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Traditional Chinese acupuncture in tension-type headache: a controlled study

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Summary Thirty patients with tension-type headache were randomly chosen to undergo a trial of traditional Chinese acupuncture and sham acupuncture. Five measures were used to assess symptom severity and treatment response: intensity, duration and frequency of headache pain episodes, headache index and analgesic intake. The five measures were assessed during a 4 week baseline period, after 4 and 8 weeks of treatment, and 1, 6 and 12 months thereafter. Before the start of the study, each patient was administered the MMPI. Split-plot ANOVAs showed that, compared to baseline, at 1 month after the end of treatment and for the 12 month follow-up, the frequency of headache episodes, analgesic consumption and the headache index (but not the duration or intensity of headache episodes) significantly decreased over time; however, no difference between acupuncture and placebo treatment was found. No single MMPI scale predicted the response to treatment, but the mean MMPI profile of acupuncture non-responders showed the presence of 'Conversion V'.

Key words: Acupuncture; Tension-type headache; Placebo; MMPI; Headache index

Introduction

Over the last decade, several studies have investigated the efficacy of acupuncture in relieving headache pain (Johansson et al. 1976; Loh et al. 1984). Psychophysiological and neurophysiological mechanisms in the analgesic effectiveness of acupuncture have been hypothesized (Kaada 1976), and recently a modification of endorphinergic system modulating pain pathways has been suggested to account for the mechanism of acupuncture analgesia (Hardebo et al. 1989).

Results obtained in the first published studies seem to support the hypothesis that acupuncture is effective for the treatment of headache, even if its efficacy seems to decrease some time after the end of treatment (Kim 1974; Poitinen and Salmela 1977). These studies, however, were pilot ones and generally biased by the fact that they were open or that either no comparison with placebo had been tried or that it had been inadequate (Lewith and Machin 1983; Vincent and Richardson 1986; Poitinen and Salmela 1977). Headache is known to be a disorder particularly responsive to placebo treatment (Hossenloop et al. 1976; Edmeads 1984). The placebo effect of acupuncture might be heightened by numerous factors intrinsic to this treatment (Kepes et al. 1976; Moore and Beric 1976; Kreitler et al. 1987). The choice of the best placebo against acupuncture is not a simple one, however, and after careful consideration we decided to follow Vincent and Richardson (1986) and use sham acupuncture. This appears most appropriate from a methodological point of view.

The aim of this study was to evaluate the efficacy of acupuncture in the treatment of headache pain, taking particular care to circumvent the methodological difficulties that characterize this type of research.

Methods

The criteria for admission into the study were as follows: (a) diagnosis of muscle-tensive headache according to the criteria of the 'Ad Hoc Committee on Classification of Headache' (1962); all pa-

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tients also satisfied the criteria for tension-type headache contained in the Classification and Diagnostic Criteria for Headache Disorders Cranial Neuralgias and Facial Pain, published after the patients had been recruited (Headache Classification Committee 1988); (b) exclusion of organic pathology; (c) frequency of headache episodes greater than once a week having a mean intensity not less than 'moderate'; (d) agreement to abstain from all other therapies previously undertaken from the beginning to the end of the follow-up, with the exception of non-narcotic analgesics taken for a headache episode, provided that this was reported in the diary; and (e) informed consent to participate in the study. All participants completed the follow-up.

After the diagnostic interview for admission and after 1 month of baseline observation, the patients were randomly and blindly assigned to two 15 subject groups, one treated with Chinese traditional acupuncture and the other by sham acupuncture. Active treatment consisted of inserting 6–10 stainless steel needles, 0.3 mm in diameter, into the head, hands and feet at a profundity of 10–20 mm until the patient manifested pain, torpor or swelling around the point. The needles were left in place for about 20 min without the use of any manual or electrical stimulation. The choice of points was made on an individual basis relative to the evaluation of the patient's 'energy' status according to the criteria of traditional Chinese acupuncture (Soulié de Morant 1952; Instit. de Médicine 1978), without establishing an a priori treatment scheme equal for all the patients, with the possibility of changing points from session to session. For placebo, the same number of needles was used, inserted at a profundity of 2–4 mm in the same regions used in actual acupuncture, but in areas without acupuncture points. The actual and false points were localized both anatomically and with a detector to determine the fall of the cutaneous electrical resistance which is characteristic of the acupuncture point. Patients in both groups underwent the same number of sessions, each lasting 20 min once a week for 8 weeks.

