The Effectiveness and Safety of Heat Sensitive Moxibustion for Anaphylactic Rhinitis: A PRISMA Compliance Systematic Review and Meta-Analysis of Randomized Clinical Trials

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Methodology

**Keywords:** Heat sensitive moxibustion, anaphylactic rhinitis, Systematic review, Meta-analysis

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Abstract

Background

Anaphylactic rhinitis (AR) is an IgE antibody-mediated, inflammatory disorder. Heat-sensitive moxibustion (HSM) has been accepted for AR in clinically. Our study was conducted to evaluate the effectiveness and safety of HSM for AR.

Methods

We conducted a comprehensive literature review of the PubMed, Cochrane Library, EMBASE, China National Knowledge Infrastructure (CNKI), Wanfang, Chinese Science and Technology Periodical Database (VIP) and Chinese Biomedical Literature Database (CBM) from their inception to April 2020 for RCTs that compared HSM with other active intervention for AR. The primary outcome measure was the total nasal symptom and sign score, and secondary outcomes include total effective rate, Rhinoconjunctivitis quality of life questionnaire (RQLQ) and adverse events. More than two authors independently conducted the process of data collection and analysis by Review Manager (Version 5.3).

Results

A total of 15 RCTs of 1087 participants were included in our study. The overall meta-analysis demonstrated that HSM were superior in relieving the symptoms and signs of AR in treatment (SMD = -1.46, 95%CI (-1.81, -1.10); P < 0.00001) or during the follow-up period (SMD = -2.87, 95%CI (-5.11, -0.63); P < 0.0001). The results also applied to the total effective rate (OR = 2.96, 95%CI (2.19, 4.00); P < 0.00001) and RQLQ (SMD = -7.80, 95%CI (-13.92, -1.68); P < 0.00001) in treatment. Subgroup analysis indicated that there was a significant difference between the HSM group and control group. There were two studies referred to the adverse effects. The overall level of evidence was low with low methodology quality.

Conclusion

This meta-analysis suggests that the effectiveness of HSM on AR were statistically significant in treatment or during the follow-up period. However, the included studies have relatively poor quality; further high-quality trials should be conducted to confirm our finding.

Systematic review registration

PROSPERO CRD42019140723

Background

Anaphylactic rhinitis (AR) is an IgE antibody-mediated inflammatory disorder [1,2]. Allergen response is the characteristic pathophysiology of the AR; the most common allergens are classified as inhalation, food and chemical [3].
Almost one in six rhinitis patients is AR [4], a multicentric trial from 13 allergy centers in Central China had shown that 33.9% of the patients had intermittent moderate-severe AR and 53.3% persistent moderate-severe AR [5]. Those conditions not only brings a huge economic burden to the family of AR but also affects people's physical and mental health [6]. In the USA, direct health-related costs of AR are reported to increase by about 2~5 billion dollars and productivity losses by about 2~4 billion dollars a year [7]. Some studies have suggested that AR may increase the risk of anxiety, hypochondriasis or suicide [8,9].

Loratadine Tablets and inhaled budesonide are recommended for AR, while the long term use of the drug accompanied by the less effective and adverse effects such as nasal dryness and epistaxis [10,11]. Researchers found when patients accepted suspended moxibustion in clinically, they may feel one or more heat sensations (heat penetration, heat expansion, heat transmission, and nonthermal sensations) on their body [12]. Heat sensitive moxibustion (HSM), as a type of suspended moxibustion, refers to practitioners administer moxibustion on heat-sensitive acupuncture points, which are extremely sensitive to the heat stimulation of burning moxa [13].

The spectrum of disease on HSM showed that AR takes up a large proportion of respiratory system diseases [14]. On the basic theory of traditional Chinese medicine (TCM), professor Chen Rixin presents the thought of on "no allergy without any deficiency". HSM is a kind of external therapy for internal disorders, directly acting on the pathogenesis, strengthening the antipathogenic qi and removing the allergic factors [15]. It can increase blood volume, speed the blood flow, and regulate the immunologic function of the patients with AR [16]. Studies have shown that HSM could reduce the serum content of IgE and IL-4 in AR rat, and reduce allergic inflammation of nasal mucosa [17].

Some randomized controlled trials (RCTs) have reported that HSM could relieve uncomfortable symptoms and improve the life quality of AR. Review of the previous systematic review and meta-analysis, they did not provide the information about protocol and registration and without assessing the evidence quality and effect on follow-up [18]. Considering the weakness of the previous, we updated studies from seven databases and applied the scientific method to provide reliable evidence about the effectiveness and safety of HSM for AR.

**Methods**

**Protocol and registration**

Our study has been registered on PROSPERO as CRD42019140723; the protocol was available from [http://dx.doi.org/10.1097/MD.0000000000018557](http://dx.doi.org/10.1097/MD.0000000000018557). This study reported following the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines [19].

**Information sources and search**

We searched through the database of PubMed, Cochrane Library, EMBASE, China National Knowledge Infrastructure (CNKI), Wanfang, Chinese Science and Technology Periodical Database (VIP) and Chinese
Biomedical Literature Database (CBM) from their inception to April 2020. We also manually searched the library of Jiangxi University of traditional Chinese medicine for supplementary. The terms “allergic rhinitis”, “perennial allergic rhinitis”, “seasonal allergic rhinitis”, “allergic rhinoconjunctivitis”, “allergic rhinitis”, “hay fever”, “nasal allergy”, “pollenosis”, “pollinosis” were searched in combination with each of the following: “Heat sensitive moxibustion”, “Thermal moxibustion”, “Heat-sensitive Point Moxibustion”, “RCT” and “randomized controlled trial”. The search was restricted to studies of human participants. Search strategy can refer to Table 1, taking PubMed as an example.

