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Acupuncture for primary trigeminal neuralgia: A systematic review and PRISMA-compliant meta-analysis

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ABSTRACT

Background and purpose: Acupuncture is increasingly used by patients with primary trigeminal neuralgia (PTN). We aimed to evaluate the efficacy and safety of acupuncture for PTN.
Methods: Seven databases were searched. Risk of bias was assessed and meta-analyses were conducted. The evidence level was assessed using Grading of Recommendations, Assessment, Development and Evaluation (GRADE).
Results: Thirty-three RCTs were included. Meta-analysis results demonstrated that the effect of both manual acupuncture (MA) and electro-acupuncture (EA) for improving response rate and recurrence rate was more significant than carbamazepine. Besides, MA achieved more significant effect on alleviating pain intensity. Moreover, acupuncture combined with carbamazepine had a more positive effect on response rate than carbamazepine alone.
Conclusions: Acupuncture might have some positive effects for PTN. Nevertheless, the level of all evidence was low or very low. We could not yet draw a firm conclusion on the efficacy of acupuncture for PTN.

1. Introduction

Primary trigeminal neuralgia (PTN) is one common kind of neuralgia, which could be characterized by recurring attacks of paroxysmal, shock-like pain within the distribution of one or more branches of the trigeminal nerve [1,2]. With an annual incidence of approximately 4–13 per 100000 people [3,4], PTN has been a major public health challenge in the world and a large spectrum of therapeutic modalities have been explored to treat it. But the efficacy of mainstream therapies (drugs such as carbamazepine, and surgical operation) remains unsatisfactory, given to the side effects caused by medication, drug dependence and high recurrence rate [5,6].

Many patients with PTN are seeking for help from complementary and alternative medicine. As an important part of it, acupuncture has been used to treat PTN in China for a long history. By penetrating needles to the acupoints on the body surface along meridians, acupuncture could be used to treat a wide range of diseases [7]. In recent years, an increasing number of trials have been performed to explore the efficacy of acupuncture for treating PTN. However, the real effect of this therapy for treating PTN remains uncertain.

Robust evidence based on systematic review (SR) and meta-analysis is still not available. To date, only one SR [8] of the effectiveness of acupuncture for treating PTN has been published in the English language literature. Nevertheless, this review was published in 2010 and it did not follow the formal recommendations for a SR. Moreover, new eligible randomized controlled trials (RCTs) have been conducted in the past few years and it was essential to integrate them into a new study. Therefore, we performed this systematic review and meta-analysis to seek a firm conclusion about the effect of acupuncture for treating PTN.

2. Methods

This systematic review and meta-analysis followed the Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) statement to report the findings.

2.1. Data sources and search strategy

The following databases were searched from their inception through 31 December 2017: (1)PubMed; (2)Embase; (3)the Cochrane Library; (4)China National Knowledge Infrastructure; (5)China Science and Technology Journal Database; (6)Chinese Biomedical Literature Database (CBM); (7)Wangfang database. No language restrictions were imposed. Search terms (e.g. acupuncture, trigeminal neuralgia, tic douloureux, trigeminal nerve, prosopalgia and randomized) were used individually or jointly to search eligible trials. References of all eligible papers were also scanned to identify additional eligible publications.

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2.2. Study selection

2.2.1. Types of studies

RCTs or quasi-RCTs involving acupuncture for treating PTN were included. Quasi-RCTs were defined as trials that were randomized by using not truly random methods, such as by alternation, date of birth and case record number. Non-randomized, uncontrolled trials were excluded. Additionally, literature reviews, animal experiments, case reports, case series, conference papers, and editorials were also excluded.

2.2.2. Types of participants

Patients diagnosed with PTN and the diagnostic criteria should be reported clearly.

2.2.3. Types of intervention

Studies involving the insertion of needles regardless of the type of acupuncture (ie, both MA and EA) were included, while studies that did not involve skin penetration, such as acupressure or moxibustion, were excluded. There were no restrictions on frequency, intensity and treatment duration. Studies that investigated the combined effects of acupuncture and other related TCM modalities (e.g. acupuncture combined with herbal medicine, acupuncture plus cupping), or studies comparing different types of acupuncture (e.g. MA vs. EA), were excluded.

Control interventions included treatments such as general conventional care for PTN (drugs, botulism toxin, etc.), sham acupuncture, or waiting list care. We also included trials that compared acupuncture plus another active treatment with the same other active treatment alone.

2.2.4. Types of outcome measures

The included trials had to report outcome measures in at least one of the following forms: (1) severity of pain (measured with Visual Analogue Scale (VAS), numerical rating scale), or other measurement tools for pain; (2) frequency of attacks; (3) response rate: the percentage of the total number of patients whose PTN symptoms have improved; (4) quality of life: measured using a validated questionnaire; (5) recurrence rate; (6) adverse events.

2.3. Data extraction

After excluding duplicate articles, two reviewers independently screened papers by reading titles and abstracts to exclude obviously unrelated papers. Full texts of all potentially eligible papers were screened based on the inclusion criteria. After including all eligible RCTs, the same two reviewers extracted data regarding author, country, participants, intervention, control types, treatment course, sessions of treatment, primary and secondary outcomes, based on a pre-defined data extraction table. If relevant data were missing, we planned to contact the corresponding authors via email. For continuous outcomes, the mean difference (MD) and standard deviation (SD) in each group of the RCT was extracted along with the total number of participants. For dichotomous outcomes, the number of responders and the total number of participants for each group was extracted. Any disagreements during RCT selection and data extraction were resolved by discussion or arbitration by a third reviewer.

2.4. Assessment of risk of bias

The risk of bias assessment tool [9] recommended by the Cochrane Handbook was used to evaluate the quality of the included RCTs. The risk of bias in each domain was rated as 'low,' 'high' or 'unclear'. Discrepancies were resolved by negotiation or by consulting other reviewers.

2.5. Data synthesis and statistical analysis

In terms of continuous data and dichotomous data, effect sizes were measured using MD and 95% confidence interval (CI), or odds ratio (OR) with 95% CI respectively. Heterogeneity within RCTs was examined based on the I^2 test, considering $I^2 \geq 50\%$ as a sign of substantial heterogeneity. Fixed effect model was employed if the included RCTs were homogeneous; while random effect model was adopted when significant heterogeneity was detected. If significant heterogeneity within studies was observed, subgroup analyses would be conducted based on clinical perspective. RevMan 5.3 (Cochran Collaboration, London, UK) software was used to perform meta-analyses. Sensitivity analyses were conducted for the robustness of the result of meta-analyses by excluding one trial at one time. Moreover, the quality of evidence was assessed according to the GRADE system and divided into four categories: high, moderate, low and very low.

3. Results

3.1. Literature search

The process of eligible RCT selection is displayed in the flowchart (Fig. 1). A total of 1389 papers were found after primary search. Finally, 33 [10–42]studies were included in this SR.

3.2. Study description

Characteristics of included studies are summarized in Table 1. The 33 trials involved 3517 participants, varying from 24 to 217.

(1) Country distribution

All trials were conducted in mainland China and published in Chinese journals.

(2) Interventions

Most studies (n = 21) [10,12,14,15,17,20–24,28,30–34,36,37,39,40,42] adopted MA in the experimental group; 7 trials [16,19,27,29,35,38,41] applied EA and the combination of acupuncture and Western medicine (carbamazepine) was used in the remaining 5 studies [11,13,18,25,26]. As a comparator, all the studies administered Western medicine (carbamazepine) to the control group.

(3) Number of acupuncture sessions and duration of treatment courses

The number of acupuncture sessions ranged from 12 to 60. Besides, the total duration of treatment courses ranged from 2 to 6 weeks.

