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Randomised trial of long term effect of acupuncture for shoulder pain☆

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Abstract

The objective of the study is to compare the efficacy of electro-acupuncture with placebo-acupuncture for the treatment of shoulder pain. This study comprised of a prospective, randomized, placebo controlled trial, with independent evaluator set in a Public primary care clinic in Spain. The participants are patients aged from 25 to 83 years with shoulder pain. Patients were randomly allocated to two treatments over eight weeks, with electro-acupuncture or skin non-penetrating placebo-acupuncture, both able to take diclofenac if needed for intense pain. Primary outcome measure was the difference between groups in pain intensity (visual analogue scale—VAS). Secondary outcomes were differences between groups in pain intensity measured by Lattinen index, in range of motion (goniometer), functional ability (SPADI), quality of life (COOP-WONCA charts), NSAIDS intake, credibility (Borkoveck and Nau scale) and global satisfaction (10 points analogue scale). Assessments were performed before, during and three and six months after treatment. At six month follow-up after treatment the acupuncture group showed a significantly greater improvement in pain intensity compared with the control group [VAS mean difference 2.0 (95% CI 1.2–2.9)]. The acupuncture group had consistently better results in every secondary outcome measure than the control group. Acupuncture is an effective long-term treatment for patients with shoulder pain (from soft tissues lesions) in a primary care setting.

Keywords: Acupuncture; Electro-acupuncture; Shoulder pain; Randomised controlled trial

1. Introduction

Shoulder pain (SP) may be due to intrinsic shoulder disorders, or referred pain from neck or thorax. (van der Heijden, 1999)

Prevalence depends on case definition (7–50%) (Pope et al., 1997; van der Heijden, 1999). Only 50% of patients consult physicians, incidence is 7%, prevalence 51%, and lifetime prevalence about 10% (van der Heijden, 1999). Post stroke patients have higher incidence (40%). (Gamble et al., 2000). Prevalence is increasing in Finnish adolescents suggesting a future burden for the adult population (Hakala et al., 2002; Vikat et al., 2000).

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In a community study, the more common conditions were: rotator cuff lesions (65%), pericapsular soft tissue pain (11%), acromioclavicular joint pain (10%) and cervical spine referred pain (5%) (Vecchio et al., 1995).

SP risk factors are: physical overloading, trauma, psychosocial environmental conditions, joint instability, coracoacromial features, cuff degeneration and musculoskeletal diseases. A systematic review finds SP risk factors weakly associated, indicating a need for studies to identify causality and interacting factors (van der Windt et al., 2000). Recent studies report work physical load, mental stress, obesity, age and female gender as positively associated, and sports and physical dynamic activities as protective factors (Ehrmann et al., 2002; Miranda et al., 2001). Physical, psychosocial and individual factors interact to develop and maintain SP (Andersen et al., 2002; Devereux et al., 2002; Fredriksson et al., 2002; Hoozemans et al., 2002).

Patients complain of pain, movement restriction, tenderness, loss of flexibility and function, or a combination. (van der Heijden, 1999) Cuff lesions can evolve to capsulitis or frozen shoulder (contraction of the joint capsule) (Lundberg, 1969).

Capsulitis risk factors are: female sex, severe or repeated trauma, surgery, diabetes, cerebrovascular events, hemiplegia and coronary ischemia (Croft et al., 1996; Gamble et al., 2002; Tuten et al., 2000).

SP has been reported as self limiting, but a 3 year follow-up report finds 54% of patients with persistent pain and 90% with disability (Macfarlane et al., 1998), causing important quality of life restriction and great burden to patients and society (Cassou et al., 2002; Daigneault and Cooney, 1998). Eighteen percent of reported Swedish disability payments were for neck and SP (Bongers, 2001; Nygren et al., 1995).

Many interventions treat SP: non-steroidal anti-inflammatory drugs, subacromial or intra-articular injections, physiotherapy, ultrasound, electro magnetic field, laser, ice, heat, arthroscopic dilation, manipulation under anaesthesia, capsular electrocautery, surgical tendon repair. Though individual trials claim benefit, systematic reviews find little overall evidence of effectiveness (Buchbinder et al., 2003; Green et al., 2000).

Chinese authors report acupuncture pain effectiveness, but systematic reviews find methodology shortcomings (sample size, follow-up, randomisation, placebo, blinding, treatment standardisation) that impede acupuncture effectiveness assessment (Patel et al., 1989; ter Riet et al., 1990).

In a search on Medline and Cochrane Database we only found several case series and controlled trials about acupuncture on SP (Berry et al., 1980; Kleinhenz et al., 1999), with a possible effectiveness but with inconclusive evidence (Jiang and Liu, 1991; Nabeta and Kawakita, 2003; Wang et al., 1990).

