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Pediatrics 2004;114:1242-1247
DOI: 10.1542/peds.2004-0744

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<http://www.pediatrics.org/cgi/content/full/114/5/1242>

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American Academy of Pediatrics

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A Double-Blind, Randomized, Placebo-Controlled Trial of Acupuncture for the Treatment of Childhood Persistent Allergic Rhinitis

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ABSTRACT. *Objective.* To compare active acupuncture with sham acupuncture for the treatment of persistent allergic rhinitis among children.

Methods. Subjects with persistent allergic rhinitis were recruited from the pediatric outpatient clinic. They were randomized to receive either active acupuncture or sham acupuncture. Main outcome measures included daily rhinitis scores, symptom-free days, visual analog scale scores for immediate effects of acupuncture, daily relief medication scores, blood eosinophil counts, serum IgE levels, nasal eosinophil counts, patients' and parents' preferences for treatment modalities, and adverse effects.

Results. Eighty-five patients were recruited from the pediatric outpatient clinic at Kwong Wah Hospital, in Hong Kong. Thirteen patients withdrew before randomization; 35 patients (mean age: 11.7 ± 3.2 years) were randomized to receive active acupuncture for 8 weeks, and 37 patients (mean age: 11 ± 3.8 years) were randomized to receive sham acupuncture for 8 weeks. Acupuncture was performed twice per week for both groups. Both the assessing pediatricians and the patients were blinded. There were significantly lower daily rhinitis scores and more symptom-free days for the group receiving active acupuncture, during both the treatment and follow-up periods. The visual analog scale scores for immediate improvement after acupuncture were also significantly better for the active acupuncture group. There was no significant difference in the following outcome measures between the active and sham acupuncture groups: daily relief medication scores, blood eosinophil counts, serum IgE levels, and nasal eosinophil counts, except for the IgE levels before and 2 months after acupuncture in the sham acupuncture group. No severe adverse effects were encountered. Numbness, headache, and dizziness were found in both the active and sham acupuncture groups, with no difference in incidence, and the effects were self-limiting.

Conclusions. This study showed that active acupuncture was more effective than sham acupuncture in decreasing the symptom scores for persistent allergic rhinitis and increasing the symptom-free days. No serious adverse effect was identified. A large-scale study is re-

quired to confirm the safety of acupuncture for children. *Pediatrics* 2004;114:1242–1247; acupuncture, allergic rhinitis, rhinitis, children, pediatric, trial, randomized, controlled trial, complementary therapy.

Allergic rhinitis is a common condition, and its prevalence seems to be increasing.^{1–4} The prevalence of school-aged children with allergic rhinitis in Hong Kong is 35% to 44%.^{5,6} Allergic rhinitis is now classified as intermittent or persistent, and persistent allergic rhinitis refers to nasal symptoms (ie, nasal obstruction, sneezing, itching, or rhinorrhea) that are present for >4 days per week and >4 weeks per year.⁷ Acupuncture is used extensively for the treatment of allergic rhinitis in traditional Chinese medicine, as evidenced by the different case series published.^{8–12} In the United States, 5% of adults with rhinosinusitis used acupuncture to treat their disease.¹³ Unfortunately, randomized, controlled trial data are sparse. To date, only 1 single-blind, randomized, controlled trial of acupuncture treatment for adults with seasonal allergic rhinitis has been performed.¹⁴ This study was designed to compare the efficacy and adverse effects of active acupuncture and sham acupuncture in the treatment of childhood persistent allergic rhinitis.

