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Fire needle therapy for moderate-severe acne: A PRISMA systematic review and meta-analysis of randomized controlled trials



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ABSTRACT

Background: Moderate-severe acne treatment involves the use of isotretinoin and antibiotics as first-line therapeutics; however, these drugs have serious side effects. Fire needle therapy, which is widely used in China, has shown good clinical efficacy for treating moderate-severe acne; moreover, it has fewer side effects, hence, it can be used as a primary treatment (as an alternative to pharmaceutical medications) or in combination with pharmaceutical medications for clinical treatment. However, current clinical evidence regarding its use has not been comprehensively evaluated.

Methods: We systematically searched several databases, including PubMed, Embase, Cochrane Central Register of Controlled Trials, China Network Knowledge Infrastructure (CNKI), China Biomedical Literature Service System (SinoMed), China Science and Technology Journal Database (CQVIP), and Wanfang Data Knowledge Service Platform, from their inception time to November 22, 2018. Randomized controlled trials conducted to compare the efficacy, acne recurrence, and adverse events associated with fire needle therapy alone, or in combination with Chinese herbs or conventional pharmaceutical medication, to those of pharmaceutical treatment were selected. RevMan 5.3 software was used to calculate risk ratio (RR) with a 95% confidence interval (CI).

Results: Ten trials, with a total of 904 participants, met the inclusion criteria. Meta-analyses showed that fire needle treatment with clindamycin or oral isotretinoin treatment had advantages over pharmaceutical medications alone in the treatment of moderate-severe acne [RR = 2.18, 95% CI (1.19, 3.99), $P = 0.03$ random model; $I^2 = 72\%$]. Moreover, the use of fire needle therapy alone in the treatment of moderate-severe acne had a better effect than pharmaceutical medications, regardless of the type of pharmaceutical medication used [RR = 2.32, 95% CI (1.77, 3.03), $P < 0.00001$ random model; $I^2 = 59\%$]. In terms of recurrence rate, there was no significant difference between fire needle and pharmaceutical medication groups [RR = 0.78, 95% CI (0.54, 1.14), $P = 0.20$ fixed-effect model; $I^2 = 0\%$]. In addition, the use of fire needles was associated with few adverse reactions, such as burning and tingling; furthermore, the adverse reactions were transient.

Conclusion: Fire needle therapy alone or combined with other treatments is effective for moderate-severe acne. However, further large-scale, rigorously designed trials are needed to confirm these findings.

Abbreviations: CI, confidence interval; RCT, randomized controlled trials; RR, risk ratios; MDs, means differences; TCM, traditional Chinese medicine

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1. Background

Acne is a multifactorial inflammatory disease that affects the sebaceous glands and hair follicles of the skin. It is a common skin disease affecting approximately 85% of the teenagers,¹ however, it can occur in most age groups. Its persistence into adulthood is less common; for instance, the prevalence of acne is 12% in women and 3% in men.² Although acne is not fatal, there is often significant physical and psychological morbidity in the form of permanent scarring, poor self-image, depression, and anxiety. The direct cost of the disease is estimated to exceed \$3 billion per year.³

As per the “Guidelines of care for the management of acne vulgaris”,⁴ the recommended treatment of moderate and severe acne involves oral antibiotics and isotretinoin. The predominant antibiotic prescribed is minocycline, a form of tetracycline. However, long-term administration of minocycline at higher doses can cause adverse reactions such as tinnitus, dizziness, and pigmentation of the skin, mucous membranes, and teeth; adverse effects also include the development of autoimmune diseases and hypersensitivity reactions such as drug reaction with eosinophilia and systemic symptoms, known as the DRESS syndrome. The most common side effects of isotretinoin involve the mucocutaneous, musculoskeletal, and ophthalmic systems, and mimic the symptoms of hypervitaminosis; furthermore, the teratogenic effects of isotretinoin and the risk of retinoic acid embryo disease are well known.⁵

Given these undesired side effects, current recommended treatments for moderate-severe acne need to be augmented, and alternative treatment options should be considered. Acupuncture, a characteristic therapy in traditional Chinese medicine (TCM), has been used to treat human diseases for more than 2000 years.⁶ The history of acupuncture therapy indicates that physicians have accumulated a vast amount of knowledge and experience in treating skin diseases with this approach. Fire needle therapy is a form of acupuncture therapy that exhibits the advantages of both conventional acupuncture and moxibustion, due to needle stimulation and thermal stimulation, as well as advantages concerning safety, cost, and effectiveness (Additional file 1: National standards of the People's Republic of China- Fire acupuncture).

Fire needle therapy is widely used for the clinical treatment of moderate-severe acne, especially for cystic cases. Some clinical studies have reported the efficacy of fire needle therapy for acne; however, to the best of our knowledge, no systematic review has evaluated the clinical evidence regarding the efficacy of fire needle therapy for

treating moderate-severe acne. Therefore, we conducted a systematic review and meta-analysis to evaluate the effectiveness of fire needle therapy for moderate-severe acne.

