Is Acupuncture Effective in Treating Chronic Pain After Spinal Cord Injury?

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ABSTRACT. Nayak S, Shiflett SC, Schoenberger NE, Agostinelli S, Kirshblum S, Averill A, Cotter AC. Is acupuncture effective in treating chronic pain after spinal cord injury? Arch Phys Med Rehabil 2001;82:1578-86.

Objectives: To evaluate the efficacy of acupuncture as a treatment for chronic pain and secondary symptoms after spinal cord injury (SCI) and to identify disease-specific variables associated with response to treatment.

Design: A within-subjects design consisting of a 7½-week no-acupuncture baseline period followed by a 7½-week treatment period and a follow-up assessment 3 months posttreatment.

Setting: Medical rehabilitation research center.

Participants: Twenty-two people with SCI who experienced moderate to severe pain of at least 6 months' duration.

Intervention: A course of 15 acupuncture treatments was administered over a 7½-week period.

Main Outcome Measures: Numeric Rating Scale of pain intensity; ratings of interference with activity, individualized symptom rating, Center for Epidemiologic Studies–Depression Scale; Speilberger State Trait Anxiety Inventory, and General Well-Being Schedule.

Results: Ten patients (46%) showed improvement in pain intensity and pain sequelae after treatment. However, 6 patients (27%) reported an increase in pain that was still present 3 months after treatment.

Conclusions: About 50% of the study sample reported substantial pain relief after acupuncture treatment, suggesting that acupuncture may provide pain relief for at least a subgroup of individuals with SCI. Future research is needed to determine what part of this effect is because of acupuncture versus nonspecific effects such as placebo effects and regression to the mean.

Key Words: Acupuncture; Pain; Rehabilitation; Spinal cord injuries; Treatment outcome.

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THE OVERALL HEALTH and short-term medical care of people with spinal cord injury (SCI) has improved in recent years, but the medical management of chronic pain and other long-term secondary complications remains a challenge. Pain is a significant secondary complication that interferes with functioning and the quality of life (QOL) in 5% to 45% of people with SCI.[1] Estimates of the prevalence of chronic pain after SCI range from 18% to 64% for severe disabling pain and 48% to 94% for mild to moderate pain.[1-3]

Pain frequently impedes people's performance of occupational and social activities. In a representative sample of 805 Americans who experience moderate to severe pain, more than 60% reported that pain disrupted their ability to engage in social activities, to participate in leisure activities, and to perform chores around the house.[4] More than 40% reported that pain interfered with their ability to perform their jobs.

For people living with SCI, chronic pain often disrupts their QOL,[5-7] social functioning,[2,6] employment,[1,3,5,6] and mood.[1,6,8] Pain also hinders an individual's ability to participate optimally in therapy and treatment,[6,9] which can be a setback during rehabilitation and follow-up outpatient treatment. Chronic pain has such a negative impact that people with ongoing pain after a SCI are likely to experience more psychologic distress and more impaired functioning than those who do not experience pain.[10,11] In a prospective, longitudinal study[8] of the determinants of depression, the experience of pain during the hospital stay was predictive of depression 2 years postinjury, even when other variables were controlled.[8]

Despite the high incidence of pain after SCI, pain management is often ineffective.[12] A recent survey[13] conducted in the United Kingdom found 2 shortcomings that compromised the effectiveness of pain management: (1) lack of consensus among spinal injury units regarding pain management guidelines and (2) lack of specialized expertise. When interviewed as part of a national survey,[4] 56% of able-bodied individuals with chronic, moderate to severe pain reported that their pain was out of control, and many had changed doctors because they continued to suffer despite receiving medical treatment. The current pharmacologic methods for managing pain, including anticonvulsants, antidepressants, narcotics, and other analgesic medications, are effective to a moderate degree, but many also produce adverse reactions, such as sedative and anticholinergic side effects, toxicity, and the potential for addiction and abuse.[14] Other SCI pain management strategies include anesthesiologic and surgical techniques, whose efficacy has not been well established because of the paucity of supporting research.[15,16]

Acupuncture is increasingly accepted in the United States as a pain management technique. Approximately 12 million Americans have received some type of acupuncture treatment,[17] primarily for pain relief.[18] In a recent survey,[19] rehabilitation outpatients were questioned about their use of com-

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Accepted in revised form January 29, 2001.

Supported by the American Association of Spinal Cord Injury Psychologists and Social Workers (grant no. 287) and the National Institutes of Health (grant no. U24-HD32994).

Preliminary data was presented at the Society for Behavioral Medicine's meeting, March 1999, San Diego, CA, and at the American Academy of Physical Medicine and Rehabilitation's 61st Annual Assembly, November 1999, Washington, DC.

No commercial party having a direct financial interest in the results of the research supporting this article has or will confer a benefit upon the author(s) or upon any organization with which the author(s) is/are associated.

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0003-9993/01/8211-6533$35.00/0

doi:10.1053/apmr.2001.26624

plementary therapies. Results indicated that pain syndromes were the most common problems for which complementary treatment was sought and that acupuncture was among the most frequently used treatments.

A recent consensus development conference at the US National Institutes of Health determined that acupuncture may be an efficacious treatment for certain types of pain (dental pain, fibromyalgia, headache, low back pain [LBP], carpel tunnel syndrome) and that research findings indicate possible efficacy for a variety of pain conditions.[20] One meta-analysis[21] combined the results of 14 randomized controlled trials and concluded that acupuncture was superior to conventional treatments for a variety of chronic pain conditions including LBP, headaches, and cervical pain. Since this meta-analysis, acupuncture has been compared with other forms of treatment, with placebo, and/or with no-treatment control groups across a wide range of chronic pain conditions, including osteoarthritis,[22-24] headache,[25,26] and LBP.[27] Overall, these studies have found acupuncture to be an effective treatment for chronic pain, producing a response rate that is significantly better than placebo and at least as good as conventional medical treatments. Acupuncture also has been observed to produce fewer negative side effects than pharmacologic treatments.[28]

Some research exists on the use of acupuncture in individuals with paralysis, though very little is specific to SCI. Several investigators[29,30] have shown that acupuncture may improve motor function in people who have experienced a stroke. Acupuncture has been used in China to treat paraplegia after spinal injuries. For example, clinical analysis of a series of 261 cases showed that the vast majority of patients experienced some improvement in nervous system functioning and/or motor functioning.[31] However, that study had several limitations. The investigators were not clear about what the goals of treatment were and their only measure of outcome was a scale not accepted as valid or reliable. Their 4-point rating scale measured gross improvement in motor functioning and urinary function, and there was no discussion of who may have made these ratings or how natural recovery may have influenced outcome. In another experimental study of persons with SCI, other researchers[32] examined the effects of acupuncture administered to rats 15 minutes or 24 hours after they were exposed to a standardized lesion at T8. Compared with control animals, rats treated 15 minutes postinjury performed better on behavioral tests and had less elevation in plasma cortisol. Rats treated 24 hours after injury were comparable to the control group.

