ORIGINAL ARTICLE

Acupuncture for Chronic Shoulder Pain in Persons With Spinal Cord Injury: A Small-Scale Clinical Trial

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ABSTRACT. Dyson-Hudson TA, Kadar P, LaFountaine M, Emmons R, Kirshblum SC, Tulsky D, Komaroff E. Acupuncture for chronic shoulder pain in persons with spinal cord injury: a small-scale clinical trial. Arch Phys Med Rehabil 2007;88: 1276-83.

Objective: To determine the efficacy of acupuncture in the treatment of chronic musculoskeletal shoulder pain in subjects with spinal cord injury (SCI).

Design: Randomized, double blind (participants, evaluator), placebo (invasive sham) controlled trial.

Setting: Clinical research center.

Participants: Seventeen manual wheelchair-using subjects with chronic SCI and chronic musculoskeletal shoulder pain.

Interventions: Participants were randomly assigned to receive 10 treatments of either acupuncture or invasive sham acupuncture (light needling of nonacupuncture points).

Main Outcome Measure: Changes in shoulder pain intensity were measured using the Wheelchair User's Shoulder Pain Index.

Results: Shoulder pain decreased significantly over time in both the acupuncture and the sham acupuncture groups ($P=.005$), with decreases of 66% and 43%, respectively. There was no significant difference between the 2 groups ($P=.364$). There was, however, a medium effect size associated with the acupuncture treatment.

Conclusions: There appears to be an analgesic effect or a powerful placebo effect associated with both acupuncture and sham acupuncture. There was a medium treatment effect associated with the acupuncture, which suggests that it may be superior to sham acupuncture. This observation, along with the limited power, indicates that a larger, more definitive randomized controlled trial using a similar design is warranted.

Key Words: Acupuncture therapy; Rehabilitation; Shoulder pain; Spinal cord injuries.

MUSCULOSKELETAL SHOULDER pain resulting from upper-limb overuse is a common secondary medical complication associated with spinal cord injury (SCI).[1,2] It can lead to substantial disability, resulting in decreased functional independence and increasing the risk for other medical complications.[3-6] Although shoulder pain has long been recognized as a significant problem for people with SCI,[7,8] little has been published about its treatment. The recently published Consortium for Spinal Cord Medicine clinical practice guidelines[2] recommend rest, pharmacologic agents (eg, nonsteroidal anti-inflammatory drugs, corticosteroid injections), modalities (eg, heat, ice, ultrasound), exercises, and surgery for treatment of shoulder injuries. These treatments, however, are based on studies of non-SCI populations and the evidence supporting their use is limited.[9-15] Some of the treatments have known deleterious side effects,[10,16-22] or may be ineffective or inappropriate for people with SCI.[23-25] Clearly, there is a need for further research into treatments for chronic musculoskeletal shoulder pain in this population that are efficacious and have minimal side effects.

Acupuncture has gained increasing popularity in the United States as a treatment for pain.[26] One advantage of acupuncture is the lower incidence of adverse effects as compared with many drugs or other accepted medical procedures used for the same condition.[27] A National Institutes of Health Consensus Development Panel[27] reported that acupuncture may be useful as an adjunct or acceptable alternative in the treatment of some types of musculoskeletal pain. A Cochrane review[26] of clinical trials that evaluated the effectiveness of acupuncture in adults with shoulder pain reported that there may be short-term benefits with respect to shoulder pain and function.

A prospective, single-subject, clinical trial[28] found that acupuncture was effective in decreasing chronic musculoskeltal shoulder pain in SCI subjects. A limitation of that study, however, was the lack of a separate group to control for nonspecific treatment factors. Because acupuncture treatments are moderately invasive, somewhat time consuming, and administered by an enthusiastic and empathetic therapist, they have the potential to function as a strong placebo.[29]

Our goal in this study was to determine the effectiveness of acupuncture in the treatment of chronic shoulder pain in people with SCI by using a randomized, double blind (participant, evaluator), placebo (invasive sham), controlled design. Invasive sham acupuncture (ie, "minimal" acupuncture—shallow needling with no manipulation at nonacupuncture points) is a recommended control for acupuncture trials for treatment of chronic pain.[30] Although invasive sham acupuncture is not physiologically inert and may have analgesic properties,[27,31,32] we hypothesized that acupuncture would be more effective than sham acupuncture in decreasing shoulder pain intensity in people with SCI.

