척추신경추나의학회지 제16권 제2호(2021년 12월)
The Journal of Chuna Manual Medicine for Spine & Nerves Vol 16. No. 2, December 2021, 69-77
https://doi.org/10.30581/jcmm.2021.16.2.69

JCMM
ISSN 1975-535X

A Comparative Study of a Deeply-inserted Acupotomy Applied to Hyeopcheok Points and Usual Korean Medicine Treatments for Lumbosacral Radiculopathy: Safety, Effectiveness, Cost-effectiveness: A Study Protocol

요천추신경병증에 대한 심부협척 도침술과 한의통상치료의 효과 비교: 안전성, 유효성, 경제성평가: 연구 프로토콜

Received: 26 November, 2021. **Revised:** 6 December, 2021. **Accepted:** 6 December, 2021

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연구 배경 최근 한국 및 중국에서 근골격계 질환에 대한 도침술의 활용이 늘고 있다. 하지만 현재까지의 임상연구는 대부분 증례보고 형태에 그치거나, 충분한 근거가 확보되지는 않은 실정이다. 우리는 요천추신경병증환자의 치료에 있어 도침치료와 통상한의치료와의 비교를 통해 도침치료의 유효성, 안전성, 경제성 평가를 시행하기 위해 본 연구를 기획하게 되었다.

연구 방법 본 연구는 예비임상 연구로, 다기관에서 진행되며, 무작위대조군, 활성 대조군을 통한 2개군 병행집단 연구로 평가자 맹검을 시행하게 된다. 이 연구에서는 총 50명의 요천추신경병증 환자를 대상으로 2개군으로 균등하게 분배하여 도침술 또는 통상한의치료를 시행하게 된다(각군당 25명). 도침술 그룹의 경우 협적혈에 도침치료를 시행 받게 되며, 통상 한의치료군은 연구자 판단하에 도침술을 제외한 적절한 한의치료를 시행 받게 된다. 두 개의 그룹은 주당 2회씩 총 3주간 치료를 받게 된다. 일차 유효성 평가는 요통으로 인한 기능장애를 평가하기 위한 Oswestry disability index를 통해 시행한다. 이차 유효성 평가지표로는 numeric rating scale, European Quality of Life 5-Dimension 5-Level, short-form McGill Pain Questionnaire, Roland-Morris Disability Questionnaire scores를 시행하게 된다.

고찰 본 예비임상연구의 결과는 추후 있을 요천추신경병증에 대한 도침치료 및 한의통상치료 비교효과 연구의 유효성, 경제성평가 본 임상연구를 위한 기초 정보 및 가능성을 확인하고 적절한 대상자수 산정에 도움이 될 것이다.

임상연구 등록정보 Clinical Research Information Service(https://cris.nih.go.kr/)에 2021년 5월 30일에등록됨. 연구등록번호 KCT0006043.

Abbreviations
LSS: lumbar spinal stenosis
RCT: randomized controlled trial
UKC: usual Korean medicine care
PNUKH: Pusan National University Korean Medicine Hospital
DKMHDU: Daejeon Korean Medicine Hospital of Daejeon University
WUKMMC: Woosuk University Korean Medicine Medical Center
IRB: institutional review board
NRS: numeric rating scale
SOP: standard operating procedure
KMD: Korean medicine doctor
ODI: Oswestry disability index
EQ-5D-5L: European Quality of Life 5-Dimension 5-level
SF-MPQ: short-form McGill Pain Questionnaire
RMDQ: Roland-Morris Disability Questionnaire
PRO: patient-reported outcome
ITT: intention-to-treat
PP: per-protocol

주제어 도침, 요천추신경병증, 무작위 대조군 임상연구, 예비임상연구, 임상연구프로토콜

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Ⅰ. Introduction

Lumbosacral radiculopathy is a pain syndrome caused by the irritation or compression of nerve roots in the lumbar spine. It can be caused by a lumbar herniated intervertebral disc, degeneration of the spinal vertebra, or narrowing of the spinal canal, lateral recess, and intervertebral foramen. Symptoms include low back pain that radiates to the leg in a sensory dermatome. Other accompanying symptoms include numbness, weakness, and loss of deep tendon reflexes.[1)]

The major diseases that cause lumbosacral radiculopathy are lumbar disc herniation and lumbar spinal stenosis (LSS).[2,3)] Lumbar disc herniation causes neuropathic pain by stimulating the spinal nerve roots by protruded nucleus through the radiation cracks of the annulus fibrosus formed due to degeneration of the intervertebral disc or injury.[4)] LSS is a disease that presents with various neurological symptoms, such as low back pain, radiating pain to the lower extremities, intermittent claudication, and impaired walking, voiding, and defecation by the compression of cauda equina or nerve roots due to narrowing of the spinal canal, lateral recess, and intervertebral foramen.[5)]

