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Study Protocol

Treatment of ankle sprain or instability in Korean medicine clinics: A protocol for a prospective multicenter observational study

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ABSTRACT

Background: Korean medicine (KM), including acupuncture, has been used to treat many patients with ankle sprains in Korea. The purpose of this prospective observational study is to determine how ankle sprains are treated using KM practice and to assess the outcomes of these treatments.
Methods: We will perform a prospective observational study to include around 200 participants from KM clinics with a chief complaint of ankle sprain or ankle instability. All participants will receive individualized KM treatments which may include acupuncture, pharmacopuncture, moxibustion, cupping therapy, and herbal medicine. The participants will be assessed on the information related to both ankle discomfort using a visual analogue scale and on the participant's overall condition including quality of life.
Discussion: Through this study, we would be able to collect specific and detailed data for various treatments from actual practice, such as the characteristics of the KM treatment system for treating ankle sprains or the method of acupuncture point selection. We also expect that the results of this study based on daily clinical practice will allow other researchers to create research questions that are beneficial from a clinical, societal, and patient's perspective.
Clinical research registration: This study has been registered at the Clinical Research Information Service (CRiS) of Korea: KCT0004016.

1. Introduction

Ankle sprain or instability is caused by a variety of causes and is one of the most common sports injuries, especially for athletes.[1–3] According to previous studies, ankle injury was one of the most frequent injuries during the 2008, 2012, and 2016 Olympic Games.[4–6]

Furthermore, recurrent ankle sprains can cause ankle instability,[7] which occurs in about 20% of patients who experience this type of injury.[8] Factors contributing to ankle instability include: postural instability,[9] proprioceptive deficits, weakness of the muscles around the ankle, ligamentous laxity, and subtalar and/or syndesmosis instability.[10] Most ankle sprains are treated with conservative therapies, and about 10% of patients require surgery when conservative treatment fails.[11–13] Generally, these conservative treatments focus on the ankle itself, not taking into account the various causes of ankle sprain/instability mentioned above.

In Korea where acupuncture treatment is provided exclusively by Korean medicine doctors (KMDs), the fifth most common complaint at Korean medicine (KM) clinics was ankle sprains and the total amount of medical care benefit of ankle sprains in KM was higher than that of ankle sprain in western medicine.[14] This situation may be different in other countries, for example in the United Kingdom, where acupuncture treatment have been mainly used for musculoskeletal disorders, but ankle problems were not ranked among the top 10 specific diseases that provide acupuncture treatment. Interestingly, ankle problems have been investigated as an important disease for physiotherapists among practitioners from various backgrounds offering acupuncture treatment in the UK.[15] Among the various treatment interventions provided by KMDs in Korea, acupuncture is the most well-known, non-pharmaceutical intervention that has been used as either a stand-alone or a

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secondary treatment for ankle sprains.[16] As it relates to neurophysiology and scientific methodology, acupuncture is used in ankle injuries to relieve pain and inflammation. The analgesic effect of acupuncture is thought be due to the ğate control theoryänd endogenous release of opioids.[17] On the contrary, according to KM theory the purpose of using acupuncture to treat ankle sprains is to correct the unbalanced energy (qi) flow which results in the injury.[18] In clinical practice, KMDs utilize acupoints which are both directly and indirectly related to ankle sprains for treatment based on both Korean and Western medical theories.[19] Besides acupuncture, interventions such as cupping, electroacupuncture, pharmacopuncture, moxibustion, Tui-na (Chuna) manipulation, and herbal medicine are also used to treat ankle problems.[20,21] According to our previous study, KMDs have most frequently used acupuncture to treat ankle sprains during sports injuries (92.4% of respondents), and KM's other treatment interventions such as cupping (69.7%), electroacupuncture (63.9%), or pharmacopuncture (58.2%) were also commonly used.[21] Unfortunately, although there are many acupuncture studies on ankle sprains, however,studies on overall KM treatment interventions including acupuncture that reflect treatment in clinical practice have been rarely performed.

As far as we know, there are no observational studies with large sample sizes in regards to treating ankle sprains or instability with KM practice. In this study, we will observe how ankle sprains are treated using KM practice and to assess the outcomes of these treatments. In addition, we will evaluate the effectiveness of the treatment and clarify how the factors related to patients' own characteristics may affect recurrence rate and symptom change. As of yet, this correlation between injury recurrence rate and patients' own characteristics was not explored in previous studies.

