Effect of stimulating acupoint Guanyuan (CV 4) on lower back pain by burning moxa heat for different time lengths: a randomized controlled clinical trial

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Abstract

OBJECTIVE: To investigate the effect of different heat-stimulating time lengths on lower back pain.

METHODS: Forty participants were randomly assigned to four groups of various heating time lengths. The short heating time length group (SL), moderate heating time length group (ML), and long heating time length group (LL) respectively received 15, 30, and 60 min of moxibustion therapy stimulating the acupoint Guanyuan (CV 4). The conventional acupuncture group (CA) received needle acupuncture treatment as a control group. The participants were treated continuously over a 2-week treatment period for a total of 10 sessions, with five sessions given per week. Participants were assessed weekly by blinded assessors, using the visual analogue scale (VAS) and Roland Morris Questionnaire (RMQ).

RESULTS: The VAS and RMQ scores reduced in all four groups during treatment. There were significant differences in VAS scores ($P < 0.01$) and RMQ scores ($P < 0.01$) between before treatment and after 2 weeks of treatment in the LL group. After treatment, the LL group reported significantly lower VAS scores compared with the CA group, ML group, and SL group ($P < 0.05$).

CONCLUSION: The long and moderate lengths of heat-stimulating time of 30 and 60 min may be more effective for relieving lower back pain than that of short stimulating time lengths.

Key words: Moxibustion; Burning moxa; Heating time length; Acupuncture; Lower back pain; Guanyuan (CV 4); Randomized controlled trials

INTRODUCTION

Lower back pain (LBP) is one of the most prevalent chronic spine diseases. Recent data show that 70%-80% of the population suffers from LBP at least
once in their life. LBP arises from various physical and psychosocial problems and may have a significant effect on quality of life by limiting emotional, social, and physical function. Patients with LBP incur substantial health care expenses, with approximately $26 billion used to treat LBP annually. LBP also leads to a reduction in workforce in many countries. Nonsteroidal anti-inflammatory drugs and physical therapy are commonly used to treat LBP, but some drugs are avoided because of various side effects. When results from drugs and physical therapy are not satisfactory, many patients seek help from complementary therapy. Two widely used complementary therapies are acupuncture and moxibustion. Acupuncture is usually adopted to treat patients with LBP; it seems to be a clinically effective treatment for acute and chronic LBP, and a considerable amount of research confirms its role in suppressing pain. Several studies report that moxibustion therapy, acupoints stimulated with heat produced by burning moxa, is also effective for LBP. It has been found to be cheaper and safer than acupuncture. Moxibustion uses heat stimulation at various temperature levels, which depends on the length of heat stimulation. Previous studies have not explained the effect of the heat-stimulating time length on analgesic results. Therefore, our trial aims to evaluate the effect of different heating time lengths on LBP.

**METHODS**

**Participants**

Participants were recruited using advertising in newspapers, posters, and on the internet in the community and the General Hospital of Ningxia Medical University. After a simple outpatient screening, participants attended the hospital to have the study processes explained. If participants agreed to all processes, they were asked to sign a consent form and were enrolled in the trial. The inclusion criteria for this trial were: (a) age from 18 to 70 years old; (b) the course of LBP ≥ 6 months; (c) visual analogue scale (VAS) scores of participants ≥ 4 (moderate to severe pain); (d) no spinal surgery within the previous 12 months; and (e) no acupuncture or moxibustion treatment for LBP in the previous 3 months. Exclusion criteria were: (a) infectious diseases, tuberculosis, and rheumatic diseases; (b) other serious diseases such as mental disorders, cancer, myocardial infarction, and stroke; (c) radicular pain indicative of nerve root compression; (d) participants diagnosed with severe spinal stenosis, spondylolisthesis, or fibromyalgia; (e) pregnancy diabetes; and (f) physical or laboratory examination determined that participants were not suitable for our study. Participants were instructed to accept acupuncture or moxibustion therapy for pain control. The use of nonsteroidal anti-inflammatory drugs or physical therapy was monitored and recorded by the researchers at every visit, and participants using these modalities were analysed separately.

A total of 62 participants who suffered from LBP passed the outpatient screening. Twelve patients were then excluded either because they did not consent to the study or they had been treated using acupuncture and moxibustion in the previous 3 months. Forty participants who met all of the inclusion criteria were randomly divided into four groups and began their respective treatments.

