Acupuncture and moxibustion as an adjunctive treatment for osteoarthritis of the knee
- a large case series

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Abstract

Background In 1997, the first Pain Management Unit, which was set up as part of primary health care within the Andalusian Public Health System, offered acupuncture among other therapies. This observational study was conducted in preparation for a randomised controlled trial.

Methods We conducted a descriptive study of patients who had been diagnosed with osteoarthritis of the knee. The patients received weekly acupuncture treatment, and related techniques, from November 1997 to November 2000. We recorded: socio-demographic data; measures of effectiveness, including intensity and frequency of pain; the daily dose of analgesic and anti-inflammatory medication; the degree of incapacity; and sleep disorders caused by pain in the knee.

Results The 563 patients who presented were mainly female (88%) with an average age of 65 years (±10.7); the average age of the male patients was 67 years (±11.8). The condition in most patients (95%) was chronic: 54% had the condition for 5-10 years and a further 23% for more than 10 years. Of the total, 85 (15%) abandoned treatment and were excluded from the evaluation, while 75% of the remainder achieved a reduction in pain of 45% or more. This study is intended to form the basis for a subsequent controlled clinical trial of the effectiveness of acupuncture as a treatment for osteoarthritis of the knee.

Conclusion The degree of pain relief experienced by patients from acupuncture justifies a more rigorous study.

Keywords

Osteoarthritis, pain, knee, acupuncture, case series.

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Introduction

Osteoarthritis of the knee is a common complaint and one of the main causes of disability.[1-3] With advancing age or worsening of the condition, the pain it causes is often associated with disability, loss of mobility, loss of independence and a consequent deterioration in lifestyle.[4] According to an epidemiological study, 67% of those suffering osteoarthritis of the knee consider their health to be 'bad' or 'fairly bad'.[2]

The standard medical approach is wide-ranging, but is mainly focused on relieving the pain by drugs, physical rehabilitation and surgery. The most common policy is to treat the condition with analgesics and non-steroidal anti-inflammatory drugs (NSAIDs), which frequently provoke serious side-effects, such as gastrointestinal bleeding, high blood pressure, congestive cardiac insufficiency and kidney disorders.[5-9]

Because resources are limited and increased healthcare expenditure has not been accompanied by significant improvements in the health of the population, there has been a re-examination of the organisational strategy of health services. It is now seen to be essential to identify alternative approaches to chronic health problems for which the healthcare system has proved incapable of providing an effective response. Interest has grown in non-conventional techniques during the last ten years in countries such as France, Germany, Great Britain and the USA. In November 1997, a consensus panel of experts was set up by the National Institute of Health (NIH) to consider the topic of acupuncture. Its conclusions, published in Bethesda (Maryland, USA), recommended the use of acupuncture and further

research into its efficacy.[10;11]

In 1997, the first Pain Management Unit (PMU) was set up as part of primary health care within the Andalusian Public Health System. This first PMU is in the Dos Hermanas 'A' Health Centre, in the Sevilla-Sur health district and in the Valme Hospital area, and is responsible for developing a strategy to test the effectiveness of non-conventional techniques or medicines. The Pain Management Unit provides a support facility for the population of the three corresponding Basic Health Zones, a population of a little over 70 000, almost equally male and female according to the population register of February 18 1998. The PMU staff consists of a specialist doctor in traditional Chinese medicine (TCM) from the Beijing University of Medical Science, and two nurses. These are in full-time attendance at the PMU, five days a week. The PMU is equipped with a computerised system to record socio-demographic data, patients' clinical history, physical examination and investigations, the treatment given or other action taken, and the results obtained.

In order to determine the clinical response to acupuncture treatment and related techniques provided at the unit, an observational study was undertaken of 563 patients suffering osteoarthritis of the knee. This study is intended to form the basis for a subsequent controlled clinical trial.

Methods

The patients included in the study were referred to the PMU by the general practitioners at the three health centres and by specialist doctors in the area who carried out the initial examination and diagnosed osteoarthritis of the knee. The 563 patients were studied from November 1997 to November 2000.

