


Acupoint herbal patching for bronchitis

A systematic review and meta-analysis

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Abstract

Background: Acupoint herbal patching (AHP) has long been used to treat patients with bronchitis in East Asia. This review assessed the efficacy and safety of AHP as a treatment for bronchitis.

Methods: We performed a literature search using the 9 databases and included randomized controlled trials (RCTs) or quasi-RCTs that used AHP for bronchitis. The methodological quality of each RCT was assessed using the Cochrane Handbook version 5.3, the risk of bias tool, and Grading of Recommendations Assessment, Development and Evaluation (GRADE).

Results: Seven RCTs were included based on the inclusion criteria. All RCTs were published in China and had a high risk of bias. Three RCTs compared AHP with conventional drug therapy for the treatment of bronchitis. The meta-analysis also showed a significant improvement in treatment effectiveness (relative risk [RR] 1.28, 95% confidence interval [CI] 1.15, 1.42; $P < .00001$; $I^2 = 0\%$). Two RCTs investigated AHP combined with conventional drug therapy versus conventional drug therapy. The meta-analysis showed that AHP was significantly more effective than conventional therapy in terms of treatment effective rate (RR 1.16, 95% CI 1.03, 1.29; $P = .01$; $I^2 = 0\%$). Three RCTs reported adverse events, and none reported severe adverse events.

Conclusions: AHP appears to be more effective than conventional drug therapy alone or a placebo. Furthermore, the AHP appears to be a safe treatment option. However, due to the small number of included trials and their poor methodological quality, future studies should include larger sample sizes and well-designed RCTs.

Trial registration number: PROSPERO: CRD 42018110380.

Abbreviations: AEs = adverse events, AHP = acupoint herbal patching, CI = confidence interval, CNKI = Chinese database China National Knowledge Infrastructure, CoE = certainty of evidence, GRADE = Grading of Recommendations Assessment Development and Evaluation, PEF = peak expiratory flow, RCTs = randomized controlled trials, ROB = risk of bias, RR = risk ratio, STRICTA = Standards for Reporting Interventions in Controlled Trials of Acupuncture.

Keywords: acupoint herbal patching, bronchitis, meta-analysis, systematic review

1. Introduction

Bronchitis is a respiratory disease characterized by persistent cough, which may produce mucus, wheezing, chest tightening, sore throat, body aches, and headaches.^[1] Bronchitis affects daily life and social activities, causing enormous social costs and increasing medical expenses by 12.4% every year.^[2] Most patients with bronchitis require antibiotic therapy and symptom management.^[3] Unfortunately, clinical research has shown that antibiotics are not effective against some types of bronchitis.^[4] Therefore, previous clinical studies have been conducted to develop effective treatments, and there is a growing interest in traditional medicine treatments such as acupuncture and herbal medicine.^[5]

Acupoint herbal patching (AHP), also known as “san fu tie,” is one of the oldest and most widely used traditional medical treatments in China, Taiwan, and Korea.^[6] In particular, it is frequently used to treat bronchitis.^[7] There are 2 types of AHP: *sanfu* AHP and *non-sanfu* AHP. *Sanfu* AHP is only applied during the *sanfu* period (dog-day), which refers to the hottest period of the year, between mid-July and mid-August. *Non-sanfu* AHP was applied without limitations to a special period.^[8] The most commonly used herbs are *Sinapis Semen*, *Asari Herba Cum Radix*, *Euphorbiae Kansui Radix*, and *Corydalis Tuber*, and the commonly used acupoints are BL13, BL43, BL23, and BL20.^[9]

Previous clinical research reports that AHP improves the forced expiratory volume in 1 second, forced vital capacity, peak

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Data associated with this paper will be provided upon request.

No ethical approval was required for this manuscript, as this study did not involve human subjects or laboratory animals.

This review authors declare that they have no competing interests.

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expiratory flow, and reduced interleukin 4 levels and increases the level of interferon- γ .^[10-13] AHP reduces airway inflammation and effectively prevents and treats symptoms of lung disorders. However, there is insufficient research evidence that any biomarker is helpful for the direct treatment of bronchitis.