METHODS

Study Design

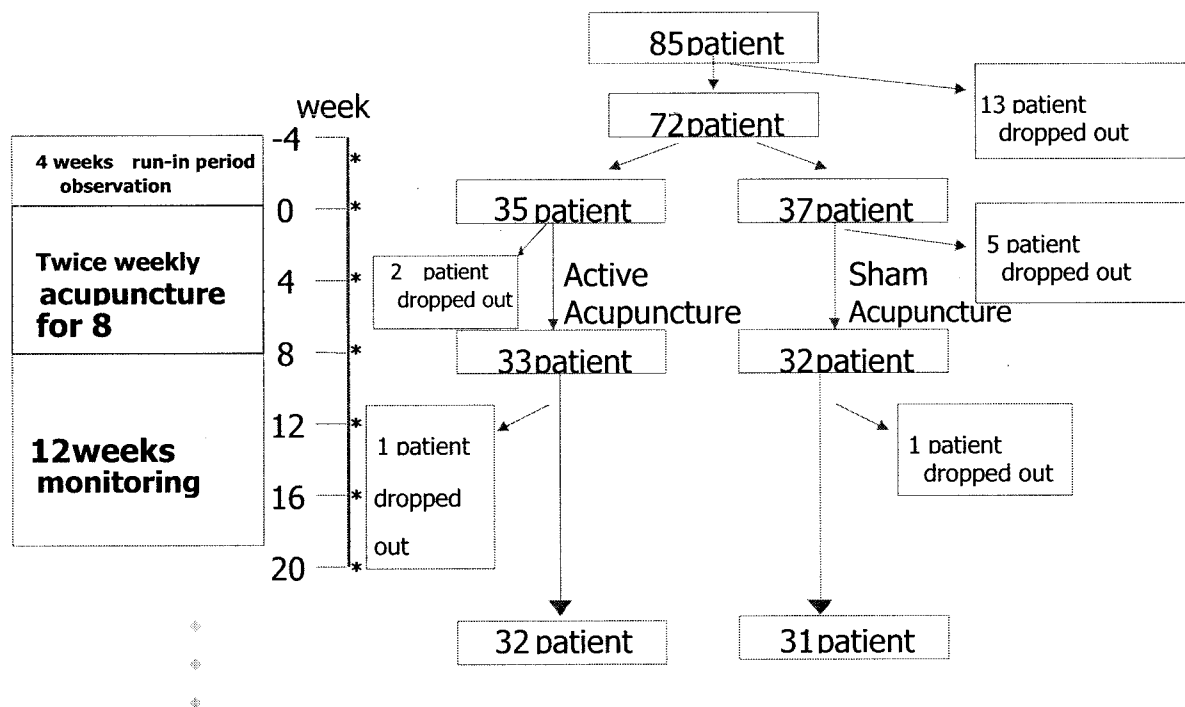
A double-blind, randomized, placebo-controlled trial was conducted in the Pediatric Respiratory Clinic of Kwong Wah Hospital, which is a nonteaching general hospital in Hong Kong. The study included the following periods: a run-in period of 4 weeks after screening, a treatment period of 8 weeks, and a follow-up period of 12 weeks (Fig 1). After screening, children who satisfied the entry requirements were entered into the run-in period. During this period, the children, with the help of their parents or caretakers, recorded 4 nasal symptoms (nasal pruritus, nasal obstruction, rhinorrhea, and sneezing) on a diary card twice per day (ie, day and night). The severity was classified with a 4-point scoring scale (0 = absent, 1 = mild, 2 = moderate, and 3 = severe). The scores were added to yield a total nasal symptoms score for each patient. The maximal score was 24, ie, 12 for daytime symptoms and 12 for nighttime symptoms. The scoring system was previously validated in another study of allergic rhinitis.¹⁵ Use of chlorpheniramine was also charted daily, as daily relief medication scores. The scores were recorded for the entire study period. At the end of the run-in period, subjects were randomly allocated to receive either active acupuncture or sham acupuncture by the acupuncturists, in accordance with a computer-generated random number list. The study was in compliance with the ethical standards of the Helsinki Declaration of 1975, as revised in 1983.

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Accepted for publication May 6, 2004.

doi:10.1542/peds.2004-0744

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* Assessment by blinded pediatricians

Fig 1. Flowchart of enrolled patients.

Informed consent was obtained from the parents or guardians. The study was approved by the ethics committee of Kwong Wah Hospital.

