

## Hegu Acupuncture for Chronic Low-Back Pain: A Randomized Controlled Trial

Mingdong Yun, MD,<sup>1,\*</sup> Yongcong Shao, MD,<sup>2</sup> Yan Zhang, MD,<sup>1,\*</sup> Sheng He, MD,<sup>1</sup> Na Xiong, MD,<sup>3</sup> Jun Zhang, MD,<sup>1</sup>  
Mingyang Guo, MD,<sup>1</sup> Defang Liu, MD,<sup>1</sup> Yong Luo, MD,<sup>1</sup> Lingling Guo, MD,<sup>1</sup> and Jiao Yan, MD<sup>1</sup>

### Abstract

**Background:** Acupuncture has long been employed for the treatment of chronic low back pain (CLBP). However, very few studies have characterized the effectiveness of the different acupuncture modes for CLBP.

**Methods:** In total, 187 patients with CLBP participated in this study. Eligible patients were randomized to *Hegu* acupuncture, Standard acupuncture, or Usual Care groups. Eighteen (18) treatments were provided over 7 weeks. Back-related dysfunction and symptom severity were assessed by the Roland-Morris Disability Questionnaire (RMDQ) and the Visual Analogue Scale (VAS), which were collected at baseline and at 8 and 48 weeks after beginning the treatment. Repeated-measures analysis of variance (ANOVA) was employed for factorial analyses.

**Results:** Significant differences were found between follow-up and the baseline scores ( $p < 0.05$ ). The *Hegu* acupuncture group had higher RMDQ scores (8 weeks, 5.3 versus 2.1; 48 weeks, 5.7 versus 3.3;  $p < 0.001$  for both) and VAS scores (8 weeks, 1.5 versus 0.5; 48 weeks, 2.6 versus 1.6;  $p < 0.001$  for both) compared with the usual care group. The standardized acupuncture group also had higher RMDQ scores (8 weeks, 4.2 versus 2.1; 48 weeks, 4.6 versus 3.3,  $p < 0.001$  for both) and VAS scores (8 weeks, 1.3 versus 0.5; 48 weeks, 2.4 versus 1.6,  $p < 0.001$  for both) compared with the Usual Care group. The *Hegu* group had higher RMDQ scores (8 weeks,  $p < 0.05$ ; 48 weeks,  $p < 0.001$ ) and VAS scores (48 weeks,  $p < 0.05$ ) compared with the standardized group. There was a significant difference between the *Hegu* and standardized acupuncture groups in repeated-measures ANOVA ( $p < 0.05$ ). Across the three testing points, significant differences were found in the RMDQ and VAS scores between the usual care group and both treatment groups ( $p < 0.001$ ).

**Conclusions:** Both acupuncture modes have beneficial and persistent effectiveness against CLBP compared with the usual care group; *Hegu* acupuncture is significantly more effective than standardized acupuncture, especially in the long term.

### Introduction

CHRONIC LOW-BACK PAIN (CLBP) is a common problem in society, especially in adults of working age.<sup>1</sup> Americans spend at least \$37 billion annually on medical care for CLBP, and the situation is even worse in China. Although a wide range of standard treatments are available,<sup>2</sup> patients with low back pain are often dissatisfied with conventional medical care.<sup>3</sup>

Acupuncture, which is convenient and effective with less side-effects,<sup>4-6</sup> has a definite effect on muscle and soft tissue pain, especially CLBP.<sup>7</sup> Five (5) special penetration acu-

puncture modes were put forward in a Chinese medicine classical and authority book entitled *Zhenjiu Dacheng*.<sup>8</sup> Among them, *Hegu* penetration mode acupuncture (*Hegu* acupuncture) was recommended for *courbature* and is patronized by many acupuncturists in China.

Acupuncture is generally applied for the treatment of CLBP in the human body<sup>7,9</sup>; however, only few studies suggest the recommended mode for penetration of the needle.<sup>10</sup> Until now, there have been no trials or reports on *Hegu* acupuncture modes for the treatment of CLBP. In this research, a randomized, sham-controlled study was proposed on patients with CLBP, with a predetermined sample size

<sup>1</sup>Chengdu Military General Hospital, Chengdu, Sichuan, PR China.