METHODS

Participants

Participants were recruited from our Model Spinal Cord Injury System database and from the surrounding metropolitan

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area through advertisements and letters. To be eligible, they had to be between 18 and 70 years of age, have had no experience with acupuncture, have had chronic musculoskeletal shoulder pain (defined as a history of musculoskeletal* shoulder pain for more than 3 months and that physical examination found to be localized to the subacromial space and/or to the regional muscles of shoulder complex), were at least 1 year post-SCI, and used a manual wheelchair as their primary means of mobility (>40h/wk). Subjects were excluded if they were pregnant or had a medical condition that would interfere with the study or the interpretation of the study's results. All participants provided written informed consent, in accordance with procedures approved by the appropriate institutional review board.

Procedures

Screening. All participants underwent a screening history and a focused physical exam of the neck and shoulders that included a series of provocative tests specific for shoulder pain.[33,34] Each participant's neurologic level of injury was based on the International Standards for Neurological and Functional Classification of Spinal Cord Injury.[35] The physician who performed the exams was blinded to treatment group assignments.

Intervention. The study consisted of 3 consecutive 5-week periods: (1) a no-treatment baseline period; (2) a treatment period; and (3) a follow-up period.

Baseline period. After the baseline period, participants were randomly assigned to either the acupuncture group or the sham acupuncture group through a stratified block randomization based on neurologic level of injury, to ensure equal distribution between treatment groups. All participants and the principal investigator were blinded as to group assignment. In an effort to maintain the blind, participants were asked to not discuss details about their treatment experience with other participants or the principal investigator.

Treatment period. Both groups received 10 treatments over a period of 5 weeks (range, 5−8wk). Treatments were given in an outpatient medical setting in a clinical research center by 2 licensed acupuncturist (PK, LB) trained in traditional Chinese medicine–style acupuncture. The 2 had more than 20 years of clinical experience, including experience in using the treatment protocol. Treatments consisted of either acupuncture or sham acupuncture.

Acupuncture. We used a hybrid version of a completely individualized acupuncture needle treatment and a standardized acupuncture needle treatment to accommodate the differences between participants and changes in symptoms during the treatment period, while still providing some consistency in the treatment. This protocol, described elsewhere,[28] is briefly summarized here. Before each treatment, up to 6 local points and 2 distal points were chosen per painful shoulder (fig 1A), according to the distribution of shoulder pain or tenderness on palpation in individual participants. Points were chosen from a list of points (appendix 1) believed to relieve shoulder or upper-limb pain and were based on traditional Chinese medicine methods.[36,37] Also needled were any ashi points ("ouch" points; local points of tenderness or sensitivity that do not correspond to classical acupuncture points) in the shoulder region (range, 1−4 points per treatment). During the treatment, stainless steel, pre-sterilized disposable acupuncture needles[a]

