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Acupuncture therapy for the treatment of stable angina pectoris: An updated meta-analysis of randomized controlled trials

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ABSTRACT

Background and purpose: Stable angina pectoris is a common symptom imperiling patients' life quality. The purpose of this meta-analysis is to assess the effectiveness of acupuncture alone or acupuncture plus medicine for the treatment of stable angina pectoris.

Methods: Seven databases were searched ranging from 1959 to February 2018. Quantitative analysis of randomized controlled trials (RCTs) was performed by RevMan 5.3 software and STATA 12.0 program, and Cochrane criteria for risk-of-bias was used to assess the methodological quality of the trials.

Results: A total of 12 RCTs involving 974 patients were enrolled in this study. The pooled results showed that both acupuncture group (RR: 0.35, $P < 0.00001$; RR: 0.49, $P < 0.00001$) and acupuncture plus medicine group (RR: 0.26, $P < 0.00001$; RR: 0.52, $P = 0.03$) were associated with **a** higher percentage of improved anginal symptoms as well as electrocardiographic (ECG) results compared to medicine group. The acupuncture plus medicine group also had a lower intake rate of nitroglycerin than medicine group (Non-event RR: 0.79, $P = 0.03$). However, there was no significant difference in the reduction or discontinuation of nitroglycerin intake between acupuncture group and medicine group. No acupuncture-related adverse effects were observed or reported in the included trials.

Conclusion: Acupuncture therapy may improve anginal symptoms and ECG results in patients with stable angina pectoris, and can serve as an adjunctive treatment for this condition.

1. Introduction

Acupuncture is one of the most important components of traditional Chinese medicine (TCM), that involves the insertion of fine needles at defined points of the body, followed by the manual or electrical stimulation of those points. So far, acupuncture has been widely used for health services in China or elsewhere for over 2000 years, and proved to be effective for various health problems, such as stable angina pectoris (SAP) [1].

SAP is a common cardiovascular problem manifested by clinical symptoms of left anterior chest pain or discomfort of adjacent areas due to myocardial ischemia [2,3]. It affects the quality of life of millions of patients [2–4], and induces billions of economic loss [5] in the United States yearly. In China, SAP has also become a severe medicine and social problem with an incidence of 2.4% in men and 3.2% in women [6]. A proportion of patients with SAP in China receive acupuncture and other TCM therapy as an adjunctive method for the prevention and treatment of angina pectoris [6], even though the efficacy and safety of acupuncture still remain controversial to date.

Acupuncture has been proven to be beneficial in cases of cerebral haemorrhage, cerebral infarction and chronic pain in the early systematic review and meta-analysis [7]. The American College of Cardiology and American Heart Association (ACC/AHA) guideline [8] recommends antiplatelet drugs, statins, β receptor blockers and nitrates as anti-ischemic treatment for SAP, but some side effects such as haemorrhage, liver dysfunction, fatigue, headaches, as well as those due to statin intake could occur [9]. Despite optimal medicine therapy, the recurrence of angina pectoris is not a rare phenomenon. Therefore, it is essential to explore some additional methods for treating SAP.

Acupuncture has been reported to treat cardiovascular diseases, including heart failure [10]and angina [11]. However, its effectiveness in relieving symptoms or improving the prognosis of patients with SAP is not consistent [12–14]. The benefit of this technique is yet to be determined. Whether the combination of acupuncture and medicine is