**Literature selection and exclusion criteria**

**Types of Studies**

We collected RCTs of HSM for AR published in Chinese and English up to April 2020.

**Types of Participants**

The included participants were diagnosed under clear criteria of AR, patients with asthma, nasosinusitis, vasomotor rhinitis, infectious rhinitis, hormonal rhinitis were excluded.

**Types of Interventions and Comparisons**

We selected the intervention group that used HSM or HSM combined with other active therapies (e.g. conventional drugs and needling acupuncture), and the control group that chose other therapies (e.g. placebo, needling acupuncture, western drug) or the same active therapies as the intervention.

**Types of Outcome Measures**

The primary outcome was the total nasal symptom and sign score [20], which was measured after cessation of treatment and on three months follow time. The secondary outcomes include total effective rate (which was assessed by the total nasal symptom and sign score) [21], rhinoconjunctivitis quality of life questionnaire (RQLQ) [22] and adverse events.

**Study Selection**

All of the retrieved studies were managed by NoteExpress 3.0 to delete the duplicated. According to the inclusion criteria, reviewers selected the eligible through titles and abstracts, then full-text of the potential were assessed further. A researcher (JY) contacted the author to obtain information about the study as for the incomplete of the relevant data. Any divergences were settled by discussion or consulting the third one (YFJ), more than two authors independently conducted the process of study selection.

**Data Extraction**

Related characteristics of the included about the first author, publication year, sample, mean age/ age range, intervention, comparison, follow time were independently extracted by two reviewers (XHZ and
The data were recorded by WPS 2019; disagreements were resolved by discussion or consulting with a third review (KL) until the agreement was accordant.

**Assessment of risk of bias**

We evaluated the methodological quality of the included trials by the Cochrane risk of bias tool [23]. Two reviewers (TY and XW) independently assessed the included studies; disagreements were settled by consulting with a third review (YFJ) during the process.

**Statistical Analysis**

Statistical analyses were performed by Review Manager (Version 5.3). Risk indices (RRs) with 95% confidence interval (CI) were standardized for dichotomous outcomes; the standard mean difference (SMD) with 95% confidence interval (CI) was used for continuous outcomes. Heterogeneity was assessed by applying a chi-squared test. $I^2$ was considered to indicate a substantial level of heterogeneity. According to the heterogeneity levels of the included systematic reviews and meta-analyses, the random-effects model ($I^2 \geq 50\%$) or fixed-effects model ($I^2 < 50\%$) was properly selected. Subgroup analysis was conducted to identify and explain the heterogeneity. Funnel plot was used to assess publication bias.

**Quality of Evidence**

The GRADE approach was used to assess the quality of evidence for the main outcomes [24]. The rating included four levels: high, moderate, low, and very low, according to the quality of the evidence from five domains (limitations, inconsistency, indirectness, imprecision, and publication bias) [25]. Two reviewers (TY, XW) separately conducted the assessment process; any disagreement was resolved through discussion and consultation with a third author (JX).

**Results**

**Study Selection and Characteristics**

We obtained 93 relevant citations from seven electronic databases and manual searches. After 58 duplicate records were removed, we screened the remaining 35 records for eligibility and excluded eight records based on titles and abstracts. Full texts of the remaining 24 citations were retrieved for further assessment, and 12 records were eliminated. Finally, we included 15 RCTs and 1088 patients of AR, which were published from 2008 to 2020. The flowchart of literature selection is represented in Figure 1. We found two studies used HSM with needling acupuncture as the intervention [27,40], and seven studies used the western drug as the comparison [29,32,33,34,36,37,39]. Two researches reported the adverse event [35,39]; eight RCTs mentioned the follow time [27,28,33,35-39]. The characteristics of the included RCTs are presented in Table 2.

**Risk of Bias Assessments**
For the selection bias, 7(46.67%) studies specifically reported the method of random sequence generation, 4(26.67%) studies explained proper allocation concealment by light-tight envelope [28.29.31.39]. Most articles only mentioned that they “randomly divided the participants”, while they failed to provide the details of random sequence generation and allocation concealment. For blinding of participants and personnel, one research adopted moxibustion compared with the intervention [35]. Two RCTs reported blinding of outcome assessment, and the data was managed by intentional analysis [30.32]. There were no studies with selective reporting. The risk of bias of the included was shown in Figure2 and Figure3.

**Total Nasal Symptom and Sign Score**

**After cessation of treatment**

Ten RCTs of 725 participants reported the total nasal symptom and sign score after cessation of treatment [27.28.30.32-35.37-39]. The overall meta-analysis demonstrated that HSM was superior in AR, while there was substantial heterogeneity between the trials (SMD = -1.46, 95%CI (-1.81, -1.10); \( P < 0.00001 \), \( I^2 = 56\% \); Figure 4). With the purpose of finding the source of heterogeneity, random-effect model and subgroup were conducted to analysis. The subgroup meta-analysis reported that HSM was more effective for AR than the western drug (SMD = -1.37, 95%CI (-1.98, -0.76); \( P < 0.0001 \), \( I^2 = 57\% \)), needling acupuncture (SMD = -1.70, 95%CI (-3.23, -0.17); \( P = 0.03 \), \( I^2 = 71\% \)), suspended moxibustion (SMD = -1.62, 95%CI (-2.66, -0.58); \( P = 0.002 \)). The same findings applied to the comparison between HSM with needle acupuncture and needle acupuncture (SMD = -1.38, 95%CI (-1.49, -1.27); \( P < 0.00001 \)).

