

# EVIDENCE-BASED INTEGRATIVE MEDICINE

## Catgut Implantation at Acupoints for Allergic Rhinitis: A Systematic Review\*

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**ABSTRACT** **Objective:** To assess the effectiveness and the possible adverse effects of catgut implantation at acupoints for allergic rhinitis (AR). **Methods:** This systematic review was carried out in accordance with the Cochrane Handbook version 5.1.0 and the Preferred Reporting Items for Systematic Reviews and Meta-Analyses statement. Extensive literature searches were conducted in PubMed, Excerpta Medical Databases, the Cochrane Library, the China National Infrastructure, Wanfang Chinese Digital Periodical and Conference Database, and the Weipu Chinese Science and Technique Journals Database. The Chinese Clinical Trial Registry Center was also searched for ongoing trials up to September 2012. Randomized controlled trials (RCTs) or quasi-RCTs were included. Risk of bias assessment was performed using the Cochrane tool for assessing risk of bias. **Results:** Five RCTs with 285 participants were found from 49 relevant studies, but there was just one RCT which met the inclusion criteria for this review. The study showed that treatment of catgut implantation at acupoints could lead to a better alleviation of the signs and symptoms of AR than the crude herb moxibustion. No adverse events were reported in this study. **Conclusions:** Because of the methodological shortcoming and the risk of bias of the included trial, catgut implantation was proved with only limited evidence for the treatment of AR. Robust RCTs with high quality and larger sample size in this field are hoped to be carried out in the future.

**KEYWORDS** catgut implantation at acupoints, allergic rhinitis, systematic review

Allergic rhinitis (AR) is a disease characterized by immunoglobulin E (IgE)-mediated inflammation of the membranes lining the nose. In most cases, AR is triggered by inhaled antigens with symptoms of nasal obstruction, itching, watery rhinorrhea, and sneezing.<sup>(1)</sup> With industrialization of most of the countries, AR has become a major health problem worldwide in recent decades. It has been estimated by the Allergic Rhinitis and Its Impact on Asthma (ARIA) 2008 document that over 600 million patients from all countries, all ethnic groups, and of all ages suffer from AR.<sup>(2)</sup> In China, an epidemiological survey in 11 major cities showed that the prevalence of AR had increased to 24.6% in 2007.<sup>(3)</sup> Furthermore, because of the similarities presented by the nasal and bronchial mucosa and the functional complementarity in nose-lung interactions, most patients with rhinitis also have asthma. The prevalence of asthma in patients with rhinitis could reach up to 40%, and most patients with asthma experience rhinitis symptoms.<sup>(4,5)</sup>

Poorly controlled symptoms of AR may contribute to sleep disturbance, daytime fatigue, and learning disability in children. AR causes impairment in quality of life (QOL) of patients and results in

significant healthcare costs.<sup>(6,7)</sup> Uncontrolled AR may lead to productivity losses. It has thus become an urgent task to seek effective treatments for AR.

Intranasal glucocorticosteroids and oral H<sub>1</sub>-antihistamines are the predominant therapies offered to patients with AR.<sup>(8,9)</sup> However, there are some problems existing with these treatments, including the unfavorable efficacy of glucocorticosteroids, and the medication-dependent local side effects, the sedative

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and anticholinergic effects of H<sub>1</sub>-blockers.

Acupuncture has been accepted as a therapeutic option for relieving symptoms of AR in China and some other countries. As a subtype of acupuncture, catgut implantation at acupoints has also been widely used for AR in China. According to Chinese medicine (CM), AR is primarily caused by the dysfunction of the Lung (Fei), Spleen (Pi) and Kidney (Shen). CM believes that retention of pathogenic heat in the Lung, insufficiency of the Lung-qi and Spleen-qi could disturb the function of the nose. CM also believes that each acupoint is on a certain energetic pathway, known as a meridian. Acupoints, such as Yintang (EX-HN3), Yingxiang (LI20) and Zusanli (ST36), could be responsible for the meridian of the Lung or the Spleen. Thus these acupoints could be used for regulating the function of the nose. By certain manipulation, the stimuli at the acupoints could pass along the meridians and reach the corresponding organs; then some dysfunction of the organs could be treated.

