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# How Effective is Acupuncture in Treating Persistent Allergic Rhinitis in Children and Adults?

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**How Effective is Acupuncture in Treating Persistent Allergic Rhinitis in Children and Adults?**

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A SELECTIVE EVIDENCE BASED MEDICINE REVIEW

In Partial Fulfillment of the Requirements For

The Degree of Master of Science

In

Health Sciences- Physician Assistant

Department of Physician Assistant Studies  
Philadelphia College of Osteopathic Medicine  
Philadelphia, Pennsylvania

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## ABSTRACT

**Objective:** The objective of this evidence based medicine review is to determine whether or not acupuncture is effective in treating persistent allergic rhinitis in children and adults.

**Study design:** Review of three published, randomized controlled trials (RCTs) published in 2004, 2007, and 2013. All English language.

**Data Source:** The three randomized controlled trials that used in this review were found using PubMed.

**Outcome measured:** Symptoms of nasal obstruction, rhinorrhea, sneezing and itching were measured with the Total Nasal Symptom Score (TNSS). Other outcomes measured were: Daily rhinitis scores, relief medication scores symptom free days and relief quality of life questionnaire scores (RQLQ).

**Results:** In the study Choi *et al*, there was a statistically significant difference in TNSS between the active acupuncture group and sham acupuncture group ( $p=0.03$ ). However, there was no change in rhinitis quality of life score between groups, but a difference between each group and baseline was noted. In the study Xue *et al*, there was a significant difference noted in the TNSS ( $p=0.01$ ), however, individuals were still permitted to used symptomatic relief medication throughout the duration of the study. In Ng *et al*, there was no significant difference in daily rhinitis scores, but there was a significant change in percentage of symptom-free days in the acupuncture group compared to the sham acupuncture group ( $p<0.0001$ ).

**Conclusions:** Evidence to support the use of acupuncture as a form of treatment for persistent allergic rhinitis at this time is inconclusive.

**Key words:** Acupuncture, Persistent, Allergic rhinitis

## **Introduction**

Allergic rhinitis (AR) is a symptomatic disorder of the nose in which an IgE-mediated response results from the exposure to allergens.<sup>1</sup> It is one of the most common allergic diseases in the United States affecting children and adults alike. However, incidence of onset is greatest in adolescence with peak prevalence being in the third and fourth decade of life.<sup>2</sup> According to the American Academy of Allergy Asthma and Immunology, in 2012, 7.5% of adults and 9% of children in the United States were diagnosed with allergic rhinitis.<sup>3</sup> Persistent allergic rhinitis (PAR), a subtype of AR, refers to having nasal symptoms such as nasal obstruction, sneezing, itching or rhinorrhea for more than 4 days per week, and more than 4 weeks per year.<sup>4</sup>

In 2010, 11.1 million visits were made to physician offices that resulted in the primary diagnoses of allergic rhinitis.<sup>3</sup> In the United States, the direct medical cost (physician services, diagnostics and medications) was 11.2 billion in 2005, double the amount (6.1 billion) that was spent in 2000.<sup>5</sup> The indirect costs of AR are also significant. There are 3.5 million workdays and 2 million school days lost in the United States each year.<sup>6</sup> Productivity decreases \$600 dollars for every employee that is affected per year.<sup>6</sup> This makes AR the fifth costliest chronic disease in the United States with 75% of costs due to decreased productivity.

Allergic rhinitis is caused by a Type I hypersensitivity reaction, which involves an excess production of IgE antibodies in response to allergen exposure. IgE antibodies attach to mast cells in the nose, the eyes and the lungs. As a consequence mast cells start to release inflammatory mediators that start to cause nasal mucosal edema and symptoms such as rhinorrhea, nasal itching, obstruction, and sneezing. Individuals with allergies have increased levels of allergen specific IgE in their nasal mucosa compared to people who do not have allergies.<sup>6</sup> In addition to these symptoms, individuals with PAR can also present with constant nasal congestion, post

nasal drip, headaches, impaired hearing, decreased taste and smell, earaches, sleep disturbances and impaired daytime concentration.<sup>1, 7</sup>

Two of the most common risk factors of AR are a history of asthma and atopy.<sup>1, 7</sup> Asthma can occur as a direct response to allergen exposure. This results in bronchospasm and an inflammatory response activated by the immune system.<sup>2</sup> Individuals with a predisposition to hypersensitivity reactions, or atopy, have a similar immune response. There are several factors that can contribute to atopy such as genetics, exposure to allergens, and environmental factors.<sup>2</sup>

