

# Effectiveness of acupuncture and related techniques in treating non-oncological pain in primary healthcare – an audit

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## Abstract

**Background** Pain is one of the principal symptoms for which the general public seeks medical attention, and it is frequently treated by GPs. Although acupuncture is mainly practised in the private field, it enjoys growing acceptance in the public system too, which helps bring down the high cost of its use. The aim of the present study is to evaluate the effectiveness of acupuncture and related techniques in treating non-oncological pain during nine years of activity at the Pain Treatment Unit (PTU) within the Andalusian Public Health System (Spain) in the field of primary healthcare.

**Methods** Retrospective review of 5981 electronically stored case histories of patients who sought treatment for non-oncological pain and were seen at the PTU between June 1997 and July 2006. We excluded from this review those patients who had on any occasion been recruited for clinical trials at the PTU. The primary result measure applied was the success rate, defined as an improvement of least 50% on the Global Assessment Index, which is made up of five variables: pain intensity, as measured on a numerical scale of 0-10, pain frequency, consumption of analgesics, level of incapacity and sleep disorders caused by pain (the latter four variables were measured on a 5-point Likert scale of 0-4).

**Results** The majority (84.5%) of the patients treated were women, with a mean age of 58.8 years (range 8-93), and they attended the healthcare clinic because of pain present for over three months (88.8%) and mainly affecting the lower back (58.8%). In the 5690 patients who completed treatment, the mean success rate was 79.7%, with highest rates (93%) being achieved in patients with cephalgia. The mean reduction in pain intensity was 5.5 (SD 2.5) points amounting to 67% fall from the baseline. There was a reduction of €7.1 in the mean weekly expenditure on analgesics per patient. From the regression model, we conclude that the patients who suffered acute or sub-acute pain presented higher success rates than did those with chronic pain (OR, 1.94; 95% CI, 1.53-2.48).

**Conclusions** Acupuncture seems to be effective in treating musculoskeletal pain, and presents no severe adverse events. With acupuncture treatment, the consumption of analgesic and anti-inflammatory drugs is considerably reduced.

## Keywords

Acupuncture, pain, primary care, medical audit, general practice, adverse events.

## Background

Pain is one of the main symptoms causing people to seek medical attention, which is often provided by GPs,<sup>1</sup> and musculoskeletal pain is the type most frequently suffered. Today, increasing use is made of non-conventional therapeutic techniques to address this kind of problem,<sup>2</sup> although facilities in this

respect tend to be limited to the private sector. In June 1987, a pilot experiment was begun in Primary Healthcare Clinics within the Andalusian Public Health System, through which the population of Dos Hermanas (75 000 people) had the opportunity to be treated at a Pain Treatment Unit (PTU) where acupuncture and related techniques were provided.

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Before this project was implemented, the referral protocols (aims, target population, criteria for inclusion and exclusion, etc) were drawn up, discussed and publicised.

Initially, the project was in operation for one day a week (four hours) with one specialised physician assisted by the necessary nursing staff. Subsequently (in March 1998), and with the development of the programme, the infrastructure of the present Unit was created, comprising a consulting room, waiting room and treatment room, the latter with five independent treatment areas. Patients are referred by their GPs from clinics in the corresponding Basic Health Zones or by specialists (rehabilitation, traumatology, etc), although the doctor may also refer a patient to the PTU at the patient's request, either because previous treatment has already produced good results or because the patient so wishes. The PTU operates seven hours a day, from Monday to Friday, and is staffed by a physician specialised in acupuncture and Traditional Chinese Medicine (qualified at the Beijing University of Chinese Medicine) and with more than 20 years' clinical practice in this speciality. Other members of staff include one full-time and one part-time nurse. The nursing staff are trained in the application of related techniques.

