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Acupuncture for Chronic Low Back Pain: A Randomized Placebo-Controlled Study With Long-Term Follow-Up

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Abstract:

Objective: The authors sought to determine whether a series of needle acupuncture treatments produced long-term relief of chronic low back pain.

Design: A blinded placebo-controlled study with an independent observer. The patients were randomized to receive manual acupuncture, electroacupuncture, or active placebo (mock transcutaneous electrical nerve stimulation). Subjects were examined and monitored by an investigator who was blinded to the treatment given.

Setting: A tertiary-level pain clinic at a Swedish university hospital.

Patients: Fifty consecutive patients (33 women, 17 men; mean age, 49.8 years) with chronic low back pain (mean pain duration, 9.5 years) and without rhizopathy or history of acupuncture treatment were included in the study.

Interventions: Treatments were given once per week for 8 weeks. Two further treatments were given during the follow-up assessment period of 6 months or longer.

Outcome Measures: The independent observer made a global assessment of the patients 1, 3, and 6 months after treatment. The patients kept pain diaries to score pain intensity twice daily, analgesic intake, and quality of sleep daily, and activity level weekly.

Results: At the 1-month independent assessment, 16 of 34 patients in the acupuncture groups and 2 of 16 patients in the placebo group showed improvement ($p < 0.05$). At the 6-month follow-up assessment, 14 of 34 patients in the acupuncture groups and 2 of 16 patients in the placebo group showed improvement ($p < 0.05$). A significant decrease in pain intensities occurred at 1 and 3 months in the acupuncture groups compared with the placebo group. There was a significant improvement in return to work, quality of sleep, and analgesic intake in subjects treated with acupuncture.

Conclusions: The authors found a long-term pain-relieving effect of needle acupuncture compared with true placebo in some patients with chronic nociceptive low back pain.

Key Words: Acupuncture—Chronic low back pain—Long-term relief—Randomized placebo-controlled trial.

Needle acupuncture, a traditional art of healing without an established scientific basis, has become a much sought-after therapeutic modality because of favorable outcomes, such as the relief of pain and other symptoms. In the 1970s, several demonstrations were made of pain-threshold increases in humans with acupuncture stimulation.[1–3] At the same time, reports were published about the use of acupuncture as a pain-relieving technique used in Chinese modern medicine.[4,5]

Subsequently, human studies were performed to evaluate the mechanisms of acupuncture,[6–11] and indicated that release of neuropeptides was critical for the pain-relieving effect produced. Experimental studies in animals[12–17] have further indicated that there are several mechanisms behind acupuncture analgesia, such as spinal and supraspinal inhibitory-control systems. Thus,

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it seems safe to conclude that a stable biological set of mechanisms has been shown, especially for short-term analgesia.

It is less obvious whether the clinical pain-relieving effects in humans are stable phenomena. Several early reviews[18–20] conclude that some controlled studies indicate a true analgesic effect. However, many studies do not support the induction of a clinically meaningful analgesia for various chronic pain conditions, mostly because of technical shortcomings.

We have been using acupuncture as a clinical treatment tool for more than 10 years. In our previous follow-up study of more than 200 patients with chronic pain who were treated every 1 to 2 weeks with needle acupuncture using a combination of local and distal points, 42% of patients experienced pain relief immediately after the treatment period, but only 17% reported pain relief 6 months after treatment.[21] This open follow-up study used questionnaires and had inherent difficulties. However, when patients where distinguished according to nociceptive, neurogenic, and psychogenic (nonorganic) origin of pain, we found that mainly those with nociceptive pain experienced pain relief after 6 months. Therefore, the current study comprised patients with chronic low back pain and used a randomized placebo-controlled blinded design with an independent observer. Preliminary data have been reported previously.[22]

METHODS

Study design

The patients were randomly allocated to one of the following three treatment groups: (1) manual acupuncture; (2) electroacupuncture; or (3) placebo stimulation. The randomization was produced from a previously computer generated list that was kept from the investigators by a secretarial assistant who was not otherwise involved in the study. All patients with chronic low back pain who were referred to the outpatient pain clinic at Malmö General Hospital during a 3-year period and who fulfilled the inclusion criteria were consecutively included in the study. Our pain clinic is a tertiary-level clinic in a university hospital setting. The patients were informed that we were studying the long-term effect of three different sensory stimulation methods that we thought would be equally effective for the management of low back pain. Participants were also informed that the placebo stimulation treatment was believed to be an equally efficient new treatment modality for acupuncture, and that the treatments might or might not give rise to sensory experiences. All patients were asked not to reveal to the independent observer the nature of the stimulation that they received. The Ethical Committee of the Medical Faculty, Lund University, approved the study, and all participants gave informed consent before enrollment.