In 1997 we started a primary care acupuncture pain programme, we found a positive evolution trend in a 201 SP case series (Guerra et al., 2003) but a rigorous design was necessary to determine acupuncture effects. Pain can be assessed in many dimensions, no standard measure can assess all dimensions. Most researchers recommend measuring pain dimensions (sensory, emotional, evaluative), function, and outcomes that matter to patients, researchers and health services (Chapman, 1998; Croft, 1998). We used an outcomes variable composite: pain intensity, functional ability, range of motion, quality of life, number of pills taken and patient satisfaction.

A randomised, placebo controlled, single blind with independent evaluator, clinical trial was designed to ascertain whether acupuncture needling is more effective that placebo needling in shoulder pain patients.

2. Materials and methods

2.1. Study design

The study was a randomised, placebo-controlled, single blind, clinical trial, with prospective blinded assessment of the two parallel groups by an independent observer.

2.2. Participants

From September 2001 to November 2002, patients with shoulder pain were ordinarily (History, physical exploration and Rx) diagnosed, and suggested for inclusion in the trial by primary care physicians of a National Health Service urban primary care clinic, who were informed about selection criteria. An independent examiner then assessed patients who were eligible and willing to participate in the study.

2.3. Initial assessment

Two physicians (Andrés Martín and Bassas y Baena de Leon) trained in clinical interview and criteria selection, performed the initial assessment. It consisted of a detailed examination to check clinical diagnosis, patient fulfilment of inclusion criteria without violation of exclusion criteria, collection of baseline data, informing the patients about the study (free treatment, use of penetrating or non penetrating needles, possible risks of infection, haematoma, and fainting) and requesting written informed consent. Selected patients were given an inclusion number.

During first evaluation the following data were recorded: demographic data (age, sex, marital status, education level, working status, habits, physical exercise), clinical data (concurrent condition, shoulder pain diagnosis, pain location, duration of symptoms, repetitive strain injury or previous trauma), credibility (measured by Borkovek-Nau scale) (Borkovec and Nau, 1972), quality of life (measured by Coop Wonca Charts) (Landgraf and Nelson, 1992), pain intensity (measured by visual analogue scale (VAS) and by Lattinen index) (Carlsson, 1983), range of arm abduction

(goniometer) (Gajdosik and Bohannon, 1987), and disability (measured by Shoulder pain and disability index, SPADI) (Roach et al., 1991). Every patient was given 21 diclofenac pills for the next week's treatment (50 mg per pill) with instruction to take one of them every 8 h, if needed, for shoulder pain. Also every patient received famotidine pills (20 mg per pills) and the instruction to take one of them every 12 h, if needed, for dyspepsia. Patients were instructed to return for acupuncturist intervention and evaluator assessment of outcomes. After initial assessment an appointment for next day was given to the patient to start acupuncture treatment.

Inclusion criteria were: diagnosis (history, examination, Rx) of shoulder soft tissues lesions: Cuff Tendonitis, capsulitis, bicipital tendonitis, bursitis with shoulder pain plus decreased movement (active, passive, counter resistance), local tenderness, and no swelling signs: local heat, redness; no recent shoulder trauma (previous 3 months); no previous acupuncture treatments; age of 18 or older, without upper limit but patient able to come to clinic for evaluation and treatment by his own means. Exclusion criteria were: critical physical or mental condition, febrile condition, systemic dermatological conditions, neoplasms, allergy to diclofenac, referred pain from neck or thorax, rupture of tendons or bone fractures, pregnancy, litigation, no intention to participate or follow instructions.

Written informed consent was obtained and the Ethics and Investigation Committee of Virgen de Valme University Hospital of Seville approved the study protocol.

2.4. Randomisation

Participants were randomly allocated to acupuncture or placebo group Randomisation was performed using computer software (Sigesmu®) without stratification or blocking procedure, via a telephone call from the independent evaluator to the external centralized office. The allocation group was revealed only to the treating acupuncturist, who had no knowledge of diagnoses or other data evaluations. Evaluation during the follow-up period, and drug treatment recommendations, were performed in different places and times and by different evaluators, who had no knowledge of the type of acupuncture (real or placebo) applied to the patient.

