9$/L)	6.61 ± 1.58	7.41 ± 1.94	0.05
Platelet count ($x10^9$/L)	305.37 ± 55.65	312.37 ± 85.76	0.669

**The cardiovascular risk factors considered, if known to the participant, were the following: hypertension, familial hypercholesterolemia, left ventricular hypertrophy, smoking, family history of premature coronary artery disease, male sex, age >55 years, proteinuria, albuminuria and body mass index >25 kg/m².*

Table 2. Efficacy and safety outcome measures in the malunggay and placebo groups at baseline and after 30 days

Variable	MALUNGGAY GROUP n=33			PLACEBO GROUP n=35			P value comparing the differences
	Baseline	After study period	Difference (Final-Baseline)	Baseline	After Study Period	Difference (Final-Baseline)	
Primary Efficacy Outcome							
LDL cholesterol (mg/dL)	136.86 ± 27.54	123.10 ± 46.44	-13.76 ± 47.55	137.73 ± 26.18	118.45 ± 31.53	-19.28 ± 28.29	0.564
Secondary Efficacy Outcomes							
Weight (kg)	56.89 ± 11.81	56.96 ± 11.24	0.07 ± 1.37	60.58 ± 11.87	60.38 ± 11.29	-0.20 ± 1.77	0.508
Body Mass Index (kg/m2)	23.09 ± 4.13	23.10 ± 3.68	0.01 ± 0.56	24.60 ± 4.47	24.49 ± 3.65	-0.11 ± 0.65	0.425
Fasting Blood Sugar (mg/dL)	75.41 ± 12.82	82.70 ± 16.48	7.28 ± 14.66	75.25 ± 14.68	77.84 ± 18.78	2.58 ± 17.07	0.232
Serum glucose 2hrs after 75g oral glucose (mg/dL)	96.77 ± 21.08	93.48 ± 26.85	-3.29 ± 28.37	99.98 ± 28.87	91.76 ± 23.32	-8.21 ± 3.37	0.462
Total cholesterol (mg/dL)	204.28 ± 32.05	209.38 ± 53.25	5.10 ± 43.33	205.74 ± 33.38	194.61 ± 39.25	-11.13 ± 35.25	0.100
HDL cholesterol (mg/dL)	51.34 ± 12.21	51.86 ± 12.12	0.51 ± 7.51	54.64 ± 14.56	51.00 ± 13.90	-3.64 ± 10.27	0.064
Triglycerides (mg/dL)	113.96 ± 46.11	115.70 ± 43.51	1.74 ± 38.84	105.34 ± 38.41	106.78 ± 51.82	1.44 ± 45.38	0.977
Secondary Safety Outcomes							
Hemoglobin (g/L)	137.58 ± 12.79	136.09 ± 14.93	-1.48 ± 6.44	139.66 ± 14.88	138.29 ± 13.19	-1.36 ± 7.96	0.946
Hematocrit (%)	0.42 ± 0.04	0.42 ± 0.05	0.00 ± 0.02	0.44 ± 0.04	0.43 ± 0.04	-0.01 ± 0.03	0.207
White Blood Cell count (x 10^9/L)	6.61 ± 1.48	7.01 ± 1.66	0.40 ± 2.12	7.31 ± 1.96	7.23 ± 1.66	-0.08 ± 2.23	0.369
Platelet count (x10^9/L)	302.24 ± 55.68	293.03 ± 69.77	-9.21 ± 61.99	312.09 ± 79.65	312.15 ± 55.58	0.06 ± 57.24	0.530
Crea(umol/L)	63.62 ± 14.22	66.85 ± 20.81	3.24 ± 12.63	65.67 ± 18.69	66.90 ± 18.95	1.23 ± 12.11	0.494
ALT (U/L)	26.93 ± 23.15	22.31 ± 31.21	-4.61 ± 21.88	20.19 ± 17.88	19.60 ± 25.60	-0.59 ± 18.76	0.846