Patients

Inclusion criteria included patients with (1) lumbar or lumbosacral low back pain for a duration of 6 months or longer; (2) no radiation of pain below the knee level; and (3) normal neurologic examination findings of lumbosacral nerve function, including deep tendon reflexes, plantar response, voluntary muscle activation, straight leg raising, and sensory function. Exclusion criteria included patients with (1) major trauma or systemic disease; (2) ongoing pregnancy; and (3) history of acupuncture treatment.

Protocol

The author (B.S.), who was not informed about which treatment group the patient was assigned to, examined the patients. Patients were first examined before start of the study using a standard physical and neurologic examination. Those who fulfilled the inclusion criteria and did not meet the exclusion criteria were asked to participate in the study and were enrolled if they gave informed consent. Participants were given pain diaries to document their experience of pain each morning and evening for 2 to 4 weeks at baseline before the start of treatment and then throughout the study and follow-up period. These diaries contained standard visual analog scales (VAS) drawn on separate pages for 7 days.

The secretarial assistant performed the randomization before the first treatment. Treatments were given by the author (CC) once per week for 8 weeks. The same amount of time and care was given to all patients in each of the three treatment groups. During the follow-up period, the patients continued to monitor their pain intensity regularly and record these data in their diaries. One follow-up treatment was given after 2 months, and the last (10th) treatment was given after an additional 2 months (Fig. 1., flowchart).

Assessments

The assessments were performed before (control) treatment began and at 1 month (after treatment number eight, first follow-up), 3 months (second follow-up), and 6 months or longer (third follow-up) after the treatment period. The independent observer (BS) examined and re-evaluated patients for present pain and classified this pain as improved, unchanged, or worse. These assessments were based on a clinical interview that included

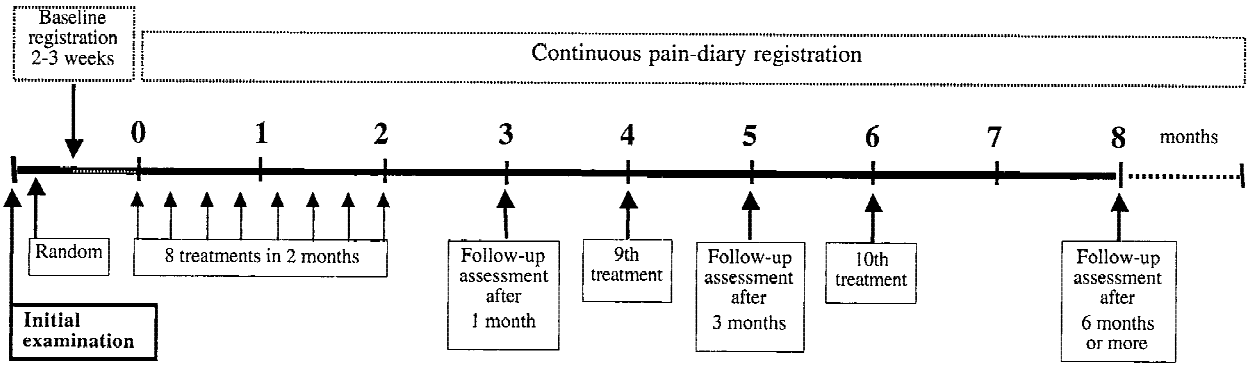

FIG. 1. Flowchart of the study design.

questions about pain-related disability, and on a physical examination that included range of motions. Subjects with pain that was not improved after the first follow-up (1 month after the treatment period) usually terminated their participation in the study, were included as "unchanged" for the rest of the study, and were offered traditional treatment of low back pain. Subjects who were still improved at the third follow-up assessment were seen assessed after another 4 to 6 months.

Treatment

Needle acupuncture was given to points of the lower back (local points) and to some points on the lower limbs and forearms or hands (distal points) (Fig. 2). The number of needles was successively increased from eight (four local and four distal needles) to 14 to 18 during the first three or four treatments. The "de-qi" feeling of numbness, soreness, heaviness, and warmth was sought in all instances, mostly at a needle-tip depth of 2 to 3 cm. The needles were stimulated three times during the 20-minute treatment sessions to restore de-qi feelings. The needles were usual disposable, stainless steel needles with a diameter between 0.30 and 0.32 mm (gauge, 29–30) and a length between 30 and 70 mm (1–3 inches).

