Randomised controlled trial of contralateral manual acupuncture for the relief of chronic shoulder pain

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ABSTRACT

Objective To explore the effects of contralateral manual acupuncture (MA) on patients with chronic shoulder pain.

Methods Eighty patients with chronic shoulder pain were randomly allocated to receive contralateral MA (n=38) for 4 weeks or to remain on a waiting list while receiving conventional orthopaedic therapy (n=42). Visual analogue scale (VAS) scores were taken as the primary outcome measure and used for *a priori* power calculation. Secondary outcome measures for the assessment of shoulder mobility and quality of life included the Jobe test, the Constant-Murley (CM) score, the Disabilities of the Arm, Shoulder and Hand (DASH) score, and the 36 item Short Form Health Survey (SF-36).

Results Intention-to-treat (ITT) analysis demonstrated significant pain relief with contralateral acupuncture, with mean differences in VAS scores compared to the waiting list group of −19.4 (−28.0 to −10.8) at 2 weeks, −40.4 (−49.0 to −31.8) at 4 weeks, −41.1 (−49.7 to −32.5) at 8 weeks, and −40.9 (−49.5 to −32.3) at 16 weeks. CM and DASH scores were also improved at all time points ($p<0.01$). Shoulder mobility, physical functioning, social functioning and mental health components of the SF-36 were also improved by contralateral acupuncture at 8 weeks. No significant adverse effects were observed.

Conclusions These results demonstrate beneficial effects of contralateral acupuncture in the treatment of chronic shoulder pain, both in terms of pain and function. Future research is required to compare directly the effects of local and contralateral acupuncture and to quantify the specific and non-specific effects.

Trial registration number NCT01733914.

INTRODUCTION

Chronic shoulder pain is a common condition in middle-aged individuals and is often accompanied by restricted mobility or stiffness. It is most commonly caused by rotator cuff disorders, adhesive capsulitis (frozen shoulder) or osteoarthrosis of the glenohumeral joint. It may be of sudden or gradual onset, is frequently accompanied by pain at night and on moving the affected joint, and is usually self-limiting with a typical duration of 1 year or longer.[1 2] Routine treatment options for shoulder pain include non-steroidal anti-inflammatory drugs, physiotherapy, cortisone injections, and conservative management.[3] Although these treatments alleviate shoulder pain in the short term, there is little convincing evidence of long-term benefit, with respect to either pain or shoulder mobility.[1–3]

Acupuncture has been used in China for over 2000 years to treat a variety of diseases such as pain and nausea. Chronic shoulder pain is considered to be one of the symptoms most amenable to acupuncture treatment. Several randomised controlled trials (RCTs) have investigated the effects of acupuncture for the treatment of shoulder pain, with different combinations of acupuncture points, treatment protocols and methods of needle stimulation,[4–14] all of which potentially influence the therapeutic outcome of acupuncture treatment.[15–19] While most acupuncture trials have involved acupuncture needling close to the site of pathology, with or without addition of distal or contralateral acupuncture points, many Chinese medical practitioners purely use acupuncture points contralateral to the site of pain to treat unilateral limb pain, such as that arising from the shoulder or leg.[15 20] However, there is little scientific evidence to validate the clinical effects of contralateral acupuncture in morbid subjects, despite there having been several studies

in animals and healthy human volunteers.[18 19] The aim of the present study was to examine the effects of contralateral manual acupuncture (MA) on pain, mobility, and quality of life measures, compared with being on a waiting list and receiving conventional orthopaedic therapy in patients with chronic shoulder pain, using an RCT design.

METHODS

Participants

Patients with chronic shoulder pain were recruited from office-based pain medicine physicians (CW, CY and WW) in the Sichuan Hospital of Integrated Chinese and Western Medicine from November 2012 to April 2013. Based on the standard diagnosis of chronic shoulder pain, the eligibility criteria included: one-sided shoulder pain of at least 6 weeks and up to 2 years duration; an average pain score of 50 mm or more on a 100 mm visual analogue scale (VAS) in the past week; age between 25 and 65 years; the ability to communicate in Mandarin; a positive Neer or Hawkins impingement sign and positive Jobe test; and willingness to participate in the study. Patients with any of the following clinical criteria were excluded: neurological disorders causing shoulder pain; referred pain from the cervical spine; osteoarthritis of the glenohumeral joint or systemic bone and/or joint disorder (eg, rheumatoid arthritis); history of shoulder surgery; current therapy involving analgesics; overt psychiatric illness; pregnancy; incapacity for work for longer than 3 months preceding the trial; diabetes mellitus; disorders of blood coagulation; history of steroid injection or physiotherapy on the affected shoulder; and unwillingness to sign the written consent form. All patients were informed about the aims, procedures and grouping possibilities of the trial and informed consent was obtained. The study was conducted in accordance with the Declaration of Helsinki and the guidelines for Good Clinical Practice. The protocol was assessed and approved by the ethics review board of Peking University Health Science Center and prospectively registered in the US National Institutes of Health registry (www.clinicaltrials.gov/ct2/show/NCT01733914).