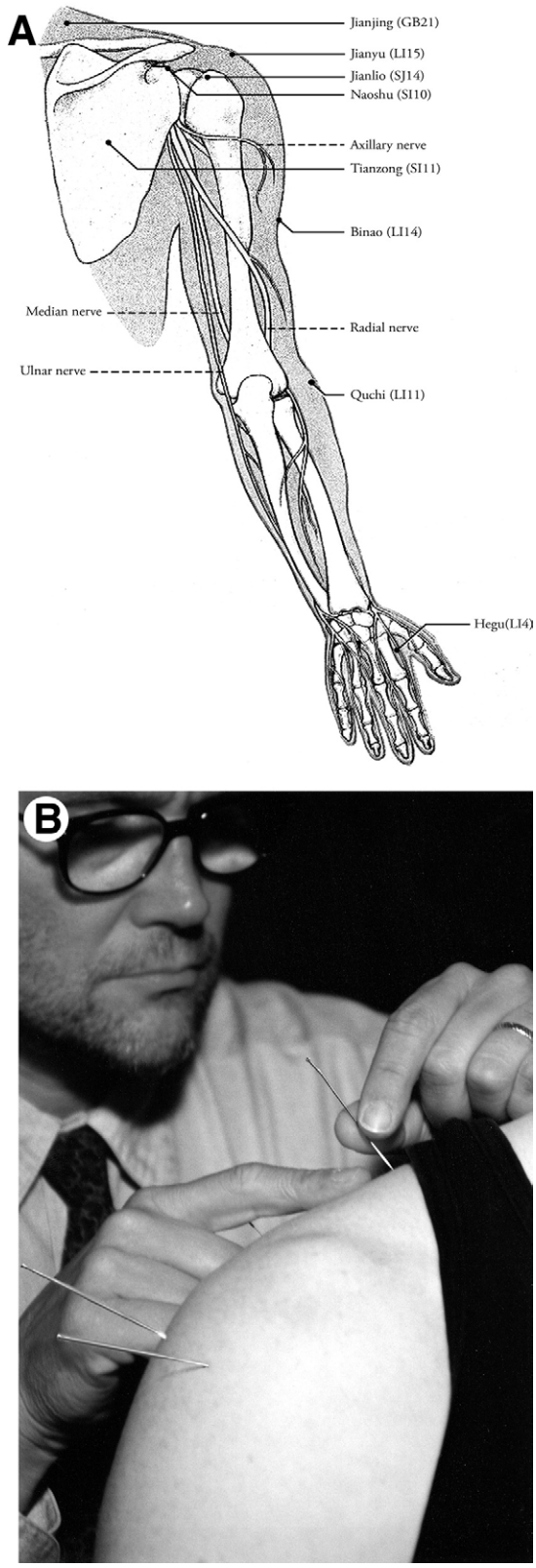

Fig 1. (A) An example of 6 local and 2 distal acupoints used for the treatment of chronic musculoskeletal shoulder pain in subjects with SCI (illustration by Jody Banks). (B) Needle acupuncture involves the insertion of fine needles into specific points on the body called acupoints.

*Spinal Cord Injury Pain Task Force of the International Association of the Study of Pain classification: nociceptive (tier I), musculoskeletal (tier II), secondary overuse syndromes (tier III).[61]

were inserted into the skin to a depth of 1 to 3cm and were manually stimulated to acquire DeQi (ie, the arrival of the Qi sensation; often described as a feeling of heaviness, soreness, or numbness) (fig 1B). Once the needles were inserted, the acupuncturist left and the participant sat quietly with the needles in place for 20 minutes, with manual stimulation repeated once by the acupuncturist during this period.

Sham acupuncture. We used an invasive sham acupuncture technique consisting of shallow needling with no manipulation (ie, minimal acupuncture) at sites located at least 1 cun (1 Chinese anatomic inch) away from established meridian points and extra points,[37] so as not to influence the superficial flow of Qi within the meridians. A total of 8 points was needled per painful shoulder: 6 local points and 2 distal points (appendix 2). During the sham treatment, the needles were tapped in with the insertion tube only to the most superficial depth, so that the needles stayed upright in the skin. DeQi and manual stimulation of the needles were avoided. Once the needles were inserted, the acupuncturist left and the participant sat quietly with the needles in place for 20 minutes, with sham manual stimulation performed once by the acupuncturist during this time. During sham stimulation, the acupuncturist gently held the needle and pretended to twirl or stimulate each needle. Again, DeQi was avoided.

No auxiliary techniques (eg, moxibustion, cupping, use of Chinese herbs), lifestyle advice, additional medications, or therapeutic exercises were prescribed during the treatment period. Participants were instructed to continue their usual daily activities and were permitted to continue taking previously prescribed pain medications as needed; they were, however, asked to document pain medication use in their weekly diaries.

Follow-up period. Subjects were followed for 5 weeks after completing the treatment. While they received no further treatment, they were asked to continue recording their pain medication use, activity level, and shoulder pain intensity.

Outcome Measures

We used an intake questionnaire based on that developed by Curtis et al[38] to collect weekly demographic data and medical history and to assess the intensity of shoulder pain experienced while subjects performed activities of daily living (ADLs). A weekly self-report questionnaire was used to collect information on activity level, analgesic intake, and to assess the intensity of shoulder pain.

Wheelchair User's Shoulder Pain Index. Shoulder pain intensity was assessed weekly with the Wheelchair User's Shoulder Pain Index (WUSPI),[39] a 15-item, self-report instrument that measures shoulder pain intensity in wheelchair users in their various ADLs. The WUSPI is a valid and reliable disease-specific measure of pain intensity and is sensitive to treatments that have an impact on shoulder pain intensity.[28,38]

Numeric rating scale. Shoulder pain intensity was also assessed weekly with a numeric rating scale (NRS). Subjects were asked to rate their average pain on an 11-point scale (ie, 0−10), anchored at the ends by "no pain" and "worst pain ever experienced." An 11-point NRS measure of pain intensity permits comparison across clinical trials of chronic pain treatment and is recommended as a core outcome measure for chronic pain clinical trials.[40]

