Systematic Review and Meta-Analysis of Efficacy and Safety of Fire Needling and Warm Needling on Acute Gout

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Department of Acupuncture and Moxibustion Medicine, College of Korean Medicine, Gachon University, 1332 Seongnam-daero, Sujeong-gu, Seongnam 13120, Republic of Korea Tel: +82-32-770-1342 E-mail: hssong70@gachon.ac.kr **Objectives:** This study aimed to evaluate the efficacy and safety of heat stimuli (e.g., fire needling, warm needling) in acupuncture for acute gout.

Methods: Four international online databases (PubMed, Cochrane, Embase, and Chinese National Knowledge Infrastructure) were searched to identify randomized, controlled trials (RCTs) that used fire needling and warm needling for acute gout. The methodological quality of the RCTs was evaluated using the Cochrane risk-of-bias (RoB) tool. Thirteen RCTs (840 patients) were included and analyzed. Three evaluation tools (total effective rate, uric acid level, and pain score) were mainly used. Comparisons were made between Western medicine (WM) and i) fire needling or warm needling treatment alone, ii) fire needling and bloodletting combination treatment, iii) combination of fire needling, bloodletting, and herbal medicine, iv) warm needling (concurrently). Heat stimuli in acupuncture alone or in combination treatment were more effective in terms of the total efficacy rates, uric acid levels, and pain scores than WM alone.

Results: In all the evaluation tools, the treatment effects in the fire needling alone or warm needling alone treatment group and the fire needling and bloodletting combination intervention group were significantly better than those in the WM control group. The warm needling and WM combination intervention groups also experienced significantly better treatment effects in terms of total efficacy rates and uric acid levels. Only the pain scores in the fire needling, bloodletting, and herbal medicine combination groups demonstrated significant improvement. Only four studies mentioned adverse reactions: one reported loss of appetite; three studies reported none. According to the Cochrane RoB tool, most studies showed either high or uncertain RoB.

Conclusion: Heat stimuli during acupuncture could be effective for acute gout. However, as the included studies were regionally biased, more high-quality studies are needed to confirm the level of evidence.

Keywords: acupuncture, gout, systematic review, meta-analysis, fire needling, warm needling

INTRODUCTION

The incidence and prevalence of gout are steadily increasing due to population aging and lifestyle changes [1]. Gout is a disease that imposes a great economic burden [2]. Acute gout attacks are characterized by a sudden onset of excruciating pain and inflammation in the joints [3, 4]. For rapid relief of pain and inflammation and improvement in the quality of life [5], non-steroidal antiinflammatory drugs (NSAIDs), mainly colchicine, and corticosteroid drugs (alone or in combination), are recommended. NSAIDs have been reported to cause side effects, such as gastrointestinal ulcers, kidney and liver disorders, and worsening of heart failure. Steroids are highly associated with hypertension and diabetes in gout patients, and colchicine

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has side effects linked to the digestive system and causes toxicity to the kidneys and nervous system [6, 7]. Consequently, complementary and alternative medicine has attracted attention. Specifically, acupuncture is known for its antiinflammatory and analgesic effects [8-10] and is used in patients with pain-related diseases.

Gout is viewed as a category of impediment disorders and painful impediments in traditional medicine, and various treatments, such as acupuncture, moxibustion, cupping, pharmacopuncture, and herbal medicines, are used in clinical practice. Fire needling therapy is a method of treating diseases by heating a needle until red hot before acupuncture and then injecting it into the acupuncture points of the human body. Its indications include impediment disorder in the "Spiritual Pivot-office acupuncture chapter," and the cold impediment disorder caused by pathogenic cold in the "Spiritual Pivot-meridian sinew chapter." Warm needling therapy involves inserting a needle with mugwort attached to the tip, and heat is applied by burning it. It is used to treat a series of diseases in which the meridian has cold stagnation and the gi-blood is blocked; hence, the meridian vessel is unblocked by warming and the qi-blood is allowed to flow well by borrowing the fire power of moxa fire through needle insertion. It is mainly used for joint diseases caused by wind-dampness and diseases triggered by cold [11].

The origin of "warm needling"-like acupuncture (burning acupuncture) is as follows: a variant of warm needling [12], a variant of warm needling and fire needling [13], "fire needling [14, 15]," "burning acupuncture [12, 16-18]," "heating-conduction acupuncture [13, 19]," and "deep heated acupuncture [20]." However, the classification of health interventions as warm needling or fire needling has been controversial. Although warm needling therapy is a method to obtain heat by burning mugwort, as a needle is inserted in the subject of this therapy, it can be considered an acupuncture method similar to fire needling [3]. Both warm needling and fire needling have the function of eliminating yin pathogens such as cold-dampness in addition to warming meridians, relaxing blood vessels, and strengthening immunity. Therefore, we reviewed the literature regarding the treatment effects of heat stimuli in acupuncture on gout by combining fire needling and warm needling therapy with acupuncture.