2.5. Masking and treatment procedure

2.5.1. Placebo needle

For this study we used a special type of placebo needle; an adhesive ring with a cone, having a central hole (that cannot be seen when attached to skin), that allows the passage of a blunt tip needle of 1.5 cun (Chinese anatomical inch), whose shaft telescopes into the handle without penetrating skin By this procedure the patient can only perceive a feeling of pressure. The patients included in both groups had no previous experience with acupuncture treatment. For real acupuncture treatment we used a sharp tip needle of 1.5 cun to penetrate the skin. In both cases the same length of needle handle could be seen outside the cone which keeps the needle in place. The needles were connected to an electro-acupuncture device with a led indicator to increase procedure credibility. The placebo group received a dummy stimulation, without current intensity. For the real acupuncture group the electrical device was set to 5–10 Hz and intensity to elicit light muscular twitching. The placebo procedure used (Park et al., 2002) is similar to other validated and published procedures (Kleinhenz et al., 1999; Park et al., 2002; Sherman et al., 2002; Streitberger and Kleinhenz, 1998).

We used this non-penetrating placebo because it has been reported that a penetrating placebo (sham) can elicit neurological response and therefore may not have an inert clinical effect (NIH Consensus Conference, 1998).

2.5.2. Treatment procedure

Patients received a real acupuncture or placebo session every week, for 8 weeks, by two licensed (three years long title on Chinese acupuncture) acupuncturists (Guerra de Hoyos and Vigára Lopez); both with more than four years experience in a primary care pain program with acupuncture and moxibustion techniques. Both acupuncturists have treated several thousand cases of shoulder pain patients and written a 201 case series (Guerra et al., 2003) and several congress communications.

The rationale for elected real acupuncture treatment was based on Chinese medicine (Bi Syndrome, channels involved, local and distant points election) and experience points Wang (Wang et al., 1990), but we used the same four points (see Box 1) for every patient to standardize treatment making for easier statistical analysis and enabling

Box 1: Classification and location of acupoints used for treatment

Local points

Jianyu LI 15. superior to deltoid muscle in a depression anterior and inferior to the acromion when the arm is abducted.

Jianliao TE 14. posterior to Jianyu in the depression inferior and posterior to the acromion when the arm is abducted.

Distal points (opposite leg to shoulder lesion)

Yanglingquan GB 34 on leg lateral side in the depression anterior and inferior to the head of the fibula.

Zhongping Extra point 1–2 cm below Zusanli ST 36 (3 cun under knee interarticular level at anterior paratibial line)

Meridian abbreviation: TE, triple energizer; LI, large intestine; GB, gallbladder; ST, stomach.