The standard procedure consists of filling in a PTU referral form with full details of the diagnosis and previous treatment applied; if the clinical process is severe, doctors are recommended to note this on their report. This form is then sent by internal mail to the PTU and classified by priorities of urgency and pathology, after which the patient is telephoned for an appointment to be made. At the first examination, the history is taken, and the patient is examined and diagnosed in accordance with the principles of Traditional Chinese Medicine (TCM), after which the number and frequency of treatment sessions are established. At least three sessions are required, so that the effectiveness of the treatment may be evaluated; after these, the number of sessions scheduled is that necessary in order to achieve an improvement in the patient's condition, unless treatment is interrupted due to lack of positive response. When the treatment is concluded, the patient is given a discharge document containing recommendations to the referring doctor. The therapeutic techniques employed at the PTU follow the principles of TCM and consist of

acupuncture, electroacupuncture, auriculopressure, auriculotherapy, moxibustion, self-adhesive pads, TENS, dietary recommendations and advice on self massage. A custom made software package is used to record the patients' clinical history and data concerning treatment, the course of the illness, secondary effects and other facts of interest.

In the present study we sought to make a pragmatic analysis of the effectiveness of acupuncture in treating a wide variety of common complaints where the main symptom is pain, and to evaluate the contribution that an acupuncture service could make if offered to such patients. In particular, we aimed to evaluate patient characteristics, their response to the treatment provided, and the best prognostic factors related to this response.

## ***Methodology***

A retrospective clinical audit was performed of all the cases for which records existed in the PTU database, from the start of its activity (June 1997) to July 2006. All patients were included except those who had been recruited for other studies, whether carried out previously or currently in progress at the PTU.

## ***Evaluations***

A baseline evaluation was performed for the patient's first examination at the PTU, followed by successive evaluations for each of the sessions carried out. The final evaluation was obtained one week after the last treatment session.

## ***Outcome measures***

The primary result measure used was the success rate (SR), defined as an improvement of at least 50% on the Global Assessment Index (GAI), which is made up of five variables: pain intensity, on an 11-point (0 to 10) numerical rating scale (NRS), pain frequency, the consumption of analgesics, the level of incapacity and sleep disorders provoked by the pain. The latter four variables were measured on a 5-point Likert scale (from 0 to 4), with a total value ranging from 0 to 26 points, with greater pain being scored more highly.

The GAI is intended to assess the different dimensions of the pain, measuring intensity on an NRS from 0 to 10. Pain frequency was evaluated using a Likert scale of 0 to 4 (0: never; 1: if the pain

appears sporadically for less than one hour per day [every day] or less than two days per week [even if the duration of the pain episode exceeds one hour]; 2: persistent pain, for up to six hours per day; 3: pain duration exceeding six hours per day, but not lasting all day; 4: continual pain). The consumption of analgesics was assessed on a 5-point Likert scale, from 0 to 4 (0: no painkillers required; 1: painkillers taken occasionally or below the dose recommended for the process; 2: the painkillers recommended for the process, in accordance with clinical guidelines, are taken; 3: the standard dose for pharmacological treatment is increased; 4: it is necessary to increase the number of painkillers and/or their dose, on a continual basis); an extra point may be added if the patient does not take analgesics or anti-inflammatory medicaments, due to pre-existing contraindications, but in no case is a score of 4 exceeded. The level of incapacity is assessed on a Likert scale from 0 to 4 (0: no degree of incapacity; 1: incapacity for heavy work or that requiring great effort; 2: incapacity for everyday tasks; 3: requires assistance for dressing or bathing; 4: total incapacity, bedridden); an extra point may be added if the patient is temporarily unable to work, but in no case is a score of 4 exceeded. Inability to sleep because of pain is assessed on a Likert scale from 0 to 4 (0: pain does not wake the patient; 1: the patient is occasionally awoken by pain; 2) the patient is awoken by pain once a night; 3: the patient is awoken by pain two or more times a night, most nights; 4: pain makes it impossible to sleep); an extra point may be added if the patient takes medication to sleep, but in no case is a score of 4 exceeded. We also recorded the pain related medicines taken by the patients at the start and end of the treatment cycle, together with the recommended retail price of these drugs (without calculating the discounts that are applied in accordance with the class of beneficiary of the Spanish public health system, which is of a universal type [normally], the beneficiary who is in employment pays 40% and the health system pays 60%, while for pensioners, 100% of the cost is financed by the health system).