Data Analysis

Efficacy analyses were performed on the intent-to-treat (ITT) population, which consisted of all randomized participants who received at least 1 acupuncture or sham acupuncture treatment. The primary efficacy variable was end-point WUSPI scores and the NRS end-point average pain intensity score was the secondary efficacy measure. A multivariate analysis of variance (MANOVA) was used to evaluate differences in WUSPI and NRS scores across the 3 time points (baseline, post-treatment, follow-up). Because baseline pain scores differed in both treatment groups, we also used post hoc analyses of covariance (ANCOVA) to evaluate the changes in WUSPI and NRS scores from baseline to post-treatment only. Baseline, post-treatment, and follow-up scores were the WUSPI and NRS scores reported in the last week of each period. The WUSPI was scored according to the methods described by Curtis et al.[38,41] The percentages of patients obtaining 30% or more reductions in pain intensity NRS from baseline were also analyzed and compared using the Fisher exact test. A reduction of 30% or more in the pain intensity NRS represents a "clinically meaningful" reduction in chronic pain, regardless of baseline pain,[40,42,43] and is also a reasonable standard for meaningful change across chronic pain conditions in SCI.[44] Age, duration of SCI, duration of shoulder pain, and activity level of the 2 treatment groups were compared using independent *t* tests. We compared medical history characteristics in the 2 groups by chi-square analysis. The threshold for statistical significance was set at *P* less than .05. All data analyses were performed using SPSS[b] and SAS[c] statistical software packages.

RESULTS

Figure 2 summarizes the flow of participants through the study. Overall, 23 manual wheelchair–using subjects (18 men, 5 women; mean age ± standard deviation [SD], 39.9±10.3y; range, 21−65y) with chronic SCI (8 with tetraplegia, 15 with paraplegia; average duration of injury, 11.9±9.3y; range, 1.25−30y) met inclusion and exclusion criteria and were enrolled in the study. Six participants (3 men, 3 women; 2 with tetraplegia, 4 with paraplegia) withdrew during the baseline period before being randomized to a treatment group. Seventeen participants completed the baseline period and were randomized to treatment (ITT population: 8 acupuncture, 9 sham acupuncture). Analysis using *t* tests revealed no significant differences between those who withdrew during the baseline period and those who were randomized to treatment with respect to age, duration of SCI, activity level, or mean WUSPI scores. There were no dropouts during treatment or follow-up periods in either the acupuncture or sham acupuncture groups.

Demographic Data

Table 1 summarizes the baseline characteristics of the 17 participants. Before treatment began, *t* tests comparing the acupuncture and sham acupuncture groups found no significant differences in age, duration of SCI, activity levels, WUSPI scores, and NRS scores at time of entry into the study. Chi-square analysis revealed no significant differences between the 2 groups with respect to medical and demographic data.

Pain Intensity: WUSPI Scores

Table 2 shows the means and SDs of the WUSPI. Shoulder pain decreased significantly in both acupuncture and sham acupuncture groups (Wilks $\lambda=.469$, $F_{2,14}=7.932$, $P=.005$, partial $\eta^2=.531$). Although the decrease in shoulder pain appeared greater in the acupuncture group than the sham acupuncture group (66% vs 43%, respectively), overall, there was no significant difference between the 2 groups (Wilks $\lambda=.866$, $F_{2,14}=1.087$, $P=.364$, partial $\eta^2=.134$). The acupuncture group had a higher mean baseline score (starting point), which, although not statistically different from that of the sham group ($P=.299$), could have affected the results. Therefore, to assess

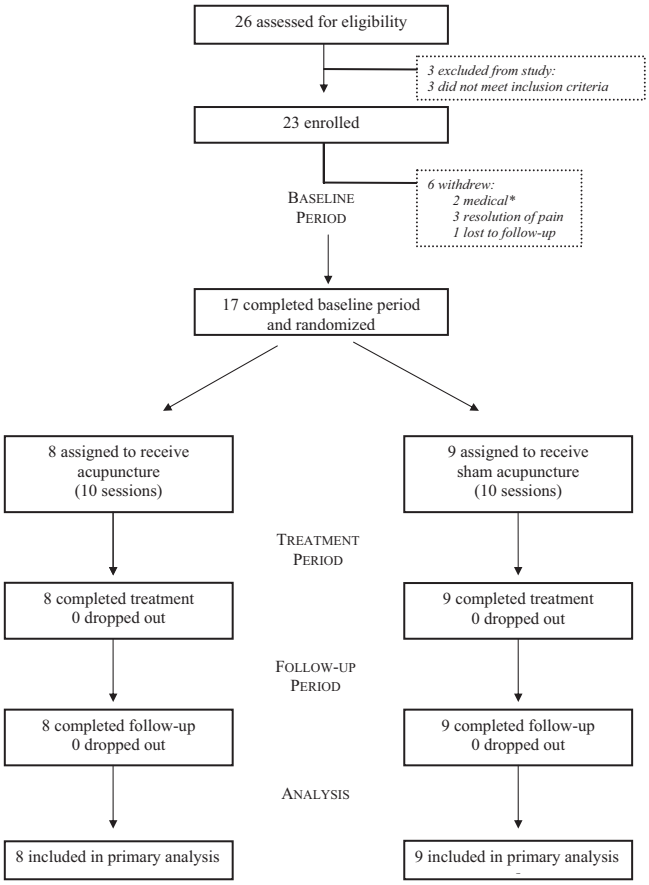

Fig 2. CONSORT flow diagram illustrating the route taken by participants entering the study. *Medical complication unrelated to study protocol.