In catgut implantation at acupoints for AR, a catgut would be embedded at the appropriate acupoint by a special needle. A period of time may be needed for the catgut to be completely absorbed by the tissue. Therapeutic effects can be achieved by the continuous stimulation caused by the catgut at the acupoint. So, compared with conventional acupuncture, a prolonged needling sensation could be obtained with this therapy. However, there remains a lack of firm clinical evidence to support the efficacy of this therapy. A systematic review is an appropriate method of assessing the evidence on actual outcomes of clinical effectiveness and safety. Thus the aim of this review is to systematically assess the efficacy of catgut implantation at acupoints for AR.

## METHODS

This systematic review was carried out and reported in accordance with Cochrane Handbook for Systematic Reviews of Interventions, Version 5.1.0<sup>(10)</sup> and the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA).<sup>(11)</sup>

### Criteria for Considering Studies for this Review

#### Types of Studies

Randomized controlled trials (RCTs) or quasi-RCTs were enrolled.

#### Types of Participants

Adults and children diagnosed with either

intermittent AR or persistent AR were included in this review. Diagnosis is generally based on the concordance between a typical history of AR and diagnostic tests. Typical symptoms of AR include rhinorrhea, sneezing, nasal obstruction, and pruritus. Skin tests or the measurement of specific IgE are necessary in the diagnostic criteria for this disease. AR with complications, such as asthma, was excluded.

#### Types of Interventions

We compared catgut implantation at acupoints with conventional medicine or with other intervention regimen. The trial, in which the intervention strategy was catgut implantation at acupoints combined with another intervention regimen, while the control measure was just "another intervention regimen", would also be included.

#### Types of Outcome Measures

##### Primary Outcomes

Improvements in AR severity and disability were assessed. The primary outcomes were likely to fall into one of the three categories: (1) improvement of overall symptoms, (2) improvement of QOL, and (3) clinical efficacy or clinical cure rate.

##### Secondary Outcomes

Because a range of biomarkers could be tested to see if catgut implantation could result in reducing allergic inflammation through different anti-inflammatory pathways, the following special parameters given in details could be used as the secondary outcomes: (1) changes of T cell functions, (2) reduction in eosinophil/ or neutrophil infiltrations, (3) blocking of nerve function or release of neurological mediators, (4) change of serum-specific IgE, and (5) change of other laboratory indicators.

### Search Methods for Identification of Studies

#### Electronic Searches

Electronic searches were carried out in PubMed (1992 to September Week 1, 2012), Excerpta Medical Databases (EMBASE, 1992 to September 2012), Cochrane Library (Issue 9 of 12, September 2012), the Chinese Cochrane Centre's Controlled Trials Register (up to September 2012), Wanfang Chinese Digital Periodical and Conference Database (1997 to September 2012), and the Weipu (VIP) Chinese Science and Technique Journals Database (1992 to September 2012). The Chinese Clinical Trial Registry

Center (up to September 2012) was also searched for ongoing trials.

The following search strategy was used in PubMed. The similar search terms were adapted to EMBASE and the Cochrane Library. If the search strategy for PubMed was taken as an example, it could be listed as the following: (1) catgut implantation, (2) catgut embedding, (3) thread embedding, (4) thread implantation, (5) #1~#4/OR, (6) AR, and (7) #5 AND #6.

Search strategy used in the China National Knowledge Infrastructure (CNKI) was as follows: Title/Topic/Keyword=("catgut implantation" or "embedding therapy") AND Title/Topic/Keyword=("allergic rhinitis" or "Biqui disease") AND Text=(random). Similar search terms were adapted to the Wanfang and VIP databases.

#### Searching Other Resources

We attempted to identify additional studies by searching the reference lists of relevant trials, conference proceedings and journals. Authors were contacted to obtain more details.

### Data Collection and Analysis

#### Selection of Studies

Titles and abstracts of articles found in the searches were reviewed. Full texts of those which appeared eligible were retrieved. Details of the trials were extracted independently by two review authors. Disagreements were resolved by consensus and, when necessary, consultation with a third review author.

