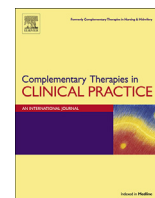




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A randomized controlled trial of electroacupuncture at body acupoints and Fenglong for regulating serum lipids in dyslipidemic patients in Thailand

Lakkana Rerksuppaphol^{a,*}, Sanguansak Rerksuppaphol^b^a Department of Preventive Medicine, Faculty of Medicine, Srinakharinwirot University, Thailand^b Department of Pediatrics, Faculty of Medicine, Srinakharinwirot University, Thailand

A B S T R A C T

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The primary objective of this randomized, controlled, open-label study was to compare the efficacy of body acupuncture and Fenglong method in controlling serum lipids in patients with dyslipidemia in Thailand. Patients were randomized into two treatment groups (body acupuncture and Fenglong) and a control group. By the end of intervention period, serum lipid level in both treatment groups was significantly lower than its baseline value while in the control group serum lipid levels significantly increased during the same period. At follow-up visit, total cholesterol and LDL cholesterol were significantly lower in both treatment groups when compared to the control group. The effect of both acupuncture interventions was seen in both obese and non-obese patients. In conclusion, body acupuncture and Fenglong method have a positive impact on the regulation of serum lipids that is sustained after the treatment regardless of patient's baseline weight.

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1. Introduction

Cardiovascular diseases (CVD) are a major cause of death worldwide. The World Health Organization (WHO) reports that approximately 17.3 million people died from CVDs in 2008 that represents 30% of all global deaths. The WHO predicts that in 2030, approximately 23.6 million people will die of CVD [1]. Dyslipidemia is considered as a major risk factor of CVD since it dramatically increases the risk of developing heart attacks, strokes, heart failures as well as other complications [2,3]. It has been shown that people with dyslipidemia have 3 times higher risk for heart attack when compared with those who have normal serum lipid levels [4].

Recent recommendations for serum lipid control include dietary management, behavioral modification, exercise and medications. However, there are inherent limitations in each method that makes a multi-aspect approach to the issue more reasonable. For example, patients on strict diets frequently show non-compliance because of different reasons including unpalatable taste of diet. There are also some barriers in the use of pharmacological treatments including medication cost, long term nature of treatment and potential sometimes serious side effects [5–7].

* Corresponding author. Department of Preventive Medicine, Faculty of Medicine, Srinakharinwirot University, 62 Mo 7, Rangsit-Nakorn Nayok Rd., NakornNayok 26120, Thailand. Tel.: +66 818483183; fax: +66 3 7395275.

E-mail address: lakkana_r@hotmail.com (L. Rerksuppaphol).

Acupuncture is a branch of Complementary and Alternative Medicine (CAM) which has been reported to have a promising efficacy for the treatment of patients with dyslipidemia while being relatively inexpensive. Fenglong (ST 40) and groups of body acupuncture have been among the most commonly-used methods for regulating serum lipids, however, the number of published studies on their efficacy remains limited [8–10]. In addition, there are unanswered questions in the available reports that require further studies to be conducted. Firstly, previous studies of electroacupuncture at Fenglong point which is located at 8 cun superior to the lateral malleolus and two-finger widths lateral to the anterior crest of tibia, used several different treatment protocols (different in terms of frequency, intensity, needle-retained time and treatment interval) depending on the type of dyslipidemia and the experience of investigators [8,9]. These variations in available studies may make it difficult for inexperienced acupuncturists to decide on what treatment protocol to use. In addition, body acupuncture points used for regulating serum lipids, are usually adopted from acupuncture points that are used for weight reduction in obesity [11–14]. Most reports that evaluated body acupuncture as a method to regulate serum lipids were done in obese patients only not the general population.

Generally, body acupuncture points are chosen based on the type of obesity as classified by traditional Chinese medicine. Therefore, the diagnosis of the obesity type is of great importance,

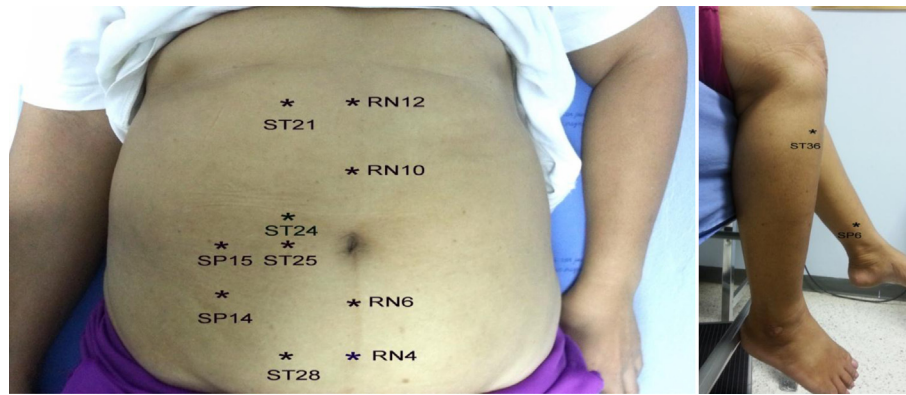


Fig. 1. Acupuncture points used in body acupuncture group: Guanyuan (RN4), Qihai (RN6), Xiawan (RN10), Zhongwan (RN12), Huaroumen (ST24), Tianshu (ST25), Shuidao (ST28), Liangmen (ST21), Daheng (SP15), Fujie (SP14), Zusanli (ST36) and Sanyinjiao (SP6).

