EFFECT OF SOY LECITHIN ON SERUM LIPID PARAMETERS OF HYPERLIPIDEMIC POSTMENOPAUSAL WOMEN REFERRING TO SHAHID FAGHIHEE HOSPITAL OF SHIRAZ UNIVERSITY OF MEDICAL SCIENCES

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Abstract

BACKGROUND: Cardiovascular disease (CVD) is the leading cause of morbidity and mortality throughout the world. Hyperlipidemia, as one of the main causes of CVD, has been diagnosed in nearly one third of Iranian middle aged women. Menopause manifests wide range of physiologic changes in women, most important of which is hyperlipidemia. Appropriate nutritional interventions can prevent or postpone some cardiovascular events in postmenopausal women. This randomized double blind clinical trial aimed to examine the effect of soy lecithin on serum lipid parameters of hyperlipidemic postmenopausal women.

METHOD AND MATERIALS: Sixty free living postmenopausal women, aged 50-60 years, with mild to moderate hyperlipidemia entered the study. Subjects were randomly assigned in one of three treatments: yogurt; or: yogurt with 16g soy lecithin granules; or: yogurt with 10g sunflower oil, containing equal amount of linoleic acid and energy as the administered lecithin. Strawberry syrup was added to ensure blindness. To assess the effects of confounding factors, BMI and waist circumference were measured. Intake of some dietary factors (energy, macronutrients, saturated fatty acids, monounsaturated fatty acids, polyunsaturated fatty acids, cholesterol, calcium and fiber) were assessed using 24 hr-food recall and 3-day food record questionnaires. Changes in physical activity level were assessed by seven day-physical activity recall questionnaire. Serum lipid parameters (TC, Non-HDL.C, LDL.C, HDL.C and TG) were measured twice at baseline and 4 weeks of treatment.

RESULTS: There was no significant difference between treatment groups, but a significant decrease was found within the intervention group (lecithin) in the average level of TC (252.33 ± 24.02 vs. 255.22 ± 24.82 mg/dl and P = 0.02), LDL.C/HDL.C (3.99 ± 0.50 vs. 4.17 ± 0.56 mg/dl and P = 0.001) and Non.HDL.C (211.94 ± 23.94 vs. 216.00 ± 23.73 mg/dl and P = 0.005) and accompanying significant increase in serum HDL.C level (40.39 ± 5.21 vs. 39.22 ± 5.58 mg/dl and P = 0.04). Likewise, no significant change was found in serum lipid profile within the control group I (sunflower oil). Decreasing LDL.C/HDL.C level (4.18 ± 0.40 vs. 4.24 ± 0.43 mg/dl and P = 0.03) was the only significant change in serum lipid profile of control group II (yogurt).

CONCLUSION: Soy lecithin treatment had no significant hypocholesterolemic effect on serum lipid profile, in a way that we can not claim any independent effect for lecithin's linoleic acid content.

Keywords: soy lecithin, hyperlipidemic, menopause, linoleic acid, lipid profile.

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Introduction

Lecithin (phosphatidylcholine) is a choline containing phospholipids, which also includes glycerol esterified with fatty acids.[1] Lecithin has emulsifying properties and is an essential component of biomembranes and lipoproteins. Liver, egg yolk and

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soy beans are especially rich sources of lecithin. Most of the commercial lecithin brands claim hypocholesterolemic effects and are therefore prescribed by health practitioners for treatment of increased lipoprotein levels. The assumption that lecithin lowers lipoprotein levels is based on evidences from studies done from the 1940s to the early 1980s[2-6] and most of these studies were poorly designed and showed controversial results. Some of the major design errors include using small, heterogenic study groups, for example a study group of eight men and women with different types of dyslipidaemia including familial hypercholesterolaemia, hypercholesterolaemia, combined hyperlipidaemia and normal lipidaemia.[2,4,6-8] Also, most studies lacked an appropriate control group.[2,4,6,9,10] Knuiman et al[11] highlighted four out of twenty four studies that attempted to balance fatty acid intakes of control and experimental groups, including Greten et al,[8] Childs et al,[7] Prack et al[12] and Kesaniemi & Grundy.[13] These studies, however, could not demonstrate any independent effects of lecithin on serum cholesterol. Moreover, in the studies with cross-over designs that used control groups, no or too short washout periods existed between control (soy bean oil or safflower oil) and lecithin treatments.[8,13] Also, control and lecithin treatment periods were not randomized and had no reference group. For example, all the subjects first followed the control diet and then switch to the experimental diet or vice versa.[7,8,10,13] Currently, lecithin supplements are among the ten most popular supplements used in North America.[14] Hypocholesterolemic claimed supplements such as lecithin have gained more popularity since NCEP based upon two large randomized clinical trials, HERS[15] and WHI,[16] stopped advising hormone replacement therapy (HRT) as a therapeutic vehicle of decreasing high levels of LDL.C, since 2002.[17]