We located only 1 study[33] that examined the use of acupuncture for pain after SCI. Twelve patients with paraplegia or tetraplegia who experienced paresthesias or hyperesthesias in addition to upper extremity weakness and depressed reflexes were treated by using electroacupuncture. Treatment was provided 3 times daily and was terminated based on the degree of improvement observed. The investigator reports that all patients' functioning improved and paresthesias decreased. However, the study did not report results on any quantifiable outcomes, nor did it include comparisons with a control group.

The present study was designed to examine the efficacy of acupuncture treatment for chronic pain in persons with SCI. In addition, we explored whether physical functioning, social functioning, and depression would improve as indirect effects of pain relief. We also sought to identify variables that predicted responsiveness to acupuncture treatment. The extent of SCI (complete vs incomplete), neurologic level of injury, type of pain (musculoskeletal vs other), and location of pain (above vs below the level of injury) were examined as potential moderators of treatment outcome.

METHOD

Participants

Participants were 22 individuals with traumatic SCI who were recruited through advertisements in newsletters and direct mailings to former inpatients of the Kessler Institute for Rehabilitation. The study was reviewed and approved by the institutional review board of Kessler Medical Rehabilitation Research and Education Corporation. To meet inclusion criteria, participants were required to be 18 years of age or older, to have sustained a traumatic SCI at least 6 months before entering the study, to have pain of at least 6 months' duration after the injury, and to rate their overall pain severity as at least 5 on a 10-point numeric rating analog scale. To ensure that the onset of pain was related to the SCI, candidates with neurologic and medical conditions such as traumatic brain injury, Parkinson's disease, multiple sclerosis, epilepsy, and diabetic neuropathy were excluded. As a standard precaution for acupuncture treatments, we also excluded individuals with bleeding disorders, artificial heart valves, or women who were pregnant. In addition, persons with pre-SCI psychiatric disorders were excluded, because a secondary aim of the study was to examine acupuncture's effect on reactive depression associated with chronic pain. Finally, people who had used acupuncture previously were excluded to minimize bias from preconceived expectations of treatment outcome.

Instruments

Pain intensity: Numeric Rating Scale. The Numeric Rating Scale[34] (NRS) is an 11-point scale that asks participants to rate the intensity of their pain from 0 to 10 (0 = no pain at all; 10 = pain as bad as it could be). In the present study, we asked participants to make 3 ratings of pain intensity at each observation point: present pain, average pain, and worst pain. Participants were asked to make average and worst pain ratings for the past 2-week period.

General health: individualized symptom rating scale. At their initial appointment, participants were asked to list the 5 most bothersome symptoms that occurred because of their pain symptoms (eg, sleep difficulties, appetite, movement). They were then asked to rate the severity of each symptom over the past week by using a 10-point Likert scale at baseline and each of the subsequent assessment points.

Pain impact and interference: activity scale. This 1-item numeric rating scale (In the past 2 weeks, how much has pain interfered with your daily activities?) was created by the authors to measure the extent to which pain interfered with daily living activities. Participants made ratings on a scale of 0 to 10 (0 = no interference; 10 = unable to perform any activities).

Mood. The Center for Epidemiologic Studies–Depression Scale[35] (CES-D) is a 20-item, self-report depression scale, in which items elicit the frequency of symptoms during the past week. Responses to questions are marked on a scale of 0 to 3.

The Spielberger State Anxiety Inventory[36] (STAI-S), from Speilberger's State Trait Anxiety Inventory, consists of 20 statements about the experience of tension, nervousness, and worry, and evaluates how respondents have been feeling during a specified time period (eg, the past week).

Psychologic well-being. The General Well-Being Schedule[37] (GWB) is a self-report measure containing 18 items that ask about life satisfaction and level of psychologic distress. Six subscales on the GWB measure anxiety, depression, positive well-being, self-control, vitality, and general health.

Expectations. To assess participants' perception of the credibility of acupuncture and expectation of treatment out-

come, Vincent's Credibility Scale[38] was used. This scale, which was adapted from Borkovec's and Nau's scale,[39] measures credibility for analog therapy rationales. It was administered at the beginning of the study, before baseline. The scale includes 4 items to which participants responded on a 10-point NRS. The items include: (1) How confident do you feel that this treatment can alleviate your complaint?; (2) How confident would you be in recommending this treatment to a friend who suffered from similar complaints?; (3) How logical does this treatment seem to you?; and (4) How successful do you think this treatment would be in alleviating other complaints?

Procedure

After providing informed consent, all participants received a comprehensive physical examination to ensure that they met inclusion criteria and to evaluate and classify their symptoms of pain. Pain categories were based on classifications described in the literature as follows: (1) *mechanical*, a sharp, aching pain localized to the site of the SCI; (2) *radicular*, caused by damage to the nerve roots at the level of the spinal cord lesion and characterized as burning, aching, stabbing, or a feeling of tightness; (3) *cauda equina*, a form of radicular pain caused by damage to the cauda equina, conus medullaris, or both, which usually has a burning or tingling quality and is distributed symmetrically, affecting the buttocks, anus, and genital regions; (4) *central*, also called dysaesthesia or deafferentation pain, characterized by burning, tingling, and/or aching below the level of the lesion; (5) *visceral*, characterized by deep, diffuse spastic pain in the abdominal and pelvic areas, for which the cause is not well understood but is believed to be associated with central pain; and (6) *musculoskeletal*, an aching pain arising from damage to or overuse of structures such as bones, muscles, joints, or intravertebral disks.[10,14,40]

