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Review Article

Systematic Review of Fire Needling or Warm Needling Treatment for Ankle Sprain

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ABSTRACT

The effectiveness of fire needling or warm needling treatment in clinical studies for the treatment of ankle sprains was reviewed using 4 international (PubMed, Cochrane library, EMBASE, CNKI) and 5 Korean databases (NDSL, RISS, KISS, OASIS, KTKP). Randomized controlled trials, that performed fire needling or warm needling treatment for ankle sprains until October, 2018 were retrieved (n = 8). All studies were performed in China, and 7 out of 8 studies were published within the last 5 years. There were 4 studies that used fire needling treatment, 3 studies used warm needling treatment, and 1 study used fire and warm needling treatment. The ashi-points and gallbladder meridian were the most frequently selected acupoint and meridian each. All intervention groups in the 8 studies showed statistically significant beneficial effects compared with control groups. The results of this study could provide preliminary data as the basis for well-designed randomized controlled trials on fire needling or warm needling treatment for ankle sprains.

Introduction

Sprains are symptomatic of loosening or atrophy of the ligaments between joints, accompanied by pain or swelling in the local area. In clinical practice, sprains of the ligaments around the ankle are common [1]. According to the 2017 Health Insurance Statistical Yearbook of the Korea Health Insurance Review and Assessment Service, about 1.9 million individuals presented with ankle sprains, and over 210 billion won has been spent annually [2]. Most ankle sprains recover almost completely [3]. However, if the ligaments do not heal fully, and continues to elongate or rupture, the stability of the ankle is lost, and the soft tissue around the ankle is repeatedly damaged. As a result, gait disorders arise, and complications such as joint instability, and cartilage damage remain in about 30% of people [4]. Therefore, the initial treatment of an ankle sprain is important [3]. Various Korean medicine treatments are available as an initial treatment for ankle joint sprains. In particular, acupuncture is a commonly used approach to treat ankle sprains [5].

Korean medicine treatments for an ankle sprain include manual acupuncture [6], auricular acupuncture [7], Dong-si acupuncture [8], acupotomy [9], burning acupuncture or heating-conduction acupuncture [10,11], bee venom acupuncture [12,13], blood-letting cupping treatment [14], direct moxibustion [15], and tendino-musculature taping [16].

It has been reported that warm needling had significant effects on the recovery mechanism of damaged ligaments [17]. In warm needling, mugwort is attached to the tip of the acupuncture needle and is burned to apply heat stimulation in the needling, aiding blood circulation [18,19]. Another approach is fire needling, which combines the concept of prolotherapy with acupuncture [20,21], which is applied to musculoskeletal disorders in the joints and ligaments. However, most of the previous studies [10,11,17,22-28] on fire needling or warm needling treatment for ankle sprains were limited to animal studies (e.g., rats), and there were no case-control studies.

In the present study, the results of randomized controlled trials (RCTs) investigating the application of heated acupuncture

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treatments such as fire needling or warm needling for ankle sprains were reviewed to determine if these are effective treatments for ankle sprain injuries.

Materials and Methods

Data sources and eligibility criteria

This study was conducted to determine if heated acupuncture treatments, such as fire needling or warm needling treatments, are effective treatments for ankle sprains. For this review, RCT using fire needling or warm needling for ankle sprain, which were conducted until October 2018 were included in this study.

Only those RCT that conducted heated acupuncture treatments, such as fire needling or warm needling for ankle sprains, were included in this systematic review, and non-RCT (nRCT), case-control study (CCS), case series, case reports, in vivo or in vitro studies, literature reviews, and protocol studies were excluded.

There were no restrictions on the year of publication, language, inclusion of a control or the type of publication. All treatments included fire needling or warm needling treatment alone, or in combination with other treatments.

Data search

There were 4 international databases (PubMed, Cochrane library, EMBASE, and CNKI) and 5 Korean databases (KISS, NDSL, RISS, OASIS, and KTKP) used to retrieve relevant publications.

The following keywords were used for the database searches with minor adjustments for each database and language: ("ankle sprain" or "ankle injury" or "ankle pain") and ("fire needling" or "fire needle" or "fire acupuncture" or "warm needling" or "warm needle" or "warm acupuncture"). In order to increase the sensitivity of retrieval, plural search terms were considered. Search terms for control group were not considered.

Data collection and screening

Data collection and screening were performed independently by 2 researchers. Two researchers reviewed the original text, until they were in agreement (by involving a 3rd researcher where necessary).

Risk of bias

Two researchers independently evaluated the final selected studies using the Cochrane risk of bias tool [29]. In the case of disagreement between 2 independent researchers, a third researcher intervened, and the case was decided by consensus.