Menopause as an important CVD risk factor manifests wide range of physiologic changes in women, most important of which is hyperlipidemia. According to recent studies, nearly one third Iranian women of ages 45-64 has total cholesterol levels ≥ 240 mg/dl.[18] Increasing life-expectancy in Iranian women to 73 years[19] means more years of exposure to CVD risk factors.

According to WHO, cardiovascular disease caused 41.3% of deaths in Iran in 2005, and is predicted to reach 44.8% by 2030.[20] CVD wastes more than 18% of Iranian life years.[21]

In this study, the effect of a soy lecithin granules product (97% phospholipids) on serum lipoproteins was assessed using a double-blind randomized clinical trial.

Materials and Methods

The study was approved by the Ethics Committee of the Iran University of Medical Sciences and an informed consent form was signed by each participant. Among postmenopausal women referring to Dr. Shahid Faghihee Hospital of Shiraz University of Medical Sciences during winter 2007, sixty postmenopausal women with mild to moderate hyperlipidemia were selected and entered the study. The study was done under free living conditions. The inclusion criteria were: more than one year of the last menses, 50-60 years old, BMI = 18.5-29.9, baseline serum total cholesterol (TC) levels = 200-300 mg/dl, baseline serum triglyceride (TG) levels 150 - <400 mg/dl, baseline serum (LDL.C) levels 130-189 mg/dl. Exclusion criteria were familial combined hypercholesterolaemia (FCHL), serum TG level ≥ 400 mg/dl, body mass index (BMI) > 29 and <18.5, taking lipid changing drugs, smoking, any specific disease such as diabetes, hypo- or hyperthyroidism supplement or any special drug or supplement intake since last 2 months or during the study and any special change in the routine physical activity or dietary habits since last 2 months or during the study.

Study design

At the time of entering the Women Clinic, the general data questionnaire was completed by all subjects. Subjects were randomly assigned to three groups (20 in each). Then, each group was randomly assigned to one of three treatments, namely: (yogurt), (yogurt with 16g soy lecithin granules,[22] or (yogurt with 10g (Aftab)-sunflower oil, containing equal amount of linoleic acid and energy as the administered lecithin.[23] Low fat yogurt (Ramak, Tehran, Iran) (1.5% fat) was chosen as the `vehicle' for administering the lecithin and sunflower oil. Sugar-free (Hersheys') strawberry syrup[24] was added to en-

sure blindness. The subjects were asked to eat the administered compounds with their daily food. They were also asked to maintain their usual diet and physical activity during the treatment. To assess the effects of confounding factors, BMI and waist circumference were measured. Intake of some dietary factors (energy, macronutrients, saturated fatty acids, monounsaturated fatty acids, polyunsaturated fatty acids, cholesterol, calcium and fiber) were assessed using 24 hr-food recall and 3-day food record questionnaires. Changes in physical activity level was assessed using a valid seven day-physical activity recall questionnaire.[25,26] Serum lipid parameters (TC, Non-HDL.C, LDL.C, HDL.C, and TG) were measured twice at baseline and 4 weeks of treatment.

Blood samples and experimental methods

The subjects were required to fast overnight (12-14 h). Venous blood samples were collected using a 21-gauge scalp vein infusion set. All samples were drawn with minimal stasis and between 07:00 and 9:00 to avoid effects of diurnal variation. Samples were centrifuged at 3000 g. All serum samples were analyzed by autoanalyzer (Prestige 24-I, Japan) at the end of the study.