Heat stimuli in acupuncture treatments, such as warm needling therapy [21, 22] and fire needling therapy [14, 23], are applied to the treatment of various musculoskeletal disorders such as those of the joints and ligaments, and active research is being conducted in South Korea and abroad [24]. In China, many clinical studies on musculoskeletal pain diseases, including gout, have reported the use of warm needling [25], with possible mechanisms of the antiinflammatory action of warm needling therapy attributed to local blood supply and relaxation of muscle spasms [26]. However, although a protocol for analyzing the efficacy and safety of fire needling for gout therapy has been published [27], there are no systematic reviews related to fire needling and warm needling. In particular, research related to Korean medicine (KM) treatment for gout is lacking [28, 29]. Only a survey on the medical condition of KM doctors in 2021 [30] and a systematic review on electroacupuncture for acute gout in 2022 [31] have been conducted; there have been no clinical trials on fire needling and warm needling. Moreover, according to a survey of KM doctors [30], because fire needling and warm needling rank very low among treatment options for gout, there is little interest in proposing recommendations for developing KM clinical practice guidelines for their use in gout therapy or to conduct gout-related clinical trials on fire or warm needling [30]. Therefore, in this study, we searched for previously published randomized, controlled trials (RCTs) on fire needling and warm needling for gout therapy to systematically review the use of heat stimuli in acupuncture for acute gout to evaluate its effectiveness and safety.

MATERIALS AND METHODS

1. Database selection and search

Two independent researchers conducted a data search using local and foreign electronic databases for papers published worldwide from the start of the application supported by search engines up to December 2020, without any limitation on the publication period or language of publication. Korean databases-RISS, OASIS, JAR, JKOM, JOP, and OOD-were searched; however, no suitable study was identified. Additionally, PubMed, Cochrane Library, Embase, and Chinese National Knowledge Infrastructure Database (CNKI) were used to search for data by configuring the search expressions according to the characteristics of each database. In PubMed, Cochrane library, and Embase, the search terms were {("Arthritis, Gouty") OR ("Gout") OR ("tongfeng") OR ("hyperuricemia") OR ("uric acid")} AND {("warm needle") OR ("fire needle") OR ("burning needle")}; in CNKI, {("痛风") OR ("痛风性关节炎") OR ("高 尿酸血症") OR ("痹症") OR ("gout") OR ("hyperuricemia")}

AND {("溫针") OR ("fire 针") OR ("warm needle") OR ("fire needle") OR ("burning needle")} was the search strategy.

2. Criteria for data selection and exclusion

This study was conducted using the participants, intervention, comparison, outcome, and study design (PICO-SD) [32].

1) Participants

The participants were patients with acute gout regardless of the cause. Chronic, acute, and unspecified gout, gouty nephropathy, and hyperuricemia patients were excluded. The study participants were adults, and no restrictions were applied with respect to race or sex.

2) Interventions

Interventions involving acupuncture with thermal stimulation, such as fire needling and warm needling, and traditional Chinese treatments, such as treatment for ethnic minorities in China and eye acupuncture, which are rarely used in Korea, were excluded.

3) Comparisons

Western medicine (WM) pharmacotherapy was compared with acupuncture, and all studies that analyzed the effects of heat stimuli on acupuncture treatment alone or in combination with other traditional medicine treatments or conventional WM drug treatment were included in the analysis. Acupuncture, moxibustion, herbal medicine, and other traditional medicine treatments were excluded from the comparison, and no restrictions were imposed on the duration and frequency of treatment.

4) Outcomes

Outcomes are tools used to evaluate interventions and these were analyzed using quantitative values related to acute gout, such as uric acid (UA) levels, visual analog scale (VAS) scores, and total efficacy rates. Studies with no reported results or those that lacked objectivity were excluded.

5) Study design

Studies with an RCT design were included. When the treatment target was not acute gout, studies that could not analyze the results of heat stimuli during acupuncture were excluded, and no restrictions on side effects were applied for the analysis of the safety of heat stimuli during acupuncture. Non-RCT studies, such as animal experiments, review protocols, literature reviews, and studies for which the original text was not available, were also excluded.

3. Data extraction

Two independent researchers searched domestic and foreign databases for studies published in Korea and abroad. After excluding duplicate studies, primary exclusion was performed based on the titles and abstracts of the remaining studies. In the case of secondary exclusion, the study was finally established by reviewing all full texts. If consensus was not reached, it was resolved by the intervention of a third researcher.

4. Bias analysis method

In accordance with NECA's guidelines [32], the risk of bias (RoB) was evaluated using Cochrane's RoB tool. For the seven items of randomization order generation, assignment order concealment, blinding to study participants and researchers, blinding to outcome evaluation, insufficient outcome data, selective reporting, and other RoB, RoB was measured as low, high, or uncertain according to the contents of the studies. Two researchers independently evaluated the quality of the eight selected studies, and all items were recognized only when specified in the text. If there was a disagreement between the two researchers, an agreement was reached through re-examination. If consensus was not reached, a decision was made through the intervention of a third researcher.