In order to come as close as possible to the double-blind experimental condition, as suggested by Hansen and Hansen (1983), each patient was followed by two physicians: the first who administered the treatment had knowledge of the group to which the patient belonged while the second physician, completely ignoring the patient's treatment, was assigned to collect the headache diary. Headaches in both groups were monitored by a daily diary which the patients compiled. They reported: (1) pain duration (in hours) of all headache episodes; (2) pain intensity according to a score from 1 to 4 (1 = slight; 2 = medium; 3 = strong; 4 = very strong); (3) intake of analgesics, specifying the type, dosage and means of administration. Monitoring of the headaches began after the patient's first interview, a month before the beginning of treatment (in order to establish a baseline) and continued during 2 months of treatment and 12 months after follow-up.

The following objective parameters were considered for evaluating both the qualitative and quantitative treatment results (Diamond et al. 1983; Gelmers 1983): (1) I = intensity: the sum of the intensity of the crises in a month/number of crises; (2) D = duration: the sum of the hours of headache in a month/number of crises; (3) F = frequency: the number of crises in a month; (4) HI = headache index, where $HI = I \times D \times F/30$; (5) consumption of analgesics, calculated as the sum total of the drugs taken in a month; (6) HII = headache improvement index, where $HII = (HI\ tn - HI\ t0/HI\ 0) \times 100$.

As a cutoff for subdividing the patients into responders and non-responders, we used the 33% threshold of reduction (Melzack 1983) as well as the more restrictive 50% one (Beecher 1959). These variables were evaluated at time t0 (baseline), halfway through treatment (t1), at the end of treatment (t2), and in the successive follow-up at 1 month (t3), 6 months (t4) and 1 year (t5).

During the baseline period each patient was asked to take the MMPI (Hataway and McKinley 1951).

The data were analyzed by means of 1-way ANOVA, the paired Student's t test, split-plot ANOVA, Tukey test and Fisher exact test (Dixon 1985). Two split-plot ANOVAs were used to analyze the variables employed to evaluate and compare the efficacy of the treatments.

In the first analysis, aimed at evaluating the immediate efficacy of treatment, only 4 time periods were considered: baseline (t0), 4 and 8 weeks of treatment (t1 and t2) and 4 weeks after treatment termination (t3). In the second analysis, the consistency or inconsistency of the follow-up of the possible efficacy of treatment was examined by considering not only t0 – t3, but also the results at 6 and 12 months after termination of treatment (t4 and t5).

Results

Thirty patients (26 women, 4 men) took part in the study, having been referred by their family physicians to the Headache Center of the IRCCS Policlinico Hospital. The two groups of acupuncture and placebo-treated patients were similar with regard to age, male/female ratio, educational level, and duration and the age of onset of the condition (Table I).

During the baseline period, the two groups did not differ with respect to the mean frequency, duration and intensity of headache episodes, the mean headache index or the mean consumption of analgesics (Table II). With regard to the MMPI scales, the group of

TABLE I

SAMPLE CHARACTERISTICS. DEMOGRAPHIC VARIABLES

Values reported indicate mean ± S.D. and range.

	Total sample	Acupuncture	Placebo	F *	P
Sex ratio (M : F)	4 : 26	2 : 13	2 : 13		
Age (years)	32.9 ± 11.6 (16–50)	32.5 ± 10 (16–46)	33.3 ± 13.3 (16–50)	0.03	n.s.
Schooling (years)	9.3 ± 4.3 (5–19)	9.1 ± 4.7 (5–18)	9.5 ± 4.1 (5–19)	0.06	n.s.
Age of onset (years)	25.2 ± 10.6 (8–42)	25.1 ± 9.2 (12–40)	25.3 ± 12.2 (8–42)	0.001	n.s.
Disease duration (years)	7.8 ± 7.9 (1–31)	7.5 ± 8.3 (1–30)	8.1 ± 7.8 (1–31)	0.001	n.s.

