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The effects of L-carnitine supplement on anemia in hemodialysis patients: A randomized clinical trial study

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Original Article

Abstract

BACKGROUND: There is no general consensus about the effect of L-carnitine (LC) on anemic factors in hemodialysis patients. In this clinical trial, the effect of LC on anemia was investigated in these patients.

METHODS: In a double-blinded clinical trial, hemodialysis patients admitted to the dialysis department of Tohid Hospital in Sanandaj, Iran, in 2017, were randomly divided into two groups of intervention (n = 40) and placebo (n = 40). Individuals in the intervention group received a dose of 1 g/day of LC, and the other group received placebo tablets of the same form for 12 weeks. Anemia factors were evaluated in both groups before and after the intervention. The data were analyzed using t-test and analysis of covariance (ANCOVA).

RESULTS: The LC supplementation increased hemoglobin (Hb) in hemodialysis patients (P = 0.043). Moreover, the mean corpuscular volume (MCV) level was decreased under the effect of LC (P < 0.001). The mean ± standard deviation (SD) scores of ferritin serum level before and after the intervention were 528.43 ± 466.96 and 737.70 ± 468.38 µg/l, respectively. This indicates a significant difference from that of the placebo group (P < 0.001). The results showed that LC supplementation did not affect red cell distribution width (RDW), platelet count (PLT), mean platelet volume (MPV), iron (Fe), and total iron-binding capacity (TIBC) levels (P > 0.050).

CONCLUSION: The effect of LC supplement on Hb, serum ferritin, and MCV levels in hemodialysis patients was significant. Therefore, LC can be used to treat anemia in this group of patients.

KEYWORDS: L-carnitine; Hemodialysis; Anemia; Randomized Clinical Trial Study; Iran

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Introduction

Chronic renal failure is one of the most debilitating diseases associated with systemic complications. One of the most important complications of chronic renal failure is anemia that occurs in the last stages of the disease.[1] The main cause of anemia in the patients is the decreased capacity of the kidneys to secrete erythropoietin. The prevalence of anemia and iron (Fe) deficiency in patients with chronic renal failure is 66.3% and 52.3%, respectively. In addition, ferritin is less than 200 mg/dl in 38.4% of these patients and more than 200 mg/dl in 61.6% of them.[2] Despite adequate protein intake in hemodialysis patients, patients

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with long-term dialysis suffer from malnourishment. Among the potential causes of malnutrition in these patients is inadequate intake of energy and micronutrients.[3]

Nikolaos et al. showed that 3 months of treatment with L-carnitine (LC) (30 m/kg for dialysis session) significantly reduced the deformability of red blood cells (RBCs) ($P < 0.004$) and significantly increased hematocrit (Ht) ($P < 0.001$).[4] Matsumoto et al. evaluated the effects of 3 months of treatment with LC (500 mg/d, oral) on anemia in a hemodialysis patient resistant to erythropoietin treatment. The results showed an increase in Ht levels ($P = 0.003$) and total ability of Fe-binding ($P = 0.050$) together with a significant reduction of serum ferritin levels ($P = 0.005$).[5]

Hurot et al. performed a systematic review to determine the effects of LC in maintenance hemodialysis patients. From 1978 to 1999, they analyzed data from 481 patients in 21 trials in which LC was used and examined changes in serum triglycerides (TGs), cholesterol fractions, hemoglobin (Hb) levels, erythropoietin dose, and other symptoms (muscle function, exercise capacity, and quality of life). In their conclusion, LC was not recommended to treat the dyslipidemia of maintenance hemodialysis patients, but they suggested that the LC could be used successfully to treat anemia.[6] LC improves the nutritional status of hemodialysis patients.[7] Inflammation and oxidative stress are prevalent in patients with chronic renal failure, including hemodialysis patients. Different studies have shown that 30-50 percent of these patients suffer from inflammation.[8] Carnitine or LC are made from lysine and methionine amino acids. They release energy from fat cells, increase the production of RBCs, stabilize RBC walls in uremic patients, increase the erythroid colony in the bone marrow, and stabilize the RBCs and their membrane phospholipids.[9,10]

Like anemia and inflammation, carnitine deficiency is prevalent in hemodialysis patients due to low dietary intake, impaired de novo carnitine renal synthesis, and loss of free carnitine from the body during hemodialysis. It has been shown that dialysis patients with anemia have less serum carnitine than nonanemic renal patients and need higher doses of erythropoietin.[11,12]

LC is an essential factor for the membrane transport of acyl-coenzyme A (acyl-CoA) compounds, especially for the intramitochondrial transport of long-chain fatty acids.