5. Meta-analysis method

Meta-analysis was synthesized using Cochrane's Review Manager (RevMan) 5.4. (The Nordic Cochrane Center, The Cochrane Collaboration, Copenhagen, Denmark). For dichotomous variables such as total treatment efficacy, the risk ratio (RR) and 95% confidence interval (CI) were used, and UA levels and VAS scores were expressed as mean differences (MDs) or standardized mean differences (SMDs) with 95% CI. The heterogeneity between papers was examined using Higgin's I² test. The fixed-effects model was used because the number of studies was small and there were no subgroups with high levels of heterogeneity. Among the selected studies, studies with the same research design (e.g., intervention method or evaluation tool) were selected and meta-analyzed.

RESULTS

1. Study selection results

We retrieved 17,275 studies from 16 databases, including 7,425 from PubMed, 327,374 from Embase, 9,149 from CNKI, and 0 from Korean databases. From these, 573 duplicate studies were excluded, and two researchers conducted the primary screening by reviewing the title and abstract. Additionally, 13,818 studies that were unrelated to acute gout and articles without original text were excluded; 2,884 studies were selected. Subsequently, secondary exclusion was conducted by reading the original text, and 2,874 studies were further excluded, including 396 studies not related to gout, 89 animal studies, 215 non-clinical reviews, 299 overlaps, 105 non-traditional medicine, 1,338 non-heat stimuli on acupuncture, 100 non-RCT studies, and 329 studies without research-related information. Finally, 13 papers were selected, and a systematic literature review was conducted on these papers (Fig. 1).



Figure 1. Flowchart describing the selection process of randomized clinical trials.

2. Analysis results of the study selection

1) Study overview

The 13 selected studies [33-45] were published in China: one each in 2007, 2010, 2011, 2012, 2014, and 2015, 2 in 2016, 1 in 2017, 1 in 2018, 2 in 2019, and 1 in 2020. Four comparisons were made between fire needling or warm needling treatment alone versus WM, eight comparisons between fire needling or warm needling treatment and other TM treatments versus WM drugs, and one comparison between combinations of warm needling and WM drugs versus WM drugs (Table 1).

2) Study participants

The total number of study participants, excluding dropouts from each RCT, was 840, and there were four times more males than females. The ages of the participants varied and were difficult to analyze accurately because they were presented as average values or ranges; however, the average value for most of the subjects was in the 50s. Among the 840 patients, we assigned 420 patients to the intervention group and 420 to the control group. Among the 13 studies, three enrolled < 60 participants (40, 46, and 56), nine enrolled 60 to 80, and one enrolled 1 (Table 1).

3) Treatment period

The treatment period of the intervention group varied from 6 to 20 days, with a mean treatment period of 9.22 days. The treatment period was 6-7, 10-14, and 20 days for six, six, and one patient, respectively (Table 1).

4) Treatment method of fire needling and warm needling

Ten articles were on fire needling and three on warm needling. The target acupuncture points were the Ashi point, SP6, ST36, LI11, SP9, LR3, ST44, SP10, and LR2. The Ashi point was the most common with 12 points, followed by SP6, SP9, and ST36 with 6 points. The needle depth was only mentioned in seven studies: 0.3-1.0 cm in four, 0.5 cm in one, 0.3-1.0 cm in one, and 0.2-0.3 cm in one. The form of acupuncture was only mentioned in seven studies: two studies used improved crafting of acupuncture needles, two studies used a diameter of 0.5 mm, and 0.35 mm × 30 mm, 0.25 mm × 40 mm, and 0.35 mm × 40 mm each in one study. The number of treatments varied from 1 to 10, 5 being the most frequent in three studies; no treatment numbers were mentioned in two studies. Regarding the frequency of treatment, four studies performed daily treatment,

