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Effectiveness of deep electroacupuncture with strong deqi and shallow electroacupuncture with no deqi for lumbar disk herniation: study protocol for a randomised controlled trial

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ABSTRACT

Introduction Lumbar disk herniation (LDH) is a common cause of low back pain and dysfunction. Studies have shown that electroacupuncture (EA) can achieve pain relief in patients with LDH. However, there is a lack of evidence regarding the effectiveness of deep EA with strong deqi and shallow EA with no deqi in patients with LDH. This study aims to evaluate the effectiveness of deep EA with strong deqi and shallow EA with no deqi in the treatment of LDH.

Methods and analysis In this randomised controlled trial, patients with LDH who have low back pain with or without radiculopathy for at least 12 weeks will be enrolled. In total, 44 patients will be recruited from the Third Affiliated Hospital of Beijing University of Chinese Medicine, Beijing, China. Patients will be randomised into the deep EA group and the shallow EA group in a ratio of 1:1 and will be administered 12 sessions of EA treatment (three times a week for 4 weeks, 20 min for each session). The follow-up duration will be 4 weeks. Low back pain intensity and leg pain intensity (in patients with radicular pain) measured using the Visual Analogue Scale (VAS) will be assessed as the primary outcomes. Function (measured using the Roland-Morris Disability Questionnaire), quality of life (measured using the EuroQol Five-Dimensional Five-Level Questionnaire) and patient-evaluated therapeutic effect will be assessed as the secondary outcomes. Patients' expectations of EA, the success of the blinding method and safety will also be evaluated. Statistical analyses will be followed by the intention-to-treat analysis.

Ethics and dissemination This study was approved by the Ethics Committee of the Third Affiliated Hospital of Beijing University of Chinese Medicine (approval number: 2019-XS-ZB06). Study results will be disseminated through publication in an open access journal.

Trial registration number ChiCTR-1900026518.

Strengths and limitations of this study

► This study will provide evidence for clinical practice regarding the effectiveness of deep electroacupuncture (EA) with strong deqi and shallow EA with no deqi.

► It will be difficult for the patients to determine which group they are in because all of them will receive electric stimulation.

► The main limitation of this study is the inability to blind the acupuncturist.

BACKGROUND

Low back pain is the second most common symptom-related reason for physician visit by patients.[1] About 10% of the patients with low back pain have disk disorder.[2] Patients with lumbar disk herniation (LDH) commonly experience low back pain recurrence, and these patients often exhibit slower recovery than those with non-specific low back pain.[1][2] Non-pharmacological interventions (acupuncture, massage, yoga and spinal manipulation) are recommended as the first-line treatment in low back pain.[3] Acupuncture is a well-accepted treatment in relieving pain, usually exerting more beneficial effects with every session.[4][5] In addition, people in China are more likely to choose acupuncture as their first choice for pain relief compared with analgesics.[6]

Studies have shown that acupuncture and electroacupuncture (EA) could relieve pain in patients with chronic low back pain.[7–9] According to the traditional Chinese medicine theory, needles are inserted into the body with sufficient manual manipulations (lifting, thrusting, twisting or rotating) and cause a deqi sensation (a comprehensive sensation of numbness, soreness, heaviness and distension) to achieve a therapeutic effect. Thus, acupuncturists tend to perform deep needle insertion and cause a strong deqi sensation.
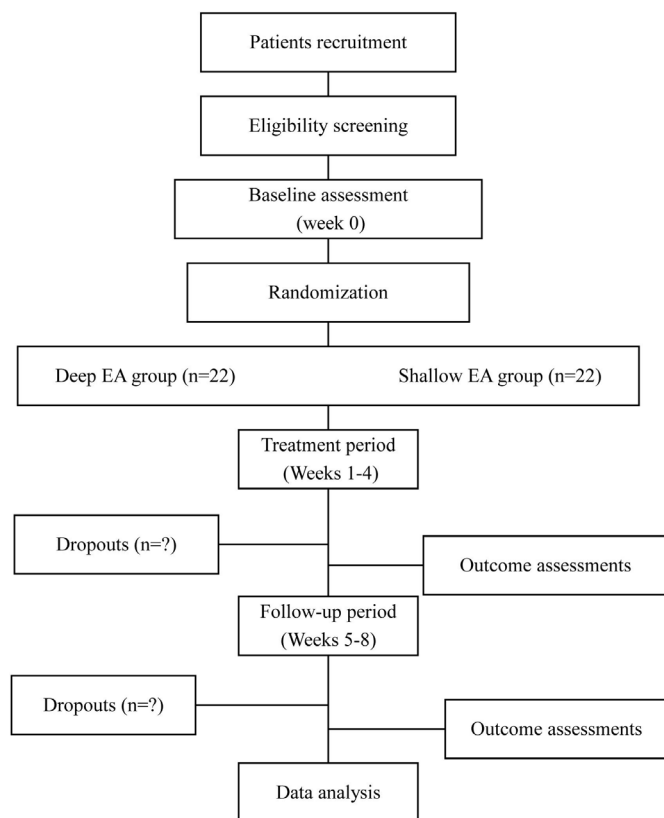
Figure 1 Study flow chart. EA, electroacupuncture.

