International Journal of Community Medicine and Public Health
Bashardoost B et al. Int J Community Med Public Health. 2019 Oct;6(10):4293-4298
http://www.ijcmph.com
pISSN 2394-6032 | eISSN 2394-6040

DOI: http://dx.doi.org/10.18203/2394-6040.ijcmph20194483

Original Research Article

Effect of omega-3 supplementation on serum lipids in patients on chronic hemodialysis

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Received: 26 June 2019
Revised: 13 August 2019
Accepted: 16 August 2019

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ABSTRACT

Background: Considering the important of effects resulting from chronic hemodialysis in patients having renal insufficiency of which cardio-vascular effect is the most important, this study has been done to examine the complementary effects of omega lipid on lipid profile serum and systemic inflammation index in these patients.
Methods: Patients in this study include two groups (intervention and control). They have been chosen from among the patient called on hemodialysis unit of Booali hospital. The interval group received one omega capsule daily and the control group received a placebo capsule one a day for three months. At the end, the results of lipid profile tests (including triglycerides (TG), low density lipoproteins (LDL) and high density lipoproteins (HDL)) and systemic inflammation index (C-reactive protein) compared before and after receiving the medicine.
Results: In this study in interval group having omega3 despite decrease in TG and increase in HDL after three months there were no meaningful changes. In group receiving placebo only increase of HDL was meaningful and despite decrease in TG after receiving placebo these changes was meaningless.
Conclusions: The results of this study showed that omega3 had no meaningful changes in lipidic profile of patients who were being hemodialysed.

Keywords: Renal insufficiency, Hemodialysis, Omega-3, Lipid profile serum

INTRODUCTION

Omega-3 family is polyunsaturated fatty acids that the first double bond is located between the third and fourth carbon in the carbon chain. Omega-3 fatty acids are essential ingredients for regulating the activity of the human body, but don't produce in the body. Essential fatty acids prevents from deposition and accumulation of cholesterol in the arteries and the progression of atherosclerosis.[1]

Several studies have shown that omega-3 fatty acids by reducing the gene expression of strolls regulatory element binding proteins (SREBPs) include SREBP-1C, SREBP-1a, and SREBP-2. They also increase the destruction of these proteins in Proteasom that reduce their concentration in the liver cells and thus reduce the gene expression of enzymes effective on fatty biosynthesis in the liver. Reduction of fatty acids synthesis in the liver caused to decrease of the synthesis of triglycerides (TG) and very low density lipoproteins (VLDL) in the liver. Therefore, entrance of the VLDL to blood is decreased

and triglycerides concentration in the blood is also declined.[2-5]

The basic precursor material for omega-3 is α-linolenic acid (α-ALA) that mainly achieved from vegetable grain's oil. In recent years, new compounds have been marketed as supplements of omega-3 that unlike to conventional omega-3 compounds with 300 mg EPA and 400 mg DHA containing 900 mg DHA and 800 mg EPA. These compounds offered with the names of Omacor capsules or Omega MAX. Higher amount of EPA and DHA of Omega MAX and its use once a day, instead of 3 times a day for conventional omega-3 capsules, resulted to high tendency for this capsule.[6]

Epidemiological studies showed a direct correlation between high intake of saturated fatty acids Hypolipidemy and death from cardiovascular diseases. These studies proved that increase of dietary unsaturated fatty acids (especially omega-3) has higher beneficial effect on cardio-vascular disease compared to reducing the amount of saturated fatty acids.[7] Although, reduction of serum low density lipoproteins (LDL) is the first immune response to reduce the diseases associated with atherosclerosis, but increase of serum triglycerides decreases high density lipoproteins (HDL) and produces the higher amount of small and more concentrated LDL particles. These changes increase the risk of coronary heart disease.[8-10]