No.	Study ID	Study -	Gender		_			Dura-		Outcome		Adverse
		design	Μ	F	Age (mean)	Intervention (n)	Comparison (n)	tion	F/U	measure- ments	Results	events
1	Wu (2020)	RCT	18 16	5 7	40-73 (56.42 ± 9.07) 42-71 (56.08 ± 9.14)	Fire needling (23)	Western medicine (23) colchicine	10 d	-	1 TER 2 VAS 3 UA	 100.00/82.61 3.40 ± 1.51/ 5.82 ± 1.49 281.16 ± 72.05/ 350.24 ± 75.92 	Ν
2	Xie et al. (2018)	RCT	21 19	9 11	31-60 (50.8 ± 9.3) 35-64 (54.6 ± 10.8)	Fire needling (30)	Western medicine (30) etoricoxib, colchicine	7 d	-	1) TER 2) VAS	① 90.0/86.7 ② 4.09 ± 1.27/ 5.73 ± 1.08	U
3	Zong et al. (2011)	RCT	13 14	7 6	34-72 30-70	Warm needling (20)	Western medicine (20) indomethacin, allopurinol	6 d	-	1) TER 2) UA	1 95/75 2 404.49 ± 15.36/ 439.22 ± 53.43	N
4	Zuo et al. (2016)	RCT	30 30	20 20	54.2 ± 4.8 54.5 ± 4.7	Warm needling (50)	Western medicine (50) allopurinol	7 d	-	1 TER	1 98/74	U
5	Ding (2017)	RCT	56	4	28-67 (51.3 ± 3.7)	Fire needling, bloodletting (30)	Western medicine (30) diclofenac	12 d	-	1 TER 2 VAS 3 UA	 96.7/83.3 3.1 ± 0.8/ 4.3 ± 1.1 300.4 ± 45.8/ 362.4 ± 53.3 	U
6	Hu et al. (2007)	RCT	40 40		32-68 (56 ± 9.1) 33-67 (56.4 ± 8.7)	Fire needling, bloodletting (40)	Western medicine (40) indomethacin, allopurinol	14 d	-	1) TER 2) UA	1 95.0/87.5 2 381.34 ± 107.70/ 395.41 ± 112.51	U
7	Kuang (2010)	RCT	32 33	8 7	56.10 ± 9.21 56.51 ± 8.82	Fire needling, bloodletting (40)	Western medicine (40) colchicine	10 d	-	 TER VAS UA 	1 97.50/87.50 2 3.37 ± 1.46/ 5.86 ± 1.52 3 281.2 ± 72/ 350.3 ± 76	N
8	Lei (2015)	RCT	22 24	12 10	33-65 (57.4 ± 7.3) 35-69 (58.1 ± 6.9)	Fire needling, bloodletting (34)	Western medicine (34) diclofenac	7 d	-	1) TER 2) UA	1 97.06/88.24 2 370.22 ± 105.17/ 439.35 ± 110.82	U
9	Zhang (2012)	RCT	24 22	6 8	42-71 (59.6) 40-69 (56.5)	Fire needling, bloodletting (30)	Western medicine (30) indomethacin	10 d	-	1) TER 2) UA	 76.67/36.67 378.20 ± 104.68/ 401.28 ± 112.91 	U
10	Wang (2014)	RCT	25 23	3 5	34-67 (53) 39-64 (49)	Fire needling, bloodletting, herbal medicine (xuanbitang) (28)	Western medicine (28) indomethacin, allopurinol	20 d	-	TER	92.86/82.14	U

Table 1. Summary of the randomized controlled trials of heat stin	nulus on acupuncture alone or combined treatment for acute gout
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Table 1. Continued

No.	Study ID	Study -	Gender		_	·		Dura-		Outcome		Adverse
		design	Μ	F	Age (mean)	Intervention (n)	Comparison (n)	tion	F/U	measure- ments	Results	events
11	Xie and Deng (2019)	RCT	29 27	1 3	34-95 (59.12 ± 6.18) 34-88 (58.09 ± 6.15)	Fire needling, bloodletting, herbal medicine (bakhoka- kyejitang) (30)	Western medicine (30) diclofenac, allopurinol	7d	-	1 vas 2 ua	 1.02 ± 0.15/ 2.28 ± 0.52 509.89 ± 45.12/ 509.85 ± 44.15 	U
12	Yang (2016)	RCT	28 29	2 1	21-68 (46) 25-71 (48)	Fire needling, bloodletting, herbal medicine (rendongteng) (30)	Western medicine (30) colchicine	10 d	-	TER	100/100	Loss of appetite (6)
13	Zhao et al. (2019)	RCT	30 29	5 6	40-50 (46.3 ± 7.3) 40-50 (45.9 ± 7.1)	Warm needling, western medicine (colchicine, indomethacin) (35)	Western medicine (35) colchicine, indomethacin	6 d	_	1) TER 2) UA	1 94.28/74.28 2 326.48 ± 45.36/ 380.96 ± 54.36	U

RCT, randomized controlled trial; nr, not reported; d, day; TER, total efficiency rate; UA, uric acid; VAS, visual analog scale.

three studies included treatments every other day or every 3 days, two studies had different frequencies for mild and severe cases, and one study had treatments every 5 days. The treatment time was 30 min in two studies and 20 min in one study. Four studies performed a single treatment of fire needling or warm needling; for other parallel treatment methods, blood-letting was conducted in five studies, bloodletting and herbal medicine treatment in three studies, and WM drug treatment in one study (Table 2).

5) Control group

The interventions of the control group used in the 13 studies were all WM drugs, with a total of nine NSAIDs, including 5 indomethacin, 3 diclofenac, 1 etoricoxib, 5 colchicine, and 5 allopurinol. Additionally, seven studies used a single WM drug, and six used two WM drugs together (Table 1).

6) Evaluation tools

The evaluation tools that were mainly used in the 13 studies were total treatment efficacy, UA levels, and VAS scores. The total treatment efficacy is a measure of the total symptom improvement after treatment. Of these tools, 12 studies used total treatment efficacy, nine used UA levels, and five used VAS scores. Seven studies used two evaluation tools; three used three evaluation tools; and three evaluated only total effectiveness.

Based on the contents of "the traditional Chinese medicine diagnosis and curative effect standard" of the Administration of Chinese Medicines, grades were classified as fully recovered, improved, or unhealed.

3. Meta-analysis

As all 13 studies used WM as the control group, RCTs with the same intervention and evaluation scale for the treatment groups were synthesized and analyzed. The treatment groups were divided into four types: fire needling or warm needling alone; a fire needling and bloodletting combination; fire needling, bloodletting, herbal medicine combination; and warm needling and WM drug combination.