Results

There were 257 studies initially retrieved in this study: 2 in PubMed, 1 in Cochrane library, 0 in EMBASE, 219 in CNKI, 11 in KISS, 8 in NDSL, 7 in RISS, 6 in OASIS, and 3 in KTKP. Of these, 21 were duplicated studies and were excluded. The titles and abstracts were checked, and a primary screening was conducted to exclude non-human clinical studies, and studies that were not related to ankle sprains. Then 208 studies were excluded through a primary screening. There were 28 studies remaining, which were read in full, resulting in 20 studies being excluded from this review (15 non-RCT studies, 1 non-verifiable study, 1 study that did not involve fire needling or warm needling treatments, 1 study that included some recently published data, 1 study that included warm needling treatment in the intervention group and the control group, and 1 study where the abstract and the body of the text did not match). Finally, a total of 8 studies that fulfilled the inclusion and exclusion criteria were selected and a systematic review was conducted.

The data collecting and screening process are illustrated in Fig. 1 using the flow chart of preferred reporting items for systematic reviews and meta-analyses.

Country and year of publication

All 8 selected studies were published in China. By year, there was 1 study published in 2006, 3 studies published in 2018, 1 study published in 2017, 1 study published in 2015, and 2 published studies in 2013. There were 7 studies conducted in the last 5 years from 2013 to 2018 (Fig. 2).

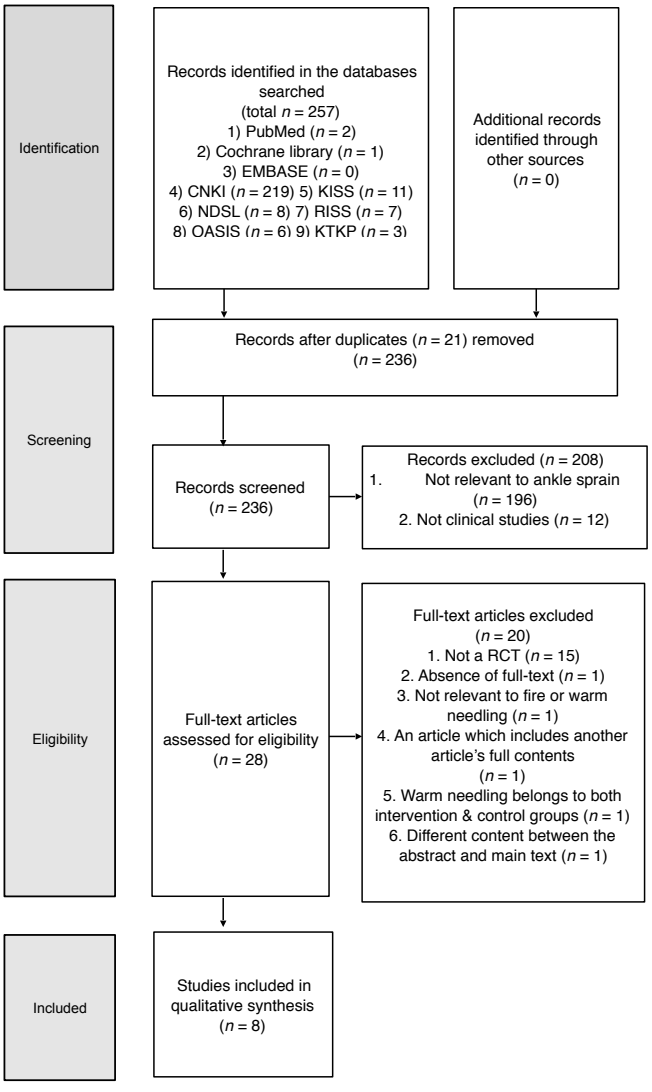

Fig. 1. PRISMA flow diagram.
RCT, randomized controlled trials; PRISMA, preferred reporting items for systematic reviews and meta-analyses.

Table 1. Data of Included Studies.

