

The effect of acupuncture on the symptoms of knee osteoarthritis - an open randomised controlled study

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Abstract

Background Using an open randomised controlled study, we examined the effectiveness of manual and electroacupuncture on symptom relief for patients with osteoarthritis of the knee.

Methods Patients with symptomatic osteoarthritis of the knee were randomised to one of three treatment groups. Group A had acupuncture alone, group B had acupuncture but continued on their symptomatic medication, and group C used their symptomatic medication for the first five weeks and then had a course of acupuncture added. Patients receiving acupuncture were treated twice weekly over five weeks. Needles were inserted (with manual and electrical stimulation) in acupuncture points for pain and stiffness, selected according to traditional acupuncture theory for treating Bi syndrome. Patients were assessed by a blinded observer before treatment, after five weeks' treatment and at one month follow up, using a visual analogue pain scale (VAS) and the Western Ontario McMaster (WOMAC) questionnaire for osteoarthritis of the knee.

Results The 30 patients in our study were well matched for age, body mass index, disease duration, baseline VAS pain score and baseline WOMAC scores. Repeated measure analyses gave a highly significant improvement in pain (VAS) after the courses of acupuncture in groups A ($P=0.012$) and B ($P=0.001$); there was no change in group C until after the course of acupuncture, when the improvement was significant ($P=0.001$). Similarly significant changes were seen with the WOMAC pain and stiffness scores. These benefits were maintained during the one month after the course of acupuncture. Patients' rating of global assessment was higher than that of the acupuncturist.

Conclusion We conclude that manual and electroacupuncture causes a significant improvement in the symptoms of osteoarthritis of the knee, either on its own or as an adjunct therapy, with no loss of benefit after one month.

Keywords

Osteoarthritis, acupuncture, knee, controlled trial.

Introduction

Osteoarthritis (OA) is the commonest joint disease, with many patients having persistent disability due to pain and stiffness. Analgesic and anti-inflammatory therapy is limited by side effects and not all patients are adequately controlled with lifestyle changes.^{1,2} Reports of the therapeutic and analgesic effects of acupuncture in OA have stimulated interest in acupuncture as complementary - or even as an alternative - to Western orthodox medicine.³⁻⁷ Many patients suffering from OA of the knee, who have not been helped by one or more Western therapy regimes, find relief from alternative medical approaches,

including acupuncture.⁸⁻¹⁹ A survey in 1996 showed that more than 50% of all cases treated by acupuncturists in the UK had OA.²⁰ It has been suggested that acupuncture, with its good safety record,²¹⁻²³ can be used to manage OA in patients for whom conventional Western treatments are inadequate or contraindicated.^{24,14,15}

Controlled trials on the effectiveness of acupuncture treatment have yielded inconsistent results,^{25,26} which may be due to a variety of technical reasons.^{27,28} A systematic review by Ezzo et al concluded that there is limited evidence that acupuncture is more effective than no treatment for chronic pain and inconclusive evidence that

acupuncture is more effective than placebo, sham acupuncture or standard care.²⁹ A further review from the same group, this time on acupuncture for osteoarthritis of the knee, found that few studies met the criteria for adequacy of acupuncture treatment.³⁰ Berman and colleagues have recently investigated the effectiveness of acupuncture for patients with OA of the knee in a randomised trial.¹⁶ This study found acupuncture to be of benefit as an adjunctive therapy. A review of non-pharmacological therapy for OA has emphasised the need for continued research in this field.³¹

International guidelines for the assessment of therapies for OA have been published and were followed in this study.³² The visual analogue scale (VAS) for pain and the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) are validated methods for monitoring symptom changes in OA.^{33,34} Although other pain assessment methods have been reported, they are not well validated for this joint.³⁵

The aim of this study was to assess, in an open, controlled randomised study, the effect of acupuncture alone or as an adjunctive therapy on the symptoms of patients with knee OA.

