Primary care

Acupuncture as a complementary therapy to the pharmacological treatment of osteoarthritis of the knee: randomised controlled trial

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Abstract

Objectives To analyse the efficacy of acupuncture as a complementary therapy to the pharmacological treatment of osteoarthritis of the knee, with respect to pain relief, reduction of stiffness, and increased physical function during treatment; modifications in the consumption of diclofenac during treatment; and changes in the patient’s quality of life.

Design Randomised, controlled, single blind trial, with blinded evaluation and statistical analysis of results.

Setting Pain management unit in a public primary care centre in southern Spain, over a period of two years.

Participants 97 outpatients presenting with osteoarthritis of the knee.

Interventions Patients were randomly separated into two groups, one receiving acupuncture plus diclofenac (n = 48) and the other placebo acupuncture plus diclofenac (n = 49).

Main outcome measures The clinical variables examined included intensity of pain as measured by a visual analogue scale; pain, stiffness, and physical function subscales of the Western Ontario and McMaster Universities (WOMAC) osteoarthritis index; dosage of diclofenac taken during treatment; and the profile of quality of life in the chronically ill (PQLC) instrument, evaluated before and after the treatment programme.

Results 88 patients completed the trial. In the intention to treat analysis, the WOMAC index presented a greater reduction in the intervention group than in the control group (mean difference 23.9, 95% confidence interval 15.0 to 32.8). The reduction was greater in the subscale of functional activity. The same result was observed in the pain visual analogue scale, with a reduction of 20.6 (18.5 to 34.8). The PQLC results indicate that acupuncture treatment produces significant changes in physical capability (P = 0.021) and psychological functioning (P = 0.046). Three patients reported bruising after the acupuncture sessions.

Conclusions Acupuncture plus diclofenac is more effective than placebo acupuncture plus diclofenac for the symptomatic treatment of osteoarthritis of the knee.

Introduction

Osteoarthritis is the most common form of joint disease, and its most common location is the knee. As the population ages or the disease worsens, osteoarthritis is associated with incapacity and a deteriorating quality of life owing to increased pain, loss of mobility, and the consequent loss of functional independence. As a result, osteoarthritis is often treated by medical or surgical intervention. The general increase in life expectancy means that increasing numbers of people present with osteoarthritis of the knee and have a reduced quality of life. Pain relief treatment is therefore a fundamental aspect in dealing with this illness.

In patients in whom standard medical practice (pharmacological treatment) is ineffective and who are not candidates for surgery (or who reject it), other pain management procedures should be considered. The role of acupuncture in osteoarthritis of the knee is still a matter of controversy, and few comparative studies of acupuncture and non-steroidal anti-inflammatory drugs (NSAIDs) for its treatment have been conducted. A recent systematic review concluded that a moderate degree of evidence exists that the effect of the acupuncture treatment could be due to the placebo, and further studies are therefore necessary to determine the true role of acupuncture.

We analysed the efficacy of acupuncture as a complementary therapy to the pharmacological treatment of osteoarthritis of the knee, with respect to pain relief, reduction of stiffness, and increased physical functioning during treatment; modifications in the consumption of diclofenac during treatment; and changes in patients’ quality of life.

Materials and methods

Study design and subjects

We conducted a randomised, controlled trial with blinded evaluation and statistical analysis of results. It was carried out at the pain management unit in a public primary care centre in southern Spain, over a period of two years. The unit caters for the population of three primary care centres (75 000 inhabitants).

All the doctors at the three health centres in the study area received information about the study and inclusion criteria. We also informed them about the procedure for referring patients to the pain management unit, to be included in the selection process, and requested their collaboration in selecting patients to take part. Such patients were outpatients in whom osteoarthritis of the knee had been clinically and radiologically diagnosed according to the criteria of the American College of Rheumatology. The illness had to be symptomatic at the moment of selection. All patients gave their informed consent before taking part in the study.