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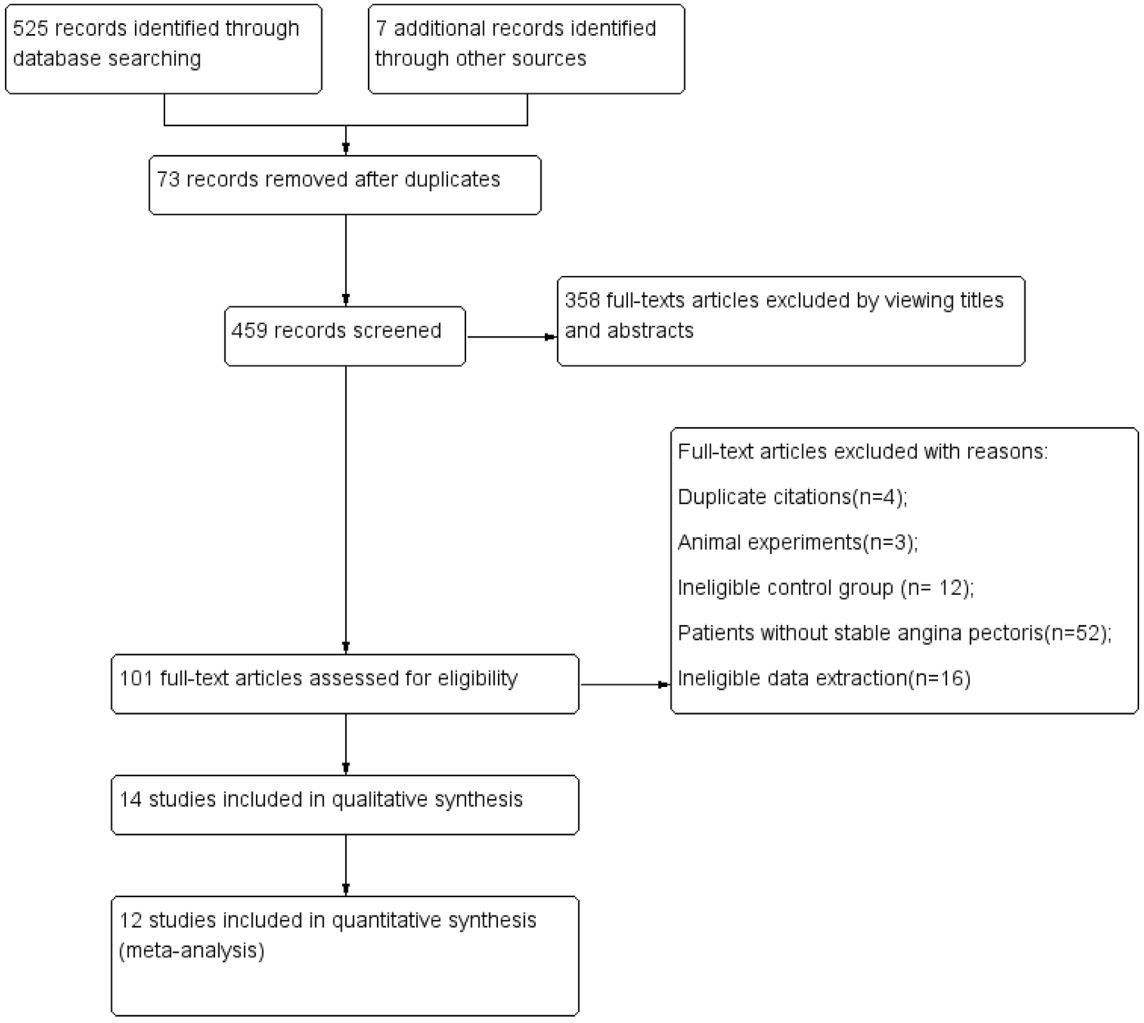

Fig. 1. Literature search and screening process.

more effective for SAP patients than medicine alone is still unclear. The purpose of this meta-analysis is to assess the effectiveness of acupuncture alone or acupuncture plus medicine in patients with SAP based on randomized controlled trials (RCTs).

2. Methods

2.1. Eligibility and search strategies

Seven databases including PubMed (1959–2018), EMBASE (1980–2018), Cochrane Central Register of Controlled Trials (CENTRAL, 1996–2018), China National Knowledge Infrastructure (CNKI, 1979–2018), Chinese Scientific Journal Database (VIP, 1989–2018), Wan Fang Database (1998–2018) and Chinese Biomedicine Literature Database (CBM,1978–2018) were searched up to February 2018. The Medical Subject Headings (MeSH) terms used for searching were as follows: ((coronary artery disease) OR (coronary heart disease) OR (coronary atherosclerotic heart disease) OR (coronary atherosclerotic cardiopathy) OR (stable angina pectoris) OR (angina pectoris) OR angina OR (precordial pain) OR cardiodyne OR (chest bi) OR (chest bi syndrome) OR (thoracic obstruction) OR (chest stuffiness)) AND (acupuncture OR electro-acupuncture OR (mild moxibustion) OR (thermal moxibustion) OR (warm acupuncture) OR moxibustion) AND ((randomized controlled trial) OR (controlled clinical trial) OR (clinical trial) OR randomized OR randomly) AND humans. The corresponding Chinese terms were used in the Chinese library. A manual search was performed to identify any potentially relevant studies of reference lists.

