

Study Protocol

Effectiveness and safety of acupotomy for lumbar disc herniation: a study protocol for a randomized, assessor-blinded, controlled pilot trialEunseok Kim^a, So Yun Kim^b, Hye Su Kim^b, Jeong Kyo Jeong^b, So-Young Jung^c, Chang-Hyun Han^{c,*}, Young-Il Kim^{b,*}^a Department of Acupuncture & Moxibustion Medicine, Graduate School, Kyung Hee University, Seoul, Korea^b Department of Acupuncture and Moxibustion Medicine, Daejeon University Dunsan Korean Medicine Hospital, Daejeon, Korea^c Clinical Research Division, Korea Institute of Oriental Medicine, Daejeon, Korea

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ABSTRACT

Background: Acupotomy aims to reduce pressure on the nerve, improve surrounding blood circulation, and recover the kinetic state of soft tissue in treating lumbar disc herniation. Although several previous studies have suggested the potential use and substantial benefits of acupotomy, there is still insufficient evidence regarding this technique. This trial is designed to determine if acupotomy is more effective than manual acupuncture in improving low back pain and/or leg pain, disability, lumbar mobility, and quality of life in patients with herniated lumbar disc.

Methods: Fifty eligible patients will be randomly assigned to an acupotomy group or a manual acupuncture group in a 1:1 ratio. The experimental group will receive acupotomy at the affected side's inner core muscles and soft tissue at the level of the herniated disc where tenderness appears (twice per week for 2 weeks). The control group will receive manual acupuncture (thrice per week for 2 weeks) at GV3 (Yaoyangguan) and the bilateral BL23 (Shenshu), BL24 (Qihaihu), BL25 (Dachangshu), and BL26 (guanyuanshu) for local points and the bilateral GB30 (Huantio), BL40 (Weizhong), and BL60 (Kunlun) for distant points. The primary outcome will be the mean change in the visual analog scale from baseline to 4 weeks (2 weeks after final treatment). The Oswestry Disability Index, Modified-Modified Schober Test, and EuroQol five dimensions questionnaire will determine secondary outcomes. Adverse events will be evaluated at every visit.

Discussion: This study will provide valuable data and insights for a confirmative, full-scale randomized controlled trial to determine the clinical effects of acupotomy.

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1. Introduction

Lumbar disc herniation is one of the most common degenerative spinal disorders in young and middle-aged patients. It may cause low back pain (LBP) and/or radicular pain, paresthesia, and weakness in the lower limbs.^{1,2} It is highly prevalent among patients aged 30–50 years, with 95% of herniated discs occurring at the L4/L5 and L5/S1 levels.³ Conservative treatment is primarily sought to reduce pain by either analgesics or decreasing pressure on the affected nerve root, except in cases of surgery owing to severe sciatica, serious/progressive neurologic deficits, or persistent symptoms lasting >6 months.⁴

Acupotomy was first introduced in China in 1976 by Zhu Hanzhang. It has been used for treating chronic pain and eliminating obstinate lesions by incising the synechia and removing the attached tissue with a flat-head bladed needle.^{5,6} Although it has more recently been investigated in Korea, the use of acupotomy has increased among Korean Medicine Doctors. Furthermore, an advanced acupotomy procedure with newly developed needles has been proposed.⁶ According to a review of the trends in acupotomy from January 1999 to May 2014,⁷ many studies have focused on musculoskeletal diseases arising in the neck and low back. In addition, four case studies regarding lumbar disc herniation reported improvements in pain and disability after acupotomy.^{8–11} When treating lumbar disc herniation, acupotomy aims to reduce pressure on the nerve, improve surrounding blood circulation, and recover the kinetic state of soft tissue.^{5,6} Although several previous studies have suggested the potential use and substantial benefits of acupotomy,^{6,8–12} there is still insufficient evidence regarding this technique level owing to small sample sizes and its combination with other therapies (e.g., acupuncture, herbal medicine, physical therapy).⁷

Therefore, in this pilot randomized controlled trial (RCT), we will evaluate the effectiveness and safety of acupotomy in treating herniated lumbar disc compared with manual acupuncture for use in a future large-scale clinical trial.