The aims of this study are to: (1) observe the change of symptoms and instability in patients with ankle sprains after 6 months of KM treatment which includes the administration of acupuncture in pragmatic setting, (2) to investigate the correlation between injury recurrence rate and the patients' own characteristics, and (3) to observe the comprehensive treatment in KM clinics and to obtain basic data for further practical research.

2. Methods

2.1. Study design

Seven KM clinics in Seoul and/or Gyeonggi-do, Korea will participate in this prospective multicenter observational study (Fig. 1). The schedules of data collection and follow-up are shown in Table 1.

2.2. Ethical approval and registration

The recruiting sites are as follows in alphabetical order: Allbaleun Korean Medicine Clinic (Goyang-si, Gyeonggi-do), Bareun Korean Medicine Clinic (Songpa-gu, Seoul), Dasarang Korean Medicine Clinic (Gangseo-gu, Seoul), Hyegang Korean Medicine Clinic (Gunpo-si, Gyeonggi-do), Jayou Korean Medicine Clinic (Seocho-gu, Seoul), PARKJIHUN Korean Medicine Clinic (Ansan-si, Gyeonggi-do), and Samjal Korean Medicine Clinic (Guri-si, Gyeonggi-do).

This study was approved by the Institutional Review Board (IRB) of Gachon University, Seoul, Republic of Korea (No. 1044396-201803-HR-078-01) on 27 March 2018, and is registered at the Clinical Research Information Service (CRiS, http://cris.nih.go.kr, registration number: KCT0004016).

2.3. Eligibility criteria

2.3.1. Inclusion criteria

1) Patients 14 years of age or older.
2) Patients who visited one of the seven designated KM clinics.
3) Patients with a chief complaint of ankle discomfort (ankle sprain or instability).
4) Patients who voluntarily agreed to participate in the study.

2.3.2. Exclusion criteria

1) Patients suspected of having a fracture according to the Ottawa Ankle Rule (OAR).
2) Patients who require treatment due to problems more urgent or severe than an ankle sprain.
3) Patients who complain of other musculoskeletal pain that is more severe than the pain of an ankle sprain.
4) Patients who have symptoms that the investigators or KMDs deem unsuitable.
5) Patients who receive concurrent treatment that the investigators or KMDs deem unsuitable.
6) Patients who have physical or mental difficulties impairing their voluntary involvement in the trial (e.g., dementia, serious mental illness, severe vision or hearing disorders, illiteracy, drug addiction).
7) Patients who have time and/or distance constraints preventing them from participating in the study.

2.4. Recruitment & informed consent

Advertisements approved by the IRB will be posted on the notice boards of the KM clinics participating in this study. When patients meeting the inclusion criteria visit the clinic, the KMDs will ask the patients whether they want more information about the study. If the patients are interested, the investigator or KMDs will explain the patients about details of study and confidentiality before participating in the study. If the patients agree to participate, informed consent will be obtained, regarding study information, decisional capacity, and voluntary participation. A copy of the consent form and other related documents will be provided to the participants. If subjects between 14 and 18 years of age participate in this study, the investigators will receive informed consent from their parents or legal guardians.

2.5. Exposure

The purpose of this study is to observe various situations from daily clinical practice, which differs from other clinical trials that evaluate the efficacy of specific interventions. Participants will receive individualized general KM treatments the basis of which is acupuncture, and other tools such as electroacupuncture, pharmacopuncture, moxibustion, cupping therapy, Tui-na (Chuna) manipulation and herbal medicine will be also used. All general KM treatments will be given to the patients in accordance with safety regulations. The KMDs, who are participating voluntarily, have over 10 years of clinical experience treating musculoskeletal disorders, particularly sports injuries. In addition, they continue to have academic exchanges, including activities such as the Society of Sports Korean Medicine.

