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Efficacy and safety of acupuncture for hypertension: An overview of systematic reviews

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ABSTRACT

Background and purpose: Acupuncture is widely used in the treatment of hypertension, yet its efficacy and safety for hypertension remain controversial. This overview aimed to summarize the evidence on acupuncture for hypertension.

Methods: Eight databases were searched. The Assessment of Multiple Systematic Reviews (AMSTAR) tool and the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach were performed.

Results: Fifteen systematic reviews (SRs) were identified. Methodological quality and quality of evidence were unsatisfactory. Acupuncture combined with Western medicine (WM) was superior to WM in systolic blood pressure (SBP) and diastolic blood pressure (DBP), efficacy rate, and traditional Chinese medicine (TCM) syndrome. Acupuncture was more effective in treating SBP and DBP than sham acupuncture plus WM. Evidence regarding the benefit of acupuncture alone for SBP and DBP, efficacy rate and TCM syndrome was inconsistent. No serious adverse effects were identified.

Conclusion: High-quality SRs and randomized controlled trials (RCTs) are required.

1. Introduction

Hypertension is the most common public health issue worldwide and is defined as systolic blood pressure (SBP) equal to or greater than 140 mm Hg and/or diastolic blood pressure (DBP) equal to or greater than 90 mm Hg [1,2]. It has been recognized as a complex disease that is determined by numerous risk factors, such as genetics, age, ethnicity, socioeconomic status, psychosocial stressors, dietary factors, and their interaction [3]. One study found that the number of adults with hypertension was 972 million (957–987 million) in 2000 and that this number will increase by approximately 60% to 1.56 billion (1.54–1.58 billion) in 2025 [4]. In addition, hypertension may result in harmful consequences if not detected early and treated appropriately, such as cardiovascular disease, stroke, and renal failure [1]. Hypertension is also considered the leading cause of mortality and is ranked third as a risk factor for disability-adjusted life-years [5]. Given the high prevalence and substantial negative effects of hypertension, it is therefore important to find effective, sustainable, and affordable treatment regimens for patients.

Pharmacological treatments have appeared to be effective in improving important health outcomes for patients with hypertension [6]. Currently, pharmacological treatments include six classes of antihypertensive agents and fixed compound preparations [7]. Despite pharmacological treatments available, there is poor blood pressure (BP) control for most patients treated with antihypertensive agents [8]. Even patients who reach the recommended BP treatment goal may still have high cardiovascular morbidity and mortality risk [9]. Consequently, patients often seek for a new effective method to manage their condition.

Complementary and alternative medicine (CAM) is accepted and widely practised in the United States, as an important complement to conventional medicine [10]. Available studies show that CAM should be offered to patients wanting to lower their elevated BP [11,12]. Acupuncture is one of treatment modalities of CAM and refers to the insertion of one or several needles into the skin at acupuncture points for therapeutic purposes [13]. It originated in ancient China and has been used for at least 2500 years [14]. Related therapies, such as electro-acupuncture and moxibustion, are also increasingly being used,

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either separately or in conjunction with acupuncture [15]. In recent years, these therapies have become more popular among hypertensive patients [16,17].

Due to the popularity of acupuncture, a number of randomized controlled trials (RCTs) have been conducted to test its efficacy and safety for use in treating hypertension [18–21]. These RCTs sometimes reach contradictory conclusions, making systematic reviews (SRs) or meta-analyses indispensable. SRs of RCTs are considered the best source of evidence to assess the efficacy of a particular intervention [22,23]. The first systematic review (SR) covering a total of 4 RCTs was published in 2009 by Lee and colleagues [24]. Subsequently, several new reviews have investigated the effectiveness of acupuncture for treating hypertension. However, the results of SRs are conflicting, and the conclusions are limited by the quantity and quality of the included studies. An overview is a new approach designed to synthesize the results from multiple SRs [25]. To overcome the limitations of an individual SR and to provide comprehensive evidence, an overview of SRs is required.

To the best of our knowledge, no overview has focused on the efficacy and safety of acupuncture for use in treating hypertension. Therefore, we conducted an overview of SRs to synthesize and critically appraise the available evidence on the use of acupuncture for treating hypertension.

2. Methods

2.1. Inclusion criteria

This overview of SRs was performed in accordance with guidelines introduced by the Cochrane Collaboration [25]. Studies were included if they fulfilled the following criteria: (1) SRs or meta-analyses of RCTs evaluated the efficacy and safety of acupuncture for hypertension. Based on the definition of a SR outlined by the Cochrane Collaboration, we required that each SR formulated a specific objective, defined an explicit methodology, implemented a comprehensive search, conducted a critical assessment of the included studies, and synthesized the evidence [25]; (2) patients were diagnosed as hypertensive if SBP ≥ 140 mm Hg and/or DBP ≥ 90 mm Hg, and there were no restrictions regarding age, gender, nationality, or ethnic background; (3) the interventions were needle acupuncture, electro-acupuncture, auricular acupuncture, moxibustion, acupressure, or any combination of the above. Studies on acupuncture combined with Western medicine (WM) were also included. For control treatments, we included WM, sham acupuncture, no treatment, or any combination of the above; and (4) each SR reported at least one of the following efficacy or safety outcomes: BP; efficacy rate; traditional Chinese medicine (TCM) syndrome; or adverse events. The term 'adverse events' refers to all harmful effects associated with acupuncture. The definitions and grades of the efficacy rate and TCM syndrome were described in Table 1.

