Systematic Review and Meta-Analysis

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Effect of traditional Chinese manipulation on ankle sprains

A systematic review and meta-analysis

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Abstract

Background: This systematic review and meta-analysis was performed to evaluate the clinical efficacy and safety of traditional Chinese manipulation in treating ankle sprains.

Methods: Seven databases were searched from inception to July 2020. A meta-analysis of randomized controlled trials comparing traditional Chinese manipulation and other conservative therapy for ankle sprains was conducted. The Cochrane Handbook tool was applied to access the quality and risk of bias of each study. The meta-analysis was performed with Review Manager 5.3 software (Nordic Cochrane Centre, Copenhagen, Denmark).

Results: In total, 14 articles and 1112 patients were included. The total effective rate of ankle manipulation was much higher than that of other conservative therapy (risk ratio [RR], 1.23; 95% confidence interval [CI], 1.17–1.30; $P < .00001$). The Baird–Jackson score (RR, 10.14; 95% CI, 5.57–14.70; $P < .0001$), visual analog scale score (RR, −1.78; 95% CI, −3.14 to −0.43; $P = .01$), and American Orthopaedic Foot and Ankle Society ankle-hindfoot score (RR, 15.70; 95% CI, 12.72–18.68; $P < .00001$) were significantly lower in the manipulation group than in the control group. Further subgroup analysis showed that the visual analog scale score of the rotating-traction-poking manipulation was significantly lower than that of the control group (RR_{RTPM}, −2.56; 95% CI, −4.54 to −0.58; $P = .01$), while there were no significant differences between the effects of other manipulations and the control group ($RR_{other\ manipulation}$, −0.62; 95% CI, −1.52 to 0.28; $P = .18$).

Conclusion: Traditional Chinese manipulation might have a better effect on ankle sprains than other types of conservative treatment. The rotating-traction-poking manipulation might achieve better effects than other manipulation techniques in terms of alleviating pain intensity. However, considering the overall high or unclear risk of bias, the evidence identified does not allow for a robust conclusion concerning the efficacy and safety of traditional Chinese manipulation for treating ankle sprains. High-quality randomized controlled trials are needed to confirm these findings.

Abbreviations: AOFAS = American Orthopaedic Foot and Ankle Society, CI = confidence interval, RCTs = randomized controlled trials, RR = risk ratio, RTPM = rotating-traction-poking manipulation, VAS = visual analog scale.

Keywords: ankle sprains, Chinese manipulation, meta-analysis, randomized controlled trial

1. Introduction

Ankle sprains are some of the most common musculoskeletal injuries. The rate of lateral ankle sprains ranges from 15% to 20% of all sports injuries.[1] Approximately 32% to 74% of patients who suffer lateral ankle sprains develop chronic ankle instability,[2,3] which presents with pain, recurrent ankle sprains, decreased neuromuscular control, weakness, an impaired sense of joint position, and diminished performance of functional

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WBJ and YXL contributed equally to the work.

No ethical approval was required for this systematic review and meta-analysis.

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The datasets generated during and/or analyzed during the current study are available from the corresponding author on reasonable request.

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activities.[4] The most common injury mechanism is a combination of inversion and adduction of the foot in plantarflexion. This injury mechanism can cause damage to the lateral ankle ligaments. Injury of the anterior talofibular ligament and calcaneofibular ligament leads to anterolateral rotary instability and tilting of the talus.[5]

Some therapeutic methods had been recommended: surgery, immobilization, cold compresses, and functional treatments with bandages, braces, balance training, and manual therapy. Balancing the advantages and disadvantages of surgical and nonsurgical treatment, a systematic review concluded that the majority of grades I, II, and III lateral ankle ligament ruptures can be managed without surgery.[6] Some researches had shown that manual therapy following ankle sprains leads to superior early dorsiflexion range compared with a traditional exercise intervention alone.[7,8] In a study, a caudal talocrural joint manipulation led to a significant plantar load distribution change. Mechanical joint alternation and altered postural control might result in this change.[9]

Ankle manipulation has a long history of use in Chinese medicine. In recent studies, the efficacy of this technique has been proven by several clinical randomized controlled trials (RCTs) for the treatment of grade I and II ankle sprains.[10,11] Compared with rest, ice, compression, and elevation (RICE) therapy, traditional Chinese manipulation can actively adjust the imbalance of joints and ligaments, can rapidly improve acute symptoms, and has a stable long-term effect. However, the evidence of the therapeutic effect on ankle sprains is insufficient. In this paper, we performed a meta-analysis to systematically review the effect and safety of traditional Chinese manipulation for patients with ankle sprains who underwent other conservative therapies. The aim of this study was to provide an objective perspective for evaluation of the effect of traditional Chinese manipulation on ankle sprains.