(3) Outcome measures

All trials used response rate as one of the outcome measures and 9 RCTs reported pain intensity, which was assessed using VAS. Moreover, 3 trials [29,38,39] reported recurrence rate. The total number of adverse events, including acupuncture syncope, dizziness or drowsiness, pigmentation near acupoints and pain during needle penetration, was assessed as an outcome measure in 11 studies [10,19–21,25,28,31–33,39,40].

Most studies completed their outcome assessment at the end of the treatment course. Apart from 6 trials [15,19,29,37–39], none of the studies conducted a follow-up evaluation for outcome measures.

3.3. Synthesis of results

3.3.1. Manual acupuncture vs. Western medicine (carbamazepine)

(1) Response rate

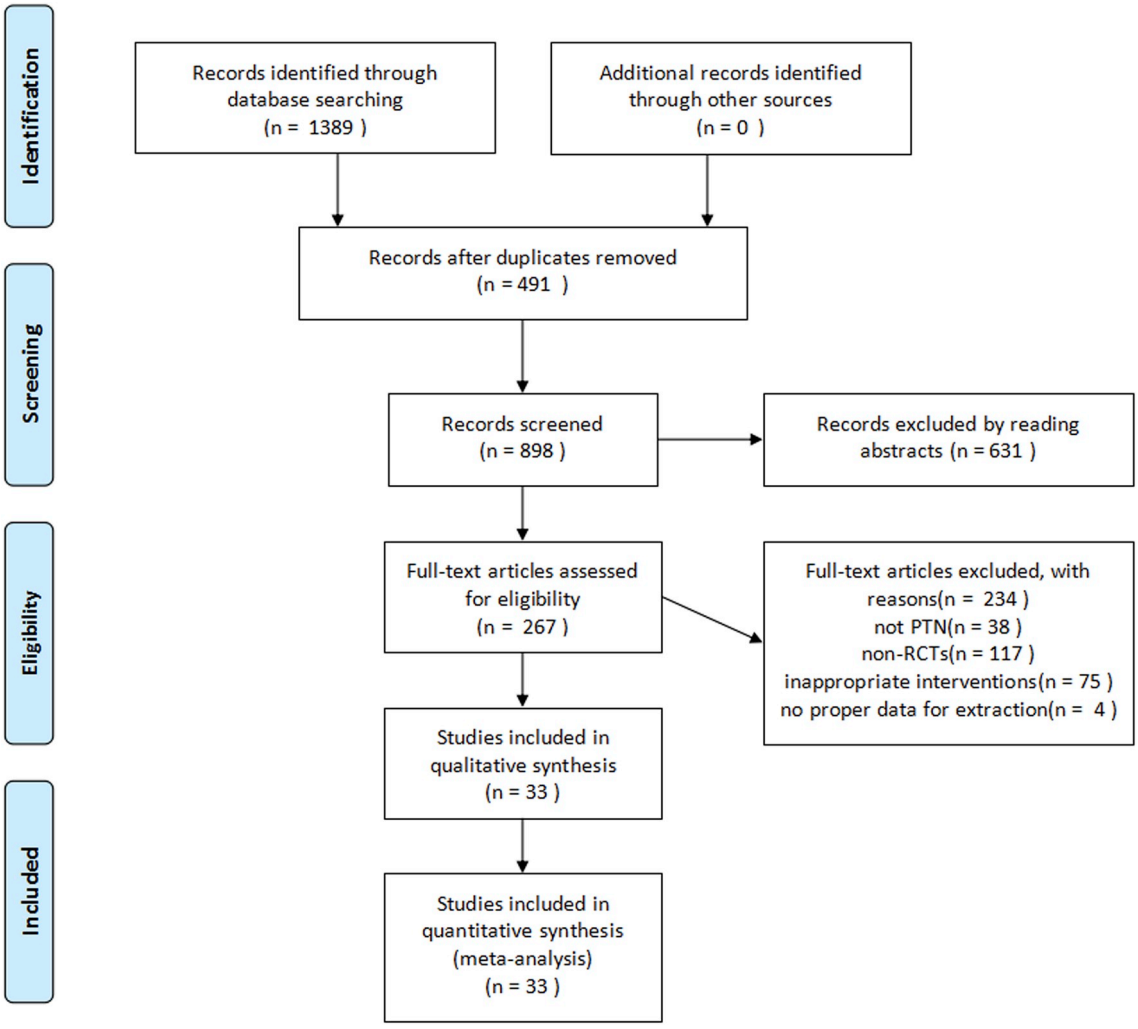

Fig. 1. Flowchart of the trial selection process. PTN = primary trigeminal neuralgia; RCT = randomized controlled trial.

Twenty-one [10,12,14,15,17,20–24,28,30–34,36,37,39,40,42] studies involving 1699 participants reported response rate as outcome measures. With no heterogeneity observed (I^2 = 34%), fix model was employed and meta-analysis results revealed that the therapeutic effect of MA was more beneficial than carbamazepine for improving response rate [Fig. 2(1): 21 trials; OR = 3.80, 95% CI:2.82 to 5.12, I^2 = 34%].

(2) Pain intensity

Five RCTs [17,22,30,32,39] were combined. Meta-analysis results proved that the group of MA versus carbamazepine demonstrated a superior effect of MA [Fig. 2(2): 5 trials; MD = -1.20, 95% CI: -2.10 to -0.30, I^2 = 96%].

(3) Recurrence rate

Only one study [39] was included. Significant difference in recurrence rate between the two groups was observed, which was in favor of the better effect of MA for reducing recurrence rate [Fig. 2(3): 1 trial; OR = 0.43, 95% CI:0.19 to 0.98].

3.3.2. Electro-acupuncture vs. Western medicine (carbamazepine)

(1) Response rate

Seven trials [16,19,27,29,35,38,41] were pooled. Compared with carbamazepine, EA achieve better effect for improving response rate [Fig. 3(1):7 trials; OR = 4.22, 95% CI:2.35 to 7.57, I^2 = 0%].

(2) Pain intensity

Only one study [41] was included and the differences were not statistically significant between the two groups for alleviating pain intensity [Fig. 3(2):1 trial; MD = 0.57, 95% CI: -0.53 to 1.67].

(3) Recurrence rate

Two RCTs [29,38] were pooled and no heterogeneity was detected among studies (I^2 = 0%). Meta-analysis results proved that the group of EA achieved more significant effect modification on reducing recurrence rate than carbamazepine [Fig. 3(3):2 trials; OR = 0.14, 95% CI: 0.05 to 0.45, I^2 = 0%].

3.3.3. Acupuncture combined with carbamazepine vs. carbamazepine

(1) Response rate

Five trials [11,13,18,25,26] involving 464 participants were pooled and meta-analysis results demonstrated that a better effect on response rate was achieved by acupuncture combined with carbamazepine in contrast to carbamazepine alone [Fig. 4(2): 5 trials; OR = 5.88, 95% CI:2.91 to 11.90, I^2 = 30%].

Table 1
Characteristics and main outcomes of included studies.

