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Safety and Effectiveness of Fluoroscopy-Guided Acupotomy for Carpal Tunnel Syndrome: Protocol for a Pilot Randomized, Patient-Assessor Blind, Parallel Clinical Trial

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ABSTRACT

Background: In Korean medicine, carpal tunnel syndrome is treated by stimulating the acupoints around the wrist. Although a deep understanding of anatomy and guidance is needed to stimulate these acupoints to avoid undesirable side-effects, currently there are no published guidelines for acupotomy treatment. The aim of this study is to evaluate the effectiveness and safety of fluoroscopy-guided acupotomy compared with conventional acupotomy treatment.
Methods: This is a randomized, patient-assessor, patient blind, parallel clinical trial. A total of 30 patients will be enrolled at Wonkwang University Gwangju Hospital, and will be allocated to either an experimental group or a control group. The experimental group will be treated using fluoroscopy-guided acupotomy and the control group will be treated using the conventional acupotomy method.
Results: The primary outcome measure will be identification of a cross-section area of the median nerve measured by ultrasonography, and the secondary outcome measure will be the alleviation of pain measured by the Visual Analogue Scale, improvement in the Nerve Conduction Study, Tinel test, Phalen's test, EuroQol 5-dimension scale, and Boston Carpal Tunnel Questionnaire score. Safety components will be measured by monitoring vital signs, electrocardiographs, blood tests, general chemical tests, urine tests and pregnancy tests. In addition, observations for adverse effects will be performed during the trial.
Conclusion: This study will provide a more effective, and less harmful way of treating carpal tunnel syndrome compared with conventional acupotomy. Fluoroscopy-guided acupotomy will help practitioners to be accurate in direction and depth of the needle for treating carpal tunnel syndrome.

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Introduction

Carpal tunnel syndrome (CTS) is caused by pressure on the median nerve in the wrist. Symptoms include numbness, tingling, and weakness. In Korean medicine, CTS is treated by stimulating acupoints around the wrist, and when the needle is applied to these acupoints accurately, acupotomy shows good results in the treatment of CTS. Acupotomy is a treatment combining the advantages of surgical release technique of Western medicine with conventional acupuncture. The acupotomy needle has a sharp blade-shaped head with a flat tip. This distinguishing shape of the needle aids incision of post-inflammatory adhesion, hyperplasia of the soft tissue such as transverse carpal ligament in the wrist, and decompresses the internal pressure of carpal tunnel [1].

Whilst treating the median nerve with surgery or acupotomy, there have been reports of side-effects such as claw hand deformity [2,3]. Treating the acupoints around the wrist (PC7, LU9, HT7) with acupotomy may cause side-effects such as fainting during treatment, hemorrhages, pain, hematoma, nerve injuries, and also infection [4]. When acupotomy is applied deeply, the median nerve is at risk of being injured in PC7, the radial artery in LU9, and the ulnar artery and ulnar nerve in HT7 [5,6]. Deep understanding of anatomy and guidance is needed to treat acupoints around the wrist but currently, there are no published guidelines.

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Using fluoroscopy-guided acupotomy will help the practitioner identify the location of the bones in the region of the wrist, so that acupotomy can be applied accurately for carpal tunnel syndrome avoiding blood vessels and nerves. The direction and depth of fluoroscopy-guided acupotomy can be visualized which is thought to reduce the side-effects of conventional acupotomy treatment using the *gol-do-bun-chon* method, and derive a better outcome in treating CTS.

The *gol-do-bun-chon* method, also called bone proportional measurement, is a conventional way to locate acupoints in traditional Korean medicine [7]. In this method, the location of acupoints and the depth of needle insertion is measured by the practitioner's eye, in which the length of the lower arm (from one's elbow crease to wrist crease) of the subject is converted to 12 *chon* (Korean traditional measuring unit, also called Cun), so if the length of the lower arm is 24 cm, 1 *chon* is considered as 2 cm, and 1 *chon* can be converted to 10 *pun*. According to this method the acupotomy needle should be inserted into the acupoints around the wrist (PC7, LU9, HT7) to a depth of 3-5 *pun*, if inserted perpendicularly to the skin surface, or 5-8 *pun*, obliquely.