**After 3 months follow time**

Three RCTs of 220 participants reported the total nasal symptom and sign score after 3 months follow time [33.35.39]. The overall result demonstrated that HSM was more effective than the control group after 3 months follow time, while there was substantial heterogeneity between the trials (SMD = -2.87, 95%CI (-5.11, -0.63); \( P < 0.0001 \), \( I^2 = 90\% \); Figure 5). Random-effect model and subgroup were conducted to analysis further. The subgroup meta-analysis reported that HSM was more effective for AR than the western drug (SMD = -4.06, 95%CI (-4.94, -3.19); \( P < 0.00001 \), \( I^2 = 0\% \)), suspended moxibustion (SMD = -1.15, 95%CI (-2.07, -0.23); \( P = 0.01 \)).

**Total Effective Rate**

**After cessation of treatment**

Fifteen RCTs of 1087 participants reported the total effective rate after cessation of treatment [26-40]. The overall meta-analysis demonstrated that HSM alone or combination of HSM with needling acupuncture and were superior in AR, and there was no significant heterogeneity among the included studies (OR = 2.96, 95%CI (2.19, 4.00); \( P < 0.00001 \), \( I^2 = 0\% \); Figure 6). The fixed-effect model and subgroup meta-analysis was conducted, the result showed that HSM was more effective for AR than the
western drug (OR = 2.79, 95%CI (1.87, 4.17); \( P < 0.0001, I^2 = 57\% \)), needling acupuncture (OR = 2.76, 95%CI (1.56, 4.87); \( P = 0.0005, I^2 = 0\% \)), suspended moxibustion (OR = 4.85, 95%CI (1.43, 16.42); \( P = 0.01 \)). The same findings applied to the comparison between HSM with needling acupuncture and needling acupuncture (OR = 3.62, 95%CI (1.35, 9.75; \( P = 0.01, I^2 = 0\% \)).

**After 3 months follow time**

Six RCTs of 535 participants reported the total effective rate after 3 months follow time [28.33.35-37.39]. The overall meta-analysis demonstrated that HSM alone or combination of HSM with needling acupuncture were superior in AR after 3 months follow time, and there was no significant heterogeneity among the included studies (OR = 5.31, 95%CI (3.66, 7.72); \( P < 0.00001, I^2 = 0\% \); Figure 7). The fixed-effect model and subgroup meta-analysis was conducted, the result showed that HSM was more effective for AR than the western drug (OR = 5.63, 95%CI (3.65, 8.69); \( P < 0.00001, I^2 = 0\% \)), needling acupuncture (OR = 4.80, 95%CI (1.45, 15.94); \( P = 0.01 \)), suspended moxibustion (OR = 4.33, 95%CI (1.70, 11.07); \( P = 0.002 \)).

**Rhinoconjunctivitis Quality of Life Questionnaire (RQLQ)**

Four RCTs of 272 participants reported the total nasal symptom and sign score after cessation of treatment [28.32.35.39]. The overall meta-analysis demonstrated that HSM was superior in improving the life quality of AR patients, while there was substantial heterogeneity between the trials (SMD = -7.80, 95%CI (-13.92, -1.68); \( P < 0.00001, I^2 = 95\% \); Figure 8). With the purpose of finding the source of heterogeneity, random-effect model and subgroup were conducted to analysis. The subgroup meta-analysis reported that HSM was more effective for AR than the western drug (SMD = -3.93, 95%CI (-7.24, -0.62); \( P = 0.02 \)), needling acupuncture (SMD = -7.76, 95%CI (-18.70, -3.17); \( P < 0.00001, I^2 = 98\% \)), suspended moxibustion (SMD = -11.75, 95%CI (-15.65, -7.85); \( P < 0.00001 \)).

**Adverse Effects**

There were two studies referred to the adverse effects [35.39]. Xu reported one case of rash which relieved after one week on the HSM group. Zhang reported that there were no adverse effects on his research.

**Publication Bias**

Funnel plot based on studies on total nasal symptom and sign score and total effective rate was performed to detect the potential publication bias by RevMan5.3.0 software. The results showed that 10 studies were distributed beyond the funnel, illustrating that there may be publication bias in the total nasal symptom and sign score of HSM for AR (Figure 9). Funnel plot of 15 studies about total effective rate manifested that there was no significant asymmetry (Figure 10).

**Level of Evidence**
The level of evidence for three outcomes (total nasal symptom and sign score, total effective rate and RQLQ) were assessed by GRADE, which was displayed in Table 3. The results showed that the overall quality of the evidence was low, and all the outcomes were biased in allocation concealment or inadequate blinding. The outcomes of the total nasal symptom and sign score and RQLQ were imprecision which was caused by small sample sizes. The outcome of the total nasal symptom and sign score and RQLQ displayed high heterogeneity for course, treatment of the patient or different control groups. The funnel plot of the total nasal symptom and sign score and RQLQ were dissymmetrical.

