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THE IMPACT OF GARLIC OIL SUPPLEMENTATION ON HDL AND TRIGLYCERIDE LEVELS IN PATIENTS WITH DYSLIPIDAEMIA: RANDOMIZED CONTROLLED TRIAL

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Abstract

Dyslipidaemia is a lipid metabolism disorder that may be characterised by an increase in total cholesterol, LDL, triglycerides, and a decrease in HDL. Complementary therapy that can be used to increase HDL and decrease triglycerides level is garlic oil. Aim of this study is to gain insight potency of garlic oil as complementary therapy in dyslipidaemia. 40 participant were divided into two groups: a control group and a treatment group. The treatment group was administered two 500 mg garlic oil capsules per day, along with 10 mg of simvastatin, while the control group was given 10 mg of simvastatin. We would like to respectfully propose that HDL cholesterol levels be measured after therapy at week 7. the difference in HDL levels between the treatment and control groups was 1.3 mg/dl. while the difference in TG levels between the treatment and control groups was -9.5 mg/dl. Result indicated that garlic oil as supplementary therapy can increase HDL level with p-value < 0,05. However TG level don't decrease significantly with p-value > 0,05.

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Introduction

Dyslipidaemia is a disorder of lipid metabolism, defined by an increase or decrease in plasma lipid fractions that can lead to an increased risk of coronary heart disease, atherosclerosis, stroke and metabolic syndrome (Faadlilah & Ardiaria, 2016). According to research, As evidenced by the 2018 Riset Kesehatan Dasar (RISKESDAS) data, dyslipidaemia affects 28.8% of the Indonesian population aged ≥15 years with total cholesterol levels above 200 mg/dl (Nanis & Bakhtiar, 2020). The 2018 RISKESDAS data indicates that the prevalence of heart disease and dyslipidaemia in East Java Province is 1.5%, equating to approximately 151,878 individuals aged ≥15 years. The principal lipid abnormalities are elevated levels of total cholesterol, LDL cholesterol, triglycerides, and reduced high-density lipoprotein (HDL) levels. (Sukma et al., 2018a). HDL is a lipid that has the capacity to dissolve the LDL content within the body. HDL is frequently referred to as 'good fat' due to its role in the clearance of LDL cholesterol from the walls of blood vessels by transporting it back to the liver, which prevents the formation of atherosclerosis (Ridayani et al., 2018). Triglycerides are stored within the body as fat reserves. with a normal value of triglycerides being less than 150 mg/dL.(Alam et al., 2018) It has been demonstrated that prolonged hypertriglyceridemia is associated with an elevated risk of acute pancreatitis and atherosclerotic cardiovascular disease (ASCVD).(Chait & Subramanian, 2019) The results of the 2018 Basic Health Research (RISKESDAS) indicate that 13.3% of the Indonesian population have

triglyceride levels above the normal threshold. 13.8% have high triglyceride levels. and 0.8% have triglyceride levels of more than 500 mg/dl.(Departemen Kesehatan, 2018)

At present, to increase HDL level in dyslipidaemia patients is used statin and to reduce triglyceride (TG) level used gemfibrozil or fibrate or combination with statins. The excessive use of statins has been associated with a range of adverse effects, including muscle pain, muscle abnormalities, and abdominal discomfort (Pekerti et al., 2019). The combination of statins and gemfibrozil has been demonstrated to result in an elevated risk of adverse muscle reactions, including rhabdomyolysis(Wiggins et al., 2016). Therapy to increase HDL and lowering triglyceride can be complemented with the use of natural substances. Complementary therapy may be defined as the utilisation of traditional therapeutic modalities in conjunction with modern medical practices. (Stöcker, 2018). A non-traditional approach to reducing elevated cholesterol levels is the ingestion of garlic (Allium sativum Linn.). Allicin, a constituent of garlic, has been demonstrated to enhance HDL synthesis and inhibit endogenous cholesterol synthesis (Sukma et al., 2018b). The results of (Chairunnisa, 2019), showed that the administration of garlic bulb extract containing 10 mg allicin and or 4000 µg allicin can reduce serum total cholesterol levels between 10-12%, HDL cholesterol increased by approximately 10%, and triglycerides decreased 15%. The results of research by Hadi et al (2019), showed that oral administration of garlic (Allium sativum Linn) can increase HDL cholesterol levels with a p-value of 0.041. A meta-analysis demonstrated that the administration of garlic can result in a reduction of triglyceride levels in diabetic patients by 12.44 mg/dl.(Shabani et al., 2019) The allicin compounds present in garlic have been observed to possess a mechanism of inhibiting HMG-CoA that is analogous to that of the statin group. (Mahdavi et al., 2020). There have not been many studies looking at the simultaneous reduction in TG levels and increase in HDL using garlic oil capsules with simvastatin as a complement. Researchers are interested in investigating the potential of garlic oil-based complementary therapy to enhance HDL levels and reduce TG levels.