Table 3. Adverse events reported in the malunggay and placebo groups

Adverse Event	Malunggay		Placebo		P-value
	n	%	n	%	
Fever	2	6.25	4	11.76	0.4361
Perceived weight loss	5	15.63	1	2.94	0.0732
Loss of appetite	1	3.13	2	5.88	0.5909
Headache	5	15.63	8	23.53	0.4197
Blurring of vision	2	6.25	0	0.00	0.1388
Dizziness	3	9.38	6	17.65	0.3277
Vomiting	0	0.00	1	2.94	0.3283
Abdominal pain	2	6.25	2	5.88	0.9501
Diarrhea	2	6.25	2	5.88	0.9501
Flatulence	3	9.38	6	17.65	0.3277
Difficulty of breathing	2	6.25	4	11.76	0.4361
Fatigue	2	6.25	2	5.88	0.9501
Cough	5	15.63	6	17.65	0.8256
Chest pain	3	9.38	2	5.88	0.5920
Palpitations	2	6.25	1	2.94	0.5190
Edema	0	0.00	1	2.94	0.3283
Frequent urination	9	28.13	4	11.76	0.0949
Decrease in urine output	1	3.13	0	0.00	0.2990
Change in urine color	5	15.63	2	5.88	0.1989
Dysuria	1	3.13	0	0.00	0.2990
Body aches	2	6.25	4	11.76	0.4361
Joint pains	2	6.25	6	17.65	0.1562
Breast enlargement	1	3.13	0	0.00	0.2990
Breast pain	0	0.00	1	2.94	0.3283
Loss of libido	1	3.13	0	0.00	0.2990
Menstrual irregularities	0	0.00	1	2.94	0.3283
Itchiness	1	3.13	1	2.94	0.9653
Rashes	1	3.13	1	2.94	0.9653

For the secondary outcome measures (Table 2), there were no significant differences in the change in body weight, body mass index, fasting blood sugar, serum glucose 2 hours after a 75-gram oral glucose load, total cholesterol, HDL, and triglycerides between the malunggay and placebo groups.

For the secondary safety outcome measures (Table 2), there were no significant differences in the changes in the serum creatinine and ALT levels and in the complete blood count between the malunggay and placebo groups.

For the self-reported adverse events (Table 3), there were no significant differences in the occurrence of these events between the malunggay and placebo groups. There were no serious adverse events reported. The most commonly reported adverse event was frequent urination in the malunggay group, and headache in the placebo group. Even if malunggay is a known galactogogue, there were no reported episodes of galactorrhea in any of the participants of this study.

Discussion

This study has shown that malunggay leaf capsules are similar to placebo with respect to their effect on the LDL cholesterol levels (as the primary efficacy outcome measure) and on weight, BMI, fasting blood sugar, serum glucose 2 hours after a 75-gram oral glucose load, total cholesterol, HDL and triglycerides (as secondary efficacy outcome measures). What would explain the similar decrease in LDL cholesterol in the two groups is that dietary advice on a low fat diet was given to all participants upon randomization. Even if beneficial effects on lipids and blood sugar levels have been demonstrated in animal studies, the same conclusions were not demonstrated in this clinical trial.

No significant adverse events occurred in this study. Likewise, the occurrence of adverse events was similar to the rates of occurrence in those given placebo. Thus, this study validates the findings in other clinical studies of malunggay leaf capsules that there are no associated adverse effects.[5,6,7,8] The previous clinical studies on malunggay dealing with breastmilk production only involved asking for symptoms to determine any adverse events. Here we have also checked for any adverse events involving the blood, kidneys, and

liver by checking the complete blood count, serum creatinine, and serum ALT levels, respectively.

The participants in this study had a relatively low level of serum LDL at baseline since our cut-off for inclusion was 2.6 mmol/L (100 mg/dL). A study may be done to see whether malunggay would be effective in lowering serum LDL if the baseline level was higher. Since the lipid-lowering effect of malunggay has not been proven in humans, it might be unethical to study its effects if given alone among those with high cardiovascular risk for whom lipid-lowering therapy is indicated.

Compliance to the patient's dietary intake and physical activity was not measured in this study and is one of its limitations. Also, we could have prescribed a longer treatment duration to show lipid-lowering effects since 30 days might not be enough time to demonstrate any results. However, several studies using plant products have showed significant effects on lipid levels in as little as 4 weeks. These clinical studies made use of beta glucan and plant stanol esters,[11] plant sterol esters,[12,13] St. John's Wort,[14] and an herbal powder mixture composed of Indian plants locally known as *guargum, methi, tundika,* and *meshasringi*.[15]

Conclusion

Malunggay (*Moringa oleifera*) leaf capsules given at a dose of 350 mg per capsule, 2 capsules three times a day for 30 days lowered LDL cholesterol to the same degree as placebo among adults with baseline serum LDL >2.6 mmol/L (>100 mg/dL) and low cardiovascular risk. The effects of malunggay and placebo were also similar with respect to the secondary efficacy outcome measures (weight, body mass index, fasting blood sugar, serum glucose 2 hours after a 75 gram oral glucose load, total cholesterol, HDL and triglycerides), and the secondary safety outcome measures (serum creatinine and ALT, and complete blood count). Occurrence of adverse events was also similar between the malunggay and placebo groups. There were no significant adverse events associated with intake of malunggay capsules.

