Trop J Nat Prod Res, January 2022; 6(1):29-33 **ISSN 2616-0684 (Print)**
ISSN 2616-0692 (Electronic)

Tropical Journal of Natural Product Research

Available online at https://www.tjnpr.org

Original Research Article

Effects of Traditional Thai Herbal Formulations in Patients with Obesity and Borderline Hyperlipidemia - A Preliminary Pilot Study

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ARTICLE INFO

Article history:
Received 07 October 2021
Revised 25 December 2021
Accepted 18 January 2022
Published online 03 February 2022

ABSTRACT

Traditional Thai herbal medicine as an alternative treatment has a long history of usage and provides therapeutic options for dyslipidemia. This study aimed to demonstrate the effects of Thai herbal formulations including hypolipidemic and laxative formulations in patients with obesity and borderline hyperlipidemia. The major herbal constituents of hypolipidemic and laxative formulations were anthraquinones from *Cassia fistula* L. and anthocyanins and polyphenols from *Hibiscus sabdariffa* L., respectively. Pre-post pilot studies were conducted in patients with obesity (healthy volunteers aged 18-40 years old with body mass index (BMI) ≥ 30 kg/m^2) (n = 7) and borderline hyperlipidemia (adults aged 25-55 years old with one of the following factors related to dyslipidemia: LDL > 135 mg and < 190 mg/dL; HDL < 40 mg/dL; total cholesterol > 200 mg/dL; triglyceride > 150 mg/dL) (n = 6). All participants consumed two capsules of hypolipidemic formulation (1000 mg) twice daily after breakfast and dinner and 30 mL of laxative formulation twice weekly before bedtime for three months. Outcome measurements including body weight, BMI, waist and hip circumference, serum lipid parameters, toxicity tests were assessed at baseline and end of treatment. Hypolipidemic and laxative formulations slightly reduced total cholesterol and low-density lipoprotein levels and were safe in patients with obesity. Furthermore, both formulations significantly decreased low-density lipoprotein levels (p < 0.05), slightly reduced total cholesterol levels and were safe in patients with borderline hyperlipidemia. The findings revealed that traditional Thai herbal formulations significantly reduced low-density lipoprotein levels and were safe in patients with borderline hyperlipidemia.

***Keywords*:** Hypolipidemic formulation, Laxative formulation, Obesity, Dyslipidemia.

Introduction

Obesity and dyslipidemia have been emerging as major public health challenges worldwide, especially in Thailand.[1-3] Dyslipidemia associated with obesity plays a major role in the development of atherosclerosis and cardiovascular diseases. Dyslipidemia is characterized by increased level of total cholesterol, triglycerides, low density lipoprotein cholesterol (LDL-C), and by lowered level of high-density lipoprotein cholesterol (HDL-C) in serum.[1] Statins are recommended as the first-line therapy for the management of high LDL level however they possess considerable side effects.[4]

Thus, searching novel hypolipidemic agents which possess high efficiency and fewer adverse effects have been focused on the treatment of dyslipidemia.

Traditional Thai herbal medicine as an alternative treatment has a long history of usage and provides therapeutic options for dyslipidemia.[5] The hypolipidemic and laxative formulations used in this study have a wide range of biological activities including anti-oxidant, anti-obesity, antidiabetic, hypolipidemic, hypoglycemic, and laxative properties (Table 1).[6-21] Four lipid-lowering mechanisms of herbal medicines have been reported including the inhibition of cholesterol absorption in enterocytes, reduction of cholesterol synthesis, elevation of reverse cholesterol transport, and promotion of cholesterol excretion in the liver.[22] However, lack of enough information in the field of drug safety and efficacy of herbal medicine in clinical trial has become an issue of public health importance. This study aimed to demonstrate the effects of Thai herbal formulations including hypolipidemic and laxative formulations in patients with obesity and borderline hyperlipidemia.

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Citation: Siriyong T, Boonya-arunnate T, Ninbodee K, Kaewmuean T, Mettriyasakul T, Jawang K, Thongmongkol P, Chanwanitsakul S, Kaewnoi K, Buachum B, Saeloh D, Noosak C, Voravuthikunchai SP. Effects of Traditional Thai Herbal Formulations in Patients with Obesity and Borderline Hyperlipidemia - A Preliminary Pilot Study. Trop J Nat Prod Res. 2022; 6(1):29-33 doi.org/10.26538/tjnpr/v6i1.6

Official Journal of Natural Product Research Group, Faculty of Pharmacy, University of Benin, Benin City, Nigeria.