Method

The research was conducted at the Clinic in Sodo Village, Pakel Subdistrict, Tulungagung Regency, January 2022 - March 2022. This experimental research method uses Randomized Controlled Trial (RCT) with a single-blind technique. Patients who agreed to participate in the research first signed informed consent. Patients with a diagnosis of dyslipidaemia and divided into two groups. The control group was treated with generic Simvastatin 10mg in a single dose, once a day at night. The treatment group was given Simvastatin 10mg once a day at night and Garlic oil capsules 500mg/capsule twice a day. The research was conducted for 7 weeks, with measurement of HDL and Triglycerides levels at week 0 and continued with the seventh-week examination. This research has passed ethical clearance from the University of Surabaya with number 16/KEI/I/2022. Garlic capsules that were used in this research are garlic capsules that have been registered and have a distribution license from Badan Pengawas Obat dan Makanan (BPOM) with registration number TR153385751.

The population in this research were all participant with a diagnosis of dyslipidaemia by a doctor at a clinic in Sodo Village, Pakel Subdistrict, Tulungagung Regency, with a total of 82 participants and willing to participate in the research project. The minimum sample size for the control and treatment groups was calculated using the formula:

$$S_2 = \left[\frac{S1^2(\mathrm{N}-1) + S2^2(\mathrm{N}-1)}{N_1 - N_2 - 2}\right]$$

$$\mathrm{N1} = \mathrm{N2} = 2\left[\frac{(\mathrm{Z}\alpha - \mathrm{Z}\beta)\mathrm{S}}{\mathrm{X}_1 - \mathrm{X}_2}\right]^2$$

Notes:

n1 : number of control subjects of the previous research
n2 : number of experimental subjects of the previous research
x1 : mean of the first measurement of the previous research
x2 : mean of the second measurement of the previous research
s : the combined standard deviation of previous research
Zα : alpha standard value obtained from the normal curve Z value (1.96)
Zβ : beta standard value obtained from the normal curve Z value (0.84)
s1 : Standard deviation of control group based on previous research
s2 : Standard deviation of intervention group based on previous research

So that each group had a minimum of 15 participants. If there is an estimated dropout of 10% (0.1) then the number of samples with an estimated dropout is:

$$n = \left[\frac{n}{1 - Do}\right]$$

The minimum number of participants involved in the research was 17 participants. When the research included 20 participants for each group. participants were randomised to the control and treatment groups. In determining patients, it is important to consider the inclusion and exclusion criteria to minimize the bias that occurred, while the inclusion and exclusion criteria in this research are

as shown below. Inclusion criteria (a) Patients with a diagnosis of Hyperlipidemia either with comorbidities or not. (b) Patients of the clinic in Sodo Village with age ≥ 15 years. (c) No allergy to statin drugs or garlic oil capsules. (d) Consuming Simvastatin 10mg. (e) Willing to follow the research process. While the exclusion criteria in this research were (a) Patients who used drugs, where the drug had interactions with garlic oil capsules Such as anticoagulant drugs for example warfarin, TB drugs, and oral contraceptive drugs or birth control pills. (b) Patients dropped out of the research.

