A randomized comparative trial of acupuncture versus transcutaneous electrical nerve stimulation for chronic back pain in the elderly

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Abstract

Sixty patients aged 60 or over with back pain for at least 6 months were recruited from General Practitioner referrals and randomized to 4 weeks of treatment with acupuncture or transcutaneous electrical nerve stimulation (TENS). All treatments were administered by the same physiotherapist and both groups had the same contact with him. The following were measured at baseline, completion and at a 3-month follow-up by an independent observer blinded to treatment received: (1) pain severity on visual analogue scale (VAS); (2) pain subscale of Nottingham Health Profile (NHP); (3) number of analgesic tablets consumed in previous week; (4) spinal flexion from C7 to S1. Thirty-two patients were randomized to acupuncture and 28 to TENS; only three withdrew (two from acupuncture, one from TENS). Significant improvements were shown on VAS ($P < 0.001$), NHP ($P < 0.001$) and tablet count ($P < 0.05$) between baseline and completion in both groups, these improvements remaining significant comparing baseline with follow-up with a further non-significant improvement in VAS and NHP in the acupuncture group. The acupuncture but not the TENS patients showed a small but statistically significant improvement ($P < 0.05$) in mean spinal flexion between baseline and completion which was not maintained at follow-up. Thus in these elderly patients with chronic back pain both acupuncture and TENS had demonstrable benefits which outlasted the treatment period. Acupuncture may improve spinal flexion. This trial cannot exclude the possibility that both treatments are ‘placebos’. © 1999 International Association for the Study of Pain. Published by Elsevier Science B.V.

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1. Introduction

Back pain is common, and a cause of much suffering, disability and consumption of resources. In younger adults, most back pain arises from physical stresses on normal spinal structures (Frank, 1993), whereas in the elderly, osteoarthrosis of the intervertebral joints and/or osteoporosis with collapse of the vertebral bodies is almost invariably present. Analgesia in the elderly is frequently unsatisfactory, and the incidence of adverse drug reactions, particularly to non-steroidal anti-inflammatory drugs, is well known (Cunningham et al., 1997). For this reason, many patients are requesting physical therapies such as acupuncture, and doctors and physiotherapists who use it have found empirically that some patients derive lasting pain relief. However, despite increasing clinical experience of the therapeutic potential of acupuncture and advances in the understanding of its effects at the neurophysiological level, it remains a controversial treatment.

Double-blind placebo-controlled trials of acupuncture are extremely difficult to perform, the main reason being selection of an effective placebo. One approach is to use ‘sham’ acupuncture, in which needles are inserted at sites distant from conventional acupoints; they are inserted very superficially and not manipulated. However, because of the phenomenon of Diffuse Noxious Inhibitory Control (Le Bars et al., 1979), sham acupuncture may have some analgesic activity itself, thus greatly increasing the sample size necessary to detect a genuine effect. In addition, achieving credibility for the patient is difficult. For these reasons and others, a recent review (Ter Riet et al., 1990) concluded...
that most studies of acupuncture to date were scientifically flawed and that the benefit of acupuncture in chronic pain remained unproven.

A different approach is to compare acupuncture with an existing, accepted treatment. Of all the non-pharmacological means of pain relief available, transcutaneous electrical nerve stimulation (TENS) is one of the most widely accepted. Whilst it can be argued that, like acupuncture, it has not been subjected to the most rigorous scientific evaluation, it is available in most pain clinics and is not regarded as ‘alternative’ medicine.

Our main aims in this study were to answer the following two questions: is acupuncture an effective treatment for chronic back pain in the elderly, when compared to an existing widely-used non-pharmacological treatment, namely TENS? If so, are the benefits maintained 3 months after the conclusion of treatment?

2. Methods

The study was approved by the Lothian Research Ethics Committee.

2.1. Subjects

Patients aged 60 or over with a complaint of back pain of at least 6 months duration were recruited by inviting General Practitioners to refer suitable patients. Patients were excluded for the following reasons: treatment with anticoagulants; treatment with systemic corticosteroids; dementia; previous treatment with acupuncture or TENS; cardiac pacemaker; other severe concomitant disease; inability of patient or carer to apply TENS machine. All patients had a plain X-ray of the spine if one had not been performed in the previous year.

2.2. Randomization

Patients were randomly allocated to 4 weeks treatment with acupuncture or TENS: random numbers were used to generate a sequence of sealed envelopes containing the treatment code, the next available envelope being opened on the patient’s entry into the trial.

2.3. Interventions

Patients in the acupuncture group were treated with two sessions of manual acupuncture weekly for 4 weeks, i.e. eight sessions in total. The needles were of a standard size (32 gauge, 1.5 inch length with guide tube). Points were chosen for the individual patient as in routine clinical practice, using only points on the back. Six needles were used on average at each treatment with a minimum of two and a maximum of eight. Treatment sessions lasted for 20 min.