TG to HDL ratio is superior in predicting myocardial infarction and arterial thrombosis than LDL to HDL ratio. Atherosclerosis and cardio-vascular disease are from the main causes of mortality in chronic kidney disease undergoing hemodialysis. Therefore, use of therapeutic procedures to cure these disorders is valuable. In order to prevent the occurrence of atherosclerosis caused by hemodialysis, prescription of blood lipid-lowering drugs and anti-oxidants is inevitable, but studies emphasized on the treatment methods that are effective in reducing the independent risk factors of atherosclerosis such as Lipoprotein-a.[11,12]

Chronic kidney disease (CKD) includes a range of different pathophysiologic processes that associated with abnormal renal function and progressive decline in glomerular filtration rate. Cardiovascular disease is the main cause of mortality in patients at any stage of CKD that related to hyperphosphatemia, and other risk factors like hypertension, hypervolemia, dyslipidemia, increased sympathetic activity and hyperhomo-cysteinemia.[13]

Chronic renal failure produces from progressive and irreversible degradation of nephrons and its treatment in the later stages carried out by hemodialysis or peritoneal dialysis and kidney transplant.[14,15] Free radicals effect on lipids, proteins and carbohydrates. Lipids have the greatest sensitivity for free radicals.[16] some studies suggested that the process of dialysis increases free radical production. Increased production of free radicals during hemodialysis in dialysis apparatus is probably due to direct contact of dialysis apparatus with patient's blood in normal oxygen pressure that creates oxidative stress.[16,17] In hemodialysis patients, high levels of systemic inflammatory parameters (C-reactive protein) is one of the major risk factors for cardiovascular disease.[8,9] Several studies showed the relation between increased plasma concentrations of Lp (a) with atherosclerosis and coronary arteries diseases caused by it, in particular in hemodialysis patients. Most of researchers declared that Lp (a) act as a risk factor for heart disease. Therefore, finding a pharmacological agents that have the ability to lower these risk factors will have great therapeutic value.[10,18] In a study carried out in the Department of Nephrology, Hospital, Aalborg, Denmark of the hemodialysis patients were fed with high doses of fish oil containing a large amounts of omega-3, a significant decrease in triglycerides in these patients was observed which resulted in a significant reduction of cardiovascular disease risk.[19]

Kooshki et al showed that omega-3 reduced the concentration of artery inflammation index that cause to reduce cardiac events in hemodialysis patients.[20] The Taliban and colleagues study indicated the positive effects supplementary fatty acids in reducing the concentration of serum triglyceride in patients undergoing hemodialysis, but had no effect on the concentration of other serum lipids and lipoproteins in hemodialysis patients.[21] Rafraf et al concluded that omega-3 fatty acids caused a significant decrease in LDL and triglycerides levels and significant increase in levels of serum HDL.[22] This study aimed to determine the effects of omega-3 fatty acids on serum lipid levels in patients under treatment with chronic hemodialysis.

METHODS

This study was a clinical trial. The study population had chronic hemodialysis patients who were undergoing dialysis in hemodialysis center of Booali hospital in Ardabil city from date 21st January 2015 to 21st June 2015. Study intervention carried out on 60 dialysis patients in dialysis section of Booali. The study groups included of 30 patients in treatment group and 30 patients in placebo group. The study conducted as a double-blind method. Patients were selected randomly and placed on study groups. The groups were dialyzed in different days (Omega group in even days and placebo group in odd days) and different place. Therefore the participants of two groups hadn't awareness from medication of each other. At the start of study the participant were under dialysis at least for 3 months and did not used any omega 3 supplements, E and C vitamins, and other effective drugs on serum lipoproteins. Serum levels of C-reactive protein (CRP), TG, HDL and LDL were measured in the laboratory of Booali hospital. TG kit was used to measure triglycerides. Diagnostic kits of HDL-C and LDL-C were used to quantitative measure of HDL and LDL in serum

or plasma by photometric method. CRP calibrator and control serum was used to measure of CRP.

Study design

For patients in group 1 to 3 months a number of Omega-MAX Omega-3 capsules after midday meal was prescribed. Omega-3 capsules for patients in Group 2 also were used as a placebo and serum levels of CRP, TG, HDL and LDL were assessed.