Medications, physical therapy, acupuncture, manipulation, and traction are commonly used to treat lumbosacral radiculopathy.[1)] Lumbar surgery is also a conventional treatment for degenerative conditions, and its use has increased rapidly in the United States.[6)] Spinal surgeries, such as decompression and spinal fusion, are reportedly associated with a large proportion of postoperative complications.[7)] Therefore, minimally invasive treatments are gaining attention.[8)]

Recently, the use of acupotomy for musculoskeletal diseases has been increasing, mainly in China and South Korea. Acupotomy refers to knife-shaped needle acupuncture, which is known to relieve muscular spasms and compressed nerves and vessels by the needle-knife detachment of soft tissue adhesions.[9)] In China, where acupotomy-related research is actively being conducted, 36 randomized controlled trials (RCTs) related to lumbar disc herniation and five RCTs related to LSS until 2017 have been reported.[10)] Most domestic studies on acupotomy are in the form of case reports, and clinical studies in the form of RCTs to evaluate the efficacy of acupotomy are insufficient. It is necessary to establish evidence for the efficacy and safety of new treatment methods, such as acupotomy. Therefore, we designed this study to assure evidence of the effectiveness, safety, and economic feasibility of acupotomy compared to conventional Korean medicine treatment for patients with lumbosacral radiculopathy.

Ⅱ. Methods

A. Objectives

The primary purpose of this study is to explore whether acupotomy can provide benefits to patients with lumbosacral radiculopathy. It is also a pilot feasibility study designed to estimate the appropriate sample size for a future trial that would verify the effectiveness of acupotomy compared with the usual Korean medicine care (UKC) on functional improvement and pain control in patients with lumbosacral radiculopathy. The dependent variables are enhanced disease-related functional status, pain relief, and improved quality of life. We also aim to conduct a cost-effectiveness analysis and a qualitative study with the pilot data, but these results will be reported separately.

B. Design

This study is a multicenter, randomized, active-con-

trolled, assessor-blinded pilot trial with two parallel arms. The trial will be conducted in the Pusan National University Korean Medicine Hospital (PNUKH), Daejeon Korean Medicine Hospital of Daejeon University (DKMHDU), and Woosuk University Korean Medicine Medical Center (WUKMMC). The protocol was approved by the institutional review boards (IRBs) of PNUKH, DKMHDU, and WUKMMC in March 2021 (IRB approval number 2021001, DJDSKH-21-BM-06, and H210202) and also registered with the Clinical Research Information Service (Identifier: KCT0006043; March 30, 2021).

C. Participants

1. Inclusion criteria

1) Adult men and women aged 19-85 years.
2) Patients diagnosed with spondylosis with lumbosacral disc disorder (injury), spinal stenosis, or lumbosacral radiculopathy through radiological examination [magnetic resonance imaging (MRI) or computed tomography (CT)] within 6 months prior to participation in the clinical trial (in case of patients suspected of lumbosacral radiculopathy but with no imaging records at the time of screening test, MRI or CT scans are performed to check whether they meet the diagnostic criteria).
3) Patients with symptoms related to lumbosacral radiculopathy, such as radiological pain, muscle weakness, and paresthesia of the lower extremities or those diagnosed with radiculopathy of the lumbosacral spine through a physical examination.
4) Patients with a numeric rating scale (NRS) score of 4 or higher with pain/discomfort due to lumbosacral radiculopathy.
5) Patients who could read, understand, and answer the symptom questionnaire.
6) Patients who volunteered to participate and approved the written consent of the IRB while agreeing to the clinical trial plan and follow-up.

2. Exclusion criteria

1) Patients with a history of spinal surgeries, such as lumbar spine intrametallic fixation and spinal fusion, or those who have undergone past spinal surgery but continue to have related pain.
2) Patients with cauda equina syndrome or motor paralysis and neurological symptoms, which are expected to be difficult to treat with conservative therapy and require surgical treatment.
3) Patients undergoing drug treatments, such as strong opioid therapy, for pain control.
4) Patients who received Korean medicine treatment within 2 weeks before the start of the clinical study (inclusion will be permitted despite treatment at another institution within the relevant period for reasons different from the indications defined for this clinical trial at the discretion of the clinical trial practitioner).
5) Patients with acupuncture hypersensitivity, metal allergy, severe atopy, keloid skin, and other skin sensitivities.
6) Patients with hemophilia.
7) Patients who are taking drugs that can cause hemostasis, such as anticoagulants, antiplatelet drugs, and aspirin, wherein it is not possible to stop the drug during the clinical trial period, according to the judgment of the clinical trial practitioner.
8) Patients who participated in other clinical studies within 30 days prior to the screening of the current clinical study and received investigational drugs, including placebos.
9) Patients with psychotic disorders, alcoholics, and drug addicts.
10) Pregnant women, lactating women, and women of childbearing potential who are not willing to use contraception during the clinical trial.