The selection of acupuncture points was based on classical treatments known to be effective for osteoarthritis of the knee, distinguishing between local points close to the painful area, and more distal points.[12;13] Standard acupuncture treatment included the insertion of sterile, single-use 30 gauge, 45mm length acupuncture needles into the following local points: GB34 (insertion of 1 to 1.6cm depth), SP9 (1 to 2cm depth), Extra point 'eye of the knee' *Neixiyan* (1 to 1.2cm depth), and ST36 (1 to 1.5cm depth). The distal points were selected depending on the diagnosis of TCM: KI3 (0.5 to 0.8cm depth), SP6 (1 to 1.5cm depth), LI4 (0.8 to 1cm depth), and ST40 (2.5 to 3cm depth). Needle sensation (*de qi*) was elicited at each of these points.

All the needles inserted into the local points were given moxibustion using pressed Artemisia cones placed on the needle handle for 20 minutes each session, except in the case of patients presenting signs of heat due to yin insufficiency; in these cases, the needles were stimulated electrically in pairs by a WQ-10D1 electro stimulator at low frequency (2.5-4Hz) in a dense dispersed pattern, with an asymmetric bipolar waveform at low amplitude.

The patients in the study also received auricular therapy, in the form of a weekly placement of *Vaccaria* seeds on each outer ear, after sterilisation with povidone-iodine, at the following points: shenmen, knee, thalamus, subcortex, kidney and spleen. Seeds were placed on both ears, and replaced each week.

Following PMU protocols for chronic conditions, sessions were held once per week up to a maximum of 15. Treatment was terminated according to the patient's response. When no improvement was observed by the third session, the treatment was suspended and the patients were referred to their general or specialist doctor for evaluation and follow up. The results for these patients were included in the analysis.

Data, in accordance with the PMU protocol, were recorded at the initial interview and during each of the clinical sessions. The preliminary interview provided socio-demographic information and data on the diagnosis, prior treatment received and the length of time since the onset of the process. During the treatment sessions (as well as in the initial interview) pain intensity was measured using a visual analogue scale (VAS) of 0 to 10; also recorded were the pain frequency, the analgesics consumed, and the disability and sleep disturbance caused by the pain; were all recorded on a Likert scale from 0 to 4.[14;15]

Cost analysis was carried out by asking each patient, at initial and final interviews, to report their consumption of non-steroidal and analgesic drugs on the previous day, which were then priced at current costs.

The clinical trials committee of the Osteoarthritis Research Society International (OARSI) has proposed a series of criteria to define patient response in the context of clinical trials of osteoarthritis, known as the OARSI Response Criteria Initiative (RCI).[16] According to these criteria, a patient with OA is classified as responsive when a pain reduction of at least 45% is observed. This was assessed by comparing baseline and final pain intensity reported by the patient. Each case was grouped into one of the following response categories:

Worse: greater pain intensity than the basal measurement

- *No improvement* - unchanged or improvement of less than 25%
- *Slight improvement* - improvement of 25% to 45%
- *Moderate improvement* - improvement of 46% to 75%
- *Considerable improvement* - improvement greater than 75%.

The sample size was estimated on the basis of a 0.70 probability of success in response (improvement greater than 45%), at a significance level of 0.05 and a power of 0.8; the minimum sample of patients required was 501.

Descriptive statistics were calculated, and are presented as ranges, standard deviations (SD), and 95% confidence intervals (95% CI) as appropriate. With regard to the group of patients who abandoned treatment, the baseline pain intensity (PI) was compared with that of those who completed the programme, using *t*-test for independent samples. Response to treatment was measured by comparing mean baseline and final values for pain intensity, using a *t*-test for related samples. We calculated the Pearson chi-square to compare the quantity of analgesics required at completion of the programme by patients in each response category. A significance level of $P<0.05$ was used throughout. Analysis was performed using Statistics Package for Social Scientists version 9.0.

Table 1 **Baseline data for patients in the study group**

	Women	Men
Cases	496 (88%)	67 (12%)
Mean (SD) age, in years	65.3 (10.7)	66.9 (11.8)
Mean (SD) duration of symptoms, in months	102.4 (84.7)	72.6 (94.5)
Mean (SD) pain intensity, VAS score	8.5 (1.5)	7.2 (1.5)

Results

The study comprised 563 patients, predominantly female (88%), whose average age was 65 years (95% CI 64-66); the average age of the men was 67 years (95% CI 64-70) (Table 1). Almost all the patients attended the PMU when their osteoarthritis was already chronic, with an average duration of osteoarthritis of the knee of 99 months (±86.3; range 1-600) (Table 2).

