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Acupuncture and Bronchial Asthma

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Seventeen patients with stable bronchial asthma were randomly assigned to receive either correct acupuncture or placebo acupuncture. The study lasted 11 weeks and consisted of a pre-therapy, therapy, and post-therapy period. The patients received 10 treatments during a 5-week period. The effect of therapy on pulmonary function was assessed daily by the patients at home. Morning and evening peak expiratory flow rate, number of puffs beta$_2$-agonist aerosol needed, as well as subjective symptoms of asthma were recorded in a diary. The correctly treated group improved significantly throughout the study. Also, compared with the placebo group, a significant improvement was found in all assessed parameters 2 weeks after beginning therapy. Hereafter, no differences could be shown.

Key words: acupuncture; bronchial asthma.

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Although acupuncture has been used in Western countries in the treatment of bronchial asthma for at least 40–50 years, very few controlled trials of the therapeutic effect have been performed. Takishima, Tashkin, Virsik, and Yu (7, 8, 10, 11) have previously described the bronchodilatory effect of only a single acupuncture session.

The aim of our study was to estimate the therapeutic effect of 10 consecutive treatments on a group of well-defined patients with bronchial asthma. The patients received either correct acupuncture, in loci selected from traditional Chinese formuale against bronchial asthma, or placebo acupuncture. The treatments were made double-blind and randomised.

MATERIAL AND METHODS

Study design

The study contained a pre-therapy period of 2 weeks, a 5-week therapy period, where 10 sessions of either correct or placebo acupuncture were given, and a 4-week post-therapy period (Fig. 1).

Patients

Seventeen outpatients, with stable bronchial asthma, gave their informed consent to participate in this study. None of the patients had previously received acupuncture therapy, or steroid or sodium cromoglycate medication.

All patients fulfilled the following criteria before admission to the study: 1) Basal forced expiratory volume during the 1st sec (FEV_1) (unmedicated) $\leqslant 70\%$ of predicted values. 2) A $\geqslant 20\%$ increase of FEV_1 after 2 puffs from a beta-agonist aerosol (isoproterenol, 160 μg). 3) A daily requirement of at least 4 puffs from a beta$_2$-agonist aerosol. 4) A $\geqslant 20\%$ decrease of peak expiratory flow (PEF) after a bronchial histamine challenge at 300 μg or less.

After the 2-week pre-therapy period, the patients were consecutively allocated to two groups. The allocation was performed by a

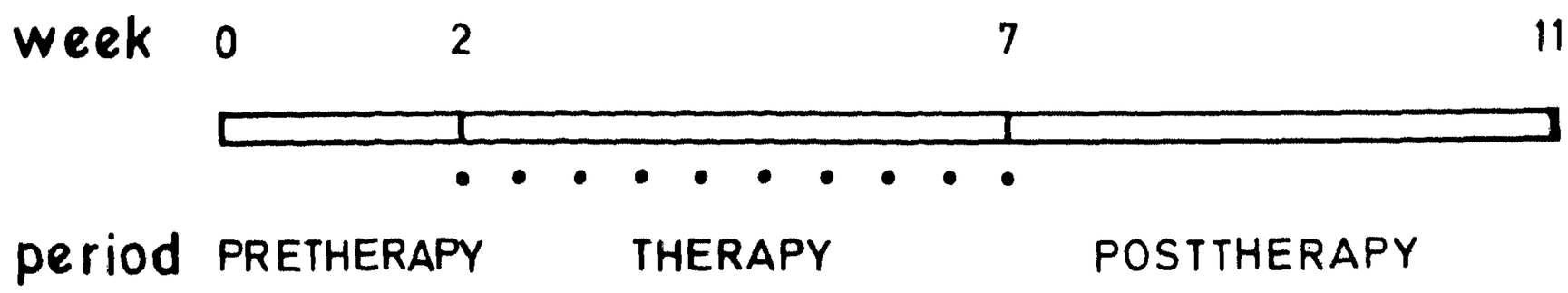

Fig. 1. The study design. Filled dots designate one acupuncture session.