the impact of the higher starting point on change, and to also control for possible regression to the mean, we did a post hoc ANCOVA with the change in WUSPI scores from baseline to post-treatment as a dependent variable after adjusting for baseline scores. The findings with the ANCOVA were similar to the overall MANOVA in that there was a significant change (decrease) from baseline within each group (acupuncture, $P=.000$; sham acupuncture, $P=.001$), but no difference between groups in the amount of change ($P=.386$). The differences in amount of change between groups were not statistically significant; however, acupuncture appeared to produce a longer lasting reduction in pain, based on change from baseline to long-term follow-up.

Pain Intensity: Numeric Rating Scores

Table 3 shows the means and SDs of the pain intensity NRS scores. There were similar findings with the NRS; however, there was a larger treatment effect size for the acupuncture group than was seen with the WUSPI. Once again, the MANOVA revealed a significant effect for time (Wilks $\lambda=.501$, $F_{2,13}=6.470$, $P=.011$, partial $\eta^2=.499$), but not for treatment group by time (Wilks $\lambda=.794$, $F_{2,13}=1.690$, $P=.223$, partial $\eta^2=.206$). Although the ANCOVA showed a significant change from baseline for the acupuncture group ($P=.003$) and a nonsignificant change for the sham group ($P=.284$), the difference in change between groups was still not significant ($P=.107$). Similarly for the long-term follow-up, the differences in amount of change between groups were not statistically significant, although acupuncture appeared to produce a longer lasting reduction in pain, based on change from baseline to long-term follow-up. Figure 3 shows the proportion of subjects in each treatment group that achieved a "clinically meaningful"[42,43] reduction in pain intensity NRS (eg, ≥30%). On completion of treatment, 75% (6/8) of participants in the acupuncture group had 30% or more pain score reductions, while only 25% (2/8) of participants in the sham acupuncture group reported similar reductions. By the end of the follow-up period, 75% (6/8) of participants in the acupuncture group had 30% or more reductions in their pain score, while 50% (4/8) of participants who received sham acupuncture reported similar reductions. These differences were not statistically significant ($P=.13$, $P=.61$, respectively).

Table 1: Participant Demographics in Acupuncture and Sham Acupuncture Groups

Characteristic	Acupuncture (n=8)	Sham (n=9)	Total (N=17)	*P*
Age (y)	36.0±10.0	41.1±12.1	38.7±11.1	0.4
Sex (female/male)	1/7	1/8	2/15	0.9
SCI diagnosis (tetraplegia/paraplegia)	3/5	3/6	6/11	0.9
Duration of SCI (y)	9.3±10.5	13.1±7.7	11.3±9.0	0.4
Shoulder pain: dominant side	1/8	1/9	2/17	0.9
Shoulder pain: nondominant side	1/8	2/9	3/17	0.6
Shoulder pain: bilateral	6/8	6/9	12/17	0.7
Performance corrected WUSPI score (0−150)	52.1±29.1	37.1±28.0	44.1±28.7	0.3
NRS: average	5.3±2.1	4.5±2.6	4.9±2.3	0.6
NRS: worst	7.1±2.5	6.3±2.7	6.7±2.5	0.6
NRS: least	2.8±1.7	1.8±1.8	2.3±1.8	0.4
Wheelchair transfers per day	10.6±7.1	7.9±6.2	9.3±6.6	0.4
Work/school (h/wk)	18.0±19.9	9.5±12.0	13.8±16.5	0.3
Driving (h/wk)	6.0±6.7	7.5±8.7	6.8±7.5	0.7
Chores (h/wk)	5.4±3.0	8.8±7.6	7.1±5.8	0.3
Personal care (h/wk)	7.9±3.0	7.8±3.2	7.8±3.0	0.9
Social/recreational (h/wk)	26.4±16.4	26.6±17.4	26.5±16.3	1.0
Sports/fitness (h/wk)	3.1±2.0	12.1±16.9	7.6±12.5	0.2

NOTE. Values are mean ± SD or n.