2. Methods

The review protocol was registered in the PROSPERO database prior to initiating the review process (CRD42018102402). This study was performed according to the Cochrane Handbook for Systematic Reviews of Interventions⁷ and is presented in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) guidelines (Additional file 2: PRISMA 2009 Checklist).⁸

We conducted a systematic review and meta-analysis of randomized controlled trials (RCTs) that evaluated the use of fire needle therapy for the treatment of moderate-severe acne. We searched PubMed, the Cochrane Central Register of Controlled Trials, Embase, CNKI (1979–2018), SinoMed (1978–2018), CQVIP (2000–2018), and Wanfang Data Knowledge Service Platform (1985–2018) for relevant RCTs from the time of inception of each database to November 22, 2018. The search terms included “fire needle” and “acne.” Unpublished postgraduate theses in Chinese databases were also searched (Fig. 1). RCTs wherein interventions for the treatment of moderate-severe acne included the use of fire needles alone, or in combination with Chinese herbs or conventional pharmaceutical medications were included in the review; findings from these trials were compared with those of placebo, or conventional pharmaceutical medications. Trials were excluded if any of the following factors were identified: (1) insufficient information concerning evaluation rates, (2) lack of fire needle treatment, (3) fire needle therapy used in the control group, or (4) animal trials. The Pillsbury grading method was used to determine acne classifications. Responses to interventions were classified as cured, markedly effective, effective, and ineffective. An intervention response was classified as cured if at least 95% of lesions faded away, leaving only mild pigmentation and scarring. A response was defined as markedly effective if at least 60% of the lesions faded away and acne severity was alleviated. If 20%–59% of lesions faded away and the lesion severity was reduced, the intervention was defined as effective. An intervention response was deemed ineffective if < 20% of lesions faded away or if the condition worsened. To calculate the primary outcome of acne skin lesion recovery rate, the sum of the cured responses and markedly effective responses were divided by the total cases between weeks 2–8. The

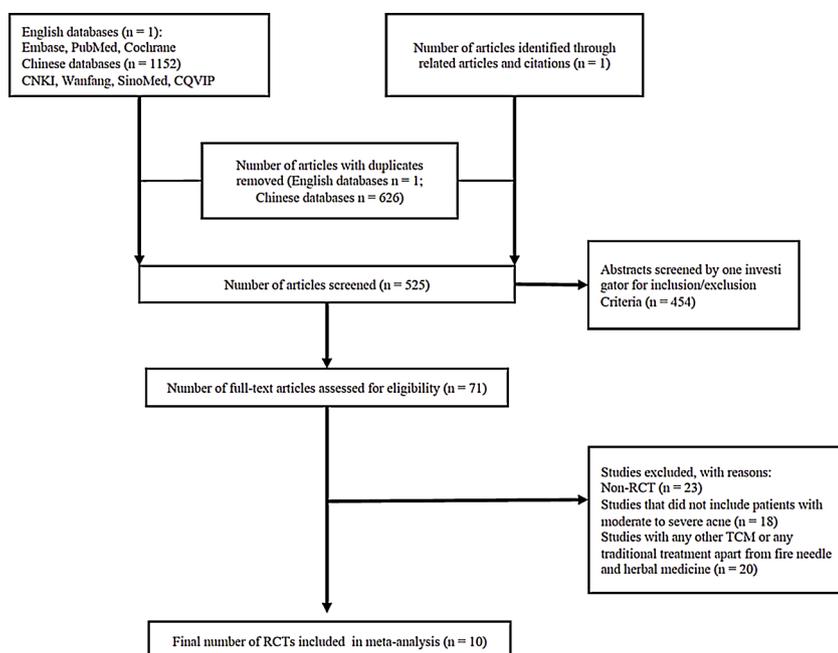


Fig. 1. Summary of the literature identification and selection process.

CNKI, the Chinese National Knowledge Infrastructure database; Wanfang, the Wanfang Data Knowledge Service Platform; SinoMed, the China Biomedical Literature Service System; CQVIP, the China Science and Technology Journal Database; RCT, randomized control trials; TCM, traditional Chinese medicine.

Table 1
Characteristics of 10 Included Trials.