ISSN 2616-0684 (Print)
ISSN 2616-0692 (Electronic)

Materials and Methods

Study design and ethical statement

Pre-post pilot studies were conducted with the participation of patients with obesity and borderline hyperlipidemia. The study protocols were approved by the faculty of traditional Thai medicine ethics committee (EC.62/TTM.01-013 and EC.63/TTM.01-002). The trials were performed according to the Declaration of Helsinki and they were in accordance with the principles of Good Clinical Practice. All participants signed a written informed consent prior to study enrollment.

Sample size

This was a proof of concept study, so a sample size of six completed patients was considered adequate.

Participants

Effects of Traditional Thai herbal formulations on obesity

Eligible participants were healthy volunteers aged 18-40 years old with body mass index (BMI) $\geq$ 30 kg/m^2. Participants with a history of herbal allergy; participants using appetite suppressant, laxative, oral steroid, thyroid hormone, amphetamine, cyproheptadine, phenothiazine; pregnant women; women planning pregnancy; and breast-feeding women were excluded from this study.[23]

Outcome measurements: primary outcomes including body weight (kg), body mass index (kg/m^2), waist circumference (cm), hip circumference (cm), and the fasting serum concentrations of lipid parameters including total cholesterol, triglycerides, low-density lipoprotein (LDL), and high density lipoprotein (HDL) were measured. Furthermore, toxicity tests (blood urea nitrogen (BUN), creatinine, alanine aminotransferase (ALT), and aspartate aminotransferase (AST) were determined as secondary outcomes.

Effects of Traditional Thai herbal formulations on borderline hyperlipidemia

Eligible participants were adult aged 25-55 years old and an experiment with one of the following factors related to dyslipidemia: LDL > 135 mg and < 190 mg/dL; HDL < 40 mg/dL; total cholesterol > 200 mg/dL; triglyceride >150 mg/dL.[24] Patients with a history of herbal allergy; patients using antihyperlipidemic agents, steroids, cigarette, alcohol; patients with diabetes, coronary-vascular disease, renal, hepatic, hematological, pulmonary diseases; pregnant and breast-feeding women were excluded from this study.

Outcome measurements including body weight (kg), body mass index (kg/m^2), the fasting serum concentrations of lipid parameters (total cholesterol, triglycerides, LDL, HDL), and toxicity tests (BUN, creatinine, ALT, and AST) were measured.

Traditional Thai herbal formulations and interventions

Traditional Thai herbal formulations including hypolipidemic and laxative formulations were shown in Table 1.

Table 1: Traditional Thai herbal formulations used in this study

Scientific name (Family)	Part used	Pharmacological activity	Phytochemicals	Ratio (%)
Allium sativum L. (Alliaceae)	bulb	hypolipidemic, hypoglycemic, antioxidant[6]	allicin	5[a]
Aloe vera (L.) Burm.f.(Aloaceae)	latex	hypolipidemic, antidiabetic, laxative, anti-oxidant, immunomodulating[7]	anthraquinones	2.4[b]
Cassia fistula L.(Leguminosae)	fruit	hypolipidemic, anti-oxidant, laxative[8]	anthraquinones (rhein, chrysophanol, emodin, physcion), flavonoids (kaempferol, quercetin, myricetin, rutin, catechin, epicatechin, procyanidin B2, epiafzelechin)	23.8[b]
Citrus aurantifolia Swing.(Rutaceae)	fruit juice	hypolipidemic, anti-oxidant[9]	limonene, γ-terpinene, β-pinene	47.6[b]
Hibiscus sabdariffa L. (Malvaceae)	calyx	hypolipidemic, anti-oxidant[10]	anthocyanins, polyphenols, flavanols	62.5[a]
Piper nigrum L. (Piperaceae)	fruit	hypolipidemic[11]	piperlonguminine, piperine, pipernonaline	2.5[a]
Rheum palmatum L. (Polygonaceae)	rhizome	hypolipidemic, antidiabetic, anti-oxidant[12,13]	emodin	2.5[a]
Senna alexandrina P. Miller (Caesalpiniaceae)	leaf, legume	anti-obesity, antidiabetic hypoglycemic[14]	rutin, sennoside-A, sennoside-B, saponin	5[a], 4.76[b]
Tamarindus indica L. (Leguminosea)	leaf	hypolipidemic, anti-oxidant[15]	flavonoids, ploy phenolic	5[a], 4.76[b]
Terminalia arjuna Roxb. (Combretaceae)	fruit	antioxidant, hypolipidemic[16]	arjunic acid	2.5[a], 4.76[b]
Terminalia bellirica (Gaertn.) Roxb. (Combretaceae)	fruit	hypolipidemic, hypoglycemic, anti-oxidant[17]	gallic acid, ellagic acid, chebulagic acid	2.5[a], 4.76[b]
Terminalia chebula Retz. (Combretaceae)	fruit	hypolipidemic[18]	saponins, phytosterols, chebulinic acid, corilagin	2.5[a], 4.76[b]
Tinospora crispa (L.) Miers ex Hook.f.&Thomson (Menispermaceae)	stem	hypolipidemic, hypoglycemic, anti-obesity, antidiabetic, antihypercholesterolemic, hepatoprotective, antioxidant[19]	berberine, borapetosides A, B, C	2.4[b]
Zingiber cassumunar Roxb. (Zingiberaceae)	rhizome	anti-obesity[20]	saponnin	5[a]
Zingiber zerumbet (L.) Roscoe ex Sm. (Zingiberaceae)	rhizome	hypolipidemic[21]	zerumbone	5[a]