Table 2 **Duration of osteoarthritis of the knee**

Duration	Number (%)
<3 months	30 (5.3)
3-6 months	45 (8.0)
7-12 months	55 (9.8)
13-60 months	127 (22.6)
61-120 months	175 (31.1)
>10 years	131 (23.3)

The baseline evaluation of pain intensity, on a visual analogue scale (VAS), varied by more than one point between men and women: the women rated pain intensity at 8.5 (±1.5; range 5-10), while the men rated pain intensity as 7.2 (±1.5; range 4-10).

Of the 563 cases, 85 (15%) abandoned treatment and, according to the protocol, were excluded from the evaluation. The mean baseline pain intensity score of those who abandoned treatment was 8.45 (±1.56), and those who completed treatment was 8.37 (±1.57). No significant differences were found (Levene test $F=0.006$, assuming equal variances, $P=0.686$). If the patients who abandoned the study are typical of other patients attending the PMU, then they withdrew mainly for external reasons, such as a change of address, work-related factors, or reasons concerning their dependent relatives, as these were the reasons given by 61% of those who did not continue treatment in this PMU in a previous survey.[17]

The remaining 478 patients attended an average of 8.9 sessions. After the intervention, there was a

Table 3 **Changes in pain and other symptoms, from baseline to final visit**

Outcome (range of scale)	Mean difference	SD of difference	95% CI for the difference	
			Lower	Upper
Pain intensity (0-10)	5.51*	2.32		
Pain frequency (0-4)	1.82	1.09		
Analgesic consumption (0-4)	1.51	1.05		
Disability (0-4)	1.35	0.98		
Sleep disturbance (0-4)	1.68	1.34		

*P<0.001, *t* test for related samples

Table 4 **Changes in pain score after acupuncture. Values are numbers (percentages) in each category**

Response category	Improvement in pain score	Number (%)
	<0%	
	<25%	
	25-44%	
	46-75%	
	>75%	

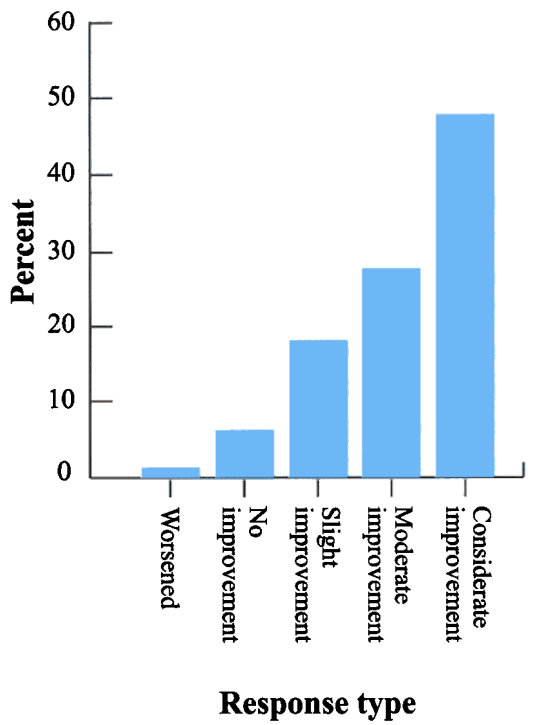

Figure 1 Percentage of patients in each category of pain relief. Those with moderate and considerable improvement had greater than 45% reduction in pain score.

significant reduction in the mean pain intensity (Table 3). A total of 359 (75%) patients reported an improvement of more than 45% in relation to their baseline score (Table 4 and Figure 1). No significant differences were observed between the number of sessions for patients whose response was 'moderate improvement' (average of 9.3 sessions) and those who achieved 'considerable improvement' (average of 8.8 sessions). In addition, all other symptoms scores reduced, and 95% confidence limits always exceeded zero.

Complications reported during or after treatment were: one case of burning, when the Artemisia cone slipped onto the skin; one case of fainting that was resolved by changing to a prone position; and four cases of bruising of the medial leg, in the SP9 zone.