In this study, the design of the protocol for evaluating the effectiveness and safety of acupotomy on CTS using the portable fluoroscopic X-ray system (PF X-ray) compared with using the *gol-do-bun-chon* method is provided.

Materials and Methods

Objective

The objective of this study is to compare the safety and effectiveness between fluoroscopy-guided acupotomy and the use of acupotomy using the *gol-do-bun-chon* method for treating CTS.

Design and settings

This is a randomized, patient-assessor, blind, parallel clinical trial targeting CTS patients. The trial will be conducted at the South Korea Wonkwang University, Gwangju Hospital. The schedule of study procedures is shown in Table 1 and a flow chart of the study is shown in Fig. 1.

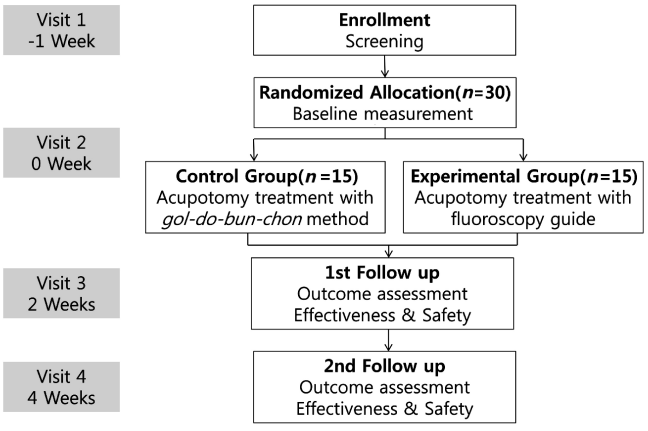

Fig. 1. Flow of the study.

A total of 30 patients will be enrolled in the trial. Patients who sign the clinical trial agreement by voluntary consent will be assessed by inclusion and exclusion criteria. Patients who meet the criteria will be allocated to either an experimental group or a control group. The experimental group will be treated by fluoroscopy-guided acupotomy and the control group will be treated using acupotomy following the *gol-do-bun-chon* method. The treatment will be performed after measuring the *pun* and *chon* of the subject. After the treatment, the patient will be monitored for adverse events.

In the experimental group, the treatment site will first be observed using fluoroscopy. Using the fluoroscopy-guide, the practitioner will be able to observe the location of the tubercle of the scaphoid, tubercle of the trapezium, the hook of hamate, and the pisiform where the transverse carpal ligament attaches so that acupotomy can be applied accurately thereby avoiding blood vessels and nerves. An acupuncture needle will first be used for probing and then acupotomy will be used.

In the control group, acupoints will be determined by the *gol-do-bun-chon* method and then acupotomy will be used. In both the experimental group and the control group, acupoints will be checked with surgical markers and disinfected using povidone-iodine swab sticks. After the acupotomy treatment, the site will be disinfected again with povidone-iodine swab sticks and covered with gauze.

Ethics statement and trial registration

The study protocol was approved by the Institutional Review Board of Wonkwang University Gwangju Hospital in Gwangju, Republic of Korea (WKIRB-2017/19), and is registered with the Clinical Research Information Service of the Korea National Institute of Health in the Republic of Korea (KCT0003067), which is a World Health Organization Registry Network registry. Written informed consent will be obtained from all participants, in accordance with the Declaration of Helsinki.

This trial was registered with the Clinical Research Information Service of the Korea National Institute of Health, Republic of Korea (KCT0003067). Any change in the protocol will be made in accordance with the official procedure, and will be approved by the Institutional Review Board, [Protocol Version: 2.3 (2018.04.03)]. As of March 2019, the trial is ongoing. The first patient was enrolled on 23 March 2018.