Sample size calculation

Assuming a standard deviation (SD) in VAS score of 16.7, derived from our pilot trial,[13] it was estimated that 33 subjects per group would be needed to detect a 15 point difference in mean change of VAS at 80% power and α level of 0.05. Taking into consideration a 20% anticipated dropout rate, we aimed to recruit a total of 80 patients.

Grouping and intervention

Patients were randomised (by HZ) to one of two parallel groups using a random number table: the contralateral acupuncture group and the waiting list (control) group. Patients in the acupuncture group received five 30 min MA treatments per week for a total of 4 weeks. MA was administered by a single experienced acupuncturist (JS). Based on meridian-based acupuncture theories, the following four acupuncture points were chosen: TE3 (*Zhongzhu*), on the dorsum of the hand, between the fourth and fifth metacarpal bones, in the depression proximal to the fourth metacarpophalangeal joint; SI3 (*Houxi*), on the dorsum of the hand, in the depression proximal to the ulnar side of the fifth metacarpophalangeal joint, at the border between the red and white flesh; LI11 (*Quchi*), on the lateral aspect of the elbow, at the midpoint of the line connecting LU5 with the lateral epicondyle of the humerus; and ST38 (*Tiaokou*), on the lower leg, midway between the tibiofemoral joint line (level with the popliteal crease) and the prominence of the lateral malleolus, one finger-breadth lateral to the anterior crest of the tibia. The following additional acupuncture points contralateral to the site of pain could be selected to treat complications such as hypertension: GB34 (*Yanglingquan*), ST36 (*Zusanli*), SP6 (*Sanyinjiao*), and BL62 (*Shenmai*). Sterile acupuncture needles (25–50 mm in length, 0.25 mm in diameter, Huatuo, Suzhou Medical Co Ltd, China) were inserted to a depth of 20–30 mm at ST38 and 10–15 mm at all other points and were twisted approximately 180° in each direction at increasing frequency from 0.3 to 1 Hz to induce the *de qi* sensation (a radiating feeling of heaviness and numbness around the needling site, considered to indicate effective needling) for 30 s. Needle manipulations were repeated every 5 min.

Patients in the control group received conventional orthopaedic therapy including physical exercise (daily gentle rising up and laying down of the affected arm), heat or cold therapy. Intensive exercises such as ball games involving the affected arm were not allowed. Diclofenac use was allowed, up to a maximum of 50 mg (1 tablet) daily for no more than three consecutive days when the patient was suffering from pain. The maximal amount of diclofenac each patient could take during the trial was 500 mg (10 tablets). Injections or cortisone applications of any kind were not allowed.

Clinical assessment

The researchers responsible for clinical assessment (CY and WW) were blinded to the group allocation. Personal data and details of the patient's medical history and present condition were obtained in the outpatient office and included age, gender, localisation and duration of shoulder pain.

Pain intensity was recorded on a 100 mm VAS by the patients themselves, with 0 mm representing 'no pain at all' and 100 mm representing the 'most intense pain imaginable'. The VAS score at the end of treatment was the primary outcome measure in this

trial. Secondary outcome measures for assessment of shoulder mobility and quality of life included the Jobe test, the Constant-Murley (CM) score,[21] the Disabilities of the Arm, Shoulder and Hand (DASH) score,[22] and the 36 item Short Form Health Survey (SF-36).[23]

On physical examination, the clinician twisted or elevated the patient's arm to test for reproducible pain (Neer's sign and Hawkin's test). The Jobe test was performed as follows, with the patient positioned supine. With the shoulder abducted to 90° and the elbow held in 90° of flexion, the shoulder was externally rotated until the patient became apprehensive. The degree of external rotation at the onset of apprehension was noted. The shoulder was then brought back to a resting position and external rotation was repeated, this time with the application of posteriorly directed force over the humeral head. The degree of external rotation when the patient became apprehensive was again noted. The test was considered positive if the range of external rotation at the shoulder was greater in the presence of posteriorly directed stress over the humeral head compared to without.