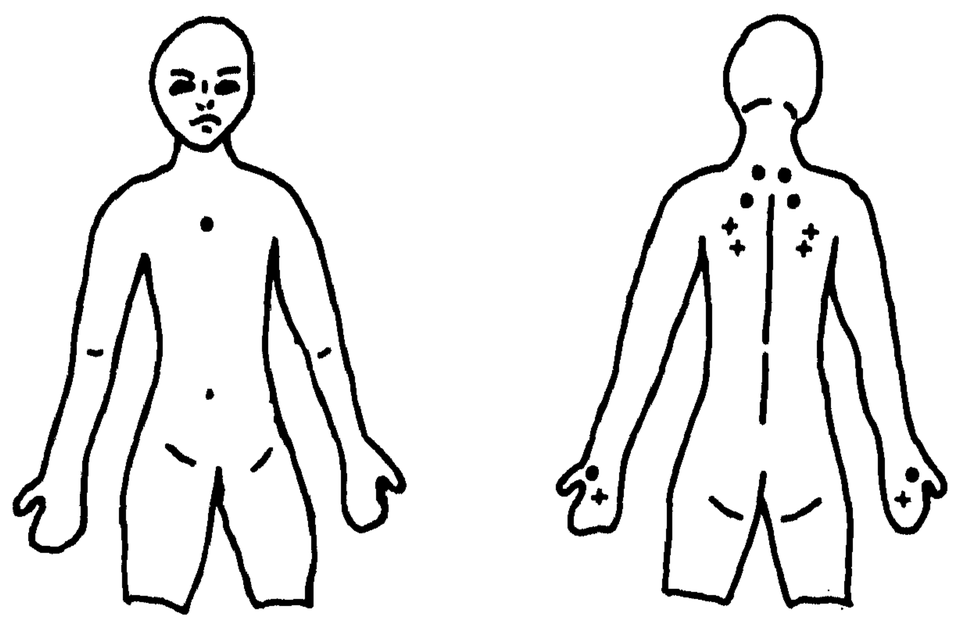

Fig. 2. Correct acupuncture loci with meridian number, Chinese name, and anatomical location (●): Large intestine 4, *HO-KO* bilaterally on the highest point of M. Interossi dorsalis I to a depth of 1.5–2 cm. Extra 17, *Dinchuan,* bilaterally 2 cm to midline between proc. spinosi C.7 and Th.1 to a depth of 3 cm. Bladder 13, *Feishu,* bilaterally to midline between proc. spinosi Th.3 and Th.4 to a depth of 3 cm. Ren 17, *Shanzhong,* at the middle of the sternum at the height of the fourth intercostal space. Placebo loci (+): in the middle of the hand bilaterally, and two loci bilaterally above the scapulae.

person not included in the data evaluation, by means of the Geigy random number table (4).

Group A comprised eight patients (5 females and 3 males) mean age 30.8 (range 20–47). This group received correct acupuncture therapy.

Group P comprised nine patients (6 females and 3 males) mean age 33.4 years (range 19–48 years). This group received placebo therapy.

Acupuncture therapy

Correct acupuncture therapy was performed in loci selected from standardised acupuncture formulae, traditionally used in the treatment of asthma (1, 9) (Fig. 2). In this study the loci were finally identified by use of the Multiple Electronic Acupunctoscope, wc-10®, using a hand-held probe. The traditionally recognized acupuncture loci can be identified objectively, as they elicit decreased skin resistance compared with the surrounding skin (2). The acupuncture needles were 10 cm, 30 gauge solid stainless steel needles. Depth of insertion varied with the thickness of the skin and subcutaneous fatty tissue above the loci. To ensure correct primary stimulation and location the patients were to report sensations of heaviness or parasthesia from the area, as described in classical acupuncture literature (9). After insertion the needles were connected to a constant current source and the patients received electroacupuncture using chain frequencies of 4 Hz and 100 Hz at an intensity, just below their pain threshold. The needles were stimulated for 20 min at each of the 10 sessions.

