

THE EFFECT OF GINGER SUPPLEMENTATION ON THE LIPID PROFILE, BLOOD GLUCOSE, QUALITY OF LIFE AND FUNCTIONAL CAPACITY IN PATIENTS WITH CORONARY ARTERY DISEASE

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ABSTRACT

Review: Background: cardiovascular disease remains the main cause of mortality in the world. Ginger is an effective way for treatment of blocking vessels and contain compounds that are useful for heart and blood vessels. The aim of this study was to determine the effect of ginger supplementation on clinical outcomes and quality of life for atherosclerosis disease. **Materials and Methods:** This study was a placebo-controlled triple blind clinical trial involving 72 patients with atherosclerosis for 2 months from October to December 2015. Cholesterol, FBS, VLDL, HDL and Tg was measured at the beginning and end. Ginger powder or a placebo were given 1600 mg per day and exercise test before and after the intervention. Test variables using

Paired T-Test, Student T-Test, Wilcoxon and Mann-Whitney were compared and $P < 0.05$ was considered significant. **Results:** In the experimental group weight, FBS, Tg, VLDL compared to the control group (placebo) decreased statistically significant ($P = 0 < 0.05$). also in Ginger consumer groups Exercise test duration and the number of METS increased statistically significant ($P = 0 < 0.05$). Total score quality of life as well as heart pain score improved in the intervention group was more effective than placebo ($P = 0 < 0.05$).

Conclusion: This study showed that taking ginger supplement for 2 months in patients with coronary artery disease is good for cardiovascular patients by reducing blood lipid, reducing mean fasting blood sugar, improve performance and quality of life and heart pain, and it that taking this supplement.

KEYWORDS: atherosclerosis, cardiovascular disease, Ginger.

INTRODUCTION

Cardiovascular disease remains the main cause of death in the world is that one third of deaths observed included.^[1] In 2025, cardiovascular mortality, according to a global benchmark from all major mortality such as infection, cancer and trauma will take precedence. According to international statistics, more than 17 million deaths worldwide annually due to cardiovascular disease, more than 82 percent of these deaths occur in low and middle income countries.^[2]

The primary reason for cardiovascular disease, is atherosclerosis. Atherosclerosis is a disease that progresses slowly over a person's lifetime and the process can begin before adulthood.^[1] In other words Atherosclerosis is a progressive inflammatory disorder that causes cardiovascular disease, stroke and peripheral arterial diseases.^[3] Plants have always been a source of traditional medicines public or are used as chemical products.^[4] According to WHO, about 3\4 of the world to traditional therapies, especially herbal remedies trust and the mid-nineteenth century, at least 80% of drugs are derived from plants.^[5]

Ginger is a member of the plant family Zingiberaceae. This plant is native to Asia and now in Africa, India and other tropical regions is growing.^[13] In the past, ginger plants to treat and relieve symptoms such as pain, vomiting, dyspepsia.^[2and3] Scientific evidence suggests that ginger has antioxidant properties, anti-clotting and anti-inflammatory and pain is reduced.^[4] Ginger is an effective way for blocking vessels, including compounds such as Gingerols, Shogaols that has many benefits for the heart and blood vessels, inhibits platelet aggregation and reduces cholesterol.^[4]

Studies have shown a 25 percent reduction in cholesterol reduces the incidence of coronary events by nearly 50 percent and the strong relationship between cholesterol and mortality has been demonstrated. One of the most important intervention to correct dyslipidemia is the use of lipid lowering agents.^[6]

America Food and Drug Administration, ginger as a food supplement in order GRAS (Generally Recognized As Safe) is known. According to the evidence and human studies, few side effects have been reported after consumption of ginger include mild digestive disorders, heartburn and diarrhea. Clinical studies have shown that ginger up to 2 grams per day has minimal toxicity to humans.^[7]

As regards medicinal plants play an important role in the traditional medical treatments and are rich sources of biological active compounds that can act as the raw material for the production of the drug will be used, on the other hand, According to the information we have so far of human research in relation to the impact of the consumption of ginger on the quality of life, functional capacity and inflammatory factors for heart patients is not, therefore the necessity for it is that the effects of ginger plant on cardiovascular patients studied, perhaps to be able as an herbal medicine with the least side effects than typical drugs to help patients recover. The aim of this study was to determine the effect of ginger supplement on the clinical symptoms and quality of life for heart patients with atherosclerosis who are not candidate revascularization and heart failure, as well.

MATERIALS AND METHODS

This study was a randomized clinical trial of three kind of blind and placebo controlled with 72 male patients with atherosclerosis at Golestan and Emam hospitals of Ahwaz in the months of October to December 2015.

