

Randomised trial of acupuncture compared with conventional massage and “sham” laser acupuncture for treatment of chronic neck pain

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BMJ 2001;322:1574-8



The full version of this paper appears on the BMJ's website

Abstract

Objectives To compare the efficacy of acupuncture and conventional massage for the treatment of chronic neck pain.

Design Prospective, randomised, placebo controlled trial.

Setting Three outpatient departments in Germany.

Participants 177 patients aged 18-85 years with chronic neck pain.

Interventions Patients were randomly allocated to five treatments over three weeks with acupuncture (56), massage (60), or “sham” laser acupuncture (61).

Main outcome measures Primary outcome measure: maximum pain related to motion (visual analogue scale) irrespective of direction of movement one week after treatment. Secondary outcome measures: range of motion (3D ultrasound real time motion analyser), pain related to movement in six directions (visual analogue scale), pressure pain threshold (pressure algometer), changes of spontaneous pain, motion related pain, global complaints (seven point scale), and quality of life (SF-36). Assessments were performed before, during, and one week and three months after treatment. Patients' beliefs in treatment were assessed.

Results One week after five treatments the acupuncture group showed a significantly greater improvement in motion related pain compared with massage (difference 24.22 (95% confidence interval 16.5 to 31.9), $P = 0.005$) but not compared with sham laser (17.28 (10.0 to 24.6), $P = 0.33$). Differences between acupuncture and massage or sham laser were greater in the subgroup who had had pain for longer than five years ($n = 75$) and in patients with myofascial pain syndrome ($n = 129$). The acupuncture group had the best results in most secondary outcome measures. There were no differences in patients' beliefs in treatment.

Conclusion Acupuncture is an effective short term treatment for patients with chronic neck pain, but there is only limited evidence for long term effects after five treatments.

Introduction

Neck pain is a common complaint with a point prevalence from 10% to 18% and lifetime prevalence from 30% to 50%. In many cases symptoms persist, causing severe discomfort and inability to work.^{1,2} Common treatment consists of drugs, massage and other physiotherapy, local and epidural injections, and patient education.^{3,4} Systematic reviews have shown that the efficacy of these interventions remains questionable.^{4,5} Current treatment increasingly

includes complementary methods, of which acupuncture is one of the most common.⁶ There is, however, a lack of evidence to support acupuncture as an effective treatment for chronic neck pain.⁷⁻⁹

We compared the efficacy of acupuncture with conventional massage and “sham” laser acupuncture for the treatment of neck pain.

Methods

Study design

The study was a randomised, placebo and alternative treatment controlled clinical trial performed at three outpatient departments at the universities in Munich and Würzburg, Germany, from 1996 to 1999.

Participants

Patients who were eligible and willing to participate in the study were assessed by an independent examiner. The main inclusion criteria were painful restriction of cervical spine mobility for longer than one month and no treatment in the two weeks before the patient entered the study. Patients who had undergone surgery or those with dislocation, fracture, neurological deficits, systemic disorders, or contraindications to treatment were excluded.

Neck pain was classified according to history, characteristics of pain, manual examination, and radiological findings.¹⁰ Myofascial pain was defined as pain and limited mobility associated with myofascial trigger-points.¹¹ Informed consent was obtained, and the study was approved by the local ethics committees.

Participants were randomly allocated to acupuncture or massage or sham laser acupuncture.

Treatment protocols

Patients were treated five times over three weeks. Each treatment lasted 30 minutes. Acupuncture and sham laser acupuncture were performed by four experienced, licensed medical acupuncturists. Massages were performed by five experienced physiotherapists. Patients took no concomitant analgesics.

Acupuncture—Acupuncture was performed according to the rules of traditional Chinese medicine, including diagnostic palpation to identify sensitive spots.^{12,13} In addition ear acupuncture and the technique of dry needling of local myofascial trigger points was performed.^{11,13,14}

Massage—Patients were treated with conventional Western massage. Techniques included effleurage, petrissage, friction, tapotement, and vibration.¹⁵ Spinal manipulation and non-conventional techniques were not performed.

Placebo—Sham laser acupuncture was performed with a laser pen, which was inactivated by the manufacturer (Laser Pen, Seirin International, Fort Lauderdale,

dale). Only red light was emitted. To strengthen the power of this sham procedure, visual and acoustic signals common for this type of laser pen accompanied the red light emission. Criteria for selection of points were identical with those used in the acupuncture group, including palpation of acupuncture points for diagnostic reasons. Every point was treated for 2 minutes, with the pen at a distance of 0.5-1 cm from the skin.