There was a significant difference between the quantity of analgesics being taken at completion of the treatment in each response category (Pearson chi-square P<0.001), ie the greater the reported improvement, the fewer the analgesics and anti-inflammatory drugs that the patients needed. Table 5 shows the distribution of frequencies. Among those patients who responded with >45% pain relief who were taking no analgesics at the time of the final visit, 85% had been taking analgesics at least 'regularly' before acupuncture (Table 6).

Cost analysis showed that the mean initial cost per patient of 0.91 (±0.84) €/day had reduced at completion to 0.18 (±0.35) €/day, which represented a daily saving of 349.50 €/day for the 478 patients.

Discussion

Systematic reviews have shown moderate evidence of the effectiveness of acupuncture in addition to

Table 5 **Distribution of frequencies of response category and analgesic consumption at end of treatment**

Analgesic consumption at end of treatment	Response category					Total
	Worsened	No improvement	Slight improvement	Moderate improvement	Considerable improvement	
None		2 (0.8)	11 (4.5)	57 (23.3)	175 (71.4)	245
Occasional		5 (4.1)	25 (20.3)	51 (41.5)	42 (34.1)	123
Regular		10 (11.5)	44 (50.6)	22 (25.3)	11 (12.6)	87
Greater than normal	2 (9.5)	14 (66.7)	4 (19.0)	1 (4.8)	21	
Very great		2 (100)			2	
Total	2 (0.4)	33 (6.9)	84 (17.6)	131 (27.4)	228 (47.7)	478 (100)

The values in the table are absolute numbers of patients. Row percentages are in brackets alongside.

P<0.001, Pearson chi square

Table 6 **Baseline analgesic consumption reported by 175 patients who gained >45% pain relief and were taking no analgesics at the final evaluation**

Reported analgesic consumption	Number	%
None	8	4.6
Occasional	16	9.1
Regular	89	50.9
Greater than normal	60	34.3
Very great	2	1.1

conventional treatment for pain caused by osteoarthritis of the knee;[18,19] however, this effectiveness might be explained by a strong placebo effect. The present study involving a series of 563 patients with osteoarthritis of the knee treated with acupuncture was carried out as a pilot project for a randomised clinical trial. We previously reported a reduction of the daily dose of NSAIDs required per 1000 inhabitants in the Basic Health Zones that were served by a PMU providing acupuncture, in comparison with the other zones within the same health district.[20] Similarly, this preliminary study shows that 75% of the patients treated reported an improvement of at least 45% in their symptoms, and at the same time consumed fewer analgesics and anti-inflammatory drugs, which may cause side effects.[3-7] In agreement with other authors, we believe novel techniques should be subjected to rigorous studies such as randomised controlled trials to test their efficacy, safety and cost-effectiveness.[21,22] However, it should also be taken into account that techniques such as acupuncture present enormous difficulties in that individualisation of treatment based on the unique presentation of each patient is considered of fundamental importance in Traditional Chinese Medicine (TCM). Osteoarthritis of the knee is approached as a painful obstructive syndrome (Bi) caused by the action of associated climatic factors. In the present study, we have found (data not reported in this article) that three syndromes are predominantly associated with this type of painful obstruction: (1) Bi-syndrome associated with kidney insufficiency; (2) Bi-syndrome associated with spleen insufficiency; (3) Bi-syndrome associated with phlegm and humidity. In this study the selection of distal points was made with the intention of individualising treatment as much as possible.

Our sample group contained a small percentage of patients (5%) with arthritis of the knee that had been diagnosed less than three months previously. In every case, however, the symptoms had been experienced for longer and thus the Bi syndrome was already established. After the ninth weekly session, no further improvement seems to have been obtained. In our study, extending treatment to the maximum number of sessions (15) was not related to any further improvement in response.

Acupuncture is a technique that is increasingly requested by healthcare service users. On the basis of existing evidence - that is the improved quality of life reported by patients who have been treated with acupuncture, together with the cost savings, its low absolute cost and the low rate of

undesirable side-effects - the Public Health System in Andalusia is continuing with approaches such as that reported from this PMU.[24] It is also extending these ideas to other units, both in hospital environments and in primary care. Conventional medicine should take into account such alternative therapies after relevant scientific evaluation (such as controlled clinical trials) to expand the range of possibilities offered to patients.

In conclusion, this case series has shown that a course of acupuncture treatment for patients with osteoarthritis of the knee is associated with a significant reduction in the mean pain score, and 75% of patients reported an improvement of more than 45%.

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