The VAS score (average pain level over the previous 7 days), Jobe test, CM, and DASH scores were evaluated before group allocation (baseline), and at 2, 4, 8, and 16 weeks after the start of treatment. The SF-36 form was evaluated before treatment then 8 and 16 weeks later. In the case of treatment protocol failures, the reasons were documented (eg, need for surgery, worsening of the condition). At the end of the trial, each patient in the acupuncture group who received at least one treatment was questioned as to whether they had experienced any adverse effects from acupuncture treatment—for example, severe pain, dizziness or needle fractures.

Data processing and analysis

Data analysis was performed by MZ using an intention-to-treat (ITT) analysis. Accordingly, patient data were analysed according to group allocation at randomisation, irrespective of compliance or adherence to the trial protocol. Missing data were replaced with data from the previous clinical assessment.

The two groups were compared using repeated measures analysis of variance (ANOVA) for metrically scaled, continuously distributed variables (age, duration of chronic pain, VAS, CM score, and SF-36), and the χ^2 test for nominally and ordinally scaled variables (gender, location of pain, and Jobe test). Data are presented as mean±SD.

RESULTS

Participants

As shown in figure 1, a total of 80 outpatients who satisfied the inclusion criteria were recruited and randomly allocated to the acupuncture group (n=38) and waiting list group (n=42). All baseline characteristics

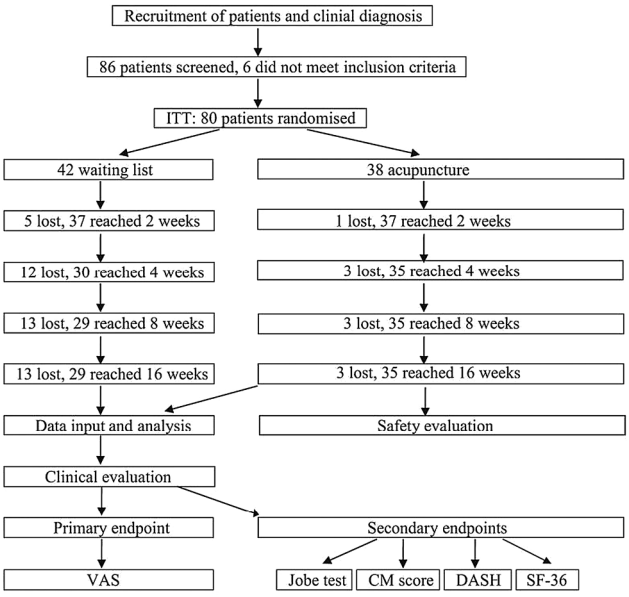

Figure 1 Flow chart of the trial. CM, Constant-Murley; DASH, Disabilities of the Arm, Shoulder and Hand score; ITT, intention to treat; SF-36, 36 item Short Form Health Survey; VAS, visual analogue scale.

(gender, age, affected shoulder, duration of pain, and baseline VAS) were similar between groups (table 1). Overall, 62.4% of all participants were female. Patients were 45.0±7.4 years old and reported moderate to severe pain that had lasted for 8.3±3.6 months on average. In 33.8% of cases the pain was in the left shoulder. During the course of the trial, 11 of 42 patients in the control group, and nine of 38 in the acupuncture group, consumed a total of 2650 mg (53 tablets) and 2150 mg (43 tablets) of diclofenac, respectively (63.1±114.8 vs 56.6±111.0 mg, p=0.8). No serious adverse effects were reported by patients in the acupuncture group.

Clinical assessment

Shoulder pain levels, measured using the VAS scale, differed significantly between the contralateral acupuncture and waiting list groups ($p<0.01$) from 2 weeks post-treatment until the end of the trial (table 2). The same pattern was observed in the CM pain score ($p<0.01$; table 3). In addition to pain, contralateral acupuncture also improved shoulder mobility, as indicated by the increasing proportion of participants with a negative Jobe test, which was significantly greater than the waiting list group from 4 weeks post-treatment onwards (table 4), as well as the CM range of motion scores and the DASH scores ($p<0.01$ each). The CM activities of daily living score also significantly increased following contralateral acupuncture at all time points ($p<0.01$), which mirrored improvements in several quality of life measurements in the SF-36 assessment at 8 weeks including physical functioning, physical role, social functioning, and

