Efficacy and safety of electroacupuncture in treatment of lumbar disc herniation: a protocol for a cohort study

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Abstract

OBJECTIVE: To compare the efficacy of electroacupuncture (deep needling) and general orthopedics in treatment of lumbar disc herniation (LDH), and to evaluate its long-term efficacy.

METHODS: This trial is a prospective cohort study. A total of 175 participants will be observed. The exposure group is obtained from department of acupuncture and moxibustion and the control group is from orthopedic department in hospital. Patients in exposed group will receive electroacupuncture in Dachangshu (BL 25), Guanyuanshu (BL 26), L4 Jiaji points (EX-B2 L4), L5 Jiaji points (EX-B2 L5) and S1 Jiaji points (EX-B2 S1) in the affected side once a day, 6 times as a treatment course for two courses (12 times). Patients in control group will receive orthopedic conventional therapy. In acute period, the treatment is mannitol injection (250 mL: 50 g) 200 mL, i.v., q.d.; 0.9% sodium chloride injection 250 mL, vitamin C injection 2 g, Dexamethasone sodium phosphate injection 10 mg, i.v., q.d.; sterile water for injection 2 mL, adenosine cobaltamine injection 1 mg, i.m., q.d., 12 d. In remission period, the treatment is Voltaren (Diclofenac diethyl lamine emulsion) external, q.d., 12 d. The researchers do not give any other intervention and record the relevant information only.

RESULTS: Modified Japanese Orthopaedic Association Scores, Visual Analogue Scale/Score, the Short Form-36 Quality-of-Life Questionnaire and Oswestry Disability Questionnaire and the second outcome measures (Adverse Event Questionnaire and Relapse Questionnaire) are measured before treatment, after the sixth treatment, and after the twelfth treatment. The follow-up periods are 3 months after the twelfth treatment, 6 months after the twelfth treatment, 1 year after the twelfth treatment.

CONCLUSION: This study will provide clinical researchers with the evidence on the safety and long-term efficacy of electroacupuncture in patients with Lumbar disc herniation.

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Keywords: Electroacupuncture; Intervertebral disc displacement; Time; Prospective studies; Cohort studies
INTRODUCTION

Low back pain (LBP) is a major public health problem that causes individual suffering and economic loss. Moreover, 70% to 85% of people suffer from low back pain some time during their lifetime. Lumbar disc herniation (LDH) is one of the most common causes of low back pain (LBP) and nerve root pain, with an estimated annual incidence of 5 per 1000. In China, about 10%-15% patients with low back pain were diagnosed with LDH. Sciatica occurs due to LDH in approximately 90% of cases, and is characterized by ipsilateral radiating leg pain secondary to an inflammatory response from nerve root irritation. The LDH can be caused by general wear associated with continuous sitting, squatting or driving. In general, LDH is due to intervertebral disc degeneration or trauma caused by nuclear, fibrous ring to the spinal canal, spinal cord or nerve root compression. Herniated discs also often occur without symptoms, as revealed by magnetic resonance imaging studies in asymptomatic people. They are only clinically relevant when they impinge on a nerve root, causing radiculopathy. As a result, many patients with LDH respond well to conservative therapy including physical therapy, pain medication, anti-inflammatory drugs and surgery. Recently, a large number of patients with LDH are turning to complementary and alternative treatments. Acupuncture as a kind of complementary and alternative treatments is often used for LDH. It is gaining popularity among LDH patients in the US and about 1 million consumers with musculoskeletal disorders utilize acupuncture annually. Stimulating the five acupoints (deep needling) for LDH treatment (LDH Five Acupoints) is a new technique proposed by Professor Zhao Jianxin for the treatment of lumbar disc herniation and has been proven effective by clinical studies. LDH Five Acupoints include Dachangshu (BL 25), Guanyuanshu (BL 26), L4 Jiaji points (EX-B2 L4), L5 Jiaji points (EX-B2 L5), S1 Jiaji points (EX-B2 S1). Many studies, including clinical reports and systematic reviews, have investigated the benefits and success of acupuncture in relieving symptoms for various chronic diseases. However, previous acupuncture clinical studies rarely use cohort study to observe and evaluate the long-term efficacy and safety of acupuncture in LDH treatment. In addition, cohort studies have no human intervention for routine medical practice, and the results are more realistic. The research method is suitable for the characteristics of multiple episodes of pain symptoms of LDH. The aim of our study is to compare the efficacy on LDH Five Acupoints (and general orthopedics treatment for LDH, and to evaluate the long-term efficacy.

METHODS

Study design

This is a prospective cohort study, belonged to dynam-ic research. The trail protocol has been approved by the research Ethical Committee of the Third Affiliated Hospital of Beijing university of Chinese medicine. The trial protocol has been approved by the Research Ethical Committee of Beijing University of Chinese Medicine Third Affiliated Hospital (STKTPJ-BZY-SY-2015-04). This trial is registered with ISRCTN at Current Controlled Trials (ClinicalTrials.gov ID: NCT02824887). During the period, there are five measurement points: before treatment, after the sixth treatment, 3 months after the last treatment, 6 months after the last treatment and 1 year after the last treatment. Trial registration: ClinicalTrials.gov ID: NCT02824887.

