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The Effect of L-Carnitine Supplementation on Weight and Body Composition in Women with Polycystic Ovary Syndrome: A Double-Blind Randomized Clinical Trial

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ABSTRACT

Background: Polycystic ovarian syndrome (PCOS), one of the most common causes of endocrine disorders with irregular menstruation, is accompanied by an increase in androgen and polycystic ovarian. The aim of this study was to evaluate the effect of weight loss regimen with and without supplementation. L-carnitine affects lipid profile, insulin, and hormone resistance indices. **Methods:** This double-blind randomized clinical trial was conducted over women within the age range of 18 to 45 years, who referred to Yazd Diabetes Center in 2019. The participants were divided into the experimental and control groups. The intervention group received 1000 mg L-carnitine (LG = 28) and the placebo group (PG = 28) received the placebo daily. All people followed a low celery diet for 12 weeks. Anthropometric indices and body composition (weight, body mass index, waist circumference, hip circumference, fat mass, and free fat mass) were measured prior to and after the intervention. Data analysis was performed using SPSS software version 22. The independent sample t-test was used to compare the mean changes between the LG and PG. **Results:** At the end of the study period, patients treated with L-carnitine showed a significant decrease in waist circumference compared to the PG (change: -1 ± 3.15, P = 0.001) and no significant difference was observed between the two groups in terms of other anthropometrics indices and body composition including fat mass, body mass index, and hip circumference (P > 0.05). **Conclusion:** The present study showed that 1000 mg oral L-carnitine had no significant effect on body weight, body mass index, body composition, and hip circumference, but had a significant effect on waist circumference size.

Keywords: *Polycystic ovarian syndrome; L-carnitine; Androgenic index; Sex hormone-binding globulin*

Introduction

Polycystic ovary syndrome (PCOS) was first reported in modern medical literature describing seven women with amenorrhea, hirsutism, and ovaries enlarged with multiple cysts

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(Azziz, 2004). Disorders affecting women with PCOS are characterized by high levels of androgens, dysfunction of the ovaries and polycystic ovaries. The clinical manifestations of PCOS are very different. Women with PCOS often seek care for menstrual disorders, hyperandrogenism, and infertility (Sirmans and Pate, 2014).

The prevalence of PCOS varies according to different criteria. According to NIH/NICHD data, its prevalence in Australia and Iran was 8.7% and 7-7.1%, respectively. The disability-adjusted life year (DALY) index of PCOS is ranked 22nd in Iran in 2010 (Forouzanfar *et al.*, 2014). The prevalence of PCOS is high in people with insulin resistance and metabolic syndrome (Panidis *et al.*, 2008). Polycystic ovary syndrome has important clinical complications including psychological problems (decreased quality of life, decreased self-esteem, depression, and anxiety), fertility manifestations (prematurity, infertility, and pregnancy complications), and metabolic consequences (insulin resistance, metabolic syndrome, and diabetes mellitus) (Teede *et al.*, 2010). They are also at risk for endometrial carcinoma, hypertension, and dyslipidemia (Knochenhauer *et al.*, 1998). Genetics play an important role in the pathogenesis of this disease. People with a history of weight gain develop clinical symptoms of PCOS (Sirmans and Pate, 2014).

Treatment modalities include lifestyle adjustment, obesity treatment, drug therapy (Legro, 2012), and symptoms related to androgens, menstruation, and infertility that include oral contraceptive pill (OCP) medications, Spironolactone, Metformin, Thiazolinedione Clomiphene citrate etc. (Sirmans and Pate, 2014). Studies were conducted over the effect of zinc (Foroozanfard *et al.*, 2015), calcium, vitamin D (Pal *et al.*, 2012), selenium (Razavi *et al.*, 2016), omega 3 (Sadeghi *et al.*, 2017), myoinositol (Emekçi Özay *et al.*, 2017), folate (Bahmani *et al.*, 2014), and chromium (Jamilian *et al.*, 2016) on PCOS. Given that obesity is one of the effective factors on PCOS, weight loss is considered as an infertility treatment in women with overweight/obesity (Jiskoot *et al.*, 2017). Obesity is associated with insulin resistance (Rafraf *et al.*, 2012), which increases insulin, decreases steroid hormone binding globulin (SHBG), increases circulating free testosterone, and results in ovarian follicle development (Teede *et al.*, 2010). Carnitine is a trimethylamine, produced in the liver by lysine and methionine, and plays an important role in the metabolism of cellular energy. Its mechanism of action involves increasing glucose oxidation as well as improving insulin sensitivity under insulin-dependent conditions. Hyperinsulinemia increases carnitine accumulation in muscle and decreases serum carnitine (Fenkci *et al.*, 2008). Carnitine is found in two forms of L-Carnitine, which is the active form, and D carnitine, which is the biologically inactive form (Ismail *et al.*, 2014).