2.2. Study selection and data extraction

Potentially relevant trials were included in the meta-analysis if they met the following criteria: 1) based on RCTs; 2) RCTs to compare groups (A: acupuncture versus medicine and/or B: acupuncture plus medicine versus medicine alone); 3) clinical outcomes: ①the number of patients with ineffectiveness of angina relief; ②the number of patients with no improvement of ischemic changes on ECG; ③ reduction or elimination of nitroglycerin use. Trials with incomplete or unclear data were excluded. Two investigators independently screened and identified the relevant trials according to their titles and abstracts. Any disagreements were subsequently resolved by discussion with a third expert to reach a consensus. The following information were extracted from each article: first author, publication year, mean age, total numbers, treatment duration, disease course, recruited sources, types of interventions in the experimental and control groups, and adverse events including subcutaneous bleeding, pain complaints and any events that led to discontinuation of treatment.

2.3. Quality assessment

The methodological quality of the included RCTs was assessed independently by two researchers (Yuan Liu and Hao-Yu Meng) based on the Cochrane risk-of-bias criteria. A total of seven items including

randomization sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data, selective reporting, and other bias were evaluated. Each quality item was graded as low risk, high risk, or unclear risk. Other bias was defined as trials sponsored by drug companies or trials in which baseline characteristics were imbalanced between groups.

2.4. Statistical analysis

Statistical analyses were conducted using the RevMan 5.3 and STATA 12.0 programs. Publication bias was evaluated by funnel plot and Egger's test. Data were summarized using relative risk (RR) with 95% confidence intervals (CI). Statistical significance was considered to be reached if the P-value was less than 0.05. Heterogeneity was tested using Q-statistic test and I [2] test. If $P > 0.1$ and I [2] < 50%, the fixed effect model was used; it was necessary to identify sources of heterogeneity when $P < 0.1$ and I [2] > 50%. Possible sources of heterogeneity were assessed by subgroup analyses [15]. If the heterogeneity persisted, the random effect model was used.

3. Results

3.1. Study selection and characteristics

The database search identified 525 references in total. Seven additional records were identified through other sources. After applying the inclusion criteria, twelve articles [16–27] were eventually included in this meta-analysis. The study selection process is shown in Fig. 1. All the 12 RCTs were conducted in China, and included 974 SAP cases with 509 patients in the treatment group and 465 patients in the control group. The number of subjects per trial varied from 26 to 128, and the duration of the treatment course ranged from 10 days to 8 weeks. The detailed characteristics of the included studies are shown in Table 1. The methodological quality of the included studies in accordance with the Cochrane risk-of-bias criteria is shown in Table 2.

Twelve trials [16–27] reported outcome measures according to the Standard on the Assessment of Curative Effect of Angina and ECG of Coronary Heart Disease, constituted by a Symposium on Integrated Western and Chinese Medicine for the Angina of Coronary Heart Disease of 1979; and according to the Standard of Guiding Clinical Research in Developing New Traditional Chinese Medicine of 1993/2002. They shared the similar criteria as follows.

“Markedly effective”: the ECG became normal or substantially normal; angina attack frequency and duration reduced by more than 80% at the same exercise level (angina disappeared or almost disappeared).

“Effective”: the depressed ST segment recovered by more than 0.05 mV after treatment, but did not reach the normal level; the inverted T wave in the main lead became shallow (up to 25% or more), or the T wave changed from flat to upright; atrioventricular or intraventricular block improved; angina attack frequency and duration reduced by 50%–80% (angina attack frequency and duration definitely reduced by more than 50%);

“Ineffective”: the ECG after treatment was unchanged compared to before; angina attack frequency and duration reduced by less than 50% (symptom level was basically the same as before);

“Exacerbation”: the ST segment became depressed by more than 0.05 mV; the inverted T wave on the main lead deepened by up to 25% or more, the upright T wave became flat, or the flat T wave became inverted; ectopic rhythm developed, atrioventricular block or intraventricular block occurred; angina attack frequency and duration increased (angina attack frequency and duration increased or became worse).

3.2. Assessment of bias

The funnel plot was symmetrical for the 10 RCTs comparing acupuncture plus medicine or acupuncture with medicine alone with regards to ineffectiveness of angina relief as outcome. Funnel plots suggested no obvious publication bias as shown in Fig. 2, which was identified by negative Egger's tests (P = 0.138; P = 0.238).

3.3. Acupuncture versus medicine

3.3.1. Angina relief

Seven studies [16–22] comparing acupuncture (n = 275) with medicine (n = 241) reported angina relief data. As shown in Fig. 3A, our meta-analysis revealed that the acupuncture group was associated with a lower incidence of ineffectiveness of angina relief than the medicine group (RR 0.35, 95% CI [0.22,0.55], $P < 0.00001$, $I^2 = 0\%$).

