Balanced appetite regulation of Shu-mu acupoint catgut embedding in abdominal obesity: secondary analysis of a randomized clinical trial

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Research Article

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Abstract

Objective

To explore the effect of Shu-mu acupoint catgut embedding (ACE) on appetite in abdominal obesity (AO) patients.

Methods

This is a secondary analysis of a multicenter, double-blind, randomized controlled trial. Which was conducted in China between July 2018 and June 2022. Eighty AO participants who received Shu-mu ACE intervention were divided into moderate appetite (MA) and strong appetite (SA) subgroups, according to the appetite at baseline. While 79 AO participants who received NACE intervention were also divided into MA and SA subgroups. All participants were given a 12-week actual intervention period and a 4-week follow-up. Appetite was assessed at baseline and after 6, 12 and 16 weeks.

Results

71 participants who received Shu-mu ACE and 74 participants who received NACE were included in the final analysis. After the Shu-mu ACE, at 16 weeks, the appetite of the SA subgroup decreased to the same level as the MA subgroup ($p > 0.05$). All 36 AO participants' appetite had decreased in the SA subgroup. While in the MA subgroup, 22 AO participants had a decrease in appetite, 7 increased, 4 had no change, and 2 had appetite data missing. During the NACE intervention and follow-up, the appetite of the SA subgroup was always higher than the MA subgroup ($p < 0.01$). In the SA subgroup, 32 decreased, 4 increased, 5 had no change, and 2 appetite data missing. While in the MA subgroup, 14 decreased, 7 increased, and 10 had no change.

Conclusions

Catgut embedding at Shu-mu acupoint could regulate the appetite of AO to the normal level, rather than dramatically inhibit the appetite.

Trial registration This study was registered in the Chinese Clinical Trial Registry (registration number: ChiCTR1800016947). 4 July 2018; https://www.chictr.org.cn/showproj.aspx?proj=28782

Introduction

Abdominal obesity (AO) is a major type of obesity characterized by abdominal fat accumulation. The AO rate in China is about 29.1% and the prevalence increased rapidly [1–3]. The regulation of appetite is
considered an important way the control fat accumulation [4]. Keeping appetite at a normal level is a reasonable and healthy way to treat AO.

Acupoint catgut embedding (ACE) is a special acupuncture therapy based on the meridian and acupoint theory of Traditional Chinese Medicine (TCM). Stimulation of the acupoints could maintain the stability of visceral function [5]. Shu-mu acupoint is the specific point where the Qi of viscera gathers in the chest and back. Our team’s previous research has shown that Shu-mu ACE could reduce waist circumference, body weight, and appetite in AO patients [6]. In this secondary analysis of the multicenter, randomized, double-blind, controlled study, we examined the efficacy of Shu-mu ACE for AO patients with different appetite from another angle. Exploring whether Shu-mu ACE has a dramatic inhibition effect on different appetite.

**Method**

**Study design**

The foregone study was undertaken between July 2018 and March 2020, without the gender requirement ($n = 137$). With the supplemented female samples ($n = 22$) between April 2020 and June 2022. Eighty AO patients received Shu-mu ACE intervention and 79 AO participants received non-acupoints catgut embedding (NACE) intervention. Finally, 71 participants (MA subgroup 35, SA subgroup 36) who received Shu-mu ACE and 74 participants (MA subgroup 31, SA subgroup 43) who received NACE were included in this secondary analysis. Every participant received a 12-week intervention period and a 4-week follow-up. Appetite was measured at baseline, 6, 12, and 16 weeks after the intervention. Possible adverse events were carefully monitored from 1 to 16 weeks. The flow chart was shown in Fig. 1.

This study was registered in Chinese Clinical Trial Registry (ChiCTR1800016947). Ethics was approved by the Hospital Ethics Committee of Sports Trauma Specialist Hospital of Yunnan Province (2018CK-001). All participants were fully informed and signed written informed consent forms.

**Participant**

All participants were recruited from the outpatient department in 4 Chinese clinical centers: Second Affiliated Hospital of Yunnan University of Chinese Medicine, Kunming Hospital of Traditional Chinese Medicine, Sports Trauma Specialist Hospital of Yunnan Province and ShengAi Hospital of Traditional Chinese Medicine.

According to the diagnostic criteria of AO by Chinese Medical Association, waist circumference (WC) is used to diagnose AO. In this study, the main inclusion criteria was: WC $\geq 90$ cm in males and $\geq 85$ cm in females. The measurement method of WC: standing position, the circumference of the waist was measured at the horizontal position of the lower costal edge of the midaxillary line and the midpoint of the iliac crest line [7]. The second inclusion criteria included body mass index (BMI) $\geq 24$ kg/m$^2$, aged between 18 and 60, and simply overweight or obese [8].
The exclusion criteria were: WC < 90 cm in males and < 85 cm in females, BMI < 24 kg/m²; secondary obesity caused by medication or endocrine disease; pregnancy, lactation and childbirth within the past 6 months; chronic obstructive pulmonary disease, coronary heart disease, liver cirrhosis, nephritis and other serious organ diseases; participants with severe mental and neurological diseases; hypertension without effectively controlled; allergic to alcohol or catgut; received weight loss treatment within past 3 months.