The participant's medical history focused on details regarding the onset and timing of the pain, location, frequency, and intensity of the pain, as well as any factors that may ameliorate or exacerbate the pain. Medications and treatment interventions currently and previously used were reviewed. To minimize the confounding effect that alterations in medication dosage may cause, participants were requested not to alter the dosage of their prescription and over-the-counter medications for the duration of the study and to keep a log of any pain medications they were taking during this period. Compliance with this request was fairly good throughout the baseline and treatment phase, but during follow-up we did find that small changes were made in the pain medications being taken. However, we did not believe that these minor fluctuations affected the outcome particularly because the predominant change was a reduction rather than an increase in medication. A comprehensive neurologic examination was performed according to the American Spinal Injury Association (ASIA) standards, as endorsed by the International Standards for Neurological and Functional Classification of Spinal Cord Injury.[41]

From the history and physical examination, we determined each participants' pain diagnosis according to the classifications previously outlined: motor level, sensory level, and neurologic level of injury, and ASIA impairment scale classification. The same examiner, an experienced SCI physician (SK), gathered history and performed all physical examinations.

After the medical history and physical examination, participants completed the questionnaires in the instruments described earlier to provide outcome measures on pain severity, impact of pain on life activities, depression, anxiety, and psychologic well-being. If participants reported having pain in more than 1 location, they were asked to identify the most problematic pain as the target of treatment and to assess pain severity. All assessments were administered twice before the start of treatment, before and after a 7½-week no-acupuncture baseline period (prebaseline, pretreatment). Participants were reevaluated after a 7½-week treatment period (posttreatment) and at 3-month follow-up (follow-up). The purpose of the multiple baseline assessments was to evaluate changes in pain in the absence of acupuncture treatment for comparison with results obtained during posttreatment assessments.

Treatment

Physiatrists trained in medical acupuncture conducted all treatments. A specific set of acupuncture points was used with all participants, and additional points were selected based on each participant's individual history and clinical examination. At the beginning of the first treatment session, each participant was asked to describe the quality and location of pain. Pulse and tongue diagnoses were performed in accordance with standard Chinese medical diagnostic protocols. For pulse diagnosis, the participants' radial pulses were palpated to determine the strength and quality of the pulse. The tongue was inspected for qualities such as coating, color, shape, and markings (cracks, raised points, scalloping).

Participants were treated for 15 sessions of acupuncture over a 7½-week period. After insertion, needles were left in place for 20 minutes and were not manually or electrically stimulated. Needles were inserted to a depth of 15 to 30mm. During each treatment, between 6 and 14 points were needled. The anatomic location of all the acupuncture points used is described in table 1. In one session, only 4 points were needled because the participant expressed discomfort. However, placing this few needles was not typical. A minimum of 6 points were typically needled and additional points were included depending on the location of pain. In all participants, GV14 was needled. In addition, Hua Tuo Jia Ji points corresponding to the level of the lesion were used. If the lesion was above T1, then BL10 was added. If the lesion was below L5, then BL40 was added. If this initial combination did not seem to be very effective, then the acupuncturist could choose to use the BL10 and BL40 combination.

Other acupuncture points were chosen based on each participant's reported location(s) of pain. If the pain was in an upper extremity, the 4 Ba Xie points located on the affected hand were used. If the pain was in a lower extremity, the 4 Ba Feng points in the affected foot, which correspond to the Ba Xie points, were used. When the pain was in the back, ulnar surface of the arm, and medial and posterior aspect of the legs, points K13, BL60, SI3, and HT3 were used. If the pain was on the lateral and medial aspects of the legs and the dorsum or volar surface of the arms, points LR3, MH6, TH5, and GB34 were used. When the pain was on the radial side of the arm, lateral shoulder, and lateral and medial side of the leg, points LU7, SP6, LI4, and ST36 were used. The acupuncturist was given the option to add up to 6 supplementary points as necessary. These included local points in the area of the pain, A-shi points (painful, nonacupuncture points), and ear points. Thus, the protocol was somewhat standardized, in that a limited number of specific points were to be used, but there was also some flexibility to allow the acupuncturists to address individual differences among patients. This flexibility was deemed necessary to reflect the clinical practice of acupuncture.

Within the above constraints, specific points to be needled were allowed to vary from session to session and were determined by the subjective response to the previous treatment session and the pulse and tongue diagnoses. The acupuncturist examined the pulse and the tongue before starting each treatment. Before each session the acupuncturist asked participants

Table 1: Anatomic Location of Acupuncture Points

Acupuncture Point	Location
Ba Xie	Four points on the dorsum of both hands immediately proximal to the web edges separating the 5 digits
Ba Feng	On the feet, corresponding to the Ba Xie points
Gall Bladder 34 (Yanglingquan)	At the point of intersection of the lines from the anterior and inferior borders to the head of the fibula
Governor Vessel 14 (Dazhui)	Between the spinous processes of C7 and T1 vertebrae
Heart 3 (Shaohai)	On the ulnar side of the elbow, at the end of the transverse cubital crease, 0.5 cun radial to the epicondylus ulnaris
Hua To Ja Ji	0.5 cun lateral to the spinous process from T1 to L5
Kidney 3 (Taixi)	Midway between the most prominent point of the malleolus medialis and the superior border of the Achilles tendon
Large Intestine 4 (Hegu)	At the highest point of the musculus adductor pollicis with the thumb and index finger adducted
Liver 3 (Taichong)	Between the 1st and 2nd metatarsal bones, 2 cun proximal to the margin of the web
Lung 7 (Lieque)	On the radial side of the forearm on the border of the radius, 1.5 cun proximal to the transverse crease of the wrist
Pericardium 6 (Neiguan)	2 cun above the transverse crease of the wrist between the palmaris longus and the flexor carpi radialis
Small Intestine 3 (Houxi)	On the ulnar border of the hand with the fist clenched, at the ulnar end of the main transverse crease of the palm; this point is located proximal to the head of the os metacarpale toward the ulna
Spleen 6 (Sanyinjiao)	On the medial side of the lower leg, 3 cun above the medial malleolus, dorsal to the posterior border of the tibia
Stomach 36 (Zusanli)	On the finger breadth lateral to the lower border of the tuberositas tibiae, 3 cun below the knee joint
Triple Heater 5 (Waiguan)	At the midpoint between the ulna and the radius, 2 cun proximal to the dorsal wrist crease, at the midpoint between the ulna and radius
Urinary Bladder 10 (Tianzhu)	Within the posterior hairline in the trapezius muscle
Urinary Bladder 40 (Weizhong)	At the midpoint of the popliteal transverse crease
Urinary Bladder 60 (Kunlun)	At the middle of the connecting line drawn between the malleolus lateralis and the Achilles tendon

Abbreviation: 1 cun = the distance of the width of the distal phalanx of the thumb of the patient.

if they had had any medical problems since the last treatment, if they had noticed any changes in their symptoms since the last treatment, and if they had experienced any problems that they attributed to the acupuncture treatments.