3.3.2. Improvement of ischemic changes on ECG

Six trials [17–22] comparing acupuncture (n = 263) with medicine (n = 229) reported data pertaining to improvement of ischemic changes on ECG. Pooled analysis showed that the incidence of failure of improvement of ischemic changes on ECG in the acupuncture group was significantly lower than that in the medicine group (RR 0.49, 95% CI [0.37,0.64], $P < 0.00001$, $I^2 = 37\%$) as shown in Fig. 4A.

3.4. Acupuncture plus medicine versus medicine alone

3.4.1. Angina relief

Four trials [23–26] comparing acupuncture plus medicine (n = 163) with medicine (n = 155) reported angina relief data. As shown in Fig. 3B, our meta-analysis demonstrated that the acupuncture plus medicine group had a lower incidence of ineffectiveness of angina relief than the medicine group (RR 0.26, 95% CI [0.15,0.46], $P < 0.00001$, $I^2 = 3\%$).

3.4.2. Improvement of ischemic changes on ECG

Two trials [23,24] comparing acupuncture plus medicine (n = 81) with medicine alone (n = 81) reported data pertaining to improvement of ischemic changes on ECG. The results of our meta-analysis shown in Fig. 4B indicated that the combination group was associated with a lower incidence of failure of improvement of ischemic changes on ECG than the medicine group (RR 0.52, 95% CI [0.29,0.93], P = 0.03, $I^2 = 36\%$).

3.4.3. Nitroglycerin reduction and suspension

Two trials [23,25] with a combined total of 186 patients reported data related to the reduction or elimination together of nitroglycerin use. The acupuncture plus medicine group had a lower nitroglycerin intake rate compared to the medicine group (Non-event, RR 0.79, 95% CI [0.64,0.97], P = 0.03, $I^2 = 0\%$) as shown in Fig. 5A. However, there was no significant difference noted between the combination group and the medicine group in terms of complete elimination of nitroglycerin use (Non-event, RR 0.93,95%CI [0.83,1.05],P = 0.23, $I^2 = 0\%$).

3.5. Adverse events

Adverse events were mentioned in five trials [16,17,19,25,26], and were reported by a total of 368 patients. No adverse effects or complications related to acupuncture therapy were observed or reported in the included trials.

4. Discussion

The results of the meta-analysis in this paper showed that acupuncture plus medicine or acupuncture alone were more effective than medicine alone on angina relief and improvement of ECG ischemic

Table 1
Characteristics of the included trials.

Study ID	Recruited sources	TG (M/F)	CG (M/F)	Mean age (mean or range)		Disease course (TG/CG)(mean or range)
				TG	CG	
Zhang 2017 [26]	In	26/10	23/7	63–83	61–80	5d-2m/6d-2m
Yan 2017 [25]	In	25/21	23/21	57	22.12	21.31y/22.12y
Wang 2012 [24]	In	20/13	21/12	59.7	58.7	3y-7y
Liu 2013 [21]	In	14/6	15/7	63	67	331d
Liu 2015 [23]	In	25/23	26/22	50.9	52.96	4.63y/4.46y
Liu 2012 [20]	In/Out	18/15	17/16	65.7	64.8	6m-15y
Zhou 2007 [22]	NR	51/21	40/16	68.7	65.2	4m-9y
Chang 2005 [16]	NR	19/11	17/5	59.5	61.1	6.4y/7.2y
Huang 2004 [19]	In/Out	22/18	21/19	55	57	5.3y/5.2y
Diao 2003 [18]	NR	23/17	18/12	56.46	57.32	7.31y/7.53y
Liu 2003 [27]	In/Out	19/13	19/12	57.6	56	24.8 m/20.6 m
Yin 2009 [16]	In/Out	24/18	22/16	52.6	52.2	7 m/8 m