2. Methods

2.1. Search strategy

Studies concerning the effects of traditional Chinese manipulation on ankle sprains reported from database inception to July 2020 were reviewed. The following electronic literature databases were searched: PubMed, Medline, Embase, China National Knowledge Infrastructure, Wanfang, VIP, and the Cochrane Library. The following keywords were used: "ankle sprain," "ankle injury," "bone setting," "manual therapy," "manipulation," "massage," and "random." The search strategy in PubMed was as follows: #1 "ankle sprain" [Abstract/Title]; #2 "ankle injury" [Abstract/Title]; #3 "#1 OR #2"; #4 "manipulation" [Abstract/Title]; #5 "manual therapy" [Abstract/Title]; #6 "massage" [Abstract/Title]; #7 "bone setting" [Abstract/Title]; #8 "#4 OR #5 OR #6 OR #7"; #9 "random" [Abstract/Title]; #10 "randomized controlled trial" [Abstract/Title]; #11 "control" [Abstract/Title]; #12 "#9 OR #10 OR #11"; #13 "#3 AND #8 AND #12."

2.2. Study selection

The inclusion criteria for this review were as follows:

(1) the study type was an RCT
(2) there was no restriction on language, blinding, target population, or publication type
(3) the diagnostic criteria for ankle sprains (ie, ankle pain, swelling, functional impairment, and absence of complete ligament rupture or fracture) were in accordance with 1 of 3 specific references: Criteria of Diagnosis and Therapeutic Effect of Diseases and Syndromes in Traditional Chinese Medicine,[12] Guiding Principles for Clinical Research of New Chinese Medicine,[13] or Orthopedics of Traditional Chinese Medicine[14]
(4) the main intervention was traditional Chinese manipulation (no restriction on academic schools), which was compared with any other conservative treatment such as RICE treatment, physical therapy, herbal fumigation, oral analgesic drugs, or others
(5) the outcomes included the total effective rate of manipulation (primary outcome), American Orthopaedic Foot and Ankle Society (AOFAS) ankle-hindfoot score, Baird–Jackson score, visual analog scale (VAS) score, and Takakura score (secondary outcomes)

The exclusion criteria were as follows:

(1) case reports
(2) duplicate publications
(3) conference papers, systematic reviews, and meta-analyses
(4) studies in which the manipulation group also received other forms of treatment

2.3. Data extraction and management

Two reviewers (B.W. and X.Y.) independently read the title, abstract, and full text of each study for potential inclusion. Disagreements were resolved by consensus among all authors. For each eligible study, the following data were extracted:

(1) basic information: first author, publication time, sample size, and age and sex of participants
(2) clinical trial method: diagnostic criteria, inclusion and exclusion standard, and randomization or blinding method
(3) intervention: type, method, and performers of manipulation; number of treatment episodes; and follow-up duration
(4) outcome data: total effective rate, AOFAS ankle-hindfoot score, Baird–Jackson score, VAS score, Takakura score, and adverse events
(5) key elements of risk-of-bias assessment

2.4. Quality assessment

Two investigators (B.W. and X.Y.) assessed each of the following study domains according to the recommendations in the Cochrane Handbook[15] for assessing risk of bias:

(1) random sequence generation
(2) allocation concealment
(3) blinding of participants and personnel
(4) blinding of outcome assessment
(5) incomplete outcome data
(6) selective outcome reporting
(7) other bias

Each domain was classified as having a high, low, or unclear risk of bias. Any disagreements were resolved by discussion. If an included study had a high risk of bias in 3 or more domains, the study was recognized as being of low quality.