Studies investigated the effects of L-Carnitine on diseases such as severe ischemia, knee osteoarthritis, coronary artery disease, hypothyroidism, diabetes, and hyperlipidemia (Kumar *et al.*, 2015). However, limited data are available regarding its effect on ovarian syndrome. For example, two studies reported that low serum carnitine levels were associated with an increased incidence of this syndrome. Furthermore, two studies found that high-dose carnitine treatment in PCOS improved fertility, congestion, lipid profile, weight loss, waist circumference and hip circumference (Ismail *et al.*, 2014, Samimi *et al.*, 2016).

Given the high prevalence of PCOS, the limited number of studies over the effect of L-Carnitine on PCOS, and the fact that no study has ever evaluated the combined effect of weight loss diet and L-Carnitine supplementation, the present study was conducted. The aim of this study was to investigate the effect of weight loss regimen with and without L-Carnitine supplementation on anthropometric indices and body composition.

Materials and Methods

Design and Population: In this double-blind study, the sample size was calculated as 31 using the significance level of 0.05, the test power of 80%, and according to the average insulin level of 26.03 (Samimi *et al.*, 2016). The L-Carnitine and placebo supplements were codified as A or B by an individual who was unaware of the study process

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and goals. Later, random allocation tables were applied using computer software and participants were allocated into the intervention or control groups.

Intervention group (CG) members were supposed to take 1000 mg L-Carnitine capsules daily and the placebo group (PG) consumed the exactly similar placebo supplements in lunch meal for 12 weeks. Every two weeks the participants were supposed to refer to the researcher, bring the empty capsule bottles, and receive the next bottle. A trained researcher also checked the participants' adherence to the diet.

Administration dose and Follow-up: The L-Carnitine capsules and placebo were obtained from Karen Corporation in Yazd city. The weight loss diet was designed by calculating the basal daily energy for each person using the Harris Benedict formula (Movahedi, 1999). To this end, the total energy consumed, the activity coefficient, and the thermic effect food were considered for each individual. In order to decrease the participants' weight, 500 kcal was reduced from the final calculated energy required for each participant.

Measurements: The patients' weights were also measured on a portable digital scale (Omeron BF511, Japan) to the nearest 0.1 kg. Waist circumference (midpoint between the upper edge of the iliac and the last rib) and hip circumference (the widest part of the hip) were measured using a plastic meter prior to and after the intervention. Body mass index (BMI) was also calculated after dividing weight (kg) by squared height (m). Furthermore, height was measured in standing position using an audiometer fixed on a straight wall to the nearest 0.1 cm. Participants were also required to complete the consent forms, demographic questionnaire containing information, items about education, age, gender, etc., items about disease and medication history, and the 24-hour food recall questionnaire.

Ethical Considerations: The patients freely volunteered to participate in this study and could withdraw from the study as they wished. Written informed consent forms were obtained from all participants. In addition, the study proposal was approved by Ethics-in-Research Commission in Shahid Sadoughi University of Medical Sciences (IR.SSU.SPH.REC.1397.014). Moreover, this study was registered in Iranian randomized clinical trial (www.irct.ir). With the code of IRCT20191016045131N1.

Data analysis: SPSS software version 22 was used for data analysis. Paired sample t-test was used to assess within-group changes. Independent sample student *t-test* was also run to compare the mean changes between the intervention and control groups. Non-parametric equivalent tests were applied for abnormal data. Meanwhile, the significance level of all tests was set at 0.05.

Results

This study was conducted on 62 patients with PCOS, who referred to Yazd Diabetes Center. As shows the **figure 1**, a total of 58 participants completed the study; three patients were excluded from the study due to pregnancy (in the PG) and three others did not want to continue the study (CG = 28, PG = 28).

The individual characteristics of patients at the beginning of the study are shown in **Table 1**. No significant difference was found between the study groups in terms of the anthropometric characteristics and age at the baseline ($P > 0.05$). The mean age of participants was 30.79 ± 6.57 years and their mean of BMI was 30.6 ± 5.85. **Table 2** includes the anthropometric changes before and 12 weeks after the intervention in both groups. Weight loss, BMI, as well as waist and hip circumference were significantly different before and after the intervention for the CG. However, only waist circumference was significantly different between the two groups ($P = 0.001$) and other anthropometric indices were not significant ($P > 0.05$).