* Acupuncture vs. placebo: 1-way ANOVA; $df = 1, 28$.

placebo-treated patients had significantly higher scores on the Psychosocial Deviance scale, the Psychastenia scale and the Schizophrenia scale. The percentage of patients with pathological scores (above 70) was closely similar in both groups for all scales (Nencini and Belcecchi 1973).

There were 5 patients with a 'Conversion V' profile characterized by high score on Hs (hysteria) and Hy (hypochondriasis) scales and low score on D (depression) scale, in the acupuncture group, and one in the placebo group (Kudrow and Sutkus 1979). Since this asymmetry was ascertained only at the end of the study, a better randomization was not possible.

The first split-plot ANOVA did not show any difference between the two groups with regard to the intensity and duration of cephalalgic episodes; instead, the following was found: (a) The frequency of episodes decreased significantly over time (from t0 to t3) ($F <$ time $> = 16, 34$; $df = 3, 84$; $P < 0.001$), with a significant effect of time × treatment ($F <$ time × treatment $> = 3, 09$; $df = 3, 84$; $P = 0.03$). However, the Tukey test on this last value was not significant. The mean decrease of episode frequency from the baseline period to t3 was 44.3% and 21.4% in acupuncture and placebo-treated patients, respectively (net difference 22.9%). (b) Even the headache index decreased significantly over time ($F <$ time $> = 19, 75$; df 3, 84; $P < 0.0001$), but no significance was found for the time/treatment interaction. Between the baseline period and t3, the headache index decreased by a mean of 58.3% and 27.8% in acupuncture and placebo-treated patients, respectively (net difference 30.5%) (Fig. 1). (c) Similarly, the analgesic consumption decreased significantly over time ($F <$ time $> = 10, 09$; $df = 3, 84$; $P < 0.0001$), with time × treatment interaction approaching significance ($F <$ time × treatment $> = 2.69$; $df = 3, 84$; $P = 0.0513$). However, the Tukey test was not significant. In the acupuncture and placebo groups, the mean decrease of analgesic assumption was 57.7% and 21.7%, respectively (net difference 36%) (Fig. 2). (d) With regard to the improvement index, at t3, 13 acupuncture-treated (87%) and 9 placebo-treated (60%) patients had exceeded the 33% threshold of improvement with respect to t0 (Fisher exact test, 2-tailed, $P = 0.125$). When the 50% threshold was considered, there were 8 and 7 responders in the active treatment and placebo groups (53% and 47%), respectively (Fisher exact test, two-tailed, $P = 1$).

No correlation was found between the headache index decrease and age, age at onset of the disease, duration of illness or school years.

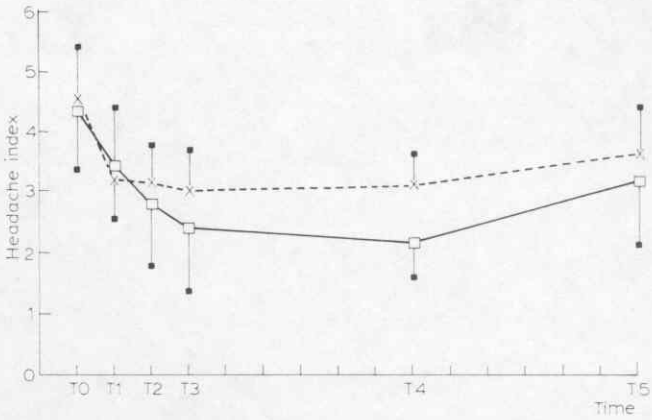

Fig. 1. Headache index (intensity × duration × frequency/30) □——□, real acupuncture (n = 15); ×---×, sham acupuncture (n = 15). Each point represents mean ± S.E.M. T0 = baseline; T1 = 4 weeks of therapy; T2 = 8 weeks of therapy; T3 = 1 month after the end of therapy; T4 = follow-up at 6 months; T5 = follow-up at 12 months.