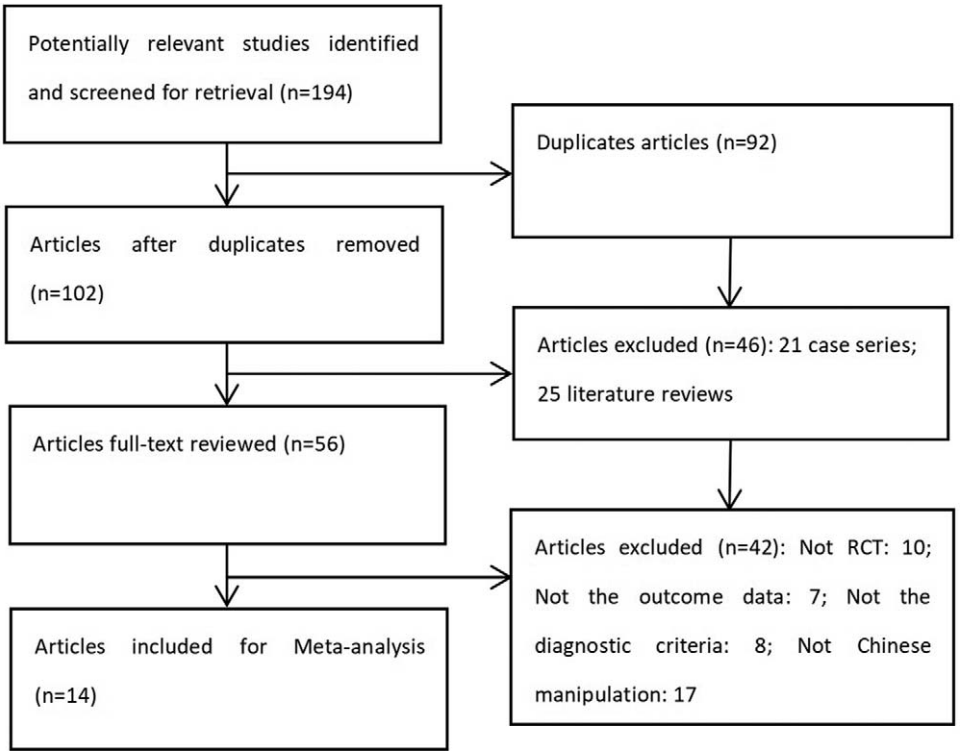

Figure 1. Flowchart of the search and study selection process.

2.5. Statistical analysis

All search results were entered into Review Manager 5.3 (Nordic Cochrane Centre, Copenhagen, Denmark) for data analysis. Dichotomous data are presented as risk ratio (RR) with 95% confidence interval (CI), and continuous data are presented as mean difference with 95% CI. The I^2 statistic was obtained from the heterogeneity test (I^2 test). I^2 values of 75%, 50%, and 25% were considered to indicate high, medium, and low heterogeneity, respectively. If $I^2 > 50\%$, a random-effects model was chosen; otherwise, a fixed-effects model was chosen. Differences with a P value of $<.05$ were considered statistically significant. Sensitivity analyses were conducted for the robustness of the results of the meta-analysis. Publication bias was assessed using a funnel plot if >10 trials were included in the meta-analysis.

2.6. Ethical statement

As all analyses were grounded on previously published studies, ethical approval was not necessary.

3. Results

3.1. Search results and study characteristics

Fifty-six candidate studies including only 14 RCTs[10,16–28] were initially identified (Fig. 1). The general characteristics of the included studies are listed in Table 1. In total, 1112 patients with ankle sprains were enrolled (568 in study group and 544 in control group). All studies compared the therapeutic effect of traditional Chinese manipulation with other treatments. Among them, 7 studies[10,16,18,20,22,24,25] involved a special manipulation called rotating-traction-poking manipulation (RTPM). Control interventions included cold compresses,[10,17,24,28] RICE therapy,[23,26,27] elastic bandage fixation,[10,24,28] oral analgesics,[17,21] functional exercise,[20,25] herbal fumigation,[18] kinesio taping stickers,[22] diclofenac diethylamine gel for external use,[19] electromagnetic wave device irradiation,[16] and ultra-laser irradiation.[21]

3.2. Risk of bias

According to the risk-of-bias summary (Fig. 2), all studies had either an unclear or high risk of bias in 1 or more methodological domains. Apart from 7 RCTs[17,19,21,23,26,27,28,] that did not report the method of randomization, the remaining 7 trials adopted a random number table, computerized randomization, or coin toss to produce a random sequence. Only 2 studies completed allocation concealment through the a central random system[10] or sealed envelope.[22] Because it was difficult to perform double-blinding of both participants and researchers with respect to manipulation or massage, all studies were considered to have a high risk of bias in terms of blinding of participants and personnel. Only 1 RCT[10] clearly illustrated and the method of "Blinding of outcome assessment (detection bias)." The remaining 13 studies did not mention the blinding method for the outcome evaluator. Two RCTs had attrition bias,[20,25] which could not be accessed the integrated information from the article. Selective reporting of all included RCTs was assessed as an unclear risk of bias because the trial protocol was not accessible. All trials were rated as having a low risk of bias in other domains.

The funnel plot comparing the total effective rate in the manipulation group and control group was asymmetrical (Fig. 3), indicating the existence of potential publication bias.

Table 1

Characteristics of study participants.

