

Warm needling moxibustion versus electroacupuncture for simple obesity due to yang deficiency of the spleen and kidney: a controlled clinical trial

温针灸和电针治疗脾肾阳虚型单纯性肥胖症的临床对照研究

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Abstract

Objective: To compare the therapeutic efficacy between warm needling moxibustion and electroacupuncture (EA) in the treatment of simple obesity due to yang deficiency of the spleen and kidney.

Methods: Seventy patients with simple obesity due to yang deficiency of the spleen and kidney were randomly divided into a warm needling moxibustion group and an EA group, with 35 subjects in each group. Same major acupoints were selected for the two groups, including Shuifen (CV 9), Guanyuan (CV 4), Daheng (SP 15), Shuidao (ST 28), Shousanli (LI 10), Zusanli (ST 36), Sanyinjiao (SP 6) and Taixi (KI 3). The warm needling moxibustion group received warm needling moxibustion, while the EA group received EA treatment. The interventions were performed once every other day, with 15 treatments as one course. The therapeutic efficacy, body weight and body mass index (BMI) were then observed and compared.

Results: The total effective rate in the warm needling moxibustion group was 85.7% versus 77.1% in the EA group, and the between-group difference was statistically significant ($P < 0.05$). The warm needling moxibustion was remarkably superior to the EA in weight loss and lowering BMI, both with statistical significance ($P < 0.05$, $P < 0.01$). At the three-month follow-up, the body weight and BMI further decreased in the warm needling moxibustion group (both $P < 0.05$), and the levels were lower than those in the EA group ($P < 0.05$, $P < 0.01$).

Conclusion: Warm needling moxibustion can produce reliable and consistent efficacy in the treatment of simple obesity due to yang deficiency of the spleen and kidney. Compared with EA, warm needling moxibustion shows advantage in both short-term and long-term efficacies, and thus is worth promotion in clinical practice.

Keywords: Acupuncture Therapy; Warm Needling Therapy; Electroacupuncture; Points, Lower Extremities; Points, Chest & Abdomen; Obesity; Yang Deficiency of the Spleen and Kidney

【摘要】目的: 比较温针灸与电针治疗脾肾阳虚型单纯性肥胖症的临床疗效。**方法:** 将70例脾肾阳虚型单纯性肥胖症患者随机分为温针灸组和电针组, 每组35例。两组均取水分、关元、大横、水道、手三里、足三里、三阴交和太溪为主穴, 温针灸组接受温针灸治疗, 电针组接受电针治疗。隔日治疗1次, 15次为1个疗程。一个疗程结束后, 对其临床疗效、体重及体质指数(BMI)等指标进行观察和比较。**结果:** 温针灸组总有效率为85.7%, 电针组为77.1%, 两组差异有统计学意义($P < 0.05$); 温针灸组在降低体重和BMI方面优于电针组, 组间差异均有统计学意义($P < 0.05$, $P < 0.01$)。治疗后3个月随访, 温针灸组的体重和BMI均较治疗后进一步下降(均 $P < 0.05$), 且明显低于电针组($P < 0.05$, $P < 0.01$)。**结论:** 温针灸治疗脾肾阳虚型单纯性肥胖症疗效确切、持久, 近期和远期疗效均优于电针治疗, 值得临床推广应用。

【关键词】 针刺疗法; 温针疗法; 电针; 穴位, 下肢; 穴位, 胸腹部; 肥胖; 脾肾阳虚

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In recent years, with social development and lifestyle changes, the number of obese patients is continuously

rising. Obesity not only brings inconveniences to our lives, but also increases the risk of cardiocerebrovascular diseases including hyperlipidemia, coronary heart disease and stroke. Therefore, more and more importance has been attached to obesity, and prevention and treatment of obesity have become a research focus within the medical field. A large number

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of studies on acupuncture, mostly electroacupuncture (EA), in treating obesity have been reported. Through clinical practice, we've found that various types of acupuncture based on pattern identification and treatment can produce satisfactory short-term and long-term efficacies on obesity. In this study, we compared the commonly-used EA with warm needling moxibustion in the treatment of obesity due to yang deficiency of the spleen and kidney. The report is given as follows.