Most previous systematic reviews have shown that AHP has a significant effect on the treatment of asthma,^[10,14] allergic rhinitis,^[8,15] and chronic obstructive pulmonary disease.^[16] Recently, a systematic review related to this topic was conducted. This review^[17] was published in Chinese, and it was concluded that the total effective rate in the AHP group was better than that in the drug group for the treatment of chronic bronchitis. However, 3 of the 5 RCTs had insufficient search strategies and intervention groups that included herbal medicine.

Therefore, this review aimed to critically evaluate the current evidence from randomized clinical trials (RCTs) on the efficacy and safety of AHP for treating bronchitis.

2. Methods

This systematic review was conducted according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidelines.^[18]

2.1. Protocol and registration

The protocol registration number was CRD 42018110380 (https://www.crd.york.ac.uk/PROSPERO/display_record.php?RecordID=110380), and a protocol article was published.^[19]

2.2. Eligibility criteria

2.2.1. Study design. RCTs or quasi-RCTs were included in this study. These dissertations were also included. Case reports, case series, cohort studies, and animal studies were excluded.

Participants. Participants included individuals of any age or sex with acute or chronic bronchitis.

Intervention Both types of AHP (*sanfu* AHP and *non-sanfu* AHP) were included with no limitations in the number, administration method, dosage, composition of herbal medicine, details of acupoint, or duration of treatment. Treatment with AHP for this review was defined as the use of an herbal preparation patch that covered acupoints for a certain period of time. If the AHP was combined with traditional medicine, such as acupuncture, moxibustion, tuina, or herbal medicine, the study was excluded.

2.2.2. Control. Comparators included usual care or placebo (sham AHP), no treatment, or conventional drug therapy. We excluded studies that used AHP or herbal medicines for comparison.

2.2.3. Outcome. Primary outcome: Treatment effective rate (number of patients whose bronchitis symptoms improved). Secondary outcomes:

1. Quality of life (QoL; including Shot-Form 36-item Health Survey [SF-36] and Asthmatic Bronchitis Quality of Life Questionnaire [AQLQ]^[20]).
2. Adverse events (AEs).

2.3. Search method and strategy

The following electronic databases were searched from their inception to May 2021: PubMed, Embase, CENTRAL, Web of Science, Google Scholar, 3 major Korean medical databases (OASIS, KoreaMed, and KMBASE), and the Chinese database (China National Knowledge Infrastructure [CNKI]). The database search terms are shown in Supplement 1, Supplemental Digital Content, <http://links.lww.com/MD/G846>.

2.4. Data extraction

Two reviewers (J.H.J. and K.H.K.) searched for relevant published studies using Korean, English, and Chinese languages. They independently identified the studies for eligibility and checked the inclusion criteria. Two reviewers (J.H.J. and K.H.K.) independently extracted data on the patients' sex and age, sample size, intervention and control group, outcome measures, results, and AEs. A third reviewer (S.P.) resolved any aspects that could not be determined.

2.5. Methodological assessment

This review used the Risk of Bias (ROB) tool according to the risk of bias criteria, Cochrane Handbook version 5.1.3.^[21] The 7 domains were as follows: random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data, selective reporting, and other biases. Each ROB item was given a high, low, or unclear rating, where high indicated a high ROB, low indicated a low ROB, and unclear indicated an unclear ROB. Two reviewers assessed the methodological quality of the included studies. The evaluation of all items was accepted only if the content was reported in the study. Any disagreements were resolved by a third reviewer (S.P.).

2.6. Statistical analysis

Statistical analysis was performed using RevMan version 5.3 and Cochrane Collaboration software (Review Manager Version 5.3 for Windows).^[21] For dichotomous data, we presented treatment effects as the risk ratio (RR) with 95% confidence intervals (CIs). For continuous data, treatment effects were expressed as mean difference (MD) with 95% CIs. Heterogeneity was assessed using I^2 test. We used a random-effects model for the meta-analysis. We used the Grading of Recommendations Assessment, Development and Evaluation (GRADE) software to determine the quality of evidence based on the Cochrane Handbook for Systematic Reviews of Interventions and created a summary of the findings in a table.