Total cholesterol (TC) and triglyceride (TG) concentrations were determined enzymatically with endpoint method.[27,28] High density lipoprotein cholesterol (HDL.C) were determined enzymatically with the direct method.[29] Low density lipoprotein cholesterol (LDL.C) was calculated with the Friede Wald formula.[30] Non-HDL.C was calculated by "Non-HDL.C = Total Cholesterol – HDL Cholesterol" formula.

Statistical analysis

Normal distribution of data was examined with Kolmogorov-Smirnov test. Significant differences within groups were determined with the Paired-sample t-test and between groups with the One–Way ANOVA. The computer software package SPSS (version 14) was used for these analyses. P-value of less than or equal to 0.05 was regarded as being statistically significant.

Results

While there were no significant difference between treatment groups, in the intervention group (lecithin), significant within group decrease was found in the average level of TC (252.33 ± 24.02 vs. 255.22 ± 24.82 mg/dl and P = 0.02), LDL.C/HDL.C (3.99 ± 0.50 vs. 4.17 ± 0.56 mg/dl and P = 0.001) and Non.HDL.C (211.94 ± 23.94 vs. 216.00 ± 23.73 mg/dl and P = 0.005) and accompanying significant increase in serum HDL.C level (40.39 ± 5.21 vs. 39.22 ± 5.58 mg/dl and P = 0.04). Likewise, in the control group I (sunflower oil), no significant within group change was found in serum lipid profile. Decreasing LDL.C/HDL.C level (4.18 ± 0.40 vs. 4.24 ± 0.43 mg/dl and P = 0.03) was the only significant change in serum lipid profile in control group II (yoghurt). Lipid profile results are shown in (Table 1).

All of the assessed confounding factors (Mean ± SD) shown in table 2, were statistically indifferent at baseline. We did not found any significant within or between groups difference for the confounding factors. All of the lipid parameters (Mean ± SD), shown in table 1, were statistically indifferent at baseline.

Discussion

Since there was no significant difference between groups in the assessed confounding factors, we can not assume them having any dependent effect on the serum lipid profile. There was no significant difference between lipid profiles of the treatment groups.

Results from clinical trials of lecithin have reported lowering effects on total cholesterol and LDL[2-6] while other studies showed no significant effects.[7-10,13] Also, some studies reported the decreasing effect of lecithin on TG-levels,[4,6,9] while other studies found no effect.[4,7,8,10] Some studies reported no effect of lecithin on HDL levels,[8,12,13] while Childs et al[7] reported an increasing effect on HDL, independent of its polyunsaturated fatty acid moiety. As discussed in the introduction, most of these studies were poorly designed and are not comparable to the present study because of the different study designs, different amounts of lecithin used, ranging from 0.7-54 g/d,[11] and different concentrations of phospholipids in lecithin products, ranging from 29%[7] to 96% in the present study. It has been demonstrated in humans that intake of

Table 1: Lipid parameters (Mean ± SD), at the baseline and end and their change.

		Yogurt	Yogurt with Lecithin	Yogurt with sunflower oil
T.C	B	259.16 ± 22.12	255.22 ± 24.82	265.0 ± 25.57
	E	258.42 ± 21.48	252.33 ± 24.02	263.07 ± 26.29
	Dif	0.73 ± 5.86	2.88 ± 4.76*	1.93 ± 5.96
LDL.C	B	159.42 ± 11.17	161.56 ± 16.32	158.0 ± 12.08
	E	158.89 ± 11.49	160.50 ± 16.80	157.20 ± 10.26
	Dif	2.14 ± 0.52	1.05 ± 4.5	0.80 ± 4.32
HDL.C	B	37.79 ± 3.15	39.22 ± 5.58	38.33 ± 3.2
	E	38.26 ± 3.46	40.39 ± 5.21	39.0 ± 4.17
	Dif	0.47 ± 1.83	1.16 ± 2.25*	0.66 ± 2.28
T.G	B	270.16 ± 36.93	269.06 ± 46.15	235.57 ± 59.31
	E	269.53 ± 35.32	265.22 ± 42.21	235.53 ± 59.31
	Dif	0.63 ± 16.59	3.83 ± 13.50	0.80 ± 4.32
Non-HDL.C	B	221.36 ± 21.52	216.0 ± 23.73	226.66 ± 26.41
	E	220.15 ± 20.33	211.94 ± 23.94	224.06 ± 27.91
	Dif	1.21 ± 6.47	4.05 ± 5.39*	2.60 ± 6.93
LDL.C/HDL.C	B	4.24 ± 0.43	4.17 ± 0.56	4.15 ± 0.48
	E	4.18 ± 0.40	3.99 ± 0.50	4.06 ± 0.40
	Dif	0.05 ± 0.11*	0.17 ± 0.19*	0.08 ± 0.20