The study by the ethics committee at the Department of Research and Technology University of Medical Sciences, Ahvaz on 19 \ 7\ 2015 proposed ethics code IR.AJUMS.REC.1394.346 do it morally permissible cholera were detected in the clinical trials database Iran IRCT2015100424348N1 code is recorded.

Inclusion criteria were: men patients with age 40 to 70 years old, with one, two or three vessel involvement and do not need to revascularization during follow up.

Exclusion criteria included: supplement intake to less than 80% of the total, change in the previous routine management of patients (change the type and amount of previous medication during 2 month intervention), drug side effects, Taking other vitamins and Uncooperative patient.

Patients were randomly assigned into groups, none of the patients and the researcher did not know in which group they were and what type of intervention received. After giving a full explanation of the study and if the patients' agreement for the study, informed consent was obtained from them. Then patients were interviewed and a questionnaire about their public characteristics and quality of life was completed. Then 5 ml blood sample was taken. Blood samples were taken immediately to the laboratory of Biochemistry and serum samples were separated. Serum samples were stored at -70°C and then studied markers (cholesterol, HDL, LDL, VLDL, FBS, and triglyceride level) were measured by spectrophotometric methods and ELISA, the same thing was repeated again at the end of a course of medication. Patients per day, 1600 mg of ginger rhizome powder or placebo (800 mg 1 capsule before lunch and 1 capsule of 800 mg before dinner) consumed.

Were asked to volunteers, during the study period not changes in routine diet and physical activity and immediately report illness or any unnatural feeling. The intervention lasted for two months. At the beginning of the study, to control for potential confounding variables, all volunteers' baseline characteristics including age, sex, history of other diseases, type and amount of medication was collected by interviewing the patients.

Exercise test with modified Bruce exercise test standard was done, before and after taking ginger to determine the exercise test time and maximum functional capacity METS. In the group receiving ginger once before and then at the end of intervention.

Because some laboratory data was the influence of estrogen and progesterone hormones, women were excluded from the study enrolled only men.

For data analysis software SPSS version 17 was used. To determine the quantitative distribution of Kolmogorov-Smirnov test and for the comparison of normally distributed variables between the two groups before and after the test Paired t-Test and comparison of the two groups, Student t-test was used. To compare quantitative data that did not follow a normal distribution Wilcoxon and Mann-Whitney test was used, P-value level of less than 0.05 was considered significant.

RESULTS

Of the 72 male patients were enrolled, 36 people participated equally in each group, at the end of the study remained 30 patients in the ginger group and 27 patients in the control group.

3 patients had Side effects in the ginger group one person was bleeding from the nose, which led to a tampon, in another person. Gastrointestinal symptoms worsen and in one person scaling lips, the first two people were removed from study, but the third one continued to the end of the study Without any risk.

The remaining patients in both groups compliance for intake of capsules was more than 90% and it was found that all patients have adhered to the study protocol as well. The average age of participants in the intervention group was 55 and in the placebo group was 56 years. According to Statistically There is no significant difference between age groups.in Ginger consumers 70% of patients one coronary artery, 16.7% two and 13.3% three -vessel coronary artery were involved. In total, 59.6% of patients were one vessel, 22.8% two and 17.5% three vessels were involved.

In Ginger consumers weight at baseline was 77.33 and at the end was 74.50 , that's mean 2.83-kg weight loss was observed that was Statistically significant ($P=0/000$).In the placebo group at baseline weight was 76.29 and 77.74 at the end of the study, the weight gain was 1.44 kg, which was statistically significant. ($P = 0/000$).

The study found that ginger could reduce 17 milligrams per deciliter of blood glucose but placebo, 2.66 mg per deciliter increase that the difference was statistically significant.(P -value=0.037).

Also the ginger could reduced TG level 43 milligrams per deciliter at the end of study versus 3.25 milligrams per deciliter in placebo group between the two groups were existed statistically significant differences (P -value =0.027).

At The end of study ginger could reduce VLDL 7.12 milligrams per deciliter But placebo increased 1.68 milligrams per deciliter, between the two groups were existed statistically significant differences (P -value = 0.022), (Table 1).

It was observed that The end of study LDL cholesterol and HDL not decreased in ginger group But HDL increased But none of these three men Statistically not significant between the two groups.

Ginger could increased duration of exercise test from 10.2 minutes to 12.8 minutes and also increased METS from 6.6 to 9.1 Which was statistically significant. In the placebo group exercise test was not performed.