Study ID	Treatment group	Control group	Treat duration	Outcome measures
Zhang 2017 [26]	(A)Moxibustion plus(B)	(B)ASP; ISMN	14d	Angina attack rate; NTG consumption; Impact on the ECG waveform
Yan 2017 [25]	(A)Moxibustion plus (B)	(B)ASP; AC; ISMN	10d	NTG consumption; Improvement of angina symptoms; Myocardial oxygen consumption
Wang 2012 [24]	(A)Moxibustion plus acupressure plus (B)	(B)ISMN; ASP; Simvastatin; Shuxuening	5w	Improvement of angina symptoms and ECG; TCM syndrome efficacy
Liu 2013 [21]	(A)Thermal moxibustion alone	(B)ASP; ISMN; CCB	10d	Improvement of angina symptoms; Impact on the ECG waveform; Angina attack rate
Liu 2015 [23]	(A)Thermal moxibustion plus(B)	(B)ASP; ISMN; MT; PST	4w	TCM syndrome efficacy; Effects in the symptom, ECG, blood lipids and NTG consumption
Liu 2012 [20]	(A)Acupuncture	(B)ASP; BET; ISMN	4w	Effects in the symptom and ECG
Zhou 2007 [22]	(A)Acupuncture alone	(B)BET; ASP; Captopril; ISMN	6w	Effects in the symptom and ECG; Angina relief time
Chang 2005 [17]	(A)Acupuncture alone	(B)ISMN or BET	2w	Effects in the symptom and ECG; NTG reduction and suspension
Huang 2004 [19]	(A)Electro-acupuncture alone	(B)CDP	4w	Effects in the symptom and ECG
Diao 2003 [18]	(A)Acupuncture alone	(B)SHC	4w	Effects in the DCG and ECG; Angina attack rate; NTG consumption
Liu 2003 [27]	(A)Acupuncture plus (B)	(B)ISMN	8w	Quality of life; Impact on the ECG waveform
Yin 2009 [16]	(A)Acupuncture plus cupping	(B)ISMN	30d	Angina attack rate; Effects in the symptom; NTG consumption; Myocardial oxygen consumption

D indicates days; w, weeks; m, months; y, years; Out, outpatient; In, inpatient; M, male; F, female; NR, No Report.TG/A, Treatment Group; CG/B, Control Group; d, days; CDP, Compound Danshen Pills; ASP, Aspirin; BET, Betaloc; ISMN, Isosorbide, mononitrate; AC, Atorvastatincalcium; SHC, Shanhaidan Capsules; PST, Pravastatin Sodium Tablets; MT, Metoprolol Tablets; CCB, Calcium Channel Blockers; ECG, Electrocardiogram; DCG, Dynamic Electrocardiogram; TCM, Traditional Chinese Medicine; NTG: Nitroglycerin.

Table 2
Risk of bias assessment in included studies based on the Cochrane handbook.

Included studies	A	B	C	D	E	F	G	Total
Zhang 2017 [26]	+	?	–	+	+	?	+	4
Yan 2017 [25]	+	?	–	+	+	+	+	5
Wang 2012 [24]	+	?	–	+	+	+	+	5
Liu 2013 [21]	+	?	–	+	+	+	+	5
Liu 2015 [23]	+	?	–	+	+	+	+	5
Liu 2012 [20]	+	?	–	+	+	+	+	5
Zhou 2007 [22]	+	?	–	+	+	+	+	5
Chang 2005 [17]	+	?	–	+	+	?	+	4
Huang 2004 [19]	+	?	–	+	+	?	+	5
Diao 2003 [18]	+	?	–	+	+	+	+	5
Liu 2003 [27]	+	?	–	+	+	–	+	4
Yin 2009 [16]	+	?	–	+	–	?	+	3

A, Random sequence generation; B, Concealment of allocation; C, Blinding of par-ticipants and personnel; D, Blinding of outcome assessment; E, Incomplete outcome data; F, Selective outcome reporting; G, Other bias; +, low risk of bias; -, high risk of bias; ?, unclear risk of bias.

markers. In terms of the rate of nitroglycerin reduction, acupuncture plus medicine was superior to medicine alone. However, there was no significant difference between acupuncture plus medicine and medicine alone on eliminating the need for nitroglycerin totally. One trial [17] revealed that acupuncture alone had no effect on the rate of reduction of nitroglycerin use or its elimination altogether. However, another trial [22] reported that the time to onset of angina relief was longer for acupuncture alone than for medicine alone. Besides, one trial [23] suggested that acupuncture plus medicine had greater effects on lipid profiles than medicine alone, including reduction of triglyceride, low density lipoprotein cholesterol and total cholesterol levels, as well as raising high density lipoprotein cholesterol level. Five trials reported occurrence of adverse events, while no acupuncture-related adverse events were noted. Another systematic review [28] suggested that acupuncture by experienced hands was inherently safe without traumatic, infectious, or other adverse events.

SAP is a clinical syndrome characterized by pain or discomfort in the chest, jaw, shoulder, back, or arms, typically induced by physical exertion or emotional stress and relieved by rest or nitroglycerin [29]. Based on the theory of TCM, acupuncture could regulate yin, yang, qi, and blood in order to enhance physical fitness and control the risk factors [30]. Richer et al. [13] found that acupuncturing Neiguan (PC6) decreased the ST-segment elevation after ligating the coronary artery of experimental dogs, which indicated that acupuncture could protect the myocardium from ischemia. The mechanism of acupuncture therapy for SAP is not very clear, and several studies have reported that it might be associated with a reduction of sympathetic excitatory cardiovascular reflexes and myocardial oxygen demand, activation of the opioid system, and coronary artery vasodilatation [31–34]. A few other studies have shown that acupuncture could promote the regeneration of microvessels, and therefore enhance collateral circulation in patients with angina, thus improving ischemic symptoms [35–38].