Inclusion criteria

1. Male or female aged more than 18 years
2. Patients suffering with knee OA (grade I-III)
3. Duration of six months or more
4. Diagnosis based on clinical and radiological findings (Kellgren & Lawrence, grade IV*)
5. Previous non-response to inpatient or outpatient treatment
6. No previous acupuncture treatment

Exclusion criteria

1. Pregnancy
2. Other type of arthritis, eg rheumatoid arthritis, psoriatic arthritis, gout and severe OA of the hip
3. Fitted pacemakers
4. Known metal allergies
5. History of prosthetic or damaged cardiac valves
6. Haemophilia
7. Anticoagulants, cortisone or oral corticosteroid medication
8. Dementia, psychiatric disease and life threatening illness
9. Uncontrolled diabetes
10. Skin diseases likely to influence the use of the acupuncture needles

* Kellgren JH, Lawrence JS. Radiologic assessment of osteoarthritis. *Ann Rheum Dis* 1957;16:494.

Box 1 Inclusion and exclusion criteria for study of patients with OA knee

Methods

Patients

During the design phase of this study, limited data were available on which to base an accurate power calculation; the study by Berman had not been published.¹⁶ Therefore, on pragmatic grounds, we chose a group size of ten. The study was approved by the University Hospital Birmingham NHS Trust and the Local Research Ethics Committee. Patients were given both written and verbal information prior to the study, and signed consent forms. All were acupuncture-naïve.

Patients who had a history of knee OA for more than six months, and who had not responded to one or more conventional medical treatments, were recruited from the Department of Rheumatology, Selly Oak Hospital. They were invited to take part in the study and given a full clinical examination, and their medical records were fully reviewed. Those who fulfilled the selection criteria (Box 1) were then randomly assigned to one of three treatment groups. Patients with bilateral knee involvement were asked to indicate which was the more painful knee, and this one was treated.

The randomisation process used block randomisation, in groups of 10, with sealed envelopes containing cards designating the treatment group prepared by a research nurse unconnected with the study. The study protocol, treatment time-table and outcome questionnaires were explained, and all patients were told that they could withdraw from the study at any time.

Treatment groups

Patients were allocated to three treatment groups. Group A received acupuncture alone, and agreed not to take their non-steroidal anti-inflammatory and analgesic drugs throughout the period of acupuncture treatment, stopping one week before. Patients in group B were given acupuncture and continued their existing analgesic and anti-inflammatory medication. Group C acted as a control group for the first five weeks, taking their current medication, after which they had a course of acupuncture for a further five weeks still continuing their medication. All groups continued with any medications unrelated to their OA.

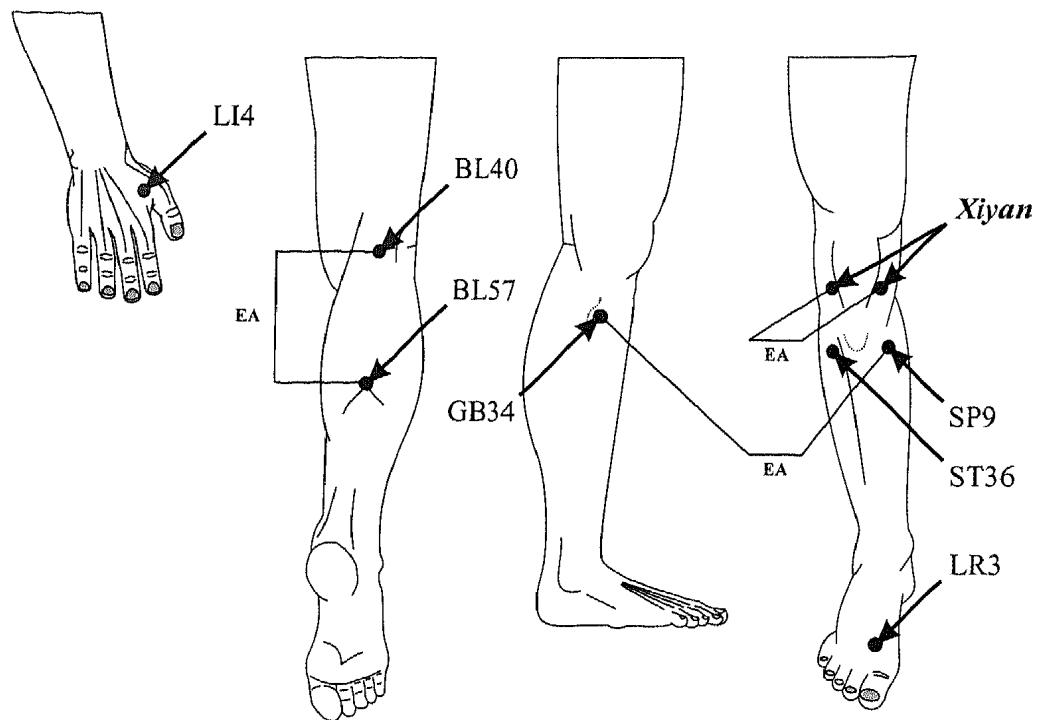


Figure 1 This diagram shows the points used in the study for the treatment of knee OA. Three pairs of points were treated with electroacupuncture (EA) as indicated.