Table 1 Baseline characteristics of recruited patients

Baseline characteristic	Waiting list (n=42)	Acupuncture (n=38)	p Value
Gender			0.13
Male	19 (45%)	11 (29%)	
Female	23 (55%)	27 (71%)	
Affected shoulder			0.93
Right	28 (67%)	25 (66%)	
Left	14 (33%)	13 (34%)	
Age (years)	45.6±7.6	44.3±7.2	0.44
Duration of pain (months)	8.5±3.9	8.2±3.3	0.72
VAS score	64.0±8.9	63.7±10.2	0.87

Data are mean±SD unless otherwise stated.
VAS, visual analogue score.

mental health. However, most of the improvements revealed by the SF-36 rebounded by 16 weeks (with the single exception of physical role). The general health and emotional role scales were not impacted by acupuncture treatment at any stage ($p>0.05$).

DISCUSSION

Chronic shoulder pain causes severe discomfort and reduces the ability to work. Its origin is multifactorial and not always clear. There are no universally accepted guidelines for the conventional treatment of shoulder pain.[1 3] Nevertheless, shoulder pain is one of the most intensively studied clinical conditions with respect to acupuncture therapy. Patients recruited in the present study had a mean VAS score of 63.9 and mean pain duration of 8.4 months, both of which are typical of chronic shoulder pain and comparable to previous studies.[4–14] Based on both traditional Chinese medical literature[20] and clinical practice, the acupuncture protocol consisted of a set of acupuncture points located on the opposite side of the body to the pain. This is very different from previous acupuncture trials on shoulder pain, which have used acupuncture points close to the shoulder[8–10] or a combination of local and distal/contralateral acupuncture points.[4–7] In the present study, some acupuncture

Table 2 Effects of contralateral acupuncture on the VAS score (primary endpoint) of patients with chronic shoulder pain

	Waiting list (n=42)	Acupuncture (n=38)	Mean difference (95% CI)
Baseline	64.0±1.4	63.7±10.2	−0.4 (−8.9 to 8.2)
2 weeks	58.6±8.7	39.2±13.4**	−19.4 (−28.0 to −10.8)
4 weeks	51.2±15.5	10.8±17.0**	−40.4 (−49.0 to −31.8)
8 weeks	51.9±17.8	10.8±15.1**	−41.1 (−49.7 to −32.5)
16 weeks	51.7±17.2	10.8±19.8**	−40.9 (−49.5 to −32.3)

Data are mean±SD unless otherwise stated. **p<0.01 compared with waiting list group, using repeated measures ANOVA.
ANOVA, analysis of variance; VAS, visual analogue score.

Table 3 Effects of contralateral acupuncture on secondary endpoints of patients with chronic shoulder pain