Study	Random sequence generation	Sample size		Intervention		Adverse events	Outcome measures
		Experimental	Control	Experimental	Control		
Yang HJ 2010	UN	60	60	Types of acupuncture: EA Local acupoints (affected side): GV20,ST8,SI19,GB20,TE17,trigger points For neuralgia in V1, add EX-HN4,GB14,EX-HN5; For neuralgia in V2, add ST2,SI18,LI20; For neuralgia in V3, add ST6,ST4, ST7, Jiachengjiang[a] Distant acupoints (bilateral): TE5,LI4,LR3,ST44,GB43,LR2 Deqi achieved?: Yes Needle retention time: 40min Number of treatment sessions: 60 Frequency of sessions and treatment courses: 2 times/day for 30days	Carbamazepine	UN	Response rate (assessment time: after 30days)
Wang FD 2009	UN	30	30	Types of acupuncture: EA Local acupoints (affected side): For neuralgia in V2, choose ST2,SI18; For neuralgia in V3, choose Jiachengjiang[a]; For neuralgia in V2 and V3, choose ST2,ST7,SI18,BL2, Jiachengjiang[a]; For neuralgia in V1, V2 and V3, choose EX-HN4,ST2,ST7, GB14,SI18,BL2, Jiachengjiang[a] Distant acupoints (bilateral): LI4 Deqi achieved?: UN Needle retention time: 30min Number of treatment sessions: 30 Frequency of sessions and treatment courses: 10/day for the first 10 days, rest 2 days; 10/day for the next 10 days, rest 2 days; then 10/day for the last 10days	Carbamazepine	UN	1.Response rate (assessment time: after 34days) 2.Recurrence rate (assessment time: at the end of one-year follow- up)
Zheng JQ 2011	Table of random number	12	12	Types of acupuncture: EA Local acupoints (affected side):ST7,GV20,ST8,SI19,GB20,TE17,trigger points For neuralgia in V1, add EX-HN4,GB14,EX-HN5; For neuralgia in V2, add ST2,SI18,LI20; For neuralgia in V3, add ST6,ST4,Jiachengjiang[a] Distant acupoints (bilateral):TE5,LI4,LR3,ST44,GB43,LR2 Deqi achieved?: Yes Needle retention time: 40min Number of treatment sessions: 60 Frequency of sessions and treatment courses: 2/day for 30days	Carbamazepine	UN	1.Response rate (assessment time: after 30days) 2.Recurrence rate (assessment time: at the end of one-month follow- up)
Han QZ 2009	Table of random number	30	30	Types of acupuncture: EA Local acupoints (affected side): ST7, trigger points For neuralgia in V1, add BL2,ST8; For neuralgia in V2, add SI18; For neuralgia in V3, add CV24,ST6 Distant acupoints (bilateral): NO Deqi achieved?: UN Needle retention time: 60min Number of treatment sessions: 30 Frequency of sessions and treatment courses: 1/day for 30days	Carbamazepine	UN	Response rate (assessment time: after 30days)
Zhou ZK 2014	UN	30	30	Types of acupuncture: EA Local acupoints (affected side): ST7 For neuralgia in V1, add GB14 For neuralgia in V2, add SI18 For neuralgia in V3, add ST4 Distant acupoints (bilateral):LI4 Deqi achieved?: Yes Needle retention time: 30min Number of treatment sessions: 28 Frequency of sessions and treatment courses: 1/day for 28days	Carbamazepine	UN	1.Response rate (assessment time: after 28days) 2.Pain intensity (VAS) (assessment time: baseline, after 28 days)
Liu AJ 2015	Table of random number	20	20	Types of acupuncture: EA Local acupoints (affected side):ST7,Ashi points Distant acupoints (bilateral): LR3,LI4 Deqi achieved?: Yes Needle retention time: 30min Number of treatment sessions: 12 Frequency of sessions and treatment courses: 6/week for 2weeks	Carbamazepine	Yes	1.Response rate (assessment time: after 2weeks) 2.Pain intensity (VAS) (assessment time: baseline, after 2 weeks, at the end of 3-month follow-up)

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Table 1 (*continued*)

Study	Random sequence generation	Sample size		Intervention		Adverse events	Outcome measures
		Experimental	Control	Experimental	Control		
Shi YC 2008	UN	32	21	Types of acupuncture: EA Local acupoints (affected side): ST7,trigger points For neuralgia in V2, add SI18; For neuralgia in V3, add CV24,ST7 Distant acupoints (bilateral): No Deqi achieved?: UN Needle retention time: 60min Number of treatment sessions: 30 Frequency of sessions and treatment courses: 1/day for 30days	Carbamazepine	UN	Response rate (assessment time: after 30days)
Ren XM 2010	UN	40	40	Types of acupuncture: MA Local acupoints (affected side):ST7 For neuralgia in V1, add EX-HN5,BL2; For neuralgia in V2, add GV26,LI20; For neuralgia in V3, add ST6,ST4 Distant acupoints (bilateral): LI4,TE5 Deqi achieved?: Yes Needle retention time: 30min Number of treatment sessions: 30 Frequency of sessions and treatment courses: 1/day for 30days	Carbamazepine	UN	Response rate (assessment time: after 30days)
Zhou ZY 2004	Coin tossing	31	18	Types of acupuncture: MA Local acupoints (affected side): SI18, Distant acupoints (bilateral):GB34,ST40 Deqi achieved?: Yes Needle retention time: UN Number of treatment sessions: 24 Frequency of sessions and treatment courses: 6/week for 4weeks	Carbamazepine	UN	Response rate (assessment time: after 4weeks)
Zheng SH 2010	Computer randomization	60	60	Types of acupuncture: MA Local acupoints (affected side): ST9 For neuralgia in V1, add GB14,BL2,EX-HN4; For neuralgia in V22, add ST2,LI20,ST7; For neuralgia in V3, add ST4,ST6,Jiachengjiang[a] Distant acupoints (bilateral): No Deqi achieved?: Yes Needle retention time: 30min Number of treatment sessions: 30 Frequency of sessions and treatment courses: 10/day for the first 10 days, rest 3 days, then 10/day for the next 10 days, rest 3 days, then 10/day for the last 10 days	Carbamazepine	Yes	1.Response rate (assessment time: after 36days) 2.Scores of McGill Pain Questionnaire (assessment time: baseline, after 36days) 3.Pain intensity (VAS) (assessment time: baseline, after 36days) 4.Recurrence rate (assessment time: at the end of one-year follow- up)
Xu X 2008	Visiting sequence	26	24	Types of acupuncture: MA Local acupoints (affected side):GV24,GV29,GV26; GB20,GB12,BL10 For neuralgia in V1, add GB14,ST8,GB15,BL2,TE23; For neuralgia in V2, add EX-HN5,GB3,ST2,SI18; For neuralgia in V3, add ST7,ST5,ST4 Distant acupoints (bilateral): LI4, TE5. Deqi achieved?: Yes Needle retention time: 20 min (manipulate needles for two times to enhance Deqi sensation during needle retention) Number of treatment sessions: 30 Frequency of sessions and treatment courses: 1/day for 30days	Carbamazepine	UN	Response rate (assessment time: after 30days)
Sun HN 2014	UN	35	35	Types of acupuncture: MA Local acupoints (affected side): GV24,GB20,GV29,GB12,BL10,GV26 For neuralgia in V1, add GB14,BL2,GB15,TE23; For neuralgia in V2, add ST2,EX-HN5,GB3; For neuralgia in V3, add ST7,ST4,ST5 Distant acupoints (bilateral): LI4,TE5 Deqi achieved?: Yes Needle retention time: 20 min (manipulate needles for two times to enhance Deqi sensation during needle retention) Number of treatment sessions: 30 Frequency of sessions and treatment courses: 1/day for 30days	Carbamazepine	Yes	Response rate (assessment time: after 30days)

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Table 1 (*continued*)