2.2. Exclusion criteria

The following were excluded: (1) commentaries, guidelines, editorials and narrative reviews; (2) SRs of other study designs, such as quasi-RCTs and non-RCTs; (3) SRs covering laser acupuncture, acupoint injection or transcutaneous electrical nerve stimulation (TENS) as treatment interventions; and (4) SRs comparing the efficacy of different acupuncture modalities.

2.3. Search methods for identification of reviews

We comprehensively searched four international databases (MEDLINE, EMBASE, the Cochrane Database of Systematic Reviews and the Database of Abstracts of Reviews of Effects) and four Chinese databases (Chinese National Knowledge Infrastructure, Chinese Biomedical Database, Chinese Scientific Journal Database and Wanfang Databases) from inception to July 19, 2017, and we did not limit the search by publication status. The search terms used were as follows: ("acupuncture" OR "electro-acupuncture" OR "auricular acupuncture" OR "moxibustion" OR "acupressure") AND ("blood pressure" OR "hypertension" OR "high blood pressure") AND ("systematic review" OR "meta-analysis"). Additional studies were identified through the reference lists in an included SR [29].

2.4. Data collection and analysis

2.4.1. Selection of reviews

First, all retrieved titles and abstracts were assessed for potentially relevant studies according to the inclusion criteria and exclusion criteria. After screening by titles and abstracts, full-text articles were obtained for further scrutiny. The selection process was independently conducted by two authors (HMZ and YY), and disagreements at each step were resolved through discussion and consultation with a third author (JL).

2.4.2. Data extraction

The following data were extracted using a standardized form from the included SRs: study characteristics (e.g., first author, year of publication, search dates, and number of included studies), patient characteristics (e.g., sample size), study methods (e.g., interventions in experimental/control groups), and outcome measures (e.g., BP, efficacy rate, TCM syndrome and adverse events). Data extraction was respectively performed by two authors (HMZ and YTL), and discrepancies were resolved through discussion and consultation with a third author (JL). We attempted to contact authors to obtain further information that we may have missed, as necessary.

Table 1
The definitions and grades of the efficacy rate and TCM syndrome.

Outcomes	Definitions	Grades	Descriptions
Efficacy rate	The efficacy rate is defined as the percentage of the total number of patients who were categorized in the first two levels [26].	Markedly effective	DBP decreased by more than 10 mm Hg reaching the normal range or DBP that did not return to normal but decreased by more than 20 mm Hg after treatment [26].
		Effective	DBP decreased by less than 10 mm Hg and reached the normal range, DBP decreased by 10–19 mm Hg but did not reach the normal range, or SBP decreased by more than 30 mm Hg after treatment [26].
		Ineffective	Not meeting the above standards [26].
TCM syndrome	TCM syndrome is defined as a combination of symptoms and signs with internal relationships to each other that occur in a patient at a specific stage during the course of a disease [27,28].	Markedly effective	Clinical symptoms and signs improved markedly, and syndrome score reduced by at least 70% [26].
		Effective	Clinical symptoms and signs improved, and syndrome score reduced by 30–69% [26].
		Ineffective	Clinical symptoms and signs did not improve, and syndrome score reduced by less than 30% [26].

TCM, traditional Chinese medicine; SBP, systolic blood pressure; DBP, diastolic blood pressure.

2.5. Quality assessment

2.5.1. Methodological quality

The methodological quality of all included SRs was evaluated independently by two authors (HMZ and YY) using the Assessment of Multiple Systematic Reviews (AMSTAR) tool [30], which is composed of 11 items. Each item was assigned a score of 1 (yes) or 0 (no, can't answer, or not applicable), and the results were summed to generate a total score that ranged from 0 to 11. Generally, studies with a score of 8–11 were considered high quality, those with a score of 4–7 were considered moderate quality, and those with a score of 0–3 were considered low quality [31]. Differences in study assessment were resolved through discussion and consultation with a third author (JL).

The quality of primary RCTs within the SRs was not reassessed. However, study quality was reported based on the SR authors' assessments.

2.5.2. Quality of evidence

Two authors (HMZ and DL) used the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach to assess the quality of evidence for each outcome [25]. The GRADE approach categorizes the quality of evidence as high, moderate, low, and very low. Evidence is graded as high based on RCTs and may be downgraded for the following five reasons: (1) risk of bias; (2) indirectness of evidence; (3) unexplained heterogeneity or inconsistency of results; (4) imprecision of results; and (5) publication bias. Any disagreement was resolved through discussion and consultation with a third author (JL).

2.6. Data synthesis

A quantitative analysis of the included SRs was not performed due to information from overlapping RCTs between SRs. Instead, a qualitative synthesis of the included studies was reported. Literature search results and data extraction results were summarized descriptively. To exclude duplicate RCTs, two authors (HMZ and YY) reviewed all of the RCTs in each SR. Two authors (HMZ and DL) presented a summary of efficacy outcomes based on the different outcome measures, controls and interventions. We reported a narrative synthesis considering the total number of SRs that reported results, the methodological quality of SRs and RCTs, and the quality of evidence for the outcomes to yield final conclusions.

3. Results

3.1. Results of the literature search

In total, 206 citations were identified by the literature search, and 153 duplicates were excluded before the screening process. Twenty-seven records were excluded on the basis of their titles and abstracts. The remaining 26 articles were retrieved in full-text format for further assessment. Eleven articles were excluded for the following reasons: seven were excluded because the review type did not satisfy the inclusion criteria, and four were excluded because the intervention type did not satisfy the inclusion criteria. Fifteen SRs [17,24,29,32–43] were suitable for inclusion in this overview (Fig. 1).