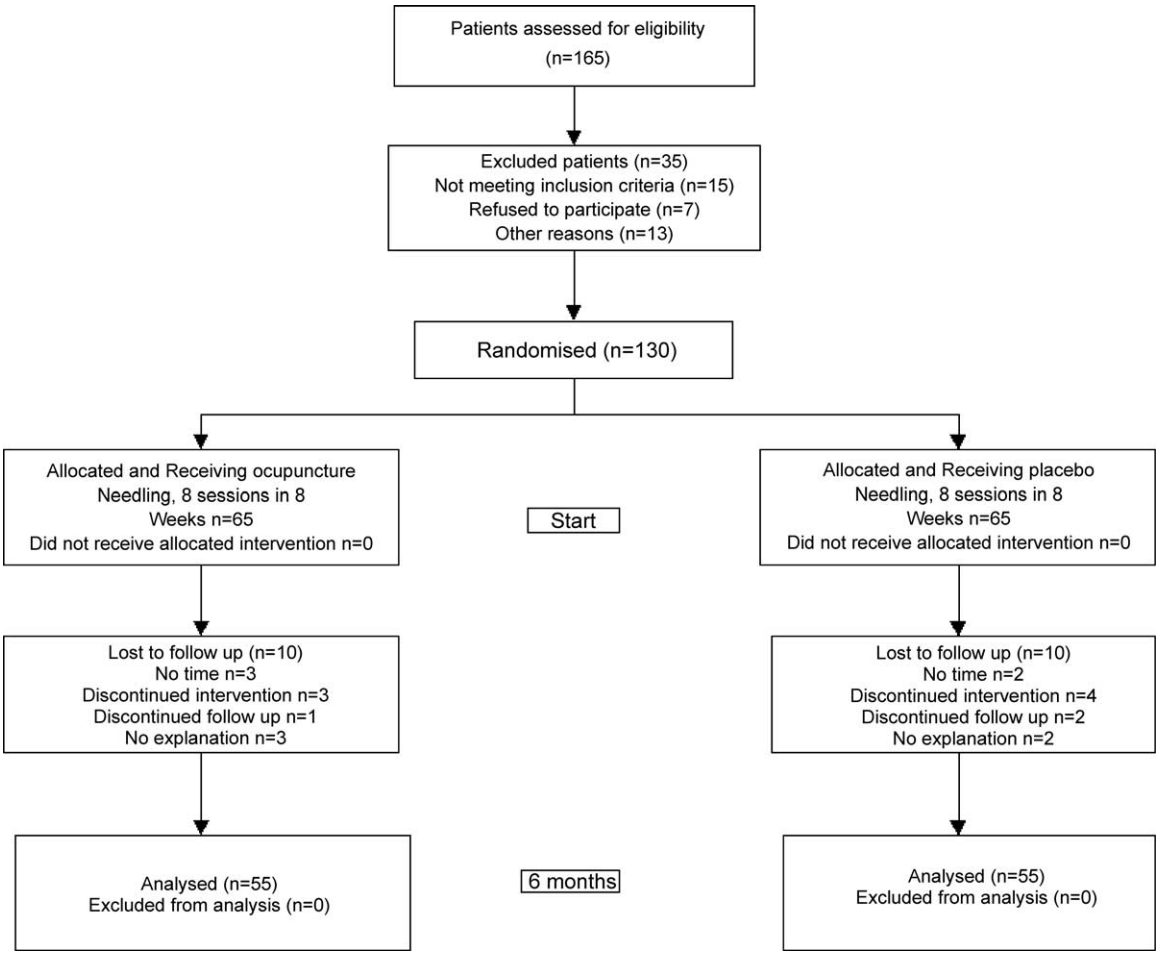

Fig. 1. Trial profile.

the acupuncturist to apply treatment without knowing symptoms or diagnosis, 2 local points on the affected shoulder and 2 distant points in the opposite leg. This procedure was tested versus individualized treatment in a pilot study at the pain program practice, finding similar effect. Depth of needle insertion was 1 cun for all the locations. The acupuncturist first inserted leg needles, elicited Deqi and connected terminal wires of the electro-acupuncture device asking the patient to elevate the arm several times with the elbow extended as much as possible for 2–3 min. After that acupuncturist inserted shoulder needles and connected them to the electro-acupuncture device. All the needles were retained for 15 min and were stimulated during retention time with dense disperse waves of 5–10 Hz at sufficient intensity to elicit light muscular twitching. For placebo-acupuncture we followed the same procedure, but with the difference that a blunt needle was used, so it did not penetrate the skin, and the electrical device gave dummy stimulation to the needles, both groups were treated in the same manner by the acupuncturist (except for placebo or real acupuncture depending on allocation group, which he knew via a telephone call) who tried not to give or receive any information to, or from, the patients, he applied the fixed set of points without having or making any diagnosis or evaluation.

We used Chinese made filiform needles (Hao type), 0.32 gauge. Blunt tip 1.5 cun length with telescopic handle, and sharp point 1.5 cun length, imported by Hispasia S.S. C/Virgen de Aguas Santas 8 41011 Sevilla and Electronic Acupuntoscope Model WQ-6F, manufactured at Beijing.

2.6. Outcomes

The primary outcome variable was the difference between groups in pain intensity measured by visual analogue scale (VAS), a widely validated numerical scale Secondary variables were differences between groups in: pain measured by Lattinen Index, an index scale for pain intensity, easier to understand by patients with low socio-cultural level; range of movement (ROM) measured with a goniometer attached to arm and thorax, asking patient maximal arm abduction; number of pills consumed every week; change from baseline on SPADI global numerical score; pain and disability subscales scores (SPADI used visual analogue scales to rate 13 items related to shoulder-specific pain with five items and disability with 8 items, rating each item from 0 to 10,

with 10 indicating the greatest pain or disability); credibility score before and after intervention; quality of life score measured with COOP/WONCA charts, an instrument that consists of six charts that measures six core aspects of functional status: physical fitness, feelings, daily activities, social activities, change in health and overall health. Each chart consists of a simple title, a question referring to the status of the patient and an ordinal five-point response scale illustrated with a simple drawing. Each item is rated on this five-point ordinal scale ranging from 1 ('no limitation at all') to 5 ('severely limited'); for 'change in health' score 1 means 'much better' and score 5 'much worse'. Global score reflects functional capacity, from 6 (no limitation at all) to 30 (severely limited); final global satisfaction with treatment measured with a numerical scale from no satisfaction at all (0) to maximal satisfaction (10). Assessment was always made the day before a treatment session. We did not separate control group from intervention group patients so as not to disclose an allocation sequence to the observer. We also registered general variables (age, gender, socio-cultural level, working status, previous trauma, litigation) that could affect outcomes.

2.7. Follow-up

Acupuncture treatment (real or placebo) was performed weekly during seven weeks. We chose a seven weeks treatment because previous findings suggested that it would be enough to produce a sustained effect.