First Author (year)	Sample size	Intervention group	Control group	Outcome measurements	Main result (I/C)	Adverse events
1. Zhou (2018) [30]	64 (33:31)	FNA + EA (n=33)	EA (n=31)	1. Baird-Jackson ankle score	1. 96.93 ± 1.90 / 86.29 ± 5.63 ($p < 0.05$)	NR
2. Yang (2015) [31]	99 (33:33:33)	MA (n=33) EA (n=33) WNA (n=33)		1. VAS 2. ROM 3. AOFAS 4. Efficacy rate	1. MA : 3.0 ± 0.4 / EA : 2.0 ± 0.3 / WNA : 2.3 ± 0.3 ($p < 0.01$) 2. MA : 8.5 ± 0.4 / EA : 9.5 ± 0.4 / WNA : 10.6 ± 0.2 ($p < 0.01$; CA) ($p < 0.05$; EA) 3. MA : 72.3 ± 3.5 / EA : 82.8 ± 2.5 / WNA : 80.1 ± 2.9 ($p < 0.01$) 4. MA : 76.7 % / EA : 97 % / WNA : 90.6 % ($p < 0.05$)	NR
3. Yan (2013) [32]	62 (32:30)	FNA (n=32)	MA (n=30)	1. Ridit average value	1. 0.6209 / 0.3709 (mean value) ($p < 0.05$)	NR
4. Wang (2013) [33]	66 (33:33)	WNA + OT (n=33)	OT (n=33)	1. Symptom score 2. VAS 3. Pain score (by Kofoed score) 4. Functional activity points (by Kofoed score) 5. Efficacy rate	1. 81.44 ± 7.47 / 77.33 ± 5.65 ($p < 0.05$) 2. 2.09 ± 1.38 / 4.10 ± 1.69 ($p < 0.05$) 3. 45.37 ± 11.78 / 40.88 ± 10.95 (unclear) 4. 20.37 ± 3.78 / 17.88 ± 3.05 (unclear) 5. 90 % / 65 % ($p < 0.05$)	Skin allergy
5. Wu (2006) [34]	80 (40:40)	FNA + WNA (n=40)	CPT + CLT (n=40)	1. Healing rate (≒ Efficacy rate)	1. 95 % / 62.5 % ($p < 0.01$)	NR
6. Xiao (2018) [35]	81 (41:40)	FNA + BC (n=41)	PRICE (n=40)	1. Swelling index score 2. AOFAS 3. VAS	All results after 8 weeks 1. 0.21 ± 0.12 / 1.02 ± 0.18 ($p < 0.05$) 2. 96.75 ± 7.69 / 60.32 ± 5.78 ($p < 0.05$) 3. 1.93 ± 0.07 / 5.54 ± 0.13 ($p < 0.05$)	NR
7. Zhang (2018) [36]	84 (42:42)	WNA + fumigation (n=42)	Exercise (n=42)	1. Efficacy rate 2. VAS 3. Baird-Jackson ankle score 4. AOFAS	1. 92.86 % / 73.81 % ($p < 0.05$) 2. 1.21 ± 0.98 / 3.75 ± 1.37 ($p < 0.05$) 3. 95.68 ± 2.46 / 88.76 ± 2.04 ($p < 0.05$) 4. 87.14 ± 1.81 / 82.16 ± 1.63 ($p < 0.05$)	NR
8. Mo (2017) [37]	100 (50:50)	FNA + BC (n=50)	PRICE (n=50)	1. Swelling index score 2. AOFAS 3. VAS 4. Efficacy rate	All results after 8 weeks 1. 0.23 ± 0.156 / 1.03 ± 0.298 ($p < 0.05$) 2. 95.14 ± 3.22 / 60.63 ± 4.73 ($p < 0.05$) 3. 1.93 ± 0.44 / 5.85 ± 0.38 ($p < 0.05$) 4. 100 % / 80 % ($p < 0.05$)	NR

I, intervention group; C, control group; FNA, fire needling acupuncture; EA, electro-acupuncture; WNA, warm needling acupuncture; MA, manual acupuncture; OT, ointment treatment; CPT, contusion paste therapy (ointment); CLT, contusion liquid therapy; BC, blood letting cupping; PRICE, protection·rest·ice·compression·elevation; AOFAS, American orthopedic foot and ankle score; VAS, visual analogue scale.

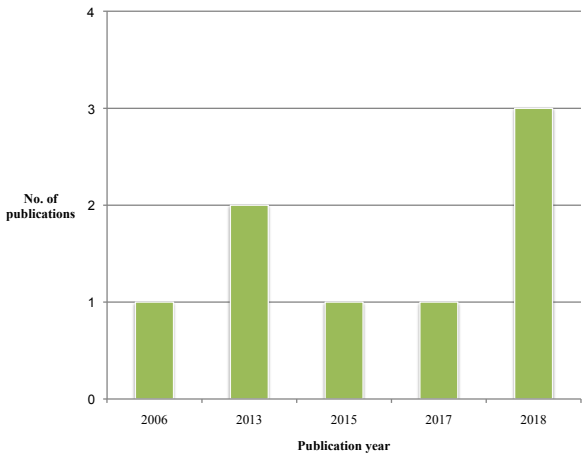

Fig. 2. Summary of publication year.

Sample size of study

There were total 636 participants across the 8 studies which included 432 men, 196 women, and 8 dropouts. In each study, the total number of participants in the intervention, and control group was at least 62 and up to 100, with 3 studies with more than 50 and under 75, 4 studies with more than 75 and under 100, and 1 study with more than 100 participants (Fig. 3).

Intervention group treatment method

In the 8 selected studies, 4 studies included the fire needling treatment, 3 studies included the warm needling treatment, and 1 study that used both fire needling and warm needling treatments combined in the intervention group (Fig. 4).

Treatment number and period

Regarding the number of times the treatment was performed, 3 studies treated their patients with under 5 times with fire or warm needling treatments (1 study treated their patients only once).