Despite the overall improvement in anemia parameters thanks to LC supplementation, a number of studies have reported contradictory results. Although most studies have been retrospective, an increased plasma carnitine level has been reported in hemodialysis patients.[13]

Considering the potential role of LC in increasing Hb in hemodialysis patients, the aim of this study is to investigate the effect of LC supplements on anemia in these patients in Kurdistan Province, Iran.

Methods

Initially, 100 hemodialysis patients were admitted to the dialysis department of Tohid Hospital in Sanandaj, Iran, in 2017. The inclusion criteria were hemodialysis patients with renal failure, age over 20, hospitalized for hemodialysis, and patients undergoing hemodialysis for more than one year. Twenty individuals were excluded because of the exclusion criteria. Candidates with infectious and liver diseases, cancer, history of using LC supplement, anti-inflammatory drugs, corticosteroids, drug, alcohol, and cigarettes were excluded.

In this double-blinded clinical trial, 80 individuals were randomly divided into two intervention (n = 40) and placebo (n = 40) groups. During the study, five individuals in the intervention group and four in the placebo group left the study because of death, migration, and discontinuation of medication, as shown in figure 1.

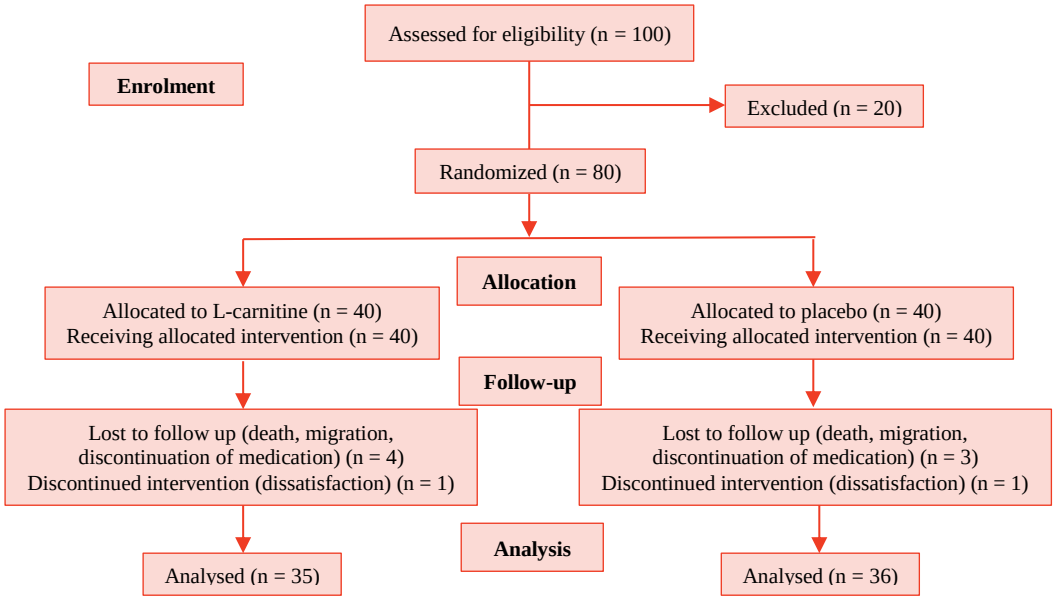

Figure 1. Flowchart of subjects undergoing hemodialysis in the intervention and placebo groups

Sampling was done randomly in the two groups, so that patients meeting the criteria were assigned by the researcher to the intervention and placebo groups in the form of dual blocks. In order to avoid bias, the first block of the experiment group was selected by the experienced personnel who were not familiar with the research objectives by flipping a coin. Then, the next samples were assigned dually by the researcher to the intervention and placebo groups. The patients in the intervention group received one g/day LC, and the placebo group received placebo tablets with the same form made by Karen Company (Tehran, Iran, Registry No. 7454) for 12 weeks. Both groups of patients underwent standard and common treatments for hemodialysis patients, including treatment with erythropoietin, Rocaltrol, calcium, and Nephro-Vite supplement (if indicated).