In the group receiving electroacupuncture, two or three sessions of manual acupuncture were given initially (to avoid temporary exacerbation of pain), followed by treatments consisting of electrical stimulation of four needles (one pair per side) in the low back. The stimulation frequency was approximately 2 Hz every 2.5 seconds, and was interrupted by a 15-Hz train for 2.5 seconds (dense–disperse) at a perceived but not painful stimulation intensity. We used a Chinese acupuncture electrostimulator (Multiple Electronic Acupunctoscope; WQ-10C, Beijing, China) for which the output could be approximately monitored by a flashing light. In addition, a similar number of needles as in the manual acupuncture group were inserted and manually activated. The physician giving all the stimulation treatments (CC) is a board-certified anesthesiologist and had considerable experience with acupuncture (>10,000 treatments) before performing this study.

The placebo stimulation treatment used a mock transcutaneous electrical nerve stimulation (TENS)[18] given by an impressive, stationary, but disconnected GRASS (gradient-recalled acquisition in a steady state) stimulator attached to two large TENS electrodes. The electrodes were placed on the skin over the most intensely painful area in the low back. During stimulation, flashing lamps were displayed and visible to the patient.

Pain diaries

Throughout the study, patients scored four different parameters in small booklets or pain diaries. Present pain intensity was recorded twice daily (morning and evening) on a standard VAS scale ranging from 0 (no pain at all) to 100 mm (pain as severe as it could possibly be). Intake of analgesics was recorded daily. Sleep quality was scored according to a three-category scale (good, slightly disturbed by pain and woke 1 or 2 times, or badly disturbed by pain and woke more than twice). Finally, patients noted what level of activity (at work or at home) that they had experienced weekly.

A nurse who had no other involvement in the study performed all measurements and analyses of the pain diaries. The "last value carried forward" method[23] was used for the statistical analysis of data of categories two, three, and four (supra), and in some instances for differences of VAS measurements (Fig. 5).

Statistics

The original sample size was 60 patients (20 in each group), but because of limiting factors only 51 patients were enrolled within the 36-month period. Because acupuncture is increasingly used in other centers, it became increasingly difficult to enroll acupuncture-naïve subjects.

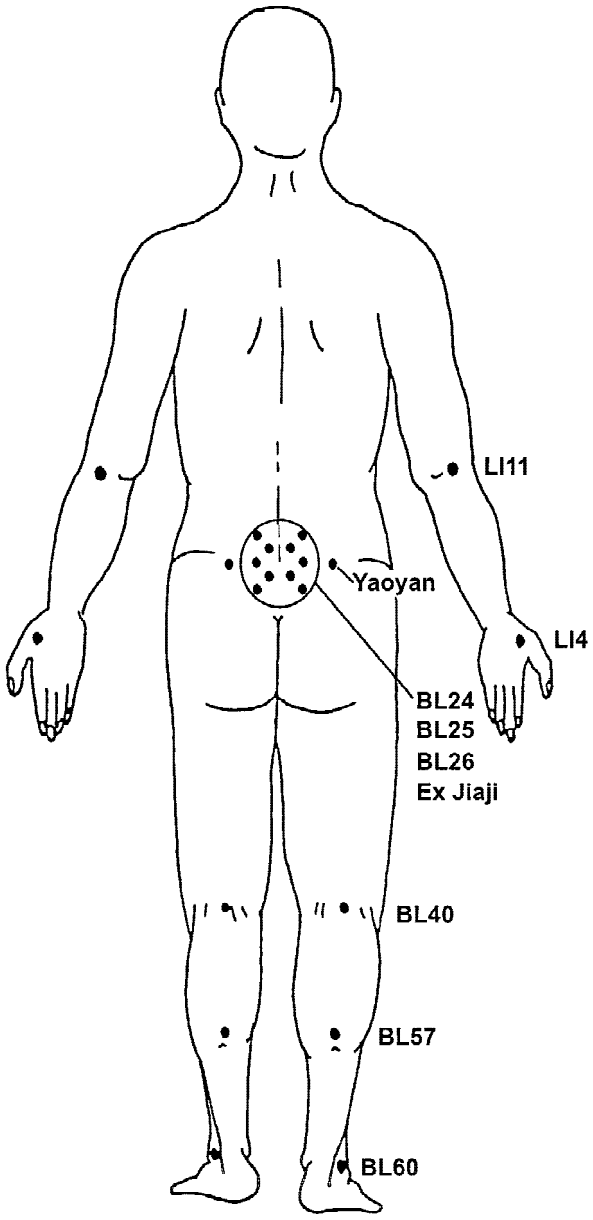

FIG. 2. Acupuncture points used in the study. The numbering of points is in accordance with the nomenclature proposed by the World Health Organization.[54]

All outcome measures and analyses used in the current study (except gender) were determined before the start of the study (e.g., global assessments by the independent observer, pain diaries containing VAS scales and questions regarding analgesic intake, sleep pattern, and activity levels).