<sup>2</sup>Academy of Military Medical Sciences, Beijing Institute of Basic Medical Sciences, Beijing, PR China.

<sup>3</sup>Hospital of Chengdu Military Joint Logistics Department, Chengdu, Sichuan, PR China.

\*Mingdong Yun and Yan Zhang are equal contributors.

and an appropriate follow-up. This trial was designed to address the following questions about the value of *Hegu* acupuncture for CLBP: (1) Is the *Hegu* penetration or standardized acupuncture mode more effective than medical care alone for CLBP; and (2) Is *Hegu* acupuncture more effective than standardized acupuncture?

## Materials and Methods

### Study design

This randomized and sham-controlled trial study was conducted in the Traditional Chinese Medicine (TCM) Department of Chengdu General Military Hospital from September 2008 to May 2010. This study was approved by the Ethics Committee of Chengdu Military General Hospital. All participants were blinded to the group allocation and gave written informed consent. Outcome assessment and statistical analysis were performed by professionals who were blinded to the patient assignment in each group.

### Study population

Patients between the ages of 20 and 45 years who presented with LBP for at least 3 months were recruited for this study. All patients came from the Army Health Care Delivery Systems in the Chengdu region of the Chinese People's Liberation Army. Exclusion criteria included the following: (1) specific causes of back pain (e.g., cancer, fractures, spinal stenosis, and infections); (2) complicated back problems (e.g., sciatica, scoliotic  $>40^\circ$  curvature, chronic spondylitis, prior back surgery, medicolegal issues); (3) possible contraindications for acupuncture (e.g., coagulation disorders, cardiac pacemakers, pregnancy, seizure disorder); (4) conditions making treatment difficult (e.g., paralysis, psychoses); (5) conditions that might confound treatment effects or interpretation of results (e.g., severe fibromyalgia, rheumatoid arthritis, concurrent care from other providers); and (6) previous acupuncture treatment for any condition.<sup>9</sup>

### Recruitment and randomization procedures

Participants were recruited by letters and telephone calls. Potential participants were asked to answer the questionnaire, and those who suffered from a severity rating of at least 3 on the 0–10 visual analogue scale (VAS)<sup>11</sup> were determined as eligible. After completing the baseline questionnaire, participants were randomly allocated to *Hegu* acupuncture, standardized acupuncture, or usual care groups, using a centrally generated variable-sized block design. The trial was described to participants only as an acupuncture points study without information about how treatments differed.

### Study treatment

A total of 18 treatments were administered to *Hegu* penetration mode and Standardized acupuncture treatment groups: every other day for 3 weeks and then twice weekly for 4 weeks. Meanwhile, massage and physical therapy were prescribed for every participant and were performed by experienced masseurs at each visit. Acupuncturists with at least 6 years' experience were asked to evaluate participants

at each visit using traditional Chinese medical diagnostic techniques. A standardized acupuncture prescription that was considered effective by experts for CLBP were given to the two acupuncture groups.<sup>12</sup> This prescription included eight acupuncture points that are commonly used for CLBP (*Du* 3, Bladder 23-bilateral, low back *ashi* point, Bladder 40-bilateral, and Kidney 3-bilateral) on the low back and lower leg.<sup>13</sup> Sterile, disposable, stainless steel needles (0.25 mm) were used for acupuncture. The penetration depth varied slightly, depending on the acupuncture point, but was generally between 1 and 3 cm.