The pain management unit applied the following criteria for inclusion in the study: patients had to be aged 45 years or older, with pain in one or both knees for the preceding three months or longer, and with radiological evidence of osteoarthritis of the knee (at least grade 1 according to the Kellgren-Lawrence classification, table 1). They had to be outpatients and willing and able to com-
The standard acupuncture intervention entailed the insertion of sterile, single use, 30 gauge, and 45 mm length acupuncture needles into the local points GB34, SP9, EX-LE5, and ST36 (fig 1). The distal points were KI3, SP6, LI4, ST40. For each of the points in question the acupuncturist determined the patient’s sensation of Deqi (an elicitation of needle sensation to check that the puncture was performed in the correct site). A WQ-10D1 electrostimulator was used to stimulate all the needles inserted into the local points electrically, in pairs. The treatment lasted 12 weeks, starting with visit 0 and ending with visit 11. The doctor carried out the final evaluation at visit 12, one week after the treatment had ended.

The same specialist carried out the placebo acupuncture, at the same frequency and for the same duration as for the group receiving the true intervention. Retractable needles went into small adhesive cylinders, such that the needle was supported but did not perforate the skin. The acupuncturist then placed the needles over the same points as were used for the true acupuncture group. He connected the same pairs of electrodes and simulated the electrical connection.

**Variables**

Our general variables were patients’ sociodemographic data and severity of illness (measured in duration of the osteoarthritis process in months, Ahlbäck score, body mass index).

**Efficacy end points**

We used as the primary efficacy end point the WOMAC index and its three subscales (pain (0-20), stiffness (0-8), and physical function (0-68)), pain in the knee on a visual analogue scale from 0 to 100, the dosage of diclofenac accumulated, and the profile of quality of life in the chronically ill (PQLI.C) instrument.

**Statistical analysis**

We used a freeware program to calculate the sample size for a mean total WOMAC score of 20 (SD 10) for the intervention group and of 33 (SD 28) for the control group, with bilateral contrast, a significance level of 0.05, and a power of 0.80. The minimum sampling size was 69. Assuming a maximum dropout rate of 20% we increased the minimum sample size to 83 patients. We selected 97 patients (fig 2).

We performed a baseline analysis of the two groups to seek clinically relevant differences, considering sociodemographics, severity of illness, and result. For the dropout analysis we used the Mann-Whitney U test for independent samples, together with Fisher’s exact statistic (table 2).

We used SPSS, version 11.5, to analyse the results by intention to treat, on the basis of the improvement in the total

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**Table 1** Radiological classification of arthritis of the knee, according to Ahlbäck

<table>
<thead>
<tr>
<th>Grade</th>
<th>Anteroposterior stress radiograph</th>
<th>Lateral radiograph</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Reduction of joint space</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Obliterartion of joint space</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Tibial plateau attrition &lt;5 mm</td>
<td>Posterior part of plateau intact</td>
</tr>
<tr>
<td>4</td>
<td>Attrition 5-10 mm</td>
<td>Attrition extends to posterior margin of the plateau</td>
</tr>
<tr>
<td>5</td>
<td>Severe subluxation of the tibia</td>
<td>Anterior subluxation of the tibia &gt;10 mm</td>
</tr>
</tbody>
</table>

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**Fig 1** Location of selected acupuncture points
WOMAC score, on the pain visual analogue scale, and the PQLC score, using Student’s t test for independent samples. We set P < 0.05 as the significance level for all the tests. For patients who withdrew, the score we used for each variable was the worst of the scores obtained for the intervention group and the best obtained for the control group. When a diagnosis of bilateral osteoarthritis of the knee had been made, the knee with the worse results at baseline was the knee we evaluated in the final analysis.

Results

Recruitment took place between January 2001 and December 2002. We selected 97 patients to participate in the study, all of whom agreed to take part. Table 2 lists the baseline characteristics of the patients; we found no clinically relevant differences in the variables that we analysed (total WOMAC, pain visual analogue scale, PQLC) at baseline. Of the nine patients who dropped out of the study, one out of 48 (2.1%) was in the treatment group and the other seven were in the control group (six left due to lack of improvement and two for personal reasons; fig 2). The only significant difference between completers and non-completers was their age (they were six years older than non-completers; P = 0.03). Adverse effects after acupuncture were limited to three patients who reported bruising at one of the acupuncture points (SP9).

In the intention to treat analysis, the WOMAC index presented a greater, and significant, reduction in the intervention group than in the control group (mean difference 23.9, 95% confidence interval 15.0 to 32.8; the magnitude of the reduction was greater in the subscale of functional activity (17.5, 11.0 to 24.0). The same result was observed in the pain visual analogue scale (reduction 26.6, 18.5 to 34.8). A reduction of 53.9 was observed in the total accumulated number of diclofenac tablets for the intervention group compared with the control group (24.7 to 63.1). The PQLC results indicate that acupuncture treatment produces significant changes in physical capability and psychological functioning (table 3).

