

Acupuncture in chronic epicondylitis: a randomized controlled trial

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Abstract

Objective. To evaluate the clinical efficacy of acupuncture in the treatment of chronic lateral epicondylitis.

Methods. In a randomized, investigator- and patient-blinded, controlled clinical study, 23 patients were treated with real acupuncture and 22 patients received sham acupuncture. Patients each received 10 treatments, with two treatments per week. The primary outcome variables were maximal strength, pain intensity (verbal rating scale) and disability scale (Disabilities of the Arm, Shoulder and Hand questionnaire). Patients were examined at baseline (1 week before the start of treatment) and at follow-up 2 weeks and 2 months after the end of treatment.

Results. There was no significant difference between the groups at baseline for any outcome parameter. Two weeks and 2 months after the end of treatment, there were significant reductions in pain intensity and improvements in the function of the arm and in maximal strength in both treatment groups. At the 2-week follow-up these differences were significantly greater for all outcome parameters in the group treated with real acupuncture. At 2 months the function of the arm was still better in this group than in the sham acupuncture group; however, the differences in pain intensity and maximal strength between the groups were no longer significant.

Conclusion. In the treatment of chronic epicondylitis lateralis humeri, acupuncture in which real acupuncture points were selected and stimulated was superior to non-specific acupuncture with respect to reduction in pain and improvement in the functioning of the arm. These changes are particularly marked at early follow-up.

KEY WORDS: Epicondylitis, Tennis elbow, Acupuncture, Placebo, Randomized controlled trial.

Lateral epicondylitis of the elbow or 'tennis elbow' is one of the commonest diseases of the arm, with an estimated incidence of 1–3% [1]. Despite the fact that 90% of patients can be initially cured with conservative treatment and rest, the complaint frequently recurs after resumption of work or sport [2]. When classical conservative treatment and the topical application of non-steroidal anti-inflammatory drugs (NSAIDs) and the injection of steroids and/or local anaesthetics have been unsuccessful or side-effects have occurred, an increasing number of patients consider the possibility of complementary medicine, particularly of needle acupuncture [3, 4]. In spite of the increased demand for complementary medicine, there is little evidence that needle acupuncture has a specific action in the treatment of epicondylitis [5]. In particular, it is unclear what is

the specific effect of the selection and stimulation of specific acupuncture points, as the insertion of a needle at any site can alleviate pain [6, 7].

The objective of the present study was to investigate the specific effect of correct point location and stimulation in the treatment with needle acupuncture of patients with chronic epicondylitis, by comparing this with sham acupuncture, in which there was no selection of specific acupuncture points.

Methods

Approval of the study by the Ethics Committee of Hannover Medical School was obtained and the Declaration of Helsinki (revised version of Hong Kong, 1989) was adhered to.

Subjects

The study was advertised in the press, and interested patients contacted us by telephone. Screening was carried out by means of a semistructured telephone

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interview. As a result of this, 54 patients who appeared to be suitable for enrolment were given an appointment so that we could assess their clinical history and run a clinical examination. In accordance with the criteria for inclusion and exclusion, 45 patients were selected and enrolled after they had given informed consent (Table 1). We invited to the clinical examination only those patients who had stated that there were no marked changes in their complaints after previous treatments and who reported no significant variation in their complaints in the previous 4 weeks; they were therefore rated as non-responders in relation to earlier treatment. Patients were randomized to the different treatment groups according to a list of random numbers prepared by the Department of Biostatistics of Hannover Medical School.

The diagnostic criteria for epicondylitis were as follows: (i) a typical history of lateral elbow pain, characteristically aggravated by (overhand) gripping or by exertion of the arm, especially by active extension of the wrist, and often alleviated by rest; (ii) pressure pain on the radial epicondyle of the humerus; (iii) aggravation of pain during extension of the wrist against resistance and a positive middle-finger test.

Contact between patients during the trial was prevented. This seemed to be necessary because communication between patients in parallel group designs can influence the result of treatment [8].

Treatment protocol

Real acupuncture treatment. Traditional Chinese acupuncture regards treatment as consisting of local, regional and specific distant points. For the acupuncture in this study, we selected points which have frequently been recommended for the treatment of epicondylitis (e.g. [9]). As local points, we selected one Ash point, LI 10 and LI 11 over the muscular origin of the lateral extensor group of the forearm and Lu 5 in the cubital region. As regional points we selected LI 4 and SJ 5 for the treatment of pain in the upper limb. In all, six needles were given. The needles were inserted down to the musculature; by twisting the needles at the start of treatment a De Qi sensation was induced. The needles remained *in situ* for 25 min.