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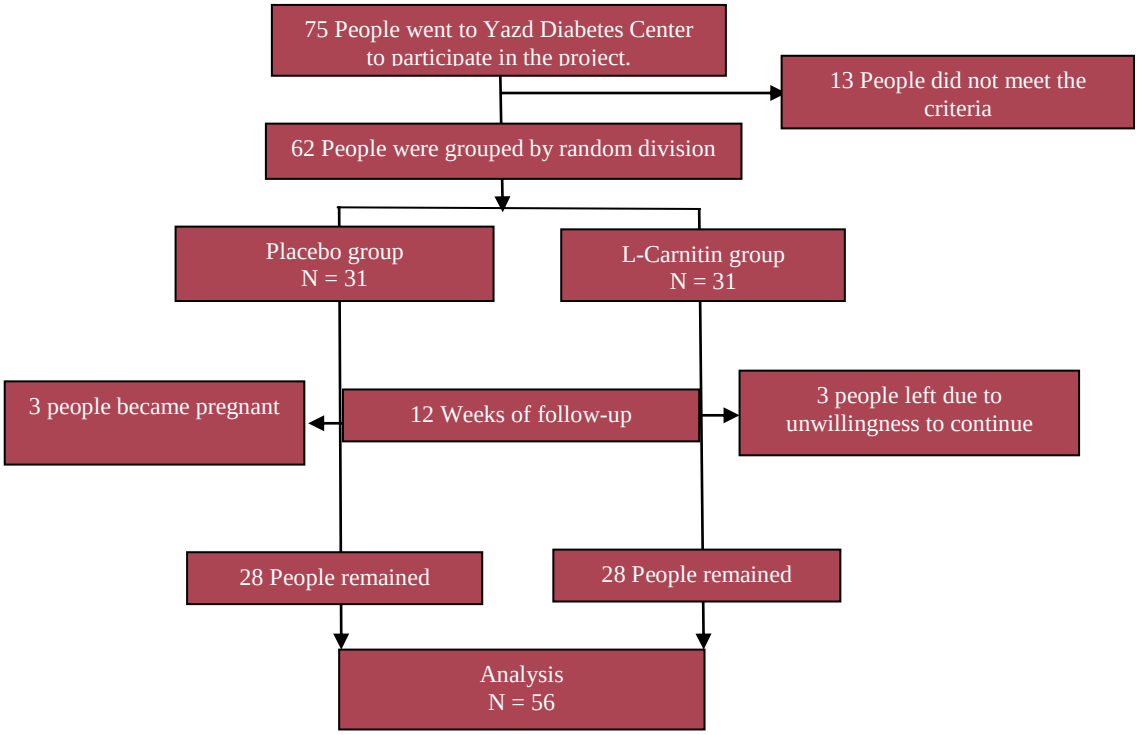


Figure 1. Flowchart of intervention

Table 1. Selected baseline characteristics of study participants

Variables	Total (n = 56)	L-carnitine group (n = 28)	Placebo group (n = 28)	P-value[a]
Age (y)	30.79 ± 6.57	30.74 ± 6.71	30.83 ± 6.53	0.95
Body mass index (kg/m^2)	30.60 ± 5.85	31.01 ± 4.62	30.8 ± 6.40	0.79
Height (cm)	162.60 ± 5.50	162.00 ± 49.17	163.5 ± 3.00	0.33
Weight (kg)	81.85 ± 1.24	81.42 ± 1.30	82.27 ± 1.20	0.77
Waist (cm)	99.08 ± 10.20	99.00 ± 11.00	99.00± 10.00	0.72
Hip (cm)	114.36 ± 10.31	113.37 ± 11.20	115.35 ± 94.35	0.45
Free fat mass (%)	26.74 ± 4.49	26.63 ± 5.52	26.84 ± 3.72	0.85
Fat mass (%)	40.88 ± 6.92	41.01 ± 7.37	40.71 ± 6.57	0.85

[a]: Student *t-test*

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Table.2: Anthropometric variable changes in patients treated with placebo and L-carnitine before and after 12 weeks of intervention

Variables	Before	After	P-value[a]	Changes
Body mass index (kg/m^2)				
L-carnitine group	81.42 ± 1.30	79.59 ± 1.20	0.04	-1.83 ± 4.6
Placebo group	82.27 ± 1.20	81.94 ± 1.26	0.39	-0.20 ± 1.2
P-value[b]	0.66	0.77		0.11
Weight (kg)				
L-carnitine group	31.01 ± 4.62	30.24 ± 4.46	0.04	-0.77 ± 2.01
Placebo group	30. 80 ± 6.40	32.27 ± 1.20	0.68	-0.08 ± 0.56
P-value	0.45	0.79		0.10
Waist circumference (cm)				
L-carnitine group	99.98 ± 11.63	96.99 ± 8.93	0.002	-1.0 ± 3.15
Placebo group	99.00 ± 10.00	99.00 ± 11.00	0.66	0.001 ± 0.0
P-value	0.56	0.72		0.11
Hip circumference (cm)				
L-carnitine group	113.37 ± 11.20	112.10 ± 10.54	0.01	-1.0 ± 2.0
Placebo group	115.35 ± 94.35	115.03 ± 95.75	0.11	0.001 ± 1.0
P-value	0.25	0.45		0.12
Free fat mass (%)				
L-carnitine group	26.63 ± 5.20	26.82± 5.93	0.89	-1.0 ± 5.5
Placebo group	26.84 ± 3.72	27.07 ± 4.01	0.58	0.7 ± 0.8
P-value	0.84	0.85		0.46
Fat mass (%)				
L-carnitine group	41.04 ± 7.37	40.45 ± 8.68	0.81	-0.39 ± 9.2
Placebo group	40.71 ± 6.57	40.81 ± 6.85	0.84	0.10 ± 1.2
P-value	0.93	0.85		0.92