Study	Random sequence generation	Sample size		Intervention		Adverse events	Outcome measures
		Experimental	Control	Experimental	Control		
Wang LF 2013	Table of random number	19	20	Types of acupuncture: MA Local acupoints (affected side):EX-HN5,trigger points,GV23,GV29,ST3,ST7,GB20,GB4 Distant acupoints (bilateral): LI7,LI4 Deqi achieved?: Yes Needle retention time: 30 min Number of treatment sessions: 30 Frequency of sessions and treatment courses: 5/week for 6weeks	Carbamazepine	UN	1.Response rate (assessment time: after 6weeks) 2.Scores of symptoms (assessment time: baseline, after 6 weeks) 3.Pain intensity (VAS) (assessment time: baseline, after 6 weeks)
Zhao N 2009	Visiting sequence	31	31	Types of acupuncture: MA Local acupoints (affected side): For neuralgia in V1, choose TE23,EX-HN5; For neuralgia in V2, choose SI18,ST2,ST7; For neuralgia in V3, choose Jiachengjiang[a],ST6 Distant acupoints: CV12(unilateral),CV4(unilateral),ST24 (bilateral),ST26 (bilateral); plus some additional acupoints based on TCM syndrome differentiation Deqi achieved?: UN Needle retention time: 30min Number of treatment sessions: 30 Frequency of sessions and treatment courses: 1/day for 30days	Carbamazepine	UN	Response rate (assessment time: at the end of 3-month follow-up)
Chen CP 2014	UN	76	36	Types of acupuncture: MA Local acupoints (affected side): GV29,GV24,GB20,GB12,BL10,GV26 For neuralgia in V1, add GB14,BL2,GB15,TE23; For neuralgia in V2, add EX-HN5,ST2,GB3; For neuralgia in V3, add ST4,ST7,ST5 Distant acupoints (bilateral): LI4,TE5 Deqi achieved?: Yes Needle retention time: 20 min; (manipulate needles for two times to enhance Deqi sensation during needle retention) Number of treatment sessions: 30 Frequency of sessions and treatment courses: 1/day for 30days	Carbamazepine	Yes	Response rate (assessment time: after 30days)
Guo SJ 2005	Visiting sequence	20	20	Types of acupuncture: MA Local acupoints (affected side): ST7,EX-HN4,ST2,Jiachengjiang[a] Distant acupoints (bilateral): No Deqi achieved?: Yes Needle retention time: 30min Number of treatment sessions: 20 Frequency of sessions and treatment courses: 1/day for the first 10 days, rest 2 days, then 1/day for the next 10 days	Carbamazepine	UN	Response rate (assessment time: after 22days)
Fu YC 2008	Visiting sequence	80	40	Types of acupuncture: MA Local acupoints (affected side): GB20,TE17,EX-HN5,Ashi points Distant acupoints (bilateral): No Deqi achieved?: Yes Needle retention time: 30 min (manipulate needles for two times to enhance Deqi sensation during needle retention) Number of treatment sessions: 30 Frequency of sessions and treatment courses: 1/day for the first 10 days, rest 3–5 days, then 1/day for the next 10 days, rest 3–5 days, then 1/day for the last 10 days,	Carbamazepine	NO	Response rate (assessment time: after 30 treatment sessions)
Jiao Y 2008	UN	96	96	Types of acupuncture: MA Local acupoints (affected side): SI18 Distant acupoints (bilateral): GB34,ST40 Deqi achieved?: Yes Needle retention time: 40min Number of treatment sessions: 24 Frequency of sessions and treatment courses: 6/week for 4weeks	Carbamazepine	UN	1.Response rate (assessment time: after 4weeks) 2.Scores of TCM syndrome (assessment time: baseline, after 4weeks) 3.Pain intensity (VAS) (assessment time: baseline, after 4weeks)

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Table 1 (*continued*)

Study	Random sequence generation	Sample size		Intervention		Adverse events	Outcome measures
		Experimental	Control	Experimental	Control		
Guo Y 2010	Visiting sequence	42	42	Types of acupuncture: MA Local acupoints (affected side): EX-HN5,ST7,ST2,CV23 Distant acupoints (bilateral): LI7 Deqi achieved?: Yes Needle retention time: 30 min Number of treatment sessions: 30 Frequency of sessions and treatment courses: 1/day for 30days	Carbamazepine	UN	Response rate (assessment time: at the end of 3-month follow-up)
Ren KJ 2014	UN	40	40	Types of acupuncture: MA Local acupoints (affected side): GV24,GV29,GB20,GB12,BL10,GV26 For neuralgia in V1, add GB15,BL2,GB14,TE23; For neuralgia in V2, add EX-HN5,GB3,ST2; For neuralgia in V3, add ST5,ST4,ST7 Distant acupoints (bilateral): TE5,LI4 Deqi achieved?: Yes Needle retention time: 20 min (manipulate needles for two times to enhance Deqi sensation during needle retention) Number of treatment sessions: 30 Frequency of sessions and treatment courses: 1/day for 30days	Carbamazepine	UN	1.Response rate (assessment time: after 30days) 2.Pain intensity (VAS) (assessment time: baseline, after 30days)
Liu K 2015	Dice rolling	42	42	Types of acupuncture: MA Local acupoints (affected side): GB20,GV29,GV26,GV24,BL10,GB12 For neuralgia in V1, add TE23,GB14,BL2,GB15; For neuralgia in V2, add GB3,EX-HN5,ST2; For neuralgia in V3, add ST5,ST4,ST7 Distant acupoints (bilateral): TE5,LI4 Deqi achieved?: Yes Needle retention time: 20 min (manipulate needles for two times to enhance Deqi sensation during needle retention) Number of treatment sessions: 28 Frequency of sessions and treatment courses: 1/day for 28days	Carbamazepine	Yes	1.Response rate (assessment time: after 28days) 2.Score of symptoms (assessment time: baseline, after 28days)
Liu YR 2016	UN	30	30	Types of acupuncture: MA Local acupoints (affected side): GB20,ST7,ST4,ST6 Distant acupoints (bilateral): LI4 Deqi achieved?: Yes Needle retention time: 30 min (manipulate needles for two times to enhance Deqi sensation during needle retention) Number of treatment sessions: 30 Frequency of sessions and treatment courses: 1/day for 30days	Carbamazepine	Yes	Response rate (assessment time: after 30days)
Xia WP 2015	UN	30	30	Types of acupuncture: MA Local acupoints (affected side): GV24,GV29,GV26,GB20,GB12,BL10 For neuralgia in V1, add GB14,BL2,GB15,TE23; For neuralgia in V2, add ST2,EX-HN5,GB3; For neuralgia in V3, add ST7,ST4,ST5 Distant acupoints (bilateral): LI4,TE5 Deqi achieved?: Yes Needle retention time: 30 min (manipulate needles for two times to enhance Deqi sensation during needle retention) Number of treatment sessions: 30 Frequency of sessions and treatment courses: 1/day for 30days	Carbamazepine	Yes	Response rate (assessment time: after 30days)
Zhou LP 2016	UN	33	32	Types of acupuncture: MA Local acupoints (affected side): GV29,GV24,GB20,GB12,BL10,GV26 For neuralgia in V1, add GB14,BL2,TE23,GB15; For neuralgia in V2, add EX-HN5,ST2,GB3; For neuralgia in V3, add ST4,ST7,ST5 Distant acupoints (bilateral): LI4 Deqi achieved?: Yes Needle retention time: 20min Number of treatment sessions: 30 Frequency of sessions and treatment courses: 1/day for 30days	Carbamazepine	Yes	Response rate (assessment time: after 30days)

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Table 1 (*continued*)