	Waiting list (n=42)	Acupuncture (n=38)	Mean difference (95% CI)
CM scores			
Pain score			
Baseline	3.5±3.0	4.6±3.4	1.1 (−0.5 to 2.8)
2 weeks	4.6±2.0	7.9±2.5**	3.3 (1.6 to 4.9)
4 weeks	7.5±3.2	13.8±2.4**	6.3 (4.7 to 8.0)
8 weeks	7.7±3.0	13.7±2.5**	5.9 (4.3 to 7.6)
16 weeks	8.1±3.1	13.4±2.9**	5.3 (3.7 to 7.0)
Activities of daily living score			
Baseline	12.5±1.4	12.8±1.7	0.3 (−1.0 to 1.5)
2 weeks	13.3±1.5	16.4±2.1**	3.1 (1.9 to 4.3)
4 weeks	14.4±2.0	18.2±1.9**	3.7 (2.5 to 4.9)
8 weeks	14.4±2.0	18.2±1.9**	3.7 (2.5 to 4.9)
16 weeks	14.3±2.4	18.5±3.5**	4.2 (3.0 to 5.4)
Range of motion score			
Baseline	23.0±2.2	22.6±1.7	−0.3 (−2.1 to 1.4)
2 weeks	23.4±2.1	28.1±2.9**	4.7 (2.9 to −6.4)
4 weeks	26.1±3.1	32.5±3.1**	6.4 (4.7 to 8.1)
8 weeks	25.9±3.1	32.5±3.2**	6.6 (4.8 to 8.3)
16 weeks	26.5±3.8	32.9±3.9**	6.4 (4.7 to −8.2)
DASH scores			
Baseline	41.0±7.9	38.9±8.5	−2.1 (−7.6 to 3.4)
2 weeks	38.3±7.3	28.6±9.5**	−10.7 (−16.2 to −5.2)
4 weeks	35.6±9.4	15.5±9.6**	−20.0 (−25.6 to −14.5)
8 weeks	32.4±12.0	11.6±9.9**	−20.8 (−26.3 to −15.3)
16 weeks	26.0±12.2	9.9±7.3**	−16.1 (−21.6 to −10.6)
SF-36 scores			
Physical functioning			
Baseline	55.2±23.5	62.4±23.7	7.1 (−6.7 to 21.0)
8 weeks	55.8±23.6	70.4±23.6*	14.6 (0.7 to 28.4)
16 weeks	56.8±25.5	57.0±28.7	0.2 (−13.6 to 14.0)
Role—physical			
Baseline	10.7±22.2	11.2±23.0	0.5 (−17.5 to 18.4)
8 weeks	10.1±22.1	36.8±49.2**	26.7 (8.8 to 44.7)
16 weeks	21.4±32.0	42.8±41.5*	21.3 (3.4 to 39.3)
Bodily pain			
Baseline	55.7±12.9	57.8±10.8	2.1 (−6.5 to 10.7)
8 weeks	61.1±15.0	70.9±13.7*	9.8 (1.2 to 18.4)
16 weeks	67.8±20.8	71.1±20.6	3.3 (−5.3 to 11.9)
General health			
Baseline	58.7±19.9	55.9±18.1	−2.7 (−13.9 to 8.4)
8 weeks	57.4±20.7	54.2±18.1	−3.2 (−14.3 to 8.0)
16 weeks	53.1±21.7	55.5±21.3	2.5 (−8.7 to 13.6)
Social functioning			
Baseline	67.0±14.3	71.7±14.4	4.7 (−3.9 to 13.4)
8 weeks	69.3±13.3	80.6±13.5**	11.3 (2.6 to 19.9)
16 weeks	72.3±18.4	73.7±22.3	1.4 (−7.3 to 10.0)
Role—emotional			
Baseline	21.4±36.7	21.9±28.2	0.5 (−20.3 to 21.3)
8 weeks	25.4±40.2	43.0±40.9	17.6 (−3.2 to 38.4)

Continued

Table 3 Continued

	Waiting list (n=42)	Acupuncture (n=38)	Mean difference (95% CI)
16 weeks	34.1±34.9	43.0±37.9	8.9 (−12.0 to 29.7)
Mental health			
Baseline	54.7±11.8	57.3±10.2	2.6 (−3.9 to 9.0)
8 weeks	57.0±12.3	64.4±8.6*	7.4 (0.9 to 13.8)
16 weeks	56.3±13.4	60.9±13.6	4.7 (−1.8 to 11.1)

Data are mean±SD unless otherwise stated. *p<0.05, **p<0.01 compared to waiting list group, using repeated measures ANOVA.
ANOVA, analysis of variance; CM, Constant-Murley; DASH, Disabilities of the Arm, Shoulder and Hand; SF-36, 36 item Short Form Health Survey.

points were added to the standard protocol, mainly to incorporate the treatment of comorbid conditions such as hypertension and diabetes. These additional points were also carefully restricted to those contralateral to the source of pain to ensure that their inclusion did not affect our hypothesis. Acupuncture is most commonly applied for pain treatment, which compelled us to use the VAS score as our primary outcome measure. However, measures of shoulder mobility and quality of life were also included to gain a more comprehensive evaluation of the effects of acupuncture on both shoulder-specific and general functional ability. Since the present study is, to our knowledge, the first to examine the potential effects of contralateral acupuncture, a waiting list group was included to control for the natural course of this self-limiting pain condition and regression to the mean. Incidentally, we observed a higher dropout rate in the waiting list group, which prompted us to apply an ITT analysis.

The main finding in this study was that contralateral MA treatment was effective at reducing pain and improving mobility in patients with chronic shoulder pain. Therapeutic effects of treatment appeared early in the trial (from 2 weeks) and lasted for at least 12 weeks after the final treatment. From the end of treatment (at 4 weeks) to the last follow-up (at 16 weeks), mean pain intensity and functional ability remained significantly improved in the acupuncture group, suggesting a medium to long-term effect. In addition, acupuncture alleviated the influence of shoulder pain and disability on patients' quality of life. Collectively these results suggest that acupuncture helped recovery from chronic shoulder pain compared to the waiting list group.