Since this study is a practice-based research, there will be no restriction on the concomitant treatments added at the patient's will, and the treatment provided by the KMDs will also be not interfered. After the treatment is terminated by the will of the patients and the KMDs at each clinic, the patients can autonomously choose the treatment that suits him if he deems it necessary, and information on this choice will be collected directly from the patient using

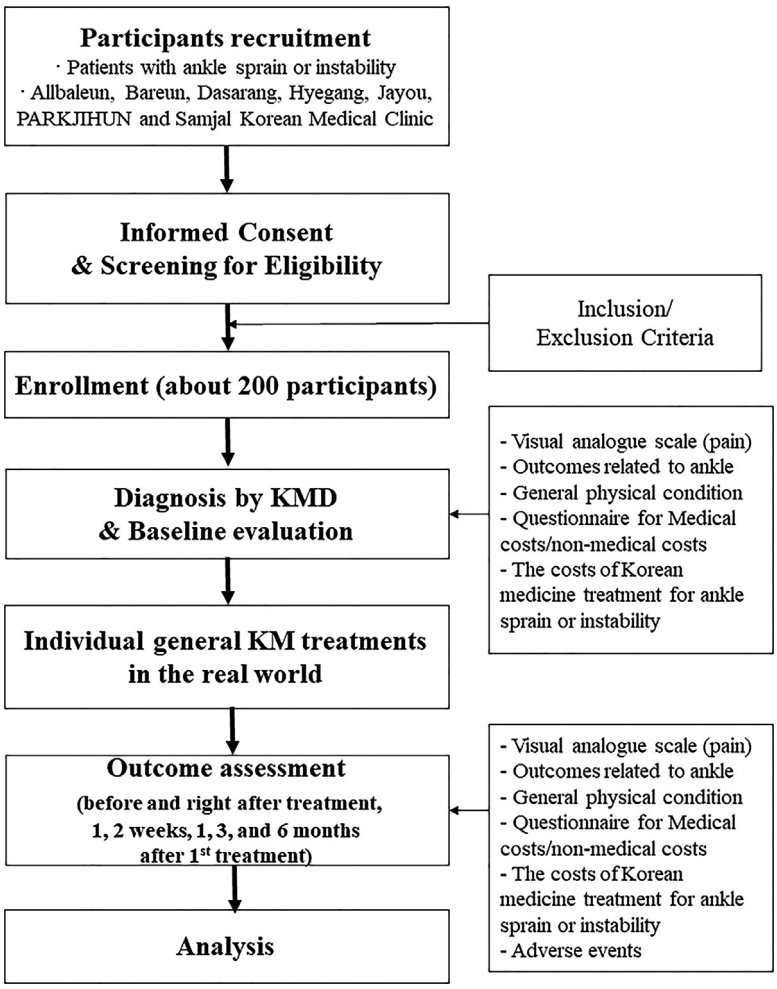

Fig. 1. A flowchart of the study. KM, Korean medicine; KMD, Korean medicine doctor.

Table 1
Schedule of study visits and assessments

	Baseline	1-week	2-week	1-month	3-month	6-month
Informed consent	V					
Baseline characteristics	V					
Chief complaint	V					
Physical examination 1 (Anterior Drawer Test, Talar Tilt Test−)	V					
Physical examination 2 (Active Straight Leg Raise Test)	V					
Range of motion (Hip internal/external rotation, Ankle plantar/dorsiflexion)	V					
Ankle circumference	V	V	V	V	V	V
Balance test	V	V	V	V	V	V
Measure yourself medical outcome profile	V	V	V	V	V	V
Visual analogue scale for pain	V	V	V	V	V	V
Cumberland ankle instability tool	V			V	V	V
Short Form (SF)-12	V			V	V	V
Sleeping status	V			V	V	V
Medical expenses due to ankle discomfort	V			V	V	V
Korean medicine treatment	V	V	V	V	V	V
The number of recurrence of ankle related symptoms				V	V	V
Adverse event		V	V			
Preference for tradition Korean medicine treatment				V	V	V

a questionnaire for medical/non-medical costs for ankle sprain or instability.

2.6. Outcome measurement

2.6.1. Items to be examined by KMD before treatment

First, the anterior drawer and talar tilt tests will be performed to check for injuries in the anterior talofibular ligament or calcaneofibular ligament and to establish a baseline. Secondly, the patient's detailed medical history and symptoms will be collected to assess the cause and severity of the ankle symptoms: (1) whether the participant sprains his/her ankle frequently; (2) the site of the injury as well as the pain level; and (3) range of motion (ankle plantar and dorsiflexion; hip internal and external rotation). Third, the active straight leg raise (ASLR) test will be utilized to evaluate the mobility of hip joint and stability of the trunk.