All the results were included in a database and analyzed with the SPSS (Statistical Package for the Social Sciences; SPSS, Inc., Chicago, IL, U.S.A.) program. Both parametric (Student *t* test) and nonparametric (χ^2 test, Fisher exact test, Mann-Whitney test, Wilcoxon signed ranks test) methods were used.

RESULTS

Fifty-one patients agreed to participate in the study and were enrolled. One patient did not present for follow up because she had moved from the area during the study period, and was excluded from the analyses. Therefore, our results come from 50 patients (17 men, 33 women). Thirty-four patients were randomized to receive acupuncture treatments (18 to manual-acupuncture and 16 to electroacupuncture groups) and 16 patients were randomly assigned to receive placebo-stimulation treatment. To avoid a type 2 statistical error due to underenrollment of study patients, we pooled the results from the manual-acupuncture and electroacupuncture groups and compared these composite results to those from placebo treatment.

The mean (± SD) age of the patients was 49.8 (15.4) years. There was no significant difference in mean age between men and women or among the various treatment groups, nor was there a significant difference in the proportion of men and women among the various groups. At the time of enrollment, 17 patients were retired, 20 were on sick leave, 12 were working full time, and 1 was unemployed. The mean (± SD) duration of pain was 9.5 (7.0) years, and there was no difference in the mean duration of pain among the treatment groups.

Of the 50 patients included, 39 had common low back pain of presumed muscular origin, whereas 11 had severe structural changes observed on plain roentgen of the spine, old compression fractures due to osteoporosis, severe spondylartrosis, or localized spinal stenosis diagnosed by the referring orthopedic surgeon. All the patients were referred from other departments (35 from orthopedic surgeons, 13 from general practitioners, and 2 from other medical departments). None was given concomitant rehabilitation while enrolled in our study.

Most patients had tried several treatment modalities (average of 2.8) before the study, including corsets, nerve blocks, analgesics, TENS, and intense physiotherapy including traction, warmth, and exercise. Two patients had undergone lumbar surgery. No patient had experienced any form of serious complication from previous treatment.

Global assessments

The independent blinded observer (BS) found that 16 of 34 patients treated with manual or electroacupuncture and only 2 of 16 patients treated with placebo stimulation were improved 1 month after the initial treatment period of eight sessions (Fig. 3A). After 3 months, 15 of 34 patients in the acupuncture groups were improved. After 6 months or longer, 14 of 34 patients receiving acupuncture and 2 of 16 receiving placebo stimulation were still

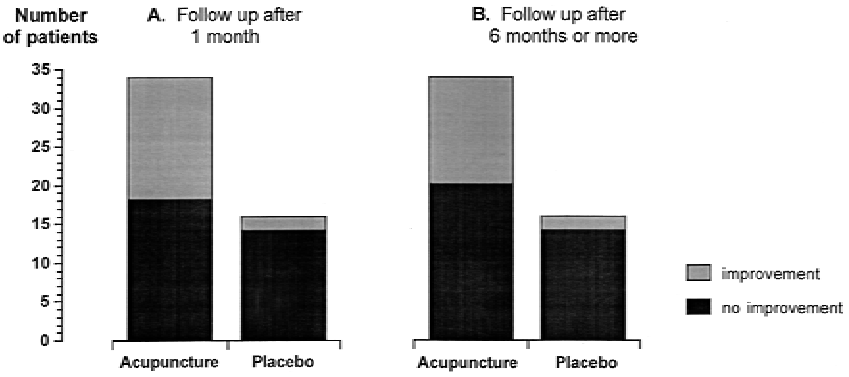

FIG. 3. (**A, B**) Global assessment by independent observer. Number of patients in acupuncture and placebo groups with improvement or no improvement at follow-up times is indicated.

improved. All of these differences were significant (Fig. 3B). Among the patients receiving acupuncture, 9 of 18 receiving manual acupuncture and 7 of 16 receiving electroacupuncture were improved at the first follow-up. After 6 months or longer, 8 of 18 patients in the manual-acupuncture group and 6 of 16 patients in the electroacupuncture group were still improved. However, these latter differences do not reach significance in a group-comparison test.