In the two acupuncture groups, the skin around the acupoint was routinely sterilized. The acupuncturist inserted the needle straight to the *de qi* point, which was perceived as a biomechanical response of the tissue as it tightened around the needle and constricted its movement.<sup>14</sup> In the Standardized acupuncture group, all the acupuncture points were needed for 20 minutes, with needle stimulation by twirling the needles at 10 minutes and again just prior to removal. In the *Hegu* acupuncture group, the acupuncturist gripped the needle, quickly pricked the skin, inserted the needle slowly until tightness was felt, and then twirled and drew back the needle such that the needle tip remained just under the skin. The acupuncturist then pressed the skin under the acupuncture point, inserted the needle upward (following the meridian) until tightness was felt, and then twirled and drew it back again. They then pressed the skin above the acupuncture point, inserted the needle downward, and twirled and drew back the needle as above. The acupuncturist then inserted the needle straight to the *de qi* point. Three penetrations were performed on in different directions like a claw. The needle was left in for 20 minutes, the same course as above was repeated in 10 minutes, and the needle was twirled and removed in another 10 minutes. In the Usual Care group, participants received no study-related care—just the care, if any, that they and their physicians chose: mostly massage and physical therapy visits and continued use of medications (mostly nonsteroidal anti-inflammatory drugs). All participants received a self-care book with information about managing flare-ups, exercise, and lifestyle modification.<sup>15</sup>

### Outcome measures

Outcomes were measured at baseline and after 8 and 48 weeks using telephone interviews by interviewers who were masked to the treatments. The primary outcome was measured using the modified Roland-Morris Disability Questionnaire (RMDQ)<sup>16</sup> for dysfunction and VAS for symptom severity.<sup>6,17,18</sup> Secondary outcomes were measured by the above measures as well as the Diagnosis and Curative Effect Standard for Syndrome of TCM<sup>19</sup> for CLBP. It includes Curing Standard, in which LBP had disappeared and no difficulty in movement was found; Effective Standard, in which the pain was relieved but slight discomfort was found; and Ineffective Standard, in which no symptom improvement was found. The effective rate ( $N_{\text{curing+effective}}/N_{\text{total}}*100\%$ ) was calculated according to these standards and was used to measure health-related quality of life. Physical and mental health component summary scores of the Medical Outcomes Study Short-Form 36 Health Survey (SF-36) were also calculated.<sup>20</sup>

The authors also asked structured questions to determine whether participants in the two acupuncture groups perceived different experiences and to assess efforts to mask the diagnosticians, acupuncturists, and outcomes assessors to the study treatments. Several doctors who were blinded to this trial were invited to monitor every participant.

### Statistical analyses

SPSS statistical software (version 15.0) was used for the analysis. The baseline differences in demographic and clinical variables were analyzed between the three groups using analysis of variance (ANOVA) for continuous variables and  $\chi^2$  tests for categorical variables.

The primary and secondary outcome measures were analyzed using General Linear Model  $3 \times 2$  repeated-measures ANOVAs with three groups as between-subject factors and the three evaluations (baseline, 8 weeks, and 48 weeks) as within-subject factors. The intersubject factors were further divided into two Helmert contrasts. The first contrast compared the mean change from baseline to 8 weeks and 48 weeks scores for the *Hegu* acupuncture and Standardized groups with the mean change from baseline to 8 weeks and 48 weeks scores for the Usual Care group. The second contrast compared the mean change from baseline to 8 weeks and 48 weeks scores for the *Hegu* acupuncture group with the mean change from baseline to 8 weeks and 48 weeks scores for the Standardized group. The authors chose to analyze the data using a relatively limited number of planned orthogonal contrasts for 2 connected reasons, namely, protection against type I errors and maximum statistical power to detect possible differences between means, which is especially important in relatively smaller cohort sizes; multivariate ANOVA was used for pairwise comparisons of the treatment group at each measurement time.

## Results

### Study recruitment and follow-up

Of the initial 329 participants, 187 were considered eligible and randomized to a group (Fig. 1). The main reasons for in-

eligibility were <3 months of back pain, sciatica, previous acupuncture, and the inability to attend treatment visits. Patients were randomized to the *Hegu* acupuncture group ( $n=64$ ), Standardized acupuncture group ( $n=60$ ), or Usual Care group ( $n=63$ ). All participants were followed up at 8 and 48 weeks.

### Baseline characteristics

The participant cohort had a mean age of 34 years; 77% were men, and 25% were college graduates. Overall mean RMDQ scale score was 10.9 and VAS score was 6.2. Most (71%) participants reported at least 1 year of pain and 41% had used the medication in the past week (Table 1).