Control treatment: sham acupuncture. The terminology for reporting acupuncture control interventions has not been standardized. Lewith and Machin used the term 'sham acupuncture' to mean needling points which were not those specified by traditional acupuncture [10]. We used puncture sites which were at least 5 cm away from the classical acupuncture points and their interconnecting lines (meridians) and also clear of painful pressure points (Ah-Shi or trigger points) [11]. The needles were inserted in exactly the same way as in the real group. In all, six needles were given per treatment session. The time frame was the same as in the real acupuncture group.

The frequency of treatment of epicondylitis with acupuncture in published studies lies between once a day [12] and twice a week [5]. In the present study, we used the latter treatment frequency as it is the experience of two of us (MF, EW) that a lower frequency is more effective.

For both treatment groups, identical sets of sterile, disposable steel needles were used (0.25 × 40 mm, B-type; Seirin, Neu Isenburg, Germany). The skin at the puncture sites was prepared with a conventional disinfecting agent. Acupuncture was carried out by a physician with sound knowledge of traditional acupuncture techniques.

Outcome parameters

Patients were examined three times in the laboratory by a member of the Department of Physical Medicine: before therapy (baseline) and 2 weeks and 2 months after the end of therapy to test early and intermediate effects of treatment. The assessor had no knowledge of acupuncture techniques and was blinded with respect to the treatment modality (acupuncture or sham acupuncture). The examination consisted of measurements of peak muscle force, pain, and functional impairment. The isometric strength of the forearm extensors was tested with a specially designed device (Laboratory for Electronic Devices, Hannover Medical School, Hannover, Germany). When the fist is closed, both the flexors and the extensors in the lower arm are activated. We therefore preferred to use this special device, which permits selective examination of the lower arm extensors, the muscles that are primarily affected in epicondylitis. Prior to the study, the test-retest reliability of the device was assessed, giving an intraclass correlation of between 0.92 and 0.96. The peak strength of three consecutive maximal extension efforts was recorded and the average was used for further evaluation. Pain was assessed five-dimensionally with a self-assessment scale (pain at rest, in motion, during exertion, duration and frequency of pain) consisting of six items with a six-point verbal rating scale (0–5). Functional impairment was measured with the DASH questionnaire (Disabilities of the Arm, Shoulder and Hand) developed by the Upper Extremity Collaborative Group (UECG) [13]. At baseline, individual factors with a possible impact on the treatment effect (i.e. age,

TABLE 1. Inclusion and exclusion criteria

Inclusion criteria	
Chronic lateral epicondylitis of the elbow (duration > 3 months)	
Unilateral localization	
No age limit	
Exclusion criteria	
Pain treatment with analgesics or NSAID in the last 2 weeks	
Diseases of the central or peripheral nervous system	
Radial nerve entrapment	
Inflammatory rheumatic diseases	
Gout	
Radio-ulnar or radiohumeral osteoarthritis	
Earlier episodes of lateral epicondylitis of the elbow treated surgically or with acupuncture	

gender, disease duration) were assessed, as was the influence of occupation.

Statistical analysis

The calculation of the number of patients was based on the primary outcome parameter of pain. The self-assessment scale for the subjective rating of pain could take values between 0 and 30. It was assumed for this study that the patients in the treatment group would have a mean of 10 at the end of treatment and the patients in the control group a mean of 15. The mean standard deviation was assumed to be 5 points. On this basis, and assuming a level of significance of 5% and a power of 80%, the number of patients necessary was calculated to be 17 per group (unpaired *t*-test). The actual sample size was achieved in both treatment groups. The data were analysed with the StatView package (Abacus Concepts, Berkeley, CA, USA) on an Apple Macintosh computer. We used the Mann-Whitney *U*-test for group comparisons and the Wilcoxon test for paired longitudinal comparisons. A *P* value of < 0.05 was considered significant.

Results

Of the 54 patients selected by the screening process, 45 were enrolled in the study. Of these 45 patients only five had not been treated previously for epicondylitis. The other patients had received different treatments, mostly involving local anaesthesia, exercise, immobilization or NSAIDs. The duration of illness (median 9.0 months), age and gender of the patient were distributed equally in the two groups and had no influence on treatment results; R^2 was 0.01 for the duration of illness/treatment success and 0.115 for age of patient/treatment success. Table 2 gives data on the drop-out rate; baseline data are shown in Table 3. Before treatment, there were no significant differences between the two treatment groups with respect to peak force, pain and disability. In both groups the treatment led to significant changes in the outcome measurement and the changes were also clinically relevant at the first follow-up. There was a significant reduction in disability (DASH) at the second follow-up in favour of the treatment group. No significant differences between groups were found at the second follow-up with respect to pain reduction and peak force. The results are summarized in Table 4. No side-effects occurred, apart from pain resulting from needling, which led one patient to drop out.