Discussion

Summary of Main Findings

Our studies included 15 RCTs of 1088 patients for meta-analysis, the result showed that HSM, which was more effective than the control group. It could relive uncomfortable symptom and improve the life quality of the patients of AR. We found that it also plays a great advantage during the follow-up period. There were two studies mentioned adverse reactions, one case of rash on the treatment, which was relieved after one week. We can not draw a conclusion on the safety of HSM for the insufficient number of researches included.

The quality of the evidence was low; the outcome of the total nasal symptom and sign score and RQLQ displayed high heterogeneity. Although subgroup analysis was conducted to explore the heterogeneity of treatment effects in RCTs, heterogeneity still existed in these comparisons. Variability of duration from six to thirty and different acupoints selected might be the possible source of bias. Majority of the RCTs was limited to low methodology quality; most studies failed to provide the details of random sequence generation and allocation concealment. The lack of blinding may exaggerate the results of the outcome measures. The conclusion of the composite outcome was not very reliable.

Strengths and Limitation

Following is the summary of the present research: (1) Comprehensive search strategies were applied to relative databases to ensure that all RCTs were identified; (2) Compared to the previous studies, we provided registration and considered the level of the evidence on our study; (3) Subgroup analysis was performed based on variable comparisons, and we considered the follow-up effect of the HSM, which could ensure the credibility of our results.

There are some limitation in the present study: (1) The low quality of the included studies with a high risk of selection bias and performance bias for without providing the details of random sequence generation and allocation concealment, losing of blinding, so the results should be interpreted with caution. (2) considering the small number of studies reported the side effects; we could not assess the overall side effects of HSM for AR. (3) Due to the treatment mode and the duration of each trial were not equivalent, we could not confirm how long HSM treatment is required to achieve the best effect for AR. (4) The outcome of total nasal symptom and sign score consisted of four symptoms and one sign; we did not
record the score of each part separately in our study, so we could not tell the symptom difference of HSM treatment.

**Opportunities for Future Research**

Through this review, we found that current evidence is of low quality. Thus further research is needed: (1) The primary RCTs should give more attention to allocation concealment and blinding, which could reduce the risk basis of the evidence. (2) Although there were some RCTs research to explore the efficacy of HSM, few studies concentrated on the adverse effects and laboratory examination such as IgE, IgM, IgG and so on. (3) More researches could pay more attention to the specific symptom improvement (sneezing, rhinorrhea, nasal itching and nasal obstruction) of AR for HSM, to explore the best effect of HSM on symptom improvement.

**Conclusion**

In conclusion, the results of this meta-analysis suggest that HSM alone or combination of HSM with needling acupuncture is more effective to relieve the symptoms and improve the life quality than the western drug, suspended moxibustion, or needling acupuncture in the treatment of AR. On the period of follow-up, the effect of HSM took more advantages over the control group. The results should be interpreted cautiously for the low quality of the evidence. There is no enough evidence to support that HSM is a safe method for AR; future studies should place more emphasis on the safety of HSM for AR. More efforts are required to improve the study quality of RCTs, and researchers should strictly adhere to the relative methodology and reporting guidelines.

**Abbreviations**

HSM: heat sensitive moxibustion

AR: anaphylactic rhinitis

RCTs: randomized controlled trials

CNKI: China National Knowledge Infrastructure

VIP: Chinese Science and Technology Periodical Database

CBM: Chinese Biomedical Literature Database

RQLQ: rhinoconjunctivitis quality of life questionnaire

TCM: traditional Chinese medicine

PRISMA: preferred reporting items for systematic reviews and meta-analyses
Declarations

Ethics approval and consent to participate

Not applicable.

Consent for publication

Not applicable.

Availability of data and materials

All data generated or analyzed during this study are included in this published article.

Competing interests

The authors declare that they have no competing interests.

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Authors’ contributions

Conceptualization: JX, JY.

Data curation: TT, XW, JY, LLX, XHZ.

Formal analysis: KL, YFJ.

Investigation: YFJ, KL.

Methodology: JX

Software: XW, TY, JY.

Project administration: JX, JY.

Supervision: YFJ, JX.

Writing – original draft: JY, XW, TY.
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Tables

Table 1: Search strategy (PubMed)

| Order | Strategy |
|-------|----------|
| #1    | Search "Rhinitis, Allergic"[Mesh] |
| #2    | Search (((((((allergic rhinitis>Title/Abstract)) OR perennial allergic rhinitis>Title/Abstract)) OR seasonal allergic rhinitis>Title/Abstract)) OR allergic rhinoconjunctivitis>Title/Abstract)) OR hay fever>Title/Abstract)) OR nasal allergy>Title/Abstract)) OR pollenosis>Title/Abstract)) OR pollenosis>Title/Abstract)) OR anaphylactic rhinitis>Title/Abstract) |
| #3    | #1 OR #2 |
| #4    | Search (((((((randomized controlled trial>Publication Type)) OR controlled clinical trial>Publication Type)) OR randomized>Title/Abstract)) OR drug therapy>MeSH Subheading)) OR placebo>Title/Abstract)) OR randomly>Title/Abstract)) OR trial>Title/Abstract)) OR groups>Title/Abstract) |
| #5    | Search (animals>MeSH Terms)) NOT humans>MeSH Terms) |
| #6    | #4 NOT #5 |
| #7    | (((Heat-sensitive moxibustion>Title/Abstract)) OR (Thermal moxibustion>Title/Abstract))) OR (Heat-sensitive Point Moxibustion>Title/Abstract)) OR (HSM>Title/Abstract)) |
| #8    | #6 AND #7 |