Two patients in the placebo stimulation group where categorized as worse at the first follow-up assessment (included in the "no improvement" group, Fig. 3) but no patient that had received acupuncture were categorized as such. It should be noted that one of the patients receiving acupuncture and two patients in the placebo-stimulation group (those who were categorised as "improved" in this group) did not present at the 6-month follow-up assessment, but were interviewed by telephone by the blinded observer.

Depending on differences in global outcome, the total follow-up time was different among patients (Fig. 1). Patients assessed as worse or unchanged from the treatment series were excluded from the study after the first (n = 17) or the second (n = 5) follow-up and were offered conventional treatment at the pain clinic. The true time for improvement for patients assessed as globally improved at the third follow-up (at least 6 months after the treatment series) was between 6 and 48 months (median, 11 months).

There was a marked difference in gender distribution (Figs. 4A and 4B). As is evident from the *post hoc* analysis in Figure 4A (left bars), only one man found the stimulation effective at the first follow-up, whereas only women remained improved after 6 months or longer (Fig. 4B, right bars). This difference in gender distribution was statistically significant (Fig. 4).

Changes in pain intensity

In the analysis of the pain diaries, we defined the mean VAS baseline levels in the mornings and in the evenings for each patient by calculating the mean of daily VAS values for the 2 to 4 week period before treatment. There were no significant differences in the mean absolute values of baseline pain intensity between males and females or among the different treatment groups.

We then calculated the mean weekly morning and evening pain-intensity values at the various follow-up times. These data were analyzed both as normalized in relation to the individual baseline period VAS values[24]

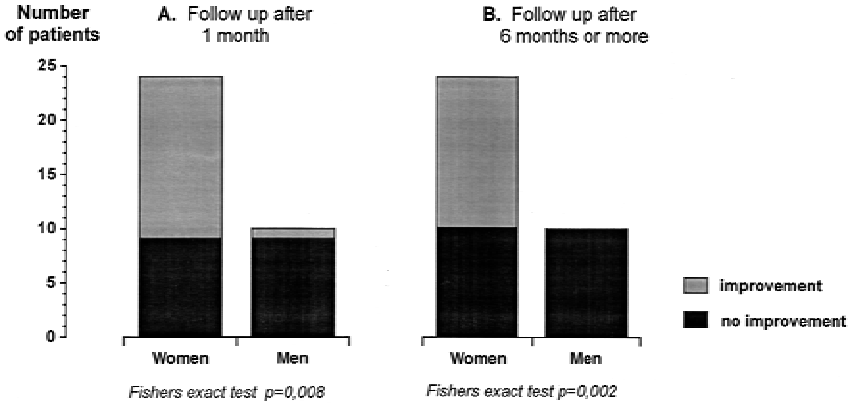

FIG. 4. (**A, B**) Number of women and men in the acupuncture group who improved or did not improve in global assessment at the follow-up times indicated.

for intergroup comparisons and as absolute values for intragroup comparisons.

Intergroup differences between acupuncture and placebo groups

The differences in mean weekly VAS (in percent of baseline values) between the acupuncture groups and the placebo group were significant 1 and 3 months after the treatment period (Figs. 5A and 5B). The values at 6 months did not reach statistical significance because of the more limited number of patients remaining at that time (n = 27). When calculating statistical significance using the last value carried forward method,[23] the differences remained significant ($p = 0.001$, Mann-Whitney test).

Intragroup differences

From Figure 6, it can be seen that weekly pain intensity was lowered in the morning and afternoon and after 1, 3, and 6 months in patients receiving acupuncture both compared with baseline ($p = 0.001$–0.04, Wilcoxon signed ranks test). However, pain intensity increased during the same periods in patients receiving placebo stimulation, but this increase was significant only for pain experienced in the mornings after 1 month ($p = 0.004$, Wilcoxon signed ranks test). The significant reduction of VAS values within the acupuncture group was found whether the last value carrying forward method was used or not, at all follow-up assessments.

No complication of any kind occurred from the acupuncture stimulation during treatments or during the follow-up period.

Activity changes

As seen in Figure 7, the activity in relation to the work place was classified according to one of three categories, work full time, sick leave half time, or sick leave full time. Within the acupuncture group, 14 patients were on sick leave before the study. Six of these went back to work full or half time. The rest of the patients were retired, but six of these improved. In the placebo stimulation group only one patient was improved over the observation period. The improvement in the acupuncture group was significant ($p = 0.024$; Wilcoxon signed ranks test), but not in the placebo group ($p = 0.655$).