1) Total treatment efficacy

(1) Comparison of fire needling or warm needling alone and WM treatment

A meta-analysis of four studies was performed to compare and analyze the effectiveness of heat stimuli during acupuncture treatment in the intervention group and WM drugs in the

No.	Study ID	Acupuncture points for one treatment	Number of needles in one treatment	Acupuncture point	Acupuncture depth	Needle type	Number of treatments	Treatment cycle	Another intervention
1	Wu (2020)	Fire needling	nr	ST44, SP8, SP3; LR2, SP10, SP6; LR4, SP9, SP36	nr	Improvement in fire needling	5	Eod	n
2	Xie et al. (2018)	Fire needling	8	A-Shi Point, SP36, GV14, SP9, SP6	0.2-0.3 cm	0.35 mm × 30 mm	1	Ed	n
3	Zong Warm et al. needling (2011)		8 or more	LI11, LI4, ST34; SP9, SP36, SP6, KI3, A-Shi Point Big toe: SP1, LR3; Ankle joint: GB39, BL60, SP5; Knee joints: SP10, ST35, SP9; Arm joint: HT3, LU5, LI10; Wrist joint: TE4, TE5, LI5	nr	0.25 mm × 40 mm	6	Ed 30 min	n
4	Zuo et al. (2016)	Warm needling	6	LI11, SP9, SP36, KI3, SP6, A-Shi Point	nr	0.35 mm × 40 mm	7	Ed 30 min	n
5	Ding (2017)	Fire needling	nr	A-Shi Point	nr	nr	3	Etd	Bloodletting
6	Hu et al. (2007)	Fire needling	nr	Pain area	0.3-1.0 inch	nr	nr	Mild: once a week Severe: eod	Bloodletting
7	Kuang (2010)	Fire needling	nr	A-Shi Point, ST44, SP8, SP3; LR2, SP10, SP6; LR4, SP9, SP36	nr	Improvement in fire needling	5	Eod	Bloodletting
8	Lei (2015)	Fire needling	nr	Pain area	0.3-1.0 cm	nr	nr	Mild: one time Severe: once a week	Bloodletting
9	Zhang (2012)	Fire needling	4	LR2, LR3, ST44, Ll4, A-Shi Point	0.3-1.0 inch	Diameter 0.5 mm	3	Etd	Bloodletting
10	Wang (2014)	Fire needling	4	LR2, LR3, ST44, LI4, A-Shi Point	0.3-1.0 inch	nr	2	Once every 5 days	Bloodletting, herbal medicine
11	Xie and Deng (2019)	Fire needling	4	A-Shi Point, LI4, ST44, LR3, LR2	0.3-1.0 inch	Diameter 0.5 mm	2	Etd	Bloodletting, herbal medicine
12	Yang (2016)	Fire needling	nr	Pain area	0.5 inch	nr	5	Eod	Bloodletting, herbal medicine
13	Zhao et al. (2019)	Warm needling	nr	A-Shi Point, LI11, LI4, KI3, SP9, SP6, SP36, SP3, LR3 Big toe: SP1, LR3; Knee joints: SP10, ST34, ST35; Arm joint: LU5, TE10, LI10; Ankle joint: BL60, SP5; Wrist joint: TE5, LI5, TE4	nr	nr	10	Ed 20 min	Western medicine

Table 2. Treatment method for heat stimulus on acupuncture

nr: not reported, ed: every day, eod: every other day, etc.: every three days.

control group [33-36]. The intervention group underwent two sessions each of warm needling and fire needling, and colchicine, etoricoxib, indomethacin, and allopurinol were the orally administered WM drugs. The heat stimulus in the acupuncture treatment group demonstrated a 1.22 times significantly higher total efficacy than in the control group (p = 0.0001) (RR: 1.22, 95% CI: 1.10 to 1.34, p = 0.27). The I² value was 23%, indicating a low heterogeneity among the studies (Fig. 2A).

(2) Comparison of a combination of fire needling and bloodletting with WM treatment

A meta-analysis of five studies was performed to compare the treatment efficacy of the fire needling and bloodletting intervention and the control group using WM [37-41]. In each study, WM drugs—diclofenac, indomethacin, allopurinol, and colchicine—were orally administered. The fire needling and bloodletting combination intervention group had a 1.19 times significantly higher total efficacy than the control group (p < 0.0001) (RR: 1.19, 95% CI: 1.10 to 1.29, p = 0.06). The I² value



Figure 2. Meta-analysis of the outcomes of total efficiency rate between heat stimulus on acupuncture alone or combined treatment vs. Western medicine (WM) treatment. (A) Heat stimulus on acupuncture alone vs. WM treatment. (B) Heat stimulus on acupuncture + bloodletting vs. WM treatment. (C) Heat stimulus on acupuncture + bloodletting + herbal medicine vs. WM treatment. (D) Heat stimulus on acupuncture + WM vs. WM treatment. was 55%, indicating a high level of heterogeneity among the studies (Fig. 2B).

(3) Comparison of combination treatment with fire needling, bloodletting, herbal medicine versus WM

Two studies comparing the treatment efficacy of the combination treatment intervention group using fire needling, bloodletting, and herbal medicine with that of the control group using WM drugs were examined [42, 44]. In the studies, WM drugs—indomethacin, allopurinol, and colchicine—were orally administered. The intervention group had a 1.06 times higher total treatment efficacy than the control group (p > 0.05) (RR: 1.06, 95% CI: 0.96 to 1.16, p = 0.07). The I² value was 65%, indicating a high level of heterogeneity between the studies (Fig. 2C).