Acupuncture procedure

Patients in groups A and B received acupuncture twice weekly, on Monday and Wednesday, from baseline to week five. Patients in group C were given twice weekly sessions of acupuncture from week five, following the completion of their control phase (baseline to week five). Acupuncture treatments were administered by one author (ET) in points selected according to standardised acupuncture formulae, traditionally used for treatment of OA of the knee (Figure 1).^{36,17} A recent review has proposed criteria for assessing the adequacy of acupuncture in therapeutic trials.³⁰ These include 10 treatment sessions, needling of at least eight points per session, eliciting *de qi*, and using electroacupuncture to supplement manual treatment; these criteria were met in this study.

The patient lay first supine with a pillow under both knees for treatment of the anterior part of the knee and then turned face down for treatment of the posterior aspect. The acupuncture needles used for treatment were 3cm, 30 gauge solid disposable filiform stainless steel needles (Asia-med, Germany). The depth of needle insertion varied with the thickness of the skin and subcutaneous fatty tissues at the site of the acupuncture points, but was usually 1-1.5 cm.^{17,37,38}

Needles were left in situ for 20-30 minutes. The therapeutic effect appeared to be at its best when the patient felt a momentary local sensation of heaviness or numbness, termed *de qi* in classical acupuncture literature.³⁹ *De qi* must be distinguished from pain or discomfort due to needling. The acupuncturist was blind to the group assignment of patients and the evaluation of outcome measures, and not involved in data collection.

In traditional acupuncture, the Bi-syndrome is somewhat equivalent to the Western meaning of 'rheumatism' or 'arthritis'. Bi-syndrome means a blockage of both energy (*qi*) and blood circulation, which is caused by cold, wind and humidity invasion of the intermediate network of channels and collaterals. Based on the theory for treating Bi-syndrome, a combination of local and distal classical Chinese acupuncture points were used: LI4, SP10, *Xiyian* ('eyes' of the knee), SP9, GB34, ST36, LR3, BL40 (*Weizhong*) and BL 57.^{3,16,17,36}

Two modes of needle stimulation were used:

1. Manual stimulation of only GB34 on the affected side, manipulating the needle in this point for a few seconds to elicit a brief sensation of electric shock. It has been observed that needling GB34 for between a