1 Clinical Materials

1.1 Study design

This study was approved by the Ethical Committee of Shanghai Jiading Hospital of Traditional Chinese Medicine and followed the *Consolidated Standards of Reporting Trials* (CONSORT) and *Standards for Reporting Interventions in Clinical Trials of Acupuncture* (STRICTA) guidelines for designing and reporting controlled trials^[1-2].

1.2 Diagnostic criteria

1.2.1 Diagnosis of obesity

Obesity was diagnosed according to the *Criteria of Diagnosis and Treatment Evaluation for Obesity* revised at the fifth National Conference on Obesity Research in 1997^[3].

Overweight: The measured weight above the standard body weight, but <20%.

Mild obesity: The measured weight above the standard body weight by $\geq 20\%$, but <30%.

Moderate obesity: The measured weight above the standard body weight by $\geq 30\%$, but $\leq 50\%$.

Severe obesity: The measured weight above the standard body weight by over 50%.

The standard body weight = [Height (cm) - 100] \times 0.9;
BMI = Body weight (kg) \div Height (m)².

1.2.2 Diagnosis by pattern identification in traditional Chinese medicine

Yang deficiency of the spleen and kidney: Obesity, fatigue, soreness and weakness of low back and knees, impotence, cold limbs, a deep, wiry and weak pulse, and pale tongue with white coating. The diagnosis can be made with 2-3 or more symptoms, along with the tongue and pulse conditions.

1.3 Inclusion criteria

Consistent with the clinical manifestations of yang deficiency of the spleen and kidney; not receiving other treatments for obesity; aged between 18 and 55 years old, without gender restriction; voluntarily joined the trial and signed the informed consent form.

1.4 Exclusion criteria

Secondary obesity caused by systemic diseases, infections, neuro-endocrinologic or metabolic disorders; those with severe primary diseases; those who were

using anorexics, anabolic stimulants or tea for losing weight that might influence the result evaluation; those were not in accordance with the TCM pattern identification; ages <18 or >55 years old; those not willing to join the trial or dropped out or lost to follow-up; with severe complications occurred during the study.

1.5 Data analysis

Data were analyzed by the SPSS software version 18.0 (Chicago, Illinois, USA). The results were presented as mean \pm standard deviation ($\bar{x} \pm s$). Paired sample *t*-test and independent samples *t*-test were used for intra-group and inter-group comparisons, respectively. Counting data were compared using Chi-square test. The level of statistical significance was set at $P < 0.05$.

1.6 General data

A total of seventy subjects were recruited from the Weight-loss Clinic in the Department of Acupuncture-moxibustion, Shanghai Jiading Hospital of Traditional Chinese Medicine. They were randomly divided into two groups, with 35 cases in the warm needling moxibustion group and the other 35 cases in the EA group. During the research, three patients dropped out, including one in the warm needling moxibustion group and two in the EA group. Among the 34 patients (7 males and 27 females) in the warm needling moxibustion group, age ranged from 18 to 50 years and was averaged at (35.4 \pm 7.4) years; of the 33 patients (3 males and 30 females) in the EA group, age ranged from 23 to 55 years and was averaged at (37.4 \pm 7.7) years. There were no significant differences in the general data at baseline between the two groups (all $P > 0.05$).

2 Treatment Methods

2.1 Warm needling moxibustion group

Acupoints: Shuifen (CV 9), Guanyuan (CV 4), and bilateral Daheng (SP 15), Shuidao (ST 28), Shousanli (LI 10), Zusanli (ST 36), Sanyinjiao (SP 6) and Taixi (KI 3).

Method: Filiform needles (0.28-0.32 mm in diameter and 40-75 mm in length) were inserted 20-50 mm into the acupoints according to the degree of obesity with even reinforcing-reducing manipulation. After needling sensation was obtained, a piece of moxa stick of 15 mm in length (Hwato refined pure moxa rolls, Suzhou Medical Appliance Factory, China) was attached to the handle of the needle and ignited for warm needling moxibustion. Two pieces of moxa were used successively for each acupoint each time. The treatment was performed once every other day for 15 times as a course of treatment. After one course of treatment, the therapeutic efficacy was evaluated, and a follow-up was conducted 3 months later.