Split-plot ANOVA	First analysis (T0–T3)			Second analysis (T0–T5)		
Source of variance	F	*df*	*P*	F	*df*	*P*
Treatment	0.03	1, 28	n.s	0.11	1, 28	n.s.
Time	19.75	3, 84	0.0000	11.31	5, 140	0.0000
Treatment × time	0.98	3, 84	n.s.	0.95	5, 140	n.s

TABLE II

SAMPLE CHARACTERISTICS. HEADACHE-RELATED VARIABLES

Values reported indicate mean ± S.D. and range.

	Total sample	Acupuncture	Placebo	F *	*P*
Intensity	2.2 ± 0.6 (1.2–3.9)	2.1 ± 0.7 (1.2–3.9)	2.2 ± 0.5 (1.3–3)	0.75	0.39
Frequency (no. of crises/month)	17.5 ± 9.2 (4–30)	18.3 ± 8.9 (7–30)	16.8 ± 9.7 (4–30)	0.18	0.67
Duration of crises (sum of duration of crises in h/no. of crises)	3.9 ± 2.5 (1.3–12)	3.3 ± 1.5 (1.4–7.8)	4.4 ± 3.2 (1.3–12)	1.58	0.22
Headache index (intensity × duration × frequency/30)	4.4 ± 3.6 (1.3–15.6)	4.3 ± 3.9 (1.3–15.6)	4.5 ± 3.4 (1.6–11.7)	0.02	0.88
Analgesic consumption (sum of the drugs taken × month)	11.5 ± 11.3 (0–42)	11.6 ± 10.2 (0–36)	11.5 ± 12.7 (0–42)	0.0	0.97

* Acupuncture vs. placebo: 1-way ANOVA; $df = 1, 28$.

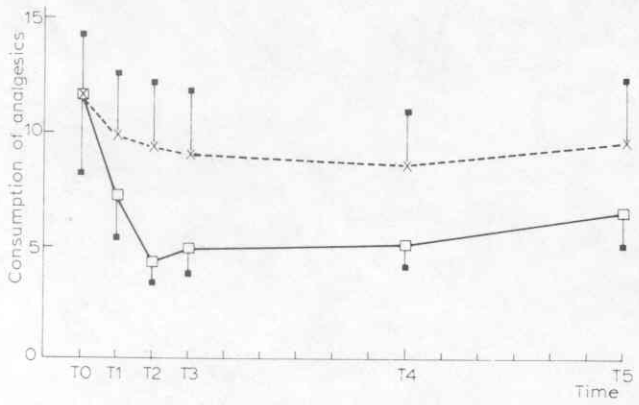

Fig. 2. Consumption of analgesics (sum of the drugs taken per month). □ ——— □, real acupuncture (n = 15); ×---×, sham acupunture (n = 15). Each point represents mean ± S.E.M. T0 = baseline; T1 = 4 weeks of therapy; T2 = 8 weeks of therapy; T3 = 1 month after the end of therapy; T4 = follow-up at 6 months; T5 = follow-up at 12 months.

Split-plot ANOVA	First analysis (T0–T3)			Second analysis (T0–T5)		
Source of variance	F	*df*	*P*	F	*df*	*P*
Treatment	0.82	1, 28	n.s.	0.33	1, 28	n.s.
Time	10.09	3, 84	0.0000	8.51	5, 140	0.0000
Treatment × time	2.69	3, 84	0.051	1.99	5, 140	0.0838