It has also been reported that acupuncture could improve the remedial effects of nitroglycerin, with fast relief of symptoms of acute angina pectoris. The combination of acupuncture and medicine therapy could thus make a significant difference in the treatment of various ischemic conditions. A recent review [39] suggested that acupuncture

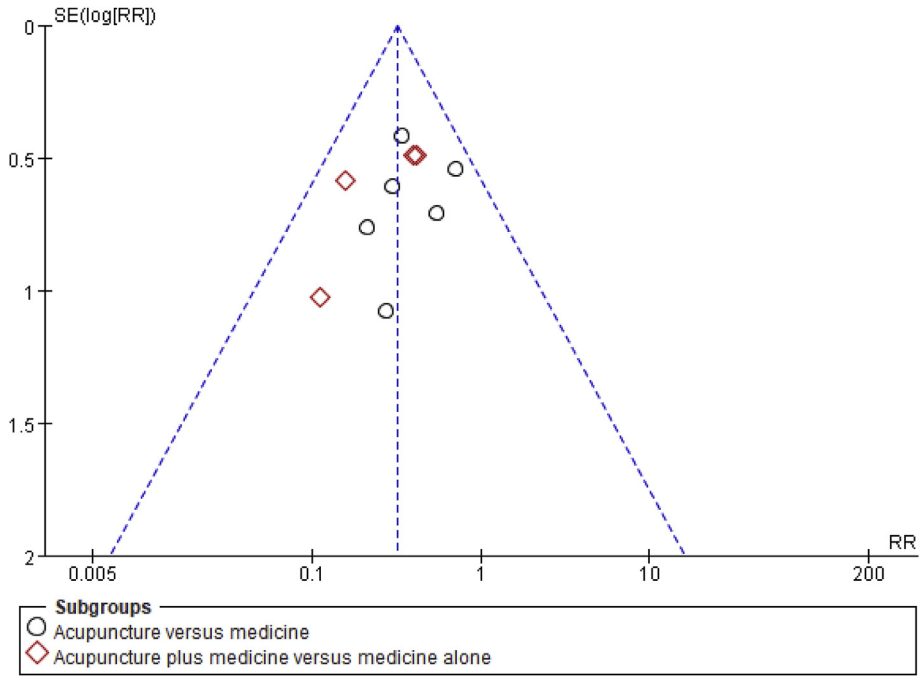

Fig. 2. Funnel plot of 10 trials for the outcome of the number of patients with ineffectiveness of angina relief in this meta-analysis. SE, standard error; RR, relative risk.