Disturbance of sleep

Before the study, 30 of 34 patients receiving acupuncture and 12 of 16 patients receiving placebo reported sleep disturbance due to pain. In the acupuncture group, the sleep pattern was significantly less disturbed after the treatment period ($p = 0.001$ at 1-month follow-up, $p = 0.025$ at 6-month follow-up; Wilcoxon signed ranks test). There was no significant difference in sleep disturbance in the placebo group ($p = 0.317$ at both follow-ups). Few patients used occasional sleeping aids at the time of enrollment, and participants were instructed not to change their drug-intake habits during the course of the study.

Analgesic intake

A total of 26 of 34 patients in the acupuncture group and 13 of 16 patients in the placebo group used analgesics (nonsteriodal anti-inflammatory drugs or weak

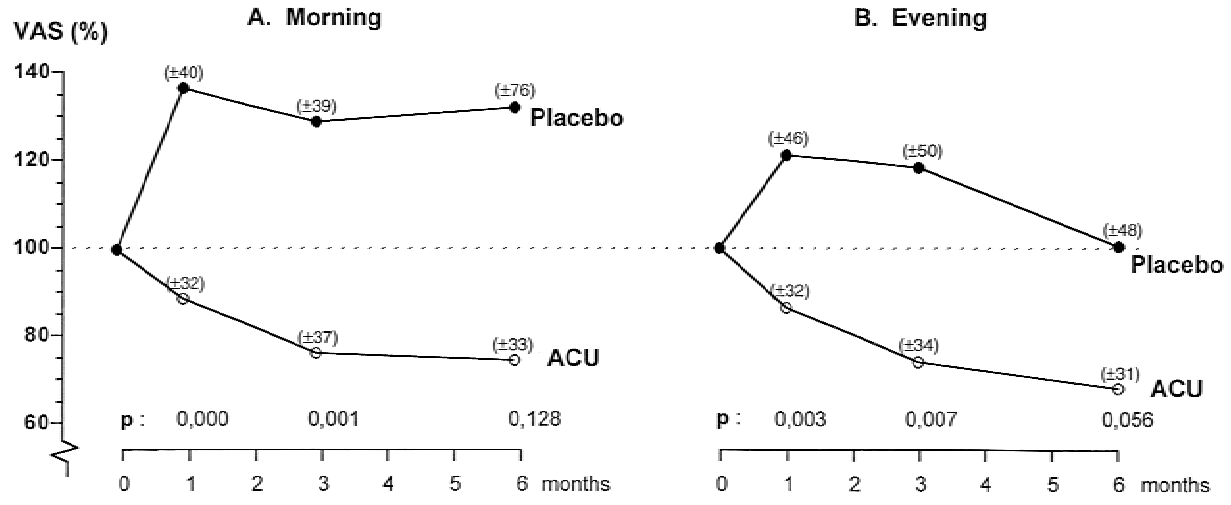

FIG. 5. (**A, B**) Mean weekly pain intensity (measured with a visual analog scale) in percent of baseline values during mornings or evenings at times indicated. Figures within brackets indicate standard deviations. The values are for patients who were still enrolled in the study at the times indicated. All patients were included at the 1-month follow-up assessment. At the 3-month assessment, there were 23 patients in the acupuncture groups and 9 patients in the placebo group. At the 6-month assessment, 21 patients in the acupuncture groups and 6 patients in the placebo group were evaluated. The *p* values were calculated from Mann-Whitney test.

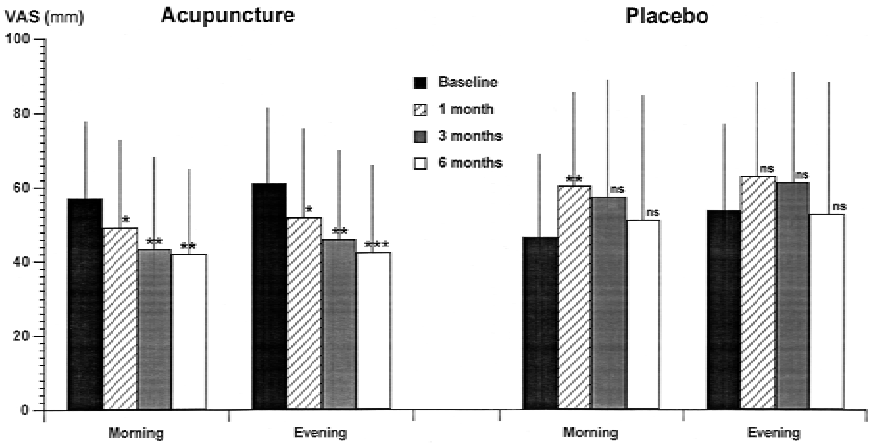

FIG. 6. Mean weekly pain intensity (measured with a visual analog scale) is given in absolute values (millimeters) within the acupuncture and placebo groups. The values for mornings and evenings are indicated. Bars indicating 1, 3, and 6 months give the values at these follow-up intervals. *p <0.05, **p <0.01, ***p <0.001, Wilcoxon signed ranks test. Thin lines indicate standard deviation.