3. Results

3.1. Description of the included trials

Of the articles identified from the 9 databases, 159 had relevant titles, and 7 RCTs^[22-28] met our inclusion criteria. A flowchart of the search process and study selection is shown in Figure 1. All relevant studies were published in China (2009–2018). The mean age of the included participants ranged from 60 to 66.5 years. The average disease duration ranged from 3.6 to 8.6 years. Six RCTs^[22-27] treated patients with AHP during the *sanfu* period (mid-July to mid-August), and 1 RCT^[28] treated patients in a *non-sanfu* period (not a special period). Five RCTs^[22,23,25,26,28] used herbal medicine preparation and ginger juice, 1 RCT^[27] added an external Western medicine (Zhunggu Musk Analgesic Ointment), and another RCT^[24] did not use excipients. The most commonly used herbs were *Sinapis Semen*, *Asari Herba*, *Cun Radice*, *Euphorbiae Kansui Radix*, and *Corydalis Tuber*, and the most commonly used acupoints were BL13, BL15, BL20, BL23, and EX-B1.

The key data from all the included RCTs are listed, and the formula compositions of the AHP are listed in Table 1.

3.2. Risk of bias

All included RCTs had a high ROB (Fig. 2). Two RCTs^[26,28] conducted computer randomization and drew lots, whereas 5 RCTs^[22-25,27] did not report any details about the randomization process. No trials mentioned allocation concealment. Two