It should be noted that in this study, determination of the adequacy of dialysis for each patient is based on the kt/v index and the use of BUN concentration, duration of hemodialysis and the rate of ultra-filtration of fluids from the body, which is derived from the information in each patient's case. Also it should be noted that during the study, 3 patients were excluded from the study for reasons such as referral for kidney transplantation and accidental death, and a total of 29 patients in the drug group and 28 subjects in the placebo group were studied.

Tools and methods for collecting information

After selecting the samples, the laboratory of Booali Hospital of Ardabil was used for the necessary preliminary tests (prior to omega) and the second (after 3 months after omega administration). For all patients, the forms were completed in both groups, including personal details, address, the cause of kidney disease, accompanying illnesses, and information on the adequacy of dialysis index and the section on the results of the tests. Data was entered into SPSS software version 16 after encoding of checklists and analyzed using descriptive statistics and analytical statistics methods using paired t-test. Significant levels were considered less than 0.05.

All information about the patient's case file was confidential and was not mentioned in the nominal study of patients. Before the beginning of the study, patients were given a detailed explanation for the study and prescription drug, and informed consent was obtained from all patients. The study approval in the Ethics Committee with code 93.48ARUMS. REC then recorded and done. The code for the clinical trial is 1N2014112520087IRCT.

RESULTS

In the present study in omega 3 groups, the mean of TG, HDL, LDL, and CRP was not statistically significant before and after the intervention by using The T-test. In the placebo group, the mean of TG, LDL, and CRP before the intervention, That is, before taking omega-3 placebo capsules, and after the administration of placebo, according to T-test, was not significant. While the mean HDL in the placebo group before intervention was 40.6 mmol/l, after the intervention, it reached 44.5 mmol/l, indicating an increase in HDL. T-test showed a significant increase (p=0.02) (Table 1 and 2).

Table 1: Descriptive indexes of TG, HDL, and LDL variables in the drug group.

Variables (mmol/l)	Before (mean±SD)	After (mean±SD)	P value
TG	217.96±125.27	194.93±115.03	0.096
HDL	33.93±7.24	37.25±11.69	0.061
LDL	98.31±34.09	103.20±36.33	0.402

Table 2: Descriptive indexes of TG, HDL, and LDL variables in placebo group.

Variables (mmol/l)	Before (mean±SD)	After (mean±SD)	P value
TG	260.96±171.52	234.32±117.42	0.192
HDL	40.60±9.60	44.50±11.41	0.020
LDL	104.17±25.97	104.89±31.30	0.854

According to the outcomes of this study, it can be concluded that in the omega-3 group, the mean TG was significantly reduced after medication (mean difference of 23.03), but due to the scattering of data concerning triglyceride, this reduction was not significant.

In the placebo group, however, there was a significant decrease in TG, although it's mean after placebo was significantly reduced (mean 24.26), but this was not significant, so it can be concluded that none of them the two groups did not show significant reductions in TG.

Regarding HDL in omega group, the mean of that after omega consumption was increased compared to before omega consumption (mean difference of 3.32) and although p=0.061 was not considered meaningful, but It can be said that omega consumption has been effective in increasing HDL.

Concerning HDL in the placebo group, with a mean difference of 3.89 and a significant increase in HDL after placebo, it can be concluded that the reason for the increase in HDL in this group was not related to the level of omega-3 fatty acids and probably have been resulted of factors like nutrition and etc.

In the case of LDL, in the omega group, considering that the mean LDL after omega consumption was slightly increased compared to the mean before omega consumption (mean difference of -89.8), due to the lack of significance of these results and the changes to a very small extent, we conclude that omega has not been shown to increase LDL. Of course, in the placebo group, LDL changes were not significant at a mean of -0.71.

In the case of the CRP in the omega group, with regard to its increase after omega consumption (mean difference of 2.5), and its non-meaningfulness, it can be said that this

increase does not correlate with omega consumption and it can be related to the inflammatory nature of chronic kidney disease and other illnesses associated with the disorder that is common in these patients, such as diabetes and the like. In the placebo group, the increase in CRP after the use of placebo with an average of -1.257 was also confirmed by the inflammatory nature of chronic kidney disease.