[a] hypolipidemic formulation
[b] laxative formulation

ISSN 2616-0684 (Print)
ISSN 2616-0692 (Electronic)

These formulations were kindly gifted from a traditional Thai medicine doctor, Mr. Somporn Chanwanitsakul. Oral herbal remedies including hypolipidemic capsule and laxative decoction were generally prepared as described in the Thai Pharmaceutical Textbook[25] at the Traditional Thai Medicine Hospital, Prince of Songkla University. Hypolipidemic capsules contained 500 mg of the extract powder. Laxative decoction contained approximately 450 mL of herbal solution in glass bottle. The participants consumed two capsules of hypolipidemic formulation twice daily after breakfast and dinner and 30 mL of laxative formulation twice weekly before bedtime for three months.

Statistical analysis

Statistical analysis was performed using SPSS Statistics for Windows, Version 20.0. Differences between the pre and post-treatment values of the parameters studied were evaluated using a paired samples t-test. Statistical significance was defined as $P < 0.05$.

Results and Discussion

According to the principle of traditional Thai medical knowledge of a traditional Thai medicine doctor, Mr. Somporn Chanwanitsakul, the use of hypolipidemic formulation in combination with laxative formulation is a strategy for management of dyslipidemia. However, limited clinical evidence of Thai herbal medicine formulations for dyslipidemia has been documented. In this study, we aimed to demonstrate the effects of Thai herbal formulations including hypolipidemic and laxative formulations in patients with obesity and borderline hyperlipidemia.

Effects of Traditional Thai herbal formulations on obesity

Seven healthy volunteers with obesity continued to the end of study and no adverse effects were observed during the study. Effects of traditional Thai herbal formulations including hypolipidemic and laxative formulations in healthy volunteers with obesity were demonstrated in Table 2 and Table 3. All biochemical parameters of lipid profiles (total cholesterol, triglycerides, low-density lipoprotein cholesterol (LDL-C), high density lipoprotein cholesterol (HDL-C)) and other variables (body mass index (kg/m^2), waist-to-hip ratio) were no significant differences at the end of study ($P \geq 0.05$). However, total cholesterol and LDL-C levels slightly decreased after the study. In addition, changes in blood urea nitrogen (BUN), creatinine, alanine aminotransferase (ALT), and aspartate aminotransferase (AST) were not detected **(**Table 4**)**. These results showed that traditional Thai herbal formulations including hypolipidemic and laxative formulations slightly reduced total cholesterol and LDL-C levels and were safe in healthy volunteers with obesity.

Effects of Traditional Thai herbal formulations on borderline hyperlipidemia

Six patients with borderline hyperlipidemia continued to the end of study and no adverse effects were noticed during the study.

Effects of traditional Thai herbal formulations including hypolipidemic and laxative formulations in patients with borderline hyperlipidemia were presented in Table 2 and Table 5. Biochemical parameters (total cholesterol, triglycerides, HDL-C) and body mass index (kg/m^2) were no significant differences at the end of study ($P \geq 0.05$).

However, LDL-C levels significantly decreased ($P < 0.05$) and total cholesterol slightly reduced after the study. In addition, changes in BUN, creatinine, ALT, and AST were not detected **(**Table 6**)**. These results revealed that traditional Thai herbal formulations including hypolipidemic and laxative formulations were effective for reducing LDL-C levels and safe in patients with borderline hyperlipidemia.

Regarding the hypolipidemic and laxative formulations, they are evident that Thai medicinal plants have a wide range of biological activities including anti-oxidant, anti-obesity, antidiabetic, hypolipidemic, hypoglycemic, and laxative properties **(**Table 1**)**.