A telephone survey was carried out in order to ascertain the reasons for patients having ceased attending the PTU; for this purpose, a random sample of 54 patients was selected from the 291 who had been recorded as having abandoned the programme

during the period under analysis, assuming a margin for error of 10%, an expected prevalence for the least frequently attending category of 5%, and a confidence level of 90%.

### **Analysis**

The results are presented as a descriptive analysis. In addition, the Student *t* test was used for related samples in order to compare the changes in the NRS and GAI variables before and after the acupuncture treatment, and also to examine the change in the weekly pharmaceutical expenditure per patient. Logistic regression models were constructed using criteria of statistical significance, taking into account the dependent variable (SR), and adjusting for possible confounders such as sociodemographic data (sex, age, marital status) and the baseline values for the severity of the illness (pain intensity, pain frequency, consumption of analgesics, type of incapacity caused by the pain, sleep disorders, duration of the pain), and also for the type of patient referral made (on the physician's initiative or at the patient's request). Values of  $P<0.05$  were considered statistically significant. All the analyses were carried out using SPSS statistical software.

### **Results**

The analysis included the records of 5981 patients who were attending for non-oncological pain (with a total of 45 395 treatment sessions). Each record included corresponded to a request for treatment at the PTU communicated by a patient's GP or attending specialist. The mean age of the patients attending was 58.2 years (range 8-93); most patients were female (84.5%) and the previous duration of the pain had exceeded three months in 88.8% of cases, this pain most commonly being located in the lower back (58.8% of cases). Table 1 shows the distribution of the principal causes for seeking medical attention, detailing those with an incidence rate exceeding 2%, while the others are grouped into a single category. A total of 291 patients (4.9%) abandoned the treatment programme.

Comparison of those who abandoned treatment and those who completed the programme revealed statistically significant differences with respect to the principal reason for attending the clinic ( $P=0.013$ ), with a larger proportion of those who abandoned having cited back pain (34.7% vs 25.3%) or 'others'

*Table 1 Baseline data*

Main reason for consultation	n (% of total)	Duration of pain (months) mean; median	Index of baseline evaluation mean; median
Neck pain	1691 (28.3)	81.9; 60	18.8; 19
Low back pain	1539 (25.7)	83.5; 48	19.1; 19
Knee pain	1012 (16.9)	99.5; 92	19.1; 19
Shoulder pain	479 (8.0)	33.5; 12	19.3; 20
Back pain	290 (4.8)	95.4; 70	19.1; 19
Hip pain	183 (3.1)	61.0; 24	19.0; 19
Cephalgia	147 (2.5)	142.4; 120	19.2; 20
Others (incidence < 2%)	640 (10.7)	56.1; 24	18.9; 19

Data are organised according to the reason for the consultation (total n=5981)

*Table 2 Absolute and relative changes in Global Assessment Index*

Main reason of consultation	n=	Absolute change	Relative change
Neck pain	1616	12.1 (5.8)	67.6% (26.0)
Low back pain	1438	11.7 (6.0)	65.2% (25.9)
Knee pain	973	11.6 (5.4)	63.0% (24.7)
Shoulder pain	458	13.0 (5.9)	70.2% (24.7)
Back pain	281	12.3 (5.4)	66.5% (25.0)
Hip pain	172	12.0 (5.5)	67.2% (23.0)
Cephalgia	144	15.3 (5.1)	80.9% (20.8)
Others (incidence < 2%)	608	12.2 (5.7)	67.7% (23.8)

Data presented are from completion of treatment, classified by the reason for the consultation.