Placebo acupuncture therapy was performed at precisely located regions (Fig. 2). These loci were outside the segmental dermatomes associated with the loci used in group A. There were

no differences in skin resistance at the anatomically defined placebo loci compared with the surrounding skin. The needles were inserted to a depth of 1–3 mm. Sensations as described in group A were not percieved. Group P received placebo electroacupuncture, i.e. the needles were connected to the constant current source, but no impulses were given. Each of the sessions lasted 20 min.

Assessments

Throughout the study, the patients' asthma symptoms were recorded daily at home in a diary. The patients were instructed to fill in the diary sheets correctly before participation. The correct aerosol inhalation technique and use of peak flowmeter (cf. below) was controlled at each visit to the clinic. The patients were told that they were to receive one of two different acupuncture therapies. The acupuncture therapist knew which treatment was prescribed, but at no time did he see the diaries, and the patients were instructed not to discuss their symptoms and treatment with him. Concurrently, to secure the double-blind design, none of the co-workers who assessed the diaries and took care of the clinical treatment at the end of each period (Fig. 1), knew which therapy the patients received until the code was broken at the end of the study. The acupuncture therapy was carried out in a different department of the hospital. Before this study started it was decided to do a diary analysis before the start of therapy (week 2), half-way through (week 4), after 5 weeks (week 7), and at the end of the study period (week 11).

Objective assessments

The patients recorded morning peak flow rate (M-PEFR) and evening peak flow rate (E-PEFR) before intake of medicine, by use of a Mini-Wright peak flowmeter. The maximum value of three consecutive measurements was recorded in the diaries. The number of puffs (NOP) $beta_2$-agonist aerosol (salbutamol or terbutaline) used during a 24-h period were also recorded.

Subjective assessments

Daily severity of asthma symptoms (DSA), using a point score: 1 (none), 2 (few), 3 (moderate), 4 (severe), and weekly severity of asthma symptoms (WSA), using a visual analogue scale score: a 10 cm line with 0 – as bad as possible to 100 – as good as possible, were recorded in the diaries.

Blood measurements

Blood samples were drawn from all patients at week 2, week 7, and week 11 (Fig. 1). Measurements of haemoglobin, leucocyte count, orosomucoid, and eosinophil count were performed. IgE (PRIST Pharmacia, variance ± 5%) and IgG, IgM, and IgA (rocket immunoelectrophoresis, Behringwerke, Germany, variance ± 6%) were also measured.

Statistics

The statistical analysis was performed by the use of Pratt's Rank Sum Test for paired differences (6), and the Mann-Whittney Rank Sum Test for unpaired data. A P value of less than 0.05 was regarded as significant.

RESULTS

The mean basal level of FEV_1 was 1.9 l, range 0.9–3.0 l. The mean predicted level (FEV_1) was 3.39 l, range 2.5–4.3 l. Basal FEV_1 in percent of the predicted value was 46%. The mean reversibility was 28%, range 21–57%.

The pre-therapy score of DSA in group A was higher than in group P. All other objective and subjective parameters between the groups showed no significant differences.

Objective assessments

M-PEFR. A significant increase was found in group A (correctly treated) at week 4 ($P < 0.01$) and at week 11 ($P < 0.05$) compared with the pre-therapy level. No significant alteration was