Study	No. of participant		Intervention		Outcome	Performers	Number of treatment episodes	Follow-up duration (mo)
	T	C	T	C				
Lin SH 2017[16]	40	40	Rotating-traction-poking manipulation (RTPM)	Electromagnetic wave device irradiation	①②	One physical therapist specializing in the RTPM with extensive clinical experience and a assistant	Manipulation: 30 min 3 times a week for 2 wk. Electromagnetic wave device irradiation: 30 min three times a week for 2 wk.	2 wk
Wang AF 2012[17]	81	81	Bone setting manipulation	Cold compress + oral analgesic	①	unclear	Manipulation: 30 min once a day for 20 d. Cold compress 48 h after injury. Oral analgesics as needed.	20 d
Li JH 2012[18]	39	37	RTPM	Herbal fumigation	①②	One experienced physical therapist named Li Junhai	Manipulation: repeat for 3 cycles, twice a week for 3 wk. Herbal fumigation: 30 min once a day for 3 wk.	3 wk
Gao CY 2015[10]	54	52	RTPM	Cold compress+ elastic bandage fixation	①③	One experienced physical therapist named Gao Jinghua	Manipulation: 20 min 3 times a week for 2 wk. Cold compress: 1 h per day for 3 d. Bandage fixation for 2 wk.	3 mo
Chen B 2012[19]	52	51	Shi ' traumatology manipulation	Diclofenac Diethylamine Emulgel for external use	④⑥⑦	Unclear	Manipulation: once a day for 2 wk. Diclofenac diethylamine gel for external use: once a day for 2 wk.	2 wk
Chen ZJ 2017[20]	52	37	RTPM	Functional exercise	④⑤	One experienced physical therapist named Chen Zhaojun	Manipulation: repeat for 7 cycles, once every 3 d for 12 d. Functional exercise: repeat for 7 cycles, once every 3 d for 12 d.	3 mo
Diao HH 2018[21]	35	35	Lin ' traumatology manipulation	Oral analgesic + ultra-laser irradiation	①⑤	One experienced physical therapist named Lin Yingqiang	Manipulation: once to twice per week for 1 wk. Oral analgesic: 0.2 g twice a day for 1 wk. Ultra-laser irradiation: 20 min once a day for 1 wk.	2 wk
Fu WB 2016[22]	30	30	RTPM	Kinesio taping stickers	①③④	One experienced physical therapist named Gao Jinghua	Manipulation: repeat for 3 cycles, 3 times a week for 1 wk. Kinesio taping stickers: 12 h once a day for 1 week.	1 mo
Li JS 2015[23]	30	30	Pulling-Shaking manipulation	RICE therapy	①	One experienced physical therapist named Zhao Wenhai	Manipulation: once a week for 2 wk. RICE therapy for 2 wk.	2 wk
Gao JH 2013[24]	21	19	RTPM	Cold compress+ elastic bandage fixation	①③④	One experienced physical therapist named Gao Jinghua	Manipulation: repeat for tree cycles, 3 times a week for 2 wk. Cold compress: 1 h per day for 3 d. Bandage fixation for 2 wk.	3 mo
Li YH 2017[25]	34	32	RTPM	Functional exercise	①④⑤	One experienced physical therapist named Chen Zhaojun	Manipulation: repeat for 7 cycles, once every 3 d for 18 d. Functional exercise: repeat for 7 cycles, once every 3 d for 18 d.	3 mo
Chen P 2016[26]	28	28	Simplified RTPM	RICE therapy	①	Unclear	Manipulation: repeat for 6 to 7 cycles, once a day for 1 wk. RICE therapy for 1 week.	1 wk
Zhang GL 2013[27]	40	40	Massage	RICE therapy	①	Unclear	Massage: once a day for 2 wk. RICE therapy for 2 wk.	2 wk
Li H 2015[28]	32	32	Three steps and 5 manipulation	Cold compress + elastic bandage fixation	①④	Unclear	Massage: once a week for 2 wk. Cold compress: 1 h per day for 3 d. Bandage fixation for 2 wk.	2 wk

① Total effective rate; ② Baird–Jackson score; ③ Takakura score; ④ VAS score; ⑤ AOFAS ankle-hindfoot score; ⑥ Pain Rating Index; ⑦ present pain intensity.