Assessments

Assessments were performed by a blinded observer before the intervention, immediately after and three days after the first treatment, and immediately and one week after the last treatment. Follow up included an assessment at three months. Patients were requested not to reveal any information about their treatment during assessment. To evaluate the adequacy of control treatments we assessed patients' beliefs about the treatment.¹⁶

Outcome measures

Primary outcome measure—The primary outcome measure was the change in maximum pain related to motion, irrespective of the direction of movement, evaluated before and one week after intervention. Patients were asked to move their head in the most affected direction and to score the intensity of pain on a 100 point visual analogue scale.

Secondary outcome measures—We measured the active range of motion with a 3D ultrasound real time motion analyser (Zebris Medizintechnik, Tübingen, Germany). It is a valid and reliable method to assess cervical mobility.¹⁷ We measured the range of six cervical spine movements. In addition, patients used a visual analogue scale to score the intensity of direction related pain for each of the six directions. We quantified the pressure pain threshold bilaterally at three anatomically defined sites and the individual maximum point using a digital pressure algometer.¹⁸ We recorded changes of spontaneous pain, motion related pain, and global complaints on a seven point scale one week and three months after treatment. To assess quality of life the patients completed the SF-36 health survey.¹⁹

Statistical analyses

Our intention was to analyse 52 patients per group, which, given a standard deviation of 18, would have provided 80% power at the 5% significance level to detect a 10 point difference in the mean change of motion related pain.

Statistical analyses of all study variables were based on intention to treat analysis. For analyses of range of motion and direction related pain we calculated mean values on the basis of the data for six movement directions (score). We used parametric variance to test quantitative variables for comparisons of mean differences, which were approximately normally distributed, followed by pairwise comparisons. For the main outcome measure and quantitative parameters we adjusted for multiple comparisons to keep the significance level to 0.05. We tested hypotheses on qualitative data with χ^2 tests or Fisher's exact test.

Results

Randomisation and progress through the trial

Of 182 patients referred for the first assessment, five did not meet entry criteria; 177 patients were included in the trial (figure). Baseline characteristics of the study sample were equally balanced between groups for most variables, but there was some difference with regard to myofascial pain (table 1). In all three groups most patients believed in the potential benefit of the treatments.

Main outcome measure

The reduction in pain related to motion one week after intervention was significantly greater in the acupuncture group compared with the massage group but not compared with sham laser (table 2). Differences between acupuncture and massage or sham laser were more distinct in the subgroup who had had pain for longer than five years and in patients with the myofascial pain syndrome.

Pain related to motion improved by more than 50% compared with baseline in 29/51 (57%) patients who received acupuncture compared with 18/57 (32%) patients who received sham laser and 14/57 (25%) patients who received massage (χ^2 test $P=0.008$).

Secondary outcome measures

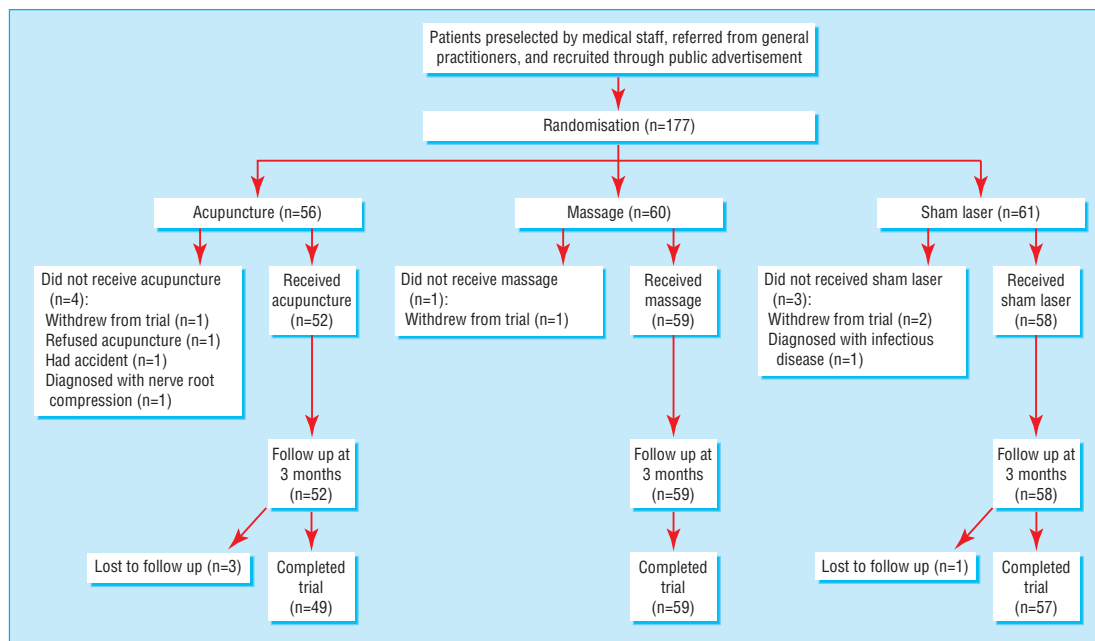
The acupuncture group achieved the best results in most of the secondary outcome measures, including significant differences compared with massage in pain related to motion and direction immediately and one week after treatment. Three months after treatment these differences were comparatively small and no longer significant.