Table 2: General characteristics of included studies
| Study       | Mean age/age range | Sample size(T/C) | Treatment group                  | Control group                                                                 | Outcomes | Follow time |
|------------|--------------------|-----------------|----------------------------------|-------------------------------------------------------------------------------|----------|-------------|
| Cao 2017   | T:36.2±4.8, C:37.1±4.6 | 43/43           | HSM + Needling Acupuncture; 50 min/d, 20d | Needling Acupuncture; 30 min/d, 30d                                          |          | 3 months    |
| Zhu 2020   | T:37.63±8.52, C:37.91±8.74 | 40/40           | HSM + Needling Acupuncture; 45 min/d, 30d | Needling Acupuncture; 25 min/d, 30d                                          |          | not mention |
| Li 2019    | T:16~55, C:16~55    | 18/18           | HSM; 40-90 min/d, 20d             | Ephedrine Hydrochloride and Nitrofurazone Nasal Drops; 3-5 drops, twice daily, 20d |          | not mention |
| Lin 2017b  | T:26.64±5.70, C:27.78±5.78 | 36/36           | HSM; 40 min/d, 20d                | Ephedrine Hydrochloride and Nitrofurazone Nasal Drops; 3-5 drops, twice daily, 20d |          | not mention |
| Lv 2013    | T:8~68, C:7~65      | 40/40           | HSM; 30 min/d, 20d                | Budesonide nasal spray; tid, 20d                                             |          | 3 months    |
| Xiong 2019 | T:41.6±10.5, C:41.2±12.2 | 30/30           | HSM; 30 min/d, 21d                | Loratadine Tablets; 10mg/d, 21d                                             |          | not mention |
| Yang 2008a | 33.7                | 68/68           | HSM; qd, 10d                      | Cetiriti hydrochloride tablets; 10mg/d, 10d                                  |          | 3 months    |
| Yang 2008b | T:15~62, 37.6, C:14~60, 39.4 | 60/60           | HSM; qd, 10d                      | Cetiriti hydrochloride tablets; 10mg/d, 10d                                  |          | 3 months    |
| Zhang 2014 | T:27.33±13.21, C:28.21±14.30 | 30/30           | HSM; qd, 30d                      | Antihistamine drug; 30d                                                      |          | 3 months    |
| Xu 2016    | T:31.85±8.66, C:33.00±10.66 | 40/40           | HSM; 40 min/d, 6d                 | Suspended Moxibustion; 40 min/d, 6d                                          |          | 3 months    |
| Huang 2020 | T:29, C:30          | 30/30           | HSM; 50 min/d, 10d                | Needling Acupuncture; 30 min/d, 10d                                          |          | 3 months    |
| Study   | T:  | C:  | Duration | Treatment | Outcome | Level of Evidence |
|---------|-----|-----|----------|-----------|----------|------------------|
| Zhang 2011 [37] | 48.6±13.2 | 49.2±15.5 | 30/30 | HSM; 40-50 min/d, 20d Needling Acupuncture; 30 min/d, 20d | Total nasal symptom and sign score (after cessation of treatment) | 3 months |
| Lin 2017a [38] | 26.5±6.2 | 27.9±6.1 | 35/35 | HSM; 30-60 min/d, 20d Needling Acupuncture; 30 min/d, 20d | Total nasal symptom and sign score (after 3 months follow time) | not mention |
| Lin 2015 [39] | 32.00±1.67 | 30.83±1.68 | 24/24 | HSM; qd, 10d Needling Acupuncture; 30 min/d, 20d | Total effective rate (after cessation of treatment) | not mention |
| Cai 2014 [40] | 16~65 | 16~65 | 20/20 | HSM; 30-60 min/d, 20d Needling Acupuncture; 30 min/d, 20d | Total effective rate (after 3 months follow time) | not mention |

- Total nasal symptom and sign score; □ total effective rate; □ Rhinoconjunctivitis quality of life; □ adverse events

### Table 3: Level of evidence

| Outcome                                                                 | Included studies                                      | Effect size                                      | Level of Evidence |
|------------------------------------------------------------------------|------------------------------------------------------|-------------------------------------------------|------------------|
| Total nasal symptom and sign score (after cessation of treatment)     | 10 RCTs, 725 participants                            | SMD = -1.46, 95%CI (-1.81, -1.10), \( P<0.00001 \), \( I^2 = 56\% \) | ⊕⊕⊕(1) (2)(4)     |
|                                                                        |                                                      |                                                 | Very low         |
| Total nasal symptom and sign score (after 3 months follow time)       | 3 RCTs, 220 participants                            | SMD = -2.87, 95%CI (-5.11, -0.63), \( P<0.0001 \), \( I^2 = 90\% \) | ⊕⊕(1) (2)(3)     |
|                                                                        |                                                      |                                                 | Very low         |
| Total effective rate (after cessation of treatment)                    | 15 RCTs, 1087 participants                         | OR = 2.96, 95%CI (2.19, 4.00), \( P<0.000001 \), \( I^2 = 0\% \) | ⊕⊕⊕⊕(1)          |
|                                                                        |                                                      |                                                 | Moderate         |
| Total effective rate (after 3 months follow time)                     | 6 RCTs, 535 participants                           | OR = 5.31, 95%CI (3.66, 7.72), \( P<0.000001 \), \( I^2 = 0\% \) | ⊕⊕⊕⊕(1)          |
|                                                                        |                                                      |                                                 | Moderate         |
| Rhinoconjunctivitis quality of life questionnaire                     | 4 RCTs, 272 participants                           | SMD = -7.80, 95%CI (-13.92, -1.68), \( P<0.000001 \), \( I^2 = 95\% \) | ⊕⊕⊕⊕(1)(2) (3)(4) |
|                                                                        |                                                      |                                                 | Very low         |