In the follow-up study, the outcome of treatment was analyzed at 6 and 12 months after termination of treatment. Here, too, there were no differences between the two groups relative to intensity and duration of headache episodes, while the frequency of episodes, headache index and consumption of analgesics decreased significantly over time. The time × treatment interaction for these variables also approached, but did not reach, significance (Figs. 1 and 2). Twelve months after termination of treatment, 8 acupuncture-treated (53%) and 7 placebo-treated (47%) patients could still be considered responders with respect to the 33% threshold of improvement (Fisher exact test, 2-tailed, $P = 1$). As for the 50% threshold, there were 6 acupuncture (40%) and 4 placebo responders (27%) (Fisher exact test, 2-tailed, $P = 0.7$). Responders to acupuncture treatment (50% decrease of HI) at 1 month after termination of treatment of treatment had scores on all MMPI scales similar to those of non-responders, except on the Depression scale. On this scale, responders had significantly higher scores than non-responders (67.2 + 12.4 vs. 51.5 + 12.8; Student's *t* test: $t = 2.4$; $P = 0.031$). The scores for all MMPI scales were similar for placebo responders and non-responders. Subsequently, responders to both treatments were grouped and compared to the total group of non-responders. Again, no difference emerged on any of the MMPI scales, either in terms of mean scores or the incidence of subjects with a pathological score (higher than 70).

Finally, the mean MMPI profile of acupuncture responders and non-responders at t3 with respect to the 50% threshold differed substantially in that 'Conversion V' was clearly evident in the non-responder group but did not appear in the responder group. The 'Conversion V' was not present in placebo non-responders.

Discussion

The results of our study indicate that traditional Chinese acupuncture is not differently effective than placebo in the treatment of muscle-tensive headache. Although frequency, headache index and analgesic consumption significantly decreased with time during the two treatments, and a trend for greater decrease in the acupuncture-treated patients was evident, none of these variables was modified by acupuncture in a significantly different way from placebo (Figs. 1, 2 and 3), neither at 1 nor at 12 months after termination of treatment.

The percentage of responders to the two treatments was not different either at 1 or 12 months after termination of treatment, considering both the 33% threshold of reduction of headache index and the 50% threshold.

A possible explanation for these findings is the wide dispersion of the values of the parameters considered able to nullify even the differences of 48%, 46% and 23% between acupuncture and placebo-treated patients found at t3 with respect to the mean headache index, analgesic consumption and frequency of episodes, respectively. This wide distribution of the values of the variables related to the clinical expression of muscle-tensive cephalea is typical of this disorder and must be taken into account in order to avoid rejecting results only because of the small size of the sample investigated. The MMPI profiles of 4 of the 7 non-responders showed the presence of the 'Conversion V' pattern, which consequently characterized the MMPI profile of the non-responders as a group. On the other hand, of the 5 acupuncture patients whose profiles showed 'Conversion V', 4 were classified as non-responders, as compared to the 1 of 10 without this personality pattern (Fisher exact test, 2-tailed, $P = 0.017$). This abnormally high percentage of patients with 'Conversion V' in the non-responder group seems to suggest that the poor response of some acupuncture-treated patients might be due to their peculiar personality profiles. Thus, Werder et al. (1981) found a poorer response to behavioral therapies (biofeedback, progressive relaxation) in headache patients with 'Conversion V' than in patients without it (Werder et al. 1981). Our study does not support the hypothesis that acupuncture is a valid therapy for muscle-tensive

headache and an alternative to pharmacological treatments.

The fact that the results of this study differ from those of previous studies may be due to differences in methodology. (1) We used traditional Chinese acupuncture which employs a diagnostic and therapeutic approach different from that of classical 'Western' acupuncture. In classical 'Western' acupuncture standardized points are chosen a priori, while the traditional Chinese system involves the utilization of points which differ from patient to patient with the possibility of varying them in subsequent sessions. (2) In contrast to the placebo techniques used in other studies, such as, for example, mock transcutaneous nerve stimulation or needles rubbed against the skin instead of being inserted into the patient, we chose the technique of sham acupuncture, i.e., superficial needle insertion in non-acupuncture sites. In this way the patient was able to experience the feeling of needle insertion and from a cognitive and emotional viewpoint 'lived' the experience of real acupuncture. (3) The follow-up on our patients was longer than in most previous studies.

It is evident that further studies using larger samples are necessary. In addition, considering the variables investigated in our study and adopting the methodological requisites outlined by Richardson and Vincent (1986), a further study should take into account personality differences as an important source of variation of the response to treatment.

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