11) Patients who are judged to be inappropriate for participation in clinical trials by the clinical trial practitioner.

D. Randomization and allocation concealment

Participants will be randomly allocated to either the acupotomy group or the UKC group with equal probability. Computer-generated block randomization will be used to ensure that both groups are assigned the same number of participants at a 1:1 ratio.

Sequentially numbered, sealed opaque envelopes of the same shape and size will be used to conceal group allocation and avoid selection bias at each recruitment site. Patients will be assigned to one of the two groups according to the randomization code, and practitioners will deliver the allocation-appropriate treatment. Each trial participation site will store the randomization numbers in a double-locked cabinet on the hospital grounds. The allocation sequence will be concealed from the outcome assessor to prevent detection bias.

E. Blinding

As the practitioners and participants in this trial cannot be blinded to the allocation of treatment groups due to the differences in interventions, only the outcome assessor will be blinded. Outcome assessors will not participate in the acupotomy or UKC treatment; they will conduct the outcome assessments in a separate room with no knowledge of participant allocation and are therefore considered safe from detection bias.[11)]

F. Education on standardization of study procedure

We will develop standard operating procedures (SOPs) for the entire trial, interventions, roles, and training of assessors, researchers, and clinical research coordinators through a consensus based on our experience with other previous trials. All researchers will be required to complete clinical trial training in accordance with their individual roles. Licensed Korean medicine doctors (KMDs) will be involved in this trial as practitioners or outcome assessors. The practitioners will have had five or more years of clinical experience after being certified with KMD licensure by the Korean Ministry of Health and Welfare. They will have undergone an educational course to standardize the study procedures, and this will ensure that they adhere to the study protocol and are familiar with the study interventions and their administration. All the practitioners involved in the trial will undergo intensive training customized based on their roles to enable full comprehension of the acupotomy procedure. It will be semi-standardized training regarding acupotomy points, needling depth, and manual stimulation methods. The study details, protocol, and outcome assessment process will additionally be standardized among outcome assessors through training based on the SOPs.

G. Interventions

1. Acupotomy group

a. Treatment point

(1) The Hyeopcheok point is the basic treatment point, but according to the judgment of the practitioner, the point on the first line of bladder meridian and the Ashi point around the affected area will be used.

(2) Acupotomy point

a) Essential points (EX-B2): Applied to the lumbar level for patients diagnosed with a disease related to lumbosacral radiculopathy by CT or MRI or to the lumbar level related to the dermatome of the patient's symptoms.

b) Points on the first line of the bladder meridian (BL 22, 23, 24, 25, and 26).

c) Ashi points around the affected area: In the case of a) and b), it can be used according to the judgment of the practitioner.

b. Treatment method

(1) Before the procedure, apply an ice pack for less than 20 min to reduce the patient's pain.
(2) After disinfecting the treatment area with alcohol, perform povidone disinfection.
(3) Perform acupotomy in the area where the procedure is scheduled.
(4) After the procedure, perform compression hemostasis using sterile gauze for about 3 min and then attach a band.
(5) Patients who have completed all procedures should rest for about 15 min to check for side effects and can then return home after receiving training to prevent infection and pain management at the treatment site.

c. Number of treatments

Twice a week for 3 weeks from visit 2.

2. UKC group

a. UKC

(1) According to the judgment of the practitioner, the appropriate traditional oriental medicine treatment, which is judged to be effective for the clinical trial subject complaining of lumbosacral radiculopathy, will be administered to the procedure site.
(2) There will be no specific restrictions on factors such as the treatment area and range.
(3) After UKC, the practitioner will record the type of intervention used for treatment in the case report form.

b. Number of treatments

Twice a week for 3 weeks from visit 2.

Ⅲ. Outcome Measurements

A. Primary outcome

The primary outcome of this trial is the Oswestry disability index (ODI), which is used to assess disability associated with back pain.[12] The ODI consists of nine questions pertaining to daily activities and includes the following: experiencing general pain, practicing self-care (e.g. washing, dressing, etc.), lifting objects, sitting, standing, walking, sleeping, traveling, and participating in social activities. The items are rated on 6-point scales scored in the range of 0-5, with higher scores indicating higher pain-associated disability. The participants will be asked to complete the validated Korean version[13] of the ODI before treatment on visits 2 and 6 and at each post-treatment follow-up (visits 9 and 10). The primary endpoint will be the ODI score at visit 10.