3.2. Description of the included reviews

The main characteristics of the included SRs were shown in Table 2. The 15 SRs included data from 91 RCTs with 7627 participants and were performed between 2009 and 2017. Of these, 14 SRs provided a cut-off date on their literature searches, with the latest search ran through 2015 [41–43]. Except for one SR [24] that provided a narrative synthesis of results, the SRs conducted meta-analyses. Seven SRs were published in English, and the remaining SRs were published in Chinese. The first authors of the SRs were predominantly based in China (86.67%).

Twelve of the 15 SRs specifically focused on essential hypertension [17,29,33–38,40–43], and the remaining three did not limit the type of hypertension [24,32,39]. In the 15 SRs, five forms of acupuncture interventions were evaluated: needle acupuncture (2 SRs) [34,35], moxibustion (3 SRs) [17,24,36], auricular pressure (4 SRs) [40–43], needle acupuncture or electro-acupuncture (4 SRs) [29,33,38,39], and needle acupuncture, electro-acupuncture, or auricular acupuncture (2 SRs) [32,37].

Four types of end points were reported among the identified SRs; 11 SRs provided outcomes on BP, 11 SRs reported adverse events, eight SRs reported efficacy rate, and five SRs reported TCM syndrome.

3.3. Assessment of methodological quality and quality of evidence

3.3.1. Methodological quality

Only one of the 15 SRs (6.67%) was classified as high quality, 11 out of 15 (73.33%) were classified as medium quality, and three out of 15 (20.00%) were classified as low quality. Overall, among the 15 SRs, the mean AMSTAR score was 5.2, indicating that methodological quality was not satisfactory. The main reasons for a SR to lose points on AMSTAR were the following: not providing an 'a priori' design (100%), not having a list of both included and excluded studies (100%), not assessing publication bias (73.33%), and not reporting conflicts of interest (60%). The details of the quality assessment were reported in Table 3.

All SRs appraised the quality of the included RCTs; 12 SRs (80%) used the risk bias tool recommended by the Cochrane Handbook for Systematic Reviews of Interventions, two (13.33%) used the Jadad scale, and one (6.67%) used the modified Oxford scale. The majority of these SRs reported that the included studies were of generally low quality. The main problems with the included RCTs were presented in Table 4.

3.3.2. Quality of evidence

The quality of evidence for 35 outcomes in 15 included SRs was presented in Table 5. Of the 35 outcomes, 4 provided high quality evidence (11.42%), seven provided moderate quality evidence (20.00%), 12 provided low quality evidence (34.29%), and 12 provided very low quality evidence (34.29%). Risk of bias (82.86%) was the most common of the downgrading factors in the included reviews, followed by publication bias (42.86%), inconsistency (11.42%), imprecision (8.57%), and indirectness (0.00%).

3.4. Efficacy of the interventions

3.4.1. BP

Eleven SRs [17,24,29,32,33,35–37,39,41,43] (quality range = 2–8, 50 RCTs, 3939 participants) included BP as an outcome measure. Ten of these SRs were conducted meta-analyses.

3.4.1.1. Acupuncture versus WM. Six SRs [17,24,29,33,35,39] (quality range = 3–8) encompassing 24 RCTs (1922 participants) reported conflicting conclusions regarding the effectiveness of acupuncture in treating BP when compared with WM. Four SRs [17,24,29,39] (quality range = 6–8) found no evidence of benefits from acupuncture when compared with WM on SBP, and there was no evidence of a difference between acupuncture and WM on DBP, as reported in five SRs [17,24,29,33,39] (quality range = 6–8). However, two SRs [33,35] (quality range = 3–7) found that acupuncture was superior to WM in reducing SBP, and one SR [35] (quality = 3) found that acupuncture also had better outcomes in reducing DBP when compared with WM.

3.4.1.2. Acupuncture versus sham acupuncture. Five SRs [29,32,33,35,37] (quality range = 3–8) encompassing 5 RCTs (440 participants) consistently showed no significant difference between acupuncture and sham acupuncture for both SBP and DBP.