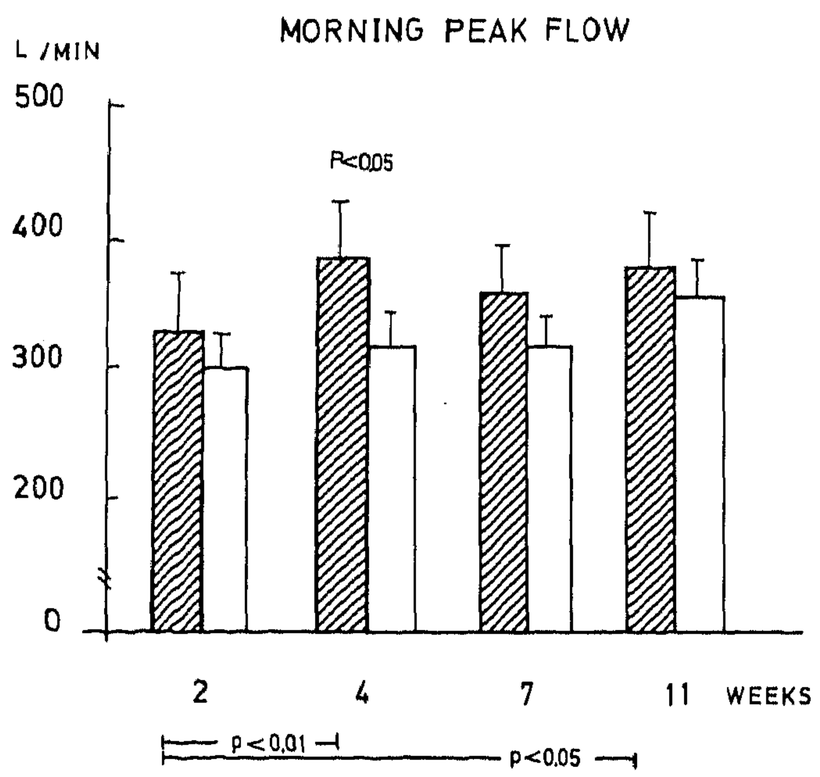

Fig. 3. Morning peak flow rate at weeks 2, 4, 7, and 11 (mean and SEM). Hatched: Group A ($n = 8$) – correct acupuncture. Non-hatched: Group P ($n = 9$) – placebo acupuncture.

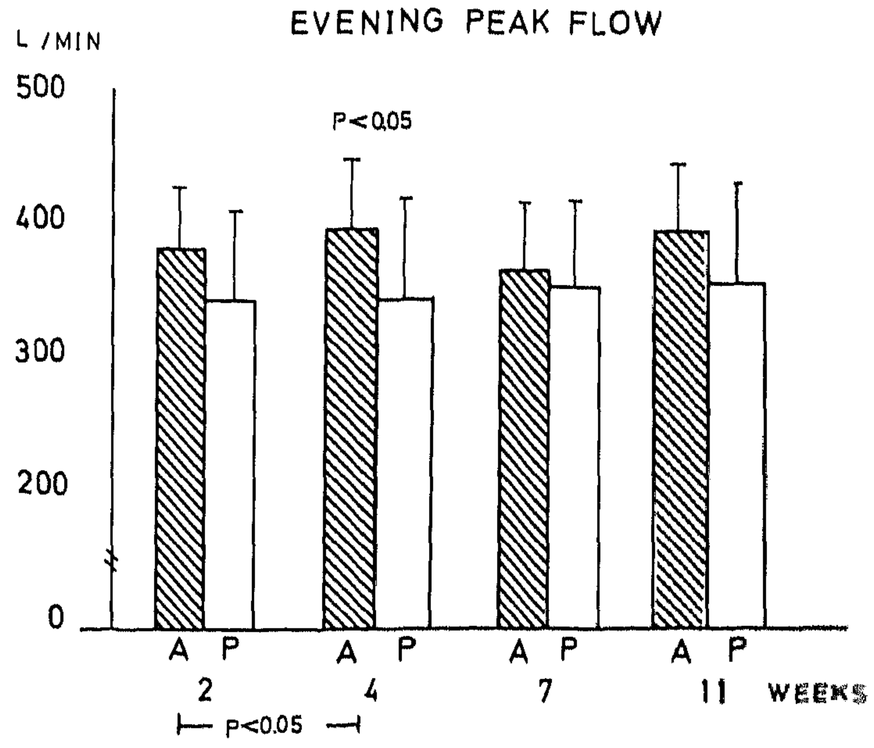

Fig. 4. Evening peak flow rate at weeks 2, 4, 7, and 11 (mean and SEM). Hatched: Group A ($n = 8$) – correct acupuncture. Non-hatched: Group P ($n = 9$) – placebo acupuncture.