Table 2: Mean Performance-Corrected WUSPI Scores in Acupuncture and Sham Acupuncture Groups

Group	Pretreatment (t1)	Post-Treatment (t2)	Follow-Up (t3)
Acupuncture (n=8)	52.1±29.1	17.7±14.5	16.1±16.3
Sham acupuncture (n=9)	37.1±28.0	21.0±18.0	20.7±24.6

NOTE. Values are mean ± SD. Wilks λ (time)=.469, $F_{2,14}$=7.932, P=.005, partial η^2=.531. Wilks λ (time by treatment group)=.866, $F_{2,14}$=1.087, P=.364, partial η^2=.134.

Activity Level, Analgesic Intake, and Other Therapies

Confounding variables that may have influenced mean shoulder pain intensity, such as activity level (number of wheelchair transfers a day, hours spent per week at work and/or at school, driving, doing household chores, personal care, social/recreational activities, and fitness-related activities), analgesic intake, or other therapies did not change significantly in either group (P>.05).

DISCUSSION

Our study is the first randomized, double blind (evaluator, participant), placebo (invasive, sham) controlled trial to evaluate the efficacy of acupuncture for chronic musculoskeletal shoulder pain in subjects with SCI. We found a significant decrease in shoulder pain intensity with acupuncture; however, this change did not differ significantly from the decrease with sham acupuncture. Because pain relief did not differ significantly between the 2 groups, our results may be interpreted in 2 ways. One, acupuncture is no more effective than sham acupuncture in reducing chronic shoulder pain (ie, point location does not make a difference). An equally plausible interpretation, however, is that acupuncture at both specific and nonspecific anatomic sites can relieve pain.[45,46] We saw a medium to large effect associated with the acupuncture treatment, indicating that it was superior to sham acupuncture in relieving shoulder pain. Because our sample size was small and SDs were large, however, our study lacked adequate power to detect the differences between acupuncture (ie, needling at acupoints) and sham acupuncture (ie, needling at nonacupoints), thus increasing the risk of a false-negative conclusion (type II error).

Indeed, an interesting finding was the strong response (43%) to our sham acupuncture control intervention. Response rates to inert placebo controls are reported to be around 30%.[47] As stated earlier, however, penetration of the skin with acupuncture needles, even light needling at nonacupoints, is not inert. Noxious stimulus to the skin during sham acupuncture may result in endorphin release through neurophysiologic mechanisms called diffuse noxious inhibitory control (DNIC).[27,31,32] It has been suggested that DNIC has a relatively minor role in acupuncture analgesia and that other systems, mediated by serotonin and noradrenaline, and changes in the autonomic nervous system, are more important.[30] There is evidence that chronic pain is mediated not only through neurotransmitters, but also through the autonomic nervous system.[30] These different mechanisms may explain the mixed picture seen in sham acupuncture-controlled trials for chronic pain and in our results. Sham acupuncture will have some effect through DNIC and will, therefore, provide a greater effect than that typically expected from placebo alone. Real acupuncture will utilize the endorphin system, but will also evoke a putative autonomic response and local trigger-point action to produce additional effects and, therefore, an increased clinical response in comparison with sham acupuncture.[30]

A limitation of our study could be our choice of the control group. There are, unfortunately, no established rules for systematically choosing the most appropriate controls in acupuncture randomized controlled trials (RCTs). The World Health Organization currently recommends the following possible control groups: (1) no treatment; (2) standard therapy; (3) mock transcutaneous electric nerve stimulation; (4) real acupuncture (at alternative sites); and (5) sham acupuncture. Unfortunately, "no treatment" and "standard therapy" (ie, physical therapy) do not control for placebo (or nocebo) effects or for nonspecific responses to needling. Furthermore, physical therapy is a generically vague term used to describe several modalities, none of which have been proven to be more effective than placebo for chronic shoulder pain. One of the challenges in clinical trials of acupuncture is identifying a suitable control with a psychologic impact similar to needle acupuncture, yet has minimal or no physiologic activity.[48] Various sham acupuncture controls have been described and include: (1) "placebo needles"; (2) superficial needling (minimal acupuncture); and (3) needling at nonacupuncture points.[31] We chose to use superficial needling at nonacupuncture points on the shoulder as our control intervention. Although nonacupoints on the shoulder might be too close to highly effective acupoints,[49] we were concerned that needling at points located elsewhere on the body would not be as convincing as those on the shoulder. Overall, we believe our sham acupuncture intervention was an effective control because the majority of participants believed they had received acupuncture, regardless of group assignment. The ones who guessed correctly that they were receiving sham acupuncture said they did so only because their shoulder pain did not seem to have improved by the end of the treatment. Other controlled trials have reported success using nonpenetrating ("placebo") needles composed of a needle (either real or blunted) in a guide tube or retractable handle that is attached to the skin with double-sided adhesive tape that masks the skin (ie, a form of noninvasive sham acupuncture).[50-53] We were concerned that the use of these more technologically sophisticated techniques would require substantial deviations from the usual practices of our acupuncturists.[45,49]