2. Methods

2.1. Study design

This study will be an equal randomized, two parallel-armed, assessor-blinded, single center, pilot clinical trial. The flow diagram for the study is displayed in Fig. 1. Since this is a pilot study preliminary to a full-scale trial, we assume that total 25 participants in each group will be an acceptable sample size, considering 20 participants in each group with a 20% drop-out rate. A total of 50 participants with symptomatic lumbar disc herniation will be recruited from the outpatients at Daejeon University Dunsan Korean Medicine Hospital (DUDKMH) through advertisements on a bulletin board, on the hospital homepage, and in local newspapers. Recruitment is expected to commence in August 2016 and end in February 2017.

At the first visit, all participants will be provided with a detailed explanation of the study protocol, written information, and an informed consent form. Study volunteers will undergo a blood test to evaluate coagulation factors and

complete blood counts. As a screening process for eligibility, potential participants presumed to have lumbar disc herniation by physical examination will undergo a computed tomography (CT) scan, if an imaging test has not been performed in the last 5 years. Eligible participants who meet the study criteria will be randomly allocated to either the acupotomy treatment group or the manual acupuncture treatment group in a 1:1 ratio. Outcomes measured at the screening visit will be considered to be baseline data. The assigned intervention will start within 3 days of the screening visit. The participants will be treated for 2 weeks and asked to visit the hospital for a follow-up visit 2 weeks after the final treatment. A participant, for any reasons (e.g., unsatisfactory treatment, worsening disease), may withdraw consent on the intervention and decline to participate further by his/her own request.

2.2. Types of participants

2.2.1. Inclusion criteria

Participants who meet all the following criteria will be allowed for enrollment:

- 1) A confirmed diagnosis of lumbar herniated disc by CT or magnetic resonance imaging (MRI) within the past 5 years
- 2) At least one of the following symptoms: LBP, radiating pain in a lower extremity, and paresthesia in a lower extremity
- 3) Age of 20–80 years
- 4) Able and willing to comply with the intervention and follow-up evaluation
- 5) Able to provide a written informed consent

2.2.2. Exclusion criteria

Participants with any of the following conditions will be excluded:

- 1) History of hypersensitivity to acupuncture
- 2) Current affliction or history of surgery to treat cauda equina syndrome or neurological symptoms, such as motor and/or sensory paralysis
- 3) History of plate internal fixation or spinal fusion operation
- 4) History of neuromyopathic scoliosis or neurodegenerative disease
- 5) Pregnancy, lactation, or a plan to become pregnant during childbearing years
- 6) History of neurotic or major psychiatric disability or cognitive instability
- 7) Terminal illness requiring active therapy
- 8) History of alcoholism or drug abuse
- 9) Hemorrhagic disease, uncontrolled diabetes, or cardiovascular disease, and/or factors that can affect hemostasis, such as anticoagulant or antiplatelet drug use
- 10) Disability affecting communication and concentration
- 11) Patients who are considered to be inappropriate for the study by the researcher

2.3. Randomization and blinding

A random allocation of the eligible participants in a 1:1 ratio will be conducted at the second visit using the block randomization method of SAS version 9.1.4 (SAS Institute, Inc., Cary,