Study	Random sequence generation	Sample size		Intervention		Adverse events	Outcome measures
		Experimental	Control	Experimental	Control		
Shangguan SH 2016	Computer randomization	40	40	Types of acupuncture: MA Local acupoints (affected side): GV24,GB20,GV29,GV26,GB12,BL10 For neuralgia in V1, add GB14,GB15,TE23,BL2; For neuralgia in V2, add EX-HN5,GB3,ST2; For neuralgia in V3, add ST7,ST4,ST5 Distant acupoints (bilateral): TE5 Deqi achieved?: Yes Needle retention time: 20min (manipulate needles for two times to enhance Deqi sensation during needle retention) Number of treatment sessions: 30 Frequency of sessions and treatment courses: 1/day for 30days	Carbamazepine	UN	Response rate (assessment time: after 30days)
Xiao F 2016	Table of random number	50	50	Types of acupuncture: MA Local acupoints (affected side): GB20,Ashi points For neuralgia in V1, add GB14,TE17,EX-HN5,ST8,TE23; For neuralgia in V2, add TE17,ST2,ST7,LI20,SI18; For neuralgia in V3, add SI18,ST7,ST6,ST4,CV24 Distant acupoints (bilateral): LI4,SP10,BL17 Deqi achieved?: Yes Needle retention time: 40 min (manipulate needles for two times to enhance Deqi sensation during needle retention) Number of treatment sessions: 24 Frequency of sessions and treatment courses: 6/week for 4weeks	Carbamazepine	Yes	1.Response rate (assessment time: after 4weeks) 2.HAMA (assessment time: baseline, after 4weeks) 3.HAMD (assessment time: baseline, after 4weeks) 4.PSQL (assessment time: baseline, after 4weeks)
Xie HL 2016	Visiting sequence	40	40	Types of acupuncture: MA Local acupoints (affected side): GV29,GB20,GV24,GB12,BL10,GV26 For neuralgia in V1, add GB14,BL2,GB15,TE23; For neuralgia in V2, add EX-HN5,ST2,GB3; For neuralgia in V3, add ST4,ST7,ST5 Distant acupoints (bilateral): LI4,TE5 Deqi achieved?: Yes Needle retention time: 20 min (manipulate needles for two times to enhance Deqi sensation during needle retention) Number of treatment sessions: 30 Frequency of sessions and treatment courses: 1/day for 30days	Carbamazepine	Yes	Response rate (assessment time: after 30days)
Zhan YP 2006	Visiting sequence	36	36	Types of acupuncture: MA Local acupoints (affected side): SI18 Distant acupoints (bilateral): GB34,ST40 Deqi achieved?: Yes Needle retention time: 40min (manipulate needles for three times to enhance Deqi sensation during needle retention) Number of treatment sessions: 24 Frequency of sessions and treatment courses: 6/week for 4weeks	Carbamazepine	UN	1.Response rate (assessment time: after 4weeks) 2.Pain intensity (VAS) (Assessment time: baseline, after 4weeks)
Li YN 2014	UN	30	30	Acupuncture combine with carbamazepine Types of acupuncture: EA Local acupoints (affected side): ST7,EX-HN4,ST2,Jiachengjiang[a] Distant acupoints (bilateral): LI4 Deqi achieved?: Yes Needle retention time: 30min Number of treatment sessions: 12 Frequency of sessions and treatment courses: 6/week for 2weeks	Carbamazepine	NO	1.Response rate (assessment time: after 2weeks) 2.Pain intensity (VAS) (assessment time: baseline, after 2 weeks) 3.Pain index (assessment time: baseline, after 2weeks)
Gao M 2008	UN	32	32	Acupuncture combined with carbamazepine Types of acupuncture: MA Local acupoints (affected side): For neuralgia in V1, add EX-HN4,EX-HN5,GB14; For neuralgia in V2, add ST7,ST2,SI18; For neuralgia in V3, add CV24,ST6,TE17. Distant acupoints (bilateral): some additional acupoints based on TCM syndrome differentiation, such as LR3,ST44 and LI11 Deqi achieved?: Yes Needle retention time: UN Number of treatment sessions: 30 Frequency of sessions and treatment courses: 1/day for the first 10 days, rest 3 days, 1/day for the next 10 days, rest 3days, 1/day for the last 10 days	Carbamazepine	UN	Response rate (assessment time: after 36days)

(*continued on next page*)

Table 1 (*continued*)

Study	Random sequence generation	Sample size		Intervention		Adverse events	Outcome measures
		Experimental	Control	Experimental	Control		
Feng SP 2016	UN	109	108	Acupuncture combined with carbamazepine Types of acupuncture: MA Local acupoints (affected side): GV29,GV26,BL10; plus some acupoints (UN) based on neuralgia in different regions of the trigeminal nerve; Distant acupoints (bilateral): TE5 Deqi achieved?: Yes Needle retention time: UN Number of treatment sessions: 28 Frequency of sessions and treatment courses: 1/day for 28days	Carbamazepine	UN	1.Response rate (assessment time: after 28 days) 2.Pain intensity (VAS) (assessment time: baseline, after 28days)
Shen QY 2016	Table of random number	40	40	Acupuncture combined with carbamazepine Types of acupuncture: MA Local acupoints (affected side): EX-HN5,ST7,LI7,GV20,GV29 Distant acupoints (bilateral): LI4 Deqi achieved?: Yes Needle retention time: UN Number of treatment sessions: 30 Frequency of sessions and treatment courses: 1/day for 30days	Carbamazepine	Yes	1.Response rate (assessment time: after 30days) 2.Pain intensity (VAS) (assessment time: baseline, after 30days)
Sheng GB 2016	UN	22	21	Acupuncture combined with carbamazepine Types of acupuncture: MA Local acupoints (affected side): ST7,GB14,ST2,CV24 For neuralgia in V1, add GB14; For neuralgia in V2, add ST2; For neuralgia in V3, add CV24 Distant acupoints (bilateral): No Deqi achieved?: Yes Needle retention time: 30min Number of treatment sessions: 18 Frequency of sessions and treatment courses: 6/week for 3weeks	Carbamazepine	UN	1.Response rate (assessment time: after 20days) 2.Pain intensity (VAS) (assessment time: after 3weeks)

Abbreviations: EA, Electro-acupuncture; HAMA, Hamilton anxiety scale; HAMD, Hamilton depression scale; MA, Manual acupuncture; MPQ, McGill Pain Questionnaire; PSQL, Pittsburgh sleep quality index; TCM, traditional Chinese medicine; UN, Unclear; VAS, Visual analogue scale; V1, Neuralgia in the region of first branch of the trigeminal nerve; V2, Neuralgia in the region of second branch of the trigeminal nerve; V3, Neuralgia in the region of the third branch of the nerve.
[a] Jiachengjiang: an extra acupoint without an international code, which is located bilaterally 1 cun besides CV24.

(2) Pain intensity

Meta-analyses of 3 studies [18,25,26] showed that there were no statistically significant differences between the two groups for alleviating pain intensity [Fig. 4(1) MD = −0.58, 95% CI: -1.91 to 0.76, I^2 = 81%].

3.4. Safety evaluation

The majority of included RCTs did not clarify whether adverse events occurred. Only two [12,18] RCTs reported that there were no adverse events in the acupuncture group. Eleven [10,19–21,25,28,31–33,39,40]studies provided details of adverse events caused by acupuncture, all of which were minor side effects as the following: (1) acupuncture syncope; (2)dizziness or drowsiness; (3)pigmentation near acupoints; (4)pain during needle penetration.

3.5. Sensitivity analyses

Sensitivity analyses were performed by excluding one study at a time. The effect estimates in each subgroup regarding different outcomes did not alter significantly, implying that small sample effect did not influence the pooled effect estimate.

3.6. Risk of bias in the included studies

Assessment of risk of bias for each included RCT is summarized in Figs. 5 and 6. All of the included studies had a high or unclear risk of bias in almost all domains. For the majority of included RCTs, domains regarding allocation concealment, blinding of outcome assessment, selective reporting and other sources of bias were rated as unclear risk of bias. Only two trials [19,39] reported blinding of outcome assessment. For the domain of random sequence generation, risk of bias for 6 trials were rated as high; ten were rated as low and 17 were rated as unclear. In addition, only one study [30] reported the numbers of withdrawals from the trial during the treatment course. None of the trials had intention to treatment analysis (ITT).

3.7. Quality of evidence

The quality of evidence for outcome measures is presented in Table 2. Overall, the quality of all the evidence measured using the GRADE system was assessed as ‘low’ or ‘very low’, which was downgraded mainly due to lack of blinding/allocation concealment, the small sample sizes of the individual studies, the heterogeneity related to the settings and interventions, and the potential for publication bias. Thus, currently available evidence is too weak to recommend the practice of acupuncture as a common treatment option for patients with PTN.