An independent observer performed an examination the day before each treatment session. In all of these evaluations data of pain intensity, functional ability, range of movement and medication recovered were recorded.

After evaluating and treating patients for seven weeks, independent evaluators performed two other evaluations at 3 and 6 months from the beginning, to test the maintenance of effects after finishing treatment (Fig. 1). In addition, in the last visit (sixth month) they recorded credibility, quality of life and final global patient satisfaction with the treatment.

2.8. Sample size

At the start of the trial we had not found any similar studies estimating possible magnitude effects. A difference in improvement between groups of 2 points in pain intensity (VAS) and 30° in range of movement were considered clinically relevant. From a pilot study of eight week of follow-up, standard deviations of 3,8 (improvement in VAS) and 50 were assumed. It was calculated that 100 patients were needed to obtain a statistical power over 80% and a significance level of 0.05 in both outcomes. We estimated a drop out of 20% and therefore we aimed to recruit 130 patients.

2.9. Statistical analysis

Baseline summary statistics are reported as mean (SD) for continuous variables and as number and percentage from total (%) for categorical variables Primary and secondary outcomes are presented as mean data and SD for each group and mean difference between group and 95% CI. A positive value in difference indicates a beneficial change. All results were evaluated after seven weeks, three and six months of treatment. Statistical analyses of all study variables were based on intention to treat analysis. Analysis of covariance was used to compare end points. We entered baseline scores into regression models as covariates. A sensitivity analysis was run to examine the possible effects of missing data. Missing data were imputed using linear regression, on the basis of baseline characteristics. Treatment group (acupuncture or control) was deliberately excluded from the model as a conservative measure. The software used was SPSS v.12.0.

3. Results

3.1. Recruitment and baseline characteristics

Between 1 September 2001 and 15 November 2002, 165 patients applied for inclusion in the study 35 patients did not qualify for inclusion or violated the exclusion criteria. One hundred and thirty patients were randomly assigned to the treatment groups after the initial assessment. Sixty-five patients were assigned to each group, placebo or treatment. Baseline characteristics are shown in Table 1.

Twenty patients dropped out and did not present for end-point assessment. In the acupuncture group three patients stopped participation due to lack of time, three did not finish treatment because they found treatment painful, one did not complete follow-up visits, and three stopped participation without any explanation. In the control group two patients had not enough time, four stopped intervention sessions because they did not notice pain relief, two did not complete follow-up visits and two stopped participation without explanation.

No additional treatments during the study were reported by any patients of either group.

3.2. Outcomes

3.2.1. Primary outcome measure: improvement in pain measured by VAS

After intervention the acupuncture group showed a significantly greater improvement in pain than placebo group, measured as difference in VAS after seven weeks of starting treatment (Table 2) In the primary analysis pain score was significantly lower in the acupuncture group The score fell by 43% in the acupuncture group compared with 20% in controls ($P<0.001$). This result was robust

Table 1
Baseline characteristics for primary and secondary outcomes measured

Characteristics	Placebo ($n=65$)	Acupuncture ($n=65$)
Mean age in years (SD)	59.7(10.0)	58.6(11.9)
Sex		
Female (%)	49(75)	48(74)
Marital status		
Married (%)	50(77)	52(80)
Others (%)		
Widowed	11(17)	6(9)
Divorced	4(6)	1(2)
Single	0(0)	6(9)
Education level		
No education (%)	9(14)	9(14)
Others (%)		
Primary school	45(69)	32(49)
Secondary school	9(14)	17(26)
University	2(3)	7(11)
Working status		
Not working (%)	16(25)	8(12)
Habits		
Smoking (%)	19(15)	12(18)
Alcohol intake (%)	6(9)	4(6)
Physical exercise		
None (%)	29(45)	36(55)
Some (%)		
Not regular	15(23)	15(23)
Regular	21(32)	14(22)
Clinical data		
Shoulder pain diagnosis		
Capsulitis (%)	9(14)	10(15)
Tendinitis (%)	56(86)	54(83)
Pain location		
Right side (%)	44(68)	40(62)
Duration of symptoms (months (SD))	5.7(6.1)	6.8(8.6)
Previous episode (%)	37(57)	27(42)
Repetitive strain injury (%)	20(31)	22(34)
Previous trauma (%)	10(15)	14(21)

Data are numbers (percentages) of participants unless otherwise indicated.