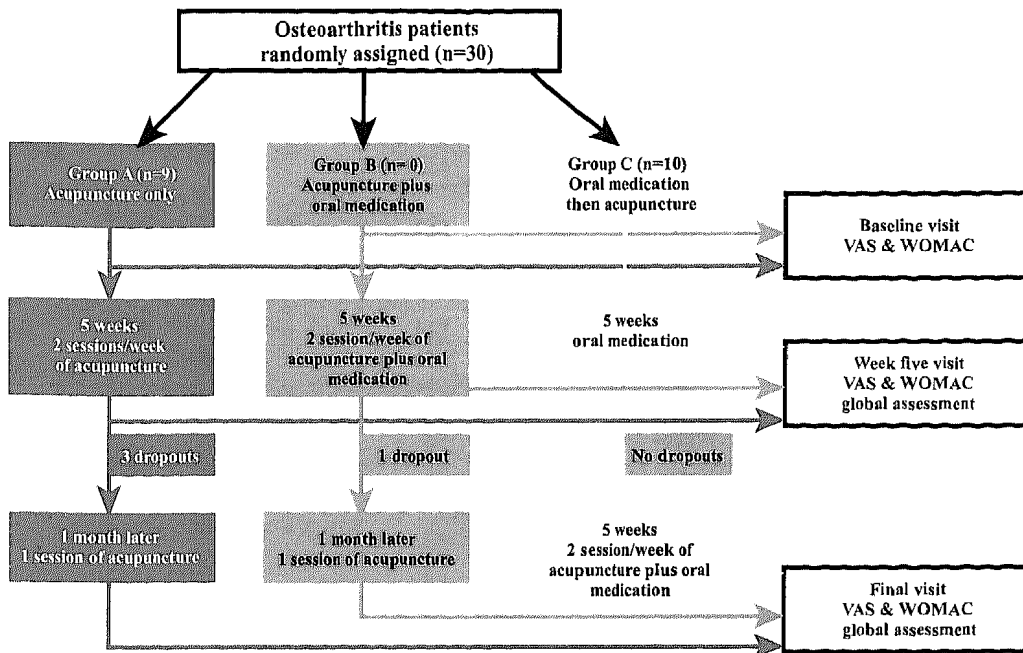


Figure 2 Flow diagram of the study

few seconds and one minute may relieve stiffness and control pain in frozen shoulder.³⁷

- Electrical stimulation using a battery-operated, four-channel electrostimulator (AS Super 4; RDG Medical, Surrey, UK), which generates low frequency, square-wave pulses of 1ms duration. Needles were attached to the apparatus in the following pairs:

- The two Xiyan points ('eyes' of the knee)
- SP9 and GB34
- BL40 and BL57

The electrical stimulation was delivered at 6Hz for 20 minutes, at an intensity just below the pain threshold.

Assessment methods

A blinded observer (ED) administered the outcome measures (see Figure 2) to groups A and B before treatment, after five weeks' treatment and at one month follow up. Patients in group C completed the same measures at baseline, after five weeks with medication only, and again after five weeks' acupuncture. The acupuncturist did not discuss the treatment response with patients during the course of treatment.

The primary outcome measure was the change in pain as assessed by a 10cm visual analogue scale (VAS).³³ Secondary end points included the WOMAC self-assessment questionnaire, which is a validated

multidimensional, self-administered health status outcome measure for pain and stiffness of knee OA. It contains questions requiring responses on five-point (none, slight, moderate, severe and extreme) Likert scales,³⁴ giving total scores in the ranges of 0-25 (pain) and 0-10 (stiffness). Additionally, patient and practitioner were asked to make a global assessment of the effect at week five and at the final visit, by marking a 10cm visual analogue scale rating labelled 'useless' and 'excellent' at opposite ends. The mark was converted into a percentage score, so that 100% indicates an excellent effect.

Statistical methods

Missing values from patients who dropped out were substituted by last values carried forward. Paired comparisons of changes within each group were made using a paired *t* test; between group comparisons of the changes in score from baseline were carried out using ANOVA, followed by a Bonferroni adjusted analysis of pairs of groups. The paired observations were found to be approximately normally distributed. Repeated measures analyses were used to examine mean differences in outcome scores for VAS and WOMAC between baseline and subsequent assessment times at five weeks and one month post-acupuncture period. All analyses were completed using SPSS for Windows, version 6.1.

Table 1 Demographic and other details of patients in controlled trial

	N	Mean age (years)	Sex (m/f)	Mean disease duration (years)	Knees treated (right/left)	Severity (Kellgren & Lawrence scale*)	
						grade 2	grade 3
Group A acupuncture only	9	61	3/6	10.3	5/4	2	7
Group B acupuncture and medication	10	60	0/10	10.1	4/6	5	5
Group C medication only	10	61	2/8	9.95	6/4	6	4

* Kellgren JH, Lawrence JS. Radiologic assessment of osteoarthritis. *Ann Rheum Dis* 1957;16:494

Table 2 VAS pain scores at three time points in trial, mean (SD)

Treatment group	Knee pain scores (10cm VAS)			Within group comparisons (t test)	
	Baseline	Week 5	Final visit*	Baseline - week 5	Week 5 - final visit
A (n=9)	6.0 (SD 1.9)	3.1 (SD 2.9)	2.4 (SD 1.2)	P=0.012	not significant
B (n=10)	6.0 (SD 1.5)	1.7 (SD 2.5)	2.8 (SD 2.9)	P<0.001	not significant
C (n=10)	7.0 (SD 1.3)	**6.9 (SD 2.3)	1.5 (SD 1.4)	not significant	P<0.001

* Final visit was nine week follow-up for groups A and B, and 10 weeks (immediate post-treatment) visit for group C.