Study Group

Children ≥ 6 years of age were recruited, because those < 6 years of age were deemed to be highly unlikely to cooperate with the acupuncturist. Because the area of research was persistent allergic rhinitis, the children must have had ≥ 4 weeks of nasal symptoms (ie, nasal pruritus, sneezing, nasal discharge, or nasal blockage) before entry into the study, together with allergic disorders at ≥ 2 other sites (skin, eyes, or airway). All participants were required to have ≥ 1 positive result among the following laboratory findings: elevated total blood IgE level (>100 IU/mL), eosinophilia (>400 cells per μL), or positive skin prick test reaction. A standard panel of antigens was used, ie, positive and negative controls, *Dermatophagoides pteronyssinus*, *Dermatophagoides farinae*, dog fur, cat fur, grass mixture, feather mixture, cockroach mixture, and mold mixture (ALK, Abello, Denmark). Children were excluded if they had congenital nasal anomalies or congenital heart disorders or had received systemically administered corticosteroid within 1 month of enrollment. Children with prior acupuncture experience were also excluded, to ensure that those who received sham acupuncture would not notice the absence of sensation of qi during the sham acupuncture. Topical nasal corticosteroid, long-acting antihistamine, and ketotifen treatments were stopped at the time of enrollment, and the participants used orally administered chlorpheniramine as necessary when they experienced severe symptoms. The subjects were assessed by the pediatricians, in a blinded manner, every 4 weeks.

Acupuncture Protocol

Acupuncture was performed by certified acupuncturists (SM, SL, DT, and MW). The acupoints chosen were yin tang (EX-HN3) (midpoint between the medial ends of the supraciliary arches), shang ying xiang (EX-NH8) (upper end of the nasolabial fold), and zu san li (ST36) (4 fingerbreadths below the depression lateral to the patella and 1 fingerbreadth lateral to the anterior border of the tibia). These acupoints were commonly reported to be useful in traditional Chinese medicine journals (Chinese references available on request).

For active acupuncture treatment, the aforementioned points were punctured with disposable, sterile, acupuncture needles. For EX-HN3, a 0.3-mm-diameter and 50-mm-long needle (Hwato, Suzhou, China) was used with 0.7- to 1.2-cm penetration, in an oblique direction with respect to the skin. For EX-NH8, a 0.25-mm-diameter and 13-mm-long needle (Hwato) was used with 0.7- to 1.2-cm penetration, in an oblique direction with respect to the skin. For ST36, a 0.3-mm-diameter and 50-mm-long needle (Hwato) was used with 1.2- to 2.4-cm penetration, in a perpendicular direction with respect to the skin. The exact depth was determined with achievement of qi (ie, paresthesia felt by patients). The needle was then rotated alternately in a clockwise or counterclockwise manner every 5 minutes for 20 minutes. For sham acupuncture treatment, the same acupoints were punctured with the same acupuncture needles; however, the needle was inserted to a depth of only 0.3 cm, and no manipulation of the needle was performed, to avoid qi.¹⁶ The active and sham acupuncture groups received 2 sessions of acupuncture per week for 8 weeks, ie, a total of 16 sessions. Pulse rate and oxygen saturation were monitored routinely with a pulse oximeter (Colin Corp, Komaki, Japan) during the procedure, as a precautionary measure. Blood pressure was measured before and after the acupuncture. After each acupuncture session, each patient was questioned by a blinded researcher regarding any discomfort. Each patient also was asked to score the immediate effects of acupuncture, with the use of a visual analog scale ranging from 0 (no improvement) to 10 cm (complete disappearance of nasal symptoms) on an unmarked 10-cm line.

The patients were examined by the pediatricians at the following times: on entering the study, at the end of the run-in period, in the middle and at the end of the treatment period, and every 4 weeks during the follow-up period (Fig 1). Each child received an oropharyngeal and nasal examination during each visit. Nasal secretions for microscopic eosinophil count assessments and blood samples for serum IgE level and blood eosinophil count assessments were collected on entry, at the end of the treatment period, and 8 weeks after the end of treatment. Diaries for rhinitis scores and relief medication scores were collected at each visit. Adverse effects of acupuncture, if any, were checked and recorded. At the end of the follow-up period, the patients and their parents were asked for their preferred treatment by the blinded pediatricians.