Participants

A total of 30 participants will be enrolled in this study. Each participant will receive an explanation of the study procedure and will be asked to sign the consent form. The patients' vital signs and relevant medical history will be recorded.

Inclusion criteria

① Experiencing numbness, tingling, or nyctalgia symptoms in the hand which result in a visual analogue scale (VAS) score of 5 or more.
② Testing positive for Tinel's sign or Phalen's sign.
③ Having a cross-section area of the median nerve over 10 mm^2 (measured by ultrasonography).
④ Willingness to participate in the study.

Exclusion criteria

① Patients who had undergone surgery to treat CTS.
② Presence of a physical abnormality in the carpal tunnel such as a tumor or malunion.

Table 1. Schedule for Study Procedure.

Trial plan		Screening Visit 1 -1wk*	Study Period Visit 2 baseline†	Follow Up Visit 3 2wk†	Follow Up Visit 4 4wk†
Confirm visit date		●	●	●	●
Written consent from participants		●			
Population, sociological survey		●			
Disease history (past history/current history/family history)		●			
Previous/current medications (history of illness/history of medications/combined therapy changes)		●			
Random allocation			●		
Effective outcome	100 mm pain VAS	●	●	●	●
	Tinel's test	●	●	●	●
	Phalen's test	●	●	●	●
	NCS		●		●
	BCTQ score		●	●	●
	Measurement of cross-sectional area of medial nerve	●	●	●	●
	EQ-5D test		●	●	●
Safety assessment	Vital sign	●	●	●	●
	Lab test	●			
	Electrocardiogram	●			
	Combined drug/therapeutic survey		●	●	●
	Documentation of adverse effects		●	●	●
Pregnancy test		●			●
Inclusion/exclusion criteria		●			
Drop out monitor			●	●	●
Acupotomy treatment			●		
X-ray shooting			●		
Assessing blindness					●

* Patients who have already taken analgesics should be instructed to stop taking the medicine 1 week prior enrollment in the study.
† ± 3 days from the designated date are allowed.
BCTQ, Boston carpal tunnel questionnaire; EQ-5D, EuroQol 5-dimension; NCS, nerve conduction study; VAS, visual analogue scale.

③ Patients who are taking medicine related to a mental disorder or an immune disease.
④ Patients taking adrenocortical hormones or a nonsteroidal anti-inflammatory analgesic to treat CTS (A patient can enroll in the study if they have stopped taking the anti-inflammatory analgesic 1 week prior to enrollment).
⑤ Patients who have skin allergies or infections.
⑥ Insulin-treated diabetic patients, patients who have cardiovascular disease or have a pacemaker implanted, and patients who have kidney disease.
⑦ Pregnant women, lactating women, women who test positive for pregnancy before random allocation, or women who do not agree to use medically appropriate contraceptives (e.g., oral medication, hormone implants, intrauterine devices, condoms, or spermicides).
⑧ Any patients deemed by a clinical research investigator, to be inappropriate for participation in the clinical trial.

Participant recruitment

The participants will be recruited through advertisements on hospital bulletin boards and local newspapers. They will be fully

briefed on the study, including the measuring methods and the procedures used. The patients interested in participating will be guided through the informed consent process by the investigator on their first visit. Once their written consent is obtained, they will be screened using the inclusion/exclusion criteria to determine their eligibility. If eligible, a physician will measure the baseline data, and the clinical research coordinator will then schedule the study procedure.

Criteria for discontinuing the allocated interventions

A patient can withdraw at any time during the study period. Any patient who falls under one of the following conditions shall be treated as a dropout, and the investigator shall clearly state the time and reason for the withdrawal.

① Patients (or their caregivers or agents) who withdraw consent to participate in the clinical trial.
② Patients who no longer meet the inclusion criteria to participate in the study.
③ Patients who now meet the exclusion criteria of the study.
④ If the investigator determines that a patient's participation is hindering the continuation of the clinical trial.