In this study, patients were examined in terms of age, sex, place of residence, body mass index (BMI), underlying disease, duration of hemodialysis, and history of anemia. Moreover, Hb, serum ferritin, Fe, total iron-binding capacity (TIBC), platelet count (PLT), mean corpuscular volume (MCV), red cell distribution width (RDW), mean platelet volume (MPV), RBC, mean corpuscular hemoglobin concentration (MCHC), hematocrit (HCT), cholesterol, TG, low-density lipoprotein (LDL), high-density lipoprotein (HDL), and albumin (Alb) levels were measured before (Table 1) and after the intervention. In order to evaluate the diet of patients, a three-day food recall questionnaire[14] was filled three times a week to evaluate the dietary factors affecting the LC status, including energy, carbohydrates, protein, and fat intake. The 24-hour food recalls were analyzed using N4 software. The patients were followed up every two weeks through a phone call for supplement consumption and prevention of sample loss. Patients' adherence to the use of supplements was determined by the number of remaining tablets at the end of the 6th and 12th weeks of the study. The patients who did not use more than 10% of the total supplements would be excluded from the study. The patients would be referred to a physician if they observed and reported the side effects of medications.

Table 1. Demographic variables and baseline characteristics of hemodialysis patients in L-carnitine (LC) and placebo groups

Demographics	LC	Placebo	P
Age group (year)			
< 60	14 (40.00)	19 (52.78)	0.280
≥ 60	21 (60.00)	17 (47.22)	
Gender			
Men	20 (57.14)	19 (52.78)	0.712
Women	15 (42.86)	17 (47.22)	
Residence			
City	28 (80.00)	32 (88.89)	0.343
Village	7 (20.00)	4 (11.11)	
Education			
Illiterate	19 (54.29)	17 (47.22)	0.593
Elementary and middle school	9 (25.71)	15 (41.67)	
High school and college	7 (20.00)	4 (11.11)	
Access			
Arteriovenous fistula	18 (51.43)	14 (38.89)	0.288
Permcath	17 (48.57)	22 (61.11)	
Disease			
Diabetes	9 (25.71)	3 (8.33)	0.071
HTN	17 (48.75)	27 (75.00)	
Diabetes and HTN	7 (20.00)	3 (8.33)	
Other	2 (5.71)	3 (8.33)	
Baseline characteristics (before intervention)			
Hb (g/dl)	9.95 ± 1.25	10.24 ± 1.55	0.393
MCV (fl)	91.64 ± 7.88	91.86 ± 7.50	0.868
RDW (%)	15.30 ± 2.25	15.05 ± 2.53	0.660
PLT ($x10^3$/ul)	177.77 ± 54.21	184.08 ± 61.38	0.593
MPV (fl)	9.40 ± 1.09	9.91 ± 1.32	0.081
Fe (mcg/dl)	101.31 ± 55.04	93.39 ± 53.85	0.666
TIBC (mcg/dl)	317.57 ± 44.34	314.86 ± 44.06	0.630
Ferritin (ng/dl)	528.83 ± 466.96	525.78 ± 529.73	0.823
TG (mg/dl)	99.03 ± 35.81	131.00 ± 92.07	0.282
Cholesterol (mg/dl)	140.74 ± 27.06	147.06 ± 42.09	0.931
RBC ($x10^6$/ul)	3.53 ± 0.58	3.69 ± 0.72	0.190
MCHC (g/dl)	30.76 ± 1.42	31.24 ± 1.33	0.140
Alb (g/dl)	4.31 ± 0.67	4.43 ± 0.77	0.511
BMI (kg/m^2)	23.90 ± 3.52	24.57 ± 4.52	0.434

Data are presented as mean ± standard deviation (SD) or number and percentage

LC: L-carnitine; HTN: Hypertension; Hb: Hemoglobin; MCV: Mean corpuscular volume; RDW: Red cell distribution width; PLT: Platelet count; MPV: Mean platelet volume; Fe: Iron; TIBC: Total iron-binding capacity; TG: Triglyceride; RBC: Red blood cell; MCHC: Mean corpuscular hemoglobin concentration; Alb: Albumin; BMI: Body mass index

The study was approved by the Ethics Committee of Kurdistan University of Medical Sciences, Sanandaj (IR.MUK.REC.1396.332). Chi-square test was used to compare the variables between the two groups, and t-test and analysis of covariance (ANCOVA) were used to compare the values of variables between the two groups before and after the intervention. The data were analyzed by Stata software (version 14, Stata Corporation, College Station, TX, USA) ($P < 0.050$).

