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Effect of Torbangun (*Coleus amboinicus*Lour) Extract Capsule on Cholesterol Levels in Womenwith Hypercholesterolemia

Trini Suryowati[1], Moskwadina Gultom[2]
[1]*Department of Biochemistry, Faculty of Medicine, Christian University of Indonesia, Jakarta 13630, Indonesia*
[2]*Department of Histology, Faculty of Medicine,Christian University of Indonesia, Jakarta 13630, Indonesia*
Corresponding Author: Trini Suryowati

ABSTRACT:High cholesterol in the blood is the main risk factor of arterial blockage which is directly related to atherosclerosis, coronary heart disease and cardiovascular diseases. Torbangun (*Coleus amboinicus*Lour) contains phenolic compounds, especially quercetin which act as antioxidants. This study aims to determine the antihypercholesterolemicactivity of Torbangun leaf aqueous extract in women with hypercholesterolemia. This study was a randomized double-blind placebo-controlled clinical trial, with 30 subjects placed in two groups, viz, experimental (CC group) and placebo (PC group). The first group received one capsules of CC (each capsule contains 500 mg extract) while the second group received one capsules of placebo (comprised of 500 mg fillers) one times daily, for 30 days for both groups. Total cholesterol (TC) was measured by GCU an automated analyzer. Oral administrationof Torbangun extract capsule exhibited antihypercholesterolemic activity on total cholesterol levels in women with hypercholesterolemia.Data were analyzed with paired sample t test with 95% significance level. The results show that there was significant decrease in TC on day 30, compared to control (P group). In CC group, the capsules significant reduction in TC levels ($p < 0.05$).Studies clearly demonstrated that Torbangun extract possesses antihypercholesterolemicactivity in women with hypercholesterolemia.

KEYWORDS – antihypercholesterolemic, Torbangun (*Coleus amboinicus*Lour).

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I. INTRODUCTION

Hypercholesterolemia is characterized by increase in serum cholesterol level above the normal values (> 200 mg/dL). Although there are many causes, hypercholesterolemia is the permissive factor that allows other risk factors to operate[1]. The American Heart Association predicts that by 2030 40.5% of the US population will have some form of CVD ranging from of heart failure, strokes, hypertension or coronary heart disease[2]. There are numerous factors that contribute to the abnormality of plasma lipids among which aremodern lifestyle, high cholesterol, diet, and inadequate physical activity[3]. Hypercholesterolemia is a common disorder which was reported in 39% of the world adult population in 2008[4]. Cholesterol has been shown to interrupt and alter vascular structure and function as it builds within the lining of vascular wall, and can interfere with endothelial function leading plaque[5]. There are many methods, such as dietary alterations and medications can be used to treat hypercholesterolemia. Anti-hypercholesterolemic drugs, such as niacin, statins, and ezetimibe, are extensively used to reduce or maintain acceptable blood cholesterol levels. Although the safety profiles of these drugs are well established, there are still serious adverse events that have been recognized and are worthy of note. In addition, the side effects of these drugs include induction of myopathy[6], hepatotoxicity[7], nephrotoxicity[8], cancer risks[9]. However these current drugs are not free from side effects[10]. Many foods, including vegetables, fruits and wine, contains flavonoids. Several phenolics have attracted the attention of researchers due to their significant antioxidant and cholesterol-lowering properties. Researchers found that phenolics are able to ameliorate the uptake and accelerate the transportation of cholesterol by promoting the expression of LDL receptors (LDLR)[11] and ATP binding cassette subfamily A member 1 (ABCA1)[12]. Torbangun (*Coleus amboinicus*Lour) is an aromatic shrub widely distributed in Indonesia. The literature survey revealed Torbangun leaf extract to have an antioxidant property[13]. The purpose of the research was to determine the antihypercholesterolemic activity of Torbangun leaf aqueous extract in woman with hypercholesterolemia.

II. MATERIALS AND METHODS

2.1.Plant materials.

Torbangun*(Coleus amboinicus*Lour) were collected from a traditional market in Jakarta Indonesia, in the months of Desember 2017. The leaf separated, cleaned, air-dried, coarsely powdered, and subjected for Soxhlet-extraction by using aqueous. Powder weighing 70 g was extracted with 600 ml of aqueous for 72 h for each batch. The solvent was recovered usingrotovapour. The semisolid mass obtained was concentrated under reduced pressure and stored in an air tight container[14]. Each 500 mg*Coleus amboinicus*Lour capsule (CC) containing 90 % dry extract of CC plant and 10 % filler and was registered for sale in Indonesia

2.2. Design study

This study was conducted between Oktober2017 – Oktober2018, and was a double-blind design, randomized controlled clinical trial, conducted in women with hypercholesterolemia in Cawang East Jakarta, Indonesia.The Ethics Committee of the Faculty of Medicine, Christian University of Indonesia, East Jakarta, Indonesia reviewed the research protocol used and approved it (Reg. no. 127/PT02.FK/ETIK/2012).