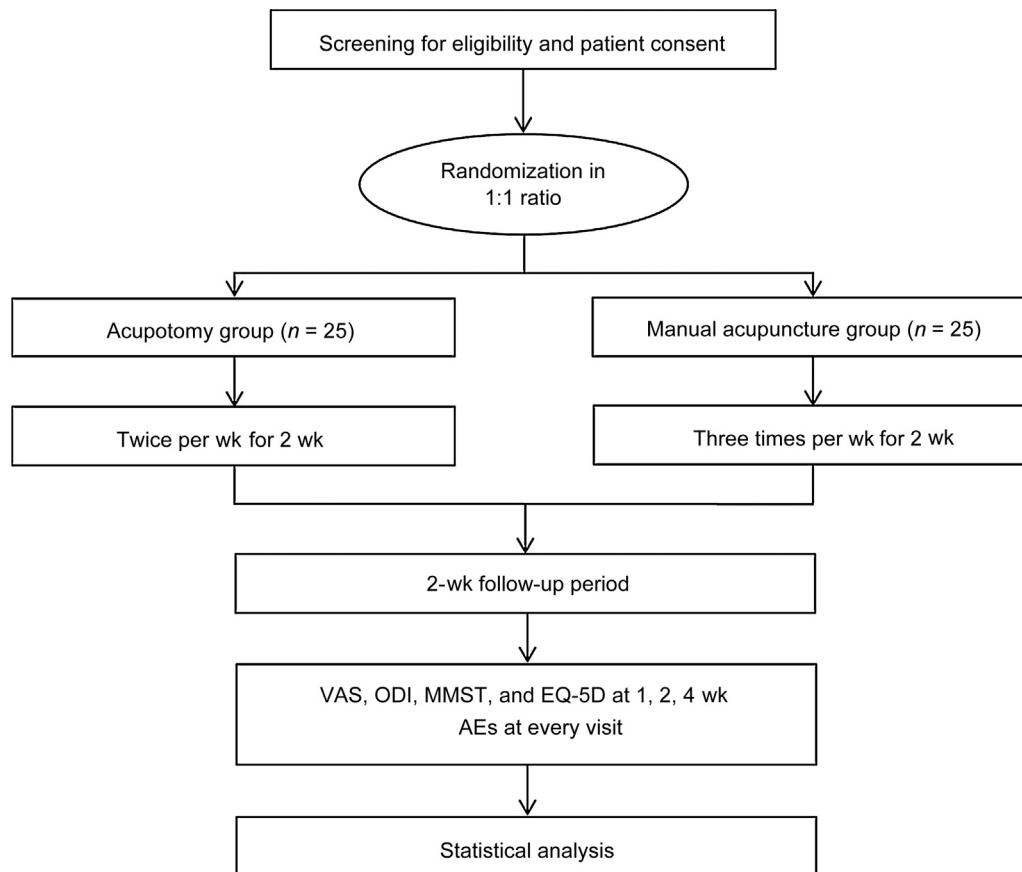


Fig. 1 – Study flow with outcome assessments.

AEs, adverse events; EQ-5D, EuroQol five dimensions questionnaire; MMST, Modified-Modified Schober test; ODI, Oswestry Disability Index; VAS, visual analog scale.

North Carolina, USA). For adequate allocation concealment, a random number list will be generated by an independent statistician, and block size will not be disclosed to other researchers. An independent, blinded statistician will conceal the file of the generated random number table with a password and will provide information regarding which group each participant is assigned to the clinical research coordinator (CRC).

Researchers who assess outcome measures and those who perform data management and statistical analysis will be blinded to each patient's allocation status. Outcome assessors will not be allowed to have any conversations with patients regarding the treatment process. However, it is impossible to blind the practitioners owing to the differences between the interventions. Thus, we will separate the acupotomy practitioner from the manual acupuncture practitioners. Each practitioner will perform only one of the interventions. This is to prevent any bias due to the deliberate interventions in treating the participants. None of the practitioners will be involved in measuring the treatment outcomes.