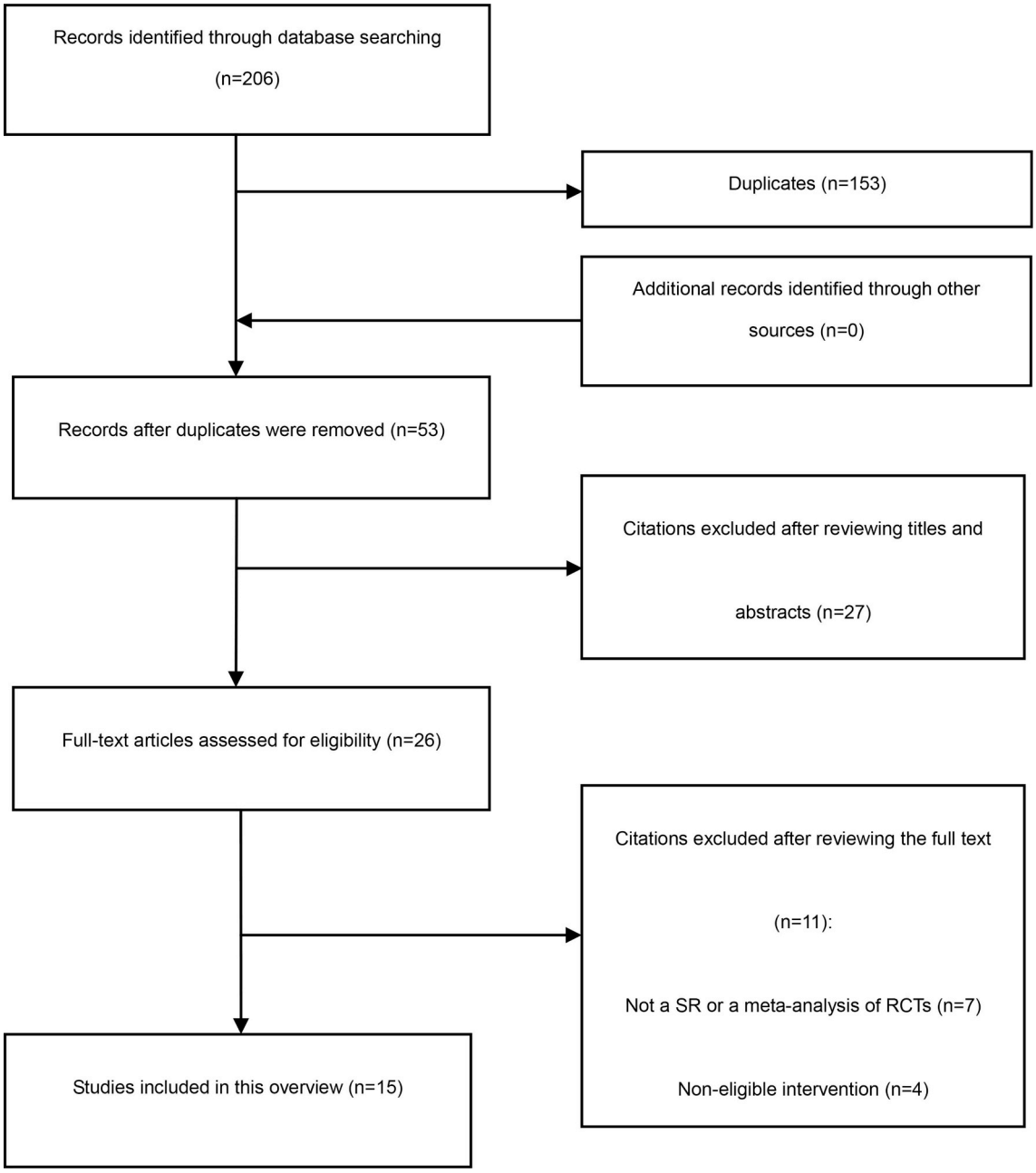

Fig. 1. Flowchart of literature selection from systematic reviews of acupuncture for the treatment of hypertension.

3.4.1.3. Acupuncture versus no treatment. One SR [24] (quality = 6) encompassing 1 randomized controlled trial (RCT) (61 participants) found positive effects of acupuncture for lowering SBP, but no positive effects for lowering DBP when compared with no treatment.

3.4.1.4. Acupuncture versus sham acupuncture plus WM. One SR [29] (quality = 8) encompassing 2 RCTs (170 participants) reported that acupuncture significantly reduced SBP and DBP when compared with sham acupuncture plus WM.

3.4.1.5. Acupuncture plus WM versus WM. Eight SRs [17,24,29,35,36,39,41,43] (quality range = 2–8) encompassing 25 RCTs (1903 participants) reported inconsistent conclusions regarding the effectiveness of acupuncture for treating BP when compared with WM. One SR [39] (quality = 6) showed no favourable effects of acupuncture combined with WM on SBP when compared with WM alone, and no evidence was found showing a difference between acupuncture plus WM and WM alone on DBP in two SRs [36,39] (quality range = 4–6). In contrast, seven SRs [17,24,29,35,36,41,43] (quality range = 2–8) indicated that acupuncture combined with WM was superior to WM alone in reducing SBP, and six SRs [17,24,29,35,41,43] (quality range = 2–8) indicated that acupuncture combined with WM was also statistically favoured over WM alone in reducing DBP.

3.4.1.6. Acupuncture plus WM versus sham acupuncture plus WM. Two SRs [32,37] (quality range = 6–7) encompassing 2 RCTs (170 participants) consistently suggested that acupuncture combined with WM was more effective than sham acupuncture plus WM in reducing both SBP and DBP.

3.4.2. Efficacy rate

Eight SRs [33,34,38–43] (quality range = 2–7, 47 RCTs, 4191 participants) reported efficacy rate, and all were meta-analyses.

Table 2
Characteristics of the included systematic reviews on the use of acupuncture for treating hypertension.