opioids) regularly. We did not change any of the patient drug prescriptions during the study, and all patients regulated their drug intake as needed using their usual prescriptions. Before treatment, patients in the acupuncture group consumed a mean of 31 tablets per person per week (SD ± 21.5), and those in the placebo group consumed a mean of 23 tablets per person per week (SD ± 17.5).

At the 6-month follow-up, the number of tablets consumed per person per week had decreased to 21.4 among patients treated with acupuncture (SD ± 21.1) and 21.5 among those receiving placebo treatment (SD ± 16.0). The change analgesic intake was significant in the acupuncture group ($p = 0.003$, Wilcoxon signed ranks test) but not in the placebo group ($p = 0.552$). Similarly, the difference within the acupuncture group between those independently scored as globally improved and those scored as unchanged or worse (i.e., not improved) was highly significant. Thus, the tablet intake among patients in the improved group was reduced from a mean of 29.6 (SD ± 20.6) to 11.0 (SD ± 13.8) tablets per person per week, whereas the reduction in the not-improved group was only from a mean of 32.3 (SD ± 23.1) to 31.8 (SD ± 22.5) tablets per person per week. This difference in tablet reduction was statistically significant ($p = 0.001$, Mann-Whitney test).

DISCUSSION

In the current study, we demonstrated a long-term pain-relieving effect of needle acupuncture compared with true placebo in some patients with chronic low back pain. This finding is supported not only by the patients' own pain estimates, but also by the repeated assessments of the independent blinded observer. Furthermore, the patients responding to acupuncture treatment showed a significant improvement in sleep pattern, activity repertoire, and analgesic consumption compared with the placebo group. These outcomes were previously suggested by Thomas and Lundeberg[25]; however, that study

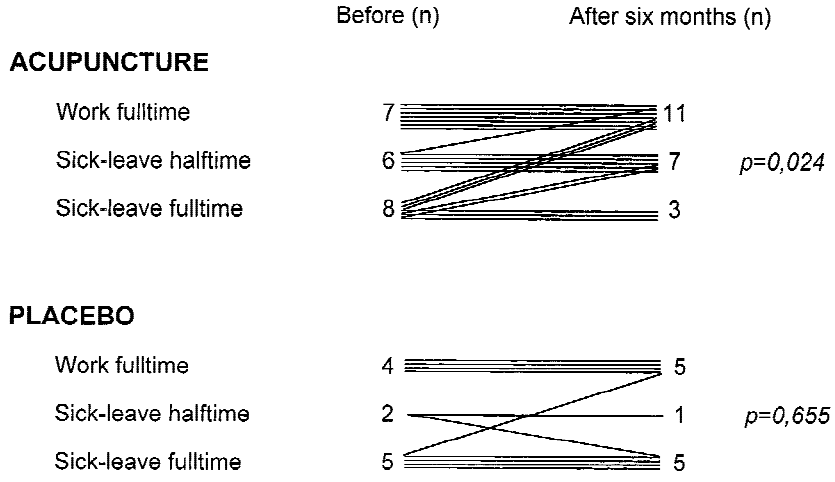

FIG. 7. Changes in workplace activity. The number of patients is given in the different categories before treatment and at the 6-month follow-up assessment. The p values were calculated from Wilcoxon signed ranks test.

suffered from unclear outcome measures and inconsistent effects, and used passive (wait-list) controls.

The difference in pain estimates between the placebo-treatment and acupuncture groups, however, is partially due to the mean pain intensity increased in the placebo group (Fig. 5 and 6). This finding is not unique; a similar increase of pain over time in a placebo-treated group was seen in a TENS study of low back pain[26]and in the wait-list control group of a study of the effect of multidisciplinary pain management.[27] We did not control for possible mood changes among the patients in our study, which could have confounded our results. However, acupuncture has not been convincingly reported to produce such mood changes, and our patient-selection criteria and study design would have counteracted such a systematic error.