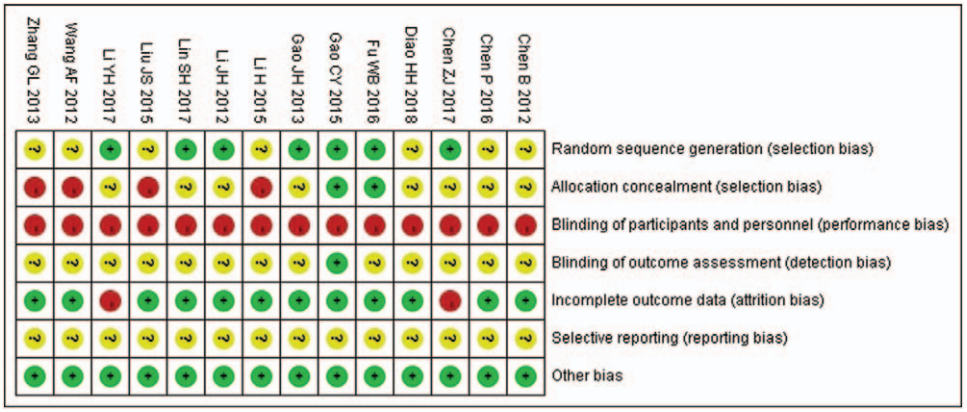

Figure 2. Risk of bias summary.

3.3. Total effective rate

Twelve studies[10,16–18,21–28] involving 920 participants reported the total effective rates. The random-effects model (Fig. 4) showed that the effect of manipulation was much better than the effect of other conservative therapy (RR, 1.23; 95% CI, 1.17–1.30; $P < .00001$). Further subgroup analysis showed that regardless of the use of RTPM or other manipulation techniques, the total effective rate was better than that in the control group (RR_{RTPM}, 1.33; 95% CI, 1.21–1.45; $P < .00001$ and $RR_{other\ manipulation}$, 1.16; 95% CI, 1.09–1.23; $P < .00001$).

3.4. Baird–Jackson score

Two trials[16,18] involving 156 participants reported the Baird–Jackson score. The random-effects model (Fig. 5) showed a significant difference in favor of the manipulation group (RR, 10.14; 95% CI, 5.57–14.70; $P < .0001$). This result indicates that manipulation alone was superior to other conservative therapies (herbal fumigating or electromagnetic wave irradiation) with respect to improvement in the Baird–Jackson score and the clinical effect.

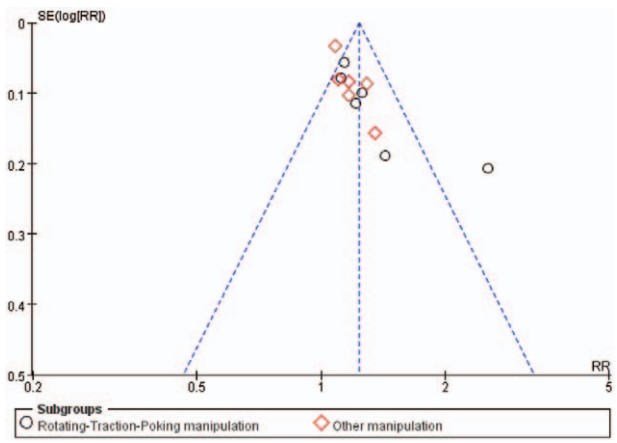

Figure 3. Funnel plot Comparison: manipulation group versus control group; Outcome: total effective rate.

3.5. Takakura score

Three studies[10,22,24] involving 206 participants reported the Takakura score. The results (Fig. 6) showed that there was no significant difference in the Takakura score between the experimental group and the control group (RR, 2.16; 95% CI, −2.12 to 6.34; $P = .32$). The effect of manipulation alone was similar to that of other conservative therapies (cold compresses + elastic bandage fixation or Kinesio taping stickers) in terms of the Takakura score.

3.6. VAS score

Five studies[19,20,22,25,28] involving 382 participants reported the VAS score. The random-effects model (Fig. 7) showed that the effect of manipulation was much better than that of other conservative therapies (RR, −1.75; 95% CI, −3.14 to −0.43; $P = .001$). The results indicated that manipulation was superior to other conservative therapies (cold compresses + elastic bandage fixation, diclofenac diethylamine gel for external use, functional exercise, or kinesio taping stickers) in terms of VAS score improvement and the clinical effect.

Further subgroup analysis showed that the VAS score for RTPM was significantly lower than that in the control group (RR_{RTPM}, −2.56; 95% CI, −4.54 to −0.58; $P = .01$), while there were no significant effects between other manipulations and the control group ($RR_{other\ manipulation}$, −0.62; 95% CI, −1.52 to 0.28; $P = .18$). Thus, the RTPM achieved better results than other manipulations in terms of pain relief of ankle sprains.