4. Discussion

4.1. Summary of the evidence

This SR evaluated the efficacy of acupuncture for treating PTN by extensively retrieving eligible trials. Finally, 33 trials were included. Based on meta-analysis results, it appears that the effect of both MA and EA for improving response rate and reducing recurrence rate is more significant than carbamazepine. Besides, MA has a more positive effect

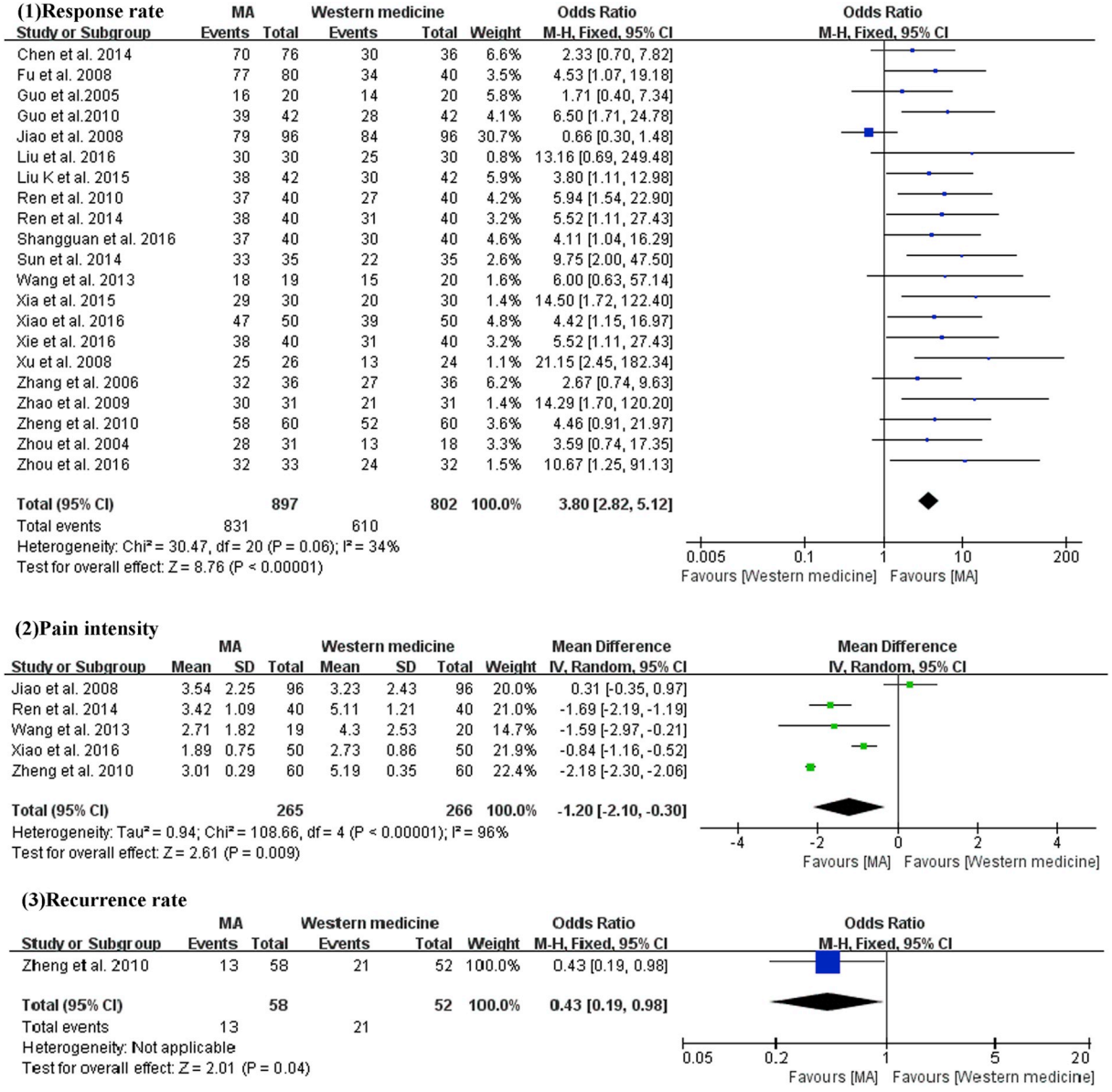

Fig. 2. Forest plot for MA vs. Western medicine. (1) Response rate; (2) Pain intensity; (3) Recurrence rate. MA = manual acupuncture; CI: confidence interval.

than carbamazepine on alleviating pain intensity, while EA is not superior to carbamazepine for alleviating pain intensity. Moreover, acupuncture combined with carbamazepine is more effective for improving response rate than carbamazepine alone, while the effectiveness of acupuncture combined with carbamazepine for alleviating pain intensity was only equal to carbamazepine alone. In addition, safety evaluation revealed that acupuncture was generally safe.

Nevertheless, aside from limitations related to the overall low methodological quality of the included RCTs, the level of all currently available evidence using the GRADE system is 'low' or 'very low'. This significantly weakens the impact, reliability and applicability of the evidence, meaning that we are very uncertain about the estimates of effect or further studies would be very likely to change the estimate of effect. Thus, the body of evidence identified cannot yet permit a robust conclusion regarding the efficacy of acupuncture for PTN. Rigorously designed and large-scale RCTs with long-term follow-up are urgently required to confirm our findings, which should assure particularly adequate concealment of allocation and blinding of outcome assessors and adopt standardized measurements as the primary outcomes measured at long-term follow-up.

4.2. Strengths and comparison with previous literature

Few SRs regarding the effectiveness of acupuncture for treating PTN have been published. To the best of our knowledge, only one relevant SR [8] has been available in the English language literature. However, this review was published in 2010 and failed to follow formal recommendations for a systematic review, which was not PRISMA-compliant.

Compared with this outdated SR, our study performed a more comprehensive search to include all eligible studies. Subsequently published RCTs in the past few years were all included in our study. Moreover, subgroup analysis based on the clinical perspective was conducted to explore the efficacy of different modalities of acupuncture. The results revealed that both MA and EA might have some positive effects for PTN.

4.3. Implications for future trials

Based on our study, there is still insufficient evidence to support the routine use of acupuncture for treating PTN. Moreover, several problems should be further explored in the future before recommending acupuncture as a treatment option for PTN.