Prior to conducting a difference test between the control and treatment groups, a normality test was performed using the Shapiro-Wilk test, given that the number of samples was less than 50. Subsequently, A paired t-test was conducted to ascertain the difference in HDL levels in the treatment groups before and after and independent t-test was conducted to analyse the difference in HDL levels between the control and treatment groups, given that the HDL level data in the control and treatment groups were normally distributed. Willcoxon test was conducted to ascertain the difference in TG levels in the treatment groups before and after and Mann-Whitney test was conducted to analyse the difference in triglyceride levels between the control and treatment groups, given that the TG level data in the control and treatment groups were not normally distributed. For data interpretation using the P-value, if the P-value ≤ 0.05, it can be declared that there is a difference in the mean HDL and TG between the control group and the treatment group.

Results and Discussion

The results demonstrated Following a period of seven weeks, a decline in TG levels and an increase in HDL levels was observed in the control group, as illustrated in Figures 1 and 2. Mean HDL level in the control group was lower than that of the treatment group, while the mean TG level in the control group was higher than that of the treatment group. Please refer to Table 1 and 2 for further details.

Figure 1. Triglyceride levels after 7 weeks

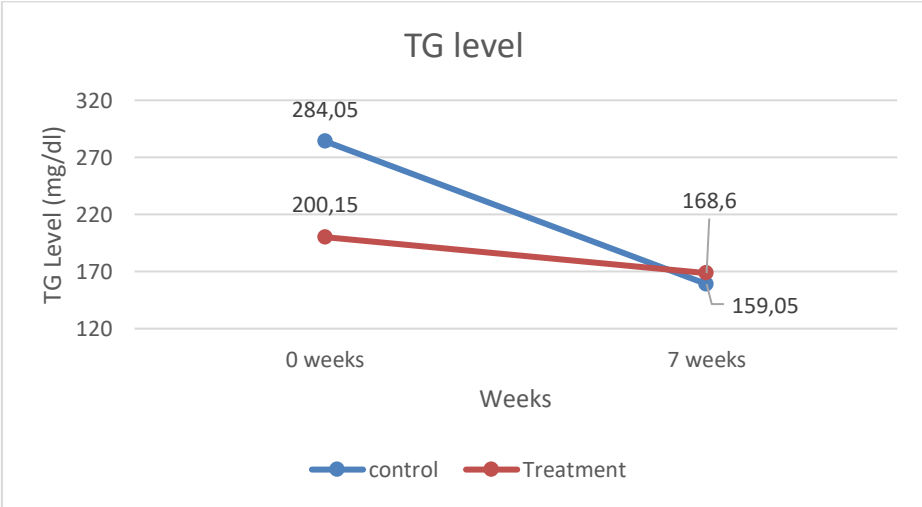

Figure 2. HDL levels after 7 weeks

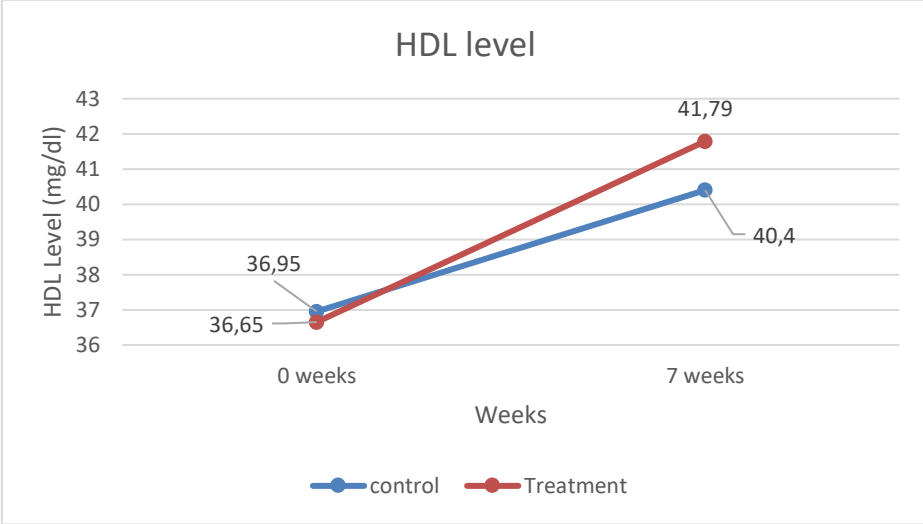

Table 1. Descriptive statistic of HDL and TG level

	HDL		TG	
	Control	Treatment	Control	Treatment
Mean	40,4	41,7	168,6	159,1
Median	41,5	41,5	137,5	127,5
Mode	42,0	43,0	201,0	102,0
Standart Deviation	5,9	3,6	123,1	81,6
Minimum	31,0	34,0	50,0	72,0
Maximum	51,0	51,0	556,0	346,0

Table 2. Mean and P-value of HDL and TG level before and after treatment group

	Group	Mean (mg/dl)	Δ Mean (mg/dl)	P-value
HDL treatment	Before	36,65	5,1	0,000
	After	41,75		
TG treatment	Before	200,15	-41,1	0,000
	After	159,05		

Table 3. Δ Mean and P-value of HDL and TG level control and treatment group

	Group	Mean (mg/dl)	Δ Mean (mg/dl)	P-value
HDL	Control	40,4	1,3	0,029
	Treatment	41,7		
TG	Control	168,6	-9,5	0,957
	Treatment	159,1		