(4) Comparison between warm needling and concurrent

WM treatment

We analyzed one study comparing the concurrent treatment efficacy of the combination treatment intervention group with warm needling and WM drugs with those of the control group using WM drugs [45]. For WM drugs in the intervention and control groups, colchicine and indomethacin were administered orally. The intervention group showed a 1.27 times significantly higher total treatment efficacy than the control group (p = 0.03) (RR: 1.27, 95% CI: 1.03 to 1.57) (Fig. 2D).

2) Pain score in the VAS

(1) Comparison of fire needling or warm needling alone and WM treatment

A meta-analysis of four studies using a heat stimulus during acupuncture as an intervention group and WM as a control group was performed to compare and analyze the treatment efficacy using VAS scores [33, 34]. Colchicine and etoricoxib were orally administered as the control drugs. The intervention group tended to have significantly lower VAS scores than those of the control group (MD: –1.46, 95% CI: –1.89 to –1.03, p < 0.00001). The I² value was 0%, indicating low heterogeneity among the studies (Fig. 3A).

(2) Comparison of fire needling and bloodletting combination treatment and WM treatment

A meta-analysis was performed with two studies using the VAS scores to compare the treatment efficacy in the fire needling and bloodletting combination intervention group with that of the control group using WM [37, 39]. In each study, WMs—diclofenac or colchicine—were orally administered. The



Figure 3. Meta-analysis of the outcomes of pain score using the visual analog scale between heat stimulus on acupuncture alone or combined treatment vs. Western medicine treatment. (A) Heat stimulus on acupuncture alone vs. Western medicine treatment. (B) Heat stimulus on acupuncture + bloodletting vs. Western medicine treatment. (C) Heat stimulus on acupuncture + bloodletting + herbal medicine vs. Western medicine treatment.

fire needling and bloodletting combination intervention group had significantly lower VAS scores than the control group (MD: -1.46, 95% CI: -1.84 to -1.08, p < 0.00001). The I² value was 17%, indicating low heterogeneity between the studies (Fig. 3B).

(3) Comparison of combination of fire needling,

bloodletting, and herbal medicine with WM

We analyzed one study using VAS scores to compare the treatment efficacy of the combination treatment consisting of fire needling, bloodletting, and herbal medicine intervention with the control group using WM drugs [43]. WMs—diclof-enac and allopurinol—were orally administered. The intervention group had significantly lower VAS scores than the control group (MD: -3.25, 95% CI: -4.04 to -2.46, p < 0.00001) (Fig. 3C).

3) Uric acid levels

(1) Comparison between fire needling or warm needling alone and WM treatment

A meta-analysis of two studies (one fire needling and one warm needling) in which a heat stimulus during acupuncture treatment was used in the intervention group and WM drugs in the control group, was compared and analyzed in terms of UA levels (μ mol) [33, 35]. WM drugs—colchicine, indomethacin, and allopurinol—were orally administered. The intervention group demonstrated a tendency to have significantly lower UA levels than the control group (MD: –0.89, 95% CI: –1.34 to –0.45, p < 0.0001). The I² value was 0%, indicating low heterogeneity between the studies (Fig. 4A).



Figure 4. Meta-analysis of the outcomes of uric acid between heat stimulus on acupuncture alone or combined treatment vs. Western medicine (WM) treatment. (A) Heat stimulus on acupuncture alone vs. WM treatment. (B) Heat stimulus on acupuncture + bloodletting vs. WM treatment. (C) Heat stimulus on acupuncture + bloodletting + herbal medicine vs. WM treatment. (D) Heat stimulus on acupuncture + WM vs. WM treatment.

(2) Comparison of a combination of fire needling and bloodletting versus WM treatment

A meta-analysis of five studies was performed to compare and analyze the treatment efficacy of fire needling and bloodletting combination treatment and WM drugs as the control with respect to UA levels [37-41]. WM drugs included orally administered diclofenac, indomethacin, allopurinol, and colchicine. The intervention group demonstrated a tendency to have significantly lower UA levels than the control group (MD: -0.59, 95% CI: -0.80 to -0.37, p < 0.0001). The I² value was 71%, indicating a high degree of heterogeneity among the studies (Fig. 4B).

(3) Comparison between fire needling, bloodletting, and herbal medicine combination treatment and WM

A meta-analysis of one study was performed to compare the treatment efficacy of a fire needling, bloodletting, herbal medicine combination treatment and of WM as the control group with respect to UA levels [43]. Diclofenac and allopurinol were the orally administered WM drugs. The intervention group had lower UA levels than the control group, although no significant difference was noted (MD: 0.04, 95% CI: -22.55 to -22.63, p = 1.00) (Fig. 4C).