Results

In this clinical trial, the effect of LC on anemia was investigated in hemodialysis patients. Findings suggested that LC supplementation affected Hb, ferritin, and MCV levels. The ANCOVA results between the two groups indicated that LC supplementation increased Hb in hemodialysis patients ($P = 0.043$).

Table 2. Comparison of laboratory findings on anemia in both groups before and after the effect of L-carnitine (LC) on hemodialysis patients

Variable	LC (mean ± SD)		Placebo (mean ± SD)		P
	Before	After	Before	After	
Hb (g/dl)	9.95 ± 1.25	11.13 ± 1.52	10.24 ± 1.55	10.28 ± 1.80	0.043*
MCV (fl)	91.64 ± 7.88	88.48 ± 6.62	91.86 ± 7.50	88.40 ± 6.24	< 0.001*
RDW (%)	15.30 ± 2.25	15.51 ± 2.89	15.05 ± 2.53	15.47 ± 2.35	0.643**
PLT ($x10^3$/ul)	177.77 ± 54.21	176.77 ± 56.14	184.08 ± 61.38	184.33 ± 83.54	0.924**
MPV (fl)	9.40 ± 1.09	9.60 ± 1.17	9.91 ± 1.32	9.80 ± 1.22	0.413**
Fe (mcg/dl)	101.31 ± 55.04	93.97 ± 50.92	93.39 ± 53.85	94.00 ± 48.91	0.533**
TIBC (mcg/dl)	317.57 ± 44.34	318.97 ± 43.31	314.86 ± 44.06	318.03 ± 36.49	0.893**
Ferritin (ng/dl)	528.83 ± 466.96	737.74 ± 468.38	525.78 ± 529.73	531.72 ± 451.12	< 0.001*
TG (mg/dl)	99.03 ± 35.81	114.14 ± 41.68	131.00 ± 92.07	114.78 ± 44.13	0.069*
Cholesterol (mg/dl)	140.74 ± 27.06	141.17 ± 29.04	147.06 ± 42.09	140.83 ± 30.51	0.804**
RBC ($x10^6$/ul)	3.53 ± 0.58	4.00 ± 0.56	3.69 ± 0.72	3.68 ± 0.72	0.657*
MCHC (g/dl)	30.76 ± 1.42	31.57 ± 1.38	31.24 ± 1.33	31.61 ± 1.31	0.140**
Alb (g/dl)	4.31 ± 0.67	4.10 ± 0.40	4.43 ± 0.77	4.07 ± 0.69	0.511**
BMI (kg/m^2)	23.90 ± 3.52	24.25 ± 3.61	24.57 ± 4.52	25.33 ± 4.53	0.271**

*T-test; **Analysis of covariance (ANCOVA)

SD: Standard deviation; LC: L-carnitine; Hb: Hemoglobin; MCV: Mean corpuscular volume; RDW: Red cell distribution width; PLT: Platelet count; MPV: Mean platelet volume; Fe: Iron; TIBC: Total iron-binding capacity; TG: Triglyceride; RBC: Red blood cell; MCHC: Mean corpuscular hemoglobin concentration; Alb: Albumin; BMI: Body mass index

Moreover, the MCV level decreased under the effect of LC ($P < 0.001$). The mean ± standard deviation (SD) scores of serum ferritin level before and after the intervention were 528.43 ± 466.96 and 737.70 ± 468.38 µg/l, respectively. This indicates a significant difference from that of the placebo group ($P < 0.001$) (Table 2).