Currently, there are many methods to treat AR, including avoidance of exposure to allergens, immunotherapy, and pharmacological agents. The most common medications used are intranasal corticosteroids, however, other medications such as antihistamines, decongestants, anticholinergic agents and leukotriene receptor antagonists are also used.<sup>1, 3, 7</sup> Nevertheless, some of these medications have to be taken for long periods of time and can cause side effects such as frequent nose bleeds or septal perforation.<sup>7</sup> It is for this reason that many individuals seek alternative methods that can help decrease their symptoms. Acupuncture, a form of complementary alternative medicine, uses insertion of needles into the skin in order to alter the body's immune response against these allergens and therefore reduce symptoms. Acupuncture may be used as an alternative treatment for individuals with PAR who wish to avoid the negative side effects caused by the more commonly used methods. This paper evaluates three randomized controlled trials (RCTs) comparing the efficacy of acupuncture as a form of treatment for patients with persistent allergic rhinitis.

### **Objective**

The objective of this systemic review is to determine whether or not acupuncture is effective in treating persistent allergic rhinitis in children and adults.

## Methods

The studies included in this review consist of three randomized controlled trials (RCTs). The criteria used for the selection of the studies depended on the target population, interventions used, comparisons between control group and active group, as well as the outcomes measured. The population was limited to individuals over the age of 6 with persistent allergic rhinitis. The intervention of interest used for participants was acupuncture. The experimental group received active acupuncture, while the control group received sham acupuncture.<sup>1, 7, 8</sup> Components such as needle size, number of needle insertion points and depth of insertion of needle varied between active and sham acupuncture groups, as well as between studies. Outcomes were measured with a total nasal symptom score (TNSS), relief medications score and number symptom-free days.

The study by Choi *et al*<sup>1</sup> was a multicenter, randomized, controlled trial. There were 238 individuals in the study. All participants were over the age of 18 and met the criteria for moderate to severe PAR. Individuals were randomly assigned to each group: 93 individuals were placed in the control group (sham acupuncture), 95 were placed in the active acupuncture group, and 42 individuals were placed on a waiting list.<sup>1</sup> In this study, both active and sham acupuncture groups received treatments three times a week, for a total of four weeks. For the active group, needles of 0.20mm in diameter X 30mm in length were inserted into 10 acupuncture points and rotated until participant and practitioner felt de qi, characterized by a grabbing or pulling sensation.<sup>1,9</sup> For the sham group, same size needles were inserted in sites that were located 1-1.5cm away from acupuncture sites to a depth of 3-5mm in order to avoid de qi sensation.<sup>1</sup>

In the study by Ng *et al*<sup>8</sup>, a double blind, randomized, placebo controlled trial, 72 children over the age of 6 with moderate to severe PAR were randomly assigned to two groups:

active acupuncture and sham acupuncture. In this study, children in both groups received acupuncture in 3 separate acupuncture points, two sessions per week for a total of eight weeks.<sup>8</sup> Needles of 0.3mm in diameter X 50mm and 0.25 in diameter X 13mm in length were used for both groups. The size of the needle used was dependent on the specific acupuncture point. In the active group needles were inserted to a depth of 0.7 to 1.2cm in each acupuncture point, and they were rotated every 5 minutes for 20 minutes.<sup>8</sup> In the sham group, same size needles were used, but the depth of insertion was 0.3cm and no manipulation of the needle was performed to avoid de qi.<sup>8</sup>

In the study by Xue *et al*<sup>7</sup>, a randomized, single blind, sham, controlled trial, 80 individuals between the ages of 16 and 70 with moderate to severe PAR, were randomly assigned to active or sham acupuncture groups. 38 individuals were placed in the active acupuncture group while 42 were placed in the sham acupuncture group.<sup>7</sup> Individuals received treatment in 3 acupuncture points, two times a week for a total of eight weeks.<sup>7</sup> Needles of 0.3mm in diameter X 30mm or 40mm in length were inserted to a depth of 10-30mm in the active group and needle manipulation was done every ten minutes as well as before needle withdrawal.<sup>7</sup> Each session was 25 minutes in length. For the sham acupuncture group, shorter needles were used (0.25mm in diameter and 13mm in length), and inserted to a depth of 3-5mm, in sites 1-1.5cm away from actual acupuncture points.<sup>7</sup>