Table 2
Primary outcome for placebo and acupuncture groups: pain measured by VAS

Time	Mean scores (SD)		Difference between groups		
	Placebo ($n=55$)	Acupuncture ($n=55$)	Mean[a]	CI 95%	P
Baseline	6.3(1.9)	6.1(2.5)	NA	NA	NA
After treatment					
7 weeks	2.8(2.6)	1.1(1.3)	1.5	0.8–2.3	<0.0005
3 months	3.0(2.8)	1.3(2.1)	1.5	0.6–2.5	<0.0005
6 months	3.5(3.0)	1.2(1.9)	2.0	1.2–2.9	<0.0005

Higher scores indicate greater severity of pain. Differences between groups are calculated by analysis of covarianza. Values are means (SD). *VAS, Visual Analogue Scales (range 0–10); NA, not applicable.
[a] Adjusted differences: positive favours acupuncture.

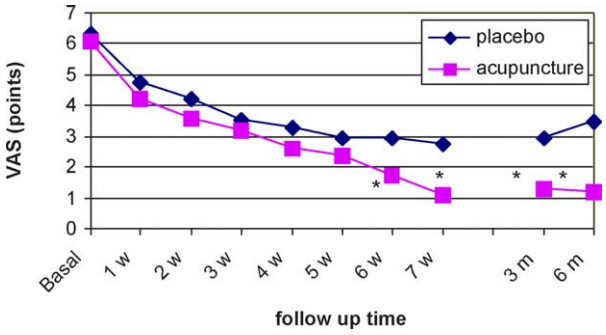

Fig. 2. Pain intensity scores (VAS) over time by intervention group.

to secondary analysis including imputed missing data (difference between groups of 1.34, $P<0.001$). The effect was already shown at the sixth week and was maintained up to 3 months and 6 months after starting treatment (Table 2 and Fig. 2). Again these results were robust to secondary analysis including imputed missing data (difference between groups of 1.5 $P<0.0005$ at 3 months; 2.0, $P<0.0005$ at 6 months) (Table 2).

3.2.2. Secondary outcomes

There were also differences between groups in pain measured by Lattinen Index (Table 3 and Fig. 3). In the same way, the acupuncture group experienced a significant improvement in pain and disability measured by SPADI scale as global score (Table 3). Differences were already statistically significant at the first week after starting treatment (Fig. 4).

The acupuncture group showed a significantly greater improvement in range of motion at seven weeks of treatment (Table 3). Again effect was maintained up to six months (Table 3 and Fig. 5).

The acupuncture group showed a significantly lower consumption of diclofenac from the first session up to seven weeks of treatment (Fig. 6). Again effect was maintained up to six months: an average of 3 tablets/week in the acupuncture group vs. 8 tablets/week in the placebo group.

Credibility and quality of life were measured at entry before placebo or acupuncture intervention and at final visit (six months). The acupuncture group showed a significantly higher change in credibility (12%, $P<0.001$). In placebo group the change was 4%. Quality of life improvement was

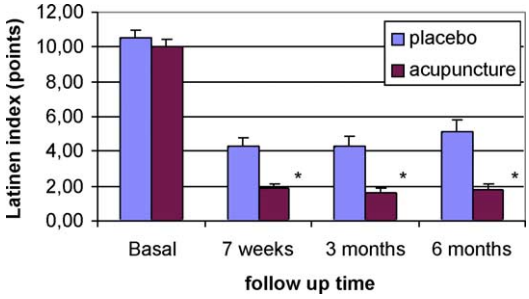

Fig. 3. Evolution in pain intensity (Lattinen index). Values are mean (SE).

Table 3
Secondary outcomes for placebo and acupuncture groups, at baseline, seven weeks (7 w), three months (3 m) and six months (6 m) after treatment: improvement of pain (Lattinen index[a], SPADI questionnaire[b]), range of motion, quality of life[c] and credibility[d]