** At week five, a highly significant difference was observed between the three groups (P<0.001, ANOVA).

Using All-pairwise comparison with a Bonferroni adjustment at significance level of 0.05, groups A and B were found to be significantly different from group C.

Table 3 WOMAC pain scores at three time points in trial, mean (SD)

Treatment group	WOMAC pain score			Within group comparisons (t test)	
	Baseline	Week 5	Final visit*	Baseline - week 5	Week 5 - final visit
A (n=9)	10.2 (SD 3.0)	6.0 (SD 4.9)	5.1 (SD 3.6)	P=0.012	not significant
B (n=10)	12.2 (SD 1.7)	4.4 (SD 4.3)	5.5 (SD 4.3)	P<0.001	not significant
C (n=10)	12.6 (SD 3.1)	**12.7 (SD 3.7)	4.7 (SD 3.4)	not significant	P<0.002

* Final visit was nine week follow-up for groups A and B, and 10 weeks (immediate post-treatment) visit for group C.

** At week five, a highly significant difference (p<0.001, ANOVA) was observed between the three groups.

Using All-pairwise comparison with a Bonferroni adjustment at significance level of 0.05, groups A and B were found to be significantly different from C.

Results

Thirty patients (five males), ranging in age from 42 to 77 years with an average age of 62 years, satisfied the entry criteria and were assigned to one of the three groups (Figure 2). There were no significant differences between the three groups at baseline in age, and disease duration (Table 1) or body mass index (data not presented) although slightly more patients in group A had stage three OA.

Four patients dropped out after completing the five week acupuncture treatment sessions: two who described gaining benefit from treatment, one who did not wish to continue, and one who noticed

only temporary relief after some sessions. One patient in group A continued taking concomitant analgesic and anti-inflammatory medication, contrary to the protocol; this patient's data were excluded from the analysis.

No side effects of acupuncture treatments were noted and all patients tolerated the acupuncture treatment without any problem.

Primary end point

The baseline pain scores were similar for the three groups. Group C showed no change in pain score during the first five weeks while waiting for acupuncture. After acupuncture there was a large

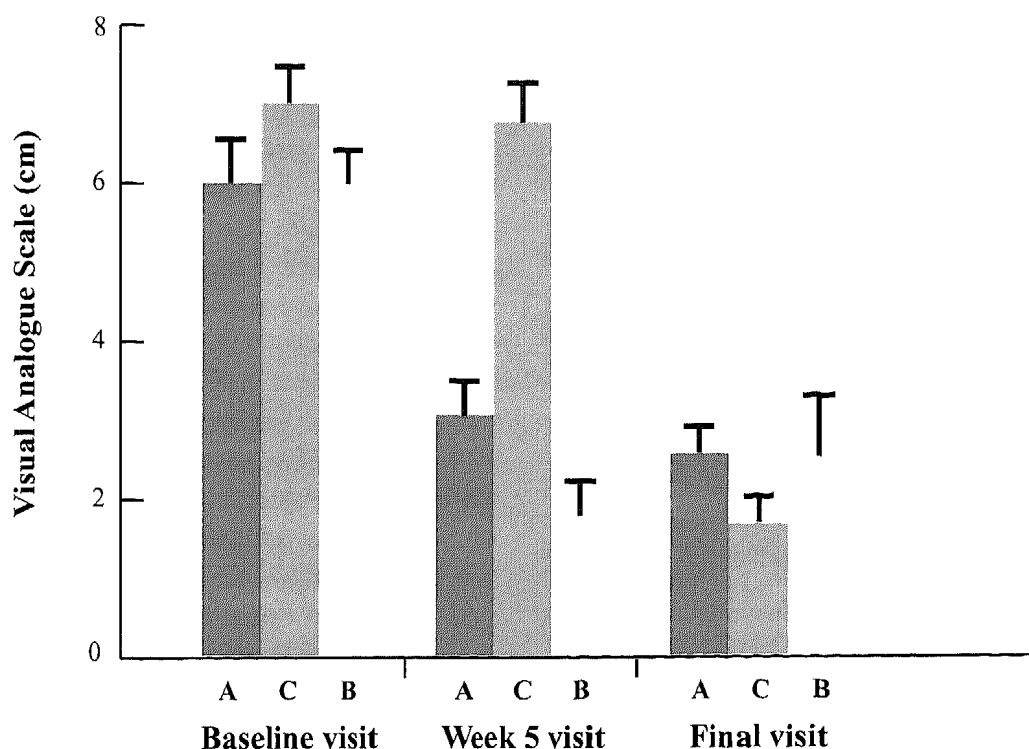


Figure 3 This figure is a diagrammatic representation of the effect of acupuncture on the VAS pain scores in groups A, B and C: error bar plots indicate standard error of the mean (SE). Acupuncture was given to groups A and B between baseline and five weeks, and to group C between five weeks and the final visit.

