Effect of Needling at CV-12 (Zhongwan) on Blood Glucose Levels in Healthy Volunteers: A Pilot Randomized Placebo Controlled Trial

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KEYWORDS
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Abstract

Introduction: Acupuncture, a key part of traditional Chinese medicine, is used to relieve symptoms of diabetes mellitus. The aim of this study was to evaluate the effect of needling CV-12 (Zhongwan) on blood glucose levels in healthy volunteers.

Materials and methods: Thirty-six individuals were recruited and randomized into either the acupuncture group or the placebo control group. The participants in the acupuncture group were needled at CV-12 (4 cun above the center of the umbilicus), and those in the placebo control group were needled at a nonexisting "sham" point on the right side of the abdomen (1 cun beside the CV-12)—a nonacupuncture point. For both groups, the needle was retained for 20 minutes without stimulation. Assessments were performed prior to and after the intervention. Statistical analysis was performed using the Statistical Package for the Social Sciences, version 16.

Results: The result of this study showed a mild reduction in random blood glucose (RBG) levels in the acupuncture group and a mild increase in RBG levels in the placebo control group. However, these changes were not statistically significant both within and between groups.
1. Introduction

Diabetes is a major public health problem that is approaching epidemic proportions globally. The number of people with diabetes is likely to increase up to 380 million by 2025. Almost 80% of total adults with diabetes are from developing countries. India leads the global top 10 countries in terms of the highest number of people with diabetes, and there is a growing incidence of diabetes at a younger age [1].

Acupuncture at CV-12 (Zhongwan) has been widely used in traditional Chinese medicine to relieve symptoms of diabetes. Previous studies using electroacupuncture on only CV-12 [2] and combining this with CV-4 (Guanyuan) [3,4], SP-6 (Sanyinjiao), and ST-36 (Houxi) have produced a hypoglycemic effect [2-4] with normalized insulin sensitivity, ameliorating both insulin resistance and hyperinsulinemia [3] in diabetic rats.

In a human study, CV-12—in combination with acupuncture points such as CV-4, CV-6 (Qihai), CV-10 (Xiaowan), ST-24 (Huaroumen), ST-25 (Tianshu), TE-5 (Wailing), SP-15 (Daheng), and KI-13 (Qixue)—was shown to decrease blood glucose levels and improve insulin resistance with no adverse effects in obese Type 2 diabetic volunteers [5].

Other studies have focused on single needling at CV-12 [2], ST-36 [6], BL20 (Pishu) [7], and GB 26 (Daimai) [8] in a rat model; however, there is lack of studies on human volunteers. Hence, the aim of this study aims to evaluate the effect of single point acupuncture at CV-12 on blood glucose levels in healthy human volunteers.

2. Materials and methods

2.1. Participants

A total of 36 healthy volunteers whose ages ranged from 18 years to 24 years were recruited from a residential college based on the following inclusion and exclusion criteria. The inclusion criteria called for male and female volunteers who were 18 years and above, and were willing to participate in the study. The exclusion criteria were as follows: individuals with a history of any systemic and mental illness, regular use of medication for any diseases, needle phobia, chronic smoking, and alcoholism. The study protocol was approved by the institutional ethics committee, and a written informed consent was obtained from each participant.

2.2. Study design

This is a pilot randomized placebo-controlled trial, in which all participants were randomly assigned into either the acupuncture group or the placebo control group. The acupuncture group received needling at CV-12 and the placebo control group received needling at a non-acupuncture point for 20 minutes. Data assessment was performed prior to and after the intervention.

2.3. Randomization

All participants were allotted with random numbers. The first volunteer was allocated to a group on the basis of a flip of a coin, then the next volunteer was assigned to the opposite group, in a randomization ratio of 1:1. Thus, all members of the group had an equal chance to be in either group. This randomization was performed by one of the authors, who was involved in intervention but was not involved in any part of the investigation.

2.4. Blinding/masking

All participants were blind to the acupuncture (CV-12) and the placebo control points. The investigator who assessed the blood glucose was blind to the acupuncture and placebo control groups.

2.5. Assessments

2.5.1. Random blood glucose

The random blood glucose (RBG) level was assessed between 10:30 and 11:30 a.m. using a portable ACCU-CHEK, Performa Nano machine (Roche Diagnostics India Pvt. Ltd, Mumbai, India). Assessments were performed prior to and after the intervention for both groups.

2.6. Intervention

2.6.1. Acupuncture group

The participants received traditional Chinese medicine-style of acupuncture. Needling was performed at CV-12 (4 cun above the center of the umbilicus) [9] at a depth of 0.5 cun. The participants were informed about the procedure, sensations of needle insertion, and response sought. The needle was left out without any stimulation. We used 0.5-cun filiform locally manufactured cupper needle with 0.38 mm diameter and 13 mm length. The participants received only one session of acupuncture for a duration of 20 minutes. The participants did not receive any treatments other than acupuncture. Needling was administered by one of the authors who is institutionally qualified with 2 years’ experience in clinical acupuncture.