Table 2. Characteristics of Intervention and Control Groups.

First Author (y)	Sample age (y) (I/C)	Sample sex ratio (M:F) (I/C)	Onset (I/C)	Needle type / Depths of insertion (I)	Acupoints (I)	Retention time (I)	Treatment session & period (I)
1. Zhou (2018) [30]	41.39 ± 8.87 /40.96 ± 9.80	13:20 / 14:17	17.15 ± 14.80 mo / 17.90 ± 15.17 mo	0.25×40 mm / unclear	BL60, GB39, GB40	Unclear	FNA 1 per 5 d, EA 1 per one d / 10 times (d) for 1 session, total 2 sessions
2. Yang (2015) [31]	Unclear (most 21-23)	(*MA/EA/ WNA) 24:6 / 20:13 / 22:10	Unclear (most 6-12 mo)	0.32×40 mm / unclear	ST41, BL60, KI3, ashi-point	10-15 min	1 per one d, 6 d per a wk, total 2 wks
3. Yan (2013) [32]	20-65 / 21-63	20:12 / 19:11	2 mo - 5 y / 1 mo - 4 y	0.30×25 mm / 0.2-0.5 inch straight thorn	Lat. – GB34, GB39, GB40, BL60, BL62, ashi-point Med. – GB34, SP6, KI3, KI6, SP5, ashi-point	No retention	1 per 2 d / a wk for 1 session, total 2 sessions
4. Wang (2013) [33]	19.81 ± 1.12 /19.40 ± 1.03	26:6 / 26:4	10.02 ± 4.98 mo / 10.38 ± 4.84 mo	0.32×40 mm / unclear	4-5 acupoints of ST41, BL60, KI3 plus ST36, SP6, KI6, BL62, GB40, GB39, LR3, ashi-point	Unclear ; complete combustion (WNA)	1 per one d / a week for 1 session, total 2 sessions
5. Wu (2006) [34]	*Total 19-24	*Total 73:7	*Total 2-3 d	unclear (FNA), 1 inch 30G (WNA) / 2-3 mm (FNA), unclear (WNA)	Ashi-point (FNA) 6 acupoints of GB40, GB41, GB42, ST41, ST42, ST43, BL59, BL62, BL63, SP5, SP4, LR3, LR4, KI3, KI2 (WNA)	No retention (FNA) unclear ; complete combustion (WNA)	1 per 2 d, 3 per a wk / a wk for 1 session, total 3 sessions
6. Xiao (2018) [35]	21.31 ± 2.51 /21.25 ± 2.45	27:14 / 28:12	Unclear (within 2 wks)	unclear / 1.5 cm	Ashi-point	No retention	Once (after 3 d, re-treatment decision based on the condition of edema)
7. Zhang (2018) [36]	35.12 ± 6.57 /33.23 ± 6.23	27:15 / 26:16	9.92 ± 2.47 mo / 9.56 ± 2.28 mo	1.5 inch 32G / unclear	ST41, BL60, KI3, ST36, SP6	Unclear ; complete combustion (WNA)	1 per one d / 10 days for 1 session, total 3 months
8. Mo (2017) [37]	Mean 21 / mean 19	36:14 / 31:19	Unclear (within 2 wks)	0.32×25 mm / 1.1-1.5 cm	Ashi-point	No retention	1 per 2 d / 3 times for 1 session, total 1 session

I, intervention group; C, control group; FNA, fire needling acupuncture; EA, electro-acupuncture; WNA, warm needling acupuncture; MA, manual acupuncture.

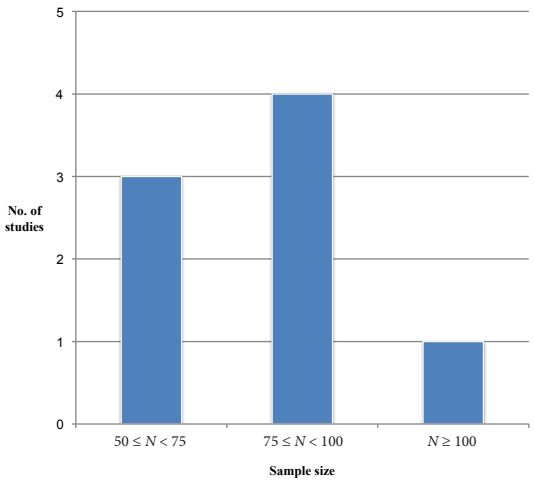

Fig. 3. Sample size of studies.