Also noteworthy in our results were the clinically relevant reductions of pain after acupuncture treatment. A reduction in pain of at least 30% represents a clinically important improvement in chronic pain intensity on an 11-point NRS regardless of baseline pain intensity,[42] and has been recommended as a core outcome measure in clinical trials of chronic pain.[40] In our study, 75% of the subjects in the acupuncture group reported a clinically meaningful reduction in pain immediately after the 10 treatments and at the 5-week follow-up, compared with 25% and 50% in the sham acupuncture group, respectively. Because of limitations in sample size, however, these differences were not statistically significant.

Table 3: Mean Pain Intensity NRS Scores in Acupuncture and Sham Acupuncture Groups

Group	Pretreatment (t1)	Post-Treatment (t2)	Follow-up (t3)
Acupuncture (n=8)	5.0±2.1	2.5±2.1	2.9±2.2
Sham acupuncture (n=8)*	4.3±2.4	3.6±2.6	3.4±3.1

NOTE. Values are mean ± SD. Wilks λ (time)=.501, $F_{2,13}$=6.470, P=.011, partial η^2=.499. Wilks λ (time by treatment group)=.794, $F_{2,13}$=1.690, P=.223, partial η^2=.206.
*One person did not complete the NRS.

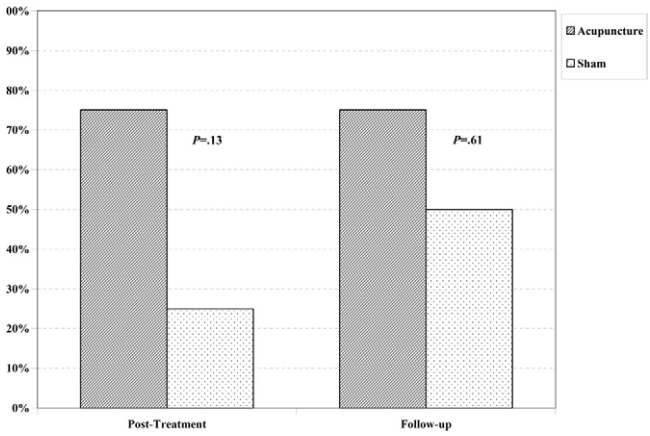

Fig 3. Percentage of participants in acupuncture and sham acupuncture groups with "clinically meaningful" reductions (≥30%) in pain intensity NRS scores immediately after treatment and after follow-up.

The results of our study are similar to those of a previous single-subject clinical trial that assessed the efficacy of acupuncture for chronic musculoskeletal shoulder pain in 9 manual wheelchair-using subjects with SCI.[28] In that study, shoulder pain intensity (WUSPI scores) decreased 53.4% after 10 acupuncture treatments and was maintained through the 5-week follow-up period. To our knowledge, that[28] is the only other study that has assessed the efficacy of acupuncture specifically for chronic musculoskeletal shoulder pain in an upper limb-dependent SCI population. In another single-subject clinical trial, Nayak et al[54] assessed the efficacy of acupuncture as a treatment for chronic pain in 22 people with SCI. Forty-six percent of their sample reported moderate to significant pain relief (NRS scores) immediately after 15 treatments and 35% reported pain relief at a 3-month follow-up, which suggests that acupuncture may be effective for pain relief in a subgroup of people with SCI. Subjects were more likely to respond to acupuncture if they had pain above rather than below their neurologic level of injury. Subjects with incomplete SCI or musculoskeletal pain were also more likely to respond to acupuncture than were those with complete SCI or neuropathic pain.

A recent Cochrane review[26] of clinical trials in which the effectiveness of acupuncture in adults with shoulder pain was evaluated reported that there may be short-term benefits associated with acupuncture with respect to shoulder pain and function; however, little could be concluded because of the small number of methodologically diverse clinical trials. The authors of that review recommended that future studies define study population by clear diagnostic criteria, use standardized outcome measures for pain and disability, give consideration to adverse effects, be adequately powered, and follow up participants to determine longer-term outcome. In our study, we were able to adequately address all of these recommendations except for the last 2. We did not measure the impact of shoulder pain on disability or physical functioning because there was not an appropriate outcome measure available for people with SCI when we conducted our study. The Brief Pain Inventory is a commonly used measure of physical functioning in chronic pain clinical trials in non-SCI populations[40,55,56] and a modified version has recently been adapted for use with SCI subjects.[57] Finally, although our study lacked adequate power, it was the first RCT of acupuncture for chronic shoulder pain in SCI. Thus, it achieved the goal of a small-scale clinical trial in that it showed feasibility, tolerability, and a trend toward a treatment effect that can be used for power calculations in future large-scale, multicenter, RCTs.[58]