(1) Allocation concealment or blinding inadequate; (2) \( I^2 >50\% \) or large heterogeneity; (3) Less sample size, wide 95%CI; (4) funnel plot dissymmetry or language limitation.

### Figures
Figure 1

Citations identified through seven electronic databases search (n=91)
- CNKI: 23
- WF: 25
- VIP: 21
- CBM: 17
- PubMed: 2
- Cochrane Library: 2
- Embase: 1

Additional records identified through Library of Jiangxi University of TCM (n=2)

Records after duplicates removed (n=35)

Records screened (n=35)

Records excluded (n=8)
- An article has been published more than once (1)
- One paper has been published in different language (2)
- Animal study (1)
- Review (2)
- Protocol (1)
- Abstract (1)

Full-text articles assessed for eligibility (n=27)

Full-text articles excluded, with reasons (n=12)
- Not RCT (9)
- Not the intervention of interest (2)
- Not the outcome of interest (1)

Studies included in meta-analysis (n=15)

Figure 1. Flowchart of literature selection
Figure 1

Flowchart of literature selection.
Figure 2

Risk of bias graph.

Figure 3

Risk of bias summary.
| Study     | Random sequence generation (selection bias) | Allocation concealment (selection bias) | Blinding of participants and personnel (performance bias) | Blinding of outcome assessment (detection bias) | Incomplete outcome data (attrition bias) | Selective reporting (reporting bias) | Other bias |
|-----------|------------------------------------------|----------------------------------------|---------------------------------------------------------|-----------------------------------------------|----------------------------------------|-----------------------------------|-----------|
| Zhu 2020  | ✔                                        | ✔                                      | ✔                                                       | ☐                                             | ☐                                      | ☐                                 | ☐         |
| Zhang 2011| ✔                                        | ☐                                      | ☐                                                       | ☐                                             | ☐                                      | ☐                                 | ☐         |
| Yang 2009a| ✔                                        | ☐                                      | ☐                                                       | ☐                                             | ☐                                      | ☐                                 | ☐         |
| Yang 2009b| ✔                                        | ✔                                      | ✔                                                       | ☐                                             | ☐                                      | ☐                                 | ☐         |
| Xu 2016   | ☐                                        | ☐                                      | ☐                                                       | ☐                                             | ☐                                      | ☐                                 | ☐         |
| Xiong 2019| ☐                                        | ☐                                      | ☐                                                       | ☐                                             | ☐                                      | ☐                                 | ☐         |
| Lin 2015  | ☐                                        | ☐                                      | ☐                                                       | ☐                                             | ☐                                      | ☐                                 | ☐         |
| Lin 2017a | ☐                                        | ☐                                      | ☐                                                       | ☐                                             | ☐                                      | ☐                                 | ☐         |
| Lin 2017b | ☐                                        | ☐                                      | ☐                                                       | ☐                                             | ☐                                      | ☐                                 | ☐         |
| Li 2019   | ☐                                        | ☐                                      | ☐                                                       | ☐                                             | ☐                                      | ☐                                 | ☐         |
| Huang 2020| ☐                                        | ☐                                      | ☐                                                       | ☐                                             | ☐                                      | ☐                                 | ☐         |
| Cao 2017  | ☐                                        | ☐                                      | ☐                                                       | ☐                                             | ☐                                      | ☐                                 | ☐         |
| Cao 2014  | ☐                                        | ☐                                      | ☐                                                       | ☐                                             | ☐                                      | ☐                                 | ☐         |

**Figure 3**

Risk of bias summary.
Figure 3

Risk of bias graph.