Study	Intervention	Control	Duration of treatment (weeks)			Outcome	Adverse events
			I	C	Mean (SD)		
Guo 2018	Fire needle twice a week (Ashi points); clindamycin tablets, 0.25 g/ BID	Clindamycin tablets, 0.25 g/ BID	2		Total recovery rate	Yes (3 patients in the intervention group reported mild nausea and diarrhea; 2 patients in the control group reported mild nausea and diarrhea)	
Huang 2004	Fire needle once a week (Ashi points)	Tretinoin cream 0.025%, applied to lesions BID	4		Total recovery rate	Yes (All patients in the intervention group reported mild erythema and edema lasting a few hours)	
Tao 2015	Fire needle twice a week (Ashi points)	Isotretinoin soft capsules; BW > 50 kg, 30 mg/QD, BW < 50 kg, 20 mg/QD	8		Total recovery rate; Recurrence rate	Yes (20 patients in the control group reported dry lips, 2 patients reported cheilitis, 5 patients reported dry skin scaling, and itching, and 1 patient reported abdominal discomfort)	
Liu 2006	Fire needle once every 5 d (Back Shu points, Ashi points)	Oral Azithromycin 500 mg/QD	2		Total recovery rate; Recurrence rate	Yes (2 patients in the control group reported nausea and abdominal discomfort, 1 patient reported diarrhea, and 1 patient reported mild elevation of ALT)	
Fan 2016	Fire needle once every 5 d (Ashi points)	Tazarotene cream once every morning, clindamycin gel once every evening	2.9		Total recovery rate	NR	
Zheng 2011	Fire needle once every 4 d (Ashi points)	Tazarotene cream once every morning, clindamycin gel once every evening	2.9		Total recovery rate; Skin-lesion counts; Recurrence rate	NR	
Huang 2006	Fire needle once every 4 d (Ashi points, Feishu and Pishu points)	Clindamycin gel BID, azithromycin Capsules 0.5 g BID	3		Total recovery rate; Skin-lesion counts	Yes (18 patients in the control group reported slight abdominal pain, dizziness, dry mouth, nausea, etc.)	
Jiang 2014	Fire needle once every 5 d (Ashi points)	Doxycycline tablets 100 mg/QD, adapalene gel once every evening	2.9		Total recovery rate; Skin-lesion counts; Recurrence rate	Yes (All patients in the intervention group reported temporary minor bleeding and edema, 13 patients in the control group reported local itching, and 7 patients in the control group reported local tingling)	
Zhang 2016	Fire needle 1–2 times a week (Ashi points); isotretinoin soft capsules, 0.25 mg/(kg·d)	Isotretinoin soft capsules, 0.25 mg/(kg·d)	4		Total recovery rate	NR	
Jiang 2015	Fire needle once a week (Ashi points); Isotretinoin soft capsules, 0.5 mg/(kg·d) (Dose increased as per body's response)	Isotretinoin soft capsules, 0.5 mg/(kg·d) (Dose increased as per body's response)	4		Total recovery rate; Skin-lesion counts; Recurrence rate	NR	

Study	Sample size (M/F)		Sample age (years)		Male		Disease duration (months)			Baseline data comparable		Incomplete outcome data		Selective reporting
	I	C	I	C	I	n%	I	Mean (SD)	C	Mean (SD)	I	C	I	
Guo 2018	40/25	35/25	13–45		12–43	60%	60.00			36.00	Yes		No	No
Huang 2004	45/26	57/36	23.60 (8.20)			63%	32.4 (25.2)			31.2 (26.4)	Yes		No	No
Tao 2015	12/18	14/16	22.00 (3.48)		22.10 (3.04)	43%	NR				Yes		No	No
Liu 2006	23/19	16/15	range: 12.00–45.00			53%	NR				Yes		No	No
Fan 2016	15/10	11/15	22.24 (4.81)		22.32 (4.53)	51%	NR				Yes		No	No
Zheng 2011	24/16	16/22	21.90 (3.61)		23.23 (4.19)	51%	18.40 (11.41)			14.84 (10.82)	Yes		No	No
Huang 2006	72/32	62/43	23.52 (5.38)		24.94 (6.26)	64%	49.92(34.58)			51.27 (54.13)	Yes		No	No
Jiang 2014	16/13	14/16	22.00 (4.00)		24.00 (4.00)	63%	30.00 (10.80)			33.60 (10.8)	Yes		1/30 missing from I group	No
Zhang 2016	15/19	16/17	22.42 (4.47)		2.48 (2.54)	54%	0.62 (0.63)			0.67 (0.56)	Yes		1/34 missing from C group	No

(continued on next page)

Table 1 (continued)

Study	Sample size (M/F)		Sample age (years)		Male n%	Disease duration (months)		Baseline data comparable		Incomplete outcome data	Selective reporting
	I	C	I	C		I	C	Yes	No		
Jiang 2015	18/10	18/11	22.00 (4.00)	22.00 (4.00)	50%	25.68 (11.40)	30.84 (9.96)	Yes	1/28 missing from C group	No	No

I: Intervention group; C: Control group; NR: Not reported; ALT: Alanine aminotransferase; BW: Body weight; NR: Not report; BID: twice daily; Ashi points: refer to nodules, pustules, or cysts in the area of the lesion.

secondary outcomes included recurrence rates (> 2 months after treatment), skin-lesion scoring and adverse events.