2.4. Intervention

2.4.1. Acupotomy

A total of four acupotomy treatments will be provided twice per week for 2 weeks (Fig. 2). Flat head screwdriver-shaped

stainless-steel disposable sterilized needles (1.2 mm in diameter and 75 mm long; Hansung Precision Manufacture, Seoul, South Korea) will be used. After pretreatment confirmation of herniated lumbar disc using MRI or CT scans, the insertion points at the corresponding disc level will be sterilized using 10% povidone solution and anesthetized using lidocaine before the surgery while the participant is in a prone position.¹⁰ Two or three needles will be inserted 20–30 mm away from the spinous process of the herniated disc into the inner core muscles and soft tissue to the depth of 50–60 mm. The practitioner will stimulate solidification of the targeted tissue by moving the needle inward, outward, upward, and downward to incise and exfoliate the tissue until tenderness is relieved.⁶ The needles will be removed immediately after the insertion procedure. After the acupotomy needling, a disposable sterilized wet-cupping will be applied to the acupotomy site with negative pressure by manual pumping and retained for 5 minutes¹³ for the purpose of extracting bleeding blood at the treated site. We will then sterilize the skin and apply gauze dressing to the site. All patients in the acupotomy group will be informed of the details of the process for prevention of infection in the treatment area.

All acupotomy treatment procedures will be performed by a single practitioner who is a doctor of Korean medicine with 4 years of acupotomy experience.