| Study or Subgroup   | Experimental Mean | SD   | Total | Control Mean | SD   | Total | Weight | Mean Difference IV, Random, 95% CI | Mean Difference IV, Random, 95% CI |
|---------------------|-------------------|------|-------|--------------|------|-------|--------|-----------------------------------|-----------------------------------|
| 1.1.1 HSM vs Western Drug |                   |      |       |              |      |       |        |                                   |                                   |
| Zhang 2014          | 5.66              | 4.78 | 30    | 9.35         | 5.27 | 30    | 1.8%   | -3.69 [-6.24, -1.14]              |                                   |
| Yang 2009b          | 4.48              | 3.68 | 60    | 6.96         | 3.93 | 60    | 5.3%   | -1.48 [-2.84, -0.12]              |                                   |
| Xiong 2019          | 4.9               | 1.5  | 30    | 5.5          | 1.3  | 30    | 12.0%  | -0.60 [-1.31, 0.11]               |                                   |
| Lv 2013             | 2.88              | 0.39 | 40    | 4.00         | 1.17 | 40    | 20.3%  | -1.20 [-1.58, -0.62]              |                                   |
| Lin 2017b           | 3.86              | 2    | 36    | 5.86         | 2.05 | 36    | 9.2%   | -2.00 [-2.94, -1.08]              |                                   |
| Subtotal (95% CI)   |                   |      |       |              |      |       |        | -1.37 [-1.98, -0.76]              |                                   |
|                     |                   |      |       |              |      |       |        |                                   |                                   |
| Heterogeneity: Test for overall effect: |                   |      |       |              |      |       |        | Z = 4.40 (P < 0.0001)           |                                   |
|                     |                   |      |       |              |      |       |        |                                   |                                   |
| 1.1.2 HSM vs Needling Acupuncture |                   |      |       |              |      |       |        |                                   |                                   |
| Zhang 2011          | 2.6               | 1.5  | 30    | 5.2          | 2.1  | 30    | 9.4%   | -2.60 [-3.52, -1.68]              |                                   |
| Lin 2015            | 3.5               | 3.14 | 24    | 3.02         | 2.56 | 24    | 4.0%   | -0.12 [-1.74, 1.50]               |                                   |
| Huang 2020          | 4.69              | 3.77 | 29    | 6.83         | 3.36 | 29    | 3.3%   | -2.14 [-3.96, -0.32]              |                                   |
| Subtotal (95% CI)   | 83                |      |       |              |      | 84    | 16.7%  | -1.70 [-3.23, 0.17]               |                                   |
|                     |                   |      |       |              |      |       |        |                                   |                                   |
| Heterogeneity: Test for overall effect: |                   |      |       |              |      |       |        | Z = 2.18 (P = 0.03)             |                                   |
|                     |                   |      |       |              |      |       |        |                                   |                                   |
| 1.1.3 HSM vs Suspended Moxibustion |                   |      |       |              |      |       |        |                                   |                                   |
| Xu 2016             | 3.93              | 2.23 | 40    | 5.55         | 2.52 | 40    | 8.0%   | -1.62 [-2.66, -0.58]              |                                   |
| Subtotal (95% CI)   | 40                |      |       |              |      | 40    | 8.0%   | -1.62 [-2.66, -0.58]              |                                   |
|                     |                   |      |       |              |      |       |        |                                   |                                   |
| Heterogeneity: Test for overall effect: |                   |      |       |              |      |       |        | Z = 3.04 (P = 0.002)            |                                   |
|                     |                   |      |       |              |      |       |        |                                   |                                   |
| 1.1.4 HSM + Needling Acupuncture vs Needling Acupuncture |                   |      |       |              |      |       |        |                                   |                                   |
| Cao 2017            | 0.37              | 0.21 | 43    | 1.75         | 0.82 | 43    | 25.9%  | -1.38 [-1.49, -1.27]              |                                   |
| Subtotal (95% CI)   | 43                |      |       |              |      | 43    | 25.9%  | -1.38 [-1.49, -1.27]              |                                   |
|                     |                   |      |       |              |      |       |        |                                   |                                   |
| Heterogeneity: Test for overall effect: |                   |      |       |              |      |       |        | Z = 23.64 (P < 0.000001)         |                                   |
|                     |                   |      |       |              |      |       |        |                                   |                                   |

Figure 4

Forest plots of the total nasal symptom and sign score (after cessation of treatment).
Figure 4

Forest plots of the total nasal symptom and sign score (after cessation of treatment).

Figure 5

Forest plots of the total nasal symptom and sign score (after 3 months follow time).
Figure 5

Forest plots of the total nasal symptom and sign score (after 3 months follow time).
Figure 6

Forest plots of the total effective rate (after cessation of treatment).
Figure 7

Forest plots of the total effective rate (after 3 months follow time).
### Figure 7

Forest plots of the total effective rate (after 3 months follow time).
### Figure 7

Forest plots of the total effective rate (after cessation of treatment).

| Study or Subgroup | Experimental | Control | Odds Ratio | Total events | Heterogeneity | Test for overall effect |
|-------------------|--------------|---------|------------|--------------|---------------|-------------------------|
| 2.1.1 HSM vs Western Drug | | | | | | |
| Kong 2019 | 23 | 30 | 22 | 30 | 10.0% | 1.19 [0.37, 3.65] |
| Lin 2017b | 30 | 36 | 24 | 36 | 7.8% | 2.50 [0.82, 7.64] |
| Li 2019 | 15 | 18 | 12 | 18 | 3.9% | 2.60 [0.51, 12.14] |
| Yang 2008a | 57 | 68 | 44 | 66 | 13.8% | 2.83 [1.25, 6.38] |
| Yang 2008b | 51 | 60 | 38 | 60 | 11.1% | 3.28 [1.36, 7.92] |
| Zhang 2014 | 36 | 30 | 19 | 30 | 4.9% | 3.76 [1.04, 13.65] |
| Lu 2013 | 35 | 40 | 25 | 40 | 6.1% | 4.20 [1.35, 13.00] |
| Subtotal (95% CI) | 282 | 282 | 57.5% | 2.79 [1.87, 4.17] |
| Total events | 237 | 184 | | | | |
| Heterogeneity: Chi² = 2.91, df = 6 (P = 0.82), I² = 0% |
| Test for overall effect: Z = 5.01 (P = 0.00001) |