Baseline evaluation of quality of life related to health showed limitations in only two of eight scales (role physical, pain index). After treatment these two scales were improved in all groups, without significant differences between groups.

Table 1 Characteristics of 177 patients with chronic neck pain included in trial

	Acupuncture (n=56)	Massage (n=60)	Sham laser (n=61)
Mean (SD) age (years)	52.3 (13.3)	52.7 (11.5)	52.2 (13.2)
Women	39	38	40
Whiplash	17	16	23
Myofascial pain syndrome	35	45	49
Duration of pain >5 years	23	24	28
Slow onset	36	47	45
Concomitant symptoms*:			
None	9	13	10
1-3	26	24	23
>3	20	22	26
History of treatment:			
Massage	45	44	47
Fango (warm pack)	44	44	35
Physiotherapy	40	40	39
Chiropractic	25	32	30
Infiltration with local anaesthetics	18	25	23
Relaxation methods	18	23	19
Acupuncture	14	23	21
Psychological pain therapy	5	5	6

*Headache, low back pain, vertigo, tinnitus, fatigue, sensitivity to noise and light, lack of motivation, nausea, unspecific visual disorders.



Participants' progress through trial and withdrawals

Table 2 Primary outcome measure: improvement of pain related to motion one week after treatment compared with baseline measurements. Group comparison and subgroup analyses

	Mean improvement on VAS (95% CI)	P value for comparison*
All participants		
Acupuncture (n=51)	24.22 (16.5 to 31.9)	—
Massage (n=57)	7.89 (0.6 to 15.2)	—
Sham acupuncture (n=57)	17.28 (10.0 to 24.6)	—
Acupuncture v massage	16.32 (4.4 to 28.3)	0.0052
Acupuncture v sham laser	6.93 (-5.0 to 18.9)	0.327
Patients with the myofascial pain syndrome		
Acupuncture (n=34)	30.05 (20.4 to 39.7)	—
Massage (n=43)	7.23 (-1.3 to 15.8)	—
Sham acupuncture (n=45)	19.02 (10.8 to 28.2)	—
Acupuncture v massage	22.8 (8.3 to 37.3)	0.0012
Acupuncture v sham laser	11.0 (-3.2 to 25.2)	0.1480
Patients with pain >5 years		
Acupuncture (n=23)	31.87 (21.9 to 41.8)	—
Massage (n=23)	13.52 (3.6 to 23.5)	—
Sham acupuncture (n=27)	17.15 (7.9 to 26.3)	—
Acupuncture v massage	18.35 (2.4 to 34.3)	0.0216
Acupuncture v sham laser	14.7 (0.6 to 30.6)	0.0617

VAS=visual analogue scale. *Dunnett's test.

Side effects

Seventeen (33%) participants reported mild reactions after needle insertion during acupuncture, mainly slight pain or vegetative reactions (sweating, low blood pressure). After a short rest they agreed to continue the treatment. Similar mild reactions were seen in four (7%) in the massage group and 12 (21%) in the sham laser group. No serious adverse reactions were observed.