Two authors (Meng Xing and Xiaoning Yan) independently screened the search results and selected the relevant RCTs according to the aforementioned inclusion criteria. One author (Meng Xing) extracted the data from the included trials and assessed the risk of bias of the included RCTs using the Cochrane collaboration tool while the other author (Xiaoning Yan) verified the extracted data and evaluated the risk of bias. Discrepancies were solved by consulting a third author (Xin Li).

Risk of bias for each study was calculated in accordance with the Cochrane Handbook for Systematic Reviews of Intervention.⁶ Six criteria were applied as follows: (1) selection bias (random-sequence generation and allocation concealment), (2) performance bias (blinding of participants and personnel), (3) detection bias (blinding of outcome assessment), (4) attrition bias (incomplete outcome data), (5) reporting bias (selective reporting), and (6) other bias. There were three potential bias judgments: (1) low risk, (2) high risk, and (3) unclear risk. A study was rated as having an unclear risk when insufficient details were reported regarding the methods and outcome, the risk of bias was unknown, a metric was not relevant to the study, particularly for assessing blinding and incomplete outcome data, or when the outcome assessed by the metric had not been measured in the study.

Dichotomous data were expressed as risk ratios (RR) with a 95% confidence interval (CI). Continuous data were expressed as mean differences (MDs) with 95% CIs. Statistical heterogeneity was tested for the ten trials. RevMan 5.3 software (Cochrane Collaboration) was used for data analyses. Meta-analyses were performed if the trials had acceptable homogeneity ($I^2 < 85%$) concerning the study design, participants, interventions, controls, and outcome measures. Fixed-effect models ($I^2 < 25%$) were used for homogeneous studies and random-effects methods were used prior to fixed-effect models in studies with substantial heterogeneity ($25% < I^2 < 85%$).⁷ To investigate the possible reasons for heterogeneity, we performed subgroup analysis and meta-regression using pre-specified variables and random-effects meta-analysis. Pre-specified sources of heterogeneity in meta-regression included treatment points, treatment intervals, and duration of treatment. Meta-regression was performed using STATA version 14.0 (STATA Corp, College Station, TX, USA).

3. Results

3.1. Characteristics of included studies

After the primary search using eight databases, 1152 citations were identified. We excluded 626 studies because they did not meet the inclusion criteria. Full-text articles of 71 studies were retrieved. Finally, 10 studies with a total of 904 participants were included in this systematic review and meta-analysis (Fig. 1). Characteristics of the included trials are listed in Table 1. Among the included trials, three studies^{9,10,11} were unpublished master's program theses.

The graph depicting the risk of bias is shown in Fig. 2. The methodological quality of all included trials was poor. Although all the analyzed trials reported randomization, only six adequately described the randomization method: two with a random number table,^{12,13} two using a computerized method,^{8,10} and one using a lottery method.¹⁴ Moreover, only one of the studies reported information such as allocation concealment or blinding of the participants and study personnel.¹¹ Three of the studies reported patient drop out, but did not describe the specific reason.^{12,13,15} All the trials adequately addressed selective reporting bias. We found no other biases in these trials; however, considering their poor methodological quality, we determined that an unclear risk of bias should be noted for all the included trials.

Zheng 2011	Zhang 2016	Tao 2015	Liu 2006	Jiang 2015	Jiang 2014	Huang 2006	Huang 2004	Guo 2018	Fan 2016	
+	?	+	+	+	+	?	?	?	+	Random sequence generation (selection bias)
+	?	?	?	?	?	?	?	?	?	Allocation concealment (selection bias)
+	?	?	?	?	?	?	?	?	?	Blinding of participants and personnel (performance bias)
?	?	?	?	?	?	?	?	?	?	Blinding of outcome assessment (detection bias)
+	?	+	+	?	?	+	+	+	+	Incomplete outcome data (attrition bias)
+	+	+	+	+	+	+	+	+	+	Selective reporting (reporting bias)
?	?	?	?	?	?	?	?	?	?	Other bias

Fig. 2. Risk of bias graph.