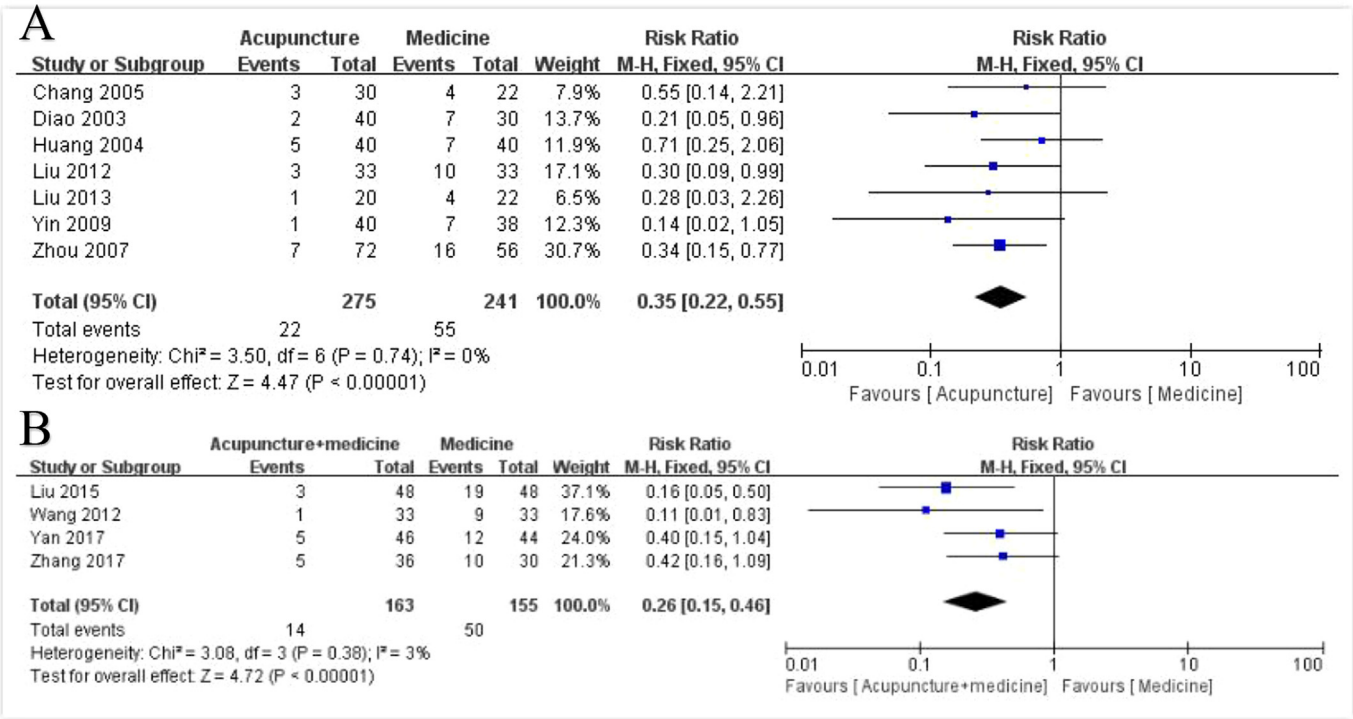

Fig. 3. Forest plot of the number of patients with ineffectiveness of angina relief between groups (A: acupuncture versus medicine; B: acupuncture plus medicine versus medicine). CI, confidence intervals.

combined with traditional medicine therapy for patients with angina pectoris could reduce the requirement frequency of anti-anginal drugs for symptomatic relief, as well as the reduction of adverse effects secondary to multi-drug therapy. The result of a meta-analysis of 21 RCTs conducted by Chen et al. [40] showed that acupuncture plus conventional medicine therapy could reduce the incidence of acute myocardial infarction, relieve anginal symptoms, and improve ischemic changes on ECG and quality of life in patients with unstable or stable angina pectoris. However, it should be noted that unstable angina belonged to acute coronary syndromes, most of which needed coronary intervention. Our meta-analysis enrolled newly-published RCTs and compared acupuncture plus medicine or acupuncture to medicine alone in terms of angina relief of SAP, thereby providing new evidence with regards to the use of acupuncture therapy in stable coronary artery disease.