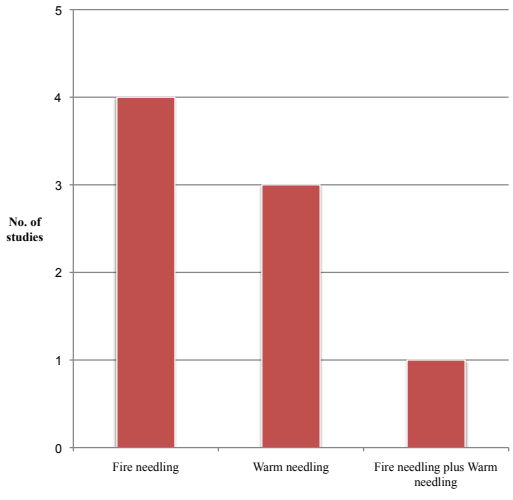

Fig. 4. The type of intervention group treatment (including combination treatment).

Furthermore, 2 studies performed the treatment with more than 5 and under 10 times, and 3 studies treated their patients more than 10 times (Fig. 5).

Regarding the treatment period, there were 4 treatments for more than 2 weeks and under 3 weeks, 2 treatments for more than 3 weeks, 1 treatment for less than 1 week, and 1 treatment for more than 1 week and under 2 weeks (Fig. 6).

Classification by morbidity period

Of the 8 studies, 3 studies had acute ankle sprains within 2 weeks, and 5 studies had chronic ankle sprains of more than 1 month (Fig. 7).

Frequency of use of therapeutic acupoints and meridians

In analyzing the frequency of use of meridians, the acupoints of the gallbladder meridian (GB) were used 11 times, the bladder meridian (BL) was used 10 times, and the stomach meridian (ST) and kidney meridian (KI) were used 8 times each. The acupoints of the spleen meridian (SP) were used 6 times, and the liver meridian (LR) was used 3 times. In analyzing therapeutic acupoints used across the 8 studies, the ashi-point (tenderness point) was selected 7 times (ca.13.2%), while BL60 and KI3 were selected 5 times (ca. 9.4%). ST41 and GB40 were selected 4 times (ca.7.5%), and GB39, BL62, and SP6 were selected 3 times (ca.5.7%) each (Tables 3 and 4).

Evaluation index

There were between 1 and 5 evaluation indexes used for each study. There were 5 studies that selected the Visual Analogue Scale (VAS), and the total efficacy rate. There were 4 studies that selected the American Orthopedic Foot and Ankle Score (AOFAS), and 2 studies that used the Baird-Jackson ankle score and the Swelling index score. The remaining evaluation indexes were used once (Fig. 8).

Treatment of control group

There were 2 studies each using electro-acupuncture, manual acupuncture, ointment patch, or Protection, rest, ice, compression, elevation (PRICE) as the control group. In addition, there was 1 study each that used exercise, and contusion paste and liquid remedy (Fig. 9).

Therapeutic effect

In all 8 studies, the intervention group showed beneficial results before and after evaluation compared with the control group. Yang [31] reported that electro-acupuncture and warm needling were statistically significantly more beneficial (using VAS, AOFAS, and total efficacy rate) in the treatment of ankle sprains when compared with manual acupuncture. However, after treatment, the VAS value was lower in the electro-acupuncture group than in the warm needling group, and the AOFAS value and the total efficacy rate were higher in the electro-acupuncture group than in the warm needling group. In the ROM index, the warm needling group showed a significant difference as compared with the manual acupuncture group and the electro-acupuncture group, respectively Wang [33] reported that the symptom score, VAS value, and efficacy rate for warm needling combination treatment showed this intervention significantly more beneficial than ointment treatment. However, the pain score and functional activity points based on the Kofoed score for warm needling combination treatment

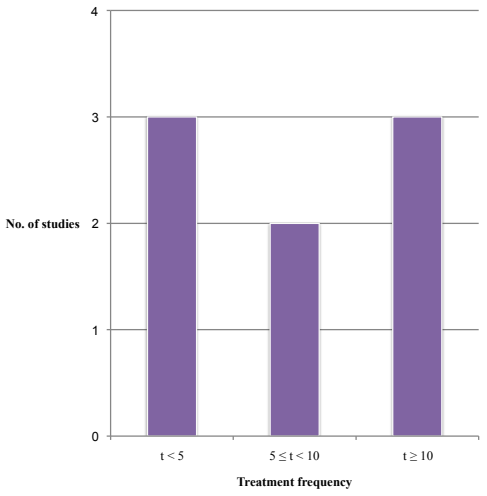

Fig. 5. Frequency of treatment.

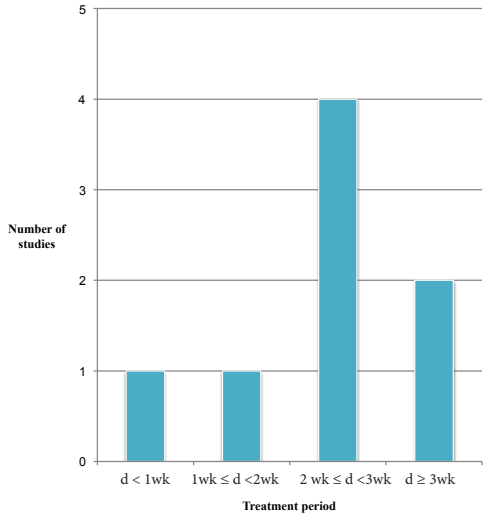

Fig. 6. Treatment period.