### Primary outcomes

Function improvement and symptom relief was found in all groups at the primary 8-week endpoint (Table 2). However, the RMDQ score for the *Hegu* Acupuncture group improved by 5.3 points, and that of the Standardized acupuncture groups improved by 4.1 points compared to an increase of 2.1 points in the Usual Care group ( $F=41.79$ ,  $p<0.001$ ). VAS scores improved by 1.5 points in the *Hegu* acupuncture group, 1.3 points in the Standardized acupuncture group, and 0.5 points in the Usual Care group ( $F=8.63$ ,  $p<0.001$ ). For multiple comparisons by treatment groups, the *Hegu* acupuncture group had a better RMDQ score than the Standardized group ( $F=0.348$ ,  $p=0.015$ ). No significant difference was found in VAS scores between the two acupuncture groups (Table 3).

### Secondary outcomes

At the 48-week endpoint, the RMDQ scores improved by 5.7 points of the *Hegu* acupuncture group and 4.2 points of the Standardized acupuncture groups compared with 3.2 points of the Usual Care group ( $p<0.001$ ). The VAS scores improved by 2.6 points of the *Hegu* acupuncture group and 2.4 points of the Standardized acupuncture groups compared with 1.6 points of the Usual Care group ( $p<0.001$ ; Table 2). For multiple comparisons by treatment group, the RMDQ score of the *Hegu* acupuncture group was lower than

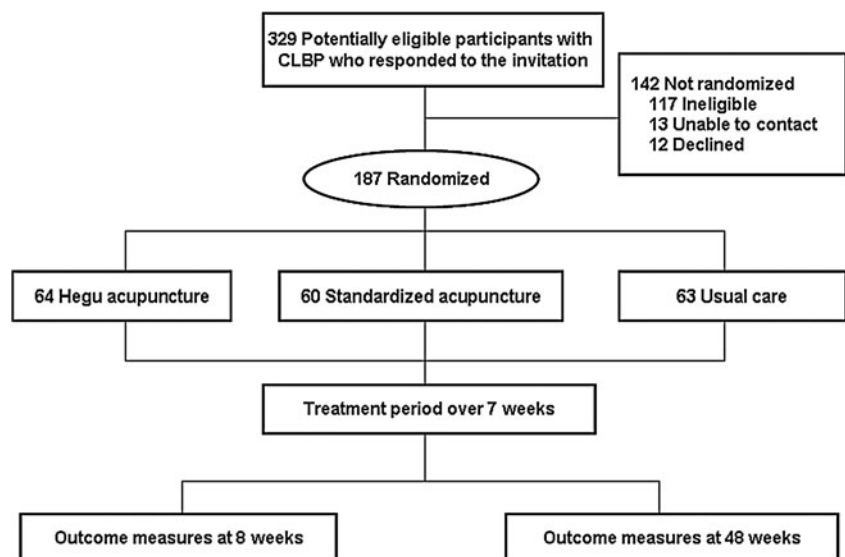


FIG. 1. Study participant flow diagram. CLBP, chronic low-back pain.

TABLE 1. BASELINE CHARACTERISTICS OF 187 PARTICIPANTS WITH CHRONIC LOW-BACK PAIN (CLBP) BY TREATMENT GROUP

Characteristics	Treatment group			Total
	Hegu acupuncture (n=64)	Standardized acupuncture (n=60)	Usual care (n=63)	
Age, mean (SD)	35 (11)	34 (12)	33 (11)	34 (11)
Men, %	78	73	81	77
Married, %	40	41	37	40
College graduate, %	27	27	24	25
Chronic pain for at least 1 y, %	69	74	70	71
SF-36 physical health, mean (SD)	42 (11)	40 (12)	42 (11)	41 (11)
SF-36 mental health, mean (SD)	37 (11)	38 (10)	40 (10)	38 (10)
VAS (0–10 scale), mean (SD)	6.1 (1.8)	6.3 (2.0)	6.1 (1.7)	6.2 (1.8)
RMDQ (0–23 scale), mean (SD)	11.0 (2.9)	10.7 (3.0)	10.8 (3.0)	10.9 (3.0)
Medication use in the past wk, %	38	41	42	41