#### Data Extraction and Management

Data on participants, interventions, and outcomes were abstracted using a standard data extraction form. In the form the following information was included: (1) general information (study's eligibility, centers involved, etc.), (2) trial characteristics (method of randomization, concealment and blinding, etc.), (3) interventions, (4) patients (distribution of sex and age, baseline status, etc.), (5) outcomes (outcome measurements, lost to follow-up, time intervals at which the variables were recorded, etc.), and (6) results.

#### Assessment of Risk of Bias in Included Studies

The quality for each trial was assessed according to the quality criteria specified by the Cochrane

Handbook for Systematic Reviews of Interventions (Version 5.1.0). In particular, the following factors were studied: (1) sequence generation (selection bias), (2) allocation sequence concealment (selection bias), (3) binding of participants, personnel and outcome assessment (performance bias), (4) incomplete outcome data (attrition bias), (5) selective outcome reporting (reporting bias), and (6) other biases.

If statements were not clear, more information on the risk of bias of the studies was acquired by telephoning the author. The judgment is expressed as "low risk", "high risk" or "unclear risk" for each bias in the study. The response "Yes" indicates low risk of bias and "No" indicates high risk of bias.

### Data Synthesis

Statistical analyses were calculated using Review Manager 5.1. Heterogeneity was evaluated by a test for heterogeneity ( $I^2$  statistic) on the level of  $\alpha=0.10$ . If there was substantial or considerable heterogeneity ( $I^2>50\%$ ), the results would be assessed by a random effects model; if not, the fixed effects model would be used. The measurement of treatment effect for dichotomous data was expressed as relative risk (RR) along with the 95% confidence intervals (CIs); for continuous data, mean difference (MD) with 95% CIs were adopted. The statistical significance for the hypothesis test was set at  $\alpha=0.05$  (two-tailed Z test). Subgroup analysis was performed according to the different types of interventions used in the study, such as catgut implantation combined with different regimens. Publication bias was assessed by a drawing funnel plot if the number of included studies exceeded 10.

## RESULTS

### Description of Studies

After searching with the strategies mentioned above, five studies<sup>(12-16)</sup> and one ongoing trial with unpublished data were found (Figure 1). Four of the five studies<sup>(12-15)</sup> were excluded because the types of interventions used did not fulfill the inclusion criteria. Details of the four excluded studies and the characteristics of the ongoing trial can be seen in Tables 1 and 2, respectively. Characteristics of the one included trial<sup>(16)</sup> can be seen in Table 3.

### Data Analysis

It had been planned to include data with the same

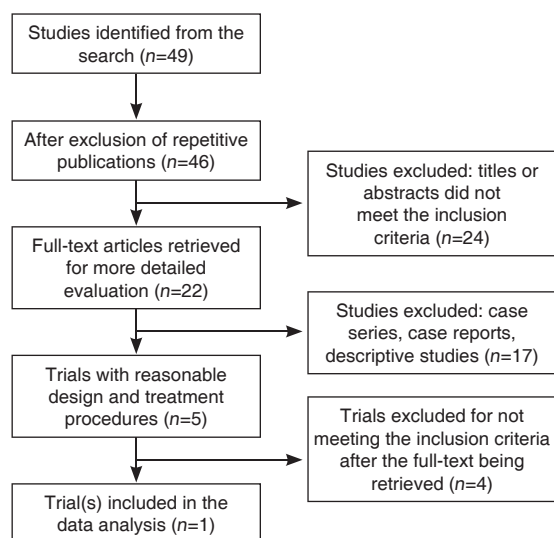


**Figure 1. Flow Diagram of the Studies Included from the Systematic Review**

**Table 1. Reason for Excluding the Four Studies**

| Study                            | Reason for exclusion                                                                                                                                                                                                             |
|----------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Luo, et al. 2010 <sup>(12)</sup> | Garlic moxibustion combined with catgut implantation at acupoints was administered in the intervention group while acupuncture therapy was implemented in the control group, which did not meet the intervention criteria.       |
| Wu 2011 <sup>(13)</sup>          | Catgut implantation at acupoints combined with polarized infrared light was administered in the intervention group while acupuncture therapy was implemented in the control group, which did not meet the intervention criteria. |
| Zou 2011 <sup>(14)</sup>         | Catgut implantation at acupoints combined with moxibustion was administered in the intervention group while acupuncture therapy was implemented in the control group, which did not meet the intervention criteria.              |
| Zhu, et al. 2009 <sup>(15)</sup> | Catgut implantation at acupoints combined with cupping glass was administered in the intervention group while conventional medicine was implemented in the control group, which did not meet the intervention criteria.          |

interventions in a meta-analysis. But because only one trial met the inclusion criteria, this was not possible.

