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Impact of green tea extract on serum lipid of postmenopausal women: A randomized controlled trial

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ABSTRACT

Background: This study aimed to evaluate the impact of green tea extract on serum lipid level in postmenopausal women.

Method: In this randomized controlled trial 100 postmenopausal women with an abnormality in at least one lipid profile were recruited and randomly assigned to one of the two groups: green tea extract (n = 50) and control group (n = 50). The intervention group received two capsules (400 mg) of green tea extract two times daily; the control group received a placebo for 4 weeks. The serum level of the lipid profile (total cholesterol, low density lipoprotein (LDL), high density lipoprotein (HDL), triglyceride, and fasting blood sugar) was measured at baseline and 4 weeks after intervention.

Results: In total, 79 women completed the study. The mean total cholesterol in the green tea group was significantly decreased after 4 weeks of intervention (mean difference –18.1 vs. –5 mg/dL in the green tea and placebo groups, p < 0.04). The triglyceride and LDL also decreased significantly in the green tea group compared to the control group (p = 0.002 and p = 0.04 respectively). The level of HDL and fasting blood sugar did not change within the group and between groups.

Conclusion: Green tea extract is cost-effective way to decrease lipid profile in postmenopausal women without major side effects. Using this herb is recommended in women who have slight lipid profile abnormalities.

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1. Introduction

Menopause is the cessation of menstruation for at least 12 months.¹ The mean age of menopause among white women is 50–52 years.² The mean age of menopause among Iranian women is estimated to be 47.6 ± 4.45 years.³ Postmenopausal women are at risk of cardiovascular disease because of a lack of estrogen.⁴ There is also an increase in lipid profile among postmenopausal women. A study on 2,659 women between 42 and 52 years of age who were followed for 7 years, showed that lipid profile, including total cholesterol, low density lipoprotein (LDL), and triglyceride, increase most in the peri- and early postmenopausal women.⁵ Another

study on 60 women between the ages of 25 and 35 years and 60 postmenopausal women (aged 45–55 years) showed that lipid profile, including total cholesterol, triglyceride, and LDL, were significantly higher in postmenopausal women without any relation to body mass index.⁶ The results of a case control study on 118 women (59 premenopausal and 59 postmenopausal women) showed that postmenopausal women had a significantly higher level of total cholesterol and LDL and reduction of high density lipoprotein (HDL).⁷

Studies showed that using oral estrogen could reduce the level of LDL and could also increase the level of HDL in postmenopausal women with normal or elevated lipid levels.^{8,9} Hormone replacement therapy is not a first line therapy for postmenopausal women; instead, according to the US National Cholesterol Education Program adult treatment Panel III guideline, diet and lifestyle changes are the first line treatment for high lipid profile in postmenopausal women.¹⁰

Some studies demonstrated the beneficial effects of plants in

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reducing blood lipids in postmenopausal women. A meta-analysis of 38 randomized controlled trials showed the lipid lowering effect of soy.¹¹

Green tea is made from *Camellia Siensis* leaves that have not undergone the oxidation process to be changed to black tea.¹² Studies have shown some beneficial effects of green tea on blood pressure and lipid profile. Ahmad et al. conducted a study on three groups of rats (two intervention groups and one control group) to determine the effects of catechins and epigallocatechin gallate (EGCG) on lipid profiles. Results showed that the level of cholesterol and LDL was significantly reduced in the rats administered green tea extract.¹³ Another study assessed the effect of green tea catechin extract (GTE) on lipid profile in 886 postmenopausal women. Women in the GTE group consumed 1200 of GTE and women in the control group received a placebo. Results showed that, after 12 months follow-up, the amount of total cholesterol, LDL, and non-HDL cholesterol were significantly reduced in the GTE group compared with the control group.¹⁴

Iranian postmenopausal women are concerned about the side effects of hormone replacement therapy, and are interested in using herbal medicines. Further, we do not have enough information on the effect of green tea on lipid profiles of postmenopausal women in Iran. Therefore, this study was designed to evaluate the effect of green tea extract on lipid profile in postmenopausal women.