Study population

Patients with LDH come from the Third Affiliated Hospital of Beijing university of Chinese medicine. The exposure group is obtained from the department of acupuncture and moxibustion of the hospital and the control group is from the orthopedic department of the hospital. Patients should meet the diagnosis criteria of LDH in "Criteria of diagnosis and therapeutic effect of orthopaedic and traumatologic diseases and symptom patterns in Traditional Chinese Medicine". The patients are free to choose the department to be treated. The researchers do not intervene the groups and record the relevant information only. The researchers should introduce the content of the study to patients and the patients should sign the informed consent form at the same time. Since this study is a dynamic cohort, new patients are allowed to enroll at any time and the time of the first visit to the new patients are not limited by other patients in the same group. To ensure the desired sample size, new patients can be promptly enrolled to supplement shedding patients (Figure 1).

Inclusion criteria

(a) Meeting the diagnosis criteria of LDH; (b) age between 18 to 75 years old; (c) duration of LDH less than 20 years; (d) Traditional Chinese Medicine (TCM) pattern of blood stasis, cold dampness pattern, hot and humid, liver and kidney deficiency license; (e) pathological classification of unilateral disc herniation or bilateral slipped disc.

Exclusion criteria

(a) Patients with severe LDH with surgical indications; (b) complicated with severe developmental spinal stenosis or other severe malformations. (c) weak constitution, or pregnant women, etc. (d) suffering from severe heart disease, high blood pressure, liver and kidney disease patients; (e) skin damage, ulceration or skin disease; (f) bleeding tendency in patients with hematologic diseases; (g) psychiatric patients.

Interventions

The investigators interview every patient enrolled. The
visit is divided into three phases: Phase 1: Japanese Orthopaedic Association Scores (JOA) and Visual Analogue Scale/Score (VAS) are collected before the first treatment. Phase 2: participants are measured after the sixth and twelfth treatment. JOA and VAS scores and adverse events are collected. Phase 3: follow-up visiting are made by phone or mail at 3 months, 6 months, and one year after the twelfth treatment (n = 174). Observation: JOA, VAS scores and adverse events are collected. Participants are measured after the sixth and twelfth treatment (n = 174). Observation: JOA, VAS scores and adverse events are collected. Patients who meet the inclusion criteria can be enrolled at any time. Investigators determine their visit and follow-up time according to individual enrollment time.

**Content of the intervention**

The intervention consists of the following content:

**Exposure group** (n = 87): LDH five points (deep needling) and Orthopedic conventional therapy. The treatment consists of the following content:

- Pre-treatment visit observation: JOA, VAS (n = 174)
- Observation: JOA, VAS, SF-36, ODQ, the recurrence rate and the recurrence cause

**Control group** (n = 87): Orthopedic conventional therapy. The treatment includes bed rest, hyperextension of the back muscle exercise and waist brace limit bending activities. Drug treatment can also be used to relax muscles, pain medication.

Acute phase of treatment: mannitol injection (250 mL: 250 g) 200 mL, i.v., q.d.; 0.9% sodium chloride injection 250 mL, vitamin C injection 2 g, Dexamethasone sodium phosphate injection 10 mg, i.v., q.d.; sterile water for injection 2 mL, adenosine cobalt amine injection 1 mg, i.m., q.d., for 12 d.

Remission period of treatment: voltaren (Diclofenac diethyl lamine emulsion) external treatment: q.d., 12 d. The patient remains lying prone or lying in bed. The drugs rubbed on the patient’s skin of L1-L5 and bilateral lumbar muscles for 10 min. So that drug ingredients can penetrate the skin to the affected area.

**RESULTS**

**Primary measures**

Modified JOA (M-JOA): M-JOA scale is known as the modified edition of JOA Back Pain Evaluation Questionnaire. We choose M-JOA scale rather than JOA scale. Because the M-JOA would be more easily accept-
ed by Asian populations than the JOA by Western populations.13 According to these criteria, a patient with LDH is assessed according to pain degree, the ability to conduct daily life and work, functional impairment, and particular clinical examinations. M-JOA scores range from 0 to 24 and LDH mild (0-9), moderate (10-20), or severe (21 and above).

VAS: VAS is an internationally recognized pain scale. The scale has 11 points, ranging from 0 (no pain) to 10 (maximal pain). Self-reported pain will be assessed using it. Participants will be well educated regarding the VAS. Pain can be rated as the following categories: no pain (0 points), mild pain (1-3 points), moderate pain (4-6 points), and severe pain (7-10 points).