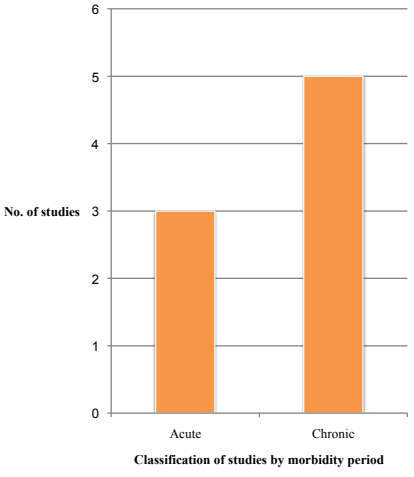

Fig. 7. Classification of studies by morbidity period.

Table 3. Frequency of Acupoints.

Frequency	Name of acupoints
7	Ashi-point
5	BL60
5	KI3
4	ST41
4	GB40
3	GB39
3	BL62
3	SP6
2	GB34
2	KI6
2	SP5
2	ST36
2	LR3
1	GB41
1	GB42
1	ST42
1	ST43
1	BL59
1	BL63
1	SP4
1	LR4
1	KI2
53	Total 22 acupoints

Table 4. Distribution of Selected Meridians.

Frequency	Name of meridians
11	Gallbladder meridian (GB)
10	Bladder meridian (BL)
8	Stomach meridian (ST)
8	Kidney meridian (KI)
6	Spleen meridian (SP)
3	Liver meridian (LR)
7	Ashi-point
53	Total 6 meridians and ashi-point

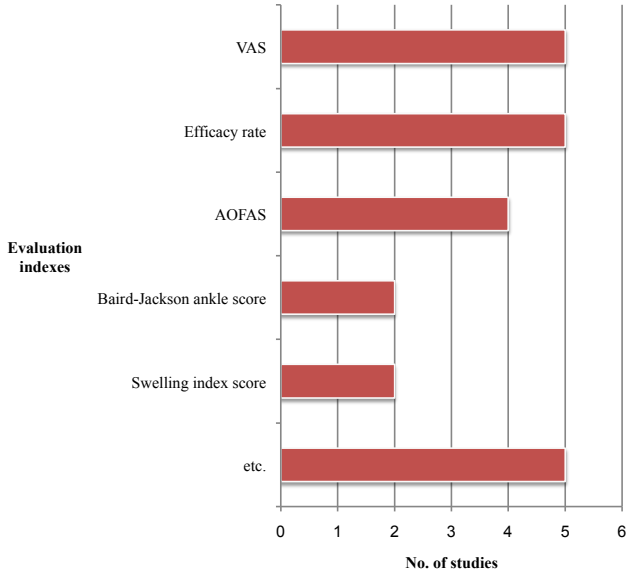

Fig. 8. Evaluation indexes.
AOFAS, American orthopedic foot and ankle Score; VAS, visual analogue scale.

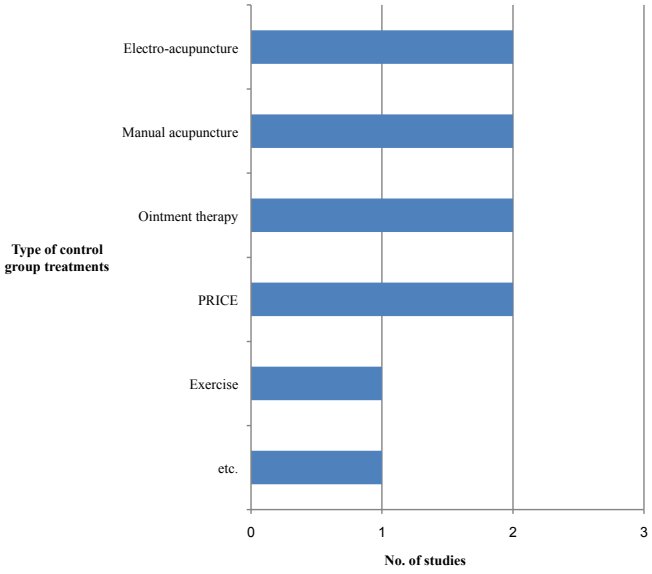

Fig. 9. Treatments of control group.
PRICE, protection·rest·ice·compression·elevation.

was less beneficial than the ointment treatment group. Except for the above-mentioned sections, the results of the 8 selected studies showed that the intervention group showed statistically significant improvement compared with the control group on all the evaluation indexes.