Concomitant treatment

All of the medicinal drugs and treatments a participant has taken will be recorded throughout the trial. Participants are instructed to keep records of their medication in the provided documents during the trial. Low doses of Aspirin (Max. 200 mg per day) for preventing cardiovascular diseases will be allowed. If there are any other medicinal drugs and treatments taken for over 4 weeks prior to enrollment, those will be considered not to affect the interpretation of the trial results will be allowed at the discretion of the researchers (with the exception of anti-inflammatory analgesics where patients can stop taking them 1 week prior to enrollment onto the trial).

Sample size

So far, there is no precedent for an investigation evaluating the effectiveness and safety of acupotomy treatments with the same experimental and control groups as this study. Also, there are no previous studies setting a cross-sectional area of the median nerve as a primary outcome to evaluate the effectiveness of the treatment. Thus, as a pilot study, considering feasibility rationale and precision of the mean and variance, the sample size of this study is measured as 12 for both the experimental and control groups [8]. Considering 20% drop out rate from the study, a total of 30 patients (15 for each group) will be recruited for this study.

Randomization, allocation concealment, and blinding

The randomization code will be generated by an independent statistician using a 1:1 ratio of experimental group to control group, using SAS (Version 9.0, SAS Institute. Inc., Cary, NC, USA). The code will be written on a piece of paper, put in a sealed envelope, and stored in a double-locked cabinet. After eligible participants have signed an informed consent form, a screening code will be given to each patient. Eligible patients will be given a randomized code, and allocation will be performed based on the code. Allocation concealment will be maintained throughout the trial.

Since the doctor using acupotomy cannot be blinded, only the patient and assessor will be blinded. The doctor treating the patient will only apply acupotomy to the patient, and the assessor will conduct the assessment based on the information in case report form. Allocation concealment will be disclosed if a severe adverse event occurs. In the case of disclosure, it will be reported to the Institutional Review Board and will be performed by a predetermined procedure.

Data collection

The data will be collected through a participant survey and through investigator measurements at baseline (on Visit 1) and at specified follow-up times (on Visits 2 to Visit 4).

Intervention

A total of 1 treatment session will be provided. The details of the treatment are described in Table 2. Disposable sterilized acupotomy needles [1.0 x 50 mm (Dongbang, Korea)] and the PF X-ray [MX-DRF0815 (Nano Focus Ray, Korea)] are used throughout the session for both groups. PF X-ray radiography mode is used for both groups to observe where the tip of the needle is positioned after a treatment session. The fluoroscopy mode is used in the experimental group to guide the needle insertion into the right direction, in real time, during a treatment session. The selected acupoint is PC7. The treatment will be performed by a doctor specialized in acupuncture with over 10 years' experience in clinical practice. After the session, the wrist posteroanterior and lateral view will be taken using PF X-ray radiography mode. A doctor specialized in radiology will assess whether the acupotomy has been applied accurately and whether the treatment has been a success or a failure. To prevent bias, the doctor who treated the patient is blinded by the result.

1) Experimental group

Fluoroscopy-guided acupotomy will be used. After inserting the tip of the needle into the acupoint PC7, the practitioner will proceed to observe the location and direction of the needle tip, and the bony structure surrounding the carpal tunnel in fluoroscopy mode. The tubercle of the scaphoid, the tubercle of the trapezium, the hook of hamate, the pisiform, the sites transverse carpal ligament attaches to, will be touched by the needle.

2) Control group

Acupotomy using the *gol-do-bun-chon* method will be applied. After inserting into the acupoint PC7, the needle will be inserted perpendicularly to the skin surface to a depth of 3 - 5 *pun*, or obliquely to a depth of 5 - 8 *pun*. When inserted obliquely to the skin surface, the needle head is to the distal end of the hand.