Key words used in the search included “acupuncture,” “allergic rhinitis,” and “persistent.” The chosen studies were all written in English and published in peer-reviewed journals between the years 2004 and 2013. Literature searches were conducted using PubMed. Articles were selected based on their relevance to my clinical question as well as outcomes that were patient oriented. The inclusion criteria consisted of randomized controlled trials written

after 2000 in the English language which contained participants over the age of six. Exclusion criteria for articles included individuals under the age of six. Data obtained from all three studies were reported as continuous and could not be converted to dichotomous data. Summary of statistics reported included P-values and change in mean from baseline.

**Table 1-** Demographics and Characteristics of included studies

Study	Type	Pts (n)	Age (yrs)	Inclusion Criteria	Exclusion Criteria	W/D	Interventions
Choi <i>et al</i> , 2013	Multicenter, Randomized Control Trial	238	Age >18	> 18 years old, with moderate to severe PAR, Symptoms > 4 days per week for > 4 consecutive weeks, $\geq 4$ rhinitis associated symptoms, $\geq 1$ positive result on allergy skin prick reaction	Serious medical condition, congenital nasal abnormalities, sinusitis, asthma, history of nose surgery, CAM therapy for allergic rhinitis in < 6 months, use systemic corticosteroids, antihistamines, decongestants in < 6 months	40	Active acupuncture in 10 acupuncture points. 3 weekly sessions for 4 weeks.
Ng <i>et al</i> , 2000	Double blind, randomized, placebo controlled Trial	72	Age >6	$\geq 6$ of age, $\geq 4$ weeks of nasal symptoms, allergic d/o at $\geq 2$ other sites, $\geq 1$ positive results: elevated total blood IgE level, Eosinophilia, positive prick test	Congenital nasal abnormalities, congenital heart disorders, received systemic corticosteroids within 1 months of enrollment, children with acupuncture experience	9	Active acupuncture in 3 acupuncture points, 2 weekly session for 8 weeks
Xue <i>et al</i> , 2007	Randomized, single blind, sham, controlled trial	80	Age 16-70	Daily TNSS $\geq 6$ , > 2 year history of PAR, positive prick tests to at least one pollen and one non-pollen	Nasal polyposis, treatment with immunotherapy or systemic corticosteroids in < 2 years, active respiratory disease, acupuncture treatment in < 2 years, pregnancy, HIV, HBV, HVC	0	Active acupuncture in 3 acupuncture points, 2 weekly sessions for 8 weeks

## Outcomes Measured

In the Choi *et al* study, the main end point was to measure a change between groups in relief of symptoms such as rhinorrhea, nasal obstruction, sneezing and itching through a total nasal symptom score (TNSS) at the end of the 4 week treatment period. The TNSS was averaged every week and symptoms were rated based on a 0-4 scale; 0 being no symptoms and 4 being very severe. A secondary end point for this study was to measure a change between groups using the Rhinitis Quality of Life Questionnaire (RQLQ) score at the end of the treatment period.<sup>1</sup> This score measured the influence of AR in quality of life by looking at 28 questions in 7 different domains (sleep, non-nasal/eye symptoms, emotional function, practical problems, nasal symptoms, eye symptoms, and activities.) Each question was rated with a number between 0-6; 0= not impaired at all and 6= severely impaired. In the study Ng *et al*, the main outcomes were measured through a change in daily rhinitis score between active and sham acupuncture, as well as a change in percentage of symptom-free days at the end of the 8 weeks.<sup>8</sup> In the study by Xue *et al*, a change in TNSS from baseline for active and sham acupuncture was obtained, as well as a change in mean difference in relief medication score between active and sham acupuncture.<sup>7</sup>

## Results

In the study by Choi *et al*, a total of 230 out of 238 subjects were included in the analysis. A total of eight participants were excluded, five (one from the active group, one in the sham group and three from the wait list) were excluded because they did not disclose the use of prohibited medications at the start of enrollment.<sup>1</sup> Three others dropped out of the study before the first assessment. No significant differences were noted between individuals in each group regarding age, underlying health status, TNSS or RQLQ score.<sup>1</sup>