B. Secondary outcome

The intensities of low back pain and radiating pain will be assessed using the NRS, on which 0 indicates the absence of pain and 10 indicates unbearable pain.[14] The NRS will be assessed before treatment at visits 2, 6, 9, and 10.

The European Quality of Life 5-Dimension 5-level (EQ-5D-5L) will also be used as a secondary outcome measurement. The quality of life of patients with lumbosacral radiculopathy will be assessed using the validated Korean version of the EQ-5D-5L. The EQ-5D-5L includes generic questions about the quality of life as it relates to personal health. It consists of five dimensions pertaining to mobility, self-care, daily activities, pain and discomfort, and anxiety/depression. Each dimension is scored on a scale of 1-5, with a lower score indicating a better state of participant health. The EQ-5D-5L will be administered before treatment on visits 2, 6, 9, and 10.

The short-form McGill Pain Questionnaire (SF-MPQ) is another secondary outcome measurement that will be used. It has 2 subscales: a sensory subscale with 11 words and an affective subscale with 4 words from the original MPQ.[15] These words or items are rated on an intensity scale as 0 (none), 1 (mild), 2 (moderate), and 3 (severe). The participants will be asked to complete the validated Korean version[13] of the SF-MPQ before treatment on visits 2, 6, 9, and 10.

The Roland-Morris Disability Questionnaire (RMDQ) measures disability in patients with low back pain. It consists of 24 questions pertaining to activities of daily living, functional mobility, and pain. Each question is worth one point, and the scores can range from 0 (no disability) to 24 (severe disability). The participants will be asked to complete the validated Korean version[16] of the RMDQ before treatment on visits 2, 6, 9, and 10. Responders, defined as participants with 2.5 or more pain relief using the NRS for pain intensity, versus non-responders (with less than 2.5 points for pain relief) will be assessed at visits 6, 9, and 10.

Meanwhile, we plan to perform exploratory evaluations of effectiveness, such as additional procedures or surgery performance rate, premature termination rate, use of rescue drugs, and assessment of cost-effectiveness, through this pilot trial. After the clinical trial, all patients will be investigated whether they have undergone additional procedures, such as nerve block or surgical treatment related to lumbosacral radiculopathy, during the last visit. Furthermore, if the clinical treatment is terminated earlier than the scheduled end of the clinical trial period at the discretion of the patient or practitioner, the rate of early termination within each group will be evaluated. In addition, after collecting information on the frequency, doses, types, and timing of administration of rescue drugs used during the clinical trial period, a comparison between the acupotomy and UKC groups will be conducted using the collected information. Cost-effectiveness assessment will be verified using direct medical expenses, direct non-medical expenses, and the iMTA Productivity Cost Questionnaire.

C. Safety

All expected and unexpected adverse events potentially related to the study will be monitored and reported by the researchers at each visit, and their progress will be recorded until resolved. The physicians will decide whether trial participation should be discontinued based on these reports. Further, patient-reported outcome- common terminology criteria for adverse events (PRO-CTCAE), a PRO evaluation questionnaire, will be used for the evaluation of patient safety. The items of the questionnaire will be composed of symptom terms related to pain, selected from the National Cancer Institute webpage that provides the questionnaire. The evaluation will be conducted at visits 6, 9, and 10.

D. Sample size

As there were no other trials with our design of RCT, we estimated the sample size on the basis of similar previous studies. In a pilot RCT to compare the treatment effectiveness of acupotomy and acupuncture in lumbar disc herniation patients, a total of 50 patients (25 patients in each group) were enrolled, considering a dropout rate of 20%.[17] In another RCT comparing acupotomy and acupuncture in lumbar disc herniation patients, a total of 40 patients were evaluated.[18]

This trial is a pilot study that estimates the results of the mutually comparable effect of acupotomy and UKC. As it is conducted to explore whether acupotomy is effective and safe compared to UKC, it should be conducted with the minimum number of patients within the limit that satisfies the objectives of the trial. Hence, considering a dropout rate of 20% and a 1:1 allocation ratio, the total sample size was calculated to be 50.

E. Statistical analysis

The statistical analysis will be performed according to the principles of intention-to-treat (ITT) analysis and per-protocol (PP) analysis. In the case of ITT analysis, we will apply the mixed model for repeated measures rule for missing data of continuous variables; missing data of other variables will be analyzed using the last observation carried forward rule. In parallel, PP analysis will be conducted without patients who dropped out of the clinical trials for any reason.