Outcome/time	Mean (SD)		Difference between groups		
	Placebo $N=55$	Acupuncture $N=55$	Mean[e]	CI 95%	P
Lattinen index					
Baseline	10.6 (3.4)	10.0 (3.5)	NA	NA	NA
7 w	6.2 (4.4)	7.9 (3.9)	2.2	1.1–3.3	<0.0005
3 m	6.2 (4.9)	8.3 (4.0)	2.6	1.3–3.8	<0.0005
6 m	5.4 (5.2)	8.0 (3.9)	3.0	1.6–4.3	<0.0005
Range of motion (degrees)					
Baseline	96.1 (29,3)	102.5 (28.9)	NA	NA	NA
7 w	26.2 (29.7)	51.0 (27.6)	27.2	16.9–37.5	<0.0005
3 m	23.2 (34.7)	54.6 (30.1)	33.9	22.8–45.0	<0.0005
6 m	21.2 (36.2)	56.9 (32.1)	38.1	26.5–49.7	<0.0005
SPADI, global index					
Baseline	76.5 (24.3)	67.6 (28.9)	NA	NA	NA
7 w	48.5 (29.7)	60.9 (28.0)	17.0	8.6–25.4	<0.0005
3 m	46.7 (33.2)	59.6 (28.0)	18.3	9.7–26.9	<0.0005
6 m	41.8 (34.1)	59.0 (28.0)	22.1	13.2–13.2	<0.0005
SPADI, pain index					
Baseline	31.0 (10.1)	27.2 (11.3)	NA	NA	NA
7 w	20.7 (13.5)	24.0 (11.5)	6.4	3.1–9.7	<0.0005
3 m	19.6 (14.2)	23.6 (12.2)	6.9	3.5–10.4	<0.0005
6 m	17.3 (14.1)	23.2 (11.9)	8.1	4.4–11.2	<0.0005
SPADI, disability index					
Baseline	44.7 (16.9)	40.4 (19.5)	NA	NA	NA
7 w	28.3 (19.3)	36.8 (18.4)	11.7	6.2–17.2	<0.0005
3 m	27.1 (21.1)	36.0 (18.0)	11.9	6.4–17.3	<0.0005
6 m	24.4 (21.3)	35.8 (18.0)	13.4	7.8–19.0	<0.0005
Credibility					
Baseline	16.1 (7.1)	16.0 (2.6)	NA	NA	NA
6 m	15.5 (3.3)	18.3 (2.2)	2.7	1.7–3.7	<0.0005
Quality of life					
Baseline	16.9 (3.7)	16.6 (3.9)	NA	NA	NA
6 m	16.3 (3.9)	13.3 (4.1)	2.6	1.2–3.9	<0.0005

Values are means (SD).
[a] Lattinen index (0–22).
[b] Shoulder pain and disability Index: Global index (0–130), Pain index (0–50) and Disability index (0–80).
[c] Credibility: Borkovek-Nau Scale (0–20).
[d] Quality of life: COOP/WONCA CHARTS (30–0): lower scores mean higher quality of life. Differences between groups are calculated by analysis of covariance.
[e] Adjusted differences: positive favours acupuncture. NA, not applicable.

also greater with active treatment: about a 5.3% for placebo and 20% for the acupuncture group (Table 3).

At final visit, at six months, final satisfaction was similar in both groups: 8.9 (SD, 1.1) for the placebo and 9.3 (SD, 1.0) for the acupuncture group.

3.3. Adverse effects

Two patients fainted during treatment, both in the intervention group, they finished treatment sessions and follow-up Three patients in the intervention group reported dizziness. Five patients reported dyspepsia, one in the intervention group and four in the control group. Three patients, one in the intervention group and two in the control group, reported anxiety reaction. Five patients reported bruising at puncture site, all in the intervention group.

4. Discussion

The statistical analysis of the results showed a significant difference in the VAS score between the groups ($P<0.001$); the results of Lattinen index are consistent with VAS.

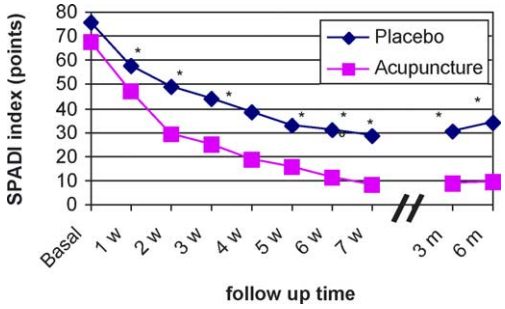

Fig. 4. SPADI score over time by group of intervention.

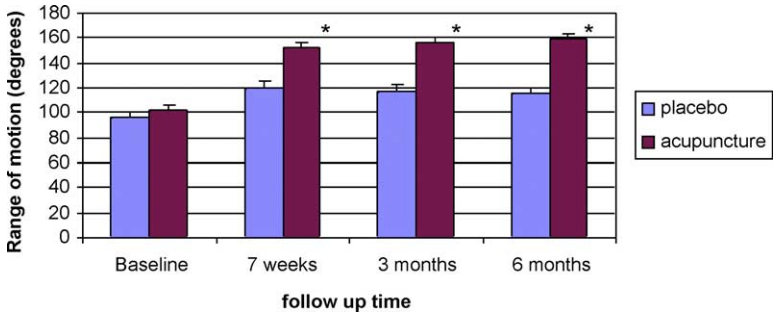

Fig. 5. Range of motion evolution. Values are means (SE).