The challenges faced and lessons learned in our small-scale clinical trial in acupuncture mirror those often faced in other clinical trials in rehabilitation medicine.[58-60] These challenges include competition for participants, adequacy of power, difficulty in blinding the participants, standardizing treatment, identifying suitable controls, and determining mechanisms of action, as well as confounds between an intervention's effect and natural recovery or uncontrolled factors that occur during the intervention or follow-up periods. Our results suggest that acupuncture may be effective in treating chronic shoulder pain in SCI subjects while causing minimal adverse effects. Therefore, rather than reject a potentially effective therapy because of its methodologic shortcomings, we recommend further research into its efficacy through larger, multicenter, clinical trials.

CONCLUSIONS

We observed a significant decrease in shoulder pain intensity with acupuncture treatment; however, this change did not differ significantly from that resulting from sham acupuncture. There appears to be an analgesic effect or a powerful placebo effect associated with both acupuncture and sham acupuncture. There was a medium to large effect associated with the acupuncture treatment, suggesting that it may be superior to sham acupuncture in relieving shoulder pain in subjects with SCI. Our sample size limited the study's power to detect significant differences between the groups, increasing the risk of a type II error. Therefore, our results should be interpreted cautiously. A larger, more definitive RCT with a similar design is feasible and warranted.

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APPENDIX 1: ACUPUNCTURE POINTS USED FOR TREATMENT

Local points (chosen according to shoulder pain symptoms)

LI 14	Binao	GB 21	Jianjing	SI 14	Jianwaishu
LI 15	Jianyu	SI 9	Jianzhen	SI 15	Jianzhong
LI 16	Jugu	SI 10	Naoshu	LU 1	Zhongfu
SJ 13	Naohui	SI 11	Tianzong	LU 2	Yunmen
SJ 14	Jianliao	SI 12	Bingfeng	PC 2	Tianquan
SJ 15	Tianliao	SI 13	Quyuan		

Distal points (chosen according to local points used)

LI 2	Erjian	LI 18	Neck-Futu	DU 14	Dazhui
LI 4	Hegu	SJ 3	Zhongzhu	GB 20	Fengchi
LI 10	Shousanli	SI 6	Yanglao	BL 10	Tianzhu
LI 11	Quchi	LU 3	Tianfu	BL 11	Dashu

Abbreviations: BL, urinary bladder; DU, Du Mai or governing vessel; GB, gallbladder; LI, large intestine; LU, lung; PC, pericardium; SI, small intestine; SJ, Sanjiao or triple energizer/burner.

APPENDIX 2: CONTROL POINTS (C) USED FOR SHAM ACUPUNCTURE TREATMENTS

Local points

C1 Located on the anterior aspect of deltoid; 1 cun* lateral to M-UE-48 (Jianneiling), which is midway between LI 15 (Jianyu) and top of anterior axillary fold.

C2 Located in the middle of the deltoid muscle, 1 cun proximal to N-UE-14 (Naoshang), which is located in the center of the triangle formed by connecting LI 15 (Jianyu), SJ 14 (Jianliao), and N-UE-14 (Naoshang).

C3 Located on the supraspinatus muscle; anterior and inferior to the acromion, 1 cun proximal to LI 15 (Jianyu) and 1 cun inferior to LI 16 (Jugu).

C4 Located posterior and inferior to the acromion; 1 cun inferior to SJ 14 (Jianliao) and 1 cun medial to SJ meridian.

C5 Located on the scapula on the line midway between SI 9 (Jianshen) and SI 10 (Naoshu).

C6 Located on the line midway between GB 21 (Jianjing) and the acromion.

Distal points

C7 Located on the dorsal aspect of the forearm; 1 cun lateral to LI 10 (Shousanli), approximately midway between LI 10 and the radius.

C8 Located on the dorsal aspect of the hand, midway between LI 4 (Hegu) and LI 5 (Yangxi) and 1 cun lateral to LI meridian, above the first metacarpal bone.

Abbreviations: see appendix 1.
*Chinese anatomic inch.

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Suppliers

a. DBC-10 spring handle (0.20×40mm); Lhasa Medical Supplies, 234 Libbey Pkwy, Weymouth, MA 02189.
b. Version 14; SPSS Inc, 233 S Wacker Dr, 11th Fl, Chicago, IL 60606.
c. Version 91; SAS Institute, 100 SAS Campus Dr, Cary, NC 27513.