3.7. AOFAS ankle-hindfoot score

Three studies[20,21,25] involving 224 patients reported the AOFAS ankle-hindfoot score. The random-effects model (Fig. 8) demonstrated a significant difference in favor of the manipulation group (RR, 15.70; 95% CI, 12.72–18.68; $P < .00001$). The results showed that manipulation alone was superior to other conservative therapies (oral analgesics + ultra-laser irradiation or functional exercise) in terms of improvement in the AOFAS ankle-hindfoot score and the clinical effect.

3.8. Safety evaluation

Among the 14 trials included in the meta-analysis, 8 trials[10,18–21,24,27–28] did not mention adverse reactions. The other 6

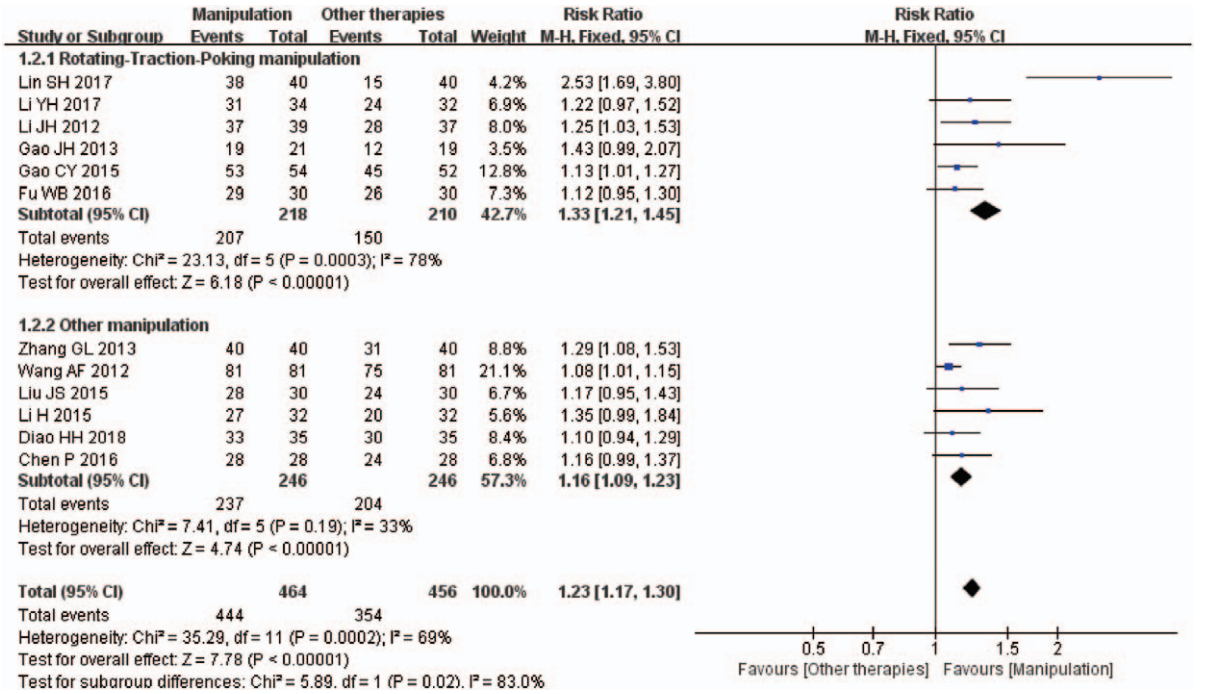

Figure 4. Meta-analysis of treatment effect of manipulation group versus other therapy group on the total effective rate.

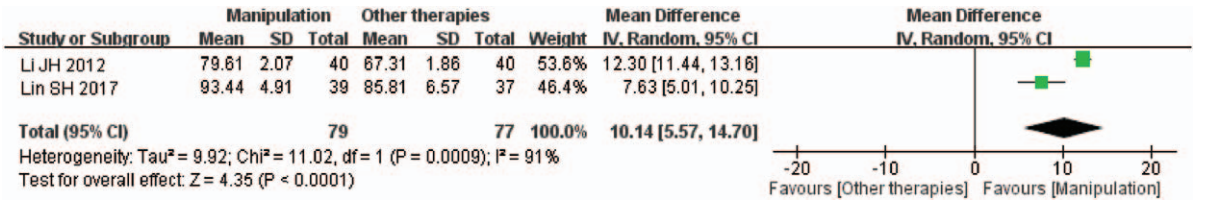

Figure 5. Meta-analysis of treatment effect of manipulation group versus other therapy group on the Baird–Jackson score.

studies[16–17,22–23,25–26] reported no adverse reactions in the treatment or control group.