TABLE 1. Pretreatment Characteristics of Patients in the 2 Treatment Groups

	Active Acupuncture (N = 35)	Sham Acupuncture (N = 37)	P Value
Male/female	22:13	25:12	.868
Age, y	11.72 ± 3.18 (range: 6–19)	11.00 ± 3.82 (range: 6–20)	.4199
No. with coexisting asthma	32	31	.718
No. with coexisting eczema	32	31	.537
No. with coexisting allergic conjunctivitis	32	31	.693
No. with coexisting urticaria	32	31	.956
No. with positive skin prick test*	13	19	.687
Eosinophil count, cells per μ L	446.88 ± 295.10	422.58 ± 348.05	.7658
IgE level, IU/mL	759.00 ± 814.50	813.68 ± 1009.24	.8135
Nasal eosinophil count, % of eosinophils per high-power field	15.06 ± 28.30	13.29 ± 24.53	.7918
Daily rhinitis score (maximal score: 24)	6.64 ± 3.70	6.35 ± 3.54	.751
Relief medication score, no. of chlorpheniramine tablets per day	0.30 ± 0.50	0.19 ± 0.36	.362

* The standard panel included positive and negative controls, *D pteromyssinus*, *D farinae*, dog fur, cat fur, grass mixture, feather mixture, cockroach mixture, and mold mixture (ALK).

Outcome Measures

The primary outcome measures included daily rhinitis scores and symptom-free days. Secondary outcome measures included visual analog scale scores of immediate improvement after each treatment, relief medication scores, side effects, treatment preferences of participants at the end of the study, blood eosinophil counts, nasal eosinophil counts, and serum IgE levels.

Statistical Analyses

The statistical analyses were conducted with SAS software, version 6.12 (SAS Institute, Cary, NC). Intention-to-treat analysis was used to analyze the results. For the primary outcome measures, subjects who withdrew were assumed to have maximal daily rhinitis scores (ie, 24) and no symptom-free days. For the secondary outcome measures, all laboratory data were assumed to be the same as pretreatment values for missing data. Randomization was performed with a computer-generated random number list. The participants and their parents were blinded, because needle penetration was achieved in every case. The assessing pediatricians were blinded, because they were not present during the acupuncture sessions. Demographic data and outcome differences between the active acupuncture group and the sham acupuncture group were compared with unpaired *t* tests (continuous variables) and χ^2 analyses (categorical variables). All results were expressed as mean \pm SD unless otherwise indicated. The Wilcoxon rank-sum test was used to detect differences in percentages of symptom-free days between the 2 groups. With the assumption that the active treatment group provides 70% improvement and the sham treatment group 30% improvement,¹⁴ a sample size of 28 subjects in each group was needed to yield a power of 80% with the type I error set at 5%.

RESULTS

Study Population

Two hundred fifty children were approached and 85 children were recruited from the outpatient clinic of the Department of Pediatrics, Kwong Wah Hospital, between November 2001 and August 2002. The flow of these patients is summarized in Fig 1. Thirteen patients withdrew before randomization. Thirty-five and 37 children were randomized to the active acupuncture and sham acupuncture arms, respectively. In the active acupuncture group, 2 patients withdrew before finishing the active acupuncture because they were too busy to come for their acupuncture sessions and 1 patient withdrew after finishing active acupuncture because the family moved from Hong Kong to mainland China. In the sham acupuncture group, 5 patients withdrew because of a lack of efficacy and 1 patient withdrew during follow-up monitoring. There was no significant difference in rates of withdrawal during treatment between the 2 groups ($P = .38$).

The demographic data and baseline variables are summarized in Table 1. There was no significant difference in any of these variables between the 2 groups. There was also no significant difference in the associated atopic features.

TABLE 2. Comparison of Clinical Findings Between the Active and Sham Acupuncture Groups

	Active Acupuncture (n = 35)	Sham Acupuncture (n = 37)	P Value
Daily rhinitis score			
Pretreatment	6.58 ± 3.21	6.51 ± 3.32	.46
Treatment period	5.25 ± 3.57	6.44 ± 3.33	.07
Follow-up period	5.43 ± 3.94	7.19 ± 3.96	.03*
Symptom-free days, %			
Run-in period	3.23 ± 0.02	1.38 ± 0.02	.081
Treatment period	11.2 ± 0.06	3.7 ± 0.03	.0001*
Follow-up period	12.7 ± 0.04	2.4 ± 0.03	.0001*
Daily relief medication scores			
Pretreatment	0.30 ± 0.50	0.19 ± 0.36	.362
Treatment period	0.23 ± 0.36	0.18 ± 0.33	.661
Follow-up period	0.29 ± 0.45	0.29 ± 0.56	.986

* Significant difference.