Values are means (SD).

*Table 3 Variables in the logistic regression model for the dependent variable ‘Success Rate’*

Variable	Raw OR (95% CI)	Adjusted OR (95%)
Number of sessions	1.11 (1.08 to 1.12)	1.13 (1.10 to 1.17)
Baseline pain intensity	0.95 (0.90 to 0.99)	0.94 (0.90 to 0.99)
Request for treatment		
Patient	1	1
Physician	1.28 (1.10 to 1.48)	1.30 (1.18 to 1.52)
Category of pain		
Chronic	1	1
Acute or subacute	1.73 (1.36 to 2.19)	1.94 (1.53 to 2.48)
Age < 65 years		
No	1	1
Yes	1.37 (1.19 to 1.56)	1.43 (1.25 to 1.64)

OR = Odds ratio

(11.0% vs 10.7%). The baseline differences were statistically significant between these two groups (ie abandoners vs completers) in the GAI (18.5 vs 19.0), pain intensity measured by NRS (7.9 vs 8.2) and age (55.5 vs 58.3 years).

Those discharged as ‘abandoned’ are excluded from this analysis. The mean number of sessions per patient was 7.7 (SD 2.4), with a range of 2-15. The success rate was 79.7% (4534/5690) of the patients who completed the treatment programme, with the

highest such rate being recorded for the patients who were treated for cephalalgia (93%, 135/144) and the lowest rate for those with pain in the knee (76.5%, 744/973).

The mean absolute change in pain intensity NRS in the whole group fell from 8.2 (SD 1.4) at the beginning to 2.9 (SD 2.3) at completion of treatment. This is a reduction of 5.5 points (SD 2.5, 95% CI of the difference 5.18 to 5.31), and a mean relative change of 66.8% (SD 24.6%).

The mean absolute change in the Global Assessment Index (GAI) – constructed with the addition of the following variables: pain intensity according to the NRS, frequency of pain, consumption of analgesics, level of incapacity and pain-related sleep disorders – on completion of the treatment programme was 12.1 points (SD 5.8%, 95% CI of the difference 11.9 to 12.2), with a relative change of 66.7% (SD 25.3%) with respect to the baseline level. Table 2 shows the changes in these variables by reason for consultation.

Table 3 shows the variables that remain in the logistic regression model for the dependent variable ‘Success rate’ (SR). We tested various interactions, but found none of them to be statistically significant. In this model, we can see the optimum profile for patients most receptive to the therapeutic technique we are examining: they are aged less than 65 years, present acute or sub-acute pain (with a previous history of less than three months) and have been referred to the PTU by their GP or specialist; the greater the intensity of the baseline pain, the lower the possibility of success.

A total of 1594 adverse events were recorded, out of a total of 45 395 sessions (3.51%). These included the following: bruising 2.02% (916 sessions); residual pain in the acupuncture site 1.2% (544 sessions); cephalalgia 0.1% (45 sessions); forgetting needles 0.12% (54 sessions); orthostatic problems 0.05% (22 sessions); auricular ulcers caused by the implantation of vaccaria seeds 0.03% (13 sessions). No severe adverse event was recorded.

The difference between the mean consumption of medicaments, due to pain, between the baseline assessment and that carried out after acupuncture treatment was €7.1 per week per patient (SD 11.0, 95% CI of the difference 6.78 to 7.34); classification of the data in accordance with the patients’ reasons for

consultation showed that the greatest saving was obtained in the case of patients with cephalgia, with a mean difference of €26.1 per week per patient (SD 46.6, 95% CI of the difference 18.52 to 33.72), while the smallest difference was recorded for the patients treated for neck pain, with a mean difference of €6.6 per week per patient (SD 8.54, 95% CI of the difference 6.15 to 6.96).