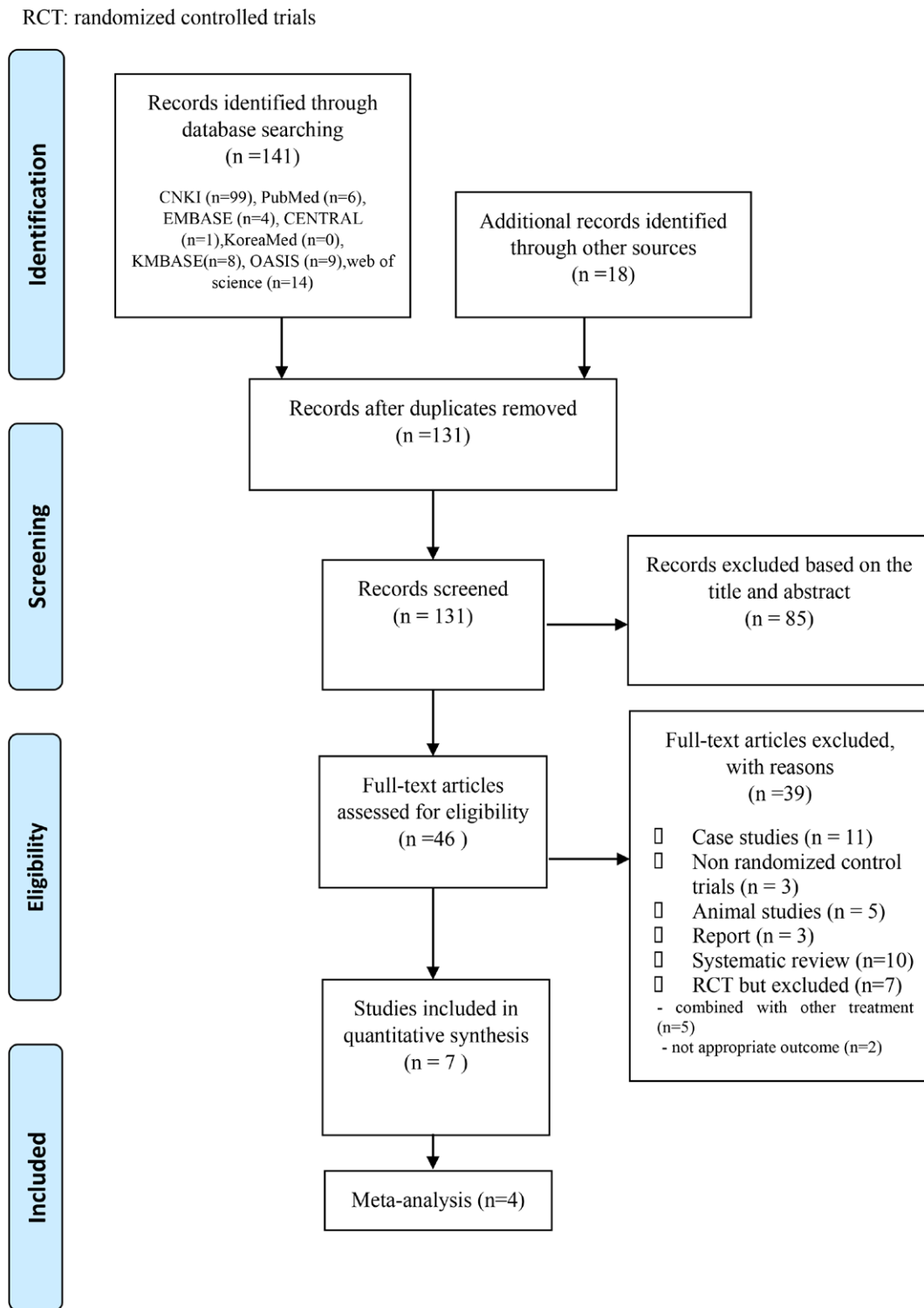


Figure 1. Flow diagram of study searches and selection. RCT = randomized controlled trials.

RCTs^[27,28] using sham AHP were given a low ROB due to the blinding of participants and personnel. All RCTs were analyzed using the intention-to-treat approach. None of the trials had any information on published protocols.

3.3. Certainty of evidence

The overall certainty of evidence (CoE) was low (Table 2).