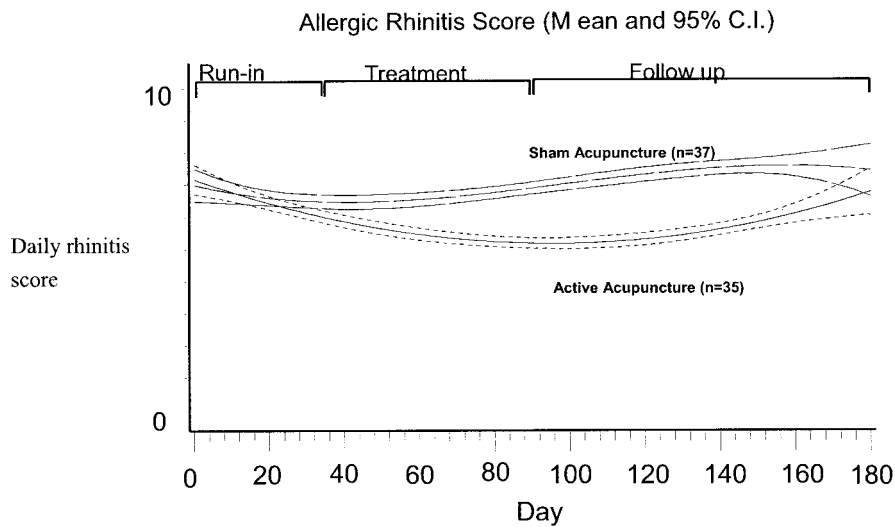


Fig 2. Daily allergic rhinitis scores during the study period.

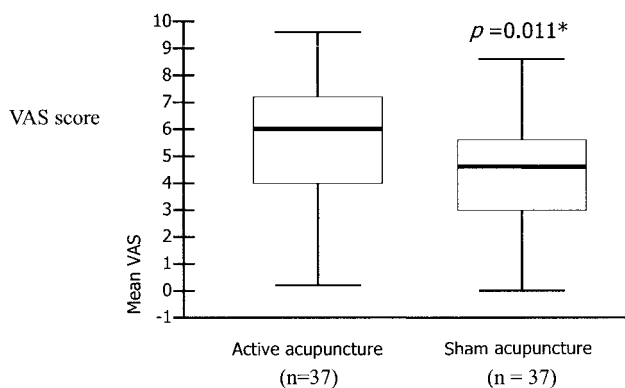


Fig 3. Box-plot of visual analog scale scores for immediate improvement after acupuncture (0 = no improvement; 10 cm = complete loss of nasal symptoms).

Efficacy

When the daily rhinitis scores for the active and sham acupuncture groups were compared, there was no statistically significant difference between the 2 groups during the run-in period. However, the allergic rhinitis scores were significantly lower during the follow-up period for the group that received active acupuncture, and the difference approached significance for the treatment period (Table 2 and Fig 2). The percentage of symptom-free days was obtained by dividing the number of patient days with 0 scores by the total number of patient days for the period. The active treatment group had significantly higher percentages of symptom-free days during the treatment and follow-up periods ($P = .0001$) (Table 2). There was no difference in the relief medication mean daily scores for the active and sham acupuncture groups (Table 2). For the visual analog scale scores for immediate improvement after acupuncture, the active treatment group had significantly better scores ($P = .011$) (Fig 3).

Laboratory Evaluations

For laboratory investigations, blood samples for eosinophil count and IgE level assessments and nasal

smears for eosinophil count determinations were obtained at entry into the study, at the end of the treatment period, and 2 months after the treatment period. Table 3 summarizes the findings. There was no significant difference between the active and sham acupuncture groups with respect to these parameters. It was noted that both blood eosinophil counts and serum IgE levels increased for both the active and sham acupuncture groups. However, only the increase in IgE levels, compared with pretreatment values, reached significant levels for the sham acupuncture group ($P = .037$).