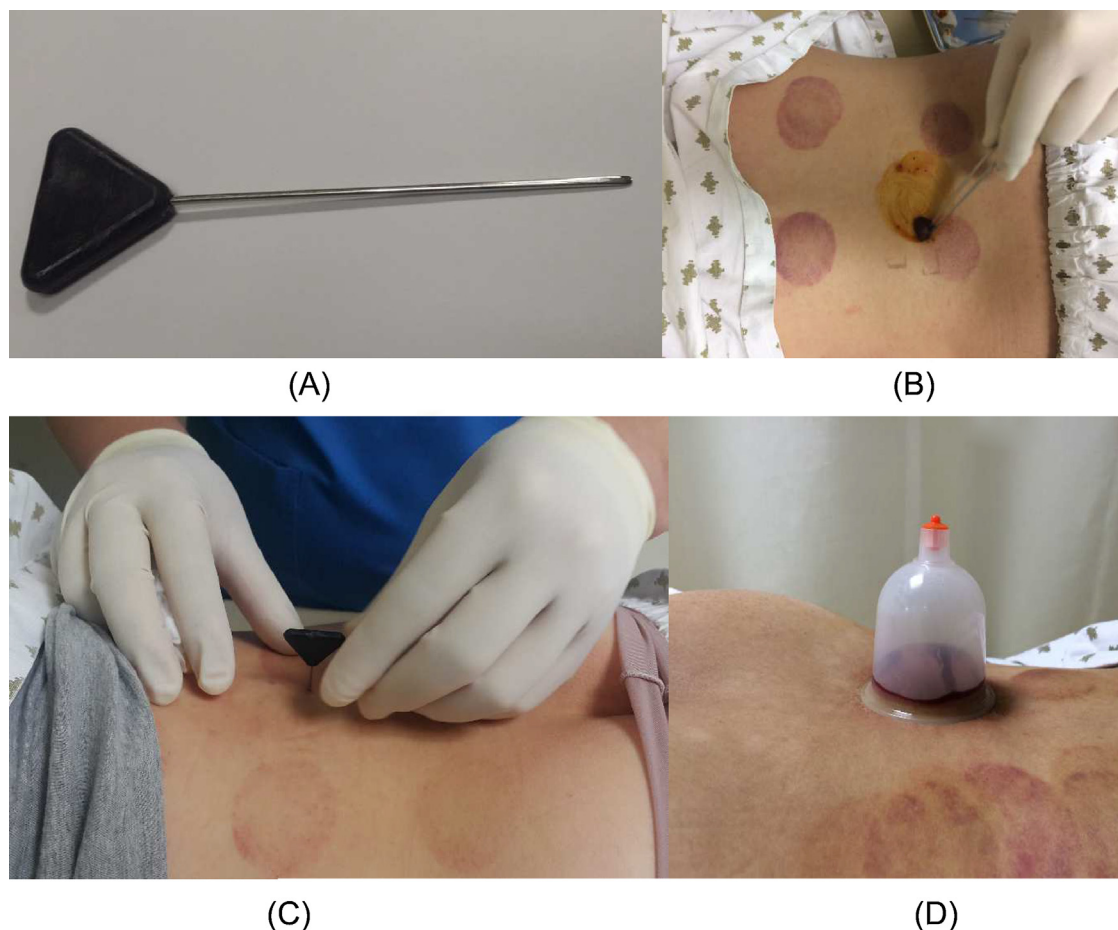


Fig. 2 – Application of acupotomy. (A) Acupotomy needle. (B) Skin disinfection. (C) Needle insertion and manipulation. (D) Wet-cupping.

2.4.2. Manual acupuncture

A total of six manual acupuncture treatments will be administered 3 times per week for 2 weeks as a control intervention. We will use 0.25 × 40 mm, single-use, sterile, stainless-steel needles (Dongbang Acupuncture Inc., Chungnam, Republic of Korea). The acupuncture treatment will be performed on the local points GV3 (Yaoyangguan) and bilateral BL23 (Shenshu), BL24 (Qihaihu), BL25 (Dachangshu), and BL26 (Guanyuanshu). The bilateral GB30 (Huantio), BL40 (Weizhong), and BL60 (Kunlun) will be the distant points. We will induce Deqi sensation by rotating the needles left and right three to five times.¹⁴ We will then retain the needles for 15 minutes. During the treatment sessions, the patient will lie in a prone position in comfort.

Study clinicians with acupuncture experience of more than 2 years will administer the manual acupuncture treatment. For compensation, the participants in the manual acupuncture (control) group will be provided with one session of acupuncture and moxibustion treatment on the lumbar region at the end of the study.

2.4.3. Cointerventions

Participants in the acupotomy group will receive the rescue medication, i.e., acetaminophen (maximum dose of

3000mg/d) to relieve postacupotomy pain. They will be instructed to take the medicine only when they experience intolerable pain. A CRC will query the patient regarding the exact dose of the rescue medication and record this information in the case report form.

All participants will be allowed to take any over-the-counter or concomitant medication that they were using before participating in the study. The participant will be asked to report any new medicine that is used after the start of the intervention. If the participant arbitrarily starts to take new medicine without reporting to the CRC, he or she will be dropped out of the trial by decision of the principal investigator who will consider the impact of the new medication on the results of the study.

2.5. Outcome measurement

Assessments will be performed before the intervention (T0, screening visit), 1 week after the screening visit (T1), 2 weeks after the screening visit (T2), and 2 weeks after the final treatment (T3, primary end point). Interim evaluations at T1 and T2 during the 2-week treatment will be completed prior to the assigned intervention. The detailed

Table 1 – Schedule for the treatment and outcome measurements.

Study period	Screening	Treatment period		Follow-up period	
Time point (wk)	0	1	2	3	4
Enrollment					
Informed consent	○				
Demographic characteristics	○				
Medical history	○				
Blood test	○				
L-spine CT	○				
Inclusion/exclusion criteria	○				
Random allocation	○				
Interventions					
Acupotomy		◎	◎	◎	◎
Manual acupuncture		●●●	●●●		
Assessments					
VAS	○	○	○		○
ODI	○	○	○		○
MMST	○	○	○		○
EQ-5D	○	○	○		○
Adverse events*		←————— every visit —————→			

◎ : 2 sessions per week for 2 weeks. ● : 3 sessions per week for 2 weeks. ○ : common in both groups.
 CT, computed tomography; EQ-5D, EuroQol five dimensions questionnaire; MMST, Modified-Modified Schober Test; ODI, Oswestry Disability Index; VAS, visual analog scale.
 * Adverse events including pain, bleeding, hematoma, contusion, dizziness, hypersensitive skin reaction, and infection will be evaluated at every visit.

schedule for the outcome measurements is provided in [Table 1](#).