found at week 7. In group P, no significant changes were found throughout the study (Fig. 3). There was a significant increase ($P < 0.05$) in group A after 2 weeks of treatment as compared with group P (placebo group), but hereafter no difference was recorded between the groups (Fig. 3).

E-PEFR. A significant increase was found in group A after 2 weeks of treatment compared with the pre-therapy level ($P < 0.05$). In group P, no significant changes were observed during the study period (Fig. 4). There was a significant increase ($P < 0.05$) in group A as compared with group P, but hereafter no difference was observed between the two groups (Fig. 4).

NOP. A significant decrease in number of puffs needed was found in group A ($P < 0.05$) at weeks 4, 7, and 11 as compared with pre-therapy levels. There were no significant differences in group P between the pre-therapy levels and the succeeding recordings of weeks 4 and 11. A significant decrease ($P < 0.01$) was found at week 7 (Fig. 5). There was a significant decrease ($P < 0.05$) of NOP in group A after 2 weeks of therapy (week 4) as compared with group P, but no other significant differences were recorded during the following weeks (Fig. 5).

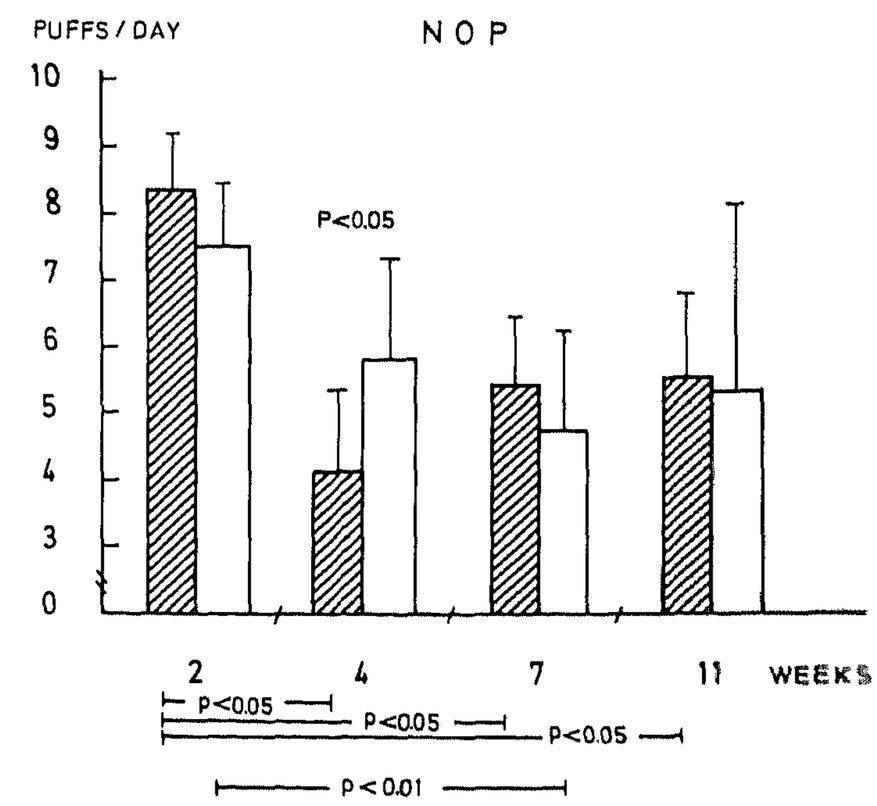

Fig. 5. Number of puffs β_2-agonist aerosol used (NOP) at weeks 2, 4, 7, and 11 (mean and SEM). Hatched: Group A ($n = 8$) – correct acupuncture. Non-hatched: Group P ($n = 9$) – placebo acupuncture.