In Choi *et al*, there was a statistically significant difference of -1.03 (95% CI: -1.96, -0.09, P=0.03) in TNSS between the active and the sham acupuncture groups after 4 weeks. This significance remained after 4 weeks of finishing treatment.<sup>1</sup> In addition, there was a significant difference in TNSS between the active acupuncture group and the wait list group after the 4 weeks of treatment.<sup>1</sup> There was a difference of -2.49 (95% CI: -3.68, -1.29, p<0.0001). The RQLQ score did not change significantly between the active acupuncture group and the sham acupuncture group at the end of the 4 weeks of treatment (difference of -0.22, 95% CI: -0.53, 0.02, P=0.07). However, there was significant improvement in the RQLQ score of active acupuncture compared to baseline at the end of the 4 week treatment (difference of -1.08, 95% CI: -1.29, -0.88, P<0.0001) as well as the 4 weeks following treatment.<sup>1</sup> Similarly, the sham acupuncture group also had a significant change in RQLQ score from baseline at the end of treatment and at the end of the 4 weeks.<sup>1</sup> A difference of -.86, 95% CI: -1.05, -0.67, P< 0.0001 in 4 weeks, and a difference of -0.99, with a 95% CI: -1.20, -0.79, P- value <0.0001, was noted 4 weeks after treatment ended.<sup>1</sup>

In Choi *et al*, one subject in the sham acupuncture group withdrew from the study.<sup>1</sup> This participant reported being hospitalized during the trial. However, this was due to enteritis and it was believed not to have been related to acupuncture treatment.<sup>1</sup> There were no exceptional adverse events reported in the other two studies.

In Xue *et al*, 80 participants with PAR, between the ages of 16 and 70 were randomly selected and allocated into one of the two groups of acupuncture: active or sham.<sup>7</sup> TNSS and relief medication scores were measured at the end of the trial. There was a significant reduction from baseline in the TNSS in the active acupuncture group compared to the sham acupuncture group after the 8 weeks of treatment, (p=0.01).<sup>7</sup> This reduction remained 12 weeks after

treatment ended, ( $p=0.001$ ). In addition, there was a significant decline in the use of relief medication scores in the active acupuncture group from baseline to 8 weeks.<sup>7</sup> At baseline, the average medicine relief score was 7.2 with a 95% CI: 4.8-9.7, compared to an average medicine relief score of 4.1 at 8 weeks with a 95% CI: 2.2-5.9;  $P=0.001$ .<sup>7</sup> No drastic changes were noted on average relief medication score of the sham acupuncture group between baseline (4.4) and 8 weeks (3.6).<sup>7</sup> Table 2 summarizes these results.

**Table 2.** Xue *et al.* Mean Difference in TNSS after 8 and 20 weeks in Active V. Sham Acupuncture (95% CI)

Time	Active Acupuncture	Sham Acupuncture	P-Value
Week 8	-17.17 (-24.57 to -9.76)	-4.16 (-10.97 to 2.66)	0.01
Week 20	-21.00 (-29.11 to -12.89)	-2.29 (-10.21 to 5.63)	0.001

In Ng *et al.*, a total of 72 participants were recruited, all were children  $\geq 6$  years of age, since children under 6 were thought to be unlikely to cooperate with the acupuncturists. Daily rhinitis scores and percentage of symptom-free days were measured in this study.<sup>8</sup> There was no statistically significant difference in daily rhinitis score between the two groups during the trial period, however, there was significant reduction in daily rhinitis scores during the follow up period for the active acupuncture group ( $P=.03$ )<sup>8</sup> The active acupuncture group also had significantly higher percentages of symptom-free days during treatment and follow up periods compared to the sham acupuncture group ( $P=0.0001$ ).<sup>8</sup> Table 3 summarizes these results.

**Table 3.** Ng *et al.* % of symptom free days in Active V. Sham Acupuncture groups

Symptom-free Days (%)	Active Acupuncture	Sham Acupuncture	P-value
Treatment period	11.2 $\pm$ 0.06	3.7 $\pm$ 0.03	0.0001
Follow-up period	12.7 $\pm$ 0.04	2.4 $\pm$ 0.03	0.0001

## Discussion

The efficacy and safety of acupuncture in the treatment of PAR in individuals over the age of 6 was investigated in this literature review by analyzing 3 different RCTs: Xue *et al.*, Ng *et*