However, some patients are unwilling to receive much manipulation or are afraid of deqi sensation during the acupuncture treatment.

To the best of our knowledge, there has been no detailed investigation of whether the effect is different between deep EA with strong deqi and shallow EA with no deqi. If shallow EA with no deqi is effective for LDH, patients with low back pain or radicular pain caused by LDH can choose shallow EA for pain relief without the need to undergo strong deqi sensation during the acupuncture treatment. This study aims to evaluate the effectiveness of deep EA with strong deqi and shallow EA with no deqi in the treatment of LDH.

METHODS
Study design
This is a single-centre, prospective, shallow EA controlled, randomised trial. Patients will receive 12 sessions of either deep EA with strong deqi or shallow EA with no deqi after randomisation. The study duration will be 9 weeks for each patient that includes baseline assessment for 1 week (at week 0), treatment period of 4 weeks (weeks 1–4) and follow-up duration of 4 weeks (weeks 5–8) (figure 1). The study method is based on the Consolidated Standards of Reporting Trials[10 11] and Revised Standards for Reporting Interventions in Clinical Trials of Acupuncture.[12]

Patients
Patients with LDH with or without radiculopathy will be enrolled. The diagnose criteria based on the North American Spine Society clinical guidelines will be used.[13] Diagnosis will be established by experienced physicians using CT scan, MRI and symptom examination. The following inclusion criteria will be applied: age 18–80 years and presence of low back pain (with or without radiculopathy) for at least 12 weeks. Patients will be excluded if they meet any of the following criteria: (1) severe LDH requiring surgery; (2) history of spinal surgery; (3) known or suspected spinal diseases (tumours, fractures, infective spine diseases, etc); (4) severe cardiovascular diseases, endocrine system diseases or pacemaker/metal implants; (5) pregnancy, or lactation, or planning to conceive during the study period; (6) current use of anticoagulant or antiplatelet drugs; (7) mental illnesses and (8) inability to speak or understand Mandarin.

Patients will be recruited through poster advertisements in the hospital and enrolments through networks from 1 December 2019 to 30 December 2021. In total, 44 patients with LDH will be recruited from the outpatient clinic of the Department of Acupuncture, the Third Affiliated Hospital of Beijing University of Chinese Medicine, Beijing, China. Baseline assessment will be conducted within 1 week before the first EA session. Written informed consent will be obtained from all the study subjects.

Blinding
Patients, outcome assessors and statisticians will be blinded. The needles in the deep EA group and the shallow EA group have the same appearance, except for the length. Both the types of needles will be carried during acupuncture to avoid patients from guessing the group they have been allocated to. Patients will be in the prone position and are therefore unable to see the inserted needles.

The success of the blinding method will be examined by an assessor who is not involved in the performance of acupuncture by asking the patients to choose one item from 'deep electroacupuncture', 'shallow electroacupuncture' or 'I don't know'. The success of the blinding method will be evaluated within 30 min of the last EA session.

Randomisation and allocation procedures
A research assistant who will not be involved in the trial intervention and evaluation will be in charge of the randomisation. The random numbers will be generated using a computerised random number generator in a block size of 4. Patients will be enrolled in a ratio of 1:1. The randomised number chits will be kept in opaque sealed envelopes and opened sequentially. The envelopes will be stored by the assistant and opened on the day the patients receive their first treatment from the acupuncturist.

Intervention

Patients will be administered 12 sessions of free EA treatment during the study period. The treatment will start on the day the patients are randomised. Dongbang disposable stainless steel needles (0.3×75 mm and 0.25×15 mm, Suzhou Dongbang Medical Equipment Co, Suzhou, China) and a Yingdi electric stimulator (Changzhou Yingdi Electronic Medical Device Co, Changzhou, China) will be used. The selection of acupoints will be made as per the clinical experience and specialist consensus. In case of radicular pain, bilateral Dachangshu (BL25), Guanyuanshu (BL26), and L3–L5 Jiaji (Ex-B2), Weizhong (BL40) and Chengshan (BL57) will be used. Patients will be administered 12 sessions of EA (three times a week for 4 weeks) and each session will last 20 min. Patients in the deep EA group will be administered EA at the acupoints in the prone position bilaterally using 0.3×75 needles. The needles will be inserted slowly and vertically to a depth of 35–70 mm as per the patient's figure to achieve deqi sensation; it is preferable if the sensation radiates down to the lower limb. After the needles are inserted, paired clips of electric stimulator will be attached transversely to the bilateral Dachangshu (BL25) and Guanyuanshu (BL26). A 5-Hz continuous wave will be used, and the current strength will be adjusted as per the patient's tolerance. Patients in the shallow EA group will be administered acupuncture treatment using the 0.25×15 mm needles that will be inserted slowly and vertically approximately 2–5 mm at the same acupoints with no deqi sensation. An electric stimulator will be connected using the same method as used in the deep EA group.