As a precaution against the unlikely event that needle insertion below the level of lesion could precipitate autonomic dysreflexia, blood pressure was measured at the beginning and end of each session.[42] The skin was cleaned with alcohol swabs before the needles were inserted. This cleansing is not standard practice during acupuncture treatments. However, we decided to take this extra precaution to minimize any risk of infection. Disposable, individually wrapped, sterilized stainless steel needles were used. Two dimensions of needles were used depending on point location: 40×0.2mm,[a] and 30×0.2mm.[a,b] Guide tubes were used for comfortable insertion.

Statistical Analysis

To examine the effect of treatment, we conducted repeated-measures analyses of variance (ANOVAs) on each outcome measure across the 4 time points (prebaseline, pretreatment, posttreatment, follow-up), followed by pairwise *t* tests to evaluate which mean differences were significant. Because multiple *t* tests were conducted, alpha inflation was controlled for by using a modified Bonferroni correction for each family of measures so that alpha levels were set at .0167 (.05/3) for the 3 pain measures, .05 each for the general health and pain interference measures, and .0056 (.05/9) for the 9 psychologic functioning measures.

RESULTS

Of the 31 SCI patients who met the inclusion criteria, 22 completed the study. Twenty participants completed the entire protocol and 2 participants completed treatment but did not return follow-up assessment materials. They were included in the final data analysis to determine posttreatment outcome. The primary reason for attrition was transportation problems ($n = 8$), and 1 participant discontinued participation because of medical problems that were unrelated to the acupuncture treatments. Table 2 presents demographic and descriptive characteristics of the participants.

Pain Intensity

Repeated-measures ANOVAs were conducted separately on each of the 3 NRS ratings of pain intensity (worst pain, average pain, present pain) over the 4 assessment points (prebaseline, pretreatment, posttreatment, follow-up) to examine whether there was a change in pain intensity over time. Means and standard deviations (SDs) are shown in table 3. Results indicate that on each of the 3 measures, pain intensity decreased significantly over time (worst pain: $F = 5.00$, $p < .05$; average pain: $F = 9.01$, $p < .01$; present pain: $F = 9.34$, $p < .01$). We used Bonferroni correction to adjust the alpha level so that the alpha value to test significance for the family of 3 pain measures was set at $.05/3 = .0167$. Pairwise comparisons of worst pain intensity between the different time points revealed a statistically significant decline in ratings of worst pain intensity at posttreatment (pretreatment vs posttreatment: $t = 3.74$, $p <$

Table 2: Demographic and Descriptive Characteristics of the Sample (n = 22)

Variable	Mean	SD
Age	43.14	11.85
Duration of injury (yr)	8.49	7.47
Duration of pain (yr)	8.46	7.46
NRS pain intensity at recruitment	8.91	0.97
Variable	**Percentage**	***n***
Gender		
Men	68.2	15
Women	31.8	7
Race		
Black	13.6	3
Hispanic	9.1	2
White	78.3	17
Education level		
Partial high school	4.5	1
High school or equivalent	22.7	5
Some college	9.1	2
College or university	40.9	9
Graduate school	22.7	5
Marital status		
Never married	36.4	8
Married or cohabitating	36.4	8
Divorced or separated	22.7	5
Widowed	4.5	1
Work status		
Full time (outside home)	27.3	6
Part time (<35hr)	13.6	3
Unable to work because of injury	50	11
Retired	9.1	2
Mechanism of injury		
Vehicular crash	45.5	10
Fall from heights	9.1	2
Gunshot or stab wound	18.2	4
Sport related	22.7	5
Other	4.5	1
Pain classification		
Mechanical	9.1	2
Radicular	9.1	2
Cauda equina	4.5	1
Central or deafferentation	54.5	12
Musculoskeletal	22.7	5
Injury level		
C1–4	27.3	6
C5–8	9	2
T1	4.5	1
T2–10	31.8	7
T11–L2	22.7	5
L3–S3	4.5	1
ASIA class		
A (complete)	54.5	12
C (incomplete)	4.5	1
D (incomplete)	31.8	7
Cauda equina	9.1	2

.01). No further decrease in worst pain ratings was present at follow-up (posttreatment vs follow-up: $t = .92$, p = not significant). The posttreatment decline in pain intensity was maintained at 3-month follow-up (pretreatment vs follow-up: $t = 3.40$, $p < .01$). We found a statistically significant difference ($t = 5.39$, $p < .001$) between pre- and posttreatment ratings of average pain intensity, and this decline in average pain ratings was maintained 3 months after the end of treatment (pretreatment vs follow-up: $t = 3.99$, $p < .01$). For the rating of pain intensity at the time of assessment (present time), however, we saw a trend that suggested a decrease during baseline ($t = 2.58$, $p = .018$) but no statistically significant change after treatment or at follow-up. "Present pain" is likely to be more variable than the other 2 pain ratings because it may be subject to momentary fluctuations, influenced by factors such as the time of day, amount of activity preceding the assessment, and so forth. In summary, on 2 of the 3 pain intensity ratings, a statistically significant decline in pain severity occurred, as assessed by the NRS, immediately after the conclusion of treatment, and that reduction was maintained for 3 months.