*al*, and Choi *et al*. While the results of all of these studies contained some statistically significant evidence suggesting that acupuncture is an effective treatment in the treatment of persistent allergic rhinitis, the clinical significance is questionable. For example, Choi *et al* showed there was a statistically significant reduction ( $p=.03$ ) in Total Nasal Symptom scores in individuals who received active acupuncture compared to those who received sham acupuncture. However, a reduction of 1.03 in TNSS is not clinically significant. This means that an individual's symptoms may have only been reduced from very severe to severe, moderate to mild, etc. In addition, the TNSS is an average of 4 symptoms, therefore it cannot be determined if the reduction was in one symptom, a few, or all. In addition, this study showed that there was no significant change between the rhinitis quality of life scores between the active acupuncture group and sham acupuncture group, yet both groups had a significant difference compared to their baseline. This occurrence can be attributed to a placebo effect.

Similarly, in Ng *et al*, there was no significant difference in daily rhinitis scores between the active acupuncture group and the sham acupuncture group. However, there was a significant difference in this score in the active group compared to baseline. This can be attributed to placebo effect. Ng *et al* was also the only study to use symptom free days as a measurable outcome to investigate if active acupuncture was effective in the treatment of PAR. There was a significantly higher percentage of symptom free days in the active acupuncture group, compared to the sham acupuncture group.<sup>8</sup>

In Xue *et al*, a statistically significant difference was noted in TNSS, however, participants in this study were permitted to take PAR symptomatic relief medication when they considered necessary.<sup>7</sup> The use of medication can be considered a confounding variable since it is unknown if the medication itself, or the acupuncture improved PAR symptoms. Furthermore,

the significant reduction in the use of relief medication scores in the active acupuncture group from baseline to 8 weeks cannot be attributed to either the medication itself or acupuncture.

While all three studies provide evidence that supports that acupuncture can be an effective treatment for PAR, the variability and methods used in each study, while similar, are different enough to warrant further research.

There were some limitations in the studies used in this review that could have affected their results. Two of the studies, Ng *et al* and Xue *et al*, had population sizes < 100 individuals, therefore, the findings of these studies could be considered less significant. Furthermore, each population varied significantly between each study, Ng *et al* looked at children in Hong Kong, while Choi *et al* looked at adults in china and Korea and Xue *et al* looked at adults in Australia. In addition, while all the studies were blinded and randomized, each study had their own specific protocol and method. The number of acupuncture insertion points varied between studies as well as location of needle insertion, depth of needle insertion, manipulation of needles during the trial, and duration of treatment. This literature review also had some limitations. All of the research used was found in the English language. Most of the research on acupuncture is done in other countries where English may not be the predominant language used.

Acupuncture is a form of complementary alternative medicine that is used for a variety of conditions such as bronchial asthma, acute sinusitis, headaches, tennis elbow, sciatica, duodenal ulcers, etc.<sup>9</sup> Acupuncture works through different mechanisms and pathways in the body.

However, the main mechanism of action is to alter the immune system's response to a specific stimulus.<sup>9</sup> For example, a needle inserted in a specific acupuncture point, stimulates the central nervous system to activate and start the release of specific chemicals and hormones that will in return alter how the body reacts to a specific condition, in this case allergic rhinitis. In 1996, the

FDA approved the use of acupuncture needles by licensed practitioners. However, even though it was approved in the United States, acupuncture costs are not covered by most insurance companies. Out of pocket costs for acupuncture can range from \$30 to \$100 dollars per treatment.<sup>9</sup> Acupuncture is considered safe with most of the common side effects being bruising, bleeding, and soreness or pain at site of insertion.<sup>9</sup>

### **Conclusion**

At this time, data that suggests acupuncture is an effective treatment for persistent allergic rhinitis in children and adults is inconclusive. It is for this reason that intranasal corticosteroids and other pharmacological agents should be used as treatment for persistent allergic rhinitis. One way to improve future research would be to standardize the way studies are executed. For example, insertion points used in sham acupuncture should be 1-1.5 cm away from actual acupuncture points to make sure that de qi does not occur. In addition, more acupuncture points, as well as standardization of needle size, could be used to improve results and the validity of future studies. Furthermore, the results of outcomes being measured can also be standardized using similar scales, such as a TNSS. This will help compare results from various studies and it will make it easier to evaluate the efficacy and safety of acupuncture in the treatment of persistent allergic rhinitis.

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