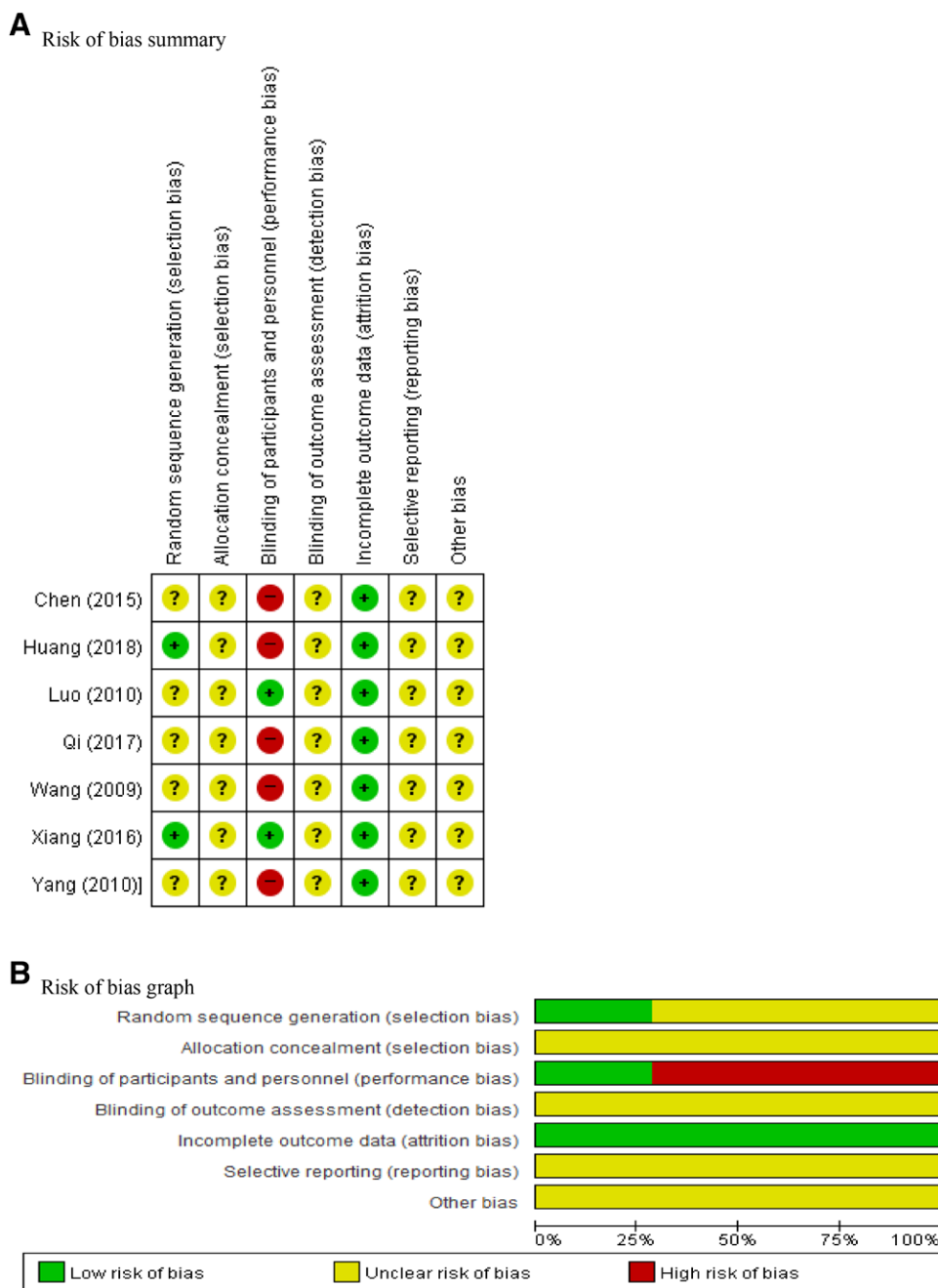
3.4. Outcome measurement

3.4.1. Treatment effect. 3.4.1.1. AHP vs drug. Three RCTs^[22-24] compared AHP with drug therapy for treating bronchitis. Three RCTs used AHP during *sanfu* periods. The meta-analysis showed a significant improvement in the treatment effect (RR 1.28, 95% CI 1.15–1.42; 3 trials, n = 436, $P < .00001$, $I^2 = 0\%$, Low CoE, Fig. 3A).

Table 1
Characteristics of the included studies.

Frist author (yr) [ref]	Sample size randomized /analyzed mean age (yr) Disease duration (yr)	Intervention group (regimens)	Control group (regimens)	Outcome	Results	Adverts events	Acupoints of AHP	Excipient of AHP	Herbal components of AHP
Wang (2009) [22]	180/180 60 6	(A) AHP (once per fu, 4–6 h, sanfu days for 9 visits, n = 90)	(B) Drug (Kernels injection 2–4 mL, 2 times weekly, sanfu days for 9 visits, n = 90)	Treatment effect	RR 1.32 [1.14–1.53], p = 0.0003	n.r.	BL13, BL15, BL17	Ginger juice	Sinapis Semen, Corydalis Tuber, Asari Herba Cum Radice, Euphorbiae Kansui Radix, Camphorum
Yang (2010) [23]	206/206 A: 64.8; B: 65.3 A: 7.9; B: 8.6	(A) AHP (once per fu, 24h, sanfu days for 3 visits, n = 126)	(B) Drug (BCG-PSN, 0.5mg, 3 times weekly for 36 d, n = 90)	Treatment effect	RR 1.26 [1.06–1.50], p = 0.01	No	GV14, BL13, BL20, BL23, EX-B1	Ginger juice	Sinapis Semen, Ephedrae Herba, Astragali Radix, Atractylodis Macrocephalae Rhizoma, Asari Herba Cum Radice, Battrycatus Bombyx Euphorbiae Kansui Radix, Sinapis Semen, Corydalis Tuber, Asari Herba Cum Radice
Qi (2017) [24]	25/25 A: 65.1; B: 65.3 n.r.	(A) AHP (once per fu, 1–2 h, sanfu days for 3 visits, n = 25)	(B) Drug (n.r., n = 25)	Treatment effect	RR 1.22 [0.92–1.62], NS	n.r.	CB14, EX-B1, BL13	n.r.	Euphorbiae Kansui Radix, Sinapis Semen, Corydalis Tuber, Asari Herba Cum Radice
Chen (2015) [25]	83/83 A: 53; B: 54 A: 5.2; B: 4.9	(A) AHP (once per fu, 3–6 h, sanfu days for 3 visits, n = 43), plus (B)	(B) Drug (Levofloxacin 0.2 g, 3 times daily for 30 d, n = 40)	Treatment effect	RR 1.20 [1.00–1.45], p = 0.05	Local redness appeared at acupoints, burning sensation, local skin pigmentation after application (A: 4)	BL13, BL20, BL23, EX-B1, EX-HN15, GV14	Ginger juice	Ephedrae Herba, Corydalis Tuber, Sinapis Semen, Euphorbiae Kansui Radix, Asari Herba Cum Radice, Moschus
Huang (2018) [26]	90/90 A: 42.6; B: 43.4 A: 3.6; B: 3.5	(A) AHP (once per fu, 4–6 h, sanfu days for 3 visits, n = 45), plus (B)	(B) Drug (n.r., n = 45)	Treatment effect	RR 1.13 [0.98–1.30], NS	Vomiting (B: 2); dizziness (B: 2); rush (A: 1, B: 1)	BL13, BL15, BL17	Ginger juice	Asari Herba Cum Radice, Corydalis Tuber, Euphorbiae Kansui Radix, Pinelliae Rhizoma, Sinapis Semen
Luo (2010) [27]	200/200 A: 65; B: 66.5 n.r.	(A) AHP (once per fu, 2–6 h, sanfu days for 9 visits, n = 100)	(B) Sham AHP (once per fu, 2–6 h, sanfu days for 9 visits, n = 100)	1. Treatment effect 2. QoL	1. RR 1.18 [1.02–1.37], p = 0.03 2. MD -0.38 [-0.53, -0.23], p < 0.00001	n.r.	1st: BL12, BL43, BL20; 2nd, last: BL13, BL21, BL52	Ginger juice, Zhuanggu Musk	Sinapis Semen, Asari Herba Cum Radice, Euphorbiae Kansui Radix, Ephedrae Herba, Zingiberis Rhizoma, Evodiae Fructus
Xiang (2016) [28]	100/100 A: 60.4; B: 61.3 A: 8.2; B: 7.7	(A) AHP (2 h, 3 times weekly) + Drug (Theophylline 0.2 mg, 2 times daily for 5 wk, n = 50)	(B) Sham AHP (2 h, 3 times weekly) + Drug (Theophylline 0.2 mg, 2 times daily for 5 wk, n = 50)	1. Treatment effect 2. QoL (AQLQ)	1. RR 1.47 [1.18–1.87], p = 0.0009 2. MD 46.56 [38.47–54.65], p < 0.00001	n.r.	BL13, BL21, BL52, CV17; BL12, BL20, BL46, CV22; EX-B1, BL23, BL15, CV12	Ginger juice	Corydalis Tuber, Sinapis Semen, Asari Herba Cum Radice, Euphorbiae Kansui Radix