Outcome measures

Primary outcome

The primary outcome is identification of a cross-sectional area of the median nerve measured by ultrasonography. It will be measured at Visit 2 as a baseline before treatment. Afterward it will be measured 2 weeks after treatment (Visit 3) and 4 weeks after treatment (Visit 4). Patients are asked to keep a position of fingers, wrists extended, hands supinated, elbow flexed to an angle of 60 degrees in a sitting posture. An ultrasound system (Ezono 4000, Jena, EZONO, Germany. Or Venue 40, GE, Wauwatosa, USA) with a linear array transducer is used for examination. The cross-sectional area of the median nerve in the axial plane of the wrist is measured at the site of the carpal tunnel inlet (at the level of scaphoid-pisiform). The ultrasound probe will be kept perpendicular to the skin surface. Images are obtained at both sides, affected side and intact side altogether for comparison.

Table 2. Standards for Reporting Interventions in Clinical Trials of Acupuncture .

	Item	Detail
1) Acupuncture Rationale	1 a) Style of acupuncture	Acupotomy procedure
	1 b) Reasoning for treatment provided, based on historical context, literature sources, and/or consensus methods, with references where appropriate	Zhu HZ, Acupotomy, Chinese Medicine Publishing Company 1992 [1] Literature sources about acupotomy in carpal tunnel syndrome [17]
	1 c) Extent to which treatment was varied	Fixed 1 acupoint
2) Details of Needling	2 a) Number of needle insertions per subject per session (mean and range where relevant)	1 acupoint
	2 b) Names (or location if no standard name) of points used (uni/bilateral)	1) PC 7 2) unilateral (lesion side)
	2 c) Depth of insertion, based on a specified unit of measurement, or on a particular tissue level	Experimental group: Insertion to the sites of the transverse carpal ligament attachment to bony structures such as tubercle of scaphoid, tubercle of trapezium, hook of hamate, pisiform guided by fluoroscopy Control group: Based on the gol-do-bun-chon method, in a depth of 3 to 5 pun (1/10 chon) if the needle is injected perpendicularly to skin surface, or 5 to 8 pun, obliquely
	2 d) Response sought (e.g. *de qi* or muscle twitch response)	Tingling sensation in palmar region by manual stimulation
	2 e) Needle stimulation (e.g. manual, electrical)	Manual stimulation
	2 f) Needle retention time	After manual stimulation, removed immediately
	2 g) Needle type (diameter, length, and manufacturer or material)	a sharp blade-shaped needle with a flat tip (1.0 mm diameter, 50 mm long; Dongbang Acupuncture Inc.)
3) Treatment regimen	3 a) Number of treatment sessions	Total 1 session
	3 b) Frequency and duration of treatment sessions	Total 1 session followed by monitoring for 4 wks Approximately 10-15 min spent per session
4) Other components of treatment	4 a) Details of other interventions administered to the acupuncture group (e.g. moxibustion, cupping, herbs, exercises, lifestyle advice)	Instruction for daily-living guidance
	4 b) Setting and context of treatment, including instructions to practitioners, and information and explanations to patients	Practitioners are instructed to provide the information about procedures, daily-living guidance to patients, and answer to any question patients have
5) Practitioner background	5 a) Description of participating acupuncturists (qualification or professional affiliation, years in acupuncture practice, other relevant experience)	Medical specialists in the department of acupuncture & moxibustion medicine with more than 10 y of clinical practice
6) Control or comparator interventions	6 a) Rationale for the control or comparator in the context of the research question, with sources that justify this choice	Literature sources about randomized controlled trials in carpal tunnel syndrome [15]
	6 b) Precise description of the control or comparator. If sham acupuncture or any other type of acupuncture-like control is used, provide details as for Items 1 to 3 above	Same conditions as the experimental group except for using the gol-do-bun-chon method in the control group: Total 1 session of acupotomy treatment followed by 4 wks monitoring

Secondary outcomes

The secondary outcomes are;

1) Alleviation of pain measured by VAS scores

Alleviation of pain will be measured at Visit 2 as a baseline before treatment. Afterward it will be measured 2 weeks after treatment (Visit 3) and 4 weeks after treatment (Visit 4). The assessor will ask a question, "What is your pain now?" and the patient will pick a point on a 100 mm pain VAS ranging from "no pain" to "the strongest imaginable pain".