4. Discussion

4.1. Summary of evidence

Ankle sprains belong to the disease category of "tendon injury" in traditional Chinese medicine. The main mechanism is "Jinchucao and Gucuofeng," which results in pain, swelling, and dysfunction of movement and other clinical symptoms of ankle injury. Traditional Chinese manipulation is one of the most effective means of treatment.[24] Various different styles and operations of ankle manipulation are used, with the representative technique being RTPM of Qinggong bone setting school.[10,18,20,22,24–25]

The present study showed that compared with other conservative therapies (RICE treatment, electromagnetic wave irradiation, herbal fumigating, oral analgesics, elastic bandage fixation, and so on), ankle manipulation alone might improve the total effective rate, Baird–Jackson score, VAS score, and AOFAS ankle-hindfoot score.

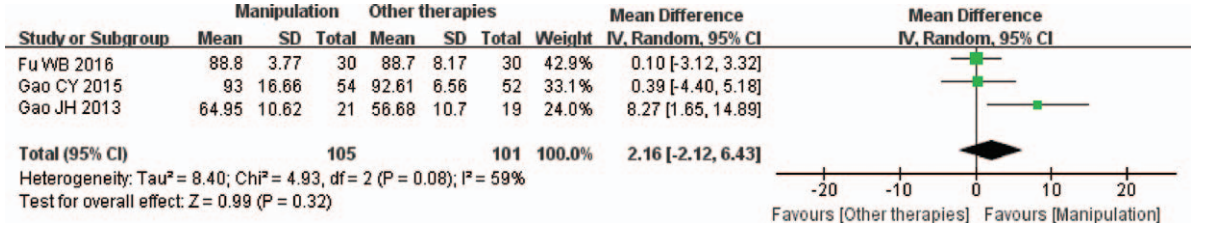

Figure 6. Meta-analysis of treatment effect of manipulation group versus other therapy group on the Takakura score.

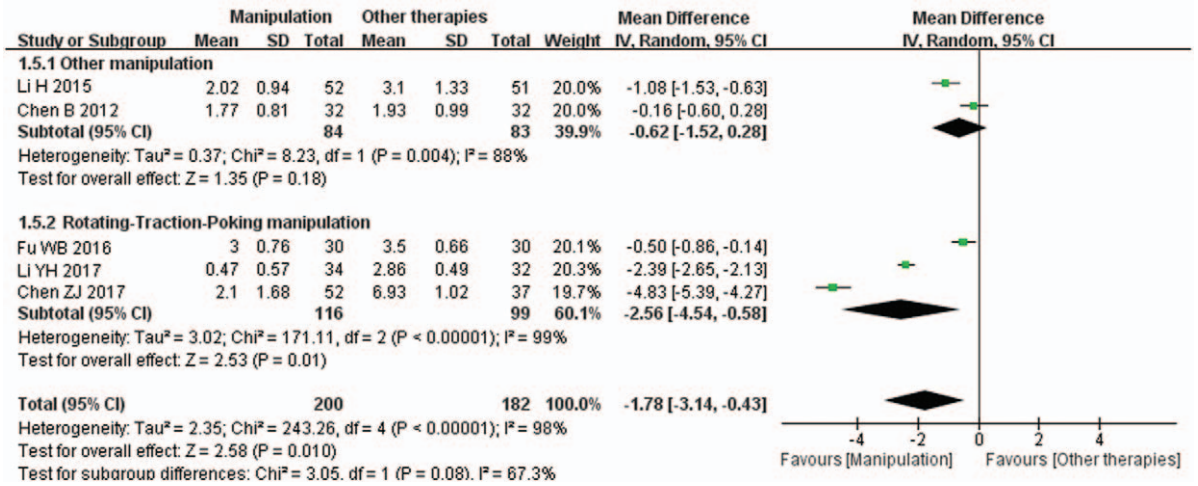

Figure 7. Meta-analysis of treatment effect of manipulation group versus other therapy group on VAS. VAS = visual analog scale.

In addition, the results of the subgroup analysis suggested that RTPM was more advantageous than other manipulations with respect to pain relief. This may result from the fact that RTPM only involves an operation of joint movement while the other manipulations involve methods of relaxation, such as kneading and rubbing manipulation to relieve soft tissue spasm[17,28] or pressing the acupoints around the ankle such as Shangqiu, Jiexi, Qiuxu, Kunlun, and Taixi.[19,22,27] In contrast, RTPM involves only 3 joint movement operations: rotating, traction, and poking manipulations. Among them, rotating manipulation can relax muscular and ligamentous spasms. Traction manipulation can temporarily increase the ankle joint space; this cooperates with the poking manipulation to restore dislocation and enhance stability of the ankle.[24] Similar results were demonstrated in the study by Sun et al,[29–30] who suggested more favorable pain-relieving effects of joint movement manipulation than relaxation manipulation because excessive stimulation of soft tissues was avoided. This might cause the RTPM to achieve better effects than other manipulations.