and statistically significant drop in the VAS pain score for all three treated groups (Table 2 and Figure 3). In groups A and B the improvement in pain score was maintained when the patients attended for the final visit. Using All-Pairwise comparison with a Bonferroni adjustment at a significance level of 0.05, groups A and B were found to be significantly different from C at five weeks. Repeating the ANOVA with gender as a covariant did not change the differences in changes of VAS score.

Secondary End Points

WOMAC pain

The pattern of pain relief shown in the primary

end point was reflected in the changes in the pain component of the WOMAC (Table 3). There was the same significant drop in the pain score after the acupuncture, which was maintained for at least four weeks in groups A and B.

WOMAC stiffness

Similar changes occurred in the WOMAC stiffness scores, which decreased by more than half in groups B and C after the course of acupuncture (Table 4). The reduction was less dramatic in group A, but still significant, and still present one month later.

Global assessment.

The patients rated their global assessment of improvement after five weeks of treatment at 68%

Table 4 WOMAC stiffness scores at three time points in trial, mean (SD)

Treatment group	WOMAC stiffness score			Within group comparisons (<i>t</i> test)	
	Baseline	Week 5	Final visit*	Baseline - week 5	Week 5 - final visit
A (n=9)	4.8 (SD 1.4)	3.2 (SD 2.1)	3.2 (SD 1.5)	P=0.01	not significant
B (n=10)	5.6 (SD 0.9)	2.3 (SD 1.6)	3.3 (SD 1.6)	P<0.001	not significant
C (n=10)	5.5 (SD 1.8)	**5.8 (SD 1.3)	2.6 (SD 1.7)	not significant	P<0.006

* Final visit was nine week follow-up for groups A and B, and 10 weeks (immediate post-treatment) visit for group C.

** At week five, a highly significant difference ($p<0.001$ ANOVA) was observed between the three groups.

Using All-Pairwise comparison with a Bonferroni adjustment at significance level of 0.05, groups A and B were found to be significantly different from group C.