Discussion

This randomised, placebo controlled trial showed that acupuncture is a safe and effective form of treatment for people with chronic neck pain. Effects on pain and mobility were better than those achieved with conventional massage. Our study population generally had

“non-specific neck pain,” which includes most patients suffering from chronic neck pain.^{20 21} Between 55% and 90% of patients with chronic neck pain have the myofascial pain syndrome^{11 22} and 20% to 50% have suffered a whiplash injury.²³ There were no significant differences between groups in the primary outcome measure and most of the secondary outcome measures three months after treatment. This is consistent with the results of recent systematic reviews that show that a single treatment approach in chronic pain does not result in long term effects.^{4 5} However, results of the qualitative verbal rating scales, which express a more subjective change of pain and global complaints, might indicate longer lasting benefits of acupuncture. Conventional massage had only a weak effect on chronic neck pain. This is in agreement with recent reviews indicating a lack of evidence for the efficacy of massage, although it is one of the most common forms of treatment.^{2 15}

Previous trials of acupuncture for neck pain have had contradictory results. In a systematic review of 14 acupuncture trials, White and Ernst found no evidence for efficacy, with outcomes equally balanced between positive and negative.⁷ The authors judged methodological quality of the studies as disappointing. In a more recent review, Smith et al assessed the analgesic efficacy of acupuncture for neck and back pain. Using a newly developed tool to measure validity of findings of randomised clinical trials, they found no convincing evidence for the analgesic efficacy of acupuncture, and, again, the quality of most trials was poor.⁹ In contrast with previous studies our trial had a large sample size, adequate measures evaluated by blinded observers, blinded patients for placebo control, individual acupuncture treatment by more than one licensed acupuncturist, data analyses by an independent institution, follow up assessments, and documentation of drop outs and adverse events.

We chose sham laser acupuncture because it does not activate somatosensory receptors, and laser

What is already known on this topic

Acupuncture is a widespread complementary treatment

Evidence from trials have given conflicting results on its use in the treatment of neck pain because of methodological shortcomings and because effects were compared either with alternative treatments or with different sham procedures imitating acupuncture, but not both

What this study adds

Compared with sham laser acupuncture and massage, needle acupuncture has beneficial effects on mobility and pain related to motion in patients with chronic neck pain

Acupuncture was clearly more effective than massage, but differences were not always significant compared with sham laser acupuncture

Acupuncture was the best treatment for patients with the myofascial syndrome and those who had had pain for longer than five years

acupuncture is a well known method. We were surprised by the results of sham laser acupuncture compared with massage. They could be explained by an enhanced placebo effect, but the assessment of credibility showed no differences between therapies before treatment. Sham laser acupuncture, however, does not really resemble needle acupuncture. Consequently, non-specific acupuncture effects can only be estimated. Also, sham laser was probably not an inert control because participants might have benefited from palpation of acupuncture points, performed before treatment to select acupuncture points.

Participants received only five treatments because we did not want to treat patients with chronic pain with placebo for longer for ethical reasons. According to traditional Chinese medicine about 10 sessions would be more appropriate.¹² Future research is necessary to evaluate the optimum number of treatments.

Conclusion

We conclude that acupuncture can be a safe form of treatment for patients with chronic neck pain if the objective is to obtain relief from pain related to motion and to improve cervical mobility. As neck pain may be a chronic condition with considerable socioeconomic impact single forms of treatment may be inadequate, and acupuncture merits consideration.

We thank K Gleditsch, Dr R Pfeiffer, Dr M Haase, H Arndt, C Müller, D Drexler, and P Köllges for their work in data collection, and all participating colleagues and physiotherapists in the department of physical medicine and rehabilitation, University of Munich, the pain unit, University of Munich, and the department of orthopaedics, University of Würzburg. We also thank the patients who made the project possible.

Contributors: DI coordinated the study, wrote the case report form, analysed the data, and wrote the paper. NB had the original idea, prepared the grant application, and coordinated the study in the first phase until 1997. HM contributed to the coordination and running of the study in Würzburg. AK coordinated the study in Würzburg and contributed to the data analysis and writing of the paper. MN contributed to the original idea

and the grant application and coordinated the study in Würzburg. MK had the main responsibility for the data analyses and contributed to writing the paper. JG, AB, ES, and PS supported and contributed to the planning of the project, the grant application, the study running, and the publication. DI and MK are guarantors for the study.