Inclusion criteria for all women was long-term treatment by Torbangun (*Coleus amboinicus*Lour) leaf aqueous extract in women with hypercholesterolemia with an increased TC > 200 mg/dL, aged over 30 years and willing to give informed consent. Exclusion criteria were suffering from other confounding diseases, including chronic inflammatory diseases, acute infections.

Thirty women were randomly assigned into two groups: CC group and the PC group. This study was a randomized double-blind placebo-controlled clinical trial, with 30 subjects placed in two groups, viz, experimental (CC group) and placebo (PC group). The first group received one capsules of CC (each capsule contains 500 mg extract) while the second group received one capsules of placebo (comprised of 500 mg fillers) one times daily, for 30 days for both groups. TC was measured by Autocheck, multi monitoring system. The body mass index, and compliance of all the subjects were assessed using a questionnaire at the end of study. Blood samples were collected twice at baseline and day 30 of study. The values of TC was determined from blood cholesterol. The TC was measured using methods by assays an automated chemistry analyzer.

2.5. Statistical analysis:

The collected data were analyzed using the statistical software SPSS, version 22. (SPSS Inc., Chicago, IL, USA) and the results were expressed as the mean± SD. The changes in anthropometric measurements and blood parameters of the participants between the beginning and end of the trial were compared by paired sample t test with 95% significance level. Differences between the data were considered significant at $P<0.05$.

III. RESULTS

All the women with hypercholesterolemia (15 woman in CC group and 15 woman in PC group) completed the study (Fig.1). Compliance was good, with all the Torbangun (*Coleus amboinicus*Lour) leaf aqueous extract capsule prescribed being consumed during the study period. No side effects were reported from participans during the study period.

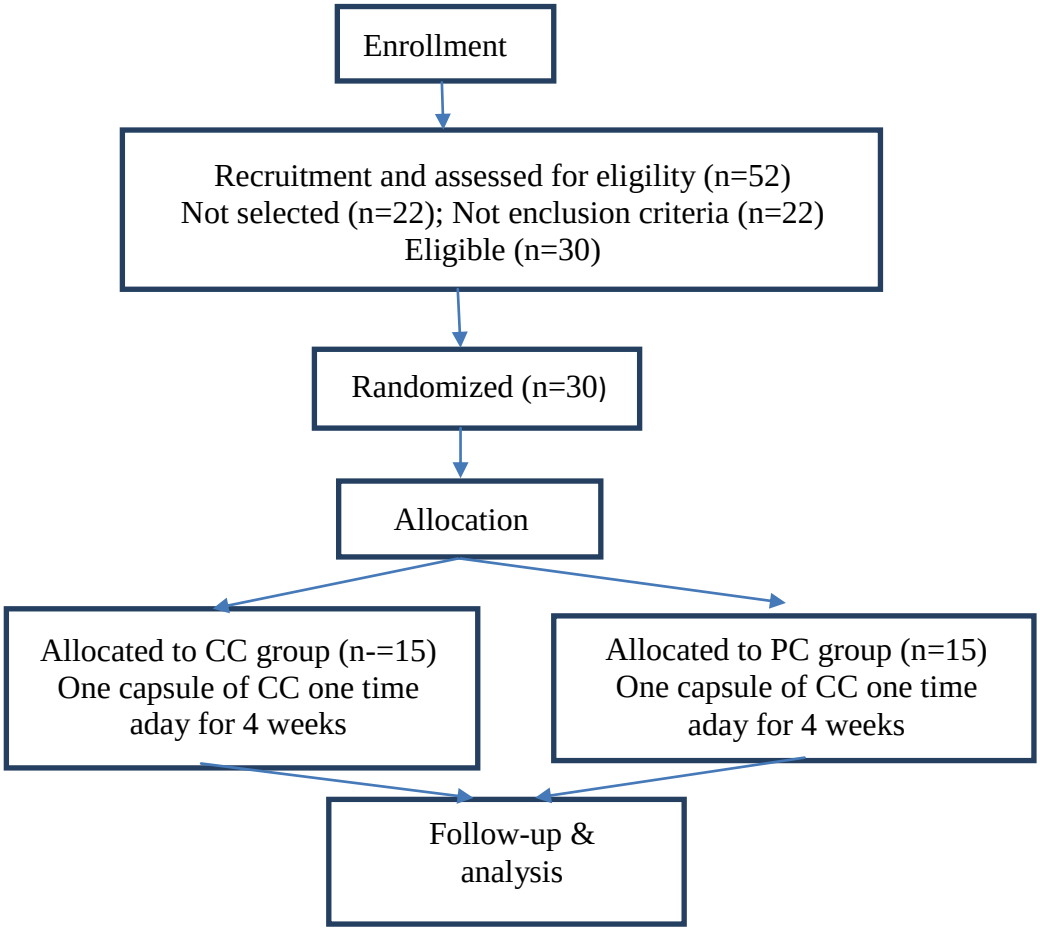

Figure 1. Participant's flow diagram

Biochemical and general characteristics of participants at the beginning and end of the study are shown in Table 1. There were no significant differences between group in BMI and BP in the beginning of the study and after 4 weeks of intervention (p=0.151). Total cholesterol levels significantly change in CC group after intervention compared to their baseline value (p=0.000), are shown in Table 2.