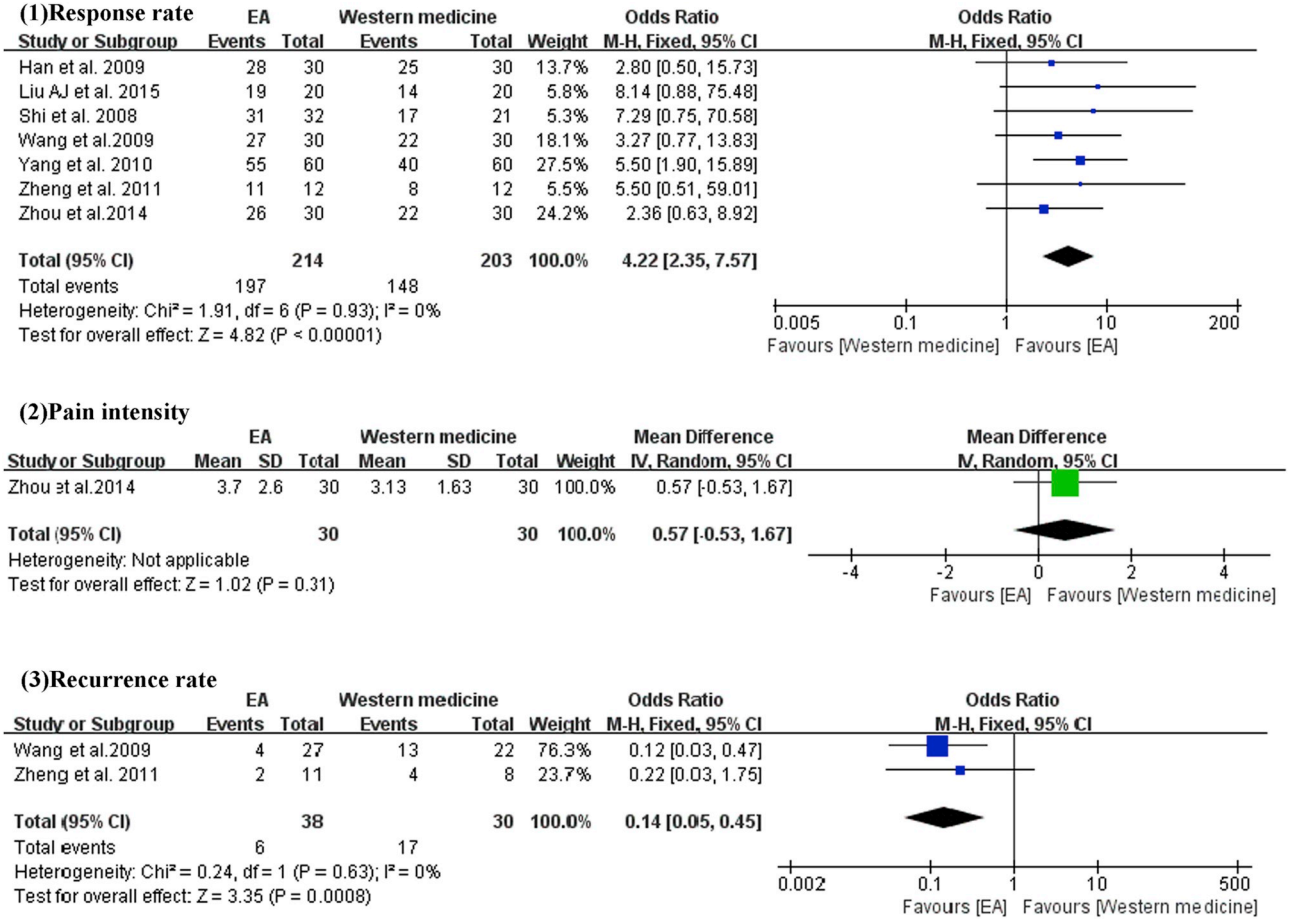

Fig. 3. Forest plot for EA vs. Western medicine. (1) Response rate; (2) Pain intensity; (3) Recurrence rate. EA = electro-acupuncture; CI: confidence interval.

Firstly, the mechanism of acupuncture for treating PTN remains not totally understood. Regarding the etiology and pathogenesis in Western medicine, it is now generally believed that PTN is mostly due to disturbances in the trigeminal nerve, such as microvascular compression of the trigeminal nerve root [43,44]. From the view of traditional Chinese medicine (TCM), the facial pain of PTN is caused by qi stagnation and blood stasis. The stomach meridian is a major meridian distributing in the face. Therefore, acupoints (such as ST7) of this meridian in the facial region play an important role for relieving pain of PTN. Besides, some researchers found that needling deep enough (60 mm) at ST7 (located bilaterally about 2 cm in front of the tragus) could reach the sphenopalatine ganglion [45]. The sphenopalatine nerve, an offshoot of the second trigeminal branch (maxillary nerve), carries sensory and autonomic fibers associated with the face [46]. This might partly explain why acupuncture on ST7 could relieve the pain of PTN from the view of Western medicine. While, from the view of TCM, acupuncture could dredge the meridians and promote the circulation of qi and blood in the face, by which it finally relieves pain.

Secondly, based on our review, different acupoints were chosen and acupuncture manipulation techniques (e.g. deep or superficial needling,

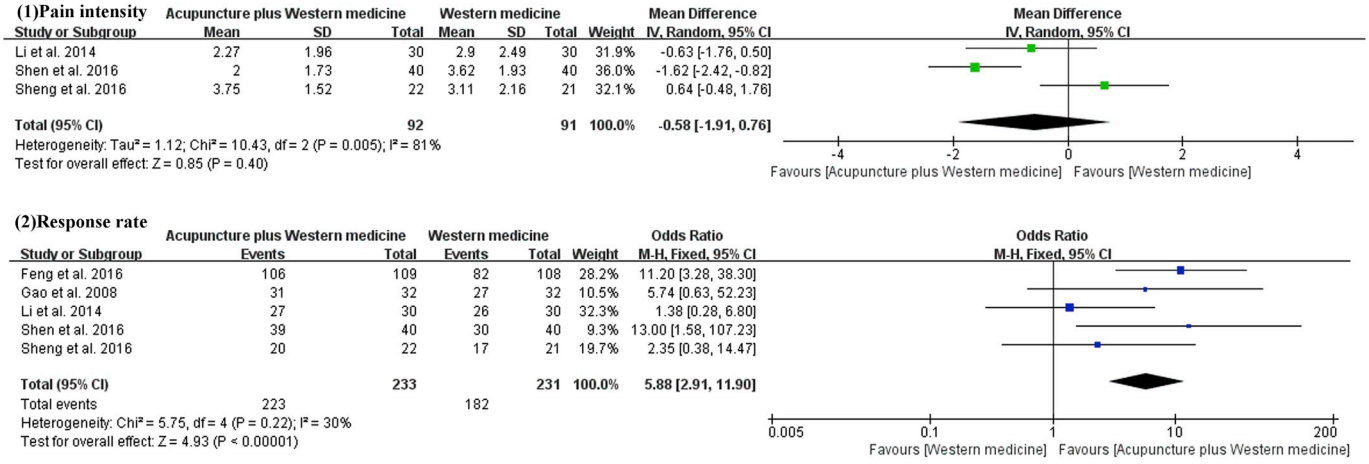

Fig. 4. Forest plot for Acupuncture plus Western medicine vs. Western medicine. (1) Pain intensity; (2) Response rate; CI: confidence interval.

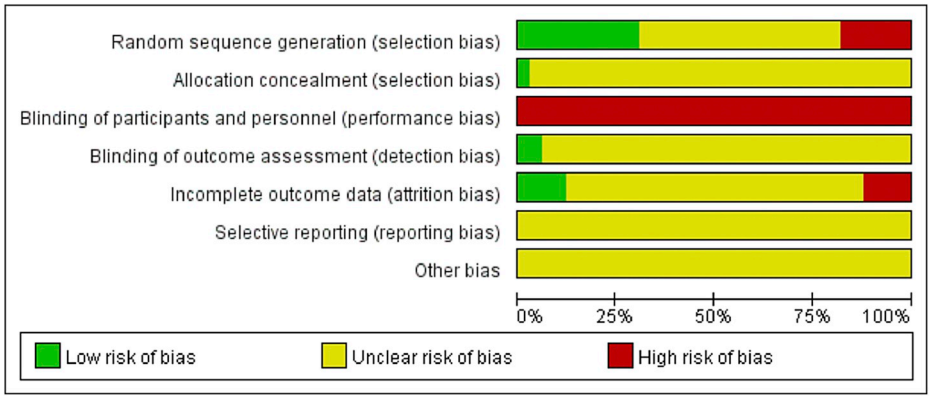

Fig. 5. Risk of bias summary of included RCTs. RCT = randomized controlled trial.