2.2 EA group

The acupoints selected in the EA group were same as those in the warm needling moxibustion group. After needling sensation was obtained, needles at Shuifen (CV 9) and Guanyuan (CV 4), and bilateral Shousanli (LI 10), Zusanli (ST 36) and Taixi (KI 3) were connected to an electric stimulator (G6805 II, Shanghai Medical Equipment Factory, China) with continuous wave at 2 Hz and a current intensity tolerable to patients. Needles at the rest acupoints were manipulated once every 10 min. The needles were retained for 40 min. The treatment course, efficacy evaluation, follow-up and observed indexes were same as those in the warm needling moxibustion group.

2.3 Assistant intervention

During the treatment, patients were not required to be on diet but recommended to have a light, balanced and regular diet, low in salt and fat and high in protein and fiber. Vegetables and fruits were recommended. Besides, the patients were suggested to do some exercises, such as one-hour jogging or fast walking.

3 Observation of Treatment Results

3.1 Efficacy evaluation criteria

The therapeutic efficacy was evaluated according to the *Criteria of Diagnosis and Treatment Evaluation for Obesity* revised at the fifth National Conference on Obesity Research in 1997 and the World Health Organization (WHO)-recommended BMI level for determining obesity in Asian populations: BMI cut-off points of 23.0-24.9 kg/m² for overweight, BMI 25.0-29.9 kg/m² for obesity grade 1, and BMI ≥30.0 kg/m² for obesity grade 2.

Recovery: Weight dropped into the range of normal weight with BMI approaching 23.0 kg/m² and no presence of symptoms.

Excellence: A decrease of more than 5 kg in body

weight and 4 kg/m² in BMI with most symptoms disappeared.

Improvement: Weight reduction between 2-5 kg and BMI decrease 2-4 kg/m² with some symptoms markedly relieved.

Failure: No changes in body weight, or a decrease of less than 2 kg in weight and 2 kg/m² in BMI with no symptoms markedly relieved.

3.2 Treatment results

3.2.1 Comparison of therapeutic efficacy

There was a significant difference in the total effective rate between the two groups ($P<0.05$), indicating that warm needling moxibustion produced a more significant efficacy than EA for simple obesity due to yang deficiency of the spleen and kidney. The three dropout cases were taken into analysis of therapeutic efficacy as failed cases (Table 1).

3.2.2 Comparison of body weight

There was no significant difference in body weight between the two groups before treatment ($P>0.05$). Body weight declined significantly in both groups after the treatment ($P<0.01$), and the decrease in body weight was more significant in the warm needling moxibustion group compared with that in the EA group ($P<0.05$). The results indicated that both methods could help lose weight of obese patients with yang deficiency of the spleen and kidney, while warm needling moxibustion produced a better short-term effect. At the three-month follow-up, there was no significant increase in body weight in the EA group, while the weight in the warm needling moxibustion group further dropped compared with the level at the end of the treatment ($P<0.05$). Besides, a significant difference was found between the two groups at the three-month follow-up ($P<0.05$), which indicated that warm needling moxibustion had a better long-term effect than EA in losing weight (Table 2).

Table 1. Comparison of therapeutic effects between the two groups (case)

Group	n	Recovery	Excellence	Improvement	Failure	Total effective rate (%)
Warm needling moxibustion	35	5	11	14	5	85.7 ¹⁾
EA	35	1	4	22	8	77.1

Note: Compared with the EA group, 1) $P<0.05$

Table 2. Comparison of body weight before and after treatment ($\bar{x} \pm s$, kg)

Group	n	Pre-treatment	Post-treatment	3-month follow-up
Warm needling moxibustion	34	76.91±12.56	68.96±11.12 ¹⁾³⁾	68.15±11.23 ²⁾³⁾
EA	33	77.64±10.97	74.47±10.42 ¹⁾	74.64±10.03

