

Real Versus Sham Acupuncture in the Treatment of Paralysis in Acute Stroke Patients: A CT Scan Lesion Site Study

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This study compared real versus sham acupuncture in the treatment of paralysis in acute stroke patients and examined the results in relationship to CT scan lesion sites. Sixteen patients with right-sided paralysis who had suffered left hemisphere ischemic infarction were randomly assigned to receive either twenty real acupuncture treatments or twenty sham acupuncture treatments over a one-month period beginning at 1-3 months post stroke onset. Results indicated that significantly more patients had good response following real acupuncture than sham acupuncture if CT scan lesion site was a variable ($p < .013$). When there was lesion in half or less than half of the motor pathway areas on CT scan, acupuncture was effective. No patients who received sham acupuncture had good response, whatever the lesion. **Key Words:** Acupuncture—Cerebrovascular disorders—Stroke—Paralysis—Tomography, x-ray computed.

Stroke is the most common cause of permanent neurologic disability in the United States; approximately 60 percent of stroke patients have some degree of residual paralysis (1). Since 1979, the World Health

Organization has listed post-stroke paresis as an impairment potentially treatable with acupuncture (2), but there are no controlled studies on the efficacy of acupuncture for paresis (3,4,5,6). Controlled studies are imperative because post-stroke paralysis shows spontaneous improvement (7). There is little information about the possible neurological mechanisms of acupuncture in this setting. Acupuncture performed on the scalp increases cerebral blood flow after stroke, but not in normal controls (5). Increased blood flow usually reflects increased cerebral metabolism, but it is not known which structures might increase activity with acupuncture. Several investigators have demonstrated that damage to particular brain regions has a powerful correlation with poor neurologic recovery (8,9). It is possible that sparing of those structures allows acupuncture-induced changes in cerebral function that lead to improved neural function in some cases. We report a small controlled study of acupuncture for post-stroke hemiparesis. We also examined CT scans for lesion site profiles that might predict or constrain response to acupuncture treatment.

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This research was supported in part by the Robert Wood Johnson Foundation Grant #09052, and in part by the Barnsider Management Corp., Hamilton, MA.

This paper was presented at the National Stroke Rehabilitation Conference sponsored by Spaulding Rehabilitation Hospital, Cambridge, MA, April 29, 1988; the Annual Meeting, American Association of Acupuncture and Oriental Medicine, Boston, MA, May 1, 1988; the Meetings of the Deutsche Arztegesellschaft fur Akupunktur, Freudensadt, Germany, September 12, 1989; and the International Council for Medical Acupuncture and Related Techniques (ICMART) Meetings, Munich, Germany, June 16, 1991.

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Methods

Subjects

Sixteen right-handed patients agreed to participate (Appendix A). All patients had suffered a left hemisphere infarction one to three months previously and had significant right hemiparesis. To be selected, patients had to have greatly reduced arm and leg power with reduced or no voluntary isolated finger movement. The patients were randomly assigned to receive either twenty real acupuncture treatments or twenty sham acupuncture treatments. There were no significant differences between the two groups in age or time postonset. All patients were inpatients at either the Boston V.A. Medical Center or Braintree Rehabilitation Hospital. They received daily standard physical therapy during the study.

Motor Evaluation

A motor examination, the Boston Motor Inventory test (10), was designed for this research project. This test measured the isolated active range of motion on the involved side for four leg and three arm movements, all proximal. Evaluations were performed by three physical therapists who were blind to the treatment. Patients

were tested before beginning treatment (pretest) and within five days of completing treatment (posttest).

Treatment

Informed consent was obtained prior to randomization and treatment. In both groups, treatment was performed five days per week, for four weeks, for a total of twenty treatments. Disposable, one-time use only, 34 gauge acupuncture needles were used.

REAL ACUPUNCTURE TREATMENTS

Needles were inserted into a limited number of standard acupuncture points (11) and left in place for twenty minutes (Table 1). Acupuncture points are areas of specific *decreased* electrical resistance on the skin (12,13). Scalp acupuncture points along the motor cortex line on the side of hemispheric infarction (left) were also used (11). Low-frequency electrical stimulation (1–2 Hz) was used on the needles on selected points listed in Table 1.