An analysis of the triglyceride results in the control group over a period of seven weeks revealed a decline in the mean triglyceride level from 283.05 mg/dL to 159.05 mg/dL. Additionally, there was an augmentation in HDL levels, with the initial mean HDL level of 36.65 mg/dL increasing to 41.79 mg/dL. p-value < 0,05 indicated that supplementary garlic oil can increase HDL and decrease TG level significant in treatment group.

The mean HDL level was found to be 40,4 mg/dl in the control group, while in the treatment group it was 41,7 mg/dl, indicating a statistically significant difference of 1.4 mg/dl. This suggests that the incorporation of garlic oil can lead to an augmentation in HDL levels. p-value < 0,05 indicated that supplementary garlic oil can increase HDL level significant. Furthermore, TG levels in the control group were 168,6 mg/dl, and in the treatment group they were 159,1 mg/dl. These findings demonstrate that the utilisation of garlic oil as a complementary therapy can reduce TG levels by 9,5 mg/dl. Nevertheless,

the decline was not statistically significant, as evidenced by the p-value being > 0.05.

Dyslipidaemia patients, the administration of simvastatin products with a combination of garlic capsules (Allium sativum Linn) can significantly reduce serum cholesterol, triglyceride and LDL levels (Siddiqui et al., 2020),. While a significant increase has been observed in HDL levels after treatment compared to patients before being treated with a P-value <0.005.

A possible factor that may occur is that the therapy time is not long enough, while the researchers refer to research (Kojuri et al., 2007) with only six weeks of therapy time has shown an effect on HDL cholesterol levels. However, after the study was conducted with a therapy time of seven weeks, the results showed no significant difference after consuming garlic oil capsules. This factor is in line with the journal (Maghfirah, 2021) which states that one of the weaknesses of herbal medicine is that its pharmacological effects are mostly weak and slow, so it requires a longer and more continuous therapy time.

Another factor that can occur is due to the use of a less large therapeutic dose of garlic oil capsules, whereas this study refers to research (Kojuri et al., 2007) only with the use of a therapeutic dose of 2 x 500 mg can already increase HDL cholesterol levels. However, the use of these therapeutic doses in this study showed no significant difference. This factor is in line with the product packaging that has listed the therapeutic dose that the use of garlic oil capsules as 2 x 2 capsules/day or 2 x 1000 mg a day.