Note: Intra-group comparison with the baseline, 1) $P<0.01$; intra-group comparison with the post-treatment level, 2) $P<0.05$; compared with the EA group at the same time point, 3) $P<0.05$

3.2.3 Comparison of BMI

There was no significant difference in BMI between the two groups before treatment ($P>0.05$). BMI declined significantly in both groups after the treatment ($P<0.01$), and the decrease was more significant in the warm needling moxibustion group compared with that in the EA group ($P<0.01$). The results indicated that both methods could help reduce BMI in obese patients with yang deficiency of the spleen and kidney, while warm

needling moxibustion produced a better short-term effect. At the three-month follow-up, BMI remained at the similar level in the EA group but further dropped in the warm needling moxibustion group ($P<0.05$). Besides, a significant difference was found between the two groups at the three-month follow-up ($P<0.01$), which indicated that warm needling moxibustion had a better long-term effect than EA in reducing BMI (Table 3).

Table 3. Comparison of BMI ($\bar{x} \pm s$, kg/m²)

Group	n	Pre-treatment	Post-treatment	3-month follow-up
Warm needling moxibustion	34	28.37±2.66	25.44±2.36 ¹⁾³⁾	25.14±2.53 ²⁾³⁾
EA	33	29.46±2.52	28.26±2.48 ¹⁾	28.33±2.31

Note: Intra-group comparison with the baseline, 1) $P<0.01$; intra-group comparison with the post-treatment level, 2) $P<0.05$; compared with the EA group at the same time point, 3) $P<0.01$

4 Discussion

Simple obesity occurs when excess body fat has accumulated to an extent that it may have a negative effect on health. It is commonly caused by excessive food intake or lack of physical activity. According to TCM, contributing factors of obesity include dysfunctions of Zang-fu organs, obstructed flow of qi and blood, and disharmony between the Thoroughfare and Conception Vessels. These factors may disturb distribution of the bodily fluids and cause retention of water, dampness and phlegm in the body, resulting in obesity. By stimulating specific acupoints, acupuncture can balance yin and yang, regulate functions of the zang-fu organs, promote qi and blood circulation, unblock meridians, and thus help control the body weight.

Modern studies have found that acupuncture not only improves the indexes of obese patients including weight, BMI and waist circumference, but also reduces the visceral and subcutaneous fat, increases water in the body, and balances metabolism^[4-5]. So far, it is believed that weight control by acupuncture is achieved by favorably regulating hypothalamus^[6-7]. On one hand, by stimulating peripheral and central nerves, acupuncture promotes endocrine metabolism and increases energy consumption, so as to dissolve more extra fat; on the other hand, acupuncture can make patients take in less food by inhibiting the appetite and slowing down the digestion and absorption. Clinical evidences have shown that acupuncture can help down-regulate the fasting serum insulin, leptin, adiponectin and lipid levels, and reduce insulin resistance^[8-9]. However, gender differences have been noticed in the effects. The decrease in subcutaneous fat content is more significant in females than that in males, while the decrease in adiponectin is more significant in males^[10]. Animal studies have also confirmed that acupuncture not only can upregulate the obestatin,

leptin and insulin in hypothalamus of obese rats, but also can promote the expression of leptin receptor (OB-R) gene, increase the excitability of vagus nerve, and boost the expression of acetyl choline (ACH) in peripheral nerves^[11-13]. Moreover, acupuncture can regulate insulin receptor substrate-1 (IRS-1) in rat hypothalamus, which may be related to the effect of acupuncture on improving insulin sensitivity^[14]. In addition, acupuncture also has an effect on peripheral insulin levels in obese rats, with certain differences between genders, too^[15]. The effect on male rats is more significant than that on female rats.

Obesity can be classified into deficiency pattern and excess pattern in TCM. Excess pattern is commonly caused by phlegm and stasis due to dysfunctions of the spleen, stomach and liver, while deficiency pattern is mainly caused by retention of water and dampness when lung, spleen and kidney fail to transport and transform water and dampness. We have found that yang deficiency of the spleen and kidney is most commonly seen in obese patients with deficiency pattern in clinical practices. In the initial stage of this pattern, due to yang deficiency, spleen and stomach fail to transport and transform water and grain, making essence harder to be generated, transformed, and distributed. On the contrary, it causes phlegm and dampness to affect the spleen and stomach and spread over muscles and skin. Therefore, fat body with poor appetite and lassitude may be present. In the long term, spleen yang deficiency will cause kidney yang deficiency and result in obesity, soreness and weakness in lower back and knees, cold extremities, edema, dizziness and tinnitus, or irregular menstruation.