SHAM ACUPUNCTURE TREATMENTS

Points for sham treatments were individually identified with a Fluke Ohm meter. Several areas of normal

Table 1. Acupuncture Points Used for Real Acupuncture Treatments

Location of Acupuncture Points	List of Acupuncture Points
Right arm (paralyzed side): ¹	LI (large intestine meridian): #4,11,15 TW (triple warmer meridian): #5,9 Three distal Baxie points
Right leg (paralyzed side): ¹	St (stomach meridian): #31,36 GB (gall bladder meridian): #34, 39 Li (liver meridian): #3
Left arm (nonparalyzed side):	LI (large intestine meridian): #4,11
Left leg (nonparalyzed side):	St (stomach meridian): #36
Right and left ears:	Shenmen
Scalp acupuncture on side of hemispheric infarction (left) ²	Four or five needles along the "motor cortex line" on the scalp

¹ Low-frequency electrical stimulation (1–2 Hz) was used on the needles on the right arm and right leg, in three pairs of points (LI 4 and 11; TW 5 and Baxie at index finger; and GB 34 and 39) for twenty minutes per treatment session. The electrical stimulation was obtained from the Electro Acupunctoscope WQ-10B from China. The intensity of stimulation was controlled by the patient and maintained at a comfortable level; the maximum output, 200 milliamperes, was never reached (range 10–200 mA).

² Low-energy electrical stimulation was also used on the scalp needles (twenty minutes).

electrical resistance were located on the nonparalyzed limbs. Acupuncture needles were inserted into these normal resistance points and left in place for twenty minutes. The sham acupuncture was done only on the nonparalyzed upper extremity and lower extremity. The patients were told that in China acupuncture is used on the nonparalyzed side to treat the paralyzed side (which is sometimes the case). Additionally, alligator clips attached to a thin insulated wire were attached to the needles. The patients were told that the clips attached to the wire were providing additional stimulation to the acupuncture points. They were further told that the stimulation was low level, and they would not feel anything. (The clips and wire were not attached to an electrical stimulation machine and the clips were only attached to the cord with string, which was not visible.)

When the treatment program had been completed (twenty sham acupuncture sessions), patients were informed that they had been in the sham group. Real acupuncture was offered at that time. Two of the six cases in the sham group elected to receive twenty real acupuncture treatments. (These cases are marked with an asterisk in the first column in Appendix A.)

CT Scan Lesion Site Analysis

In most cases, CT scans were performed at two months postonset or later in order to better visualize the complete borders of the infarct. For two cases, CT scans done only at one week or one month postonset were available. The CT scans were analyzed in a retrospective manner after the entire study had been completed. Neuroanatomical diagrams for the hypothetical location of descending pyramidal tract pathways for the leg and arm on CT scan (Figure 1) were developed for this project from previously published studies (8,9,14,15).

The CT scan neuroanatomical areas shown in Figure 1 were visually assessed for amount of infarction (extent of lesion) for each case, using the following scale: 0 = no lesion; 1 = equivocal lesion; 2 = small, patchy or partial lesion; 2.5 = patchy, less than half of area has lesion; 3 = half of area has lesion; 3.5 = patchy, more than half of area has lesion; 4 = more than half of area has solid lesion; 5 = total area has solid lesion. We have used a similar scale and methodology in previous CT scan studies with an interrater reliability coefficient of .93 (16).

Areas specifically examined for infarction on CT scan included the motor cortex plus immediate subjacent white matter and the descending pyramidal tract pathways in the periventricular white matter (PVWM), posterior limb internal capsule (PLIC) (14), down to the level of the cerebral peduncle in the brainstem. Lesions

were analyzed in a sequential manner from the cortical level to the subcortical levels (PVWM and PLIC) to the brainstem. Extensive lesion at an upper level rendered additional lesion at the lower levels less important.

Results

Real vs. Sham Acupuncture

The pre- and posttest scores for all motor evaluations and a summary of the total number of improved tests for all sixteen patients are presented in Appendix A. Four of ten patients receiving real acupuncture showed at least a 10 percent increase in isolated active range of motion for at least two of the seven tests (good response). None of the six patients receiving sham acupuncture improved by at least 10 percent on at least two of the seven tests; all were considered to have poor response. These results were analyzed for a possible significant difference between the two groups in posttreatment response category (good response versus poor response), using Fischer's Exact Test with the table shown below. (Fischer's Exact Test is a nonparametric statistic specifically designed for use in studies with small n's.)

	Cases Receiving Real Acupuncture, N = 10	Cases Receiving Sham Acupuncture, N = 6
Good response	4	0
Poor response	6	6

$p < .115$

The application of Fischer's Exact Test to this 2 x 2 table revealed no significant difference between the two groups regarding good response versus poor response.