| 2.1.2 HSM vs Needling Acupuncture | | | | | | |
| Lin 2015 | 20 | 24 | 19 | 24 | 6.2% | 1.32 [0.31, 5.65] |
| Lin 2017a | 29 | 35 | 26 | 35 | 7.7% | 1.67 [0.52, 5.34] |
| Cal 2014 | 15 | 20 | 11 | 20 | 3.3% | 2.43 [0.64, 9.39] |
| Huang 2020 | 26 | 29 | 21 | 30 | 4.2% | 3.71 [0.89, 15.48] |
| Zhang 2011 | 25 | 30 | 13 | 30 | 4.2% | 6.54 [1.97, 21.74] |
| Subtotal (95% CI) | 138 | 139 | 28.5% | 2.76 [1.56, 4.87] |
| Total events | 115 | 90 | | | | |
| Heterogeneity: Chi² = 3.80, df = 4 (P = 0.42), I² = 0% |
| Test for overall effect: Z = 3.49 (P = 0.0005) |

| 2.1.3 HSM vs Suspended Moxibustion | | | | | | |
| Ku 2016 | 36 | 40 | 26 | 40 | 5.1% | 4.85 [1.43, 16.42] |
| Subtotal (95% CI) | 40 | 40 | 5.1% | 4.85 [1.43, 16.42] |
| Total events | 36 | 26 | | | | |
| Heterogeneity: Not applicable |
| Test for overall effect: Z = 2.63 (P = 0.01) |

| 2.1.4 HSM + Needling Acupuncture vs Needling Acupuncture | | | | | | |
| Zhu 2020 | 36 | 40 | 29 | 40 | 5.6% | 3.41 [0.98, 11.95] |
| Cao 2017 | 41 | 43 | 36 | 43 | 3.3% | 3.99 [0.78, 20.43] |
| Subtotal (95% CI) | 83 | 83 | 8.9% | 3.62 [1.35, 9.75] |
| Total events | 77 | 65 | | | | |
| Heterogeneity: Chi² = 0.02, df = 1 (P = 0.88), I² = 0% |
| Test for overall effect: Z = 2.55 (P = 0.01) |

| Total (95% CI) | 543 | 544 | 100.0% | 2.96 [2.19, 4.00] |
| Total events | 465 | 365 | | | | |
| Heterogeneity: Chi² = 7.77, df = 14 (P = 0.30), I² = 0% |
| Test for overall effect: Z = 7.06 (P = 0.00001) |
| Test for subharbour differences: Chi² = 0.93, df = 3 (P = 0.82), I² = 0% |
### Figure 8

Forest plots of RQLQ (after cessation of treatment).

| Study or Subgroup                      | Experimental | Control | Mean Difference IV, Random, 95% CI |
|----------------------------------------|--------------|---------|-----------------------------------|
| **3.1.1 HSM vs Western Drug**          |              |         |                                   |
| Zhang 2014                              | 10.6         | 6.62    | -3.93 [-7.24, -0.62]              |
| Subtotal (95% CI)                       | 30           | 30      | -3.93 [-7.24, -0.62]              |
| Heterogeneity: Not applicable           |              |         |                                   |
| Test for overall effect: $Z = 2.32$ ($P = 0.02$) |              |         |                                   |

| **3.1.2 HSM vs Needling Acupuncture**  |              |         |                                   |
| Huang 2020                              | 40.69        | 2.75    | -13.27 [-14.72, -11.82]           |
| Lin 2017b                               | 7.73         | 6.96    | -2.11 [-5.03, 0.81]               |
| Subtotal (95% CI)                       | 68           | 66      | -7.76 [-16.70, 1.17]              |
| Heterogeneity: $Tata = 60.93$, $Chi^2 = 45.02$, df = 1 ($P < 0.00001$), $P = 0.92$ | 68           | 66      | -7.76 [-16.70, 1.17]              |
| Test for overall effect: $Z = 1.39$ ($P = 0.16$) |              |         |                                   |

| **3.1.3 HSM vs Suspended Moxibustion** |              |         |                                   |
| Xu 2016                                 | 31.39        | 0.12    | -11.75 [-15.65, -7.85]            |
| Subtotal (95% CI)                       | 40           | 40      | -11.75 [-15.65, -7.85]            |
| Heterogeneity: Not applicable           |              |         |                                   |
| Test for overall effect: $Z = 2.30$ ($P = 0.01$) |              |         |                                   |

Total (95% CI) 136 136 100.0% [-7.80 [-13.92, -1.69]]

Heterogeneity: $Tata = 38.62$, $Chi^2 = 61.04$, df = 3 ($P < 0.00001$), $P = 95$

Test for overall effect: $Z = 2.50$ ($P = 0.01$)

Test for subgroup differences: $Chi^2 = 8.97$, df = 2 ($P = 0.01$), $P = 77.7$

### Figure 9
Funnel plot of the total nasal symptom and sign score.

Figure 9

Funnel plot of the total nasal symptom and sign score.
Figure 9

Forest plots of RQLQ (after cessation of treatment).

![Forest plots of RQLQ](image)

Subgroups:
- ○ HSM vs Western Drug
- ▲ HSM vs Needling Acupuncture
- □ HSM vs Suspended Moxibustion
- △ HSM + Needling Acupuncture vs Needling Acupuncture

Figure 10

Funnel plot of the total nasal symptom and sign score.
Figure 10

Funnel plot of the total effective rate.
Figure 11

Funnel plot of the total effective rate.