Patients are allowed to take analgesics when their pain becomes unbearable. Any analgesics that are used will be recorded in the case report form (CRF).

Outcome measures

Primary outcome

The primary outcome will be the change from baseline in the patients' worst low back pain intensity and leg pain intensity (if patients have radicular pain) measured using the VAS, at weeks 2, 4, 6 and 8. The VAS is a ruler with a length of 0–100 mm. Patients will be asked to make a mark on the ruler that represents their worst low back pain intensity and leg pain intensity during the previous week, with 0 mm representing no pain and 100 mm representing unbearable pain.

Secondary outcomes

The following secondary outcomes will be measured: (1) change in the Roland-Morris Disability Questionnaire (RMDQ) scores at weeks 2, 4, 6 and 8 compared with that at baseline. The RMDQ is a 24-item self-reported questionnaire that assesses low back function. The item will be scored 1 point if the patient indicates that the item is applicable to them; if the item is not applicable, a score of 0 will be assigned. The total score will be calculated by adding the points for all items (range 0–24). A higher score indicates a worse condition; (2) change

in the EuroQol Five-Dimensional Five-Level Questionnaire (EQ-5D-5L) at weeks 2, 4, 6 and 8 as compared with that baseline. The EQ-5D-5L is a five-dimension self-rated questionnaire for assessing the health state. It contains a five-dimension questionnaire and an EQ-VAS for the assessment of the health status. The five dimensions include mobility, self-care, usual activities, pain/discomfort and anxiety/depression. Each dimension has five levels, described as 'no problems', 'slight problems', 'moderate problems', 'severe problems' and 'extreme problems'. Patients will be asked to choose one item in each dimension that indicates his/her health state on the assessment day. The health state will be represented by the index value, which is derived by applying a formula to each level in each dimension. Calculation of the index value will be conducted by a syntax file provided by the EuroQol office. The EQ-VAS records the patients' health on a vertical VAS. The EQ-VAS is a 100 mm scale labelled 0–100 mm, representing 'best imaginable health state' to 'worst imaginable health state', Patients will be asked to choose one number between 0 and 100 that represents their health status on the day of the assessment; (3) patient self-evaluation of the therapeutic effect will be assessed by asking the patients to choose an answer from 'No help', 'Little help', 'Medium help' and 'Great help'. The self-evaluation will be assessed at weeks 2, 4, 6 and 8.

A three-question expectation assessment will be conducted at baseline. Patients will be asked to choose one answer from 'yes', 'no' or 'unclear' for the following two items: (1) In general, do you believe that electroacupuncture is helpful for disease treatment? and (2) Do you believe that electroacupuncture is helpful with your lumbar disk herniation? Patients will choose one answer from 'no help', 'little help', 'medium help', 'great help' or 'I do not care' for the item 'What degree do you think electroacupuncture will be helpful with your lumbar disc herniation?'

Safety assessment

Any adverse events (AEs) during the study period will be recorded, assessed and treated. The details of the AEs will be recorded in the CRF. AEs will be categorised as treatment related (eg, broken needle, fainting, dizziness, nausea, vomiting, palpitations, localised hematoma, localised infection or localised severe sharp pain) or non-treatment related (eg, common cold, diarrhoea, cough or headache) within 24 hours of occurrence. Patients will not be blinded and treatment will be discontinued if serious AEs occur (eg, causing disability to work or requiring hospitalisation). Serious AEs will be immediately reported to the Ethics Committee of the Third Affiliated Hospital of Beijing University of Chinese Medicine and suspend the study. The AEs occurrence ratio will be calculated.

Sample size calculation

Power Analysis and Sample Size (version 11.0) was used for calculating the required sample size. The primary

outcome was the change from baseline in the patients' low back pain VAS score at 4 weeks. In previous studies,[7 8] the change from baseline in low back pain VAS score after 4 weeks of treatment was 27.8±11.9 mm in the deep EA group and 14.6±13.2 mm in the shallow EA group. Considering a two-sided significance level of 5% (α) and a test power of 90% (β), 21 patients would be required in each group. Considering a dropout rate of 5%, 22 patients would be required in each group. The required sample size was 44 in this trial.

Data collection, management and monitoring

Patients will undergo free treatment and outcome evaluation during the study period. Dropouts and withdrawals will be recorded with the respective reasons in the CRFs. Patients who discontinue treatment but do not drop out will be invited to enter the follow-up period and complete assessments.