To test the influence of occupation on the treatment results, the patients were divided into two subgroups according to the amount of physical strain associated with their occupation: patients in subgroup 1 performed frequent or regular heavy physical work or work with a repetitive motion pattern; patients in subgroup 2 performed light physical work or work without a repetitive motion pattern. The distribution of these subgroups was equal in both treatment groups (Table 3). Real

TABLE 2. Drop-out rate

	Real acupuncture	Control acupuncture	Total
Before the study	23	22	45
Treatment phase			
Did not attend	0	1	1
Discontinued	1	1	2
First follow-up	22	20	42
Excluded	1	0	1
Did not attend	1	0	1
Second follow-up	20	20	40

TABLE 3. Baseline data prior to treatment

	Acupuncture	Sham acupuncture
Male, female	19, 23 (45.2, 54.8%)	12, 26 (31.6, 68.4%)
Age (yr; mean \pm S.E.M.)	52.5 \pm 8.7	51.6 \pm 10.0
Duration of disease (months; median; n.s.)	8	10.5
Occupational strain		
Physical work and/or RMP (n.s.)	16	16
Non-physical work, no RMP (n.s.)	6	4
Baseline data on outcome measures		
DASH (mean \pm S.E.M.; n.s.)	36.0 \pm 2.5	44.6 \pm 3.2
Pain questionnaire (mean \pm S.E.M.; n.s.)	16.8 \pm 0.6	19.1 \pm 0.8
Maximal strength (N, mean \pm S.E.M.; n.s.)	84.4 \pm 7.2	106.4 \pm 6.9

RMP, repetitive motion pattern; n.s., not significant.

TABLE 4. Outcome parameters (mean + S.E.M.)

Outcome parameter	Baseline	2 weeks	2 months
Strength (N)			
Acupuncture	90.5 + 10.8	128.2 + 11.13*	142.9 + 11.11
Sham acupuncture	77.7 + 9.4	92.75 + 8.98*	114.2 + 11.9
Pain (VAS, mm)			
Acupuncture	16.46 + 0.83	8.03 + 1.23*	6.01 + 1.36
Sham acupuncture	17.17 + 0.97	12.28 + 1.07*	8.73 + 1.3
DASH (score points)			
Acupuncture	38.08 + 3.65	14.38 + 2.5*	11.14 + 3.5*
Sham acupuncture	33.72 + 3.37	25.18 + 3.52*	18.85 + 3.55*

VAS, visual analogue scale.

*Significant difference between groups ($P < 0.05$).

acupuncture treatment led to similar improvement in the two subgroups. Under sham acupuncture treatment, the subgroups with high or varying occupational strain showed significantly less improvement than patients with low strain ($P < 0.05$). There was a significant difference between treatment effects in subgroup 1 between real and sham acupuncture ($P < 0.05$). The results are depicted in Fig. 1.

Discussion

The effect of treatment (real vs sham) was particularly marked at the first follow-up and was clinically relevant at that time. The overall results were affected

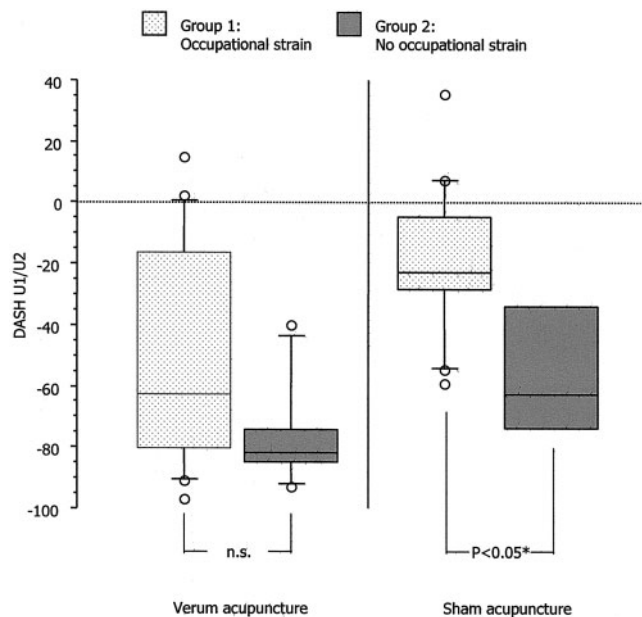


FIG. 1. Efficacy of the two types of acupuncture in patients with different degrees of occupational strain. Group 1 comprised patients whose occupation involved physical strain (e.g. lifting and carrying) or with a repetitive pattern of motion (e.g. working at a computer or on a production line). Group 2 comprised patients whose occupation involved only little or no strain and did not have a repetitive pattern of motion.

by the degree of occupational strain. The overall effect of real acupuncture was better because the improvement in the complaints was unrelated to occupational strain, whereas with sham acupuncture the patients with occupational strain exhibited significantly less improvement.