The results also showed no significant difference in RDW levels after the intervention ($P = 0.643$). There was no significant difference in PLT, MPV, Fe, and TIBC levels after the intervention ($P > 0.050$). There was no significant difference between the two groups in terms of cholesterol, TG, LDL, HDL, and Alb levels before and after the intervention ($P > 0.050$) (Table 2).

Discussion

The effects of LC supplement on anemia in hemodialysis patients were investigated. The findings suggested that LC supplementation affected Hb, ferritin, and MCV levels.

The results also showed that LC supplement increased Hb levels in hemodialysis patients. In the study by Emami Naini et al., LC supplementation increased the Hb concentration,[15] which is consistent with the results of the present study. In the study by Sabry on the therapeutic effect of LC and erythropoietin on hemodialysis patients, the results showed no significant improvement in Hb levels and erythropoietin dosage.[16] The results by Wanic-Kossowska et al. about the effects of LC and erythropoietin on anemia in patients indicated an improvement in Hb levels.[17] Kadiroglu et al. showed that carnitine increased Hb and HCT levels.[18] However, there was no significant relationship between LC usage and Hb level in other studies. The therapeutic role of LC in the treatment of anemia in patients with chronic hemodialysis is still a controversial topic.[6,19] It seems that the discrepancy in the study results is due to multiple factors contributing to the development of anemia with an unknown impact level in these patients. It is not possible to eliminate all factors affecting the Hb level or homogenize the two groups in terms of these factors due to the high number of causes which

are sometimes unknown. This has led to such contradictory results.

An increased serum level of HCT in the intervention group after taking LC was observed in this study, which is consistent with the results of the study by Matsumoto et al.[5] Additionally, the results showed that the TIBC level in the intervention group was similar to that in the placebo group. The results of a study by Bellinghieri et al. to measure 3-month effects of LC therapy on anemia in hemodialysis patients resistant to erythropoietin therapy showed that LC increased the level of HCT and TIBC and significantly reduced serum ferritin levels.[9] In other studies, however, there was no relationship between the use of LC and blood factors in hemodialysis patients,[20] which could be due to the effect of LC dose and duration.[21,22]

The levels of MCV, number of platelets, and the average number of platelets in the two groups did not show any significant difference before and after the intervention. A study by Al-Fifi on the serum level of carnitine in children with Fe deficiency anemia reported a statistically significant difference between the intervention and placebo groups in terms of serum MCV, MCH, and MCHC levels.[21] Oral or intravenous (IV) administration of LC in children and adults may be associated with the lack of difference in the results and heterogeneity of anemia factor.[6]

The serum ferritin levels in the two groups were different after LC administration. Najafi and Taheri studied patients treated with erythropoietin and simultaneously receiving oral LC in addition to subcutaneous erythropoietin. The subjects' mean Hb levels increased significantly to 1.1 mg/dl, and mean HCT levels increased significantly up to 2.7 times. Moreover, LC reduced transferrin and ferritin; that was why the increased use of serum Fe and stored Fe increased the effects of erythropoietin on bone marrow.[19]

There was no significant difference in the RBC level between the two groups after the intervention. However, in other studies, the use of LC in hemodialysis patients showed an increase in the survival rate of RBC.[23] The results of a study about the effects of LC on the metabolism of lipids, free radicals, and RBC count in 6 months showed that the use of erythropoietin decreased along with co-administration of LC.[9] In a study by Labonia, the use of LC supplementation improved RBC levels in hemodialysis patients.[12] The heterogeneity of the results of clinical trials can be attributed to differences in baseline TG concentrations, carnitine supplementation dose, and administration manner (oral or venous).[15]

The results indicated that Fe and RDW levels were similar between the two groups after the intervention, which is consistent with the results by Ahmadi et al.[22]

The results also showed that LC did not affect the BMI, while in other studies, LC supplement in hemodialysis patients resulted in an improvement of physical function and preservation of lean body mass (LBM).[24]

The small sample size and some possible contributory factors such as folate that were not measured are the limitations of this study.

Conclusion

Based on the results of this study, the effects of LC on Hb, serum ferritin, and MCV levels in hemodialysis patients were significant. Therefore, although it needs greater studies with a more considerable number of patients, it is suggested that LC can be used to treat anemia in this group of patients.

Conflict of Interests

Authors have no conflict of interests.

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