At the end of the study the quality of life in the intervention group than the control group increased more and statistically was significant, in the experimental group Quality of life score increased 828 and in the control group Quality of life score increased only 276score. The higher scores mean a better quality of life ($P = 0/000$), (Table2).

Table: 1. Summary of the Mean changes, Std. Deviation and P-value of TG, FBS, VLDL in two groups after the end of study.

Group	TG	FBS	VLDL
Ginger			
N	30	30	30
Mean	-43	-17	-7.12
Std. Deviation	78.35	28.03	33.89
Control			
N	27	27	27
Mean	-3.25	2.6	1.68
Std. Deviation	81.93	40.77	14.94
P-value	0.27	0.037	0.22

Table: 2. Summary of the Mean changes, Std. Deviation and P-value of quality of life in two groups after the end of treatment

Group	N	Mean	Std. Deviation	p-value
quality of life	ginger	30	828.6667	0.000
	control	27	257.4074	

After finished the study chest pain scores in the ginger group compared to the placebo group, chest pain scores improved more in the ginger group compared to placebo that was statistically significantly in the ginger group, improved 78 scores in the ginger group comparison with only 2 scores improvement in the placebo group ($P = 0/000$), (Table 3).

Table: 3. Summary of the Mean changes, Std. Deviation and P-value of chest pain in two groups after the end of treatment

Group	N	Mean	Std. Deviation	p-value
chest pain	ginger	30	78.1667	0.000
	control	27	2.2222	

DISCUSSION AND CONCLUSION

At the end of the study compared two groups and we found there is statistically significant differences between two groups. The findings of this study showed that general health aspect in the case group was higher and statistically significant ($p = 0.000$) than the control group at the end of study. So far, studies on the effects of ginger on the quality of life in the heart patients, has not been done.

The findings of this study showed that after the intervention, Physical function aspect in the intervention group Statistically significantly improved ($p = 0.000$), but not significant in the control group. In other words 226 score increased in the ginger group but only 25 score increased in the control group.

In the Ginger group heart pain after the intervention Statistically significantly improved ($p = 0.000$).

It seems that ginger through inhibiting the activity of enzymes involved in glucose metabolism, including enzymes α - glucosidase and amylase in the intestine, reduces the absorption of glucose in the body.^[8]

Paul et al. in 2013 showed that ginger extract has the effect of preventing an increase in triglycerides.^[9]

SHADLI and colleagues in 2014 showed that 6 weeks of alcoholic extract of ginger reduces triglycerides in diabetic rats, respectively.^[10]

In this study, none of the two group were unable to reduce plasma cholesterol. Talaei and colleagues study on 81 patients with type 2 diabetes showed that a daily intake of 3 grams of powdered ginger for 8 weeks on the the levels of total cholesterol, HDL ($p = 0/37$) and ($p = 0/06$) APO B100 is ineffective.^[11]

HDL levels increased in both groups, the difference was not statistically significant. SHADLI and colleagues in 2014 showed that 6 weeks of alcoholic extract of ginger was an increase in HDL in diabetic rats.^[12]

Paul and colleagues showed in 2013 that Ginger increased HDL.^[9]

According to the findings of research mentioned, Ginger does not have a significant effect on increasing HDL. This is probably due to changes in dietary components are less affected HDL.

SHADLI and colleagues in 2014 showed that 6 weeks of alcoholic extract of ginger was improved LDL in diabetic rats.^[10]

LDL levels increased in the Ginger group but decreased in the control group, the ginger could not reduce LDL levels.

After the end of intervention, Level of VLDL significantly statistically decreased in the ginger group compared to the control group. ($P = 0.02$) in the Goyal study and Kadnur also, after eight weeks, the group that receiving ginger, levels of VLDL significantly reduced in ginger group compared to control group.^[13]

Ginger could increase METS (functional capacity) As well as the duration of exercise test significantly. ($P = 0/000$), according to the findings of the study on the effect of ginger on the pattern of blood glucose, lipid level, quality of life and functional capacity It seems Ginger due to a lot of antioxidant compounds, including gingerols and shoals is valuable compounds to control glucose, lipids, and improve exercise capacity, angina and increase the ability of heart disease activity and its consumption can reduce blood sugar, improve blood lipid pattern, chest pain, quality of life and increase the ability to be active.

On the other hand the ginger plant has very low side effects and is as the Safe known plants on the list of US FDA.

Under this basis, ginger can play a significant role in the prevention and treatment of multiple diseases. Significant point in this study was that no change was observed in the diet and medications of our patient. Another strong point of this study is placebo-controlled triple-blind design.

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