However, at the 2-month follow-up the treatment effects were less evident. This may be explained if the therapeutic effect was dominant at the start of the follow-up period and if, at the 2-month follow-up, this treatment effect was disguised by the natural course of the disease. This is difficult to assess, however, as it was not possible in this study to have a second control group receiving no treatment at all for 3 months. A further limitation in the evaluation of our results could be connected with our exclusive recruitment of patients through press advertisement, which might have caused a bias in selection.

TABLE 5. Effect size calculation

	CER	EER	RRR	ARR	NNT	Odds ratio	95% confidence interval
Present study	0.55	0.7	0.333	0.15	6.666	1.909	0.4362–8.6347
Molsberger and Hille [18]	0.25	0.792	0.7222	0.5417	1.85	11.4	2.5144–55.2888
Haker and Lundeberg [5]	0.237	0.523	0.375	0.286	3.50	3.53	1.236–10.293
Hay <i>et al.</i> [19]							
Naproxen vs placebo	0.483	0.472	-0.0213	-0.011	-90.9	0.9566	0.4238–2.1584
Steroid and lignocaine vs placebo	0.483	0.774	0.563	0.291	3.44	3.661	1.4925–9.1088

CER, control event rate; EER, experimental event rate; RRR, relative risk reduction; ARR, absolute risk reduction; NNT, number needed to treat.

The possible reasons for the better effectiveness of real acupuncture are unclear. The stimulation of afferent pathways is thought to be responsible for the analgesic effect of acupuncture. The excitation of afferent A- δ -fibres can cause segmental pain modulation [14] as well as modulation through the activation of descending pain inhibiting systems (e.g. [15]). If the analgesic effect were only the result of segmental counter-irritation, we would expect no difference between the two groups in our study, as the acupuncture points and the non-acupuncture points were in the same dermatomes (C5–C8). Morphological differences between acupuncture points and other areas of skin or muscle are questionable. There are unconfirmed hints in the literature that classic acupuncture points are in regions of relatively high density of A- δ -fibres [16]. In the specific treatment, pricks at real acupuncture points might elicit a higher degree of stimulation than those at non-acupuncture sites.

Comparison with other studies

Although acupuncture has been recommended repeatedly as a method of treatment [17], a Medline search from 1996 to 2001 showed that only two controlled studies have been carried out on the specific activity of needle acupuncture in tennis elbow. Molsberger and Hille [18] found a significant immediate effect of treatment in alleviating pain after one treatment session, using distant points in the lower extremities in the treatment group. Haker and Lundeberg [5] found that needling to a normal depth with mechanical stimulation was superior to superficial needling, both carried out at acupuncture points.

To compare the results of our study and the two acupuncture studies of Haker and Lundeberg and of Molsberger and Hille with conventional treatment options, the results of a clinical trial were selected in which a single injection of 20 mg methylprednisolone plus lignocaine and naproxen 500 mg twice daily for 2 weeks was compared with placebo tablets [19]. To compare the effect size, the number needed to treat (NNT; Table 5) was calculated [20] on the basis of a minimal improvement of 50% in the complaint. For this purpose, the values from the first follow-up of these studies were used. On the basis of this comparison, it may be concluded that the results of real acupuncture treatment in the present study are lower than in the

other acupuncture studies. On the basis of the calculated experimental and control event rates, this seems to be predominantly due to differences in the efficacy of the control treatments in these studies (present study > Molsberger and Hille > Haker and Lundeberg), which results in an increased NNT. This could be due to the different forms of control treatment used in the studies. Whereas our control patients were needled to a normal depth within the dermatome of the affected joint, the patients in the control group of Molsberger and Hille were touched at the dorsal trunk area with a pencil-like probe. The control group in the study of Haker and Lundeberg were pricked at the correct acupuncture sites, but only superficially. We therefore suggest that the design and manner of performing the control procedure influences the outcome. This hypothesis is supported by Arango [21] in a systematic review. Studies using non-acupoints close to real acupoints more frequently failed to show any difference between real and control acupuncture treatment than studies using non-acupoints which lay well clear of real acupoints.

A comparison of the results of acupuncture studies with the results of studies with naproxen and steroid injection, on the basis of the NNT, suggests that naproxen has the least effect, in the same range as that of the control treatment with placebo tablets. A comparison of acupuncture with steroid plus lignocaine injection suggests that the injection treatment gives results that are in the middle range of the acupuncture results. Although appearing to show an advantage for acupuncture, this may also be regarded as a potential disadvantage of acupuncture compared with local steroid injection with respect to treatment costs.

The results of Haker and Lundeberg and of the present study indicate that acupuncture with correct location and stimulation according to the recommendations of traditional Chinese acupuncture seems to alleviate pain and improve function in epicondylitis. It is more effective than acupuncture that is carried out without any particular training, comparable to the unaimed puncturing used in the control group of this study. The treatment of epicondylitis with acupuncture might be a useful alternative to classical conservative methods in chronic epicondylitis, and where other treatment modalities have failed.

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