Patients in the TENS group were treated using a standard make and model of machine (TPN 200, Physio-Med-Services), using 50 Hz stimulation with the intensity adjusted to suit the patient, again as in routine clinical practice. The patient was given her/his own machine to use at home, and instructed to use it during the day as required for up to 30 min per session to a maximum of 6 h per day. She/he was also seen for 20 min twice weekly by the physiotherapist, ensuring the same contact with him. At each visit, symptoms were reviewed, treatment discussed and the optimum use of the TENS machine ensured.

All treatments (acupuncture and TENS) were administered by the same physiotherapist. The patients were advised to continue existing medication but not to commence any new analgesics or any additional physical treatments for the duration of the trial. The patients were treated in one of two hospital out-patient clinics or in the patient’s home, at the patient’s preference, with the treatment site being the same throughout the trial.

2.4. Outcome measures

Four outcome measures were recorded: (1) visual analogue scale (VAS); (2) pain subscale of the 38-item Nottingham Health Profile Part 1 (NHP); (3) number of analgesic tablets consumed in the previous week; (4) spinal flexion measured from C7 to S1. For the VAS, the patient was asked to mark his/her average pain level over the previous week on a standard ungraduated line, marked at one end ‘no pain at all’ and at the other end ‘the worst pain possible’. A 200 mm line was used for the benefit of subjects with poor visual acuity. The NHP is a well-validated questionnaire for measuring quality of life (Hunt et al., 1985). Number of analgesic tablets consumed in the previous week was assessed by subjective report. Spinal flexion was measured by noting the surface markings of C7 and S1 and measuring the distance between these landmarks with a tape measure with the patient in the erect standing posture and again in full flexion.

These were recorded three times: at baseline prior to the first treatment; 4 days after the final treatment; and at a follow-up visit 3 months after the conclusion of treatment. Measurements were made by an independent observer, blind to treatment received.

2.5. Statistics

Sample size calculation was difficult, but by the method of Lewith and Machin (1983), if 75% of patients responded to acupuncture and 40% to TENS then a sample size of 30 in each group would give the trial a power of 80% to detect statistical significance at a probability level of $P = 0.05$.

For VAS score, tablets and NHP score, non-parametric tests were used for analysis: Wilcoxon signed ranks tests for within-group differences and Mann–Whitney $U$-tests for between-group differences. For spinal flexion, the equiva-
lent parametric tests were used: paired $t$-tests for within-group comparisons and unpaired $t$-tests for between-group comparisons. All tests two-tailed.

3. Results

Eighty-one patients were assessed for the trial, of whom 21 were excluded, leaving 60 who were entered into the trial. Thirty-two patients were randomized into the acupuncture group and 28 into the TENS group. The number of withdrawals was small: two in the acupuncture group and one in the TENS group. Thus 30 patients in the acupuncture group and 27 in the TENS group completed treatment and were available for evaluation. Of these, all except one in the TENS group attended the 3-month review. The age range of the two groups was similar: mean age 75 years (range 60–90) for acupuncture and 72 years (range 60–83) for TENS. Female/male ratio was also similar in the two groups: 30/2 for acupuncture and 24/4 for TENS. Treatment site (home/hospital) was not significantly different between the two groups: 20/12 for acupuncture and 13/15 for TENS.

Reasons for withdrawal were acute depression in one TENS patient; influenza in one acupuncture patient and immobility following dental treatment in a second which required hospitalization. Other than these, reported side effects were minimal: three acupuncture patients reported dizziness and three TENS patients developed skin reactions.

Results are shown in Figs. 1–4. The two groups appear different at baseline, with patients in the acupuncture group having higher VAS and NHP pain scores, reduced spinal flexion and lower tablet consumption compared to the TENS group. These differences are of borderline statistical significance: $P = 0.064$ for NHP, $P = 0.089$ for VAS, $P = 0.10$ for tablets and $P = 0.16$ for flexion, but they are felt to make intergroup comparisons post-treatment difficult as even a small imbalance between initial values may affect the pain relief obtained by different treatments (Huskisson, 1974).

Concerning intragroup comparisons, there is a highly significant reduction in average VAS score of approximately 50% between baseline and completion in both groups ($P < 0.001$). Results for the NHP scores are similar. At follow-up, these improvements are maintained ($P < 0.0001$ for acupuncture and $P < 0.01$ for TENS, baseline vs. follow-up) and there is a trend towards further improvement in the acupuncture group which does not reach statistical significance ($P = 0.10$ for VAS and $P = 0.086$ for NHP, completion vs. follow-up).