(4) Comparison of concurrent warm needling and WM drug treatment versus WM

We analyzed one study comparing the treatment efficacy in the concurrent warm needling and WM drug treatment intervention group and the control group using WM with respect to UA levels [45]. In both intervention and control groups, colchicine and indomethacin were commonly administered orally as the WM drugs. The intervention group had significantly lower UA levels than the control group (MD: -54.48, 95% CI: -77.94 to -31.02, p < 0.0001) (Fig. 4D).

4. Assessment of study quality

Risk of bias (RoB) was evaluated in the 13 selected studies using the Cochrane RoB tool [33-45]. Regarding the randomization order of the generated items, three randomized studies using a random number table were found to have a low RoB, and eight randomized studies that did not mention the exact method were considered to have an uncertain RoB. Two studies that did not mention randomization were rated as having a high RoB. As none of the 13 studies mentioned any concealment of the assignment order, they were considered to have an uncertain RoB. As none of the intervention and control groups were



Figure 5. Risk of bias summary (A) and graph (B). +: low risk of bias; -: high risk of bias; .: unclear risk of bias.

blinded with respect to the study participants or researchers, all the 13 studies were considered to have a high RoB. As none of the 13 studies mentioned any blinded item for outcome evaluation, they were considered to have an uncertain RoB. In the case of insufficient outcome data, no missing values were recorded in any study, suggesting a low RoB. As optional reporting items were not mentioned in any of the studies, they were considered to have an uncertain RoB. Moreover, since the possibility of additional bias in the other RoB category was uncertain in all the studies, they were considered to have an uncertain RoB (Fig. 5).

5. Adverse reaction report

Of the 13 studies, four mentioned adverse reactions. Anorexia was reported in one study, whereas the other three studies reported no adverse reactions. The other nine studies did not mention any adverse reactions (Table 1).

DISCUSSION

Both fire needling and warm needling are two procedures of acupuncture and moxibustion involving fire heat transfer to the human body, which increases the yang qi of the human body and raises the meridian qi, thus invigorating the yang qi of the viscera and bowels to prevent and treat diseases. If yang qi in the human body is fully exuberant, the yin-cold qi can be relieved. When the qi-blood is harmonized, all diseases will be healed by removing the cold, disturbing the lumps, and letting the meridians extend without hesitation. Accordingly, fire needling and warm needling focus on joint diseases caused by wind-dampness and various diseases triggered by cold; they occasionally borrow fire power to expel heat toxins and treat diseases involving swelling and heat pain caused by local qiblood depression and stagnation or fire depression [11]. These are considered the treatment points of fire needling and warm needling for gout.

Despite the mechanism of gout treatment with fire needling and warm needling, clinical studies are lacking. Although systematic review studies have been conducted on general acupuncture treatment for gout [46, 47], systematic review studies on the effects and safety analysis of fire needling and warm needling on gout are lacking. Despite gout-related studies in Korea [30-32], only a systematic review study on electroacupuncture for acute gout in 2022 [33] has been reported; no clinical studies related to fire needling and warm needling therapy were identified. Moreover, considering the results of a survey [32] of doctors practicing KM, research and interest in KM treatment for gout may be insufficient in the KM community.

The 13 studies [33-45] selected in the present systematic review were all published in China. The number of study participants varied from 40 to 100, and the total number of study participants was 840. Since the publication has been continuous since 2000, and the number of study participants is not small, clinical studies applying either fire needling and warm needling treatment alone or in combination for treatment of acute gout can be considered to be active. However, since all the selected studies were conducted in China, studies on fire needling and warm needling should also be conducted in other countries.

Among the target acupuncture points, the Ashi point was the most common (12 studies), followed by SP6, SP9, and ST36 (six studies). In clinical practice, when treating gout patients with fire needling or warm needling, it would be better to consider the first Ashi point, SP6, ST36, and SP9, as treatment acupuncture points. Various needle depths and types of acupuncture needle were mentioned in only seven studies. The number of treatments varied from 1 to 10, wherein 5 was the most frequent number in three studies and no numbers were mentioned in two studies. Regarding the treatment frequency, we analyzed four studies with daily treatment, three studies with every other day or every 3 days, two studies with mild and severe cases, and one study with every 5 days. Treatment time was mentioned as 30 min in two studies and 20 min in one study but was not mentioned in the other 10 studies. The number of treatments and the frequency of treatment varied greatly; two studies did not mention the number of treatments, and the treatment time was not mentioned in 10 studies; thus, it was difficult to standardize. Additional clinical studies are needed to suggest standard treatment methods, including needle depth, needle type, number and frequency of treatments, and treatment time for fire needling and warm needling for acute gout therapy.

The treatment period in the intervention group varied from a minimum of 6 days to a maximum of 20 days, and the mean treatment period was 9.22 days. The treatment period was < 1 week in six cases, < 2 weeks in six cases, and 20 days in one case. Based on this, if fire needling and warm needling are used to improve symptoms of acute gout, a treatment period of < 3 weeks can be considered in future clinical research designs and KM standard clinical pathways.

The control group interventions were all WM drugs, with a total of nine NSAIDs and five each of colchicine and allopuri-

nol, which are UA-lowering drugs. Additionally, seven studies used a single WM drug, and six studies used two WM drugs together. A limitation of the present review is that several types of WMs were set as one control group without any distinction between single and parallel drugs. Additional studies are needed to select the optimal WM drug as a control or combination treatment drug.