Table 4 Effects of contralateral acupuncture on Jobe test in chronic shoulder pain patients

	Jobe test (negative/positive)		
	Waiting list (n=42)	Acupuncture (n=38)	p Value
Baseline	0/42	0/38	N/A
2 weeks	2/40	3/35	0.56
4 weeks	4/38	25/13	<0.001
8 weeks	5/37	29/9	<0.001
16 weeks	4/38	28/10	<0.001

Our results demonstrating reduced pain are in keeping with several previous clinical studies,[9–11] suggesting that acupuncture is superior to conservative management.[14] The most important finding from the present study is that acupuncture treatment for shoulder pain does not necessarily require needling at any acupuncture points on the painful side of the shoulder. One advantage of such contralateral acupuncture is that patients are able to freely move their affected shoulder in order to increase the range of motion while receiving treatment on the healthy side. Such movements were not allowed during the course of MA treatment in the present study to avoid a confounding influence on outcome measures, but they are commonly performed by some acupuncturists.

The present study has several limitations that must be acknowledged. Firstly, we were are unable to quantify the contribution of any placebo effects to the overall therapeutic response due to the lack of participant blinding or inclusion of a sham acupuncture group. This is particularly true for pain outcomes, which could have been affected by expectation. However, the assessment of motor function of the shoulder (a more objective measure) is arguably less likely to have been susceptible to such influences, particularly given that we blinded the assessors. As an effectiveness trial, the primary aim of the present study was to examine whether contralateral acupuncture affects the natural course of shoulder pain, therefore a waiting list group was chosen as the appropriate control for the effectiveness and safety of acupuncture. Secondly, the relatively high dropout rate in the waiting list group could have biased our results. It is possible that the attrition was of those patients that potentially experienced pain relief with conservative management, which could have left patients with a relatively more severe phenotype within the trial, potentially biasing the result in favour of acupuncture by increasing average VAS scores in the control group. However, previous studies have shown that 'self-limiting' shoulder pain usually lasts 1–3 years,[1 2] which is much longer than the duration of follow-up in this trial. Thirdly, we are unable to tell for sure whether contralateral acupuncture treatment is more effective than ipsilateral treatment, given that we did not perform a direct comparison between these two different approaches. Very few studies have compared different acupuncture protocols against each other in patients. In some clinical trials, acupuncture points distant from the pathological site are chosen as control acupuncture.[9] However, these are usually randomly chosen acupuncture points, and therefore such studies do not rule out the possibility that relatively more selective needling on the contralateral side may

have stronger efficacy. The therapeutic effects reported in the present study are comparable to the outcomes of other studies using acupuncture alone or acupuncture as an adjunct to physiotherapy.[4–14] However, we are ultimately unable to determine whether contralateral acupuncture is superior or equivalent to ipsilateral acupuncture with this design. Future RCTs comparing local and contralateral acupuncture would help answer this question and a valid sham intervention would additionally be required to completely control for the potential placebo effects. Finally, as the duration of pain in the patients recruited ranged from 6 weeks to 2 years, it remains unknown whether acupuncture might be more effective in pain of shorter versus longer durations.

In comparison to previous reports of acupuncture treatment on shoulder pain where local acupuncture points were used, the underlying mechanism of action for our treatment protocol is more likely to involve centrally-driven processes, such as descending pain inhibition and/or the immune and endocrine systems.[24 25] The release of analgesic substances such as opioids by needling could account for the non-specific component of contralateral acupuncture on pain.[24] However, the longer term therapeutic effects that were observed imply other mechanisms, such as anti-inflammatory factors for example. We hypothesise that modulation of pain- and motor-related neural circuits by acupuncture might also play a significant role. For example, many pain-related cortical and subcortical nuclei such as the anterior cingulate cortex (ACC) have large, bilateral receptive fields. Pathological and acupuncture-induced signals may well reach the same neuronal populations and interact to produce biomodulation.[18 19 25] In a previous study,[18] we showed that lesioning the ACC completely abolished the analgesic effects of contralateral electroacupuncture (EA) but had little influence on local EA.

In conclusion, the present study has demonstrated that contralateral acupuncture provides some beneficial effects in chronic shoulder pain without obvious adverse effects. Future research is required to directly compare the effects of local and contralateral acupuncture, and to determine the best method of stimulation for this particular condition.

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Contributors HZ, MY and YW raised the scientific question. HZ, LL, MY and YW designed the study. CW, CY and WW recruited the patients. JS performed the acupuncture treatment. WW and CY performed the clinical assessment. MZ performed the statistical analysis. HZ and MY drafted the manuscript. All authors read and approved the final version.

Competing interests None declared.

Patient consent Obtained.

Ethics approval Medical ethics committee of Peking University.

Provenance and peer review Not commissioned; externally peer reviewed.

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