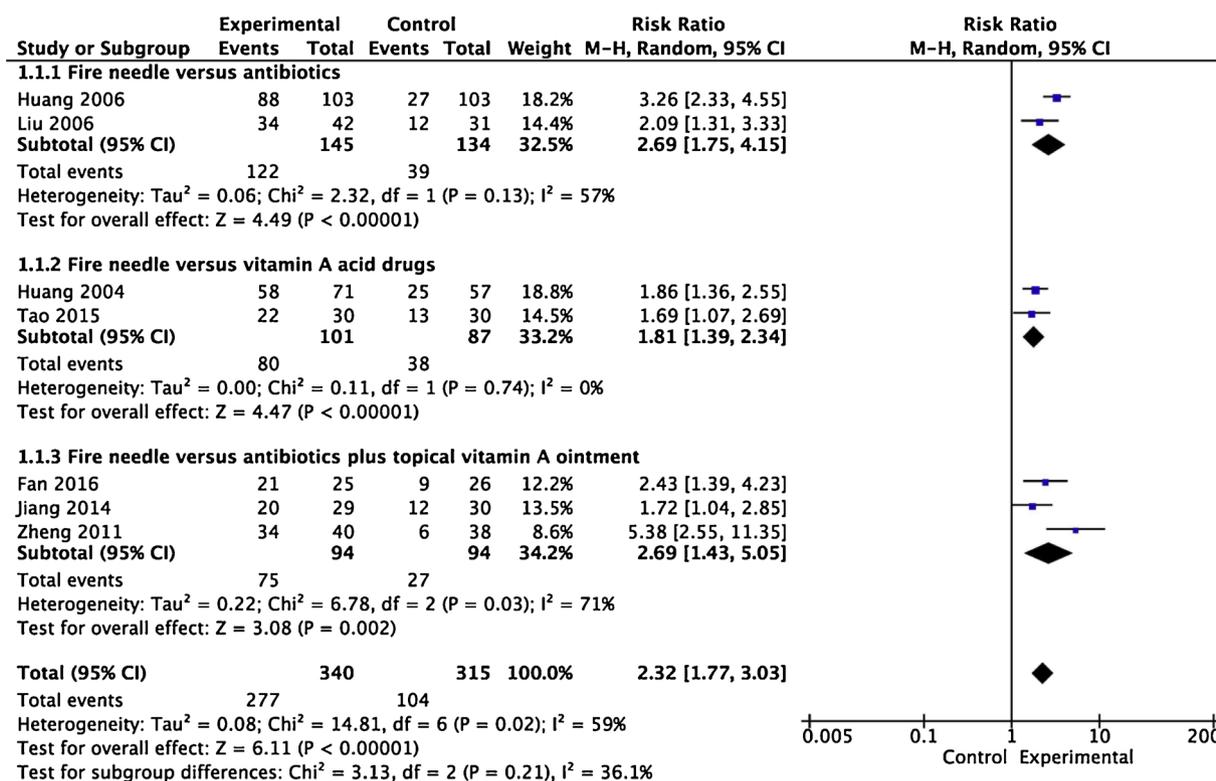


Fig. 3. Meta-analysis of the recovery rate with fire needle treatment versus pharmaceutical medication.

3.2. Meta-analysis outcomes

3.2.1. Primary outcomes

3.2.1.1. Effect of fire needle therapy versus pharmaceutical medications. Seven studies^{9–12,14,16,17} compared fire needle therapy with pharmaceutical medications. There was a statistically significant difference between the number of patients cured with fire needle therapy and pharmaceutical medications [RR = 2.32, 95% CI (1.77, 3.03), P < 0.00001 random model; I² = 59%], demonstrating that fire needle therapy had a superior curative effect compared to the control group (Fig. 3).

Two studies^{11,16} found that fire needles have more therapeutic advantages for moderate-severe acne than Vitamin A acid [RR = 2.69, 95% CI (1.43, 5.05), P < 0.00001 random model; I² = 0%]; one of the two studies compared fire needles with tretinoin cream [RR = 1.86, 95% CI (1.36, 2.55), P = 0.001 random model; I² = 59%] and the other compared fire needles with isotretinoin [RR = 1.69, 95% CI (1.07,

2.69), P = 0.03] (Fig. 3). Also, three studies^{9,12,14} compared the recovery rate for fire needle treatment to the recovery rate with antibiotics plus topical vitamin A ointment [RR = 2.69, 95% CI (1.43, 5.05), P = 0.002 random model; I² = 71%]. The results indicated that the recovery rate with fire needle therapy was significantly higher than with antibiotics plus topical vitamin A ointment (Fig. 3).

Meta-regression was also performed using pre-specified variables to assess the possible sources of study heterogeneity, which reported a significantly higher strength of treatment points (OR 0.312, 95% CI -0.724–0.884 for studies with Ashi points vs OR 0.288, 95% CI -0.460–1.022 for studies with Ashi points combined with other points, P = 0.009 for comparison) (Table 2).

3.2.1.2. Effect of fire needle therapy plus pharmaceutical medication versus pharmaceutical medication alone. Three studies^{13,15,18} compared fire needle treatment combined with pharmaceutical medication with pharmaceutical medication alone. There was a significant difference

Table 2
Potential pre-specified sources of heterogeneity explored among studies reporting recovery rate of patients with psoriasis compared with controls.