2.6.2. Primary outcome measures

The numeric rating scale (NRS) for pain will be used as the primary measure to evaluate the participant's improvement regarding discomfort due to ankle sprain or instability. The scale ranges from 0 (no pain) to 10 (the most severe pain). The NRS measurements will be assessed at baseline (before and immediately after treatment), and then again at 1-week, 2-week, 1-month, 3-month, and 6-month time points. The changes from before and after treatment as measured with the NRS will be analyzed.

2.6.3. Secondary outcome measures

1) *Outcomes specific to the ankle*

(1) Ankle edema (ankle circumference measured at baseline, 1-week, 2-week, 1-month, 3-month, and 6-month): to select indicators related to ankle edema, we considered three principles: (1) If possible, use objective indicators, (2) be simple to make self-measurements, and (3) be able to ensure reliability in repeated measurements. Under these principles, considering the previous studies related to ankle edema measurement[22,23] and referring the clinical experience of the participating KMDs, we will collect ankle circumference measurements data as follows: when measuring the ankle circumference, a tape measure will be provided to allow the patient to measure the circumference around the lower part of the medial and lateral malleoli of both ankles (Fig. 2a). The participants will be trained how to correctly measure at the first visit.

(2) Stability of ankle and trunk (balance test measured at baseline, 1-week, 2-week, 1-month, 3-month, and 6-month): the stability of the ankle and trunk will be confirmed indirectly through a balance test. The balance test in this study involves closing the eyes and measuring how many seconds the participants can stand on one foot (Fig. 2b). We will educate the participants on how to perform the balance test (with the help of others for safety reasons), and we will educate participants to perform the test in a sufficiently large space where there are no objects (for safety reasons). We will also encourage participants to get help from others so that they can make accurate measurements.

(3) The instability of the ankle (Cumberland ankle instability tool[24,25] measured at baseline, 1-week, 2-week, 1 month, 3 month, and 6 month): this is a patient-reported questionnaire composed of nine items. The maximum score is 30, where a lower score indicates decreased functional ankle stability.

(4) Recurrence rate (measured at 1-month, 3-month, and 6-month): after the first data collection, patients will be asked whether the ankle discomfort has recurred and why.

2) *General physical condition*

(1) Body mass index (height and weight measured at baseline)

(2) Measure yourself medical outcome profile (MYMOP)[26] (measured at baseline, 1-week, 2-week, 1-month, 3-month, and 6-month): This is a patient-generated outcome instrument that can measure effects from a wide range of health care interventions, mainly primary care and complementary treatment. In this study, the MYMOP will be included to explore symptoms that the patients are most concerned about and to evaluate changes of these symptoms over time following treatments.

(3) Short Form 12[27] (measured at baseline, 1-month, 3-month, and 6-month): a short version of the Short Form-36 Health Survey (SF-36), one of the most widely used general-purpose tools for evaluating health-related quality of life (HRQoL), which is abbreviated to eight scales (physical functioning, role-physical, bodily pain, general health, vitality, social functioning, role-emotional, and mental health) and twelve questions. The Korean SF-12 version 2 will be used in this study.

(4) Questionnaire for sleep status (measured at baseline, 1-month, 3-month, and 6-month): documents the participants' overall sleep status over the past month, including average wake-up time, bedtime, time to fall asleep, and their quality of sleep (five-point scale ranging from very bad to very good).

3) *Others*

(1) Questionnaire for medical/non-medical costs due to ankle sprain or instability: the number and type of all treatments for ankle discomfort over the past week (measured at 1-week and 2-week) or month (measured at baseline, 1-month, 3-month, and 6-month).

(2) The costs of KM treatment(s) for ankle sprain or instability: this data will be collected from each KM clinic.

2.7. Data collection

The participants' chief complaint and the results of their physical examinations will be collected during face-to-face visits with the KMDs. The other measures will be collected using an online questionnaire at the baseline, 1-, 2-week, 1-, 3-, and 6-month time points. Due to the nature of the study, the number of treatments may vary from patient to patient, so we will define the data recording points of 1-, 2-week, 1-, 3-, and 6-month based on the first treatment date of individual participant. The online questionnaire will be sent to the participants via text message, and the participants will have 3 days to respond to the survey. If participants don't respond within 3 days, there will be a reminder text. The data to be collected are presented in Table 1. In addition, we will analyze the specific and detailed treatment options for each patient (such as which acupuncture points will be selected and why each treatment will be given) based on the data obtained from the KMDs. Each participant may or may not be receiving treatment for the follow-up period (1-, 2-week, 1-, 3-, and 6-month), which can be analyzed through the result data to be collected by KMDs.