AHP = acupoint herbal patching, AQLQ = asthmatic bronchitis quality of life questionnaire, BCG-PSN = Bacillus Calmette Guerin–Polysaccharide and Nucleic Acid injection, MD = mean difference, n.r. = not reported, NS = non-significance, QoL = quality of life.



+ = low risk bias; ? = unclear risk of bias; - = high risk of bias

Figure 2. Risk of bias. (A) Risk of bias summary: review authors’ judgments about each risk of bias item for each included study. (B) Risk of bias graph: review authors’ judgments about each risk of bias item presented as percentages across all included studies. + = low risk of bias, ? = unclear risk of bias, - = high risk of bias.

3.4.1.2. AHP + Drug vs Drug. Two RCTs^[25,26] assessed the effect of AHP plus drug therapy on the treatment effect compared with drug therapy alone. Two RCTs used AHP in the *sanfu* periods. The meta-analysis showed that AHP combined drug therapy was superior to drug therapy (RR 1.16, 95% CI, 1.03–1.29; 2 trials, n = 173, P = .01, I² = 0%, low CoE; Fig. 3B).

3.4.1.3. AHP vs sham AHP. One RCT^[27] compared the effects of AHP with sham AHP, and it showed favorable effects of AHP on the effective rate (RR 1.18, 95% CI 1.02–1.37; P = .03).

3.4.1.4. AHP + drug vs sham AHP + drug. One RCT^[28] compared AHP plus drug therapy with sham AHP plus drug

therapy on the treatment effect. The results reported a favorable effect of AHP on the treatment efficacy rate (RR 1.48, 95% CI 1.18–1.87; P = .0009).

3.4.2. Quality of life. Two RCTs^[27,28] reported QoL. One RCT^[27] used SF-36 and another RCT^[28] used AQLQ. In 1 RCT^[27] where AHP was compared with sham AHP, AHP significantly improved QoL (MD -0.38, 95% CI -0.53 to -0.23, P < .00001). Another RCT^[28] reported that AHP plus drug therapy improved the QoL (MD 46.56, 95% CI 38.47–54.65, P < .00001), compared with sham AHP plus drug therapy.