Pre-specified Source of Heterogeneity	No. of Studies	Random-Effects Meta-Regression (95% CI)	P
Treatment points			0.009
Ashi points	5	0.312(-0.724 -0.884)	
Ashi points combined with other points	2	0.288(-0.460 -1.022)	
Treatment intervals			0.128
Twice a week	1	0.527(-1.773 -1.581)	
Once a week	1	0.393(-1.346 -1.159)	
Once every 4 d	2	0.376(-0.532 -1.876)	
Once every 5 d	3	0.393(-1.159-1.346)	
Duration of treatment			0.221
8 weeks	1	0.546(-1.603 -1.876)	
4 weeks	1	0.564(-1.892 -1.698)	
3 weeks	1	0.574(-1.596 -2.057)	
2 weeks	1	0.594(-1.458 -2.345)	
2.9 weeks	3	0.579(-1.753 -2.158)	

CI: confidence interval.

in the recovery rates between fire needle treatment with pharmaceutical medication and pharmaceutical medication alone [RR = 2.18, 95% CI (1.19, 3.99), $P = 0.03$ random model; $I^2 = 72\%$], demonstrating that fire needle treatment with pharmaceutical medication was superior to pharmaceutical medication alone (Fig. 4).

Based on the different treatment methods, the intervention groups were divided into the fire needle plus clindamycin¹⁸ and fire needle plus oral isotretinoin groups^{13,15} for analysis. Studies of the fire needle plus clindamycin group showed superior curative effects compared to the control group and the difference was statistically significant ($P < 0.01$) (Fig. 4). A comparison of the clinical efficacy of fire needle treatment with oral isotretinoin versus oral isotretinoin alone showed that oral isotretinoin in conjunction with fire needle treatment was more advantageous than oral isotretinoin alone ($P < 0.05$). However, when we combined the data from the two trials, the results showed that there was no statistically significant difference between the efficacy of fire needle combined with oral isotretinoin and oral isotretinoin alone [RR=1.85, 95% CI (1.01, 3.41), $P = 0.05$, random model; $I^2 = 74\%$] (Fig. 4).

3.2.2. Secondary outcomes

3.2.2.1. Skin-lesion scoring. Four studies^{9,12,13,17} used a skin-lesion scoring system and showed that the fire needle therapy was superior

to pharmaceutical medications for reducing the skin-lesion area [weighted mean difference = -2.70, 95% CI (-4.50, -0.89), $P = 0.002$ random model; $I^2 = 79\%$] (Fig. 5).

3.2.2.2. Recurrence rate. Five studies^{9–13} analyzed the recurrence rates. The results showed that there was no statistically significant difference between the recurrence rates of moderate-severe acne treated with fire needle therapy and that of moderate-severe acne treated with pharmaceutical medications [RR = 0.78, 95% CI (0.54, 1.14), $P = 0.20$ fixed-effect model; $I^2 = 0\%$] (Fig. 6).

3.2.2.3. Adverse events. A total of six^{10–12,16–18} studies demonstrated that fire needle therapy had a good safety and tolerability profile. Fire needles can cause mild burning and itching during treatment, as well as slight redness and swelling of the skin, but these side effects disappear within thirty minutes to an hour. Only one study¹⁶ classified these phenomena as adverse reactions. One study reported adverse reactions for clindamycin,¹⁸ the main symptoms were mild nausea and diarrhea. One study reported the symptoms of itching and tingling with topical adapalene gel.¹² The main adverse reactions seen with oral isotretinoin^{11,17} were dry mouth and abnormal skin sensation. One study¹⁰ mentioned liver function abnormalities.

4. Discussion

Based on a systematic evaluation of the ten studies, fire needle therapy used alone or combined with pharmaceutical medication was more effective than pharmaceutical medication alone in improving the rate of treatment in patients with moderate-severe acne. The different treatment points may have specific effects on the efficacy of fire needle therapy. However, no difference was observed in recurrence rates between the use of fire needle therapy and pharmaceutical medications. Fire needle therapy is not considered to be associated with adverse reactions. The only adverse effects of treatment are mild burning, stinging, and itching during treatment, and slight redness and swelling of the skin, but these effects disappear within thirty minutes to an hour; thus, the effects are transient and are not regarded as severe. Therefore, fire needle therapy is a viable treatment option for the clinical treatment of moderate-severe acne.