2.8. Sample size calculation

This study is a prospective, observational, preliminary study in an actual clinical setting, which will require a large number of study subjects due to the expected high heterogeneity of subjects and the high expected variance of data. However, since this study is a preliminary study based on real clinical practice, it is difficult to calculate the sample size calculation statistically. We have roughly identified the ankle sprain patients' ratio among the outpatients in research clinics in advance, and from this, we could arbitrarily expect the minimum and maximum number of people who could be recruited in consideration of not accepting the study. Although we had a prior study that provided an approximate number of visits to the KM clinic for a week for the treatment of ankle sprains,[21] we determined that estimating the number of participants in the study could be affected by a variety of variables. Through discussions between a KMDs and a researcher, the target number of initial maximum recruits was set to 200 subjects. Also, it was decided not to set a minimum/maximum number of participants to recruit at the clinic, but to do their best to recruit patients in each clinic during the study period (1 year after the IRB approval). Furthermore, as this is a survey, we plan to increase the response rate by providing appropriate rewards (coffee gift cards) to respondents to avoid any potential bias due to a low response rate.

2.9. Statistical analysis

Results on continuous variables will be presented as mean and standard deviation, whereas categorical variables will be expressed as frequency and percentage. For all statistical tests, a two sided p-value is used and the type 1 error is set as 0.05 with a 95% confidence interval. For comparison of these proportions, the Chi-squared test

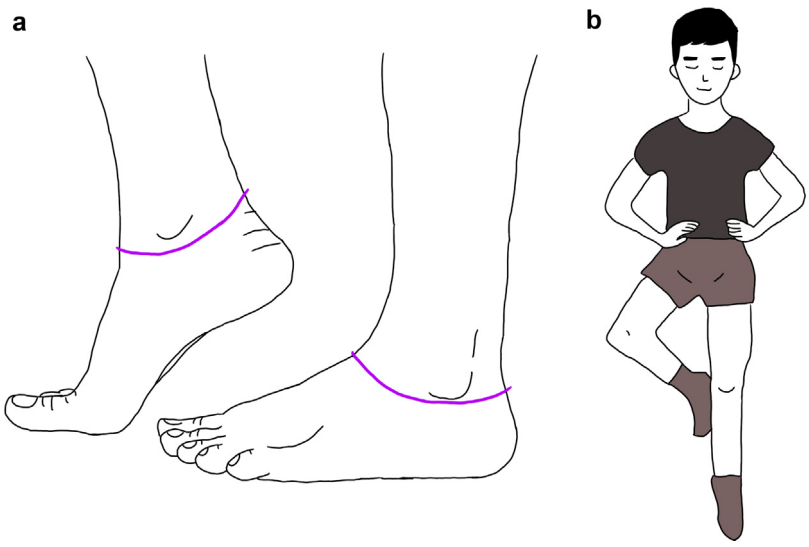

Fig. 2. Measurement of ankle edema (ankle circumference) and the stability of ankle and trunk (balance test). Participants will be trained on their first visit to self-measure their own ankle circumference (a) and the stability of ankle and trunk through the balance test (b). The diagram will be provided for each online questionnaire so that the participants can understand it intuitively.

or Fisher's exact test is utilized when necessary. Statistical analysis of changes after a certain period (1-, 2-week, 1-, 3-, 6-month) since the beginning of the first treatment will be made using a paired Student's *t*-test and a Wilcoxon Signed Rank Test for normally distributed data, and the skewed data will be analyzed using a Kolmogorov–Smirnov normality test. The baseline and other confounding variables (sex, age, etc.,) will be analyzed after adjustment according to the general characteristics. We will also conduct a sub-analysis based on the treatment types, such as whether the group's Cumberland Ankle Instability Tool (CAIT) score is more or less than 25, causes of sprains, severity, recurrence, and sports injuries. Comparisons of scores between groups will be performed using unpaired Student's *t*-test and Mann–Whitney *U* tests for normally distributed data and skewed data, respectively. Also we will conduct logistic regression analysis based on the treatment type to explore what factor influence clinical outcome of ankle sprain. Missing data will be imputed using the last observation carried forward method. Although there are no comparators, we will calculate results for increased cost and effectiveness using the SF-12 and medical service usage questionnaire. All statistical analyses in this study will be conducted using SAS software, version 9.4 (SAS Institute Inc., Cary, NC, USA).