3.4.3. Adverse events. Three RCTs^[23,25,26] assessed the AEs. One RCT^[23] found no adverse events. One RCT^[25] reported AEs in

Table 2
Summary of findings.

AHP or AHP + drug compared to drug for bronchitis					
Outcomes	No. of participants (studies) follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Risk with control group	Anticipated absolute effects Risk difference with intervention group*
Treatment effect (AHP vs drug)	436 (3 RCTs) ^[22,23, 24]	⊕⊕○○ Low†,‡	RR 1.28 (1.15–1.42)	687 per 1000	192 more per 1000 (103 more to 289 more)
Treatment effect (AHP + drug vs drug)	173 (2 RCTs) ^[25,26]	⊕⊕○○ Low†,‡	RR 1.16 (1.03–1.29)	812 per 1000	130 more per 1000 (24 more to 235 more)

GRADE Working Group grades of evidence.

High certainty: we are very confident that the true effect lies close to that of the estimate of the effect.

Moderate certainty: we are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.

Low certainty: our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect.

Very low certainty: We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect.

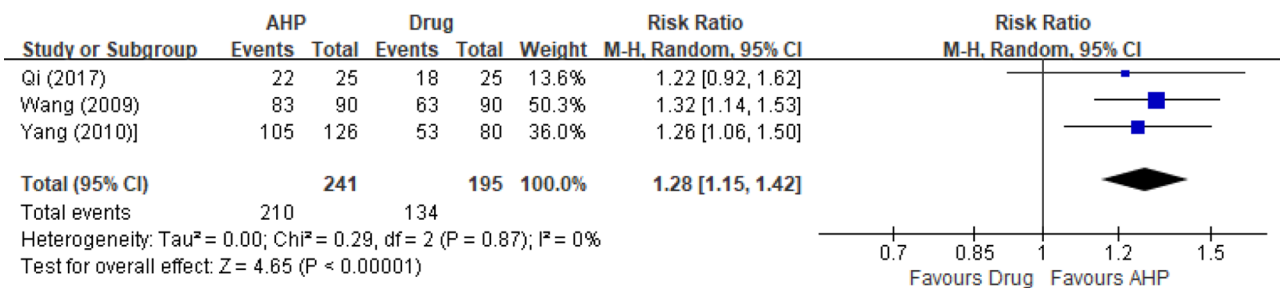
AHP = acupoint herbal patching, CI = confidence interval, RR = risk ratio.

*The risk in the intervention group (and its 95% confidence interval) is based on the assumed risk in the comparison group and the relative effect of the intervention (and its 95% CI).

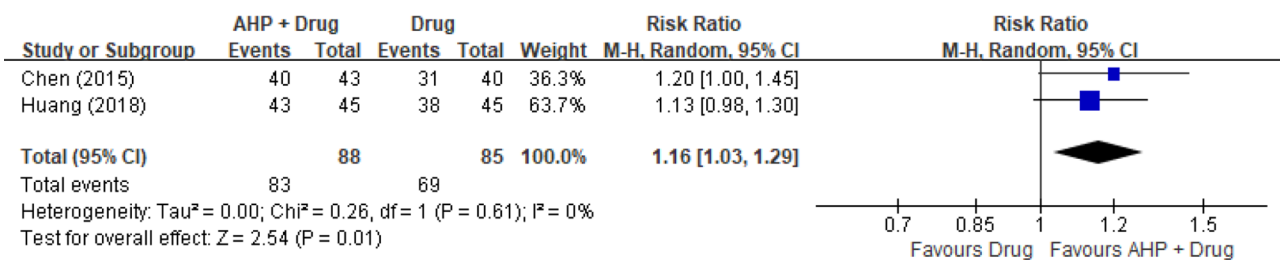
†Downgrade by 1 level: unclear or high risk of bias.

‡Downgraded by 1 level: small sample size.