Acknowledgments

This study has been supported by a Philippine Lipid and Atherosclerosis Society (PLAS)-Pfizer research grant. We are thankful to the Department of Industrial Pharmacy, College of Pharmacy, University of the Philippines Manila for the manufacture of placebo capsules; to Ms. Rhoda Montemayor and Ms. Hazel Jayohoy of the Medical Research Laboratory, Philippine General Hospital for the performance of the laboratory assays; and to Mr. Mark Javellosa and Mr. Kevin Carl Santos of the School of Statistics of the University of the Philippines Diliman for the statistical analysis.

References

1. Mehta K, Balaraman R, Amin AH, Bafna PA, Gulati OD. Effects of fruits of *Moringa oleifera* on the lipid profile of normal and hypercholesterolaemic rabbits. J Ethnopharmacol. 2003; 86(2-3):191-5.
2. Ghasi S, Nwobodo E, Ofili JO. Hypocholesterolemic effects of crude extract of leaf of *Moringa oleifera Lam* in high-fat diet fed wistar rats. J Ethnopharmacol. 2000; 69(1):21-5.
3. Chumark P, Khunawat P, Sanvarinda Y, et al. The in vitro and ex vivo antioxidant properties, hypolipidemic and antiatherosclerotic activities of water extract of *Moringa oleifera Lam*. leaves. J Ethnopharmacol. 2008; 116(3):439-46.
4. Ndong M, Uehara M, Katsumata S, Suzuki K. Effects of oral administration of *Moringa oleifera* Lam on glucose tolerance in Goto-Kakizaki and Wistar rats. J Clin Biochem Nutr. 2007; 40(3):229-33.
5. Briton-Medrano G, Perez ML. The efficacy of malunggay (Moringa oleifera) given to near term pregnant women in inducing early postpartum breast milk production – a double-blind randomized clinical trial. Ospital ng Makati. 2002. Unpublished.
6. Estrella MCP, Mantaring JBV III, David GZ, Taup MA. A double-blind, randomized controlled trial on the use of malunggay (Moringa oleifera) for augmentation of the volume of breastmilk among non-nursing mothers of preterm infants. Philipp J Pediatr. 2000; 49(1):3-6.
7. Yabes-Almirante C, Lim CHTN. Effectiveness of Natalac as a galactogogue. Journal of Phil Med Assoc. 1996; 71(3):265-72.
8. Co MAM, Hernandez EA, Co BG. A comparative study on the efficacy of the different galactogogues among mothers with lactational insufficiency. Philipp J Pediatr. 2002; 51(2):88-92.
9. Clinical Practice Guidelines for the Management of Dyslipidemia in the Philippines. Philippine Heart Association. 2005.
10. Hunninghake DB, Miller VT, LaRosa JC, et al. Hypocholesterolemic effects of a dietary fiber supplement. Am J Clin Nutr. 1994; 59(5):1050-4.
11. Theuwissen E, Mensink RP. Simultaneous intake of beta-glucan and plant stanol esters affects lipid metabolism in slightly hypercholesterolemic subjects. J Nutr. 2007; 137(3):583-8.
12. Saito S, Takeshita M, Tomonobu K, et al. Dose-dependent cholesterol-lowering effect of a mayonnaise-type product with a main component of diacylglycerol-containing plant sterol esters. Nutrition. 2006; 22(2):174-8.
13. Thomsen AB, Hansen HB, Christiansen C, Green H, Berger A. Effect of free plant sterols in low-fat milk on serum lipid profile in hypercholesterolemic subjects. Eur J Clin Nutr. 2004; 58(6):860-70.
14. Eggertsen R, Andreasson A, Andren L. Effects of treatment with a commercially available St John's Wort product (Movina) on cholesterol levels in patients with hypercholesterolemia treated with simvastatin. Scand J Prim Health Care. 2007; 25(3):154-9.
15. Bhardwaj PK, Dasgupta DJ, Prashar BS, Kaushall SS. Control of hyperglycemia and hyperlipidaemia by plant product. J Assoc Physicians India. 1994; 42(1):33-5.