Subjective assessments

DSA (Table 1). The patients in group A recorded a significant decrease ($P < 0.01$) of

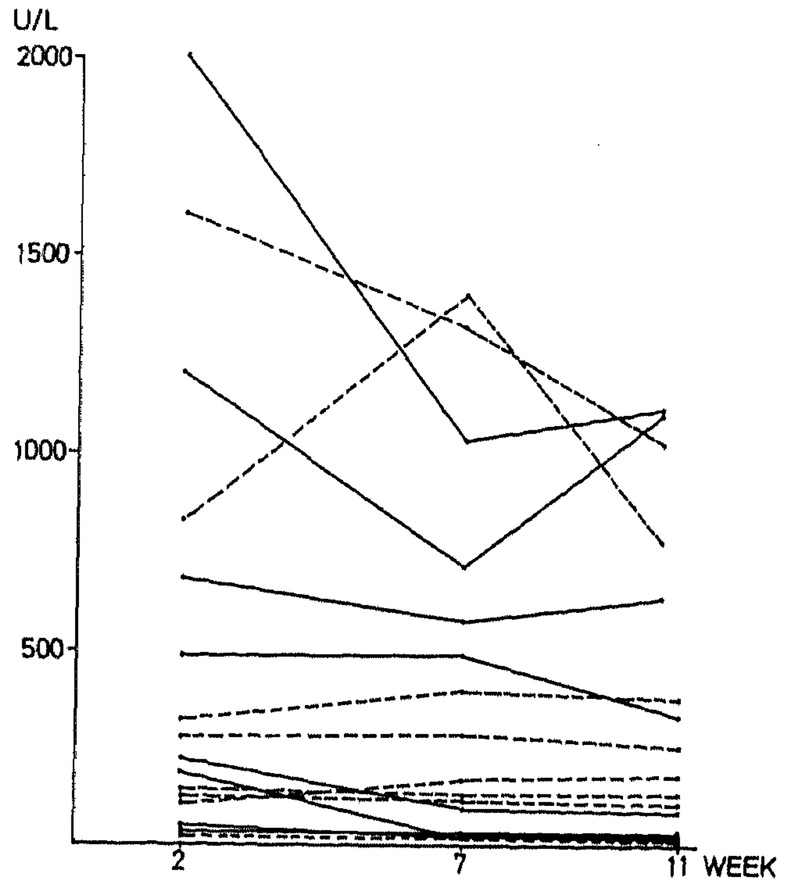

Fig. 6. Individual variations in IgE at weeks 2, 7, and 11. Solid lines: correctly treated group A; broken lines: placebo group B.

DSA at week 4, and the DSA was significantly decreased ($P < 0.05$) throughout the rest of the study compared with the pre-therapy level. There were no significant differences in group P. The DSA score of group A was significantly higher ($P < 0.05$) than that of group P before treatment, but no significant difference was found during or after therapy.

WSA (Table 1). There was a significantly higher score ($P < 0.05$) in group A throughout the study compared with the pre-therapy score. No significant differences were observed in group P throughout the study. The score in group A was significantly higher ($P < 0.05$) at week 4 as compared with group P, but hereafter no difference was observed.

Laboratory assessments

There was a significant decrease in the mean blood IgE levels to 333 U/l (range 42–1035 U/l) at week 7 ($P < 0.01$), and 435 U/l (range 42–1105 U/l) at week 11 ($P < 0.05$), compared with the pre-therapy value of 510 U/l (range 45–2000 U/l) in group A (Fig. 6). No significant differences in IgE levels were observed in group P, or between the two groups, during the study. No alterations in the other laboratory parameters measured were found in either group A or P.