Study ID	Country	Search period	Condition	Nature of the acupuncture treatment and related interventions	Nature of the control interventions	Number of primary studies included	Number of participants included	Meta-analysis	Outcome measures
Lee, 2009	South Korea	Inception-2007	No restriction on hypertension type	Needle acupuncture, electro-acupuncture, or auricular acupuncture with or without WM.	Sham acupuncture, WM or sham acupuncture plus WM	11	847	Yes	BP, adverse events
Kim, 2010	South Korea	Inception-2010	No restriction on hypertension type	Moxibustion with or without WM.	WM or no treatment	4	241	No	BP, TCM syndrome
Tang, 2011	China	Inception-2010	Essential hypertension	Needle acupuncture, electro-acupuncture with or without WM.	Sham acupuncture, no treatment, or WM	9	735	Yes	Efficacy rate, BP, TCM syndrome, adverse events
Liu, 2012	China	Inception-2010	Essential hypertension	Needle acupuncture with or without WM.	WM	10	782	Yes	Efficacy rate, TCM syndrome, adverse events
Zhang, 2013	China	2007–2012	Essential hypertension	Needle acupuncture with or without WM.	Sham acupuncture or WM	11	1072	Yes	BP, adverse events
Wang, 2013	China	Inception-2013	Essential hypertension	Needle acupuncture, electro-acupuncture with or without WM.	WM, sham acupuncture, sham acupuncture plus WM	35	2539	Yes	BP, adverse events
Yang, 2014	China	1980–2013	Essential hypertension	Moxibustion with or without WM.	WM or no treatment	4	250	Yes	BP, adverse events
Xiong, 2014	China	Inception-2013	Essential hypertension	Moxibustion with or without WM.	WM or no treatment	5	357	Yes	BP, adverse events
Li, 2014	China	Inception-2012	Essential hypertension	Needle acupuncture, electro-acupuncture, or auricular acupuncture with or without WM.	Sham acupuncture	4	386	Yes	BP, adverse events
Xiao, 2015	China	2004–2014	Essential hypertension	Needle acupuncture, electro-acupuncture with or without WM.	Sham acupuncture, no treatment or WM	15	1118	Yes	Efficacy rate, adverse events
Zhao, 2015	China	Inception-2014	No restriction on hypertension type	Needle acupuncture, electro-acupuncture with or without WM.	Sham acupuncture or WM	23	1788	Yes	Efficacy rate, BP, adverse events
Zhang, 2016	China	NR	Essential hypertension	Auricular pressure with or without WM.	WM	14	1683	Yes	Efficacy rate, TCM syndrome, adverse events
Yang, 2016	China	Inception-2015	Essential hypertension	Auricular pressure plus WM.	WM	15	1435	Yes	Efficacy rate, BP, TCM syndrome
Zhang, 2016	China	1980–2015	Essential hypertension	Auricular pressure plus WM.	WM	8	1066	Yes	Efficacy rate
Zhang, 2017	China	Inception-2015	Essential hypertension	Auricular pressure with or without WM.	WM	9	919	Yes	Efficacy rate, BP

WM, Western medicine; BP, blood pressure; TCM, traditional Chinese medicine; NR, not reported.

Table 3
The quality assessment of the included systematic reviews on the use of acupuncture for treating hypertension.

	Lee, 2009	Kim, 2010	Tang, 2011	Liu, 2012	Zhang, 2013	Wang, 2013	Yang, 2014	Xiong, 2014	Li, 2014	Xiao, 2015	Zhao, 2015	Zhang, 2016	Yang, 2016	Zhang, 2016	Zhang, 2017
1. Was an 'a priori' design provided?	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
2. Was there duplicate study selection and data extraction?	CA	Y	Y	Y	CA	Y	CA	Y	Y	Y	Y	Y	Y	CA	Y
3. Was a comprehensive literature search performed?	Y	Y	Y	Y	N	Y	N	Y	Y	N	Y	CA	Y	Y	N
4. Was status of publication (e.g. grey literature) used as an inclusion criterion?	Y	Y	N	N	CA	Y	Y	Y	Y	N	Y	Y	CA	CA	CA
5. Was a list of studies (included and excluded provided)?	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
6. Were the characteristics of the included studies provided?	Y	Y	Y	CA	Y	Y	CA	CA	Y	CA	Y	CA	CA	CA	N
7. Was the scientific quality of the included studies assessed and reported?	Y	CA	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	CA
8. Was the scientific quality of the included studies used appropriately in formulating conclusions?	Y	Y	Y	Y	Y	Y	Y	Y	CA	Y	Y	CA	Y	CA	Y
9. Were the methods used to combine the findings of studies appropriate?	CA	NA	Y	Y	CA	CA	CA	CA	Y	Y	CA	Y	Y	Y	CA
10. Was the likelihood of publication bias assessed?	N	NA	Y	N	N	Y	CA	N	N	Y	CA	CA	Y	CA	N
11. Was the conflict of interest stated?	Y	Y	N	N	N	Y	Y	Y	Y	N	N	N	N	N	N
Total score	6	6	7	5	3	8	4	6	7	5	6	4	6	3	2

N, no; Y, yes; CA, can't answer; NA, not applicable.

3.4.2.1. Acupuncture versus WM. Five SRs [33,34,38–40] (quality range = 2–7) including 24 RCTs (2266 participants) reported conflicting results regarding the advantages of acupuncture in terms of its efficacy rate relative to WM. Four SRs [33,34,39,40] (quality range = 4–7) revealed no significant difference between acupuncture and WM in terms of efficacy rate, whereas the remaining SR [38] (quality range = 2–5) showed that acupuncture had a greater efficacy rate than WM.

3.4.2.2. Acupuncture versus sham acupuncture. No SRs found any RCT that compared the effect of acupuncture on efficacy rate to that of sham acupuncture.

3.4.2.3. Acupuncture versus no treatment. No SRs found any RCT that compared the effect of acupuncture on efficacy rate to that of no treatment.

3.4.2.4. Acupuncture versus sham acupuncture plus WM. No SRs found any RCT that compared the effect of acupuncture on efficacy rate to that of sham acupuncture plus WM.

3.4.2.5. Acupuncture plus WM versus WM. Seven SRs [34,38–43] (quality range = 2–6) including 25 RCTs (2335 participants) consistently reported that the effect of acupuncture combined with WM was superior to that of WM alone.

3.4.2.6. Acupuncture plus WM versus sham acupuncture plus WM. No SRs found any RCT that compared the effect of acupuncture plus WM to sham acupuncture plus WM.

3.4.3. TCM syndrome

Five SRs [24,33,34,40,41] (quality range = 4–7, 15 RCTs, 1343 participants) provided data on TCM syndrome, and four of these SRs were meta-analyses.