Table 1: BMI, TC and BP Characteristics of the women with hypercholesterolemia at baseline and after intervention

Variabel		Mean	N	Std. Deviation
BMI	Before	25,298	15	3,500
	After	24,612	15	3,805
TC	Before	258,800	15	28,917
	After	224,333	15	35,361
BPSistole	Before	137,133	15	16,221
	After	137,200	15	12,924
BP Diastole	Before	78,267	15	8,216
	After	79,533	15	8,114

BMI : body mass index; TC : Total Cholesterol, BP : Blood Pressure; SD : Standard Deviation

Base on results of BMI, TC respondents there were decreased, but BP levels were increased. The changes in BMI, BP and TC between the beginning and end of the trial were compared by paired samples t test.

Table 2. Paired samples t test

Variable	Paired Differences		t	df	Sig. (2-tailed)	p value
	Mean	Std. Deviation				
BMI_before - BMI_After	,686	1,751	1,519	14	0,151	No Significant
TC_before - TC_After	34,467	20,815	6,413	14	0,000	Significant
BP sistole_Before – BPD sistole _After	-,067	17,950	-,014	14	0,989	No Significant
BP diastole_Before – BP diastole _After	-1,267	11,467	-,428	14	0,675	No Significant

BMI: body mass index; TC: Total Cholesterol, BP: Blood Pressure; SD : Standard Deviation

Table 2 illustrated changes in paired samples t test, the levels of BMI, TC and BP of studied group and during 4-weeks period of study. No significant differences were in BMI and BP between two study groups. The results show that there was significant decrease in TC on day 30, compared to control (P group). In CC group, the capsules strongly significant reduction in TC levels ($p < 0.05$).

IV. DISCUSSION

This randomized, double-blind, placebo-controlled 4 week trial represents a total cholesterol comparison between women with hypercholesterolemia individuals taking a 500 mg/day of Torbangun (*Coleus amboinicus*Lour) leaf aqueous extract capsule (CC) versus a placebo group (PC).The biomarkers examined included total cholesterol, blood pressure. Body mass index was measured of body fat based on high and weight that applies to women. The present study was conducted to assess the antihypercholesterolemic activity of Torbangun leaf aqueous extracts in women with hypercholesterolemia. However, of these 52 volunteers, 22 could not participate throughoutthe entire study period and were excluded from the study. The remaining 52 volunteers were assigned to either the control or trial group. The volunteers in both groups were also given information/educational intervention from the physicians and gave informed consent. None of the volunteers had either diabetic, hypertension, hepatic or renal diseases. All of the volunteers in both groups were educated on diet control and doing exercises. Therefore, it could be considered that there were similarities between thevolunteers assigned to each group.

Results from this work also indicate that the capsule extract, especially thedose of trial 500 mg after 4 weeks of intervention produced more alleviating effects. This observation confirms the fact that Torbangun leafaqueous extractcapsule of plants are generally known for their high contents in chemical compounds capable of producing biological activities [15]. With regard to the lowering total cholesterol concentrations in women with hypercholesterolemia, it could be proposed that Torbangun (*Coleus amboinicus*Lour) may act by (1) stimulating biological activity by producing satiety and reducing food intake [16], (2) polyphenols and a water extract of these polyphenols exhibited cholesterol-lowering abilities in vitro and vivo [17], (3)reduces the reabsorption of bile cholesterol[18]. Baseon results of body mass index no significant decrease, and the blood pressure of sistoleand diastole levels were slightly increased, but the total cholesterol level of respondents there were strongly significant decreased.

The strengths of the present study were the double blind placebo-controlled design with no drop-out, However, our study had some limitations including the short study duration of 4 weeks, small sample population and use of a fixed dose of Torbangun leaf aqueous extract capsule. This study also included women with BMI≥25 kg/m^2. The results of our study may not be applicable to underweight or normal weight women with hypercholesterolemia or different intervention period. Studies are warranted to evaluate the effects of Torbangun leaf aqueous extracts on human with hyperglicemia. Despite in vitro and in vivo evidence of the cholesterol-lowering benefits of polyphenols, there is not enough clinical evidence to support these results. Therefore, it is important for additional studies to be conducted to detect the specific mechanisms of polyphenols for lowering cholesterol. These alleviating effects clearly denote the antihypercholesterolemicpotential of Torbangun[19]. It could also be suggested that this antihypercholesterolemiceffect of Torbangunleaf aqueous extract capsule pass through a decrease in intestinal cholesterol absorption or a decrease in the biosynthesis of cholesterol specifically by decreasing the activity of HMG-CoA reductase inhibitors [20].

V. CONCLUSION

In conclusion, the present study indicates treatment of women with hypercholesterolemia by administration of Torbangun (*Coleus amboinicus*Lour)leaf aqueous extract capsule, for four consecutive weeks could restore the biotransformation by shifting the balance of cholesterol metabolism. The extract showed significant antihypercholesterolemicwith very crucial effects on cholesterol levels.

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CONFLICTS OF INTEREST DISCLOSURE

None of the authors have any conflict of interests associated with the study.

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