Acne is a multifactorial inflammatory disease. Studies have found that fire needle therapy has an anti-inflammatory effect and promotes the repair of inflammatory tissues. According to a recent study, using a fire needle to stimulate the site of the disease and the reflection points can reduce the release of inflammatory factors,¹⁹ accelerating

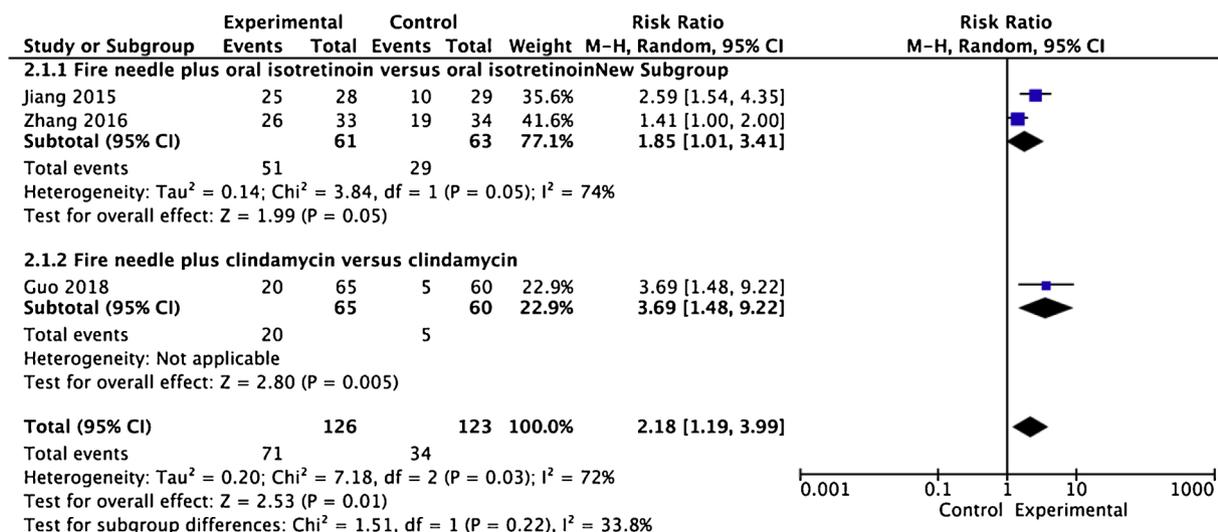


Fig. 4. Meta-analysis of the recovery rate of fire needle treatment plus pharmaceutical medication versus pharmaceutical medication alone.

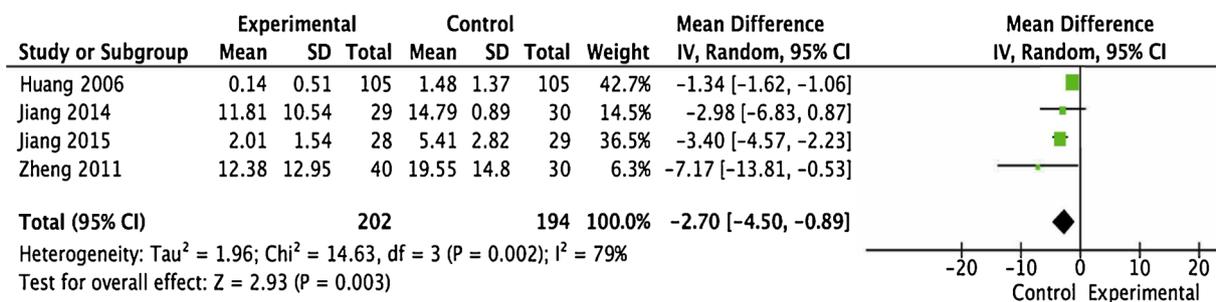


Fig. 5. Meta-analysis of skin-lesion scoring after treatment with fire needle versus pharmaceutical medication.

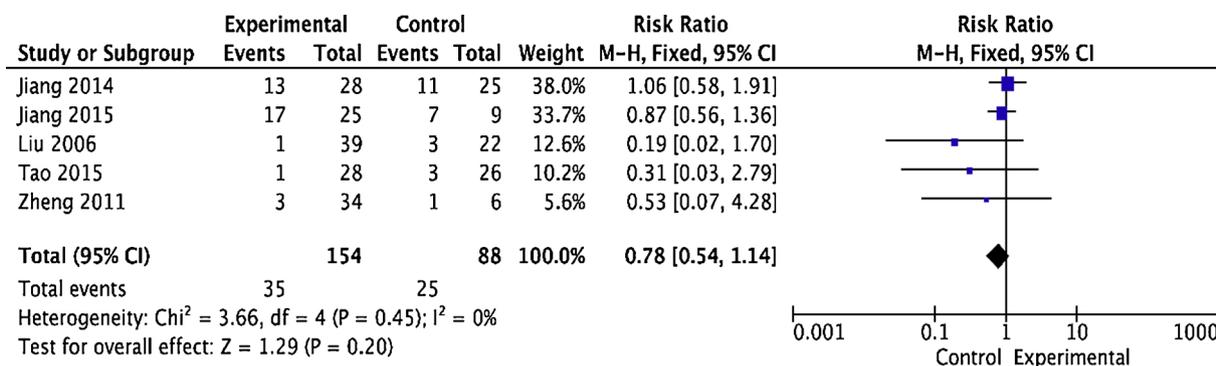


Fig. 6. Meta-analysis of the recurrence rate of moderate-severe acne treated with fire needle therapy versus pharmaceutical medication.

circulation, promoting metabolism, and restoring damaged tissues,²⁰ which in turn can eliminate or attenuate pathological changes such as edema, hyperemia, exudation, adhesion, calcification, contractures, and ischemia.