2) Improvement on a nerve conduction study (NCS) test

NCS will be measured at Visit 2 as a baseline before treatment. Afterward it will be measured 4 weeks after treatment (Visit 4). The change between the 2 NCS tests will be recorded.

3) Improvement on a Tinel test

Tinel's sign will be measured at Visit 2 as a baseline before treatment. Afterward it will be measured 2 weeks after treatment (Visit 3) and 4 weeks after treatment (Visit 4). It is performed by lightly tapping (percussing) over the nerve with a hammer to elicit

a sensation of tingling. If there is pain or pins and needles, the test result is positive.

4) Improvement of Phalen's test

Phalen's test will be measured at Visit 2 as a baseline before treatment. Afterward it will be measured 2 weeks after treatment (Visit 3) and 4 weeks after treatment (Visit 4). The patient is asked to hold their wrist in complete and forced flexion (pushing the dorsal surfaces of both hands together) for 30-60 seconds. If there is pain or pins and needles, the test result is positive.

5) EuroQol 5-dimension scale (EQ-5D)

EQ-5D will be measured at Visit 2 as a baseline before treatment. Afterward it will be measured 2 weeks after treatment (Visit 3) and 4 weeks after treatment (Visit 4). EQ-5D is a standardized instrument developed by the EuroQol Group as a measure of health-related quality of life that can be used in a wide range of health conditions and treatments.

6) Boston carpal tunnel questionnaire (BCTQ) score

BCTQ will be measured at Visit 2 as a baseline before treatment. Afterward it will be measured 2 weeks after treatment (Visit 3) and 4 weeks after treatment (Visit 4). BCTQ is a standardized questionnaire for evaluating the severity of CTS. Patients are asked to score 1 to 5 for each question about symptom severity and functional status.

7) Grip strength test

Grip strength will be measured at Visit 2 as a baseline before treatment. Afterward it will be measured 2 weeks after treatment (Visit 3) and 4 weeks after treatment (Visit 4). A hand dynamometer (DHS-176, DETECTO, Missouri, USA) is used. Patients are asked to grip the dynamometer as firmly as possible. Both hands are measured for comparison.

8) Safety evaluation outcomes

Vital signs (blood pressure, pulse rate, temperature) will be checked at every visit (Visit 1 - Visit 4). An electrocardiogram will be conducted at the first visit. If the patient has had an electrocardiogram within 1 month, the previous electrocardiogram can be used. Lab test samples (blood, general chemical, urine) will be taken at the first visit. Pregnancy tests for females will be performed at the first visit and fourth visit. Any sign of adverse effects during trials will be monitored and recorded.

Statistical analysis

To ensure sensitivity analyses, analyses of the primary and secondary outcomes will be conducted on the full analysis set, per protocol set, and safety set. In the full analysis set, the Intention-to-treat principal will be applied. The per protocol set contains those who adhered perfectly to the clinical trial instructions as stipulated in the protocol. The safety set included all the patients who are allocated into either group by randomization. Outcomes will be analyzed in both the full analysis set and per protocol set, it is important that the results be consistent. Since the control group also receives treatment per protocol set will be the primary analysis.

Baseline characteristics will be presented having applied the *t* test or Wilcoxon rank-sum test for continuous outcomes, and the chi-squared test or Fisher's exact test for categorical outcomes.