Nevertheless, the evidence obtained in this meta-analysis was not robust enough to permit a firm conclusion regarding the efficacy and safety of traditional Chinese manipulation for ankle sprains because of the overall high or unclear risk of bias of most included studies.

4.2. Implications for future research

At present, traditional Chinese manipulation for ankle sprains is not uniform and varies greatly in real-world practice. No agreement has been reached on the best manipulation procedure, leading to difficulties in assessing the real efficacy of this treatment. Therefore, we suggest exploration and standardization of the optimum manipulation procedure before large-sample RCTs are performed.

Moreover, high-quality RCTs are not only important for conducting authoritative systematic reviews, but they are also the foundation of health assessment reports and policy decision reports. For the sake of judging the validity of RCTs, researchers and readers should acquire all details about random sequence generation, allocation concealment, blinding methods, and other parameters of study quality. With regard to the risk of bias associated with the methodological contents among the included studies, most trials conducted in China failed to adequately report allocation concealment and blinding methods, which greatly reduced the quality of the RCTs. Therefore, we also suggest more rigorous design, performance, and reporting of future RCTs. This could be realized by applying standardized reporting criteria, such as the CONSORT criteria, in the training of researchers.

4.3. Limitations

This meta-analysis had 3 main limitations that should be mentioned. First, all of the included studies were small-sample RCTs. Second, with regard to randomization, allocation concealment, and blinding, most of the included studies had a high/unclear risk of bias. In general, the completeness of the study

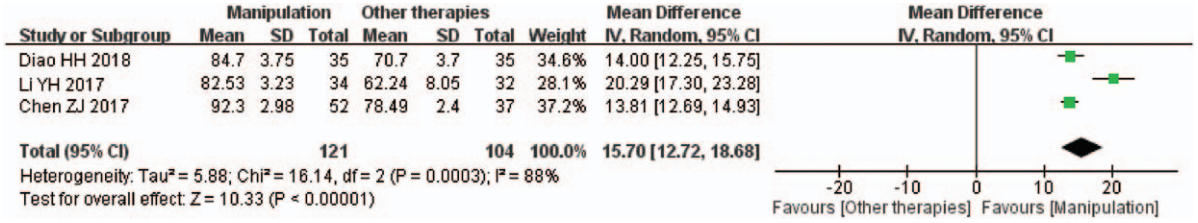

Figure 8. Meta-analysis of treatment effect of manipulation group versus other therapy group on AOFAS ankle – hindfoot score. AOFAS = American Orthopaedic Foot and Ankle Society.

information was inadequate, causing a high number of studies to have an unclear risk of bias. The most important shortcoming was that patients were not blinded to the intervention condition in any of the studies. It is certainly hard to effectively blind patients in this kind of clinical trials. Blinding of patients might partly be established by including naive patients (no previous experience with the intervention under study) or by using a sham therapy.[31] Additionally, blinding of the therapists and outcome assessors should also be attempted in such studies to reduce the performance and assessment bias. Third, most outcomes seemed to have high heterogeneity. However, the sensitivity analysis revealed no significant change in heterogeneity after literature exclusion, changing to a random-effects model and subgroup analysis. The follow-up time of the same outcome in each study was also inconsistent. Additionally, the trial durations varied to some extent. All of these aspects might have contributed to the high heterogeneity among the trials. These significant methodological defects and high heterogeneity of the included studies greatly decreased the quality of evidence. The evidence obtained from this meta-analysis was of low quality and should be cautiously recommended.

5. Conclusions

The current evidence indicates that compared with other conservative treatments, traditional Chinese manipulation has a positive effect on ankle sprains, leading to improved ankle function and an increased total effective rate. Additionally, RTPM achieved better effects than other schools of manipulation in terms of alleviating pain intensity. However, because of the overall high or unclear risk of bias of the included studies, the current evidence is of low quality and very limited. Therefore, this body of evidence cannot provide a robust conclusion concerning the efficacy and safety of traditional Chinese manipulation for treating ankle sprains. Large-scale, long-term, and high-quality RCTs with rigorous methodological input are urgently needed to verify the stability of these findings.

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