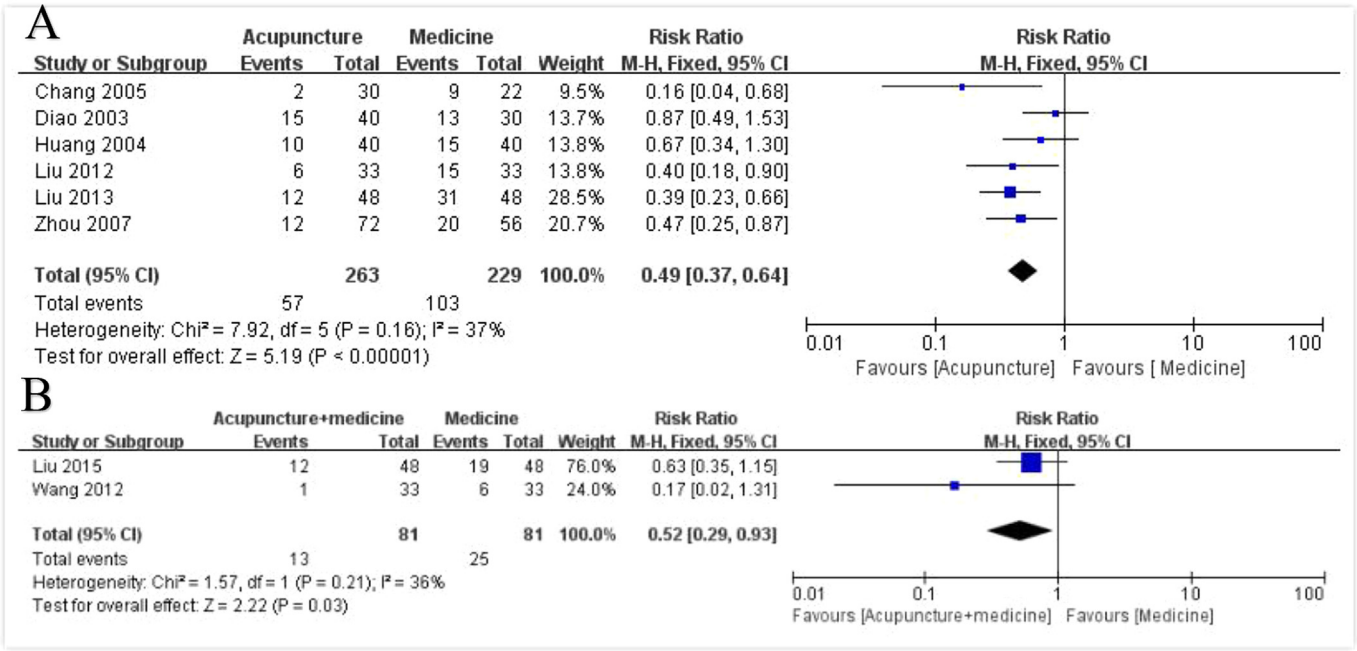

Fig. 4. Forest plot of the number of patients with no ECG improvement between groups (A: acupuncture versus medicine; B: acupuncture plus medicine versus medicine). CI, confidence intervals.

5. Study limitations

Several limitations are worth noting in our meta-analysis. First, the quality of the included trials was inconsistent according to the Cochrane Handbook. In most of the included trials, the sample size was small, the randomization method was mentioned without further details, and double-blinding was not conducted. Second, our study did not include data from clinical trials written in other languages except mandarin Chinese. In addition, the classification of markedly effective, effective, ineffective and exacerbation did not conform to international standards.

6. Conclusions

In conclusion, our meta-analysis indicated that acupuncture plus medicine, or acupuncture alone may improve anginal symptoms and ECG results in patients with SAP. Acupuncture plus medicine could reduce the rate of nitroglycerin prescription. Acupuncture therapy may be an adjunctive treatment for SAP. In the future, inclusion of RCTs with better study designs and larger sample size is needed to further verify the efficacy and safety of acupuncture in SAP treatment. Furthermore, future clinical trials evaluating the treatment effects of acupuncture on SAP symptoms that conform to international standards should be conducted.

Conflicts of interest

The authors declare no conflicts of interest.

Acknowledgements

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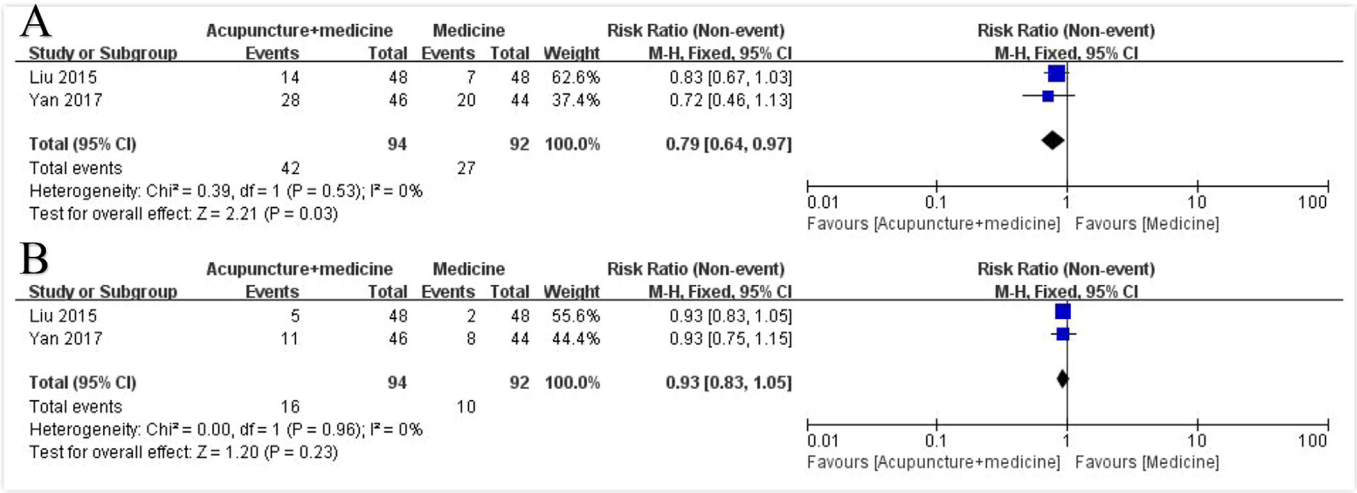

Fig. 5. Forest plot on reduction (A) or suspension (B) of nitroglycerin between acupuncture plus medicine group and medicine group. CI, confidence intervals.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.ctcp.2018.12.012.

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