To assess clinical impact more directly, we examined the distribution of pain intensity ratings both after completion of the treatment protocol and at 3-month follow-up. For these analyses we combined the 3 ratings of pain intensity (worst, average, present) to produce a single average pain intensity score at each point in time. As shown in figure 1, at posttreatment, 18% reported significant improvement (>3 points on the NRS) in pain intensity, 27% reported moderate improvement in pain intensity scores (2–3 points on the NRS), 36% of the sample reported minimal pain relief (0–1.9 points on the NRS), whereas 18% reported an increase in pain intensity. At 3-month follow-up, 18% reported significant, 14% reported moderate, and 27% reported minimal pain relief. Twenty-seven percent reported an increase in pain intensity and 5% reported no pain relief. Despite the decline in mean pain intensity scores for the group as a whole, more than half the sample reported little or no effect or a worsening of pain after treatment (54.5%, n = 12) and that number remained about the same (59%, n = 13) at follow-up. Of the 12 participants whose pain did not respond to the acupuncture treatment, 8 reported no change in pain intensity at the posttreatment evaluation and the other 4 reported an increase in pain intensity (average increase = 1.08 points on the NRS). It is still encouraging that 46% of the sample experienced substantial pain relief (2+ points on the NRS) at posttreatment and 41% continued to report pain relief at follow-up. In other words, after the course of 15 treatments, acupuncture appeared to have provided substantial pain relief for about half the sample and for the other half it had little or no effect at all, and, in some cases, perhaps worsened the pain. Figure 2 shows the average pain intensity for responders and nonresponders over the course of the study. Responders refer to those individuals who reported an improvement of 2 points or greater on the NRS immediately after the course of 15 acupuncture treatments. Nonresponders are those who reported less than a 2-point improvement on the NRS.

Not all responders continued to report pain relief at 3-month follow-up. Only 6 of the 10 (60%) of those who reported better than a 2-point improvement on the NRS continued to do so at follow-up, whereas for 3 (30%) participants, pain relief was not maintained at follow-up (data were missing on 1 participant).

We conducted exploratory analyses to determine how responders differed from nonresponders. No statistically significant differences existed between the 2 groups on any demographic variables. One pain-related factor differentiated responders from nonresponders: location of pain. The 3 participants who had pain located above the level of injury responded to treatment; the 12 whose pain was below their level of injury ($\chi^2 = 4.17$, $p < .05$) did not. We found large but nonsignificant differences between responders and nonresponders on 2 other injury- and pain-related factors: (1) type of injury: participants with incomplete injuries were more likely to respond to treatment than were participants who had complete injuries (60% of

Table 3: Pain Intensity Scores as Measured by the NRS

Outcome Measure	Prebaseline Week 0	Pretreatment Week 7½	Posttreatment Week 15	Follow-up Week 28	Repeated-Measures ANOVA F
Entire Sample (*n*)	22	22	22	20	
Worst pain	8.91 ± 0.97	8.77 ± 1.31	7.05 ± 2.40	6.60 ± 3.24	5.00*
Average pain	7.71 ± 1.71	7.02 ± 1.97	5.23 ± 2.05	5.05 ± 2.72	9.01†
Present pain	6.64 ± 2.08	4.96 ± 2.48	3.91 ± 2.07	4.85 ± 2.91	9.34†
Mean pain intensity score‡	7.75 ± 1.27	6.92 ± 1.38	5.40 ± 1.90	5.50 ± 2.74	9.73†
Nonresponders (*n*)	12	12	12	11	
Mean pain intensity score	7.76 ± 1.35	6.49 ± 1.10	6.31 ± 1.45	6.18 ± 1.80	2.46
Responders (*n*)	10	10	10	9	
Mean pain intensity score	7.73 ± 1.25	7.43 ± 1.55	4.30 ± 1.86	4.67 ± 3.52	18.47†

NOTE. Values are mean ± SD, unless otherwise indicated.
* $p < .05$.
† $p < .01$.
‡ Mean intensity score is the mean of the worst, average, and present pain intensity scores.

those with incomplete vs 33% of those with complete injuries); and (2) type of pain: 80% of the participants with musculoskeletal pain responded to treatment, whereas only 42% of those with central pain responded. The only variable that differentiated which participants would continue to report pain relief at follow-up was severity of average pain intensity at the onset of the study: responders who continued to report pain relief (2+ points on the NRS) at 3-month follow-up had reported only moderate levels of average pain intensity on the NRS at the onset of the study (mean ± SD, 7.83 ± .75) compared with those who did not report pain relief at 3-month follow-up (mean, 9.67 ± .58; F = 13.04, $p < .01$). One participant who reported no pain relief at posttreatment indicated that he had significant pain relief at follow-up. We found no distinguishing characteristics for the individuals who reported an increase in pain intensity after treatment. These trends should be interpreted only as suggestive because the number observed in each group was small.

Expectations and Treatment Outcome

To examine the possible effects of expectations on outcome, we calculated Pearson's correlation coefficients between each of the 4 items on the Credibility Scale and reduction on each of the 3 NRS pain intensity scores. None was statistically significant. This finding suggests that participants' expectation of treatment outcome was not associated with the amount of pain relief they experienced.

Secondary Outcomes

To explore the secondary benefits of acupuncture, we analyzed changes on measures of pain interference, general health, mood, and psychologic well-being for the entire sample. Because no significant differences existed on any of the secondary outcome measures between baseline and pretreatment assessments, we combined those 2 scores to produce a single mean pretreatment score for each measure. We conducted repeated-measures ANOVAs across 3 time points: pretreatment, posttreatment, and follow-up, and then conducted post hoc *t* tests of mean differences to examine short-term (pretreatment-posttreatment) and long-term (pretreatment–3-mo follow-up) changes. For these *t* tests, we set the alpha level at .05 for the general health and pain interference measures and used a Bonferroni correction for the family of psychologic function measures (.05/9 = .0056).

General health. This instrument asked participants to list the 5 most bothersome symptoms that were secondary to their pain symptoms (eg, sleep difficulties, appetite, movement) and rate the severity of each symptom by using a 10-point Likert

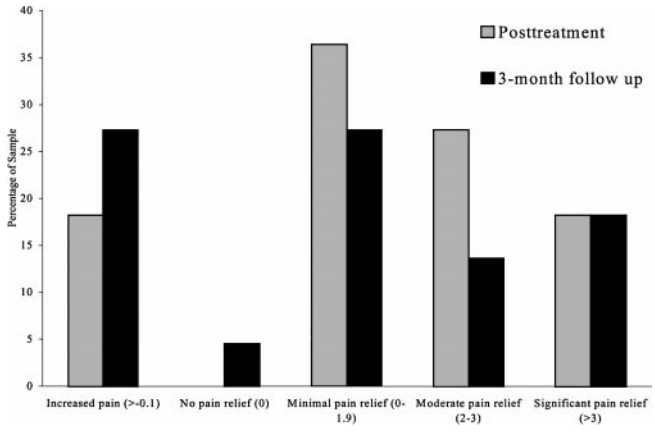

Fig 1. Percentage of sample who reported pain relief (on the NRS) immediately after treatment and at follow-up.