Discussion

Mean results

Acupuncture as a complementary therapy to pharmacological treatment of osteoarthritis of the knee is more effective than pharmacological treatment alone, in terms of reducing pain and rigidity, and improving physical functioning and health related quality of life.

According to the criterion that an improvement in quality of life requires changes in at least two of the variables measured by the PQLC, the acupuncture provided to the intervention group was more effective than the placebo treatment in improving patients’ quality of life.

True and placebo acupuncture

We decided to use a technique in the control group that did not require transcutaneous penetration, thus avoiding neurophysiological and neurochemical responses owing to the stimulation of cutaneous receptors; the intervention and control groups received treatments that were apparently identical: real acupuncture plus medication versus placebo acupuncture plus medication. By supplying both groups with medication, we sought to overcome possible ethical objections related to the role of the control group in the study.

Blinding procedure

Although the standard treatment was given for 12 weeks, participants who dropped out of the study were mainly from the control group, and only six people were lost to the study because their condition did not improve. To reinforce the blinding of the groups we expanded the criteria for selection of study patients to include the requirement that they should not have received previous acupuncture treatment; none of the participants lost to the study made any reference to belonging to one or the other of the two groups. Both the evaluation of the results and the statistical analysis were carried out in a blind fashion. These factors reinforce our belief that the blinding procedure applied was successful.

Limitations of the study

Observation of the sample groups over a period of 12 weeks may be insufficient to evaluate the effects of treatment in the medium term. Moreover, we did not test the patients’ awareness of belonging to one or the other group, and so their complete “blindness” cannot be assured. Another possible limitation was the absence of techniques to verify the behaviour of the therapist, although the time spent with each patient was recorded; this was always close to the mean value (29.4 minutes).

Taking into account the duration of the study (12 weeks), we recorded patients’ body mass index at the beginning and the end of the study.
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Comparison with other studies and outlook

The studies published to date have methodological deficiencies in the description and application of the method chosen for randomisation, the concealment of the treatment assignment scheme, the homogeneity of the groups to be compared, the control of co-interventions, the absence of a placebo was a serious limitation to the validity of the conclusions; a third study incorporated a placebo, but the results were provided by the Sevilla-Sur health district authorities.

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We considered the "total accumulated area, and Spain's index of quality of life (PQLC ) as a valid test for describing secondary effects and the success of the technique in improving the patient's quality of life (PQLC)."

Similar results were found in a small, short term and long term study, carried out by using the waiting list as the control group,35 and in another study that compared acupuncture plus baseline treatment with baseline treatment alone.36 In these studies, the absence of a placebo was a serious limitation to the validity of the conclusions; a third study incorporated a placebo, but in a hospital environment considered to be of low quality,37 whereas treatment was of greater intensity and duration of treatment was shorter.38 Another study compared acupuncture with sham acupuncture and found no statistically significant differences.39

Future research should extend the observation period after treatment in order to evaluate the duration of the improvement obtained and to establish treatment protocols.

We thank M J Cano, J G de Hoyos, E Bassas, and C Andrés for their work in the conduct of the study, and J G de Hoyos for his useful comments on the initial protocol.

Contributors: JV, CM, EP-M, and JML designed the study. EV, MAB, MDP, OG, FS-R, IA, and RJ contributed to conduct of the study and writing of the final version of the manuscript.

Ethical approval: Valme Hospital Ethics Committee, Seville.
What is already known on this topic

Acupuncture is widely used to treat chronic pain in osteoarthritis.

Various clinical trials have indicated that acupuncture may be beneficial in treating the pain that arises from osteoarthritis.

The placebos used in earlier trials, based on stimulation by transcutaneous penetration, achieved an excessively high success rate, possibly owing to the neurophysiological and neurochemical responses caused by stimulation of the cutaneous receptors.

The methodological quality of previous studies, in terms of randomisation, homogeneity of the groups compared, blinding, and other factors, has been put into question.

What this study adds

Acupuncture, as a complementary therapy to pharmacological treatment for osteoarthritis of the knee, is more effective than pharmacological treatment alone.

This manifests itself in terms of pain relief, easing stiffness, and improving physical function.