Interaction of Acupuncture and CT Scan Lesion Sites

Analysis of extent of lesion in specific CT scan motor pathway areas revealed that for most patients in this study (12/16) paralysis was primarily due to lesion in the periventricular white matter (PVWM) area. The PVWM is located just superior to the posterior limb, internal capsule (PLIC), on CT scan slices labeled SM and SM+1. The PVWM is diagrammed in coronal and axial sections in Figure 1. The extent of lesion in the PVWM was rated in four separate areas, including second quarter and third quarter of PVWM at slice SM, and second quarter and third quarter of the PVWM at slice SM+1. If complete lesion was present in all four quarters of the PVWM area,

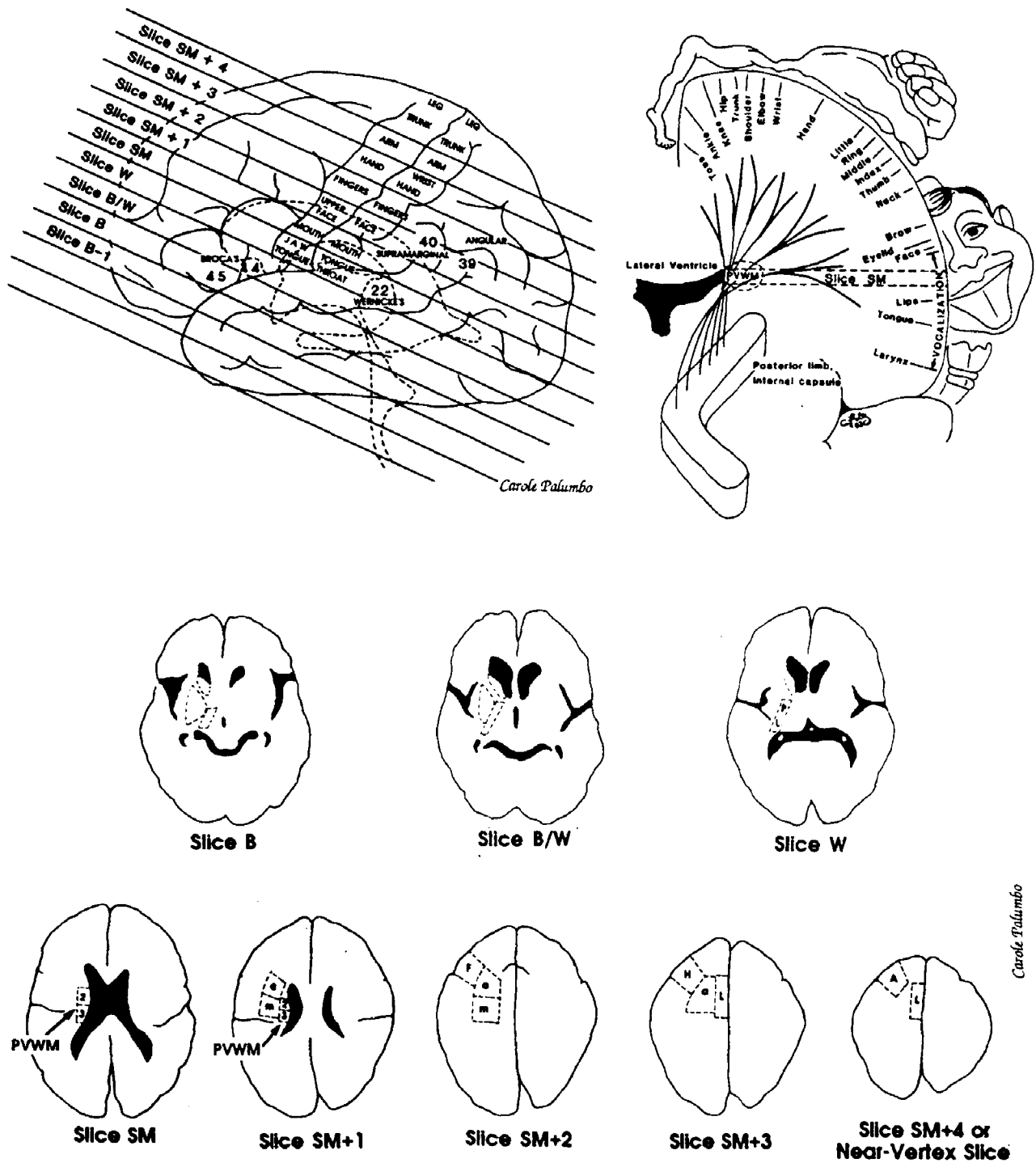


Figure 1. Lateral, coronal, and cross-sectional diagrams showing location of neuroanatomical areas visually assessed for extent of lesion (amount of infarction) on CT scan, containing, in part, descending pyramidal tract pathways. The deep, subcortical periventricular white matter area (PVWM) is outlined in the upper right coronal diagram and shown on CT scan slices SM and SM+1 (arrows). The total extent of lesion in the second and third quarters of the PVWM area was related to good response, versus poor response, following real acupuncture treatments. Key to abbreviations: L = leg cortex area; A = arm cortex area; H = hand cortex area; F = fingers cortex area; a = anterior white matter area; m = middle white matter area; 2 = second quarter PVWM; 3 = third quarter PVWM; PL = posterior limb, internal capsule (continues on slices B and B/W). The head of the caudate and putamen were also assessed for extent of lesion. (CT scan angle is approximately 15–20 degrees to the cantho-meatal line.)