Adverse Effects

In the active acupuncture group, 3 participants experienced numbness of the acupuncture sites, 1 had headache, and 1 had lightheadedness. In the sham acupuncture group, 2 subjects experienced numbness of the acupuncture sites and 2 experienced lightheadedness. All adverse effects were transient and mild. The vital signs for all children were normal during acupuncture. No serious adverse effect was noted. No significant difference in occurrence was found between the 2 groups.

Preferences

For the patients, the most popular treatment was orally administered chlorpheniramine; acupuncture was the second most popular. There was no difference between the active and sham acupuncture groups. For the parents (Fig 4), the most popular treatment was acupuncture for both active and sham treatment groups (38% vs 33%), although those in the sham acupuncture group were more likely to have no preference ($P < .0001$).

DISCUSSION

As far as we could find, this study was the first reported randomized, double-blind, placebo-controlled trial of acupuncture for the treatment of allergic rhinitis among children. This study showed that the active acupuncture group had lower daily rhinitis scores and a higher percentage of symptom-

TABLE 3. Comparison of Laboratory Investigation Results Between the Active and Sham Acupuncture Groups

	Active Acupuncture (n = 35)	Sham Acupuncture (n = 37)	P Value
Blood eosinophil count, cells per μL			
Pretreatment	451.43 \pm 283.23	445.95 \pm 393.41	.946
Immediate posttreatment	425.71 \pm 245.36	545.95 \pm 420.71	.146
2 mo posttreatment	457.14 \pm 289.31	521.62 \pm 375.01	.419
Serum IgE level, IU/mL			
Pretreatment	751.46 \pm 791.43	799.57 \pm 936.93	.815
Immediate posttreatment	840.34 \pm 724.74	881.00 \pm 964.83	.841
2 mo posttreatment	858.91 \pm 816.30	934.00 \pm 1080.73	.741
Nasal eosinophil count, %			
Pretreatment	15.49 \pm 26.70	15.27 \pm 29.33	.974
Immediate posttreatment	17.14 \pm 29.29	11.46 \pm 22.86	.360
2 mo posttreatment	20.11 \pm 28.30	17.14 \pm 28.03	.655

free days. These findings were in line with those reported by Xue et al,¹⁴ who performed a crossover, single-blind, clinical trial on the efficacy of acupuncture for the treatment of seasonal allergic rhinitis. In the study by Xue et al,¹⁴ 30 subjects who experienced seasonal allergic rhinitis were randomly assigned to receive active or sham acupuncture. There was subjective improvement (symptom scores) for the active acupuncture group. In contrast to the study by Xue et al,¹⁴ a standard set of acupuncture points was selected in the current study. Two acupuncture sites were common to both the current study and the study by Xue et al,¹⁴ ie, yin tang (EX-HN3) and zu san li (ST36). The effectiveness of this standard set suggested that differentiation into different syndromes, according to the traditional Chinese medicine classification, may not be necessary, in contrast to the recommendation by Xue et al.¹⁴ No difference in the daily relief medication scores was found between the 2 treatment groups, despite the higher percentage of symptom-free days in the active treatment group. This was likely related to the very low baseline daily relief medication scores (score: 0.19-0.3 tablet per day) for both groups.

Lau et al⁸ showed decreases in blood eosinophil counts, serum IgE levels, and nasal eosinophil counts for 64% of subjects with allergic rhinitis who were treated with acupuncture in an uncontrolled case

series of 22 subjects. No difference in blood eosinophil counts, serum IgE levels, and nasal eosinophil counts was found between the 2 treatment groups in the current study, although significantly higher serum IgE levels was found in the follow-up period for the sham acupuncture group, compared with the pretreatment levels (934 \pm 1080 IU/ μL vs 800 \pm 937 IU/ μL). This decrease in serum IgE levels might be attributable to other concomitant factors, such as allergen exposure, rather than sham acupuncture. This was supported by the fact that there was no significant difference between the active treatment and sham treatment groups with respect to observed changes in serum IgE levels, blood eosinophil counts, and nasal eosinophil counts. This highlighted the importance of a control group, and the effect reported by Lau et al⁸ might not be related to acupuncture.