The primary outcome is the mean change in the visual analog scale (VAS) score for LBP and/or leg pain from baseline (T0) to 4 weeks (T3). The VAS score at the screening visit will be the baseline value. Participants will be asked to mark the degree of pain in the affected leg and the low back on a 100-mm VAS, with “0” indicating no pain and “100” indicating the worst pain imaginable.

The secondary outcome measures will be the Korean version of Oswestry Disability Index (ODI), the Modified-Modified Schober Test, and the EuroQol five dimensions questionnaire.

The ODI is a self-reporting questionnaire comprising 10 items used to assess the levels of pain and disability during different physical activities in patients with spinal disorders.¹⁵ The Korean version of ODI¹⁶ omits the sex life item because participants may be reluctant to answer this question owing to the cultural background in Korea. Therefore, the total score on the ODI will range from 0 to 45.

The Modified-Modified Schober Test¹⁷ will be used to measure the range of motion of lumbar flexion. Blinded assessors will mark the midline horizontally at the level of the posterior superior iliac spine. Two other marks will be drawn 10 cm above and 5 cm below the first landmark. The participant will then be asked to bend over and touch his or her toes as long as possible without increasing pain. The assessors will measure the increase in distance between the superior and inferior marks. The length increment, which is the difference between the 15-cm distance (neutral position) and the increased distance (anterior flexion posture), will be calculated to determine the range of motion of the lumbar spine.

We will also use the Korean version of EuroQol five dimensions questionnaire,¹⁸ which is one of the most widely used instruments for measuring quality of life.

2.6. Adverse events

At every visit, researchers will evaluate adverse events (AEs), which are defined as unexpected or unfavorable responses that occur during and after treatment. All participants will be taught to report all AEs even if they are not necessarily related to acupotomy or manual acupuncture. We will evaluate the causality and severity of the AEs, which may include pain, bleeding, hematoma, contusion, dizziness, hypersensitive reaction of the skin, and infection, and take appropriate action. If serious AEs, such as severe disability, deformity, and life-threatening events, occur, the participant will be dropped from the trial by decision of the principal investigator.

2.7. Statistical analysis

Statistical analysis will be carried out on an intention-to-treat set and a per-protocol set. The intention-to-treat set will be used for the main analysis and is defined as instances wherein a participant receives the corresponding intervention and outcome measurement more than once after random allocation.

Demographic and medical data will be presented as mean ± standard deviation for continuous variables and frequencies with percentage for categorical variables. Depending on the normality of the data, baseline assessments for the two groups will be performed using t test or Wilcoxon signed-rank test for continuous variables and by Chi-square or Fisher's exact test for categorical variables.

To compare the mean changes in primary and secondary outcomes from baseline (T0) to 4 weeks (T3) between the two

groups, analysis of covariance will be performed with the baseline score as a covariate and study group as a fixed factor. Paired *t* test or Wilcoxon signed-rank test will be used to compare the outcomes before and after treatment in each group. Repeated measures analysis of variance will be used to assess the differences between groups over time. Subgroup analyses can be performed based on the baseline characteristics for the primary and the secondary endpoints. A *p* value less than 0.05 will be considered statistically significant. Multiple imputation will be used to handle missing data. All analyses will be performed using SAS version 9.1.4 (SAS institute, Inc., Cary, NC, USA) by a statistician blinded to participant allocation.

2.8. Ethics and monitoring

This study was designed in accordance with the Helsinki Declaration and Korean Clinical Practice Guidelines and was approved by the Institutional Review Board of DUDKMH (number DJDSKH-16-BM-05) in South Korea. The protocol has been registered in Clinical Research Information Service, which is recognized as the primary registry of the WHO as well as a national public clinical trial registry in Korea (Registration number: KCT0002188). All source documents regarding the trial will be classified with a unique subject code and will securely be kept in storage with locks in DUDKMH. At the end of the study, independent researcher will conduct the compiling, classifying, and coding of data for statistical analyses. Monitoring of data and research performance will be conducted regularly by researchers from the Korea Institute of Oriental Medicine.