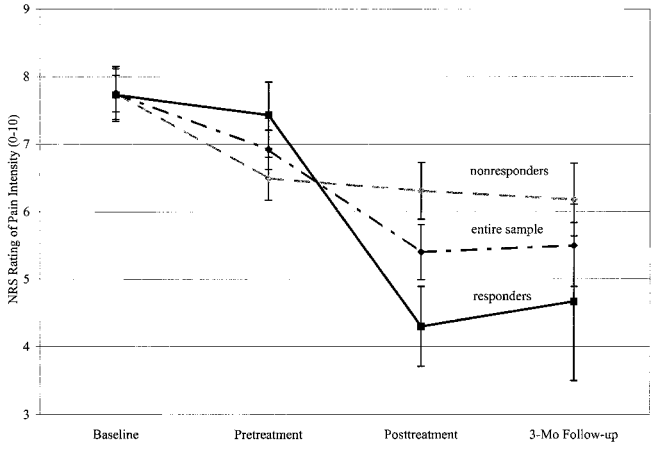

Fig 2. Mean ratings of average pain intensity scores (worst, average, present) and standard errors on the NRS for responders, nonresponders, and the entire sample.

scale. Frequency analyses of the various symptoms secondary to pain indicated that the most commonly reported symptoms were sleep difficulties (81.8%), difficulty with movement and range of motion (50%), activity level (45.5%), and mood (36.4%). Because our sample size was small, we combined the symptoms to produce an overall symptom severity score at each time point (table 4). A repeated-measures ANOVA indicated a statistically significant decrease in severity of symptoms over time ($F = 11.70$, $p < .01$). The *t* tests comparing pre- and posttreatment scores revealed a statistically significant decline in symptom severity from pre- to posttreatment ($t = 5.27$, $p < .01$). This decline was maintained at follow-up as indicated by a significant difference between pretreatment and follow-up scores ($t = 3.69$, $p < .01$), suggesting the existence of long-term improvements in pain sequelae after acupuncture treatments.

Pain interference. We found a statistically significant ($F = 4.67$, $p < .05$) decrease in (pain-related) interference with activities of daily living (ADLs) (table 4). Post hoc tests comparing pre- and posttreatment interference scores indicated that responders displayed a statistically significant ($t = 3.67$, $p < .01$) reduction in interference with daily activities at posttreatment. This improvement in pain interference was not maintained at follow-up.

Mood. Repeated-measures ANOVAs on the CES-D and the STAI showed no statistically significant change in depression or anxiety scores over time (table 4). In other words, acupuncture treatments were not associated with any substantial improvement in depression or anxiety.

Psychologic well-being. A significant ($F = 3.99$, $p < .05$) change occurred in mean scores on the GWB over time. Pairwise comparisons of mean well-being scores showed a trend indicating an improvement ($t = -2.92$, $p = .008$) in general well-being from pre- to posttreatment at the Bonferroni corrected alpha value of .0056. However, this improvement is statistically significant at the .01 alpha level. This improvement in psychologic well-being was not maintained at follow-up.

Each of the 6 subscales on the GWB was then examined to determine which aspects of general well-being contributed to the overall improvement on the GWB (table 4). Omnibus ANOVAs showed no statistically significant improvement in depression, anxiety, positive well-being, or self-control. On the vitality subscale, a significant improvement occurred over time ($F = 4.22$, $p < .05$). The 3 items on the vitality subscale ask participants about their energy level, whether they are waking up fresh and rested, and whether they are feeling worn out, exhausted, and tired. Improvement in vitality was short-term, with post hoc comparisons showing a significant change only at posttreatment ($t = -3.48$, $p < .0056$), but not at 3-month follow up. This finding suggests that participants were reporting short-term improvements in strength and energy levels after treatments, but the gains were not maintained. There was also a significant improvement reported on the general health subscale ($F = 9.25$, $p < 0.01$). The *t* tests of mean differences on the general health subscale, which consists of 2 items that ask participants to rate how concerned or worried they have been about their health, showed a statistically significant improvement in mean scores at posttreatment ($t = -3.67$, $p < .0056$), and a trend indicating that this improvement was maintained at follow-up ($t = -2.58$, $p = .018$).

DISCUSSION

Acupuncture may be effective in treating a subgroup of individuals who have chronic pain after SCI. Forty-six percent of the present study sample reported moderate to significant pain relief immediately after the course of 15 treatments and 35% of the sample continued to report pain relief at 3-month follow-up. Our data provide preliminary evidence indicating that the subgroup reporting pain relief after acupuncture had chronic pain located above the level of their SCI. Several theories about the mechanism of acupuncture may explain why this occurs. One suggests that the insertion of acupuncture needles stimulates the release of endorphins.[43] Pain above the level of injury may respond better because the pathway to the

Table 4: Mean and SD on Secondary Outcome Measures for the Entire Sample

Outcome Measure	Pretreatment ($n = 22$)	Posttreatment ($n = 22$)	3-Month Follow-Up ($n = 20$)	Repeated-Measures ANOVA F
General health				
Individualized symptom rating scale	6.69 ± 1.28	4.65 ± 2.01*	4.53 ± 2.07†	11.70‡
Pain interference				
Activity scale	5.07 ± 1.92	3.27 ± 2.16*	3.85 ± 2.82	4.67§
Mood				
CES–D Scale	13.73 ± 8.90	11.32 ± 9.13‖	11.80 ± 9.83	1.50
STAI	48.02 ± 10.74	45.86 ± 8.97	47.55 ± 11.56	1.80
Psychologic well-being				
GWB total	69.07 ± 17.11	76.64 ± 18.53*	73.35 ± 18.42	3.99§
Anxiety	18.66 ± 4.72	20.55 ± 5.11	19.90 ± 4.81	1.28
Depression	16.57 ± 3.98	17.23 ± 3.98	16.60 ± 3.87	1.01
Positive well-being	11.84 ± 3.50	12.32 ± 2.72	12.50 ± 2.88	0.40
Self control	15.34 ± 2.22	15.50 ± 2.39	15.85 ± 1.95	0.27
Vitality	13.25 ± 4.01	15.05 ± 4.81¶	14.55 ± 3.78	4.22§
General health	7.41 ± 3.23	10.00 ± 3.40¶	7.95 ± 3.94**	9.25‡