The evaluation scales mainly used were total treatment efficacy, UA levels, and VAS scores; total efficacy was used in 12 studies, UA levels in nine studies, and VAS scores in five studies. Seven studies used two evaluation tools, three cases used three evaluation tools, and three papers evaluated only total treatment efficacy. With the exception of UA levels, most studies used subjective indicators based on subjective symptom improvement and personal evaluation. In the future, various treatment outcomes using more objective and reliable evaluation scales will have to be evaluated to serve as a scientific basis for clinical treatment.

In this study, the meta-analysis revealed that the fire needling or warm needling alone treatment group had significantly better total treatment efficacy, pain scores, and UA levels than those of the WM control group. Future high-quality clinical research should be conducted to improve the level of evidence for recommending fire needling or warm needling for gout therapy.

Acupuncture, bloodletting, and herbal medicine treatments have also been reported to be highly useful in a clinical KM utilization survey for acute gout [30], and the textbook of acupuncture medicine used in KM colleges specifies that bloodletting should be applied to painful areas in cases of acute gout [11]. In this review, both fire needling and bloodletting were used in parallel with other KM treatments, and herbal medicine was additionally used in three studies, for which the treatment efficacy was better than that of the WM control group. In the fire needling and bloodletting intervention groups, the total treatment efficacy, pain scores, and UA levels were significantly better than those of the WM control group. The addition of herbal medicine may produce a better synergistic effect, although significant results were observed only in the pain scores in the study in which a combination of fire needling, bloodletting, and herbal medicine was used. Since the types of herbal medicines are different and the number of studies to determine their therapeutic effects is insufficient, additional clinical studies on the combination of herbal medicines are needed in the future.

The needling and WM combination intervention group

demonstrated a significantly better treatment efficacy in terms of total treatment efficacy and UA levels than the WM control group. Therefore, in places where WM and KM cooperative treatment is possible, KM warm needling treatment can be considered when creating a cooperative treatment model for acute gout.

Although the number of studies is small and there are limitations in that there are many studies in which all evaluation scales have not been used, the results indicated treatment efficacy in all the intervention groups. In particular, all evaluation scales in interventions of fire needling or warm needling alone or in combination with bloodletting were significantly improved. Therefore, in the future, clinical research and treatment for gout using fire needling and warm needling alone or in combination with bloodletting, or in combination with WM, can be considered preferentially. Additional clinical studies, such as a comparison of treatment efficacy for each treatment method in the intervention group, are needed in the future.

Of the 13 studies, only four mentioned adverse reactions. Anorexia was reported in one study, whereas the other three studies reported no adverse reactions. Although adverse reactions in this study were few, there is no evidence of safety because the majority of studies have not even mentioned adverse reactions. Burns can happen when using fire needling and warm needling, but there was no report in any of the 13 studies. Since fire needling and warm needling treatment are invasive and highly irritating due to their therapeutic characteristics, tissue and nerve damage caused by thermal stimulation should be treated with caution, and blisters caused by burns should be disinfected to prevent infection [11, 24]. Additional safety-related studies, including active observation and reporting of adverse reactions, are needed to ensure the safety of fire needling and warm needling treatment in the future.

Although RCTs are recognized as a method to accurately evaluate the intervention effects of a treatment, studies with a high RoB may report false effects by underestimating or overestimating the intervention effects in the estimation of outcomes. Therefore, RoB assessment is mandatory [32, 48]. The Cochrane RoB assessment tool was used for evaluation in the present review. Hence, many evaluations had uncertain or high RoB, which made evaluating bias for all items difficult, and the number of included studies was small (only 13 studies). All studies had a limitation due to a regional bias because the documents retrieved from the Chinese database were all RCTs conducted in China.

Our review indicates that heat stimuli during acupuncture alone or as combination treatment (e.g., fire needling and warm needling) in acute gout had more limited therapeutic effects than did WM treatment. Our results may serve as evidence for using fire needling and warm needling more actively for gout in clinical practice. However, because the number of included studies was small, the validity and reliability of the evaluation scale are limited. Moreover, the possibility of missing papers due to research in the database not used for searches or the exclusion of studies published in other languages cannot be ignored. In the case of combination therapy, it is difficult to know which treatment is more effective, so the evidence for the therapeutic effect is limited. Further studies are needed to independently determine the effectiveness of each treatment. Moreover, since most of the studies are of uncertain or high RoB, caution is required to interpret the results of this meta-analysis. A highquality, large-scale, randomized, comparative clinical trial study with a unified treatment method using evaluation scales with proven reliability and validity in relation to treatment is needed. Although this review is a limited report, it could be used as supporting data. Moreover, we attempted to search for studies on chronic gout but found no RCTs. Thus, additional studies related to gout other than acute gout are also needed.

CONCLUSION

Heat stimuli during acupuncture alone or as combination treatment (e.g., fire needling and warm needling) could be effective for acute gout. However, due to limitations such as the small number of included studies and regional bias, higherquality, large-scale RCT studies are needed to confirm the level of evidence.

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CONFLICT OF INTEREST

The authors declare no conflict of interest.

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