SF-36, Medical Outcomes Study Short-Form 36 Health Survey; SD, standard deviation; VAS, visual analogue scale; RMDQ, Roland-Morris Disability Questionnaire.

that of the standardized group ( $F$  value=0.329,  $p < 0.001$ ), and the same condition was found for the VAS score ( $F$  value=0.196,  $p = 0.037$ , Table 3). Significant differences were found in RMDQ scores across the three testing points between the Usual Care group and the pooled treatment groups ( $p < 0.001$ ). There were significant differences between the *Hegu* acupuncture and Standardized acupuncture groups in repeated-measures ANOVA ( $F = 0.242$ ,  $p = 0.018$ ). The results for symptom severity (VAS) were generally similar, but significant differences were found between the two acupuncture groups ( $F = 0.153$ ,  $p = 0.030$ ; Fig. 2).

At 8 weeks, the proportion of effectiveness was 67.2% in the *Hegu* acupuncture group, 63.3% in the Standardized acupuncture group, and 46.0% in the Usual Care group ( $\chi^2 = 6.608$ ,  $p < 0.037$ ). At 48 weeks, the proportion was 87.5% in the *Hegu* acupuncture group, 76.7% in the Standardized acupuncture group, and 57.1% in the Usual Care group ( $\chi^2 = 15.507$ ,  $p < 0.001$ ). In the *Hegu* acupuncture group, a significant difference was found between the value at 8 weeks and 48 weeks ( $\chi^2 = 7.535$ ,  $p = 0.006$ ), but no difference was found among the other groups (Fig. 3).

TABLE 2. MEAN ROLAND-MORRIS DISABILITY QUESTIONNAIRE (RMDQ) AND VISUAL ANALOGUE SCALE (VAS) SCORES AT BASELINE AND FOLLOW-UP BY RANDOMIZED TREATMENT ASSIGNMENT

Score	Mean (SD)		
	Baseline	8 Wk	48 Wk
RMDQ			
<i>Hegu</i> acupuncture	11.0 (3.0)	5.7 (1.7)	5.3 (1.6)
Standardized acupuncture	10.7 (3.0)	6.6 (1.5)	6.5 (1.7)
Usual care	10.9 (3.0)	8.8 (2.4)	7.6 (2.2)
<i>p</i> -Value		<0.001	<0.001
Symptom severity (VAS)			
<i>Hegu</i> acupuncture	6.1 (1.8)	4.6 (1.3)	3.5 (1.0)
Standardized acupuncture	6.3 (2.0)	5.0 (1.4)	3.9 (1.1)
Usual care	6.1 (1.7)	5.6 (1.6)	4.5 (1.2)
<i>p</i> -Value		<0.001	<0.001

Wk, weeks; SD, standard deviation.

The use of medicines (mostly nonsteroidal anti-inflammatory drugs) for back pain in the past week was similar across groups at baseline, but had decreased from 54% to 26% in the *Hegu* acupuncture and from 57% to 24% in the Standardized acupuncture groups compared to the decrease from 55% to 43% in the Usual Care group at 8 weeks ( $p < 0.01$ ). This difference persisted even at 48 weeks.

There was no overall group difference at 8 weeks in SF-36 mental scores; however, at 48 weeks the two acupuncture groups had better scores than the Usual Care group ( $p < 0.05$ ).

Participants rated the two kinds of acupuncture treatments almost identically with regard to provider skills and caring. The diagnostician acupuncturists rated the two acupuncture groups very similarly with regard to apparent efficacy and the likelihood of receiving individualized treatment.

**Discussion**

This trial was the first randomized study to demonstrate the use of the *Hegu* acupuncture mode treatment for CLBP and compare it with the standardized acupuncture and usual care. Furthermore, it was found that the effect of *Hegu* acupuncture mode lasts much longer than that of the standardized acupuncture mode, indicating a significant difference in the mode of acupuncture chosen for the treatments of CLBP.