In China, the use of fire needles for acne is a part of the Chinese Acne Treatment Guidelines.²¹ In clinical settings, fire needle therapy is used for skin-lesions such as nodules, cysts, and pustules. Practitioners of TCM believe that fire needle therapy can promote qi (vital energy) and blood circulation. Encouraging the generation of healthy qi is important because a healthy qi eliminates harmful conditions including sepsis. Moreover, with the functions of guiding and diverging qi, pathogenic-fire, pathogenic heat, and pathogenic toxins can be dispersed improving the circulation of qi and blood, eliminating pathogenic factors, and detoxifying the body. Wind, cold, summer-heat, damp, dryness, and fire are the six climatic factors that correspond to normal seasonal changes. However, if and when the six-qi become abnormal or excessive, they may become the six excesses, the pathogenic factors that cause diseases. The method can be used to open the meridians to the outside by burning the acupuncture points of the human body, so that visible pathogenic factors such as pus, blood stasis, and dampness, and invisible pathogenic factors such as pathogenic-wind, pathogenic-cold, pathogenic-damp, pathogenic-heat, and pathogenic-fire, are directly discharged from the pinholes.²²

While this study elucidated fire needle therapy as a suitable treatment option for moderate-severe acne, there are a few limitations to this meta-analysis such as the inclusion of published literature and unpublished master’s program theses, the small sample sizes of the trials, and the high risk of bias. In most studies of this review, insufficient randomization and lack of blinding methods led to potential performance bias and detection bias. Also, in the fire needle intervention group, pharmaceutical medications were also used, either orally or topically. Additionally, across studies, the use of pharmaceutical medication was neither guideline-based nor consistent in dosage (Table 1). Moreover, patients had different levels of acne; some had abscesses as the clinical presentation and some had cysts as the clinical presentation. Further, population differences (environmental or diet differences) and the subjective nature of the efficacy rating scale may all have

contributed to the heterogeneity in the different studies. However, more importantly, studies regarding the use of fire needles for the treatment of moderate and severe acne were lacking in terms of meticulous design. Also, the quality of the methodology of the studies included in this review was generally poor, indicating a high risk of bias.

This study confirmed that the clinical efficacy of fire needle treatment is worthy of recognition. We believe that this ancient traditional therapy may provide new ideas for the treatment strategy for moderate to severe acne; however, there is a lack of high quality and large-scale research to systematically confirm the effectiveness of the treatment for acne. To improve the quality of future studies, on the one hand, in addition to the participation of dermatology professionals, researchers also need to involve professionals for relevant statistics, clinical epidemiology, evidence-based medicine and other aspects. This can reduce the risk of bias in the design and implementation process by combining multidisciplinary advantages. On the other hand, we recommend that researchers should carefully study the consort statement and thoroughly implement the guidelines in the design, implementation, and reporting of the experiments. Furthermore, systematic reviews and meta-analyses should adhere to the PRISMA guidelines to ensure clarity and completeness of reporting. In future, relevant clinical research will be carried out to provide more advanced clinical evidence in terms of fire acupuncture treatment of moderate-severe acne, so that this simple, safe, and effective treatment method is promoted worldwide.

5. Conclusions

Although the evidence for the effectiveness of fire needle therapy for the treatment of moderate-severe acne is encouraging, it is not conclusive due to the low methodological quality of the available RCTs. Therefore, more high-quality RCTs, with low risk of bias and adequate sample sizes are required to demonstrate its effectiveness.

Author contributions

MX, XY, XS, BZ, SW, MZ, LK, LL, YL, XL, and BL, had full access to all the study data and take responsibility for its integrity and the

accuracy of the analysis. MX, XY, and XL were responsible for the study concept and design. MX and YL were responsible for data acquisition, and XS and MX were responsible for data extraction. The assessment of bias risk was performed by XY and LK; data analysis and interpretation were performed by LL and BZ. The paper was drafted by XL and BL, while MX and XY provided critical review of the paper for important intellectual content. XL performed statistical analyses and BL supervised the study. MX, XY, XS, MZ, BZ, SW, MZ, XL, and BL contributed to the revision of the manuscript. All authors have read and approved the final manuscript.

Ethics approval and consent to participate

This study was based on previously published studies; therefore, ethical approval and patient consent are not relevant.

Consent for publication

Not applicable.

Availability of data and materials

Ethical approval is not required in this study because the data used include peer-reviewed publications that do not comprise any information that could identify subjects.

Competing interests

The authors declare that there are no conflicts of interest regarding the publication of this paper.

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Appendix A. Supplementary data

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