something that an inexperienced acupuncturist may struggle with. On the other hand, our recent study using body acupuncture showed that a single standardized set of body acupuncture points could result in weight reduction in all types of obesity. But, that study does not explore the efficacy of acupuncture in reducing serum lipid levels [15]. Up until now, there has been no consensus regarding the standard acupuncture protocol in patients with dyslipidemia. There is no study that compares the efficacy of body acupuncture and Fenglong acupuncture for regulation of serum lipids. The current study aims to compare the efficacy of body electro-acupuncture and Fenglong electro-acupuncture for regulation of serum lipids in patients with dyslipidemia regardless of their nutritional status.

2. Materials and methods

This was a prospective randomized controlled open-label study that was conducted between August 2012 and February 2013 at the Preventive Medical Clinic of Srinakharinwirot University in Thailand. Patients who were diagnosed with dyslipidemia (defined as triglycerides ≥ 150 mg/dL, or total cholesterol (TC) ≥ 200 mg/dL or HDL-cholesterol (HDL-C) < 40 mg/dL (men) or HDL-C < 50 mg/dL (women) or LDL-cholesterol (LDL-C) > 130 mg/dL) and were not taking any lipid-lowering drugs were invited to participate in the study.

Patients who had a history of bleeding disorders or were receiving anticoagulant or anti-platelet aggregation medications, had epilepsy, uncontrolled hypertension, and active dermatological lesions at the area of acupuncture, as well as pregnant women or those patients whose mental disabilities made their participation in the study difficult were excluded from the study.

The study was done according to the principles of the Declaration of Helsinki. The study protocol was approved by the ethics committee of the Faculty of Medicine, Srinakharinwirot University. Written informed consents were obtained from all participants before their enrollment into the study.

Participants were randomized into one of the 3 groups (as described below) by a statistician who was not involved in the implementation phase of the study using a computerized program (GraphPad QuickCals). Participants were informed that they would be randomly assigned to one of the 3 study groups below. Due to the nature of the intervention it was not possible to conceal the study treatment from patients.

Participants in group 1 (body acupuncture group) were needled by using disposable silver needles (0.25×25 mm) at 20 acupuncture points at the body region including Guanyuan (RN4), Qihai (RN6), Xiawan (RN10), Zhongwan (RN12), and bilateral

Huaroumen (ST24), Tianshu (ST25), Shuidao (ST28), Liangmen (ST21), Daheng (SP15), Fujie (SP14), Zusanli (ST36) and Sanyinjiao (SP6) as shown in Fig. 1. An electric stimulation (SDZ-II model, Hwato, China) was connected to the needles which delivered a constant current, a 40 Hz and 3 mA, for 30 min per session. After each session, the needles were removed. Participants were treated for 2 sessions per week for 8 consecutive weeks.

Participants who were assigned to group 2 (Fenglong Group) were needled at bilateral Fenglong (ST 40) using the same type of needles used for group 1 (Fig. 2). Electric stimulation was applied to the acupoints using the same machine and method as in group 1. All acuinctures in both group 1 and 2 were performed by one acupuncturist (LR), a member of the research team, who had 7 years of experience in providing needle acupuncture.

Participants in all three groups including the control group (group 3) were instructed to maintain their normal daily activity with minimal calorie and lipid intake during the study period. No acupuncture treatment was provided for group 3.

2.1. Data collection and monitoring

After enrollment, demographic characteristics and anthropometric data including age, sex, weight, height, waist and hip circumference were recorded by a nurse. Weight was measured to the nearest 100 g using an electronic scale (Seca[®], Model 767, Hamburg, Germany). Standing height was measured by a height rod (Seca[®], Model 220, Hamburg, Germany). Waist and hip circumferences were measured by a non-stretch tape to the nearest millimeter. Waist circumference was measured at the midpoint between the lower costal margin and the top of the iliac crest while the subject was in the standing position. Hip circumference

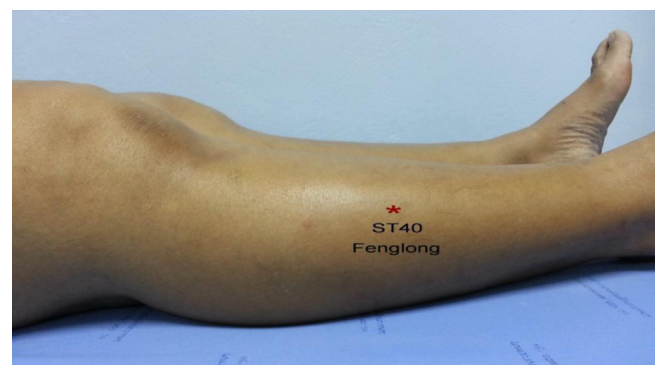


Fig. 2. Acupuncture points used in Fenglong group (ST 10).

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