3.4.3.1. Acupuncture versus WM. Three SRs [24,33,34] (quality range = 5–7) containing 7 RCTs (433 participants) reported contradictory evidence regarding the benefits of acupuncture on TCM syndrome when compared with WM. One SR [24] (quality = 6) showed no significant difference in TCM syndrome between acupuncture and WM, but the remaining two SRs [33,34] (quality range = 5–7) found that acupuncture produced a significant effect on TCM syndrome when compared with WM.

3.4.3.2. Acupuncture versus sham acupuncture. No SRs found any study that compared the effects of acupuncture versus sham acupuncture on TCM syndrome.

3.4.3.3. Acupuncture versus no treatment. No SRs found any study that compared the effects of acupuncture versus no treatment on TCM syndrome.

3.4.3.4. Acupuncture versus sham acupuncture plus WM. No SRs found any study that compared the effects of acupuncture versus sham acupuncture plus WM on TCM syndrome.

3.4.3.5. Acupuncture plus WM versus WM. Three SRs [34,40,41] (quality range = 4–6) containing 8 RCTs (910 participants) consistently demonstrated that the effects of acupuncture combined with WM on TCM syndrome were better than those of WM alone.

3.4.3.6. Acupuncture plus WM versus sham acupuncture plus WM. No SRs found any study that compared the effects of acupuncture plus WM versus sham acupuncture plus WM on TCM syndrome.

Table 4
The quality of the included RCTs in systematic reviews on the use of acupuncture for the treatment of hypertension.

Study ID	Quality assessment tools	The main problems
Lee, 2009	Modified Oxford scale	The methodological quality of the included trials in our review was generally poor. More specifically, only two sham-controlled studies were awarded the maximum points of 5 on the modified Oxford scale. One study received four points, because it was not assessor-blinded, and another study got three points for being randomized, subject blinding, and reporting withdrawals and dropouts. The other seven included studies suffered from poor methodological quality of one or two points. Regarding the credibility of a sham control, only one of the three sham-controlled trials examined the success of subject blinding.
Kim, 2010	Cochrane Handbook for Systematic Reviews of Interventions	None of the included RCTs reported any methods of sequence generation or allocation concealment. One trial mentioned drop-outs and withdrawals. All of the included RCTs failed to report evaluator blinding.
Tang, 2011	Cochrane Handbook for Systematic Reviews of Interventions	Most studies were described as 'random' without providing details on random sequence generation. Only one study implemented adequate allocation concealment and blinding.
Liu, 2012	Jadad scale	Most of the included studies did not describe allocation concealment, blinding and loss to follow-up.
Zhang, 2013	Cochrane Handbook for Systematic Reviews of Interventions	All RCTs did not describe the details of allocation concealment. The successful implementation of blinding was not reported. For selective outcome reporting and other sources of bias, only one study was rated as low risk.
Wang, 2013	Cochrane Handbook for Systematic Reviews of Interventions	The methodological quality of most included trials was generally poor. The randomized allocation of participants was mentioned in all trials; however, most trials did not state the randomization method. Allocation concealment was only mentioned in four RCTs. Double-blind was not mentioned in all trials. Only one trial reported drop-outs or withdrawals. No trials used an intention-to-treat analysis. None of the trials had a pre-trial estimation of sample size. Selective reporting was generally unclear in the RCTs.
Yang, 2014	Cochrane Handbook for Systematic Reviews of Interventions	None of the included RCTs reported any methods of sequence generation or allocation concealment. All of the included RCTs failed to report evaluator blinding. In addition, only one trial mentioned drop-outs and withdrawals.
Xiong, 2014	Cochrane Handbook for Systematic Reviews of Interventions	The majority of the included trials were assessed to be of poor methodological quality. The randomized allocation of participants was mentioned in all trials; however, only one trial stated the methods for sequence generation. Allocation concealment, blinding of participants and personnel, and blinding of outcome assessment were not mentioned in all trials. No trial reported drop-outs. None of the trials included a pre-trial estimation of sample size.
Li, 2014	Jadad scale	All RCTs included in our meta-analysis were classified as high quality with a mean Jadad score of 4.75.
Xiao, 2015	Cochrane Handbook for Systematic Reviews of Interventions	Allocation concealment, blinding of participants and personnel, and blinding of outcome assessment were not mentioned in most RCTs.
Zhao, 2015	Cochrane Handbook for Systematic Reviews of Interventions	Allocation concealment, blinding of participants and personnel, blinding of outcome assessment, and selective reporting were generally unclear in most trials.
Zhang, 2016	Cochrane Handbook for Systematic Reviews of Interventions	Most studies were labeled as 'random' without details on random sequence generation. Allocation concealment and blinding were not mentioned in most studies.
Yang, 2016	Cochrane Handbook for Systematic Reviews of Interventions	Most studies did not state the method of randomization used. In all studies, allocation concealment was not mentioned. The successful implementation of blinding was not reported in most studies. Regarding selective outcome reporting and other sources of bias, all studies were unclear.
Zhang, 2016	Cochrane Handbook for Systematic Reviews of Interventions	No trial reported allocation concealment, blinding, and drop-outs.
Zhang, 2017	Cochrane Handbook for Systematic Reviews of Interventions	NR

RCTs, randomized controlled trials; NR, not reported.