2.6.2. Placebo control group

The participants in this group received needling in the right side of the abdomen 1 cun lateral to CV-12 where there is no known acupuncture point.

Conclusion: The result of this study suggests that although 20 minutes of needling at CV-12 without stimulation produced a mild reduction in RBG levels in healthy volunteers, it did not produce a statistically significant result.
2.7. Data analysis

All data were checked for normality using Kolmogorov–Smirnov and Shapiro–Wilk tests. Statistical analysis was performed using Student paired t test (within groups) and analysis of variance (between groups) was carried out using Statistical Package for the Social Sciences (SPSS) for Windows, Version 16.0, Chicago, SPSS Inc.

3. Results

Of 41 volunteers, five did not meet the inclusion criteria and were subsequently excluded from the study. All recruited participants (n = 36) were randomly divided into either the acupuncture (n = 18) or the placebo control group (n = 18). Needling was performed at CV-12 and at the right side of the abdomen 1 cun lateral to CV-12 in the acupuncture and placebo control groups, respectively. Baseline and posttest assessments were done prior to and after the intervention. Demographic (Table 1) and the baseline blood glucose levels (Fig. 1) were comparable, and there were no significant changes between the groups.

Even though the result of this present study showed mild reduction in RBG levels in the acupuncture group and mild increase in the placebo control group, these changes were not statistically significant both within and between groups (Fig. 1).

4. Discussion

CV-12 is known as the stomach control point in Korean medicine and is located on the abdominal wall associated with the pancreas. Although it is located on the Conception Vessel Meridian, it is considered a therapeutic point for diseases of the digestive organs such as the stomach, pancreas, and spleen [10]. For example, electric stimulation at the CV-12 was used for treatment of diabetic rats [2,10].

The results of this present study showed that a 20-minute single session needling at CV-12 acupuncture point without any stimulation (manual or electrical) produced a mild reduction in RBG levels in healthy volunteers. At the same time a 20-minutes single session of needling at the placebo control point produced a mild increase in RBG levels in healthy individuals. However, these changes were not statistically significant.

Only one session was administered on CV-12 to check for the immediate effect on RBG. This may not be sufficient to produce significant changes. Needling was performed without stimulation, however, including either manual, electrical, laser, or catgut embedding stimulation, which might have produced a more significant effect in reducing RBG. It should be noted that in previous studies on electroacupuncture at CV-12 alone in diabetic rats [2] and in combination with other acupuncture points in diabetic rats [3,4] and human studies [5], laser irradiation on CV-12 along with other points in metabolic syndrome [9], and catgut embedding in CV-12 along with other acupuncture points in diabetic rats [11] have been shown to reduce blood glucose [2–5,11] and fasting insulin [9,11].

As healthy individuals have normal physiological functions and do not have abnormally elevated blood glucose/reduced insulin levels, CV-12 might have not influenced the blood glucose levels. In previous studies, the hypoglycemic effect of CV-12 alone [2] and in combination with other acupuncture points were reported mainly in diabetic rats [3,4,11], and in diabetic patients but not in healthy individuals [5]. Hence, we expect needling at CV-12 to be effective in participants with high blood glucose levels; however, this needs to be confirmed in further studies.

4.1. Strength of the study

This is the first randomized placebo controlled study to evaluate the effect of CV-12 on RBG levels in healthy volunteers. Both the participants and the investigator were blind to the acupuncture and placebo control groups.

4.2. Limitations of this study

Sample size was not calculated based on the previous study. The present study evaluated only the immediate effect without stimulation and did not evaluate its short-term or long-term effect with or without stimulation. Assessment of variables such as fasting blood glucose, postprandial blood

<table>
<thead>
<tr>
<th>Variables</th>
<th>Acupuncture group</th>
<th>Placebo control group</th>
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<tbody>
<tr>
<td>Age (y)</td>
<td>19.61 ± 1.975</td>
<td>19.22 ± 1.517</td>
</tr>
<tr>
<td>Sex</td>
<td>9 males/9 females</td>
<td>9 males/9 females</td>
</tr>
<tr>
<td>Height (cm)</td>
<td>161.78 ± 11.855</td>
<td>164.00 ± 9.628</td>
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<tr>
<td>Weight (kg)</td>
<td>54.94 ± 8.003</td>
<td>56.28 ± 8.372</td>
</tr>
<tr>
<td>Body mass index (kg/m²)</td>
<td>21.40 ± 3.520</td>
<td>20.90 ± 2.288</td>
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All values are expressed as mean ± standard deviation, except for values of sex.
glucose, glycosylated hemoglobin, and insulin levels was not performed. Hence, long-term studies with either manual or electric stimulation are required in a larger sample size, and more variables such as fasting blood glucose, postprandial blood glucose, HbA1C, and insulin levels should be measured in order to better understand the effect of CV-12 on blood glucose levels.

5. Conclusion

The result of this present study suggests that 20 minutes of needling at CV-12 without stimulation produces a mild reduction in RBG levels in healthy volunteers; however, it did not produce a statistically significant result.

Disclosure statement

The authors declare that they have no conflicts of interest and no financial interests related to the material of this manuscript.

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