Acupuncture is a popular complementary and alternative treatment for chronic back pain.<sup>9</sup> Recent various randomized clinical trials have investigated the efficacy of acupuncture for CLBP.<sup>21–24</sup> This trial found that both *Hegu* acupuncture and standardized acupuncture had beneficial and persisting effects on CLBP compared with usual care, and that both could result in clinically meaningful improvement in function and mental condition.

Both clinical and animal experiments have shown that acupuncture and electroacupuncture have significant analgesic effects at the spinal level and affect many transmitters, receptors, cytokines, and gene expressions related to pain modulation.<sup>25,26</sup> The spinal dorsal horn is a relay station that receives pain information. Research has shown that acupuncture can release endomorphins, dynorphins, and substance P in the spine of rats to alleviate pain.<sup>27</sup> Changes in

TABLE 3. MEAN DIFFERENCE AND 95% CONFIDENCE INTERVALS FOR PAIRWISE COMPARISONS OF ROLAND-MORRIS DISABILITY QUESTIONNAIRE (RMDQ) AND VISUAL ANALOGUE SCALE (VAS) SCORES BY TREATMENT GROUP AND TIME SINCE RANDOMIZATION

Score	8 Wk		48 Wk	
	Standardized acupuncture	Usual care	Standardized acupuncture	Usual care
<b>RMDQ</b>				
Hegu Acupuncture	-0.86* (-1.54 to -0.17)	-3.05** (-3.73 to -2.37)	-1.17** (-1.82 to -0.52)	-2.30** (-2.94 to -1.66)
Standardized acupuncture		-2.20** (-2.89 to -1.51)		-1.13*** (-1.78 to -0.48)
<b>Symptom severity (VAS)</b>				
Hegu acupuncture	-0.43 (-0.94 to 0.08)	-1.05** (-1.55 to -0.55)	-0.4* (-0.80 to -0.03)	-1.04** (-1.42 to -0.66)
Standardized acupuncture		-0.62* (-1.13 to -0.11)		-0.63*** (-1.02 to -0.24)

\* $p < 0.05$ ; \*\* $p < 0.01$ ; \*\*\* $p < 0.001$ .  
Wk, weeks.

those transmitters in nociceptive neurons in the spinal dorsal horn are one of the major factors that cause hyperalgesia.<sup>28</sup> The research of Xu et al. suggested that the phosphor-p38 (p-p38) signal pathway plays an important role in the creation and development of shapeable changes in neurons of the spinal dorsal horn.<sup>29</sup>

Various trials have used different types of control groups, such as placebo acupuncture, sham acupuncture, and a waiting list.<sup>16,30-32</sup> These trials suggest similar short-term benefits from real and sham acupuncture needling. Many of these trials provided strong and consistent evidence that real acupuncture needling using the Chinese meridian system was effective for CLBP and the same as various purported

forms of sham acupuncture. However, many experts do not agree with this opinion; instead they believe that the reason could depend on the novelty factor, failure of diagnostic assessment of both conventional medicine and TCM, lack of placebo contrast, and so on.<sup>4</sup>

In *Lingshu*, a classical book of TCM, special methods of penetration modes were recommended, and *Hegu* acupuncture was recommended for courbature. Fan et al.<sup>33</sup> found that the direction, angle, and depth of needle insertion were key influences on acupuncture analgesia. In the *Hegu* acupuncture mode, the needles were penetrated at three different directions and angles following the meridian in one treatment (i.e., stronger stimulations were put forward). As a