There was no break of blinding in our study because the observer was never aware of the treatment sessions and avoided questions related to the treatment when making assessments at separate occasions. Admittedly, we did not ask the patients about their beliefs about whether they were subjected to active treatment. A placebo acupuncture needle has recently been developed,[28] but produces a sensation and is therefore not inert. The placebo treatment used in this study, mock TENS, has been advocated by others as a suitable acupuncture-study procedure[18] because sham acupuncture (i.e., the insertion of needles in nonacupuncture points) may still activate central analgesic mechanisms through sensory stimulation.[29] Here, mock TENS was given from an impressive stationary (GRASS) stimulator with flashing lights. Furthermore, patients were informed that the treatment might or might not be felt, and only acupuncture-naïve patients were recruited. These factors seem sufficient to establish a true placebo treatment in the current study.[30] Interestingly, two patients responded positively to our placebo treatment during the follow-up period and for more than 1 year. Furthermore, there was no indication that electroacupuncture is more effective than manual acupuncture to relieve chronic low back pain.[25]

One remarkable result of this study is that only women responded to the acupuncture treatment. It is not known from other studies or from clinical experience whether such a marked gender difference in acupuncture effects exists. However, several conditions in women respond well to acupuncture treatment, such as primary dysmenorrhea[31] and true migraine.[32,33] The discovery of oestrogen receptors on the membranes of nociceptive cells in the central nervous system[34] may be relevant to this finding, because a premenopausal decrease in hormone levels may influence nociceptive transmission in women. The finding that twice as many Swedish women as men are referred for medical treatment of chronic pain[35] may also influence our results. In addition, the low back pain mechanism in our women participants was more susceptible to acupuncture (e.g., because of a presumed muscular origin).

There is now reasonable evidence that acupuncture has a clinically relevant pain-relieving effect on certain forms of chronic pain. MacDonald et al.[36] demonstrated a short-term effect on back pain, and dysmenorrhea,[31] migraine,[32,33] epicondylitis pain,[37] osteoarthritis pain,[38] fibromyalgia,[39] and myofascial neck pain[40] have since been found to respond to acupuncture in controlled clinical studies.

Some controlled studies have indicated no significant effect of acupuncture on chronic pain.[41–48] However, several of these studies had methodological flaws. First, the sensitivity of some of these studies was inadequate because of the small number of patients included.[19,41,47] Crossover designs are not always fulfilled.[45] In some studies, the mode of active acupuncture stimulation is not limited to manual needling or electroacupuncture, but a biologically inert light beam ("laser acupuncture") is considered a valid alternative[43] or the placebo treatment consists of "sham acupuncture", which may have biological effects.[29,42,45] Sometimes, the main outcome measure is not specific to acupuncture.[46] Unfortunately, it is difficult to draw the conclusion that acupuncture does not produce pain relief[49] when studies of low design or treatment quality are included for analysis. Van Tulder et al.[50] recently attempted to perform a meta-analysis of acupuncture for low back pain, but found the available studies to be too heterogeneous and made only a qualitative analysis, with little evidence for a positive treatment effect of acupuncture. A negative finding was reported by Smith et al.,[51] who made a considerable effort to characterize the study designs but included a number of "problem" studies with low treatment quality. Another recent meta-analysis[52] found limited evidence for an effect of acupuncture in chronic pain as compared with no treatment, at least if six or more treatments were given. However, a more stringent meta-analytic review of nine acupuncture studies involving back pain[53] found acupuncture to be superior to control interventions, but not to placebo.

It is important to consider the category (and thereby the mechanism) of the pain condition that is to be treated by acupuncture. It would be as correct to assess the effect of acupuncture on all types of pain as it would be to study the effect of common penicillin on all types of bacterial infections and calculate some form of "average." In a previous study, we found that neuropathic pain responds less well than nociceptive pain to acupuncture,[21] and that psychogenic (nonorganic) pain does not respond at all. In

a British study, postherpetic neuralgia likewise was not found to respond to acupuncture.[44] This finding is in agreement with the recent failure of acupuncture to relieve neuropathic pain related to acquired immune deficiency syndrome.[48] The interpretation of the latter finding is also hampered because needle acupuncture in "control points" was used for comparison (supra).[29,30] Thus, acupuncture does not seem to be a suitable treatment modality for neuropathic pain. However, the clinical use of acupuncture is sometimes indicated for the treatment of chronic nociceptive pain. Our study is the first to show that acupuncture may have a long-term effect on chronic low back pain superior to that of placebo. In the present patients, it is likely that the majority of low back is of nociceptive origin. Therefore, it is vital that before acupuncture is applied, a thorough analysis of the pain condition is performed to preclude the indiscriminate, unnecessary, and costly use of this treatment technique.

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