NOTE. *t* tests, pretreatment-posttreatment difference.
* $p < .01$.
† Pretreatment follow-up difference, $p < .01$.
‡ $p < .01$.
§ $p < .05$.
‖ $p < .05$.
¶ Bonferroni corrected $p < .0056$.
** Pretreatment follow-up difference, $p < .05$.

central nervous system is still intact. This hypothesis might also explain why participants with incomplete injuries appear to do better than those with complete ones. A second possibility is that people with complete injuries are more likely to have central pain than musculoskeletal pain. Although not statistically significant, responders were also more likely to have incomplete rather than complete SCIs and musculoskeletal rather than central pain. Despite the fact that response to acupuncture was not as good among participants with central pain, it is still encouraging that 42% of them reported moderate to significant pain relief immediately after treatment. Given that central pain is more refractory to conventional treatment,[44] this finding suggests that acupuncture may provide a viable treatment alternative for some individuals with this kind of pain. Another preliminary finding is that the participants with moderate levels of pain intensity were more likely to experience long-term (3mo) pain relief than those who started out with more severe pain intensity.

Expectancy is an unlikely explanation for the treatment effect observed. Participants' expectations of treatment credibility and success were not associated with the amount of pain relief they experienced, suggesting that factors other than expectations of treatment outcome were responsible for the improvements observed. The fact that the present sample consisted of a group of first-time acupuncture users probably minimized any preconceived expectations that may have influenced treatment outcome. However, it is possible that the improvement in pain scores observed among the responders is attributable to a placebo effect and may not be from the acupuncture per se. This possibility does not seem very likely, considering that most participants had tried multiple treatments for their chronic pain with little success. Nevertheless, a placebo-controlled study will be necessary to determine whether acupuncture was effective or whether the observed changes were a placebo response.

Participants reported some secondary benefits to acupuncture. Significant improvement in pain-related sequelae, such as sleep difficulties, and reduced movement and activity were reported both immediately after treatment and 3 months later. Also, a decrease in pain interference with ADLs occurred after treatment but not at follow-up. However, in terms of mood, we found no improvement in anxiety or depression (CES-D, STAI, or GWB mood subscales). Because the group was not markedly depressed or anxious to begin with, it is possible that a floor effect minimized any changes that might have otherwise been apparent. Participants did, however, show improvement in overall psychologic well-being (GWB) after treatment. This change was because of improved energy levels and a reduced concern with one's health. An alternative explanation for these psychologic benefits may be that the changes observed are associated with the nonspecific effects of consistent and frequent contact with a health care professional rather than the direct result of acupuncture.

Because treatments involved the insertion of needles both above and below the level of injury, we considered autonomic dysreflexia to be a potential risk and blood pressure and other symptoms were carefully monitored throughout the study. Results are reported elsewhere.[42] One adverse effect observed in the present study was from a small group of participants who reported a slight increase in pain after the course of treatments and at follow-up.

There are several limitations to the present investigation. First, the lack of a no-treatment control group or a comparison group receiving an alternative treatment makes it difficult to definitively attribute changes to the treatment per se. However, this was a pilot study designed to explore whether acupuncture had any effect at all on chronic pain in this population, regardless of the source of the treatment effect. Therefore, as a first step, only a baseline control phase was included in the design. To draw more definitive conclusions about the effect of acupuncture requires a larger placebo-controlled study. Another potential problem with the present study is that treatments were offered in a single 15-session course and then withdrawn, which is unlike the practice of acupuncture in the real world, where treatments are usually tapered off gradually. Furthermore, we used a standardized acupuncture protocol, with only a small degree of flexibility in the choice of acupoints, to make treatments comparable across participants. Although this approach makes it easier to interpret results, it represents a departure from the practice of traditional acupuncture in which treatment protocols are tailored to the individual's symptoms and personal characteristics and are constantly modified to maximize treatment benefit. Therefore, the moderate results observed in the present study may actually have been larger had the acupuncturist been allowed to tailor treatment to the individual more completely.

CONCLUSION

Acupuncture may be an effective treatment for chronic pain for a subgroup of individuals with SCI. About half of the present study sample (46%) reported pain relief after acupuncture. Participants also reported improvements in pain sequelae, general well-being, and pain interference. One of the study's more noteworthy findings was that 42% of participants with central pain and 80% of participants with musculoskeletal pain experienced pain relief. This result is encouraging considering that little research evidence exists that supports the efficacy of acupuncture for the treatment of central pain. In the present study, among the participants who did not respond to acupuncture, 4 reported an increase in pain intensity. These findings must be replicated in a longer term study that has a larger sample, including a nonacupuncture control group. Some issues that merit further investigation include determining which individuals with SCI will benefit from acupuncture; the longer term effects of acupuncture; and whether individualized treatments will be more successful than the fixed protocol approach used in the present study.

Acknowledgment. The authors gratefully acknowledge the assistance of Richard Serano, MD, and Robert Matheis, MA.

References

1. Cairns DM, Adkins RH, Scott MD. Pain and depression in acute traumatic spinal injury: origins of chronic problematic pain? Arch Phys Med Rehabil 1996;77:329-33.
2. Anson CA, Shepherd C. Incidence of secondary complications in spinal cord injury. Int J Rehabil Res 1996;19:55-66.
3. Mariano AJ. Chronic pain and spinal cord injury. Clin J Pain 1992;8:87-92.
4. Roper Starch Worldwide Inc. Chronic pain in America: roadblocks to relief. Available at: http://www.ampainsoc.org/whatsnew/toc_road.htm. Accessed April 12, 2001.
5. Britell CW. Outcomes for spinal injury: the long view [editorial]. J Am Paraplegia Soc 1992;15:1-2.
6. Johnson RL, Gerhart KA, McCray J, Menconi JC, Whiteneck GG. Secondary conditions following spinal cord injury in a population-based sample. Spinal Cord 1998;36:45-50.
7. Richards JS. Chronic pain and spinal cord injury: review and comment. Clin J Pain 1992;8:119-22.
8. Craig AR, Hancock KM, Dickson HG. Spinal cord injury: a search for determinants of depression two years after the event. Br J Clin Psychol 1994;33:221-30.
9. Calodney A. Pain after spinal cord injury. Pain Digest 1993;3:112-5.