The response rate for the sample of patients who had abandoned the treatment programme (54 patients) was 81.5% (10 patients had not answered the telephone after at least six attempts had been made, at different times of the day). The rate of patients abandoning, classified by sex (79.6% of them were female) was very similar to that of the patients admitted to the PTU during the same period of time (of whom 80.6% were female). The following reasons for abandoning the programme were offered: problems in travelling to the PTU for treatment (61.4%); lack of response to the treatment (18.2%); improvement in the condition (15.9%); fear of the treatment (4.6%). The main motive cited was related to transport problems, but not so much because of the size of the metropolitan area (420 hectares) but due to the patients’ dependence on a means of transport that would enable them to attend the PTU, as not all the urban areas are well served by public transport.

### **Discussion**

The activity of the PTU responds to the increased demand by patients for analgesic acupuncture treatment. In principle, the patients seen at the PTU are referred there after the failure of other treatment programmes prescribed by their GPs or by specialised physicians. However, the profile of these patients has changed as physicians in the region in question have become more familiar with the conditions for which acupuncture provides the most suitable remedy.

The fact that the population treated is mainly female is a consequence of the profile of the use of healthcare services, although we should also note that the predominant occupational activity in the zone, that of the industry of stoning, stuffing and bottling olives, in which the workforce is traditionally female and where the prevailing atmosphere is cold and humid, probably favours the pathologies of an osteoarticular type such as osteoarthritis.

The number of treatment sessions per patient ranged from 2 to 15, with an average of 7.7 and a median value of 8. The sessions were normally weekly, given the high number of patients with a chronic pathology who were treated at the PTU. In acute cases, treatment sessions were offered two or three times per week. In each session, the prescription of acupuncture points was normally modified according to the patient's progress, such that the treatment was individualised; moreover, diverse techniques were often employed. The increasing demand for the treatment offered by the PTU obliged us to establish a cut-off point, in order to reassess the option of continuing the treatment or terminating it if the hoped for response was not obtained. This decision was taken after three treatment sessions; if a response rate of at least 25% had not been achieved, the patient was referred to his or her doctor (GP, traumatologist, etc) with a report detailing the treatment provided and the degree of response obtained.

No severe adverse events were recorded, in line with the belief that these are normally associated with the lack of skill with which the acupuncture technique is applied.<sup>3</sup> We did not record adverse events per puncture, but rather per treatment session, which would have reduced still further the incidence of such events, as an average of eight punctures per patient per treatment session were performed, and when local adverse events occurred (such as bruising or residual pain), these did not normally affect more than two punctures per treatment session.

Although special attention was paid at the PTU to the diligent compilation of the electronic records, errors may have arisen, either because of missing records or because patients forgot to tell us of certain changes, such as concomitant interventions. These aspects produce a considerable degree of uncertainty, which is common to all such audits,<sup>4</sup> and therefore the results of the present study must be interpreted with caution.

It should be made clear that in analysing the influence of the treatment on the reduced consumption of medicaments, we are not addressing the question of economic analysis. We only consider the savings in terms of the medicines prescribed, and do not take into account the expenses of medical personnel, fixed costs and materials, or the adverse effects caused by the medication normally prescribed for pain relief.

Most of the patients who abandoned the treatment programme informed us that this was due to difficulties in travelling to the PTU. This information is useful for the design of a possible strategy to improve matters in the future. Although the results of this study are of a local nature, and applicable therefore only to the environment in which the study was performed, they do contribute general information that can be of use in other healthcare clinics. In our case, the results pointed to the need to establish priority criteria for inclusion in the PTU treatment programme, favouring the possibility of treating patients aged less than 65 years and those with an acute or sub-acute condition. Nevertheless, the favourable response rate obtained for most of the patients, the absence of severe adverse events and the reduction in the consumption of analgesic and anti-inflammatory drugs all suggest that our experience could profitably be extended to other Primary Healthcare Clinics for the treatment of non-malignant pain.

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