Studies have revealed that warm needling moxibustion can better control the body weight in obese patients with yang deficiency of the spleen and kidney, improve the levels of total cholesterol and high density lipoprotein cholesterol (HDL-C), regulate

abnormal lipid metabolism and produce a dual role of losing weight and reducing lipid^[16]. Many studies on EA treating obesity have been reported. It has been found that EA acting as insulin sensitizer can promote lipid metabolism, and remarkably reduce the waist and hip circumferences when combined with auricular acupuncture^[17-18]. However, reports on losing weight by EA are limited to obesity due to excessive heat in the stomach and intestine and spleen deficiency related dampness^[5,19-20]. Effects of EA on obesity due to yang deficiency of the spleen and kidney have been rarely reported.

Therefore, this study compared the therapeutic effects of warm needling moxibustion and EA on obesity due to yang deficiency of the spleen and kidney. We found that although both groups were treated at the same acupoints, the total effective rate was 85.7% in the warm needling moxibustion group and 77.1% in the EA group. The between-group difference was statistically significant and the warm needling moxibustion group was superior to the EA group in therapeutic effect ($P < 0.05$). Besides, compared with EA, warm needling moxibustion showed better effects in reducing weight ($P < 0.05$) and improving BMI ($P < 0.01$). At the 3-month follow-up, weight and BMI in the warm needling moxibustion group further dropped (both $P < 0.05$) and more significant long-term effects in lowering weight and BMI were seen in the warm needling moxibustion group than in the EA group ($P < 0.05$, $P < 0.01$).

Our study preliminarily showed that in terms of weight loss and BMI improvement, warm needling moxibustion was preferable to EA in treating obese patients with yang deficiency of the spleen and kidney since it showed better short-term and long-term therapeutic effects. The acupoints selected in this study are mainly for regulating the functions of the spleen and kidney. For example, Taixi (KI 3), the Yuan-Primary point of the Kidney Meridian, combined with Guanyuan (CV 4), the key point for tonifying Yuan-Primordial qi, can reinforce kidney essence, activate yang and dispel cold. Daheng (SP 15) along with Sanyinjiao (SP 6) can tonify qi to invigorate the spleen and unblock water passage. Shuidao (ST 28) and Zusanli (ST 36) can simultaneously regulate spleen and stomach to unblock water passage. Shuifen (CV 9) acts to regulate the waterways to drain water and dampness, while Shousanli (LI 10) can unblock meridians, clear intestines and promote enteric function. Warm needling moxibustion combines both needling and moxibustion, that's probably why it produced better therapeutic effects with same acupoints selected. Acupuncture works better in dredging meridians and promoting qi and blood circulation, while moxibustion excels in warming and reinforcing. Combining these two therapies can play the role of reinforcement and

elimination at the same time. For obese patients with yang deficiency of the spleen and kidney, warm needling moxibustion targets both root cause and symptoms, since it can not only reinforce spleen yang and kidney yang, but also drain retained water-dampness. Besides the marked effects in reducing weight and improving other symptoms, also acted better than EA in the long run according to the 3-month follow-up. It was reported that warm needling moxibustion could improve the functions of autonomic nerves and relevant indexes of fat-insulin axis including fasting blood glucose, fasting insulin and insulin sensitivity index. This indicates that warm needling moxibustion may improve the abnormal lipid metabolism in obese patients by regulating fat-insulin axis and functions of autonomic nerves^[21]. Therefore, it is important to select different acupuncture therapies for different patterns of obesity to maximize the therapeutic efficacy.

Conflict of Interest

The authors declared that there was no potential conflict of interest in this article.

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Statement of Informed Consent

Informed consent was obtained from all individual participants included in this study.

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