10. Anke AG, Stenehjem AE, Stanghelle JK. Pain and life quality within 2 years of spinal cord injury. Paraplegia 1995;33:555-9.
11. Summers JD, Rapoff MA, Varghese G, Porter K, Palmer RE. Psychosocial factors on chronic spinal cord injury pain. Pain 1991;47:183-9.
12. DeLisa JA, Kirshblum S. A review: frustrations and needs in clinical care of spinal cord injury patients. J Spinal Cord Med 1997;20:384-90.
13. Ravenscroft A, Ahmed YS, Burnside IG. Chronic pain after spinal cord injury: a survey of practice in UK spinal injury units. Spinal Cord 1999;37:25-8.
14. Ragnarsson KT. Management of pain in persons with spinal cord injury. J Spinal Cord Med 1997;20:186-99.
15. Segatore M. Deafferentation pain after spinal cord injury. Part II. Management. SCI Nurs 1992;9:72-8.
16. Tunks E. Pain in spinal cord injured patients. In: Bloch RF, Basbaum M, editors. Management of spinal cord injuries. Baltimore: Williams & Wilkins; 1986. p 180-211.
17. Podolsky D. Nod to an ancient art. US News & World Rep 1996 May 13;78-90.
18. Lewith GT. How effective is acupuncture in the management of pain? J R Coll Gen Pract 1984;34:275-8.
19. Wainapel SF, Thomas AD, Kahan BS. Use of alternative therapies by rehabilitation outpatients. Arch Phys Med Rehabil 1998;79: 1003-5.
20. NIH Consensus Conference. Acupuncture. JAMA 1998;280: 1518-21.
21. Patel M, Gutzwiller F, Paccaud F, Marazzi A. A meta-analysis of acupuncture for chronic pain. Int J Epidemiol 1989;18:900-6.
22. Christensen BV, Iuhl IU, Vilbek H, Bulow HH, Dreijer NC, Rasmussen HF. Acupuncture treatment of severe knee osteoarthrosis. A long-term study. Acta Anaesthesiol Scand 1992;36:519-25.
23. Takeda W, Wessel J. Acupuncture for the treatment of pain of osteoarthritic knees. Arthritis Care Res 1994;7:118-22.
24. Thomas M, Eriksson SV, Lundeberg T. A comparative study of diazepam and acupuncture in patients with osteoarthritis pain: a placebo controlled study. Am J Chin Med 1991;19:95-100.
25. Hesse J, Mogelvang B, Simonsen H. Acupuncture versus metoprolol in migraine prophylaxis: a randomized trial of trigger point inactivation. J Intern Med 1994;235:451-6.
26. Tavola T, Gala C, Conte G, Invernizzi G. Traditional Chinese acupuncture in tension-type headache: a controlled study. Pain 1992;48:325-9.
27. Thomas M, Lundberg T. Importance of modes of acupuncture in the treatment of chronic nociceptive low back pain. Acta Anaesthesiol Scand 1994;38:63-9.
28. Birch S, Hammerschlag R, Berman BM. Acupuncture in the treatment of pain. J Altern Complement Med 1996;2:101-24.
29. Johansson K, Lindgren I, Widner H, Wiklund I, Johansson BB. Can sensory stimulation improve the functional outcome in stroke patients? Neurology 1993;43:2189-92.
30. Naeser MA, Alexander MP, Stiassny-Eder D, Galler V, Hobbs J, Bachman D. Acupuncture in the treatment of paralysis in chronic and acute stroke patients: improvement correlated with specific CT scan lesion sites. Acupunct Electrother Res 1994;19:227-49.
31. Gao X, Gao C, Gao J, Han C, Han F, Han B, et al. Acupuncture treatment of complete traumatic paraplegia—analysis of 261 cases. J Tradit Chin Med 1996;16:134-7.
32. Politis MJ, Korchinski MA. Beneficial effects of acupuncture treatment following experimental spinal cord injury: a behavioral, morphological, and biochemical study. Acupunct Electrother Res 1990;15:37-49.
33. Wen HL. Acute central cervical cord syndrome treated by acupuncture and electrical stimulation (AES). Comp Med East West 1978;6:131-5.
34. Jenson MP, Karoly P. Self report scales and procedures for assessing pain in adults. In: Turk DC, Melzack R, editors. Pain assessment. New York: Guilford Pr; 1992. p 135-51.
35. Radloff LS. The CES-D scale: a self report depression scale for research in the general population. Appl Psychol Meas 1977;1: 285-401.
36. Spielberger CD, Gorsuch RL, Lushene R, Vagg PR, Jacobs GA. Manual for the State-Trait Anxiety Inventory (form Y). Palo Alto (CA): Consulting Psychologists Pr; 1983.
37. McDowell I, Newell C. Measuring health: a guide to rating scales and questionnaires. 2nd ed. New York: Oxford Univ Pr; 1996.
38. Vincent CA, Richardson PH. Evaluation of therapeutic acupuncture: concepts and methods. Pain 1986;24:1-13.
39. Borkovec TD, Nau SD. Credibility of analogue therapy rationales. J Behav Ther Exp Psychiatry 1972;3:257-60.
40. Siddall PJ, Taylor D, Cousins MJ. Pain associated with spinal cord injury. Curr Opin Neurol 1995;8:447-50.
41. Maynard FM, Bracken MB, Creasey G, Ditunno JF Jr, Donovan WH, Ducker TB, et al. International Standards for Neurological and Functional Classification of Spinal Cord Injury. American Spinal Injury Association. Spinal Cord 1997;35:266-74.
42. Averill A, Cotter AC, Nayak S, Matheis RJ, Shiflett SC. Blood pressure response to acupuncture in a population at risk for autonomic dysreflexia. Arch Phys Med Rehabil 2000;81:1494-7.
43. Stux G, Pomeranz B. Basics of acupuncture. New York: Springer; 1989. p 6-72.
44. Roth E. Controlling pain in spinal cord injury. Rehabil Manage 1991;Feb-Mar:63-7.

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