**Study design**

This was a randomized clinical trial, in which the assessors were blinded. Forty participants were included in the study during the period from May 2012 to May 2013 at the General Hospital of Ningxia Medical University in China. These participants were assigned according to a random number table into four groups: short heating time length group (SL), moderate heating time length group (ML), long heating time length group (LL), and conventional acupuncture group (CA). Outcome assessment and statistical analysis were performed by professionals who did not participate in the treatment and who were blinded to the patient assignment in each group. This study was approved by the Ethics Committee of the General Hospital of Ningxia Medical University. If participants agreed to all processes, they were asked to sign a consent form and were enrolled in the trial.

**Treatments**

Moxibustion treatment was carried out by certified acupuncturists who had ≥ 5 years’ clinical experience in the General Hospital of Ningxia Medical University. In the three moxibustion groups, the 70 mm (length) × 60 mm (width) × 80 mm (height) single-hole moxibustion boxes (Hanyi Moxa, Nanyang, China) and 21 mm (diameter) × 200 mm (length) moxa sticks (Hanyi Moxa, Nanyang, China) were used. Acupuncturists placed participants in a comfortable supine position for treatments in all three moxibustion groups. Treatment rooms were kept well ventilated and the ambient temperature was 25-29 °C.

In the three moxibustion groups, a moxa stick was lit by the acupuncturist and inserted into a single-hole moxibustion box. The moxibustion box was placed on Guangyuan (CV 4) with the end of the ignited moxa stick that moved down 2 cm every 10 min to achieve persistent heat stimulation. Participants in the SL, ML, and LL groups respectively received 15, 30, and 60 min of moxibustion therapy on Guangyuan (CV 4). The participants were treated over a 2-week treatment period for a total of 10 sessions; five sessions were given per week with an interval of 2 days between each session. If participants in any of the SL, ML, and ML groups felt a moxibustion sensation (De QI), the acupuncturist recorded the time and type of its occurrence.
Conventional acupuncture group
Participants in the conventional acupuncture group (CA) had acupuncture treatment at selected points according to Traditional Chinese Medicine diagnosis. The selected points have been extensively used to treat LBP: Shenshu (BL 23), Dachangshu (BL 25), Mingmen (GV 4), Yaoshu (GV 2), Weizhong (BL 40), and Kunlun (BL 60). Acupuncture was carried out by certified acupuncture doctors who had ≥ 5 years’ clinical experience in the General Hospital of Ningxia Medical University. Acupuncture doctors placed participants in a comfortable prone position for treatments. After sterilizing the skin, disposable stainless steel needles (0.3 mm × 40 mm; Huatuo Acupuncture, Suzhou, Jiangsu, China) were inserted 1-1.5 cm, until the needle could be vertically fixed in the skin. Acupuncture sensation (De Qi) was achieved in the acupuncture treatments, through acupuncture needle manipulation of lifting and thrusting. After retaining the needles for 30 min, all needles were taken out with a sterile cotton swab to avoid bleeding. The participants were treated continuously over a 2-week period for a total of 10 sessions; five sessions were given per week with an interval of 2 days between each session.

Evaluation
The primary outcome measurement in this trial was pain intensity. Before treatment, the standing participants were instructed to adopt the posture that produced the worst pain, and then use their index finger to indicate the degree of pain on a scale from 0 (absence of pain) to 100 mm (the worst pain imaginable) on the 10-cm VAS. Researchers recorded VAS scores and the posture that produced the worst pain. VAS scores were measured subsequently at the end of the first and second week while participants again adopted their most painful posture. The secondary outcome measurement in this trial was exercise limitation caused by LBP. The exercise limitation was assessed by the roland morris questionnaire (RMQ), range 0-24 points, with the worst condition being 24. The RMQ is composed of 24 questions, each with two possible responses. The RMQ scores were assessed before the first treatment and subsequently 1 and 2 weeks after the first treatment.

Statistical analysis
Data were processed with SPSS 11.5 (International Business Machines Corporation, Armonk, NY, USA). P values less than 0.05 were considered statistically significant. The measurement data were expressed as mean ± standard deviation (x ± s). Analysis of variance was performed to explore the differences among the four groups. The Chi-squared test was used in categorical variables.