the total lesion extent value was 20, reflecting a rating of 5 (area has solid lesion) times 4 (all four quarters); a total lesion extent value of 10 reflected lesion in approximately half of the PVWM area. The total lesion extent within the PVWM area for each patient is listed in Appendix A, last column. Three patients had paralysis due to lesion in the motor cortex. One patient had paralysis due to lesion in the cerebral peduncle.

Patients were divided into two groups: 1) cases with lesion in <1/2 of the motor pathway areas; and 2) cases with lesion in >1/2 of the motor pathway areas. This created four groups overall—real and sham acupuncture, <1/2 motor pathway lesions, and >1/2 motor pathway lesions, resulting in the table shown below.

The application of Fischer's Exact Test to this 2 x 4 table including the lesion site data revealed a highly significant difference in response category between the real acupuncture group versus the sham acupuncture group ($p < .013$). The important difference was found in the patients with lesion in less than half of the motor pathway areas, and most of the patients with this lesion configuration receiving real acupuncture had good response (3/4). No patients receiving sham acupuncture had good response. For the nine patients with lesion in more than half of the motor pathway areas, eight had poor response whether they had real or sham acupuncture. The critical lesion site variable for good response following real acupuncture was lesion in only half or less than half of the motor pathway areas, especially the PVWM area. The patients with good response following real acupuncture had total lesion extent values of 10 or less for the PVWM area. The patients with poor response following real acupuncture had total lesion extent values of greater than 10 for the PVWM area (Appendix A, last column).

Two patients who originally received sham treatment beginning at one or two months postonset subsequently received twenty real acupuncture treatments beginning at three months postonset. Both patients had poor response following the sham acupuncture and also following the real acupuncture (cases GJ and RJ). Each patient had lesion in more than half of the PVWM area. Total lesion extent in the PVWM area was rated as 17.6 for case GJ, and 19.3 for case RJ (Appendix A, last column).

Case Examples

Patient CR received real acupuncture and had good response (CT scan in Figure 2, top). Patient LH received sham acupuncture and had poor response (CT scan in Figure 2, bottom). Neither patient had lesion in more than half of the PVWM. Thus, each patient had some potential for recovery, but only case CR, who received the real acupuncture, had good response. See Figure 2.

Patient SH had good response following real acupuncture (CT scan in Figure 3, top); lesion was present in less than half of the PVWM area and was not immediately adjacent to the body of the lateral ventricle. Patient GJ had poor response following real acupuncture (CT scan in Figure 3, bottom); lesion was present in more than half of the PVWM area and was immediately adjacent to the body of the lateral ventricle at slice SM+1.

The PVWM lesion at CT scan slice SM for case SH is of particular interest (Figure 3, top). This patient had no improvement in any of the arm tests. Scores were all zero (pre- and posttests). She did, however, show improvement for three of the four leg tests. No lesion was present in the motor cortex areas for the leg or the arm. Some lesion was present in PLIC. There was sparing of the deepest PVWM area, immediately adjacent to the body of the lateral ventricle on slices SM and SM+1. Thus, good recovery of leg, but not arm, in case SH may be a specific effect of sparing of the most medial portion of the PVWM (Figure 3, top).

Discussion

This is the first controlled study of acupuncture in the treatment of paralysis after infarction. Although the study is small, there was a significant therapeutic effect of acupuncture. This significant positive response was, however, highly dependent on CT scan lesion site. Only the treated patients with lesion in less than half of the motor pathway areas improved by at least 10 percent on at least two of the seven motor tests. None of the six patients who received sham acupuncture improved by

	Cases Receiving Real Acupuncture, N = 10		Cases Receiving Sham Acupuncture, N = 6	
	Cases with lesion in <1/2 Motor Pathway Areas, N = 4	Cases with lesion in >1/2 Motor Pathway Areas, N = 6	Cases with lesion in <1/2 Motor Pathway Areas, N = 3	Cases with lesion in >1/2 Motor Pathway Areas, N = 3
Good response	3	1	0	0
Poor response	1	5	3	3

$p < .013$