### Risk of Bias in the Included Study

There was one study included in this review.<sup>(16)</sup> In this trial, the short-term efficacy of catgut implantation was compared with that of the crude herb moxibustion. Risks of bias in this trial were assessed according to the quality criteria specified by the Cochrane Handbook (Version 5.1.0).

### Randomization Procedure

A random number table was used to generate

**Table 2. Characteristics of the Ongoing Trial**

| Content item        | Detail                                                                                                                                                                                                                                                |
|---------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Study name          | A randomized, sham-controlled trial of catgut implantation at acupoints for the treatment of AR                                                                                                                                                       |
| Methods             | Randomized, double-blind, parallel, controlled study                                                                                                                                                                                                  |
| Participants        | Outpatients with AR                                                                                                                                                                                                                                   |
| Interventions       | Real versus sham catgut implantation at acupoints                                                                                                                                                                                                     |
| Outcomes            | Visual analogue scale for the measurement of severity of nasal symptoms, SF-36 questionnaire of QOL, serum allergen-specific IgE, nasal inflammatory cells counts (mast cells, eosinophils, basophils), relief medication scores, side effects scores |
| Starting date       | Dec. 1, 2012                                                                                                                                                                                                                                          |
| Contact information | Department of Otorhinolaryngology-Head and Neck Surgery, Teaching Hospital of Chengdu University of Traditional Chinese Medicine, No39, Shi-er-qiao Road, Jinniu District, Chengdu (610072), Sichuan, China                                           |

**Table 3. Characteristics of the One Included Trial**

| Content item                   | Detail                                                                                                                |
|--------------------------------|-----------------------------------------------------------------------------------------------------------------------|
| Study name                     | Comparison of short-term therapeutic effects of acupoint catgut embedding and crude herb moxibustion on AR            |
| Language                       | Chinese                                                                                                               |
| Methods                        | Randomized, parallel, controlled study                                                                                |
| Diagnostic criteria            | Chinese standard of diagnosis and curative effect evaluation criteria of AR (Revised in 1997, Haikou) <sup>(17)</sup> |
| Participants                   | 72 outpatients with AR                                                                                                |
| Interventions                  | Catgut implantation at acupoints versus crude herb moxibustion in the mid-summer                                      |
| Duration of follow-up          | About 40 days                                                                                                         |
| Withdraw and loss to follow-up | 0                                                                                                                     |
| Outcomes                       | Scores of symptoms and signs of AR were improved in the study group compared with the controlled group                |
| Starting date                  | Jul. 2003                                                                                                             |
| Contact information            | The Second Clinical Medical College, Guangzhou University of Traditional Chinese Medicine, Guangzhou (510120), China  |

a random number sequence. The number of participants in the two groups was in the ratio of 1:1. The allocation numbers were put into the envelopes in sequence. According to their hospital record number, the participant then chose one of the envelopes. The participant was then allocated into either the intervention or control group according to the random number sealed in the envelope. Other details of the

allocation concealment were not specified in the trial.

#### Allocation

Allocation concealment was not specified in this trial. In properly designed clinical trials, allocation concealment should be conducted by an independent person who should not participate in recruiting the participants. Then the allocation sequences should be put into an opaque container and stored securely. Because of the lack of allocation concealment, or more details of the randomization procedure, there might be a high risk of selection bias in this trial.

#### Blinding

Blinding was not mentioned in this study. In order to avoid risk of performance bias, the participants and/or healthcare provider should be blinded. Blinding is necessary for ensuring the compliance of a trial. Because the assessment of the severity of AR symptoms was proposed as the primary outcome in this study, blinding should have been used to try to secure the objectivity of the results. It is possible that blinding was difficult because the materials and manipulations used in the treatment were totally different in the test group than the control group. However, the outcome assessors should at least be blinded. Because there was no blinding in this study, there might be a high risk of performance bias.