Randomization and blinding

The randomization was computer generated by the Clinical Research Center of Yunnan University of Chinese Medicine. Stratified randomization was performed in the 4 clinical centers. Opaque envelopes with a random number were managed by an independent coordinator. Participants, inspector and analyst were all blinded to the allocation. The acupuncturist performed the catgut embedding after the assistant lays the drapes. Therefore, the acupuncturists were also blinded to the allocation.

Interventions

Participants received catgut embedding intervention every 2 weeks for 6 sessions. Catgut embedding manipulations were performed by an acupuncturist with national medical qualifications. The acupoints of the Shu-mu ACE group were Zhongwan (CV12), Tianshu (ST25), Zhangmen (LR13), Pishu (BL20), Weishu (BL21) and Dachangshu (BL25). The non-acupoints were beside the acupoints, which were labeled NA1 (1.5 cun to the left of the Zhongwan), NA2 (1 cun outward from the Tianshu), NA3 (2 cun forward from the Zhangmen), NA4 (2 cun outward from the Pishu), NA5 (2 cun outward from the Weishu) and NA6 (2 cun outward from the Dachangshu).

The assistant marked the position of acupoints and non-acupoints, conventionally disinfected the skin of the operation area, and then layed the sterile drapes. Took the sterile medical catgut with a length of 1-2 cm (the length depends on the location of the acupoint), placed it on the front end of the trocar, then connected the needle core, lifted the partial skin with the thumb and forefinger of one hand, pierced the needle with another hand. When the piercing reached the desired depth, implanted the catgut in the subcutaneous tissue or muscle layer. After the needle was removed, pressed the needle hole with a dry cotton ball for half a minute to stop bleeding, and then pasted a bandage to protect the needle hole. Participants were requested not to bathe for 24 hours and keep the embedding area dry.

The thread-embedded needle was 8# disposable needle (Jiangxi Glance Medical Equipment Co. Ltd. Production, Nanchang, China). The medical catgut was an absorbable collagen line with the specification of 2 – 0, 2 cm*20 length (Jiangxi Longteng Biotechnology co., LTD, Nanchang, China).

Participants’ diet and physical activity were not restricted during the whole course, they could continue their lifestyle.

Outcome measures

Outcome measurements were performed at baseline, 6 and 12 weeks in the intervention period, and 16 weeks in follow-up. No eating or drinking for 2 hours before the test. The outcome of this secondary
analysis was the visual analogue scale (VAS) of appetite. Assessed appetite by VAS as reported in the article [9]. As shown in Fig. 2, no appetite and minimal intake (0 score). Slight appetite and small amount of intake (1–3 score). Moderate appetite and moderate intake (4–6 score). Strong appetite and large intake (7–10 score).

Statistical analysis

All data were analyzed by SPSS (vers 28.0, SPSS Institute, Chicago, IL, USA) and GraphPad Prism (vers 7.0, GraphPad Software, San Diego, CA, USA). The outcomes described and baseline characteristics were based on the intention-to-treat (ITT) population, which included participants who have received the whole intervention. Continuous data were presented as the mean and standard deviation (SD). Categorical variables were described as numbers and percentages. As the missing data were all in follow-up, the last observation was carried forward and the expectation maximization method was not suitable. Therefore, the missing data was disposed by listwise deletion. The significance level for the statistical analysis was 5% with 2-tailed testing.

Normality of continuous variables was determined by Shapiro-Wilk test, Kolmogorov-Smirnov test. Homogeneity of continuous variables was determined by F test. Independent-Sample t-test was used when compared between every two groups. One-way ANOVA test was used to compare the repeated measurements (≥ 3) within the group. The $\chi^2$ test was performed to evaluate the significance of the difference for the categorical data.

Results

Participants and baseline characteristics

Approximately 600 potential people were invited. After the initial screening, 159 participants (80 received Shu-mu ACE and 79 received NACE) were submitted to the randomized process. However, a total of 71 participants (MA subgroup 35, SA subgroup 36) who received Shu-mu ACE and 74 participants (MA subgroup 31, SA subgroup 43) who received NACE were included in the ITT population (Fig. 1). During all interventions phases, 159 participants (100%) completed 6 treatments and 3 tests. Noted that 3 participants were unwilling to undergo follow-up. During the follow-up test, 1 participant had an emergency and failed to complete the measure. Meanwhile, the recruiters mistakenly included 13 participants who were abdominal pre-obesity. The baseline characteristics were shown in Table 1.
Table 1
Baseline characteristics of 145 participants included in the ITT analysis