2. Material and method

In this randomized controlled trial, 100 women were randomly recruited. The protocol of this study was approved by the Ethics Committee of Ahvaz Jundishapur University of Medical Sciences (Ref No: 1392; 216 ajumsREC). The protocol was also registered in the Iranian registry for randomized controlled trials (Ref No: IRCT 2014021816625N1). This study started in October 2013 and was completed in March 2014. The inclusion criteria were as follows: women in whom at least one year had passed from their last menstruation, and with abnormality in at least one serum lipid profile, aged 45–60 years. The exclusion criteria were as follows: any medical disorders, such as thyroid dysfunction, diabetes, hypertension, renal disease and cancer, a history of gall bladder or liver disorders, stroke, abnormal menopause, or regular consumption of green tea.

2.1. Participants

We used following formula for sample size, when $S_1 = 1$, $S_2 = 0.9$, $X_1 = 3.7$, $X_2 = 3.1$, $Z_{1-\alpha/2} = 1.96$, $Z_{1-\beta} = 0.84$. The power of study set at 90%. We added 25% to this number in each group for withdrawal and the final number of participants was calculated as 50 in each group.

$$n = \frac{(Z_{1-\alpha/2} + Z_{1-\beta})^2 (S_1 + S_2)}{(X_1 - X_2)^2} = 40$$

2.2. Randomization

All supplements (green tea or placebo) were packed and labeled by a research assistant that was blind to the aim of this study. Eligible women were assigned to one of the groups using random table generated by Excel program by ratio of 1:1.

2.3. Measures

A socio-demographic questionnaire and a checklist were used to

collect data. Postmenopausal women who attended the number 1 eastern health clinic in Ahvaz, Iran, were screened regarding inclusion criteria. Five mL venous blood was drawn from all eligible women. Blood samples were centrifuged to separate plasma in 1 h and frozen at the appropriate temperature until being assessed in one reference laboratory. Women with at least one borderline lipid profile were recruited for this study.¹⁵ The blood cholesterol, triglyceride, LDL, HDL, and blood sugar of all eligible women were measured in one reference laboratory. According to the results of the laboratory tests, of 194 eligible women, 83 women had normal lipid and glucose levels. Eight women were excluded from the study because of high blood lipid levels, and three women because of high blood sugar levels. All laboratory tests were repeated after the 4-week intervention. Blood lipids were measured using Auto-analyzer BT-3000 (Italian made). These measures were done using calorimetric by Pars Azmoon kit (Iranian Made). Weight and height of participants measured using SECA scale and stadiometer. Body mass index calculated using the formula (kg/m^2).

2.4. Preparation of green tea and placebo capsules

Capsules containing green tea extract or placebo were prepared by the Medical Plant and Natural Products Research Center at the Ahvaz Jundishapur University of Medical Sciences. Each green tea capsule contained 400 mg green tea extract (including 40–47 mg polyphenol). Iranian green tea leaves were used to provide green tea extract. Green tea leaves were dried in the factory by dry heat without any oxidation. Green tea extract was drawn by maceration, after green tea leaves had been soaked for 48 h in a suitable solvent. Then, the material was filtered using Büchner Vacuum Filtration Funnels and concentrated by rotary. Green tea extract were packed in capsules after appropriate formulation. Placebo capsules contained starch and had a similar appearance to green tea capsules.

2.5. Intervention

Women with one lipid profile abnormality were recruited for this study. Green tea (Gt) capsules (400 mg) and placebo were packed by a researcher blind to the aim of this study and was assigned the code "A" or "B." One of the researchers (SM) was responsible for the distribution of green tea or placebo. Participants were asked to take their green tea capsules or placebo two times daily after breakfast and dinner for 4 weeks. Every participant received a phone call weekly regarding correct consumption of green tea or placebo.

2.6. Outcome measures

Lipid profile, including blood total cholesterol, LDL, triglyceride, HDL, and fasting blood sugar was measured at baseline and 4 weeks post-intervention.

2.7. Statistics

All data were entered into SPSS version 19. Continuous data were screened for normality. An independent *t*-test was used to detect differences between the two groups for continuous data (age, age of menopause, BMI, systolic and diastolic blood pressure) and a chi-square test was used for categorical data (education, job and economic situation). A paired *t*-test was used to measure differences before and after intervention. The Univariate Analysis of Variance was used to compare lipid profile before and after intervention in two groups. $p < 0.05$ was considered significant.

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