3. Discussion

This trial is designed to compare the clinical effectiveness of two different types of acupuncture methods, acupotomy and manual acupuncture. The evaluation will be based on improvements in pain, disability, lumbar mobility, and quality of life in patients with herniated lumbar disc. We will also investigate the adverse effects of both treatments.

Herniated lumbar discs generally cause LBP and/or leg pain due to physical pressure, chemical stimulation by inflammatory reactions, microhemocirculation disorders, or edema on the nerve root at the level of the herniated nucleus pulposus.^{1,19} As mentioned previously, acupotomy is thought to have a better therapeutic effect than manual acupuncture. This is because acupotomy can resolve chronic adhesion with contracture, impairment of dynamic balance, and circulatory disturbances in the blood flow surrounding the affected nerve.^{6,20,21} In a previous study, Inoue et al²² investigated the clinical efficacy of three different acupuncture stimulation methods for lumbar spinal canal stenosis or herniated lumbar disc. Approximately half of the patients who received acupuncture stimulation of EX-B2 (paravertebral points 1–2 cm outward from the spinous process of the disordered level, at the stiffest point) reported amelioration of their symptoms. Electroacupuncture stimulation of the pudendal nerve improved lower limb symptoms, such as radiating pain, dysesthesia, and claudication rather than LBP. In addition, considerable immediate and sustained relief (3 months after

the final treatment) was observed in patients who received electroacupuncture at the relevant nerve root under X-ray fluoroscopy. The authors also found increased sciatic nerve blood flow after lumbar muscle acupuncture in a rat study. Therefore, they concluded that one mechanism of action of acupuncture and electroacupuncture stimulation could be a transient increase in blood flow at the sciatic nerve and the nerve root in addition to activation of the pain inhibitory system. Considering that the insertion points will be anesthetized with lidocaine in this study, effects of acupotomy would most likely involve the recovery of mechanical function and amelioration of decreased blood flow rather than the activation of the pain inhibitory system induced by percutaneous stimulation. The wet-cupping procedure at the acupotomy site in this trial will also contribute to the effects of acupotomy by removing blood congestion and reducing tension at the treated site.¹⁰

Our research team has widely applied acupotomy in patients with spinal disorders in clinical practice. We have reported the potential use and beneficial effects of acupotomy treatment in previous case-series studies.^{8–10} However, we have been unable to determine the clinical effectiveness of acupotomy owing to inherent limitations of case reports and its combinations with other Korean medicine therapies. Meanwhile, clinical observations of patients treated with either acupotomy or manual acupuncture have led us to establish a research question and to conceive of this study design. This study focuses on increasing external validity by accurately reflecting the clinical setting and the use of each acupuncture method. The differences in the components of treatment between the two acupuncture methods should be considered acceptable for clinical and practical applications. In South Korea, acupotomy for the treatment of herniated lumbar disc is generally performed once or twice per week at two to three insertion points proximal to the sites of herniation, while manual acupuncture is implemented more frequently at multiple acupoints on local and/or distant parts of the body. In addition, the time point at which we expect to observe the largest clinical effect of acupotomy is empirically 2 weeks after the treatment (post-treatment).

This study has some limitations. First, we investigate treatment outcomes over a short follow-up period. Second, the sample size is small. Third, the needling components (e.g., location, insertion depth, and stimulation) and nonspecific parameters (e.g., credibility and expectation)²³ are different between the experimental and control groups. The strength of this study is the confirmed diagnosis of herniated lumbar disc. We will include patients who meet all diagnostic criteria based on image examination (CT or MRI), physical examinations, and related symptoms in the lumbar spine and/or lower limb. Another advantage of the study design is the exclusion of bleeding disorders by considering medical history and blood tests performed as part of the screening procedure. The results of this pilot RCT are expected to provide valuable data and insights for a confirmative full-scale RCT to determine the clinical effects of acupotomy.

Conflict of interests

The authors declare that they have no conflict of interests.

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