A Acupoint herbal patching vs. Drug therapy



B Acupoint herbal patching + Drug therapy vs. Drug therapy



AHP: acupoint herbal patching; HM: herbal medicine

Figure 3. Forest plots of treatment effect. (A) AHP vs drug therapy. (B) AHP + drug therapy vs drug therapy. AHP = acupoint herbal patching, CI = confidence interval, HM = herbal medicine.

the intervention group alone, including local redness appearing at acupoints, burning sensation, and local skin pigmentation after application. Another RCT^[26] reported AEs such as skin rash (n = 1) in the intervention group and nausea and vomiting (n = 2) and dizziness (n = 2) in the control group. No severe adverse reactions were observed in any of the included studies.

4. Discussion

4.1. Summary of the main results

AHP originated from ancient Chinese traditional medicine and has been widely used to date. AHP is a part of one of the health

promotion programs offered by hospitals in China to promote oriental medicine during the *sanfu* period and is used by many patients.^[29] Recently, AHP has been used for the prevention and treatment of bronchial asthma and allergic rhinitis in the pediatric population in Korea.^[30] This systematic review assessed AHP or AHP combined with drug treatments, and such therapies appeared to be more effective than drug therapy in terms of the efficacy rate for bronchitis. Only 3 RCTs reported AEs. No serious AEs were reported from the 7 RCTs, and the AHP treatment was shown to be relatively safe. Thus, AHP may be a suitable alternative for treating bronchitis. The most common acupoint described in the reviewed studies was the BL13 (Fei Shu). The

acupoint BL13, located 1.5 cun lateral to the lower border of the spinous process of the third thoracic vertebra (T3), is associated with lung function and was used in all the included studies. BL13 is an acupoint in the urinary bladder meridian pathway that is used to treat respiratory diseases. According to recent studies, when beneficial effects are seen after treatment at the pulmonary acupoint for bronchial asthma, BL13 improves lung damage.^[31]

4.2. Certainty of the evidence

Seven RCTs^[22–28] showed that AHP is an effective treatment for bronchitis. However, the quality of evidence assessed through GRADE was rated low because of the small sample size (Table 2). Upon evaluating the included literature, the quality of evidence for most articles was found to involve a high ROB. The reason is that skewed data due to publication bias cannot be excluded, as all articles were published in China. Additionally, the described information was insufficient. Future research needs well-designed RCTs.

4.3. Potential biases in the review process

First, all studies were conducted and published in China. While the present evidence suggests that AHP may have therapeutic effects, clinical studies from other countries may show different results. Therefore, additional clinical studies on AHP are required to confirm its effects. Second, AHP treatment can be divided into *sanfu* period and non-*sanfu* period applications. Studies comparing AHP treatment during the 2 periods are needed to determine the effective treatment period.

4.4. Agreements and disagreements with other studies or reviews

One previous review^[17] assessed AHP in bronchitis and found that AHP appeared to have a potential effect. However, we reviewed 5 new RCTs^[22,24,25,27,28] compared to a previous review that also demonstrated the apparent effectiveness of AHP.

4.5. Implication for practice

We inferred that AHP may be safe and can be applied for the treatment of patients with bronchitis. AHP alone or in combination with drug therapy may improve QoL and treatment effects. However, due to insufficient evidence, the objectivity of efficacy assessment was compromised.

4.6. Implication for research

This study had a few limitations. First, the sample size of the included studies was small. AHP therapy was found to be effective for bronchitis; however, there were a small number of trials, which were poor in quality. Second, the evaluation of the quality of evidence for the included articles showed a high level of bias. The included RCTs did not report concealment of treatment allocation, blinding of the participants, personnel, outcome, and assessment. Future studies should focus on improving the quality of the data using the Reporting Guidelines^[32] and Standards for Reporting Interventions in Controlled Trials of Acupuncture.^[33]

5. Conclusion

AHP is associated with objective improvements in bronchitis. However, owing to the small number of studies and the high ROB, the evidence is uncertain. Future studies with larger sample sizes from other countries are needed to confirm the effectiveness of AHP in treating pulmonary diseases.

Author contributions

Conceptualization: JHJ, KHK

Data curation: JHJ, KHK

Resources and software: JHJ, KHK, LA

Writing – original draft: JHJ, ES, KHK

Writing – review and editing: JHJ, ES, SJP

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