Adverse events

There were no reports of adverse events reported in 7 studies. In the study by Wang [33], skin hypersensitivity was observed in 5 patients (2 cases during ointment treatment were reported in the

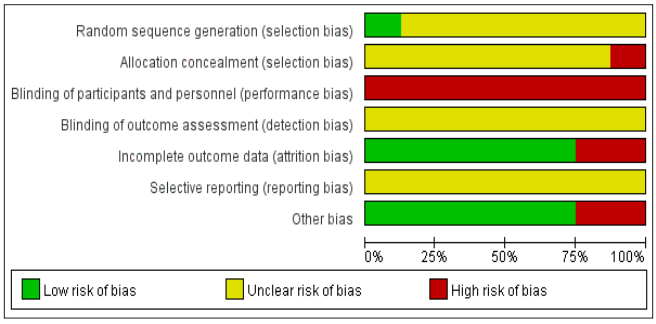

Fig. 10. Risk of bias graph.

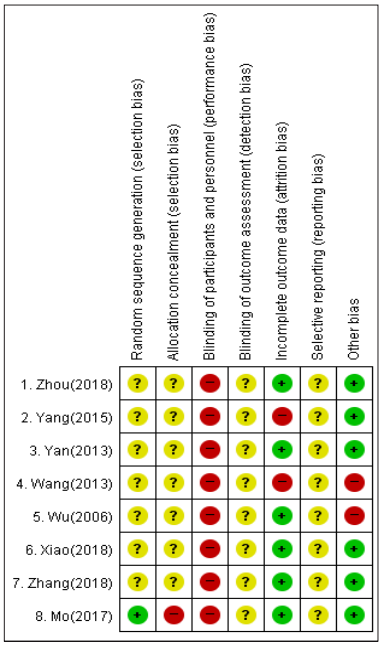

Fig. 11. Risk of bias summary. (+) : Low risk of bias, (-) : high risk of bias, (?) : unclear risk of bias.

intervention group, and 3 cases in the control group).

Risk of bias assessment

The risk of bias was assessed for 8 studies using the Cochrane risk of bias tool. The results of the bias risk assessment are plotted using the Revman program (Figs. 10 and 11).

Random sequence generation

In 1 low-risk study, random assignments were made using a lottery ticket. In the remaining 7 studies, the expression "random assignments" was used without describing how this was performed. Since the randomization method was not specified, it was classified as an unclear risk.

Allocation concealment

One high-risk study was randomized using a raffle table with randomized ordering and was classified as high risk because there was no concealment or safeguarding. The remaining studies were classified as an unclear risk because there was no mention of concealment order allocation.

Blinding of participant and personnel

All studies were classified as high risk because sham treatment was not used in any study. Due to the nature of the interventions (fire needling or warm needling) blinding of the participant and personnel was not possible

Blinding of the outcome assessment

There was no mention that the results were blinded to the evaluator in the evaluation of the study, so all 8 studies were classified as an unclear risk.

Incomplete outcome data

A total of 6 studies were classified as low risk, because the total number of participants in the intervention and control groups had no missing value before and after the start of the study. In 2 studies, the number of missing values was uneven in the intervention and control groups, and thus these studies were classified as high risk.

Selective reporting

All 8 studies were classified as an unclear risk because there was no mention of protocols and preplanning.

Other bias

In 2 studies, the treatment time of the ointment patch applied to the control group was not clear, therefore, it was classified as high risk, because there was a risk of other distortions. In the remaining studies, no additional bias risk was identified and thus the studies were classified as low risk.

Discussion

Fire needling is a treatment used for various conditions/diseases by heating the tip of a needle prior to inserting into a specific part of the body or acupoints. Fire needling uses "heat" as a therapy as an adjunct to the effects of acupuncture and moxibustion combined [1]. Warm needling is an acupuncture method that treats blocked meridians and acupoints by applying the power of moxibustion heat into the meridians, to strengthen energy and move the blood [1].

Recently, some studies have been conducted due to the increased interests in the treatments of fire needling or warm needling for ligament damage such as ankle sprains [22,23,28]. However, the effect of the treatments is still not clear and the numbers of RCT studies are lacking.

In this present study, fire needling or warm needling for ankle sprains was reviewed in 8 RCT. All 8 studies were published in China, with most published in the 2010s. Across the 8 RCT there were a total of 636 participants with more than 50% more males than females. This may be due males participating in more frequent and vigorous exercise.

As for interventions, there were 4 studies containing the fire needling treatment, 3 studies containing the warm needling treatment, and 1 study using the fire and warm needling treatment together. One study compared fire or warm needling treatments with other acupuncture treatments and, there were 2 studies that used blood-letting therapy as a combination therapy for the fire needling treatment. In addition, there was a study that did not mention the blood-letting therapy in the title or abstract. It may be necessary to consider whether this therapy is used to remove exudates that flow out around the point after fire needling

treatment, and should be seen as a clear combination of fire needling treatment and blood-letting therapy.

