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by Trini Suryowati

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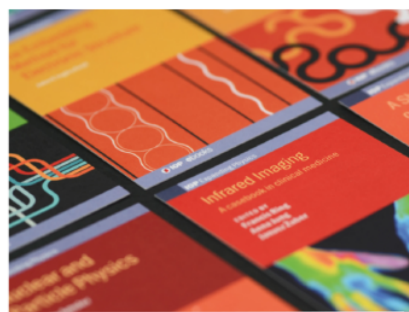
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Effect of torbangun (*Coleus amboinicus* Lour) on blood pressure in women with hypercholesterolemia

T Suryowati^{1*}, M Gultom²

^{1*}Department of Biochemistry, Faculty of Medicine of Universitas Kristen Indonesia, Jakarta 13630, Indonesia

²Department of Histology, Faculty of Medicine of Universitas Kristen Indonesia, Jakarta 13630, Indonesia

*Corresponding author: trinisuryowati11@gmail.com

Abstract. Torbangun is known for medicinal properties, as antihyperlipidemic, antihyperglycemic. We investigate the effect of a phenolic-rich Torbangun leaf aqueous extract on women with hypercholesterolemia. The first step of this study was analyzed bioactive compound of Torbangun aqueous extract. The next step was administered orally of Torbangun extract to control and women with hypercholesterolemia for 30 days, 30 subjects placed in two groups, viz, experimental (CC group) and placebo (PC group). The first group received one capsule of CC (contains 500 mg extract) while the second group received one capsule of the PC (comprised of 500 mg fillers) one times daily for both groups. Blood pressure (BP), body mass index (BMI) and total cholesterol (TC) were measured in the first and the end of the intervention. Data were analyzed by paired sample *t*-test with 95% significance level. The results show that there was a significant decrease in TC on day 30, compared to control (PC group), and not significant for BMI. In CC group, the capsules significant reduction in TC levels ($p=0.000$). Studies clearly demonstrated that Torbangun extract possesses antihypercholesterolemic activity in women with hypercholesterolemia. Based on the results of this study Torbangun extract reduced BMI but has not antihypertensive property.

1. Introduction

Cardiovascular disease (CVD) is the leading cause of debility, premature death and the major public health problem. Out of the major risk factors, which include diabetes, smoking, and dyslipidemia, hypertension by far the most prevalent trigger for CVDs, and its comorbidity with other risk factors is even more puissant [1]. The estimated to double for every 20 mmHg rise in SBP and 10 mmHg in DBP are the risk for cardiovascular [2]. The global concern and effects of hypertension approximately 75 million adults in the United States and if left untreated, increases risk of stroke, myocardial infarction and vascular disease [3]. Diagnosis and treatment of high blood pressure are essential to prevent mortality and morbidity [4].

The association between blood pressure and cardiovascular risk is continuous, and even small reductions in blood pressure substantially reduce cardiovascular risk [5]. Dietary supplements of flavonoids and Nutraceuticals are becoming increasingly popular in the treatment and prevention of cardiovascular disease. The examined obese and overweight individuals with metabolic syndrome found reductions in BP accompanied by lower oxidized LDL after 6 weeks of daily quercetin



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supplementation [6]. The antihypertensive is yet to be fully identified; however, a wide variety plant polyphenols are known to have antihypertensive potential as a result of their ability to enhance arterial dilatation, primarily via increased nitric oxide (NO) production in endothelial cells [7]. The demonstrated of cohort studies, dietary intake of flavonoids in general and of quercetin in particular is associated with a decreased risk for CVD [8]. Although several pathways have been suggested, the mechanisms by which flavonoids possibly affects blood pressure (BP) are not well-understood. These pathways include (i) improvement of vascular function in an endothelium-dependent or endothelium-independent manner, (ii) decrease in oxidative stress and/or (iii) interference with the renin-angiotensin-aldosterone system [9]. Medicinal plants are believed to be an important source of new chemical substances with potential therapeutic effect. The Torbangun is an aromatic shrub widely distributed in Indonesia. The literature survey revealed Torbangun leaf extract to have an antioxidant property. This extract has been used in Indonesian traditional medicine for treatments of antihyperglycemic, antihyperlipidemic and antihyperuric acid effects [10, 11]. The purpose of the research was to investigate the possible antihypertensive effects of the Torbangun extract in women with hypercholesterolemia.