DISCUSSION

The results of the present study indicate an effect, albeit modest, of acupuncture on both the objective assessments and subjective symptoms in this group of patients with bronchial asthma. There was a difference between the correctly treated group and the placebo group at least 2 weeks after beginning therapy. The correctly treated group had at this point increased their morning and evening peak flows by 22% (range −3 to 77%) and 7% (range −6 to 17%), respectively. Concurrently, the daily

Table 1

Daily severity of asthma symptoms (DSA) (point score: 0 – good to 4 – severe) (mean and range), and weekly severity of asthma symptoms (WSA) (visual analogue scale: 0 – as bad as possible to 100 – as good as possible) (mean and range) at weeks 2, 4, 7, and 11, for group A – correct acupuncture and group P – placebo acupuncture

DSA	Group A ($n = 8$)	2.4 (1.4–3.0)[§]	1.4 (1.1–2.3)**	1.8 (1.0–2.2)*	2.0 (1.1–2.9)*
	Group B ($n = 9$)	1.5 (1.1–2.6)	1.6 (1.1–2.9)	1.1 (1.0–3.6)	1.2 (1.0–2.2)
WSA	Group A ($n = 8$)	36 (21–46)	62 (20–92)[§]*	51 (34–82)*	55 (16–84)*
	Group P ($n = 9$)	42 (13–70)	42 (13–51)	46 (21–83)	45 (10–88)

Differences within the groups: *$P < 0.05$ or **$P < 0.01$. Differences between groups A and P: [§]$P < 0.05$.

amount of b_2-agonist aerosol needed decreased by 53% (range −6 to 100%).

It is noteworthy that other controlled studies have shown that acupuncture has an effect on bronchial asthma, although all of these studies evaluated patients after only one treatment with acupuncture. Takishima et al. (7) studied alterations of airway resistance during acupuncture and found significant decrease in resistance as compared with placebo. Virsik et al. (10) showed a significant increase in peak flow and FEV_1 with a significant decrease in airway resistance, in patients with acute bronchospasm, after acupuncture therapy. The effect was evident up to 60 min after therapy and returned to normal values 120 min after acupuncture therapy. Tashkin et al. (8) studied the effect of acupuncture in reversing metacholine-induced bronchospasm. The results suggested the bronchospasm was reduced to a greater extent with acupuncture than with placebo acupuncture, but the reduction was less than that caused by inhalation of isoproterenol. Yu et al. (11) found that patients with acute bronchial asthma had significantly increased FEV_1 and FVC after acupuncture compared with placebo acupuncture. It was characteristic in our study that the condition of the patients receiving correct acupuncture was better throughout the study compared with their pre-therapy condition. Although the assessment parameters showed small and generally nonsignificant changes in the placebo group between pre-therapy and the rest of the study, it was impossible to distinguish group A from P after 2 weeks of therapy. The changes in the placebo group could be ascribed to a weaker and slower acupuncture effect due to the non-specificity of the loci stimulated, but is probably a pure placebo effect. The fall in NOP in the placebo group could also indicate a possible initial over-treatment with $beta_2$-agonist aerosol. During the study the patients were only to use the aerosol p.n., thereby possibly masking a beneficial effect of acupuncture in the following weeks.

We found a significant decrement of serum IgE in the correctly treated group throughout the study. It could be speculated that the changes in IgE might be secondary to an increase in serum corticol after acupuncture as described by Liao et al. (5) and Cheng et al. (3). They suggest that acupuncture in some way exerts an effect on the hypothalamic-hypophysial-adrenocortical system, maybe stimulating secretion from cells storing lipoprotein, beta-endorphin, and ACTH.

In conclusion, the present study did not show that the treatment of stable bronchial asthma with our acupuncture method produces any substantial effect on either objective parameters or subjective symptoms of asthma. The improvement in the correctly treated group is constant throughout the study compared with the pre-therapy condition, but compared with the placebo group, the effect is only evident 2 weeks after the beginning of therapy.

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