Table 2: Demographic characteristics of patients with obesity and borderline hyperlipidemia

	Obesity group	Borderline hyperlipidemia group
Number		
Female	6	3
Male	1	3
Age (year)		
Mean	20	46.5
Minimum	20	40
Maximum	21	55

Table 3: Comparison of variables before and after the intervention of traditional Thai herbal formulations in patients with obesity

Variables	Traditional Thai herbal formulations ($n = 7$)		*P*-value
	Before	After	
Body mass index (kg/m^2)	33.82 ± 2.67	33.90 ± 2.50	0.58
Waist-to-hip ratio	0.87 ± 0.06	0.89 ± 0.06	0.37
Total cholesterol (mg/dL)	211.43 ± 42.04	201.71 ± 36.38	0.25
Triglyceride (mg/dL)	136.43 ± 65.93	135.86 ± 99.69	0.97
LDL- cholesterol (mg/dL)	137.29 ± 34.24	130.29 ± 35.51	0.45
HDL- cholesterol (mg/dL)	46.71 ± 10.71	44.29 ± 10.78	0.14

Data were presented as mean ± standard deviation.
LDL-C, low density lipoprotein cholesterol; HDL-C, high-density lipoprotein cholesterol; * Significant difference within groups by paired t-test $P < 0.05$.

Table 4: Biochemical profile of patients with obesity

Patient	BUN (mg%)		Creatinine (mg %)		AST (U/L)		ALT (U/L)	
	Before	After	Before	After	Before	After	Before	After
1	7.2	7.2	0.68	0.73	14	9	13	7
2	12.3	12.5	0.73	0.72	13	16	27	19
3	10.6	10.6	0.76	0.82	18	16	13	6
4	8.7	8.9	0.76	0.83	18	22	27	25
5	10.8	11.9	0.77	0.76	24	24	31	20
6	11.2	10.1	0.88	0.92	30	24	27	29
7	12.4	12.3	0.8	0.7	17	16	22	19

Table 5: Comparison of variables before and after the intervention of traditional Thai herbal formulations in patients with borderline hyperlipidemia

Variables	Traditional Thai herbal formulations (n = 6)		*P*-value
	Before	After	
Body mass index (kg/m^2)	26.01 ± 7.35	25.18 ± 6.43	0.26
Total cholesterol (mg/dL)	255.67 ± 13.11	224.83 ± 42.12	0.11
Triglyceride (mg/dL)	137 ± 46.61	140.33 ± 71.71	0.86
LDL- cholesterol (mg/dL)	179.67 ± 10.56	153.33 ± 29.53	0.04*
HDL- cholesterol (mg/dL)	52.3 ± 11.8	53.33 ± 12.42	0.33

Data were presented as mean ± standard deviation.
LDL-C, low density lipoprotein cholesterol; HDL-C, high-density lipoprotein cholesterol; * Significant difference within groups by paired t-test $P < 0.05$.

The main therapeutic properties of these traditional Thai herbal formulations are to reduce lipid profiles and to detox the accumulation of the old foods. Moreover, the ethnomedical uses are consistent with the pharmacological activities reported. Thus, therapeutic benefits in patients with obesity and borderline hyperlipidemia results from the combined biological activities from medicinal plants.

In conventional medicine, statins are recommended as the first-line therapy for the management of high LDL level however they possess considerable side effects.[4] However, in order to achieve target lipid levels of multiple dyslipidemic conditions in high-risk patients, combination of statins and diet therapies are required in the treatment.[26] In traditional Thai medicine, the concept of polyherbalism to achieve greater therapeutic efficacy has similarly been documented.[27,28] In this study, traditional Thai herbal formulations including hypolipidemic and laxative formulations demonstrated therapeutic effects with no adverse effects.

Table 6: Biochemical profile of patients with borderline hyperlipidemia

Patient	BUN (mg%)		Creatinine (mg %)		AST (U/L)		ALT (U/L)	
	Before	After	Before	After	Before	After	Before	After
1	9	10	02.1	87.0	15	17	35	36
2	14	10	83.0	82.0	24	23	30	32
3	8.9	9.8	61.0	58.0	19	16	19	15
4	10.6	13	55.0	59.0	17	16	11	14
5	16	14	73.0	62.0	23	22	20	21
6	11.5	10	72.0	62.0	29	27	38	39

Conclusion

The findings revealed that traditional Thai herbal formulations including hypolipidemic and laxative formulations significantly reduced LDL-C levels and were safe in patients with borderline hyperlipidemia. Therefore, hypolipidemic and laxative formulations may be used as alternative therapy for hyperlipidemia.

Conflict of Interest

The authors declare no conflicts of interest.

Authors' Declaration

The authors hereby declare that the work presented in this article is original and that any liability for claims relating to the content of this article will be borne by them.

Acknowledgements

This study was funded by Faculty of Traditional Thai Medicine, Prince of Songkla University and National Research Council of Thailand (NRCT) (Grant No. N41A640071).

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