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Randomized clinical trial of facial acupuncture with or without body acupuncture for treatment of melasma



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ABSTRACT

Objective: To evaluate the efficacy of acupuncture treatments in treating facial melasma, contrasting treatments involving facial acupuncture with facial/body acupuncture.

Method: Women suffering with melasma were randomly assigned into: 1) facial acupuncture (n = 20); or 2) facial/body acupuncture (n = 21). Each group was given 2 sessions per week for 8 weeks. Melasma area and darkness of its pigmentation were assessed using digital images.

Results: 95.2% and 90% of participants in facial/body and facial acupuncture, respectively, had decreased melasma areas, with a mean reduction area being 2.6 cm² (95%CI 1.6–3.6 cm²) and 2.4 cm² (95%CI 1.6–3.3 cm²), respectively. 66.7% (facial/body acupuncture) and 80.0% (facial acupuncture) of participants had lighter melasma pigmentation compared to their baselines (p-value = 0.482).

Conclusions: Facial acupuncture, with or without body acupuncture, was shown to be effective in decreasing the size of melasma areas.

This study is registered with the Thai Clinical Trial Registry (TCTR20140903004).

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1. Introduction

Melasma (also called Chloasma in pregnant women) is a commonly acquired dermatological disorder characterized by hyperpigmented patches on sun exposed areas of the skin, mostly on the face. Studies have shown that the prevalence of melasma varies according to gender, ethnicity, skin type and degree of sun exposure of the population [1]. The prevalence was reported to range between 1.5% and 33.3%, and 90% of the cases occur in women [1,2]. The exact pathogenesis of melasma is not completely understood. Multiple factors have been implicated in its etiology, such as sunlight exposure, genetic predisposition, hormonal influences, pregnancy, thyroid disease, oral contraceptive pills and drugs [2,3].

Although melasma is not a severe disorder, the frequent location of melasma on the face makes it a significant cosmetic condition that has a strong emotional impact on the individual, affecting their quality of life to an extent that they frequently seek treatment

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[2,4,5]. Several treatment options are available including depigmenting agents, chemical peels, dermabrasion and laser therapy [6–8]. Currently, a combination of hydroquinone (HQ) with steroids and tretinoin is considered the first line of treatment for melasma. However, the side effects and safety issues associated with long-term use of HQ are significant areas of concern [3,6]. Other chemical compounds and extracts of natural agents such as kojic acid, azelaic acid, ascorbic acid, tranexamic acid and arbutin have been tried as stand-alone or adjuvant therapies. However, variations in effectiveness as well as adverse effects result in low frequency of their use.

Intervention procedures such as chemical peels are prescribed as the second choice, while laser, intense pulsed light and dermabrasion are therapies usually reserved for patients who are refractory to other treatments; this selective use of these agents is due to their potential risk of worsening the disease [9]. Although the existing list of therapeutic modalities for the treatment of melasma consists of a variety of agents, recent reviews found that these treatment options usually have low efficacy. More research work is needed to assess the efficacy and safety of novel treatment modalities for melasma [6,7].

Acupuncture, a branch of Complementary and Alternative

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Medicine (CAM), is commonly used for treating a wide range of conditions including melasma. It has been recognized by the World Health Organization as a promising therapeutic modality for melasma, but very few controlled trials have been reported [10]. Variations have been found in the treatment protocols in the choice of acupuncture points. These points are chosen following the classification of Traditional Chinese Medicine (TCM) for different types of melasma [11]. For a successful outcome, it is very important to choose the correct category of acupuncture treatment for a specific type of melasma based on TCM classification.

Generally, acupuncture points used for melasma treatment in most studies can be divided into two groups, which are body points and facial points [11–14]. The existing literature lacks enough evidence to reach a conclusion regarding the standard acupuncture protocol for treatment of melasma [13]. To the best of our knowledge, no study comparing the efficacy of body acupuncture with concomitant facial acupuncture versus facial acupuncture alone for the treatment of melisma has been reported. This study aimed to investigate the efficacy of facial acupuncture with and without a single standardized set of body acupuncture points for reducing melasma area and color in Thai women.