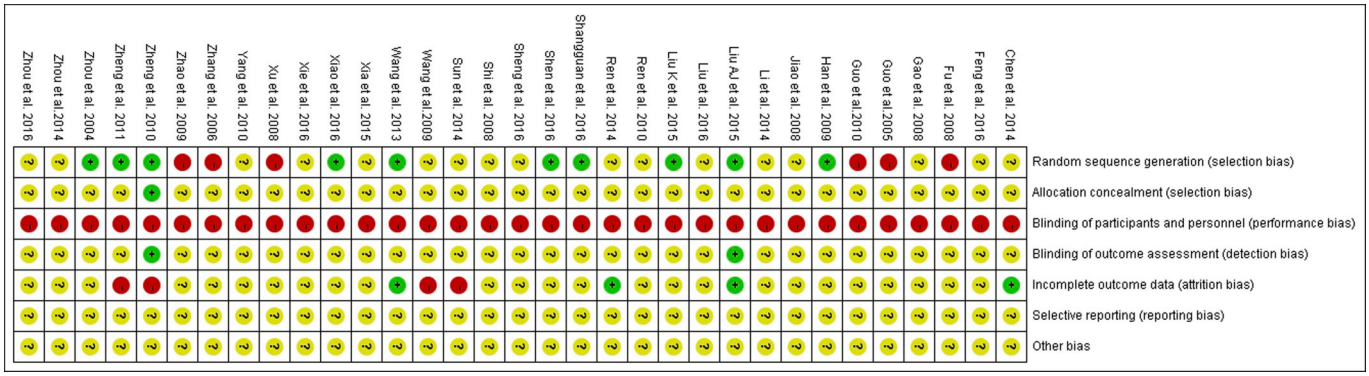

Fig. 6. Risk of bias assessment for each included study.

strong or mild stimulation, eliciting Deqi sensation or not) varied across trials. Besides, the needle retention time, the number of acupuncture sessions and duration of treatment courses varied across trials. All these variances were likely to influence the clinical outcomes of individual studies. It is important to note that the facial hyperalgesia can sometimes result in acute or longer-term worsening of the pain if acupuncture (especially using deep needling or strong needle stimulation) is performed in the facial neuralgic region, which might be one major problem with acupuncture in PTN. Thus, it seems that a majority of researchers tend to recommend superficial needling or mild needle stimulation in the neuralgic area when treating PTN with acupuncture [47]. By contrast, some acupuncturists think that performing deep needling or achieving strong sensation in some acupoints (such as ST7, SI18 and EX-HN5) of the facial neuralgic region will produce more significant clinical effect [48]. However, no agreement has been reached yet on this topic. Therefore, more clinical trials with rigorous methodology should be conducted to investigate what kind of acupuncture methods and acupoints are more suitable for treating PTN [49]. Only then could these researches be used to produce reliable evidence-based recommendations for the contemporary practice of acupuncture.

4.4. Implications for future research

High-quality RCTs is not only the foundation of health assessment reports and policy decision reports, but also an important part for conducting authoritative SRs. In order to judge the validity of RCTs, researchers and readers should be informed of all the important aspects in details. In regard to methodological quality of the included studies in this SR, most trials failed to adequately report methodological items involving allocation concealment, blinding of participants/personnel and blinding of outcome assessment, which in turn greatly reduced the quality of RCTs. Consequently, for future research, the design, performance and reporting of RCTs should be more rigorous, which could be achieved by training of researchers, using standardized reporting criterion such as the 'Consolidated Standards of Reporting Trials' for TCM [50]. In addition, reporting of detailed accounts of patient withdrawals and loss during trials or intent-to-treat analysis should be strengthened.

4.5. Limitations

Several limitations of this meta-analysis should be addressed. Firstly, this meta-analysis included lots of RCTs that were associated with a high risk of bias. In the future, more large-scale, rigorously designed, multicenter, randomized, placebo-controlled trials are warranted. Secondly, due to the small number of studies conducting follow-ups, this meta-analysis was unable to assess the long-term effect of acupuncture for treating PTN. Thirdly, all included RCTs were conducted in China. Therefore, the findings might be specific to this subset of Asian populations. More trials are warranted in Western countries. In the future, when more RCTs are available in the English literature, our systematic review will be updated.

5. Conclusions

Current evidence reveals that acupuncture might have some positive effects for treating PTN and it is safe. Nevertheless, all current evidence is very limited due to the overall low methodological quality of the included RCTs. The level of all currently available evidence is low or very low. Thus, the body of evidence identified cannot yet permit a robust conclusion regarding the efficacy of acupuncture for treating PTN. Large-scale, long-term RCTs with rigorous methodological input are urgently required to confirm the outcome validity of this review. Current evidence remains insufficient to recommend acupuncture as a common treatment option for PTN.

Table 2
GRADE evidence profile in the meta-analysis.

Certainty assessment							№ of patients		Effect		Certainty
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Experimental group	Western medicine	Relative (95% CI)	Absolute (95% CI)	
Response rate - MA vs. Western medicine											
21	Randomized	Serious [a]	Not serious	Not serious	Not serious	Publication bias strongly suspected [b]	831/897 (92.6%)	610/802 (76.1%)	OR 3.80 (2.82–5.12)	163 more per 1000 (from 139 more to 181 more)	⊕⊕◯◯ LOW
Pain intensity - MA vs. Western medicine											
5	Randomized	Serious[a]	serious[c]	Not serious	Not serious	Publication bias strongly suspected[b]	265	266	–	MD 1.2 lower (2.1 lower to 0.3 lower)	⊕◯◯◯ VERY LOW
Recurrence rate - MA vs. Western medicine											
1	Randomized	Serious[a]	Not serious	Not serious	Serious[d]	None	13/58 (22.4%)	21/52 (40.4%)	OR 0.43 (0.19–0.98)	178 fewer per 1000 (from 5 fewer to 290 fewer)	⊕⊕◯◯ LOW
Response rate - EA vs. Western medicine											
7	Randomized	Serious[a]	Not serious	Not serious	Not serious	Publication bias strongly suspected[b]	197/214 (92.1%)	148/203 (72.9%)	OR 4.22 (2.35–7.57)	190 more per 1000 (from 134 more to 224 more)	⊕⊕◯◯ LOW
Pain intensity - EA vs. Western medicine											
1	Randomized	Serious[a]	Not serious	Not serious	Serious[d]	None	30	30	–	MD 0.57 higher (0.53 lower to 1.67 higher)	⊕⊕◯◯ LOW
Recurrence rate - EA vs. Western medicine											
2	Randomized	Serious[a]	Not serious	Not serious	Serious[d]	Publication bias strongly suspected[b]	6/38 (15.8%)	17/30 (56.7%)	OR 0.14 (0.05–0.45)	412 fewer per 1000 (from 196 fewer to 505 fewer)	⊕◯◯◯ VERY LOW
Pain intensity - Acupuncture combined with Western medicine VS Western medicine											
3	Randomized	Serious[a]	serious[c]	Not serious	Serious[d]	Publication bias strongly suspected[b]	92	91	–	MD 0.58 lower (1.91 lower to 0.76 higher)	⊕◯◯◯ VERY LOW
Response rate - Acupuncture combined with Western medicine VS Western medicine											
5	Randomized	Serious[a]	Not serious	Not serious	Not serious	Publication bias strongly suspected[b]	223/233 (95.7%)	182/231 (78.8%)	OR 5.88 (2.91–11.90)	168 more per 1000 (from 127 more to 190 more)	⊕⊕◯◯ LOW

Abbreviations: CI: Confidence interval; EA, Electro-acupuncture; GRADE: Grading of Recommendations, Assessment, Development and Evaluation; OR: Odds ratio; MA, Manual acupuncture; MD: Mean difference.
Support for judgement:
[a] Most studies had a high risk of bias in methodology.
[b] All studies were from China.
[c] Considerable heterogeneity.
[d] Total number of events is < 300.

Conflicts of interest

The authors declare no conflicts of interest.

Disclosure statement

The authors have nothing to disclose.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.ctcp.2018.12.013.

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