#### Incomplete Outcome Data

In this study, there was no calculation of the sample size. In the whole process of the treatment for about 40 days, none of the 72 participants had dropped-out or withdrawn. If this was the case, incomplete bias might be low. In general, the participants' dropping-out, withdrawing or loss to follow-up during the treatment period or during the process of follow-up might lead to incomplete bias. To lower the loss rate of the participants, sample size with an allowance of 10%–20% of the loss number should be evaluated properly beforehand. If there is any case lost in the follow-up phase or withdrawal from the trial, the causes should be clarified. Furthermore, intention-to-treat and per-protocol analyses should be conducted.

#### Selective Reporting

In order to lower the reporting bias, all the results should be reported objectively and completely, no matter whether the results were positive or negative. It may be feasible to assess the reporting bias by comparing the results in the final reports with those in the protocol. However, this study had not been registered in the clinical

center and no protocol could be found. Therefore it was difficult to assess the reporting bias. The risks of reporting bias might be considered "unclear".

#### Effects of Interventions

Since there was just one identified study which met the inclusion criteria, data was extracted from Guo, et al<sup>(16)</sup> and the following results were found.

##### Improvement in the Signs and Symptoms of AR

According to the Chinese standard of diagnosis and curative effect evaluation criteria of AR in 1997,<sup>(17)</sup> clinical scores were used for the assessment of the severity of signs and symptoms. Symptoms, such as nasal obstruction, rhinorrhea, sneezing, and itch of the nose, were assessed. The size of the inferior and middle turbinate and whether there was a nasal polyp were all taken into account for the clinical scores. As a result, this study showed scores of the signs and symptoms of the test group were lower than that of the control group ( $2.05 \pm 1.98$  vs.  $3.56 \pm 2.32$ ,  $P < 0.01$ ). Therefore catgut implantation at acupoints was an effective therapeutic intervention for AR in this study.

##### Laboratory Examination

No biomarker was reported to determine whether catgut implantation at acupoints could result in reduced allergic inflammation through different anti-inflammatory pathways.

##### Adverse Events

No adverse effects were reported during treatment.

## DISCUSSION

#### Summary of the Main Results

There was no data that could be presented.

#### Overall Completeness and Applicability of Evidence

In the included trial, efficacy of catgut implantation at acupoints was assessed compared with that of crude herb moxibustion. Because of the low quality of the trial, it was difficult to draw any appropriate conclusions.

#### Quality of the Evidence

It may be a common occurrence in Chinese journal articles that methodological information was always not given in adequate. Because of a lack of contact information, the reliability of the randomization allocation procedure used in this trial could not be clarified by

telephoning the original authors of the study. It was showed that neither allocation concealment nor a blinding method was used in the trial, which could lead to a high risk of selection, performance and detection bias. In addition, bias may be due to the limited number of included trials. Another problem was that most of the trials did not receive ethical approval or had been registered, and therefore the validity of the trials may be in doubt.

### Implications for Practice

At present, there is no evidence from RCTs to recommend the routine use of catgut implantation at acupoints for AR. In addition, the safety of catgut implantation is not known due to the lack of reports of adverse events.

### Implications for Research

Catgut implantation at acupoints is generally believed to be a safe and effective treatment for improving the signs and symptoms of AR when used properly. But due to the absence of RCTs in this field, a conclusion for recommendation could not be drawn. Additional, well-designed RCTs needed be carried out to provide a definitive answer with adequate power. For many Chinese researchers, allocation concealment and blinding should be emphasized and the procedure should be reported clearly. It may be advisable to follow the updated guidelines for reporting parallel-group randomized trials (CONSORT).<sup>(18)</sup> Adverse effects should also be reported in detail, which would provide important information for clinicians.

### Conflict of Interest

No author has declared a conflict of interests with respect to this study.

### Author Contributions

Zhang QX contributed to the conception and design of the study. Li XR drafted the manuscript. Liu M, Chen Q and Liu Y contributed to data collection. All authors contributed to the data analysis and further writing of the manuscript. All authors read and approved the final manuscript.

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