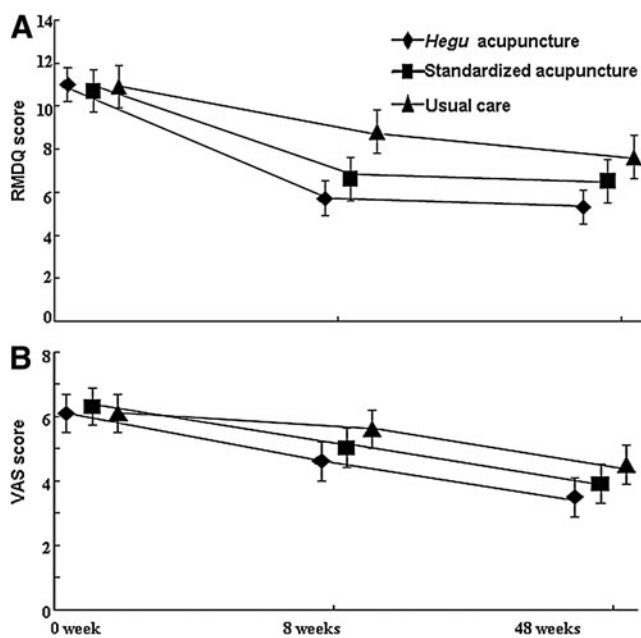


FIG. 2. Mean Roland-Morris Disability Questionnaire scores (RMDQ) (A) and visual analogue scale (VAS) scores (B) and 95% confidence intervals by treatment group and time since randomization.

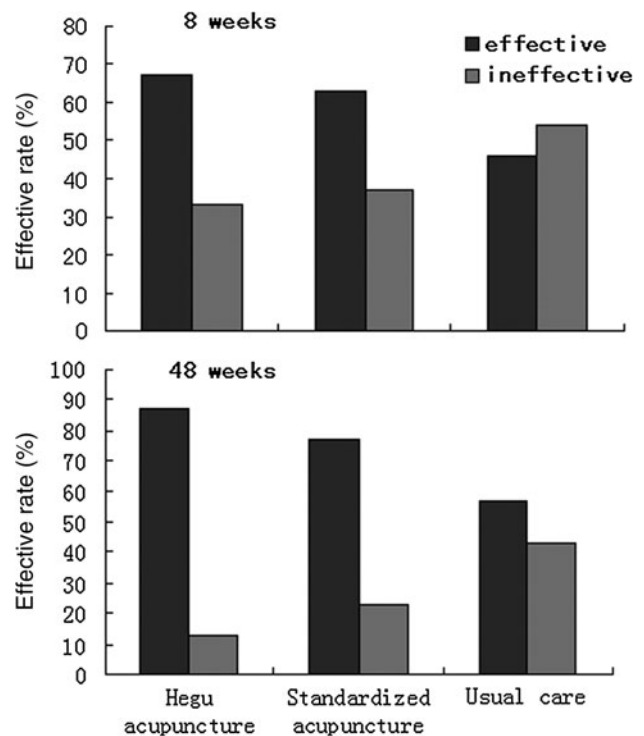


FIG. 3. Effectiveness rating by treatment group and time since randomization.

result, many acupuncturists in China know and use this mode. However, few study trials for the clinical effect of this penetration mode are available.<sup>34</sup> This trial was designed to measure the efficacy of *Hegu* acupuncture and compare it with standardized acupuncture and to assess the function of the different penetration modes. Compared with standardized acupuncture, although the same acupoints were prescribed, participants who were administered *Hegu* acupuncture obtained better RMDQ, VAS, and SF-36 scores, effectiveness rate, and so on. This study indicated that *Hegu* acupuncture is an effective mode for the treatment of CLBP.

Although great progress has been made in recent years in investigating the analgesic mechanisms of acupuncture, many issues remain unsolved, including the analgesia transduction pathway, and the effect of acupuncture on signal molecules and pathways. This trial implicated that penetration mode was the important factor that determined the effect of acupuncture. However, the mechanism underlying the superior effects of this kind of penetration mode are yet to be elucidated. Further research should focus on these issues.

### Conclusions

*Hegu* acupuncture and standardized acupuncture have beneficial and persistent effects on CLBP compared with usual care, and both can result in clinically significant improvement in function and mental condition. However *Hegu* acupuncture was significantly more effective than standardized acupuncture, especially with regard to long-term effects.

### Disclosure Statement

No competing financial interests exist.

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Address correspondence to:

*Yongcong Shao, MD  
Academy of Military Medical Sciences  
Beijing Institute of Basic Medical Sciences  
27 Taiping Road  
Beijing 100850  
PR China*

*E-mail: budeshao@yahoo.com.cn*