Tables for statistical analysis of data are presented in two groups of drugs (omega) and placebo. The presented tables also include mean, standard deviation and p value variables before and after drug and placebo imposition (Table 3).

Table 3: Compares the changes before and after the indices between the two groups of drugs and placebo.

Variable (mmol/l)	Drug mean	P value	Placebo mean	P value
TG	23.03	0.096	26.64	0.192
HDL	3.32	0.061	-3.89	0.020
LDL	-4.89	0.402	-0.71	0.854
CRP (mg/dl)	-5.20	0.072	-1.27	0.582

DISCUSSION

Chronic renal failure is one of the most common kidney diseases, which, due to sever and irreparable complications, require special care and observation patients. Patients with end stage renal disease require dialysis or kidney transplantation to survive. These patients are prone to cardiovascular disease due to the nature of the end stage kidney disease and also due to the common diseases associated with them, including diabetes and the like. One of the known causes of cardiovascular disease in these patients is lipid abnormalities, the most important of which are triglyceride, HDL and LDL disorders. This study was conducted to evaluate the effects of omega-3 fatty acid supplementation on lipid profiles and systemic inflammatory markers in patients undergoing hemodialysis.[23] Several studies have been done to evaluate the effects of fatty acid supplements on lipid profiles of normal people and patients from different groups, some of them on hemodialysis patients.[19] For example, in a study done by Kooshki and et al in the title of the effect of supplementing omega-3 fatty acids on the concentration of lipids and serum lipoproteins, it was concluded that receiving omega-3 supplementation did not result in any decrease in lysophosphatidic acid (LPA) concentration, However, after 10 weeks of treatment, serum triglyceride levels were decreased compared to placebo group. In this study, the mean concentration of LPA in the omega-3 fatty acid group was 30.2±3.23 and in the placebo group 22±18, which was not significant between the two groups.[20]

Serum triglyceride concentrations in the omega group were 113±32.3 and in the placebo group 109±19, which was after the end of the study in the omega group, 101±25 and in the placebo group, 17±115 which in the group receiving omega-3 fatty acid supplements By the end of the tenth week, the study had a significant reduction in the starting time of the study ($p<0.01$). While in the placebo group, it did not change over the course of the study. Also, serum triglyceride concentration reduction in the omega-3 fatty acid supplement group was statistically significant ($p<0/004$).[21] On the other hand, at the onset of this study, in the omega-3 fatty acid group, the mean HDL-C and LDL-C concentrations were 43±5 and 42±3.5 and in the placebo group were 10±8 and 8±5.9, respectively. The difference there was no significant statistical relationship between the two groups. At the end of the study, the concentration of HDL and LDL in the fatty acids group was 42±5.4 and 41±5 and in the placebo group, 12.5±12 and 5±3, respectively, which was not statistically significant.

In the study, supplementation with omega-3 fatty acids in omega group did not significantly increase serum HDL-C concentrations compared to placebo group. In concurrence with the study, some studies have shown that omega-3 fatty acids do not increase serum HDL-C concentrations, but some studies have shown that omega-3 fatty acids increase serum HDL-C concentrations. Contradiction in the effects of omega-3 fatty acid supplements on serum HDL-C concentrations is may be due to the difference in serum triglyceride concentration changes due to the use of omega-3 fatty acids, as the reduction in serum triglyceride concentration decreases the amount of triglyceride is present in serum HDL2, and in this case, HDL-2 lipoproteins are not suitable substrates for the liver lipase enzyme any more. As a result, converting of HDL-2 lipoproteins to HDL3 lipoproteins those rates of catabolism is higher than that of HDL2 lipoproteins, decreases. Thus, decreasing triglyceride concentration due to supplementation of omega-3 fatty acids 3 can affect serum levels of HDL. In the study, patients with hemodialysis had a normal level of serum triglyceride concentrations, so that, the use of supplementation of omega-3 fatty acids reduced the serum triglyceride concentration significantly, which was about 12 milligrams Grams in deciliter. Therefore, because the reduction in serum triglyceride concentrations was slight in this study, the serum HDL-C concentration has not increased.[21]