Funding: German Ministry for Education and Research (BMBF, formerly BMFT) (Project 01 KT 9406/1). Preparation of the manuscript was supported by the German Medical Acupuncture Association (DÄGfA).

Competing interests: None declared.

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Endpiece

The most difficult of arts, reigning

How often is it the interest of four or five ministers to combine together to deceive their sovereign. Secluded from mankind by his exalted dignity, the truth is concealed from his knowledge; he can see only with their eyes, he hears nothing but their misrepresentations. He confers the most important offices upon vice and weakness, and disgraces the most virtuous and deserving among his subjects. By such infamous arts the best and wisest princes are sold to the venal corruption of their courtiers.

Emperor Diocletian

Commentary: Controls for acupuncture—can we finally see the light?

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Irnich et al are to be congratulated for performing this rigorous trial. Funding is not easy to obtain for trials of acupuncture, so a sample size of 177 is considered large in this specialty. The result is hard to interpret. Advocates of acupuncture will call it a “positive” result. Opponents will argue that acupuncture is no better than placebo and that a similar trial on low back pain gave the opposite result.¹ We are left to speculate on whether acupuncture has specific efficacy in neck pain. A response rate of 57% would certainly be typical of an effective treatment in acute and chronic pain,² but even if this trial had shown a significant effect of acupuncture over sham laser acupuncture, we would still be unsure of the size of the non-specific component related to the needle.

Sham laser acupuncture was a good choice of control when this trial was designed. It can be considered inert, and it controls for the concept of having “acupuncture” in the mind of a participant who recognises it as a valid form of treatment. We cannot be sure, however, that this would equate to controlling for the concept of needle insertion. In the past, researchers have focused on the concept of acupuncture points, and, ironically, controls were often chosen simply by missing the real point—that is, inserting needles at sites not classically described as acupuncture points. The pressure stimulus applied to the nervous system from a solid needle, however, in the absence of direct impingement on a nerve bundle, is likely to be comparable at any soft tissue site within the same region, so the stimulus applied in such trials was virtually identical in the real and control groups. The response rate seen with such controls often reaches 50%. Reviews that fail to take this into account, by assuming that penetrating sham controls represent inert placebos, are open to criticism.³

Within the past three years the “placebo” needle has been developed. Such a device aims for credible simulation of needle penetration with minimal sensory stimulus. Rather like a stage dagger, the shaft of the placebo needle disappears into its own handle as the blunted tip presses on to the skin at the site of simulated insertion. The remaining challenge is in supporting the needle if it is to be left in place for any length of time. The first randomised controlled trial to use such a device yielded positive results for acupuncture in the treatment of supraspinatus tendonitis.⁴ Further trials with a similar type of needle are underway at the department of complementary medicine in Exeter University.

In the light of these methodological developments, the suggestion from Irnich et al that acupuncture is likely to be more effective in the myofascial pain syndrome, and the considerable empirical support for this suggestion, we can be confident that future studies of sufficient size will determine whether or not the acupuncture needle has efficacy beyond placebo. Musculoskeletal pain has such an important impact on the community⁵ that we must find funding for large scale, methodologically sound trials of this simple, relatively safe, and potentially efficacious technique.

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Specialist registrars' plans for working part time as consultants in medical specialties: questionnaire study

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BMJ 2001;322:1578-9

Almost 40% of all specialist registrars who hold national training numbers in medical specialties are women.¹ Little is known about their career intentions, and specifically on how they plan to cope with the competing pressures of family and career when they become consultants. Questions on this issue were therefore included in a recent national survey of specialist registrars.

Participants, methods, and results

The Royal College of Physicians sent a questionnaire in December 1999 to all 2495 trainees in England,

Wales, and Northern Ireland holding national training numbers in medical specialties. Replies were received from 1362 (55%), of whom 1311 answered the question, would you like a part time (eight sessions or less) post when you become a consultant? They had five options: “yes—definitely,” “yes—probably,” “yes—possibly,” “no—probably not,” and “no—definitely not.” The number and percentage of women (n=541) giving each response were 83 (15%), 105 (19%), 186 (34%), 120 (22%), and 47 (9%), and those of men (n=770) were 19 (2%), 34 (4%), 117 (15%), 265 (34%), and 335 (44%). A total of 1309 answered the question about whether they would consider a “job share”