The results also showed statistically significant differences in Spadi score, ROM (Range of Motion) scores, Coop Wonca score and NSAIDS intake. Between the groups, differences increased after treatment finished. Difference in the magnitude of effect on range of movement and functional ability were greater than those obtained on pain intensity, showing greater effect on more objective outcomes. All results consistently suggested that real acupuncture is more effective than placebo-acupuncture to treat pain and disability in patients with shoulder pain from different causes, mainly rotator cuff disease and capsulitis.

The placebo procedure and the therapeutic setting used, were similar for both groups, the placebo procedure has been validated on volunteers and patients (Kleinhenz et al., 1999; Park et al., 2002). The connecting of needles to the electro-acupuncture device could increase procedure credibility as the patient can watch the device led light, but this have not been studied, patients allocated to placebo experienced pressure from blunt needles and had not previously experienced acupuncture treatment so the procedure could be credible. We did not find a way to keep the therapist blinded so they could be influenced by patients reports, but they were instructed not to ask patients symptoms, and outcomes were evaluated on a different day to the technique application by a different independent evaluator blinded to patient group allocation, final credibility score only changed 4% from starting baseline in this group. Credibility scales ascertained no statistical differences between groups on patients' expectations at the beginning. Baseline credibility score was high showing patients in both groups expected that acupuncture could help

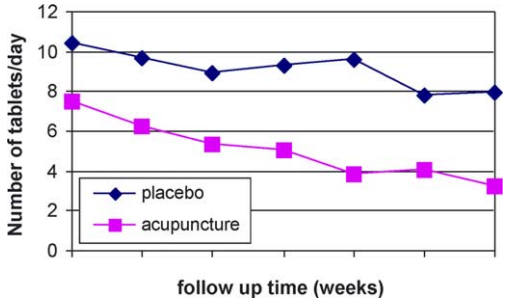

Fig. 6. Diclofenac consumption over time by intervention group. Values are means.

their problems, and this could have contributed to pain relief in both groups. Credibility scores showed little change from baseline to six month follow-up scores showing patients were kept reasonably blinded; slight increase in intervention group and slight decrease in the placebo group was probably because patients in the intervention group noticed more pain relief and higher functional increase than placebo group patients.

The control group improved from baseline level probably by a combination of placebo effect, diclofenac effect, natural recovery and regression to the mean phenomenon. Final satisfaction was high for both groups without statistically significant differences between groups, probably because patients in both groups found fulfilment of pain relief expectations, were happy with investigators care and were not aware of differences of results between the groups and blinded for real acupuncture or placebo-acupuncture.

Berry et al. do not find significant differences; they used lower sample size and different acupuncture techniques than us. We chose longer follow-up time and greater sample size, producing results with statistically significant differences. Kleinehenz et al. find significant results on 52 sportsmen using manual acupuncture on a combination of up to 12 points (local and distal) and a non-penetrating placebo similar to ours, but different outcome measures preclude the comparison of effect magnitudes.

From the end of treatment at eight weeks to the 6-month follow-up, mean pain intensity increased and functional ability decreased in the control group, and differences with the intervention group increased. The intervention group maintained or increased the effects after finishing treatment. This is consistent with studies on natural history that show that a subgroup of patients evolves to chronic shoulder pain, by contrast, effect is maintained in most intervention group patients suggesting a long term effect, and that 8 weeks treatment with these acupuncture techniques is enough to reach sustained effect in most patients. We cannot state the same conclusion for others acupuncture techniques or for shoulder pain radiating from neck or chest.

We are not able to make an economic evaluation of both interventions. Differences in costs between groups come from disposable needles costs in acupuncture group

and differences in drug use between groups. This favours the acupuncture group; but the control group is not a usual care group so we can not make conclusions. We would need rigorous cost evaluation studies of acupuncture intervention compared with usual care that comprise consultations, products, adverse reactions, interactions and other costs and direct benefits. Treatment of pain by acupuncture may lead to considerable savings by prevention of adverse effects of NSAIDs (Ernst et al., 2001).

There are many different acupuncture techniques. To prove which techniques are effective for what diseases we need rigorous trials using valid placebo, long follow-up, sufficient sample size, and acupuncture techniques performed by teams experienced in both acupuncture and research, we also need consensus on outcome measures making it possible to pool results from different trials.

5. Conclusion

We conclude that this acupuncture technique can be a safe and effective form of treatment for patients with shoulder pain (from soft tissues origin) if the long term goal is pain relief, increasing functional ability, quality of life and patient satisfaction, and reducing NSAIDS intake. As shoulder pain has an important patient, social and economic impact, acupuncture deserves consideration.

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