2. Materials and methods

2.1. Study design and subjects

A randomized clinical trial was conducted at the Preventive Medical Clinic of Srinakharinwirot University, Thailand, between August 2014 and February 2015. Women with melasma, defined as irregular patches of hypermelanosis on cheeks, forehead or chin, were invited to participate in the study. Those with chronic liver disease, renal disease, psychiatric problems or other neurological disabilities, cardiovascular disease including uncontrolled hypertension, bleeding tendency or receiving anticoagulants or antiplatelet aggregation drugs, as well as pregnant women, were excluded from the study. Patients who were already taking any treatment for melasma were also excluded.

The trial followed the ethical principles of the Declaration of Helsinki and approval was obtained from the human research ethics committee of Srinakharinwirot University, Thailand. Written informed consent was obtained from all participants before their enrolment into the study. Participants were allowed to withdraw from the study at any time. The study is registered with the Thai Clinical Trial Registry with the following trial number: TCTR20140903004.

2.2. Randomization

All enrolled participants were randomly assigned into one of the two acupuncture procedure groups: 1) facial and body acupuncture; or 2) only facial acupuncture. Randomization was performed using a computerized program (GraphPad QuickCals) by a statistician who was not involved in the implementation phase of the study. The group assignment was kept in sealed opaque envelopes which were opened just before the acupuncture procedure.

2.3. Measurement of baseline characteristics

After enrollment, demographic characteristics and anthropometric data were recorded by a nursing staff. Weight was measured to the nearest 100 g using an electronic scale (Seca[®], Model 767, Hamburg, Germany). Height was measured by a height rod (Seca[®], Model 220, Hamburg, Germany). Waist circumference was measured at the midpoint between the lower costal margin and the top of the iliac crest using a non-stretch tape to the nearest millimeter. Hip circumference was measured in the standing position at the maximum circumference over the buttocks using the same tape. Body mass index (BMI) was calculated as the ratio of weight/height² [kg/m²].

Melasma severity was measured by two parameters including melasma areas and pigmentation by using digital images. Digital images of the frontal view and both lateral views of face were taken using a digital camera by a trained visual engineer. A 3-step algorithm of image processing was used to measure melasma severity. In the first step, light intensity was calibrated by using a standard object to standardize the brightness of each image. Then, melasma and normal skin pixels were discriminated based on the pixels of their image. The size of the melasma area from the accumulated area of hyperpigmented macules on the face was measured next. Finally, melasma pigmentation was calculated from the intensity of melasma pixels and was graded as per shading scales ranging from 0 (black color) to 255 (white color). Lower shading scales indicated a darker color than the higher shading scales.

2.4. Intervention

Participants in facial/body acupuncture group were needled by using disposable silver needles (0.25×25 mm) at 11 acupuncture points in the body region including Qihai (CV6), and bilateral Hegu (Ll4), Xuchai (SP10), Zusanli (ST36), Taichong (LR3) and Sanyinjiao (SP6), as shown in Fig. 1. In addition, facial acupuncture was performed using disposable silver needles (0.16×25 mm) at the rims of melasma lesion (Fig. 2). The transverse penetrating method was used in which the needle tip penetrated the skin at an angle of 15° with the needles pointing toward the center of the lesion. Participants who were assigned to facial acupuncture only were needled only at the rims of melasma lesion using the same type of needles and points as described above (Fig. 2).

Acupuncture needles at body acupuncture points were stimulated using an electric stimulator (SDZ-II model, Hwato, China) which delivered a constant current of 3 mA at 40 Hz for 30 min per session. The needles were removed after the completion of each session. Facial and body acupunctures were performed for 2 sessions per week for 8 consecutive weeks. No specific instructions



Fig. 1. Needle points used for body acupuncture: Qihai (CV6), Hegu (Ll4), Xuchai (SP10), Zusanli (ST36), Taichong (LR3) and Sanyinjiao (SP6).

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