The significance of the differences in the various data in each group will be analyzed using the paired t-test or Wilcoxon signed-rank test, and the significance of the differences between groups will be analyzed with an analysis of variance or the Kruskal-Wallis test. The significance level will be set at 5%. If differences between groups are identified, a post-mortem verification will be performed.

A chi-squared test or Fisher's exact test will be performed to analyze categorical data, such as additional procedures or surgery performance rate and premature termination rate, which are recorded and described as frequencies (%). The interim analysis will not be applied because we expect this small pilot trial to have a minimal risk associated with acupotomy. All statistical analyses will be performed by a statistician using the SPSS statistical software (IBM Corporation, Armonk, NY, USA) for Windows, version 19.0.

F. Data collection, management, and monitoring

All expected or unexpected adverse events related to this study will be monitored and reported for every trial by the participating researchers, and their progress will be recorded until resolved. The research team will report any differences in the safety of the experimental and control groups. Data and safety monitoring will be conducted in the Korean medicine clinical trial center of Kyung Hee University Korean Medicine Hospital. Monitors will oversee study protocol compliance, informed consent documents, the overall progress of the trial, participant recruitment, data quality and timeliness, performance of the intervention, and all fields and processes of the trial. If any important protocol modification exists, we will resubmit the amended protocol to IRB. Important protocol modifications will be announced to relevant parties (e.g., investigators, IRB, trial participants, trial registries, and the sponsor).

Ⅳ. Discussion

According to a review published in 2014, acupotomy is mainly used for musculoskeletal diseases, most often for the lumbar region.[19] Furthermore, in the Korean medicine clinical practice guideline for lumbar disc herniation developed in 2017, it is recommended to consider concurrent treatment with acupotomy if the patient's symptoms persist or worsen.[20] However, only a few clinical trials have evaluated the effectiveness of acupotomy for treating lumbosacral radiculopathy. We have designed this pilot RCT to guide the design of a full-scale randomized trial. The results of this trial will determine the appropriate sample size for a future feasible, comparative effectiveness RCT to evaluate the efficacy and cost-effectiveness of acupotomy compared with those of UKC in the treatment of lumbosacral radiculopathy. From our exploratory evaluations for effectiveness, such as additional procedures or surgery performance rate, premature termination rate, use of rescue drugs, and assessment of cost-effectiveness, we will explore the potential factor(s) related to the difference in the effectiveness of acupotomy.

Additionally, this clinical trial protocol was conducted to strictly conform to the STRICTA statement[21] and CONSORT statement.[22] We expect that this pilot study will provide the clinical basis and information required

to assess the feasibility of a future large-scale trial. The sample size for the future clinical study was estimated by comparing the mean difference in the ODI for lumbosacral radiculopathy between the acupotomy and UKC groups in this pilot trial.

Trial Status

Protocol version: 1.4

Protocol date: April 8, 2021

Recruitment began on: ??-????-2021

Approximate completion date of recruitment: December 2021

This trial was prospectively registered before the recruitment.

Ethics Approval

The protocol was approved by the institutional review board (IRB) of Pusan National University Korean Medicine Hospital, Daejeon Korean Medicine Hospital of Daejeon University, and Woosuk University Korean Medicine Medical Center in March 2021 (IRB approval number: 2021001, DJDSKH-21-BM-06, and H210202) and also registered with the Clinical Research Information Service (Identifier: KCT0006043; March 30, 2021), which is one of the World Health Organization's International Clinical Trials Registry Platforms. If protocol modifications are necessary, it will be reported to the IRB. The personal information of the patients will be kept confidential and processed anonymously.

Funding

This study is supported by the Traditional Korean Medicine R&D program funded by the Ministry of Health and Welfare through the Korea Health Industry Development Institute (KHIDI; Grant number: HF20C0012). This funding source had no role in the design of the study and will not have any role during the collection, management, analysis, and interpretation of data, writing of the report, and the decision to submit the report for publication (Contact details of trial sponsor: Min-Jung Park. IT-KoM, Room 1207, Namsan Square 12F, 173, Toegye-ro, Jung-gu, Seoul 04554, Republic of Korea. Tel: +82-2-3393-4599. E-mail: mj.park@nikom.or.kr).

Availability of Data and Materials

Not applicable.

Conflicts of Interests

The authors of this work have nothing to disclose.

Acknowledgments

The authors would like to express appreciation for the contributions of patients with lumbosacral radiculopathy who will be participating in this trial.

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