Regarding tablet consumption there are highly significant reductions of approximately 50% in the acupuncture group and 33% in the TENS group between baseline and completion ($P < 0.05$). These improvements are maintained comparing baseline and follow-up ($P < 0.01$). This is admittedly a crude measure because the tablets were not physically counted by the observer and analgesic strength is not considered (though the individual patients did not change their tablets for the duration of the trial). Spinal flexion is very limited in both groups. In the acupuncture group there is a 10% improvement between baseline (4.93 cm ± 0.38) and completion (5.41 cm ± 0.39) which is sta-
tistically significant ($P < 0.05$). It is not maintained at follow-up. There is no significant improvement in spinal flexion in the TENS group.

4. Discussion

Acupuncture and TENS are thought to work by different neurophysiological mechanisms, both consistent with the Gate Theory of pain. TENS analgesia is mediated by large diameter afferent fibres (type 1 muscle afferents and A beta skin afferents) releasing GABA to cause presynaptic inhibition of adjacent pain fibres, whilst acupuncture analgesia is mediated by small diameter muscle afferent fibres (types 11 and 111) releasing endorphins which have segmental, distant and systemic effects (Stux and Pomeranz, 1990). Our clinical experience suggests that the benefits of acupuncture accumulate with successive treatments whilst the effects of TENS tend to lessen with time as tolerance develops, and tend to be dissipated once the treatment is terminated.

In this group of elderly patients with chronic back pain, a 4-week course of either acupuncture or TENS had demonstrable benefits on subjective measures of pain (VAS and NHP score) and allowed them to reduce their consumption of analgesic tablets. The benefits of both treatments remained significant 3 months after completion, with a trend towards further improvement in the acupuncture patients. However, whilst it was our intention in the trial to compare 1 month’s acupuncture with 1 month’s TENS, both treatments being conducted broadly in a manner that mimics routine clinical practice, at least five patients in the TENS group who had benefited from the treatment had purchased their own machine and used it between the end of the treatment period and the follow-up visit. This would have happened in routine clinical practice and it would have been unethical to prevent it. Thus the apparent long-term benefit of TENS in this trial may be due, at least in part, to patients having ongoing use of the apparatus.

In the acupuncture group there was a small, statistically significant improvement in spinal flexion, which is an objective measurement. This is of doubtful clinical benefit however and was not maintained at follow-up.

The trial does not contain a ‘placebo’ group and therefore the data presented cannot refute the hypothesis that all the benefits from both treatments are due to non-specific effects of participation in the trial, contact with the physiotherapist, or patient expectation. However, if this were the explanation, one might have expected the benefits to be lost by the follow-up visit. Further, the reductions in pain assessments of over 50% seen in this trial are greater than those usually ascribed to placebo (Richardson and Vincent, 1986).

Whilst a formal economic analysis was outside the scope of this trial, both acupuncture and TENS are inexpensive treatments, with potential savings in analgesic drug costs. Of the two treatments, acupuncture is more demanding of therapists’ time whilst TENS is more expensive in materials. Both acupuncture and TENS were demonstrably safe.

We are aware of only two previous studies in which acupuncture has been compared with TENS in the treatment of back pain (Fox and Melzack, 1976; Lehmann et al., 1986). Both were small studies in younger patients (six per group and 18 per group, respectively); there are no previous randomized trials of acupuncture in the elderly. A potential problem with any research in elderly subjects is their greater physiological variability. Results obtained from trials in the fit, well-preserved elderly cannot automatically be extrapolated to the ‘frail’ elderly with multiple pathology who attend Care of the Elderly departments. However, some of the participants of this trial were clearly frail, so it is likely that our results are relevant to practising Elderly Care clinicians. The participants in this trial all had spine radiographs. Although taken primarily to exclude malignant disease, all showed some evidence of degenerative disease or osteoporosis, in common with patients attending day hospitals and receiving in-patient treatment.

This trial has a number of limitations. Firstly, the differences between the baseline scores in the two patient groups made between-group comparisons after treatment difficult. Secondly, even if this had not been the case, we recognize that our patient numbers may have been insufficient to detect a difference between the two groups. Thirdly, longer-term follow-up of patients undergoing these treatments would be desirable. Fourthly, we have already discussed the contamination of the follow-up data in the TENS group.

Notwithstanding these limitations, we feel that the results of this trial demonstrate that both acupuncture and TENS are effective treatments for chronic back pain in the elderly, and provide some grounds for therapeutic optimism in both patients and staff. We would support the more widespread training of physiotherapists in acupuncture techniques. As with all physical treatments, there are wide individual variations in response to acupuncture and TENS. Since this trial shows no clear advantage of one treatment over the other, choice in the individual patient should be based on...
resource considerations, patient preferences or a therapeutic trial in the individual patients.

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References