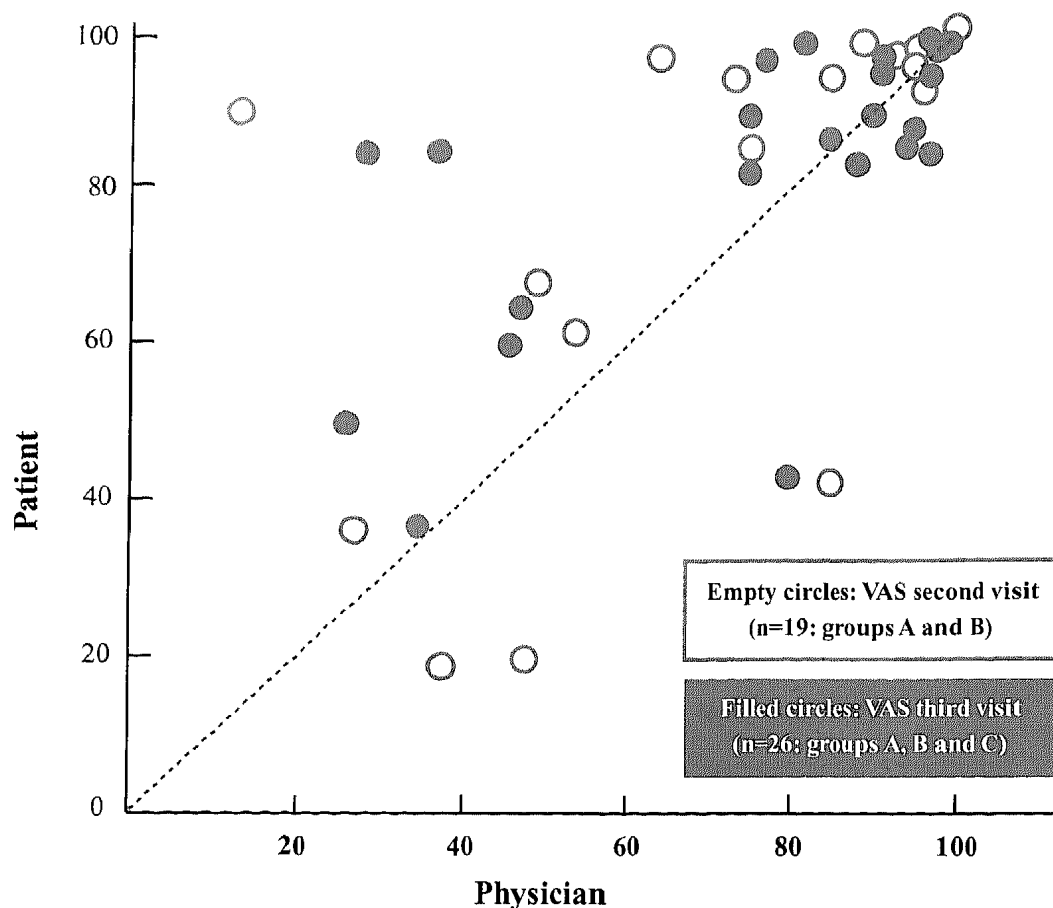


Figure 4 Global assessment by patient and acupuncturist.

in group A and at 85% in group B. At the final visit the rating was 61% in group A, 83% in group B and 88% in group C. The global assessment of the patient was rated by the acupuncturist after five weeks' treatment at 54% for group A and 89% for group B. At the final visit the rating was 69% for group A, 76% for group B and 75% for group C. A comparison was made of the patient's and acupuncturist's global assessments of benefit (Figure 4). In general the patients gave a more favourable assessment than the acupuncturist.

Discussion

Traditional Chinese acupuncture, like other complementary therapies, has aroused great interest in Western medicine for its analgesic property in the treatment of pain,⁴⁰ particularly in knee OA.^{3,13} Initial open, uncontrolled studies evaluating acupuncture for the treatment of knee OA concluded that the therapeutic effect of acupuncture is better than standard care.^{41,11}

Improvements have been introduced in the quality of clinical research in this field,⁴² using

methods such as cross-over design, randomisation, sham control and single or double-blinding.^{43-45,12,13} International guidelines have also helped with standardisation.³² While there are guidelines for assessment of osteoarthritis, there is no such internationally recognised guidance for the use of acupuncture. The recent review by Ezzo has proposed some minimum adequacy criteria which were met for this study.³⁰

Berman and colleagues, in a pilot study of 12 patients with knee OA, showed that acupuncture relieved symptoms, decreased swelling and increased range of motion.¹⁵ This work has been extended with a further open study that showed that acupuncture was an effective adjunctive therapy in patients awaiting knee replacement surgery.¹⁶ WOMAC scores in the acupuncture treated group improved significantly, while those of the controls showed no change. The authors concluded that acupuncture therapy is a safe and effective adjunctive therapy in knee OA. Reviews by this research group have further reiterated the effectiveness of acupuncture in the treatment of

OA.^{46,30} Our results support their data by showing a significant benefit in the adjunctive therapy group.

The persistence of effect is an important factor to consider. The present study had only a one month follow-up but there was no significant loss of effect at that time point, which is in keeping with results of Berman's study.¹⁶ Long term studies are rare, although benefits have been reported after three months' follow-up,⁴⁷ and a one year study indicated that single treatments at monthly intervals maintained the benefit gained from a course of traditional treatment.¹²

The open design of these studies does not provide information about the mechanism of the perceived pain control. A report from Collier et al suggests that the patient's attitudes and knowledge of acupuncture do not influence the response to the treatment,⁴⁸ and another study found that psychological factors do not play an important role in the response to acupuncture in patients with knee OA.⁴⁹ The pitfalls of sham acupuncture (needling in 'neutral' areas) have been well reviewed,²⁹ and the use of blunted non-penetrating needles may provide a better placebo control.^{50,51}

The present study supports the evidence from other studies and shows that acupuncture treatment of knee OA, given either alone or as an adjunct to conventional treatment, can produce a beneficial effect on subjective symptoms.^{16,23} The mechanism of this effect remains to be elucidated.

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