2. Material and method

Torbangun (*Coleus amboinicus* Lour) were collected from a traditional market in Jakarta, Indonesia, during the months of December 2017. The leaf separated, cleaned, air-dried, coarsely powdered, and subjected to 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 using rotary evaporator. The semisolid mass obtained was concentrated under reduced pressure and stored in an airtight container [12]. 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.

This study was conducted between October 2017–October 2018, 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 of Universitas Kristen Indonesia, East Jakarta, Indonesia reviewed the research protocol used and approved it (Reg. No. 127/PT02.FK/ETIK/2012).

Inclusion criteria for all women with 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 capsule of CC (each capsule contains 500 mg extract) while the second group received one capsule of placebo (comprised of 500 mg fillers) one time 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 beginning and end of the study. Blood samples were collected twice at baseline and day 30 of the study. The blood pressure was measured using a blood pressure monitor. 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 \pm 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 $P < 0.05$.

3. Result and discussion

All the women with hypercholesterolemia (15 women in CC group and 15 women in PC group) completed the study. Compliance was good, with all the Torbangun leaf aqueous extract capsule

described being consumed during the study period. No side effects were reported by participants during the study period.

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 the group in BMI and BP at the beginning of the study and after 4 weeks of intervention ($p=0.151$) and ($p=0.989$ and $p=0.675$). The total cholesterol levels significantly change in the CC group after intervention compared to their baseline value ($p=0.001$ and $p=0.000$), are shown in Table 2.

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

Variable		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
BP systole	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

Table 2. Paired samples *t*-test illustrated changes in paired samples *t* test, the levels of BMI, TC and BP of the study group and during 4-week period of study. No significant differences were in BMI and BP between two study groups. The results show that there was a significant decrease in TC on day 30, compared to control (P group).

Hypothesis	Paired Differences		t	f	Sig. (2-tailed)	Result
	Mean	Std. Deviation				
BMI_before - BMI_After	.686	1.751	1.519	4	0.151	No Significant
TC_before - TC_After	34.467	20.815	6.413	4	0.000	Significant
BP systole_Before – BP systole_After	-.067	17.950	-.014	4	0.989	No Significant
BP diastole_Before – BPdiastole_After	-1.267	11.467	-.428	4	0.675	No Significant

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

Based on results of BMI and TC respondents there were decreased, but BP levels were slightly increased. The changes in BMI, BP and TC between the beginning and end of the trial were compared by paired samples *t*-test. A healthy lifestyle is known to prevent hypertension and plays an important in the therapy for blood pressure. The lifestyle changes recommended for lowering blood pressure

include limiting the salt and alcohol intake, increasing the consumption of vegetables, fruits that a lot of antioxidants and low fat meal, reduction in body weight, regular physical exercise, and cessation of smoking. The clinical condition of antihypertensive drugs recommended by ESH 2013 includes diuretics (thiazide, chlortalidone and indapamide), β -blockers, calcium antagonists, ACE inhibitors, ARB, renin inhibitor, α receptor inhibitor, and drugs that work centrally. Women with high blood pressure level generally need long-term therapy, so the side effect of drugs cannot be avoided [13]. A possible mechanism responsible for the antihypertensive may be an improved balance between relaxing and contracting factors in the endothelium of blood vessels [14].

This randomized study, 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 and BMI. 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 and reduced of BMI. However, of these 52 volunteers, 22 could not participate throughout the 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 for 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 the volunteers assigned to each group.

Based on results of body mass index no significant decrease, and the blood pressure of systole and diastole levels were slightly increased, but the total cholesterol level of respondents there was 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/m². 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 hyperglycemia. Despite in vitro and in vivo evidence of the body mass index and 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 blood pressure.

4. 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 and body mass index, but has not antihypertensive property.

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