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CLINICAL STUDY

Comparative effects of artemisia vulgaris and charcoal moxa stimulating Zhongwan (CV 12) on body temperature in healthy participants: a cross-over single-blind randomized study

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Abstract

OBJECTIVE: To evaluate the efficacy, safety, satisfaction, discomfort and patient preference of moxa cones of artemisia vulgaris and charcoal moxa.

METHODS: This comparative study of moxibustion treatment with Artemisia vulgaris and charcoal moxa cone stimulating Zhongwan (CV 12) is a cross-over single-blinded, randomized clinical trial. A total of 40 healthy subjects (24 males and 16 females) participated in this study. Two subjects dropped out of the trial. Thirty-eight subjects were treated with Artemisia vulgaris and charcoal moxa cones for 30 min in a cross-over design. After treatment, the patients underwent a 30 minute waiting period, and then the temperatures at Tanzhong (CV 17), Zhongwan (CV 12) and Guanyuan (CV 4) were measured using digital infrared thermal imaging.

RESULTS: After the use of Artemisia vulgaris moxa, the patients' body temperatures were slightly lowered at Tanzhong (CV 17), Zhongwan (CV 12) and Guanyuan (CV 4), but the changes were not statistically significant. After the use of charcoal moxa, the patients' body temperatures were somewhat increased at Zhongwan (CV 12) and Guanyuan (CV 4), but the changes were not statistically significant. After Artemisia vulgaris moxa use, the body temperature difference between Zhongwan (CV 12) and Guanyuan (CV 4) was significantly increased. After charcoal moxa use, the body temperature difference between Tanzhong (CV 17) and Zhongwan (CV 12) was

significantly decreased in males and in the whole group. This change was caused by the difference in the moxibustion type and by gender differences.

CONCLUSION: This pilot study found that moxibustion did not raise the body temperature, but temperature differences between acupoints were affected. Further large-scale randomized controlled trials are needed for the effect of moxibustion on body temperature.

Key words: Moxibustion; Point CV12 (Zhongwan); Artemisia; Body temperature; Cross-over studies; Single-blind method; Randomized controlled trial

INTRODUCTION

Moxibustion is therapeutic procedure that uses burning material to apply heat to acupoints or areas of the body surface to treat disease by regulating the function of meridians / channels and visceral organs.[1]

By warming the meridians, relieving the obstruction of collateral vessels, and regulating the *Zang-Fu* organs, moxibustion has been used to treat and prevent diseases for more than 2500 years.[2-4]

Traditionally, moxibustion has been used to treat indigestion, fatigue, cold sensation and other disorders in East and North Asia. Since 2003, an increasing number of diverse clinical trials for moxibustion have been conducted.[2] In Korea, moxibustion treatment has been widely used to prevent and treat diseases, and its use is increasing among Korean medicine practitioners.[2,3]

At present, there are different types of moxibustion based on the materials and procedures used. Mugwort leaves (*Artemisia vulgaris*) are the most commonly used material in moxibustion; they are purified and prepared to form a fine, soft moxa floss.

In Korea, many kinds of moxibustion and moxibustion apparatuses have been developed, and the sale and use of moxibustion materials are increasing. However, no studies have compared the use of different types of moxa cones. The aim of this study is to evaluate the efficacy and safety of different types of moxa cones on body temperature.

METHODS

Study design

Trial registration: ClinicalTrials.gov identifier: NCT01366456. This study was a cross-over design, single-blinded, randomized, controlled clinical trial evaluating the efficacy on body temperature and safety of burning Artemisia vulgaris and charcoal moxa cones. We chose a single-blind design because practitioners knew which kind of moxa cone was used, thus making a double-blind study impossible. To ensure the quality of this clinical trial, we used an objective endpoint (digital infrared readings) and received self-reported information from the subjects.

Inclusion and exclusion criteria

Target samples of patients were recruited from Semyung University Chungju Hospital, a traditional Korean medicine hospital. Participants who met all of the eligibility requirements were eligible for enrollment. The eligibility criteria were as follows: males or females aged between 18 and 65 years who gave their written informed consent to participate and agreed to comply with the study regulations. Patients with any of the following conditions were excluded from the study: any type of thyroid dysfunction, heart disease (heart failure, angina pectoris, and myocardial infarction), uncontrolled hypertension (SBP > 145 mm Hg or DBP > 95 mm Hg), impaired hepatic or renal functions, and diabetes mellitus. Women who were pregnant, breast feeding or were of reproductive age and not using proper contraception were also excluded.

Sample size

We had difficulties determining adequate sample size, as preliminary studies were insufficient. Therefore, we adopted a pilot study design. This clinical trial was a pilot study with a cross-over design. A total of 40 subjects were recruited, and each group had 40 subjects.

Patient characteristics

We collected data pertaining to the patients' age, sex, quality of life, and health. For quality of life and health, we used the World Health Organization-Quality of Life (WHO-QOL).

Body temperature measures

We used digital infrared thermal imaging (DITI) to measure body temperature. We measured body temperature at Tanzhong (CV 17), Zhongwan (CV 12) and Guanyuan (CV 4).

Patient satisfaction, discomfort and preference according to moxa cone type

To determine moxa preference, we asked the patients whether they preferred the first moxa, the second moxa or both. We used a numeric rating scale to rate moxa satisfaction and discomfort.

Moxa cone

Two kinds of moxa cones used that are common in clinical practice in Korea. The first was a Shingi-gu (the product's name in Korea) Artemisia vulgaris moxa cone (registered as number D101389 by Korean Food and Drug Association; Haitnim, Inc., Incheon, Korea).