CRF will be first filled in the paper copies and entered into the Microsoft Excel by two independent researchers. Data monitoring and validation will be regularly conducted throughout the study. The original CRFs and consent forms will be kept in the Department of Acupuncture at the Third Affiliated Hospital of Beijing University of Chinese Medicine with limited access authority for 3 years after publication. Original clinical information will not be accessed without the permission of the principal researcher ZH. The Monitoring Committee of the Third Affiliated Hospital of Beijing University of Chinese Medicine will check the CRFs two times each month.

Statistical analyses

Data will be analysed as per the intention-to-treat principle. Missing data will be filled in by multiple imputation. IBM SPSS (V.20.0; International Business Machines Corporation, China) will be used for data analysis. A two-sided test will be conducted with a significance level of 0.05% and 95% CIs. Between-group differences in the VAS scores, RMDQ scores and EA-5D-5L scores will be analysed with Analysis of Covariance (ANCOVA) or non-parametric test, based on the normality of the data. Expectation assessment will be analysed with general linear regression to assess if there is a correlation between the primary outcome and patient expectations. The success of the blinding method will be evaluated using χ^2 test. Means and SDs or means and 95% CIs will be used to present continuous data in case of normal distribution. Medians and interquartile ranges will be used to present continuous data for non-normal data. Frequencies and percentages will be used to present the categorical data.

Quality control

All the investigators will undergo special training regarding the purpose, content and treatment strategies to achieve quality control. EA will be performed by an acupuncturist who has undergone at least 5 years of undergraduate education and attained a certificate in traditional Chinese medicine practice. The Monitoring Committee of the Third Affiliated Hospital of Beijing

University of Chinese Medicine will monitor the safety of this study and review the study results.

Patient and public involvement

No patient involved.

Ethics and dissemination

This study was approved by the Ethics Committee of the Third Affiliated Hospital of Beijing University of Chinese Medicine (approval number: 2019-XS-ZB06) and registered at the Chinese Clinical Trial Registry. All patients will be fully informed about the trail and given enough time to decide whether to participate in the study. All patients will be asked to sign an informed consent form if they agree to participate in the study. Study results will be published at an online access medical journal.

DISCUSSION

Study results will provide an understanding of the effectiveness of deep EA with strong deqi sensation and shallow EA with no deqi sensation in patients with LDH. Current studies mainly focus on the effectiveness of acupuncture and have compared acupuncture with sham or placebo acupuncture related to chronic low back pain.[9] However, to our knowledge, no detailed trials have compared deep EA with strong deqi sensation and shallow EA with no deqi related to LDH. A strong deqi sensation could be an unpleasant experience for some patients; therefore, we wish to optimise our treatment for patients who are unwilling to go through the deqi sensation.

The concept of determining whether there is a difference between deep EA and shallow EA was first proposed by a patient who preferred shallow needle insertion to deep needle insertion. Moreover, the patient stated that strong deqi sensation stressed him during the acupuncture treatment. Acupuncture is usually performed at a shallower level in Western countries than in China, with effective in pain relief. Patients in China are difficult to blind because of their cultural background.[14] Thus, we involved EA to minimise the changes of patients' recognising the group assignment.

Dysfunction caused by pain is a critical issue that affects patients' productivity and quality of life.[1] In our clinical experiences, even with low-intensity pain (<30 mm on a 100 mm VAS), patients reported that it greatly compromised their daily life. Therefore, we did not restrict the minimum pain intensity in the inclusion criteria. The function and quality of life will be assessed in order to explore whether EA can improve the function and quality of life in patients with LDH. RMDQ is for assessing physical disability caused by low back pain, and it is more sensitive to change in patients with mild to moderated disability than the Oswestry Disability Index; a change of 2–3 points between groups in RMDQ should be considered the minimum clinically important change.[15 16] The EQ-5D-5L was developed based on the EQ-5D-3L to improve the sensitivity and reduce the ceiling effects by increasing the severity levels from 3 to 5.[17 18] Both these questionnaires are short, and are not specifically difficulty

to read or understand, and can be completed in 5 min. Thus, the response burden is low.[15 18] Patients' expectations might present therapeutic benefits in clinical practice.[19] Thus, the effects of expectation on outcomes will be assessed to determine whether there is an association between patients' expectations and the primary outcome. Moreover, the success of the blinding method will be assessed. Many psychological scales have been used as indicators of the evaluation of chronic low back pain.[20 21] However, tedious questionnaires of these scales might cause the patient to become uninterested and thus less cooperative. Therefore, we plan not to use psychological scales.

This study will provide evidence for clinical practice about the effect of deep EA and shallow EA and thus aid acupuncturists in decision-making while treating patients with LDH.

The main limitation of this study is the inability to blind the acupuncturist.

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