[a]: Pared *t-test*; [b]: Student *t-test*

Discussion

The effect of L-Carnitine on anthropometric indices showed that supplementation with 1000 mg L-Carnitine for three months did not lead to a significant weight loss in the two studied groups. A significant decrease was observed in the waist circumference between the two groups. The results of studies in this area are contradictory. For example, L-Carnitine administration (15 mg/kg/day) did not affect weight loss among bipolar patients treated with valproate for 26 weeks on a low-fat diet (Elmslie *et al.*, 2006). Furthermore, oral L-Carnitine supplementation had no effect on weight loss in patients with impaired glucose metabolism (Molfino *et al.*, 2010) and in obese women (Villani *et al.*, 2000). A study over people with PCOS showed no significant decrease in weight, BMI, and waist circumference after taking 250 mg L-Carnitine supplementation daily for 12 weeks (Samimi *et al.*, 2016). A study conducted in 2013 evaluated the effect of L-Carnitine supplementation for eight weeks with a daily dose of 2 g in obese women with type 2 diabetes who underwent low calorie diet. After intervention, a significant decrease was found in anthropometric indices of the intervention group, however, this decrease was not significant compared to the control group (Barzegar *et al.*, 2013).

The results of our study are in contradiction with the results of a study in which 250 mg L-Carnitine was administered for a 12-week intervention period. This study showed a significant decrease in BMI and weight of the intervention group compared with the control group (Jamilian *et al.*, 2017).

In animal studies, L-Carnitine supplementation resulted in significant weight loss in the intervention group (Center *et al.*, 2000). In another study, clomiphene citrate-resistant PCOS women

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were required to intake 1 mg/day L-Carnitine for 5 weeks. The findings showed a significant reduction in BMI of the intervention group (Ismail *et al.*, 2014). A meta-analysis over 7 randomized controlled trials found a significant reduction in weight and BMI of patients who used 1.8 to 4 g of L-Carnitine daily (Pooyandjoo *et al.*, 2016). A recent meta-analysis conducted in 2019 showed that different doses of L-Carnitine (less than 2 g daily) reduced body weight and BMI, but had no effect on body fat percentage. This meta-analysis showed that a dose of less than 2 g did not affect body fat mass (Center *et al.*, 2012).

Empirical evidences also show that L-Carnitine stimulates pyruvate dehydrogenase complex activity by reducing acetyl-CoA to CoA after trapping acetyl groups. Simultaneous depletion of CoA acetyltransferase in the cytosol is further involved in activation of the glycolytic pathway. So, L-Carnitine plays a key role in the metabolism of glucose and assists in fuel-sensing (Barzegar *et al.*, 2013).

L-Carnitine intake may decrease body weight, BMI, waist circumference, and hip circumference by increasing beta-oxidation of fatty acids (Askarpour *et al.*, 2020) and increasing basal metabolic rate (Seim *et al.*, 2002).

In our study, the observed weight loss and BMI decrease in the L-Carnitine group confirms the results of previous studies. However, these changes were not significant compared to the control group, which could be explained by administration of the low calorie diet in both study groups.

Strength of this study includes investigation of PCOS patients in terms of their compliance with a low calorie diet by taking into account the effect of L-Carnitine supplementation. Weaknesses of the study are administration of a low dose of L-Carnitine and short duration of the intervention. Furthermore, we could not measure the participants' hormone levels, lipid profile, and glycemia.

Conclusion

Based on the findings, the weight loss and BMI reduction were only observed in the L-Carnitine group. However, these changes were not significant compared to the control group, which can be justified by administration of a low calorie diet in both groups.

Conflict of interest

The authors declare that they have no competing interests.

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Authors' contributions

Hosseinzadeh M designed the study concept and revised the manuscript. Pakravanfar F collected the data and prepared the manuscript. Fallahzadeh H performed the statistical analyses. Nadjarzadeh A was also involved in designing the study and revising the manuscript. Ghadiri A was also involved in designing the study and revising the manuscript.

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