The 100 mm pain VAS, NCS test, Tinel's test, Phalen's test, EQ-5D, cross-sectional area of the median nerve measured by ultrasonography, and BCTQ score will be compared between treatment and control group, before and after treatment. The intergroup differences in the comparisons of the means will be analyzed using the paired *t* test, and the intragroup comparisons of the mean values will be analyzed with a 2-sample *t* test. The difference in the interaction of treatment by time will be analyzed by repeated-measures analysis of variance.

The accuracy rate will be measured by the rate of accurate acupuncture treatment. Wrist posteroanterior, lateral view will be taken using PF X-ray radiography mode. The rate will be calculated and the location of the needle will be identified.

Data handling

The investigators will enter the information required by the protocol into case report forms. Non-obvious errors or omissions will be entered into data query forms that will be returned to the investigational site for resolution. Participant information will be treated confidentially. The final data set will be accessible by the principal investigator.

Adverse events

The investigators will record adverse events and unexpected responses. Adverse events will be reported by the participants and will be evaluated by the investigators as mild, moderate, or severe according to the World Health Organization Draft Guidelines for Adverse Event Reporting. When a severe adverse event happens, the trial participant will discontinue the trial.

Monitoring

Monitoring will be conducted regularly by a clinical research monitor. At the time of the visit, the monitor will check the original patient record, medical device management record, and data archive (e.g. study file).

Provisions of post-trial care

This study's aim is to analyze the safety and effectiveness after a single treatment, so no further treatments will be performed after Visit 2. If a patient wants to be treated after Visit 2, he or she will be treated after the clinical trial for that patient has ended. If a severe adverse event happens during or directly after finishing the trial, appropriate compensation will be awarded in accordance with the Victims' Compensation Code.

Discussion

CTS develops due to excess pressure on the median nerve in the wrist. Overuse of the wrist, external injuries may cause inflammation and result in swelling of the carpal tunnel which puts pressure on the median nerve. CTS is one of the most common entrapment neuropathies of the upper limb [9].

In treating CTS, there are many conservative ways such as cutting back on overuse of the wrist, wearing a wrist splint, and use of painkillers. Oral steroids or local injection of corticosteroid can be given by the doctor if symptoms persist. If these conservative ways fail and the patients CTS worsens, surgical treatment options like the open or endoscopic release of the transverse carpal ligament can be performed to release the nerve [10]. However, there are issues with these treatments, for example, long-term exposure to steroids may have side-effects, cause nerve injury or not be a cure for the patients CTS with recurrence of the symptoms in a matter of months. Also, many patients with wrist splints

complain about the restriction of the hand [11,12]. In the case of either open or endoscopic release of carpal tunnel, the potential to injure nerves, vessels, or tendons in the wrist can't be excluded, and resultant complications such as paresthesia in the palm, reduced grip strength, or long-lasting ache at the operation site can also develop [13].

In mild and moderate CTS cases, acupuncture can be a cost-effective treatment compared with other conservative treatments. It has been reported in randomized controlled trials that acupuncture treatment of CTS alleviates symptoms and improves nerve conduction compared with sham acupuncture or oral intake of steroids [14-16], but more acupotomy research in the treatment of CTS is necessary. One study reported that acupotomy can be a good option to treat CTS by reducing the cross-section area of the median nerve [17]. Acupotomy can be effective when acupotomy treatment is conducted in the correct anatomical region. However, there has not been a study to date considering the accuracy rate of acupotomy treatment of CTS.

This study protocol is intended to evaluate the effectiveness and safety of fluoroscopy-guided acupotomy for the treatment of CTS. In addition, the rate of accurate location of acupoints can be evaluated compared with conventional acupuncture using the conventional proportional method. Moreover, this study protocol will help practitioners use fluoroscopy-guided acupotomy to accurately treat CTS by reducing the risks and side-effects that may be associated with acupotomy and increase the effectiveness of treatment. The protocol for this clinical trial may provide a new perspective on the practice of acupotomy using PF X-ray.

Acknowledgments

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Conflicts of Interest

The authors have no conflicts of interest to declare.

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