The number of treatments in fire and warm needling treatment groups varied from 1 treatment to daily treatments for 3 months. Although warm needling treatments were frequently performed every day, there were no studies of fire needling treatment every day, and treatments were performed at least every other day, so warm needling treatments tended to be more frequent than fire needling treatments.

The duration of treatments varied from 1 day to 3 months, with the greatest number of studies conducted over 2 weeks. Although there were no significant differences between fire needling and warm needling treatments during the treatment period, warm needling treatments were performed almost every day, and fire needling treatments were relatively spaced apart. The differences may have been due to the fact that fire needling is more invasive and irritating than warm needling.

In the classification of acute and chronic phases according to the duration of the disease, all 8 studies mentioned expressions of acute and chronic status. In 3 studies there were acute ankle sprains (within 2weeks), and 5 studies had chronic ankle sprains (more than 1 month). The 2 studies on acute ankle sprains did not specify the exact duration of illness, but there was an indication that patients within 2 weeks of the onset of an ankle sprain were enrolled in the RCT recruiting patients with acute stage ankle sprains. Indeed, most patients with ankle sprains are acute patients within days or weeks of onset. However, considering the results of the study that heated acupuncture treatments such as fire and warm needling are effective in repairing damaged ligaments, we also considered a large pool of patients with chronic ankle sprains.

As a result of analyzing the acupoints selected in each study, the ashi-point, was selected 7 times (about 13.2%), which makes it the most frequently used point. Except for KI3 and SP6, most of the frequently selected acupoints were on the outside of the foot. This is because ankle sprains often cause lateral ligament injury. In general, fire needling treatment, rather than warm needling treatment, tends to be performed mainly on tenderness points. Stimulation of a small number of painful areas within a short time is thought to be due to the nature of the fire needling where a high temperature needle is directly inserted into the tissue.

All the selected meridians pass through the ankle joint, and as the ankle sprain often causes a lateral ligament injury, a number of meridians along the mid and lateral part of the foot were selected as observed across the 8 studies.

There were 10 evaluation indexes used for evaluation across the RCT. There were 5 studies using the VAS (Visual Analogue Scale) as the evaluation index and 5 studies using the total efficacy rate as the evaluation index. In most of the studies, subjective indexes based on subjective symptom improvement, and individual evaluation were used. In addition to the development of more objective indexes, various studies using objective indexes will need to be conducted. In addition, some studies evaluated results using only 1 index. In future studies, various results should be evaluated through various evaluation indexes.

The intervention group in the 8 RCT showed statistically significant improvements in each evaluation result before and after treatment, as compared with the control group. In the study by Yang (2015) [31], each result showed a significant difference from the comparison with the manual acupuncture group. However, the results of the VAS and AOFAS scores between the electro-acupuncture group and the warm needling group were not statistically significant. In the study by Wang (2013) [33], there was no mention of *p* value in some of the indexes, and no significance was found between the intervention and control groups.

Adverse events were reported in only 1 RCT. In addition, 2 of the 7 remaining RCT for which no adverse events were reported, mentioned adverse events and sequelae were not observed, while 5 others did not mention that there were no adverse events. It is likely that observation and management of adverse events will be necessary in the long term after the end of treatment, since fire and warm needling treatments are invasive and irritating treatments.

RCT studies are recognized as a research design method for an accurate assessment of the interventional effects of a treatment. However, studies with a high risk of bias may report false effects by underestimating or overestimating the interventional effects in estimating outcomes. Therefore, the awareness and application of risk assessment is becoming increasingly apparent [38,39]. In this study, the Cochrane "Risk of bias" was applied to evaluate bias in 7 categories : random sequence generation, allocation concealment, blinding of the participants and personnel, blinding of the outcome assessments, incomplete outcome data, selective reporting, and other sources of bias. As a result, there were many "unclear risk" results that made it difficult to assess the bias for all items. In analyzing the results of the risk assessment of the bias, most RCT in this review lacked the references related to the assessment of bias, and there were some difficulties in evaluating the risk of bias. Korean medicine treatments such as acupuncture, moxibustion, cupping therapy have limitations regarding blinding procedures. Therefore, further research is needed to establish new research methods in the future. All RCT reviewed in this study did not include reference to IRB approval.

The results of the review demonstrate that fire or warm needling have a significant effect on ankle sprains. However, the study is limited by the databases used for retrieving relevant studies, and studies published in all languages were not considered. In addition, some studies combined fire or warm needling and other treatments, and there are some limitations in confirming the effect of a fire or warm needling in a combined treatment as opposed to a single treatment. Other limitations were that many studies used subjective evaluation indexes, which complicated the assessment of the quality of the study, and there was no mention of bias assessment. In the future, clinical studies are needed to overcome some of the limitations observed in the 8 RCT reviewed in the present study.

Conflicts of Interest

The authors have no conflicts of interest to declare.

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