Another factor that may be caused by the participants lifestyle is still not maximally controlled, based on the results of interviews with participants included in this study, their daily diet still consumes foods that contain high carbohydrates and fatty foods. This factor is in line with research (Utami et al., 2017) that excessive carbohydrate intake can cause an increase in cholesterol levels

A review of the literature reveals that women tend to have higher triglyceride levels than men. This finding is consistent with studies conducted in Japan, Taiwan, and Australia, which also demonstrated that female patients exhibited higher triglyceride levels than men.(Lin et al., 2018) Similarly, studies in Indonesia have reported comparable results. For instance, a study in Yogyakarta indicated that women had higher triglyceride levels than men.(Apriliany et al., 2021)

One of the factors that contribute to an elevation in triglyceride levels is genetic predisposition. A family history of hypertriglyceridemia is a factor that influences the patient's triglyceride levels.(Simha, 2020) The results demonstrated that 75% of patients in the control group and 65% of patients had a family history of hypertriglyceridemia.

Majority of patients in both the control and treatment groups exhibited a low level of compliance with regard to the administration of pharmaceutical agents. Number of factors have been identified as influencing the level of patient compliance with respect to the use of pharmaceuticals. These include sociodemographic characteristics, as well as the specific characteristics of the drugs themselves, such as the frequency of administration, the presence of potential adverse effects, the quantity of the drug, and other factors.(Edi, 2020) Furthermore, additional factors that impact the utilisation of dyslipidaemia medications include female patients, those who are newly initiating dyslipidaemia medication, the occurrence of adverse effects associated with drug use, and patients with comorbidities such as depression and diabetes.(Lopes & Santos, 2021)

The use of a monotherapy with a statin is insufficient to achieve the desired reduction in triglyceride levels. A study conducted at the Jetis Community Health Centre in Yogyakarta demonstrated that a single simvastatin treatment over a three-month period was not sufficient to produce a statistically significant reduction in triglyceride levels, necessitating the introduction of additional therapeutic measures.(Apriliany et al., 2021)

The results of the study indicated a reduction in triglyceride levels in the treatment group following the administration of garlic oil capsules for a period of seven weeks. The initial mean triglyceride level of 284.05 mg/dl decreased to 159.05 mg/dl. However, when triglyceride levels were compared with the control group at week 7, no significant difference was observed between the treatment and control groups, with a p-value of 0.957.

A meta-analysis demonstrated that the administration of garlic can reduce triglyceride levels, although not to a statistically significant extent in both the control and treatment groups.(Sun et al., 2018) This can be postulated due to the analogous mechanism between allicin and statins in reducing cholesterol in the blood, as it operates on HMG-CoA reductase receptors, yet is not significant in reducing triglycerides.(Nazeri et al., 2021) Drugs employed to reduce triglyceride levels, such as fenofibrate and gemfibrozil, have a disparate mechanism that activates peroxisome proliferator-activated receptor-alpha (PPAR-α). An in silico study corroborated this finding, demonstrating that the binding energy of organosulfur compounds present in garlic on PPAR-α receptors was higher than that on HMG-CoA reductase receptors. This suggests that garlic may possess the potential to reduce triglyceride levels, although the effect is

not statistically significant.(Nickavar, 2022)

The use of herbal medicine generally necessitates a prolonged period of time to achieve the anticipated effect, therefore a seven-week period may not be sufficient to provide the expected triglyceride-lowering effect. (Marwati & Amidi, 2019) This was corroborated by a study that examined the impact of garlic supplementation on the lipid profile of patients with dislipidaemia. Patients who consumed garlic for a period of 60 days exhibited a reduction in triglyceride levels in comparison to the levels observed at day 40. (Zeb et al., 2018).

This study did not regulate participants dietary intake. therefore, it is recommended that future research control patients diets in order to more rigorously assess the intervention's efficacy in reducing triglyceride levels and elevating HDL cholesterol. Furthermore, given that this investigation represents a pilot study, subsequent trials should involve a larger number of patients or multiple research centers.

Conclusion

Garlic oil supplementation combined with simvastatin showed a statistically significant increase in HDL levels in patients with dyslipidaemia. However, the use of garlic oil did not significantly reduce triglyceride levels. Larger and longer-duration trials are required to confirm these findings.

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