3.5. Safety of interventions

Eleven SRs [17,29,32–40] (39 RCTs, 1803 participants) evaluated adverse events related to acupuncture. Among them, 4 SRs [17,34,36,40] (34 RCTs, 1789 participants) reported that no adverse events were observed during the interventions. The remaining seven SRs [29,32,33,35,37–39] (5 RCTs, 14 participants) reported mild and transient adverse events including spot-bleeding (9 participants), pain (3 participants), headache (1 participant), and syncope (1 participant). No serious adverse events associated with the acupuncture treatments were reported.

4. Discussion

4.1. Summary of the main results

In this overview of 15 SRs, evidence on the efficacy and safety of acupuncture for hypertension was synthesized from 91 RCTs that included 7627 participants. Overall, the existing evidence suggested that acupuncture plus WM was more effective than sham acupuncture plus WM for treating both SBP and DBP, demonstrating that acupuncture had add-on benefits for WM. Similarly, regarding efficacy rate and TCM syndrome, it was observed that the combination of acupuncture and WM was better than the use of WM alone. When compared with sham acupuncture plus WM, acupuncture showed favourable effects on SBP and DBP. On the other hand, contradictory evidence was found regarding the benefits of acupuncture versus WM in reducing SBP and DBP, and this was also true for efficacy rate and TCM syndrome. Furthermore, conflicting evidence was found regarding the benefits of the combination of acupuncture and WM in reducing SBP and DBP when compared with WM alone. No significant difference was found between acupuncture and sham acupuncture in terms of SBP and DBP reduction. In contrast, acupuncture had positive effects on SBP and no positive effects on DBP when compared with no treatment. Regarding safety, no serious adverse effects were associated with acupuncture.

4.2. Interpretation of findings

As shown in the present study, acupuncture was no more effective than sham acupuncture in controlling SBP and DBP. There are several possible explanations for this finding. It is possible that sham acupuncture had some physiological effects [44]. Needling at non-acupoints may affect the correct receptive field in terms of physiology. Therefore, the physiological responses to needling at incorrect sites may be identical to those of real acupuncture [44]. Another explanation is that sham acupuncture might be associated with particularly potent placebo effects [45]. Relevant factors including treatment setting, patient expectations and attitudes, the acupuncturist's confidence in the treatment, and patient-acupuncturist interaction may influence the outcome [46]. In addition, relatively small sample sizes and short treatment durations may have contributed to the non-significant difference between acupuncture and sham acupuncture. Recent meta-analyses with large sample sizes indicated that acupuncture was statistically superior to sham acupuncture for back and neck pain, osteoarthritis, headache, and shoulder pain [47,48]. Similar results may be observed for hypertension in studies with large numbers. Additional

Table 5
Quality of evidence in the included SRs assessed by the GRADE approach.

Study ID	Outcomes	Risk of bias	Indirectness	Inconsistency	Imprecision	Publication bias	Quality of evidence
Lee, 2009	BP	No	No	No	Serious	No	Moderate
	Adverse events	No	No	No	No	No	High
Kim, 2010	BP	Very serious	No	No	No	No	Low
	TCM syndrome	Very serious	No	No	No	No	Low
Tang, 2011	BP	Serious	No	No	No	No	Moderate
	Efficacy rate	Very serious	No	No	No	Serious	Very low
	TCM syndrome	Very serious	No	No	No	No	Low
	Adverse events	Serious	No	No	No	No	Moderate
Liu, 2012	Efficacy rate	No	No	No	No	No	High
	TCM syndrome	Very serious	No	No	Serious	No	Very low
	Adverse events	No	No	No	No	No	High
Zhang, 2013	BP	Serious	No	Very serious	No	No	Very low
	Adverse events	Serious	No	No	No	No	Moderate
Wang, 2013	BP	Serious	No	Very serious	No	Serious	Very low
	Adverse events	Serious	No	No	No	No	Moderate
Yang, 2014	BP	Very serious	No	Very serious	Serious	Serious	Very low
	Adverse events	Very serious	No	No	No	Serious	Very low
Xiong, 2014	BP	Serious	No	No	No	Serious	Low
	Adverse events	Serious	No	No	No	Serious	Low
Li, 2014	BP	No	No	Serious	No	No	Moderate
	Adverse events	No	No	No	No	No	High
Xiao, 2015	Efficacy rate	Very serious	No	No	No	No	Low
	Adverse events	Very serious	No	No	No	No	Low
Zhao, 2015	BP	Very serious	No	No	No	Serious	Very low
	Efficacy rate	Very serious	No	No	No	Serious	Very low
	Adverse events	Serious	No	No	No	Serious	Low
Zhang, 2016	Efficacy rate	Serious	No	No	No	Serious	Low
	TCM syndrome	Very serious	No	No	No	Serious	Very low
	Adverse events	Serious	No	No	No	Serious	Low
Yang, 2016	BP	Very serious	No	No	No	No	Low
	Efficacy rate	Serious	No	No	No	No	Moderate
	TCM syndrome	Very serious	No	No	No	No	Low
Zhang, 2016	Efficacy rate	Very serious	No	No	No	Serious	Very low
Zhang, 2017	BP	Very serious	No	No	No	Serious	Very low
	Efficacy rate	Very serious	No	No	No	Serious	Very low

SRs, systematic reviews; GRADE, Grading of Recommendations Assessment, Development and Evaluation; BP, blood pressure; TCM, traditional Chinese medicine.

large, long-term studies comparing the efficacy of acupuncture and sham acupuncture for treating hypertension are required.