RESULTS
Out of 40 participants, there were 18 males and 22 females, with ages ranging from 18 to 70 years. There were no differences between the four groups at baseline age, gender, duration, pain intensity level (VAS), and exercise limitation (RMQ) status (Table 1). The mean baseline score for the VAS was 67.4, indicating a moderate pain intensity level of LBP.

Two participants in the CA group, one participant in the LL group, one participant in the ML group, and one participant in the SL group dropped out as they accepted additional treatments that were prohibited in our trial. One participant in the SL group halted study participation because of deterioration of symptoms. Another participant in the ML group dropped out for unknown reasons. The total dropout rate was 17.5%, and no statistical differences in dropout rate were found between the four groups. The statistics and analyses were carried out on the 33 participants who accomplished the full course of the trial and provided the required information (Figure 1).

Adverse events
In the ML group, one participant had mild diarrhoea on the fifth day of treatment. This alleviated spontaneously after 2 days with no special treatment. In other groups, there were no adverse reactions reported. There were no participants who dropped out of the trial because of adverse events. Adverse events were monitored and recorded by the researchers at every visit.

Pain intensity scores (VAS)
Changes in VAS scores before and after the interven-

<table>
<thead>
<tr>
<th>Item</th>
<th>SL (n = 8)</th>
<th>ML (n = 8)</th>
<th>LL (n = 8)</th>
<th>CA (n = 9)</th>
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</thead>
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<tr>
<td>Age (years)</td>
<td>42.6±8.5</td>
<td>44.2±5.6</td>
<td>43.4±6.3</td>
<td>41.9±4.8</td>
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<tr>
<td>Sex [n (%)]</td>
<td>Male</td>
<td>3 (37.5)</td>
<td>4 (50.0)</td>
<td>4 (50.0)</td>
</tr>
<tr>
<td></td>
<td>Female</td>
<td>5 (62.5)</td>
<td>4 (50.0)</td>
<td>4 (50.0)</td>
</tr>
<tr>
<td>Duration</td>
<td>5.2±1.2</td>
<td>4.8±0.8</td>
<td>4.9±1.1</td>
<td>4.8±0.3</td>
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<tr>
<td>VAS score</td>
<td>65.7±8.4</td>
<td>67.3±11.7</td>
<td>66.5±9.3</td>
<td>68.1±11.7</td>
</tr>
<tr>
<td>RMQ score</td>
<td>14.4±2.2</td>
<td>13.8±3.1</td>
<td>15.1±1.8</td>
<td>14.1±1.5</td>
</tr>
</tbody>
</table>

Notes: SL: short heating time length group; ML: moderate heating time length group; LL: long heating time length group [SL, ML, and LL respectively received 15, 30 and 60 min of suspended moxibustion on the Guangyuan (CV 4) point]; CA: conventional acupuncture group (acupuncture treatment at selected points); VAS: visual analogue scale; RMQ: roland morris disability questionnaire.
tion are shown in Table 2. Within the groups, the mean VAS scores reduced in all four groups after treatment. In the LL group, mean VAS scores before treatment of 66.5 significantly decreased by the end of 1 week of treatment to 55.4 and by the end of 2 weeks to 22.4 (P < 0.01, by repeated multiple comparisons). In the SL, ML, and CA groups, VAS scores significantly decreased between before treatment and after 1 week and 2 weeks (P < 0.05, by repeated multiple comparisons).

In the intergroup comparison, the mean VAS score of the SL group after 2 weeks of treatment showed significantly higher pain intensity than the VAS scores of the LL, ML, and CA groups (P < 0.05). After 2 weeks of treatment, the mean VAS scores of the LL group showed lower pain intensity than the VAS scores of the SL, ML, and CA groups (P < 0.05). However, there were no significant differences in mean VAS scores between the ML and CA groups after 2 weeks of treatment (P > 0.05).