In another study by the Department of Nephrology, Aalborg Hospital, Denmark, conducted a double-blind study in this study, patients with hemodialysis underwent to high-dose fish oil supplementation that contains large amounts of omega-3. Finally, after statistical analysis found a significant reduction in the Triglyceride level but no other lipid profiles were altered.[22]

Another study by Hamilton and colleagues concluded that omega-3 has an effect on the balance of serum lipids, leading to improved cardiovascular complications. In this study, the patients were divided into two groups, one

group of fish oil containing omega-3, and another group of olive oil, which had much lower omega-3 content. The mean of TG in the omega-3 group before the intervention was 3.3±0.3 which was 2.7±0.5 after intervention. The mean HDL before the intervention was 0.96±0.04 and after intervention 0.91±0.05. The mean of TG in the olive oil group before the intervention was 3.3±0.3 and after intervention 3.4±0.6 and the mean of HDL in the olive oil group before the intervention was 96.9±0.04 and after intervention, 0.08±0.03. Finally, it was concluded that although TG reduction was significant in patients receiving Omega-3, the increase in HDL was not significant. But the same reduction in TG has had a significant impact on the risk of cardiovascular morbidity.[24]

In the present study, we have tried to prove that omega-3 fatty acids improve lipid profiles by decreasing TG and LDL and increasing HDL. Meanwhile, we examine the effect of omega-3 fatty acids on the reduction of systemic inflammatory markers such (CRP).

In the present study, although the use of omega-3 in the treatment group resulted in a non-significant decrease in triglyceride levels, this could be due to reasons such as a small number of samples and the dispersion of the initial data, and it certainly doesn't mean non-acceptance of The results of previous studies have shown that omega-3 fatty acids have not significantly decreased TG. Additionally, in this study, HDL in the placebo group, in contrast to the treatment group, has made significant changes, which can be noted: The lack of significant increase in HDL in the omega group may be due to the lack of significant reductions in TG in this group, since, as in other studies, the positive effects of omega fats on HDL elevation on condition of TG reduction are also possible in this study. According to the results of changes in LDL and CRP in this study and other similar studies, it can be concluded that in general, omega supplements have no effect on LDL and inflammatory systemic index.

Low number of patients, lack of attention to the TG of the patients in the two groups before the intervention, which leads to a large dispersion of data and the impossibility of nutritional measures (including regular consumption of fish and foods containing omega-fatty acids) were the limitations of the present study.

Considering that the effect of omega-3 fatty acids on the increase of HDL and TG and LDL reduction in this study, has not been meaningful, so it is scientifically not possible to categorically recommend this drug for all patients with hemodialysis. However, according to previous studies, the use of these supplements in hemodialysis patients, even if there is no significant reduction in lipid profiles, will not be detrimental. In order to achieve definitive results, it is better to select larger number of patients as sample and with consideration of factors such as the effects of a specific diet of each patient and the level of baseline serum lipids will be resumed at other times.

Finally, although there were no significant differences in lipid profile in hemodialysis patients, many patients in the omega-3 group showed a significant reduction in musculoskeletal pain, which is a common complaint in chronic hemodialysis patients. They expressed satisfaction that this could be more accurately and comprehensively studied in other near-term interventions with omega-fatty acid supplements.

CONCLUSION

This study concluded that omega consumption did not have a significant effect on reducing serum lipids (TG and LDL) and increase in lipid (HDL) and systemic inflammatory index (CRP) ($p>0.05$).

ACKNOWLEDGEMENTS

Thus, the authors would like to thank the personnel of Ardabil Booali hospital for all efforts.

Funding: No funding sources
Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee

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Cite this article as: Bashardoost B, Habibzadeh S, Shahbazzadegan B, Ahari SS, Ardabili EK, Haddad A. Effect of omega-3 supplementation on serum lipids in patients on chronic hemodialysis. Int J Community Med Public Health 2019;6:4293-8.