Despite the lack of a significant difference between acupuncture and sham acupuncture, acupuncture plus WM was better than sham acupuncture plus WM in reducing SBP and DBP. Previous studies have shown that acupuncture plus WM is not only superior to WM alone or sham acupuncture plus WM but also to acupuncture alone [49,50]. Thus, acupuncture might enhance the beneficial effects of WM [51]. Poor BP control is seen in patients receiving antihypertensive agents [8]. Furthermore, more adverse effects occur with the use of higher dosages of antihypertensive agents [52]. Therefore, acupuncture is recommended as an adjunctive therapy to WM [10,53]. By combining acupuncture with WM, smaller dosages of WM may be used to produce similar therapeutic effects and thus result in fewer side effects caused by pharmacological treatment.

In this overview, conflicting results were reported regarding the effects of acupuncture versus WM on SBP and DBP, efficacy rate and TCM syndrome. Moreover, inconsistent results were also reported regarding the effectiveness of the combination of acupuncture and WM on SBP and DBP when compared with WM alone. These differences in results produced by different SRs may be due to the different RCTs included, types of acupuncture, types of hypertension, and numbers of RCTs and participants included.

Regarding safety, one prospective study included 73,406 patients receiving acupuncture treatment [54]. Adverse effects from acupuncture were observed in 5440 patients, but most of these events were minor and were mainly treated by the patients [54]. Common adverse effects included bleeding, haematoma, and pain [54]. No deaths resulted from acupuncture [54]. In another prospective study involving 229,230 patients, 19,726 patients experienced at least one adverse effect [55]. Most of the adverse effects were mild, such as bleeding, haematoma, pain or vegetative symptoms [55]. No acupuncture-associated deaths or permanent injuries occurred in the large sample [55]. Therefore, our result was consistent with those found in two studies showing that acupuncture appeared to be safe [54,55].

4.3. Methodological quality and quality of evidence

Overall, the majority of the SRs were of moderate quality; three SRs were considered as low quality, and only one SR was rated as high quality. Consistent methodological shortcomings included (1) the lack of an ‘a priori’ protocol; (2) the lack of a list of included and excluded studies; (3) the lack of an assessment of publication bias; and (4) no declaring conflicts of interest.

In general, the majority of included RCTs within these SRs were of low quality. Consistent methodological drawbacks included the following: (1) RCTs were described as randomized without providing the method of random sequence generation; (2) most RCTs did not explicitly state that treatment allocation was concealed; and (3) most of the RCTs were open label studies, so blinding of practitioners and patients would not be possible, though ideally the assessors should have been blinded.

The quality of evidence for the outcomes in the included SRs ranged from very low to high, and 68.58% of the outcomes showed low or very low quality of evidence. The main reasons for the quality of evidence being downgraded included risk of bias, publication bias, and inconsistency.

4.4. Strengths

This overview has several strengths. First, the included studies were confined to SRs or meta-analyses of RCTs because such studies yield the highest-quality evidence for evaluating intervention effectiveness. Second, we used comprehensive search strategies in eight databases to ensure that all relevant reviews were identified, and we followed the guidelines introduced by the Cochrane Collaboration to synthesize the obtained evidence. Third, we used the AMSTAR tool and the GRADE approach to quantify the methodological quality and the quality of evidence. Fourth, the literature selection, data extraction, and quality assessment were independently performed by two authors to minimize potential bias during the overview process.

4.5. Limitations

This overview has several potential limitations. First, the methodological quality of both the included SRs and primary RCTs was not high, and the quality of evidence for the outcomes was unsatisfactory; therefore, the conclusions from this overview should be interpreted with caution. Second, although we assessed the methodological quality of the included SRs using the AMSTAR tool, we did not reassess the study quality in the included RCTs within these SRs. Third, we did not include evidence from individual RCTs evaluating the efficacy and safety of acupuncture for hypertension. Fourth, we were unable to conduct a quantitative analysis of the included SRs, because the RCTs overlapped between the SRs. Finally, we synthesized evidence of the use of acupuncture for treating hypertension and did not separate different types of acupuncture interventions based on the aim of this overview. There is a need for further studies to compare the efficacy of different acupuncture interventions.

4.6. Implications for practice

This is the first summary of evidence derived from SRs of RCTs on the efficacy and safety of acupuncture for hypertension. According to our findings, acupuncture as an adjunct to WM has been proved as an effective treatment option for patients with hypertension and should be used in daily clinical practice. Additionally, the evidence regarding the use of acupuncture alone in treating hypertension is inconsistent; therefore, there is a need for further research to yield firm conclusions.

4.7. Implications for research

According to our assessment, future research in this area should place more emphasis on the following:

1. High quality RCTs with large sample sizes are necessary to demonstrate the clinical effectiveness of acupuncture alone or combined with WM for treating hypertension.
2. Future RCTs should comply with the Consolidated Standards of Reporting Trials (CONSORT) [56] guidelines as well as the Standards for Reporting Interventions in Controlled Trials of Acupuncture (STRICTA) [57].
3. Future SRs and meta-analyses should adhere to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement [58].
4. Future SRs should also assess the quality of evidence and grade the strength of recommendations using the GRADE approach [59].

5. Conclusion

In conclusion, the current evidence based on 15 SRs of variable quality demonstrates that acupuncture can be considered a useful adjunctive therapy to WM for reducing SBP and DBP, improving the efficacy rate, and addressing TCM syndrome. Conflicting evidence exists regarding the effectiveness of acupuncture alone on SBP and DBP, efficacy rate, and TCM syndrome. We found that acupuncture might be a safe procedure without serious adverse events. More efforts are required to improve the study quality of SRs and RCTs.

Authorship

All authors made significant contributions to the study design, collection and analysis of data, drafting and revising the article, and final approval of the article.

Conflicts of interest

There are no conflicts of interest.

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