B: Baseline, E: End, Dif: Difference, *: Significant within group, **: Significant between groups

Table 2: Confounding factors' (Mean ± SD), at the baseline and end of the study.

		Yogurt	Yogurt with Lecithin	Yogurt with sunflower oil
Age (y)	B	54.6 ± 1.87	55.0 ± 1.69	55.31 ± 1.75
Waist Circumference (cm)	B	91.52 ± 6.44	90.94 ± 5.97	90.40 ± 5.50
BMI (kg/m^2)	B	26.88 ± 1.10	26.97 ± 1.2	26.93 ± 0.89
	E	26.96 ± 1.08	27.07 ± 1.4	27.02 ± 1.09
Physical activity (kcal/kg/d)	B	32.15 ± 1.08	32.11 ± 1.15	31.96 ± 1.10
	E	32.10 ± 0.99	32.05 ± 0.96	31.97 ± 1.06
Energy (Kcal)	B	1674.8 ± 151.8	1659.6 ± 57.9	1664.9 ± 66.4
	E	1664.1 ± 205	1671.3 ± 197.0	1652.6 ± 84.3
CHO (g)	B	255.3 ± 89.8	244.3 ± 97.1	245 ± 92.9
	E	251.4 ± 97.3	244.9 ± 109.6	242.2 ± 98
Protein (g)	B	53.6 ± 6.1	54.1 ± 13.9	54.2 ± 11.7
	E	52.8 ± 9.0	56.8 ± 17.3	56.1 ± 14
Fat (g)	B	47.3 ± 18.4	49.8 ± 16.9	50.0 ± 14.5
	E	49.1 ± 13.5	47.7 ± 19.1	49.6 ± 17.3
SFA (g)	B	21 ± 6.8	20.55 ± 8.6	20.64 ± 7.6
	E	19.5 ± 7.4	19.1 ± 6.7	19.94 ± 6.6
PUFA (g)	B	17.9 ± 8.8	19.7 ± 8.3	21.46 ± 7.4
	E	17.5 ± 6.3	17.5 ± 6.8	18.2 ± 8.1
MUFA (g)	B	9.2 ± 3.8	9.9 ± 2.3	9.9 ± 6.8
	E	9.6 ± 7.7	9.7 ± 8.1	10.1 ± 7.3
Cholesterol (mg)	B	249.5 ± 22.4	257.8 ± 17.9	257.5 ± 22.5
	E	242.4 ± 26.5	267.4 ± 58.8	262.3 ± 31.0
Fiber (g)	B	16.9 ± 5.9	15.8 ± 7.2	16.8 ± 6.1
	E	15.5 ± 3.7	14.7 ± 3.5	14.1 ± 2.6
Calcium (mg)	B	727.6 ± 88.5	720.7 ± 94.7	712.4 ± 79.8
	E	730.2 ± 65.8	706 ± 73.8	770 ± 84.3

lecithin[13] and infusion of lecithin intraduodenally[31] decreases the absorption of cholesterol in the small intestine. Kesaniemi & Grundy[13] suggested that if lecithin is given in multiple doses throughout the day, the inhibition of cholesterol absorption might be higher and that the amount of dietary cholesterol may also have an effect on the results. This may, in part, explain why lecithin did not lower TC levels in Oosthuizen et al study, because those subjects followed a low cholesterol diet.[32] Other studies in which subjects followed a low cholesterol baseline diet could also not demonstrate TC lowering with lecithin.[8,13]

Conclusion

Soy lecithin treatment had no significant hypocholesterolemic effect on serum lipid profile, in a way that we can not claim any independent effect for lecithin's linoleic acid content.

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