2.10. Safety

All investigators and KMD will be educated in research ethics. Participants will be asked by KMDs whether or not any adverse event (AE) has occurred at each treatment and also in online surveys at 1 and 2 weeks post-treatment. If any AEs occur, we would immediately provide appropriate treatment to the participant according to guidelines of the clinic, and then observe the participant's progress during the follow-up visit. The name, severity, duration, and cause of all AEs that occur during the study period will be recorded. After the study period, any connection between the AE and the KM treatment will be evaluated by investigator. If there is a correlation, the investigator will take the appropriate action immediately. If there are ambiguities when assessing severity and causality of AEs, final decision will be made based on an agreement of the independent researchers. If a serious AE occurs, investigators will report it to the IRB within 24 hours of disclosure. In addition, all investigators will be trained to protect the participants' personal information and will sign a pledge to keep the information they acquired confidential.

2.11. Quality control

The quality of this trial will be monitored by an independent investigator. This independent investigator will examine the following: (1) the informed consents and case report forms, (2) serious AEs, and (3) the obtained data set.

3. Discussion

This article describes the protocol of a prospective multicenter observational study, which aims to monitor the changes in symptoms and instability of patients in Korea who have been treated with KM treatments including acupuncture. In evidence-based medicine, the number of systematic observational studies actually performed is very small, although the appropriateness of clinical observational studies is often emphasized. A carefully planned and performed prospective observational study does not guarantee an outcome showing a definitive relationship between therapeutic intervention and efficacy, and there are clearl limits to the research design itself for generalization of the results. These studies can, however, make a contribution in fitting the pieces of evidence for KM interventions.[28]

In the process of developing research protocols, we found that it is practically difficult to use an appropriate sampling method to select practitioners who will participate in the research. In order to facilitate this study, we asked some of the KMDs who own their clinics, including the board members of the Society of sports Korean medicine, to participate in the study. This may have a negative impact on issues related to representativeness and generalization of research results in the future. Nevertheless, the clinic-based study requires one-sided sacrifice, such as disruption of consultation hours, for practitioners participating in the study, so many practical problems are involved. Activation of research using practice-based research network (PBRN) may help with this problem. A recent growing PBRN research provides the grounds for generalizable solutions to clinical problems, proposed by a

group of practice with the aim of examining health care processes arising from practice, in community-based settings.[29,30] This study is not intended to construct and utilize PBRN, but as a practice-based research, we reflected the opinions of practitioners at different stages of the research design process. For example, this study will provide an opportunity for doctors to study about several clinical questions that have some empirical clues in clinical practice for ankle diseases, but have no solid evidence. For this reason, questions that seem to be somewhat unrelated to musculoskeletal disorders, such as sleep or digestive system conditions, were also included as one of the measurements in this study.

Ankle sprains, whether first occurring or recurring, are one of the top-ranking complaints in patients visiting KM clinics.[14] According to a previous survey conducted by our research team, 97.1% of the responding KMDs used acupuncture with cupping, electro-acupuncture, and pharmacopuncture to treat ankle sprains.[21] The data collected through this proposed study would be more specific and complex than the data collected through simple surveys. This protocol provides evidence for future clinical research such as randomized control trials (RCTs) by observing the actual data from these treatments as seen in real world situations. In addition, any correlation between a patient's injury recurrence rate and patient-specific characteristics will be confirmed. Through this study, we will be able to collect specific and detailed data for various treatments from actual practice, such as the characteristics of the KM treatment system for treating ankle sprains or the method of acupuncture point selection (i.e., A-Shi, Saam, or Dongsi acupuncture). We also expect that the results of this study based on daily clinical practice will allow other researchers to create research questions that are beneficial from a clinical, societal, and patient's perspective.

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Author contributions

Conceptualization: SYK. Methodology: SYK. Validation: GH and SYK. Formal analysis: MMK and YSL. Investigation: SYK. Resources: SYK. Data curation: GH and SYK. Writing – original draft: GH. Writing – review & editing: GH, MMK, SYK and YSL. Visualization: SYK. Supervision: SYK. Project administration: SYK. Funding acquisition: SYK.

Conflict of interest

The authors declare no conflict of interest.

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Ethical statement

This research was approved by the Institutional Review Board (IRB) of Gachon University, Seoul, Republic of Korea (No. 1044396-201803-HR-078-01).

Data availability

The data will be made available upon reasonable request.

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