SF-36: SF-36 is a very popular instrument for evaluating Health-Related Quality of Life.14 And the SF-36 forms have been used often in examining orthopaedic patient populations.15 It consists of 36 questions, which are grouped into eight health categories as follows: (a) limitations in physical function because of health problems; (b) limitations in social function because of physical or emotional problems; (c) limitations in usual role activities because of physical health problems; (d) body pain; (e) general mental health (psychological distress and well-being); (f) limitations in usual role activities because of emotional problems; (g) vitality (energy and fatigue); and (h) general health perceptions.16

Oswestry disability questionnaire (ODQ): self-reported measures of disability are widely used to measure the outcome of the treatment received for low back pain.17 ODQ has been one of the most commonly used disease-specific measures for patients with LBP.18 This tool is a self-administered 10-item questionnaire that takes less than 5 min to complete. Each item scores from 0 to 5, higher scores being worse, which is transformed into a 0-100 scale.19 The total is calculated through multiplying the sum of the scores by 2, giving a range of 0 to 100; a higher score reflects higher disability. It has show good reliability (r = 0.96)20 and responsiveness.21

Secondary measures

Adverse event questionnaire: this is our self-made Adverse Event Questionnaire showing in Table 1. Participants should report any adverse event they experience, including discomfort or bruising at the sites of needle insertion, nausea, or feeling faint after each treatment.

Relapse questionnaire: this is our self-made Relapse questionnaire showing in Table 2. The main purpose of this questionnaire is to observe the duration of efficacy and the factors that induce relapse.

Statistical analysis

Analysis will be conducted using SPSS software (SPSS 20.0, IBM SPSS Statistics for Windows, IBM Corp., Armonk, NY, USA). Data with tested normal distribution were expressed as mean ± standard deviation (x ± s). The accepted level of significance for all analyses will be P < 0.05.

First, the collected data are analyzed by t test and the rank data are analyzed by rank sum test in order to evaluate the total effective rate, the improvement of VAS evaluation and the improvement of quality of life of the exposed group and the control group. Second, χ² test or Fisher’s exact test is performed. The χ² test of Cochran-Mantel-Haenszel is performed by sex, age,
body mass index, treatment, Traditional Chinese Medicine symptom patterns and pathologic classification. In order to objectively evaluate the effect and avoid the influence of confounding factors, this study use propensity score method to balance the two groups of covariates. Statistical methods: propensity score with covariates Weighted Logistic regression (weighted by propensity scores, balancing most of the confounders and adding covariates).

DISCUSSION

Our research protocol has 3 innovations. Firstly, the study is a prospective cohort study and observes the long-term efficacy and safety. Many clinical studies have confirmed the curative effectiveness of treatment for LDH. But they often ignored to observe of the long-term efficacy and safety. And the clinical research was far from the clinical practice. The research method is suitable for the characteristics of multiple episodes of pain symptoms of LDH. And our study is a dynamic cohort research. Dynamic cohort research have made the initiation time of the patients no time of the patients no longer limited. The patients can be long term followed up and the long term efficacy can be observed. Researchers of the cohort study can observe the impact of the results caused by the exposure factor or a certain factor on the outcome by setting up the inclusion criteria and measurement standard in advance. In addition, the cohort study data derives from observation and conventional medical practice without human intervention. The results come from the objective reality. Therefore, cohort study is closer to clinical practice. And the evidence level of cohort study in evidence-based medicine is II , second to randomized controlled trials. The results have high credibility. Secondly, LDH Five Acupoints treatment is a new technique proposed by Professor Zhao Jianxin for the treatment of LDH. Deep needling is the key point. The muscle branch of L4 and L5 nerve roots are under the Dachangshu (BL 25) and Guanyuanshu (BL 26). Puncture the points deeply can directly stimulate to the nerve roots and nerve stems. Therefore, acupuncture can adjust the sciatic nerve flow25 and regulate the release of inflammatory mediators31 in order to ease pain. Thirdly, the experience of controlling the loss rate is summarized in the process of early cohort study. As the test process up to 1 year, controlling the lost rate is the key to complete the experiment and get the test data. Therefore, we propose the following plan to control the lost rate:

(a) An increase of 15% of the sample size as a replacement for patients lost. (b) Researchers introduce the study to the patients who are included, making the patient clear their rights and obligations, and signed informed consent. (c) The investigator keeps the patient’s information in order to ensure the patient’s compliance and the completeness of the test results. (d) According to drop criteria, stopping criteria and exclusion criteria, the researcher handles the abnormal situation during the experiment and indicates the specific reason. (e) Since this study is a dynamic cohort study, the study has made the initiation time of the patients no longer limited. Researchers can always incorporate new patients to ensure that the sample size reaches to the desired value.

However, our study has several limitations. One limitation is that the evidence level of our trial is not the highest in clinical study, although our trial is closest to the clinical reality. Another limitation concerns the fact that we will recruit patients with various types of LDH, although all the patients referred to acupuncture department will be eligible for the study. However, effectiveness of acupuncture for different types of LDH is not evaluated.

This result of our study will provide clinical researchers with the evidence on the long-term efficacy of electroacupuncture in patients with LDH.

REFERENCES


Table 2 Relapse questionnaire

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