<table>
<thead>
<tr>
<th>Baseline Characteristics</th>
<th>Shu-mu ACE (n = 71)</th>
<th>NACE (n = 74)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>MA (n = 35)</td>
<td>SA (n = 36)</td>
</tr>
<tr>
<td>Women, No. (%)</td>
<td>31 (88.57%)</td>
<td>27 (75.00%)</td>
</tr>
<tr>
<td></td>
<td>58 (81.69%)</td>
<td>65 (87.84%)</td>
</tr>
<tr>
<td>Age, mean (SD), y</td>
<td>36.77 (11.04)</td>
<td>34.17 (9.44)</td>
</tr>
<tr>
<td></td>
<td>35.45 (10.27)</td>
<td>35.49 (8.74)</td>
</tr>
<tr>
<td>Appetite, mean (SD)</td>
<td>5.57 (0.78)</td>
<td>7.86 (0.68)</td>
</tr>
<tr>
<td></td>
<td>6.73 (1.36)</td>
<td>6.96 (1.58)</td>
</tr>
</tbody>
</table>

Appetite outcomes

For the participant who received *Shu-mu* ACE intervention. At baseline and 6 weeks, the appetite of the SA subgroup was significantly higher than the MA subgroup \((p < 0.01)\). At 12 weeks, the appetite of the SA subgroup was still higher than the MA subgroup \((p < 0.05)\). At 16 weeks, the appetite of the SA subgroup showed no significant difference from the MA subgroup \((p > 0.05)\). During intervention and follow-up, the appetite \((7.86 \pm 0.68)\) of the SA subgroup significantly decreased to the normal level \((5.00 \pm 0.72)\). All participants’ appetite\((100\%)\) in the SA subgroup had decreased. Though the appetite \((5.57 \pm 0.78)\) of the MA subgroup has also decreased \((4.82 \pm 1.24)\). The appetite was still at a normal level. What’s more, in a total of 35 participants, 22 participants \((62.86\%)\) had a slight decrease, 7 participants’ appetite increased \((20.00\%)\), 4 had no change \((11.43\%)\), and 2 had appetite data missing. The results were shown in Fig. 3 and Table 2.

Table 2
Changes in appetite of AO participants between 16 week and baseline

<table>
<thead>
<tr>
<th>Intervention</th>
<th>Subgroup</th>
<th>Decreased</th>
<th>Increased</th>
<th>No Change</th>
<th>Data Missing</th>
<th>Decreased Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>Shu-mu</em> ACE (n = 71)</td>
<td>MA (n = 35)</td>
<td>22</td>
<td>7</td>
<td>4</td>
<td>2</td>
<td>62.86%</td>
</tr>
<tr>
<td></td>
<td>SA (n = 36)</td>
<td>36</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>100.00%</td>
</tr>
<tr>
<td>NACE (n = 74)</td>
<td>MA (n = 31)</td>
<td>14</td>
<td>7</td>
<td>10</td>
<td>0</td>
<td>45.16%</td>
</tr>
<tr>
<td></td>
<td>SA (n = 43)</td>
<td>32</td>
<td>4</td>
<td>5</td>
<td>2</td>
<td>74.42%</td>
</tr>
</tbody>
</table>

For the participant who received NACE intervention. During the whole course, the appetite of the SA subgroup was always higher than the MA subgroup \((p < 0.01)\). In the SA subgroup, 32 AO participants
had a decrease in appetite (74.42%), 4 slightly increased (9.30%), 5 had no change (11.63), and 2 were appetite data missing. The proportion of participants with decreased appetite was significantly lower than that of Shu-mu ACE ($p < 0.01$). For the MA subgroup, 14 participants (45.16%) had a slight decrease in appetite, 7 participants’ appetite increased (22.58%), and 10 had no change (32.26%). The proportion of participants with decreased appetite was not significantly different from the Shu-mu ACE ($p > 0.05$).

**Conclusion**

Catgut embedding at Shu-mu acupoint could regulate the viscera function and balance appetite to the normal level of AO. Rather than dramatically inhibiting the appetite. Catgut embedding at non-acupoint could not stably regulate the appetite of AO.

**Declarations**

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**Author Contributions** TPG and FRL designed this trial. CHX reviewed the ethics of the trial. QFL, GYZH, XMP, XT and RRZ recruiting participants. XHZ managed the random numbers and kept them blind to participants, inspectors, and analysts. QFL, SWZ and TPG performed the treatment. RY and LL detected related indicators. QFL analyzed the data. XHZ and TPG conducted this manuscript. All authors reviewed the article.

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**Availability of data and materials** Data will be available upon request from the corresponding author.

**Conflict of Interest** The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

**References**


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Figures
Figure 1

Flowchart of the screening, enrollment, randomization, and follow-up.
Figure 2

Visual analogue scale (VAS) of appetite.

In the assessment of appetite, integer was taken.

Figure 3

Appetite during the treatment and follow-up.
Data were presented as mean (SD). Independent-Sample t-test was used when compared between every two groups. One-way ANOVA test was used to compare the repeated measurements within the group. 

**p<0.01, *p<0.05.