There is some evidence showing that acupuncture can regulate the cytokines in allergy. In one study, acupuncture reduced serum levels of interleukin-10 in chronic allergic rhinitis.¹⁷ Other objective measures of treatment effects in allergic rhinitis include acoustic rhinometry assessments of changes in nasal geometry, ie, the minimal cross-sectional area and the total nasal volume,¹⁸ and peak nasal inspiratory flow and rhinomanometry assessments.^{19,20} The magnitude of symptom improvement is difficult to

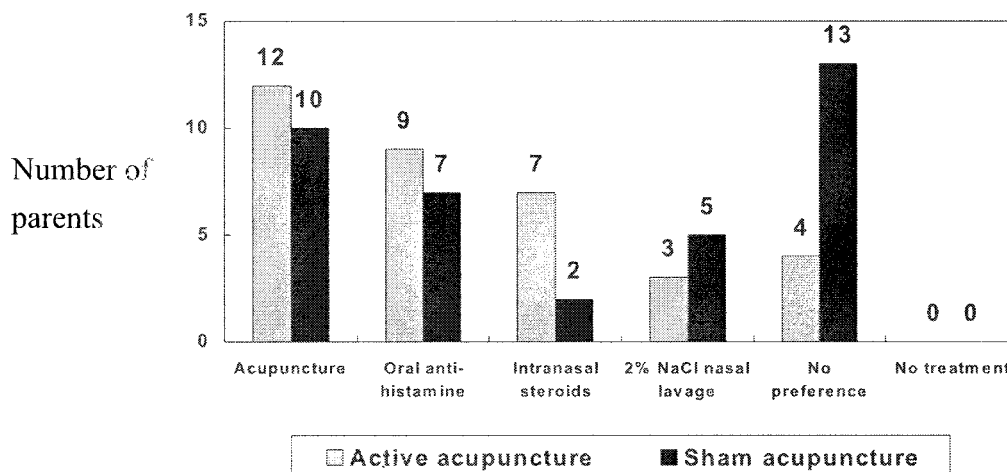


Fig 4. Parents' preferences at the end of the study (all parents were located for the preference evaluation).

assess with rhinitis scores alone, although relief of symptoms is related to improvement in the quality of life, which is the aim of treatment. To be more comprehensive, measures of quality of life in future studies are warranted.²¹ Additional studies incorporating these additional outcome measures would be required to document the full impact of acupuncture treatment.

This study showed that the effects of acupuncture wore off after 10 weeks (Fig 2). Therefore, this study raises the possibility that acupuncture treatment must be repeated, but the frequency, intensity, and duration need to be addressed in future studies.

Adverse effects of acupuncture include bleeding after withdrawal of the needle, bruising or infection at the site of insertion, and fainting.^{22,23} In our study, there were only transient minor adverse effects. There was no serious adverse effect. No withdrawals were attributable to adverse effects of acupuncture.

To our surprise, acupuncture was more popular than topical nasal corticosteroid treatment and nasal saline lavage for children, despite the common perception that acupuncture was more threatening than topical nasal corticosteroid treatment. These results showed that acupuncture was an acceptable treatment option even for children. It was also interesting to note that parents in the sham acupuncture group were far more likely to have no preference than were those in the active acupuncture group. This result probably reflected the lack of effect of sham acupuncture as perceived by the parents, who were not happy with any of the available treatment options for allergic rhinitis. The main limitation in this study would be the selection bias, because the study population, with subjects who agreed to join the study, might be biased in favor of acupuncture. It is important to conduct similar studies in other places with different cultures. Given the observed difference in effect between active and sham acupuncture in this study, any future study should enroll at least 80 patients in each arm, to achieve a power of 0.8 with a type I error of 0.05.

CONCLUSIONS

This study showed that active acupuncture was more effective than sham acupuncture in decreasing the symptom scores for persistent allergic rhinitis and increasing the symptom-free days. However, no difference was found in relief medication use, serum IgE levels, blood eosinophil counts, or nasal eosinophil counts. No serious adverse effect was identified in this study. A large-scale study is required to confirm the safety of acupuncture for children.

ACKNOWLEDGMENT

The study was supported by a research grant from the Tung Wah Group of Hospitals.

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