**RMQ scores**

The RMQ scores reduced in all four groups after 2 weeks of treatment (Table 2). In the LL group, significant decreases were found between the RMQ scores before treatment and after 2 weeks (P < 0.01 by repeated multiple comparisons). The before treatment RMQ scores were also significantly decreased compared with the RMQ scores after 2 weeks in the SL, ML, and CA groups (P < 0.05, by repeated multiple comparisons). After 2 weeks of treatment, the RMQ scores between

<table>
<thead>
<tr>
<th>Group</th>
<th>n</th>
<th>Baseline</th>
<th>1 week</th>
<th>2 weeks</th>
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<tbody>
<tr>
<td>SL</td>
<td>8</td>
<td>65.7±8.4</td>
<td>60.5±5.9</td>
<td>43.6±11.4</td>
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<tr>
<td>ML</td>
<td>8</td>
<td>67.3±11.7</td>
<td>56.4±8.2</td>
<td>31.1±9.6</td>
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<tr>
<td>LL</td>
<td>8</td>
<td>66.5±9.3</td>
<td>55.4±6.4</td>
<td>22.4±6.2</td>
</tr>
<tr>
<td>CA</td>
<td>9</td>
<td>68.1±11.7</td>
<td>68.15±0.35</td>
<td>30.90±8.32</td>
</tr>
</tbody>
</table>

Notes: SL: short heating time length group; ML: moderate heating time length group; LL: long heating time length group [SL, ML, and LL respectively received 15, 30 and 60 min of suspended moxibustion on the Guangyuan (CV 4) point]; CA: conventional acupuncture group (acupuncture treatment at selected points); VAS: visual analogue scale; RMQ: roland morris disability questionnaire. Compared with before and after therapy within each group, *P < 0.05, **P < 0.01; compared with SL, *P < 0.05 ; compared with LL, *P < 0.05; compared with M, *P > 0.05.
the four groups were not significantly different ($P > 0.05$). LBP relief was found in all four groups after 2 weeks of moxibustion treatment. There were also decreases in VAS scores and RMQ scores for the SL, ML, and CA groups after 2 weeks of treatment. After 2 weeks of treatment, the VAS scores of the LL group were significantly lower than in the SL, ML, and CA groups. This suggests that moxibustion therapy using long heating time lengths is more effective than moxibustion therapy of short heating time lengths, moxibustion of moderate heating time lengths, and needle acupuncture therapy for LBP in terms of VAS and RMQ scores.

In our study, clinical results suggested that the large moxibustion dose therapy had a better analgesic effect than acupuncture treatment, the moderate heating time length therapy had a similar effect to conventional acupuncture treatment, and the effect of the short heating time length therapy was inferior to conventional acupuncture treatment. Acupuncture and moxibustion are similar in theory, except that their stimulation methods are different.

Moxibustion uses the heat generated by burning moxa sticks to stimulate acupoints. Acupoints can be exposed to more than 1-2 h of total heat stimulation from moxibustion, which appears to produce cumulative treatment effects; patients had a variety of different moxibustion sensations (De Qi) with increasing treatment time. This warming treatment is thought to deeply penetrate into the body, and could restore the balance between Yin and Yang and promote flow of vital energy through acupoints. The moxibustion sensation might last as long as 3-4 h after treatment. In contrast, acupoints cannot accept more than 30 min of mechanical stimulation from needles before treatment intolerance occurs. Most of the acupuncture sensation (De Qi) quickly disappears after needle removal. Acupoints accept heat and mechanical stimulation in different ways; because moxibustion is a non-invasive procedure, it is better accepted by patients than acupuncture needle therapy. Therefore, the long heating time length of moxibustion therapy provided sufficient heat stimulation and a better analgesic effect than the shorter stimulation time of the acupuncture needle treatment.

Several limitations were identified in our study; small sample size, finite treatment time, and difficulties in achieving sufficient blinding of patients and assessors. Because of the nature of the moxibustion, it was not possible to blind therapists to treatment. Further studies with larger sample sizes and more efficient stick calibration are needed. Also, more rigorous and validated sham moxibustion should be developed and employed in future studies.

The results suggest that moxibustion treatment using long and moderate heating time lengths of 60 and 30 min may be the most effective for treating chronic LBP based on reduced pain intensity and improved function during the treatment period. The treatment time used in this study ranged from 15 to 60 min, with the effect of the moxibustion on Guanyuan (CV 4) gradually improving with increasing treatment time.

**REFERENCES**