

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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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,

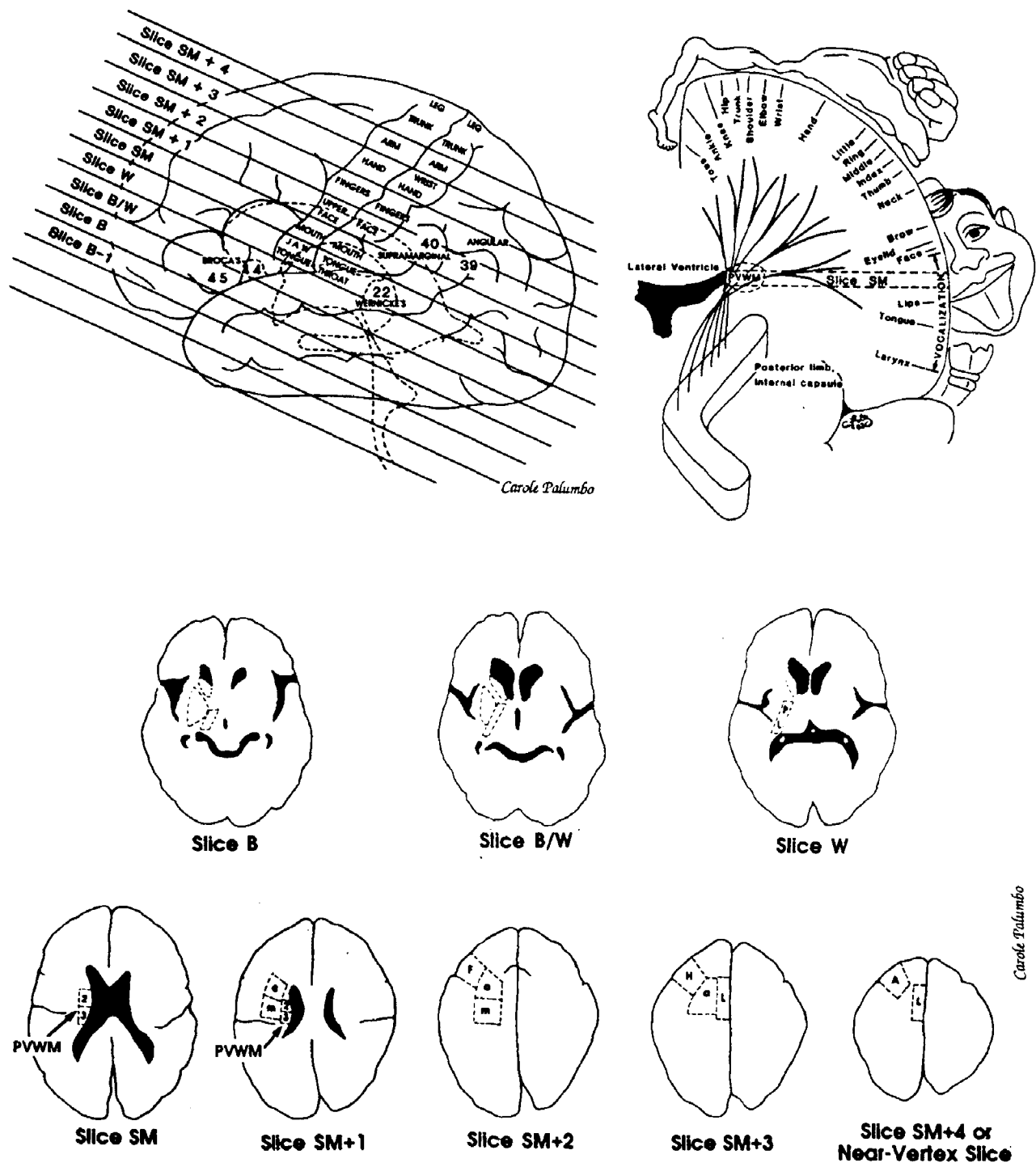


Figure 1. Lateral, coronal, and cross-sectional diagrams showing location of neuroanatomical areas visually assessed for extent of lesion (amount of infarction) on CT scan, containing, in part, descending pyramidal tract pathways. The deep, subcortical periventricular white matter area (PVWM) is outlined 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.

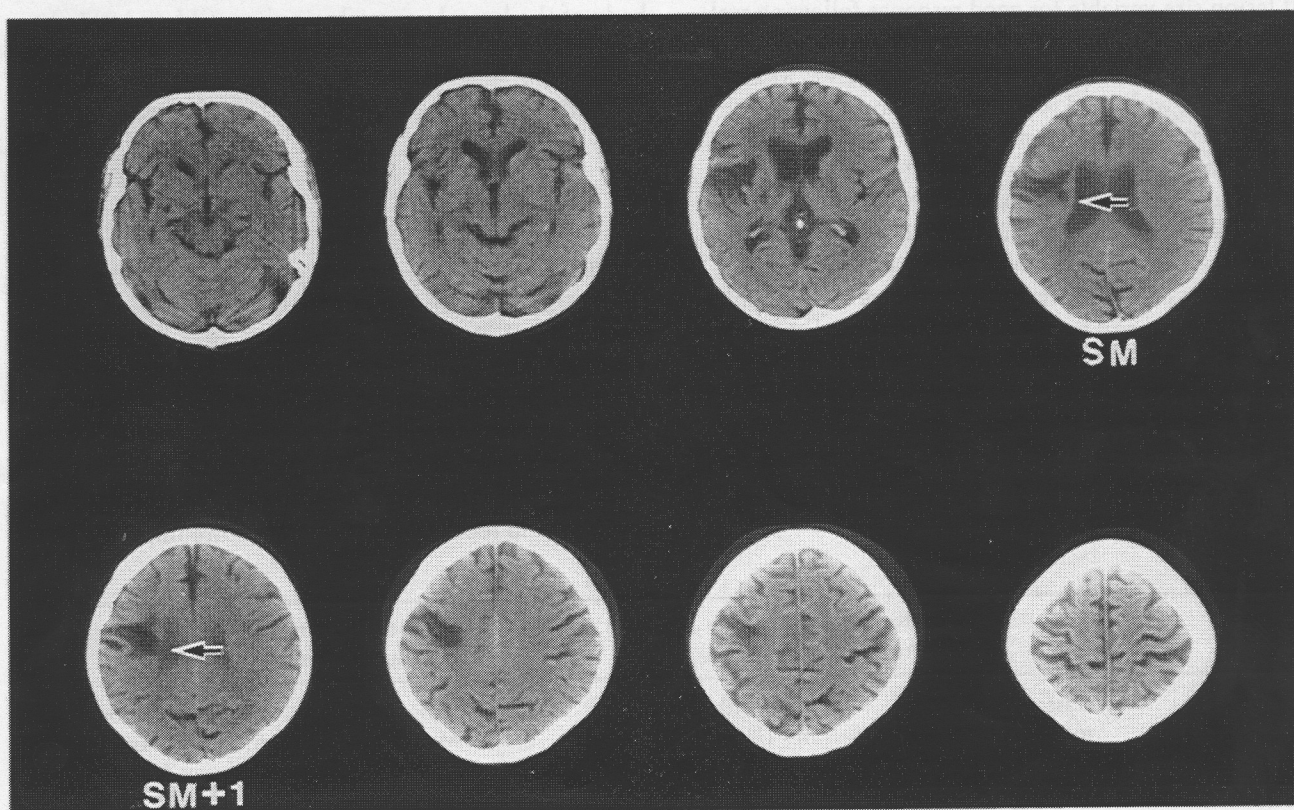
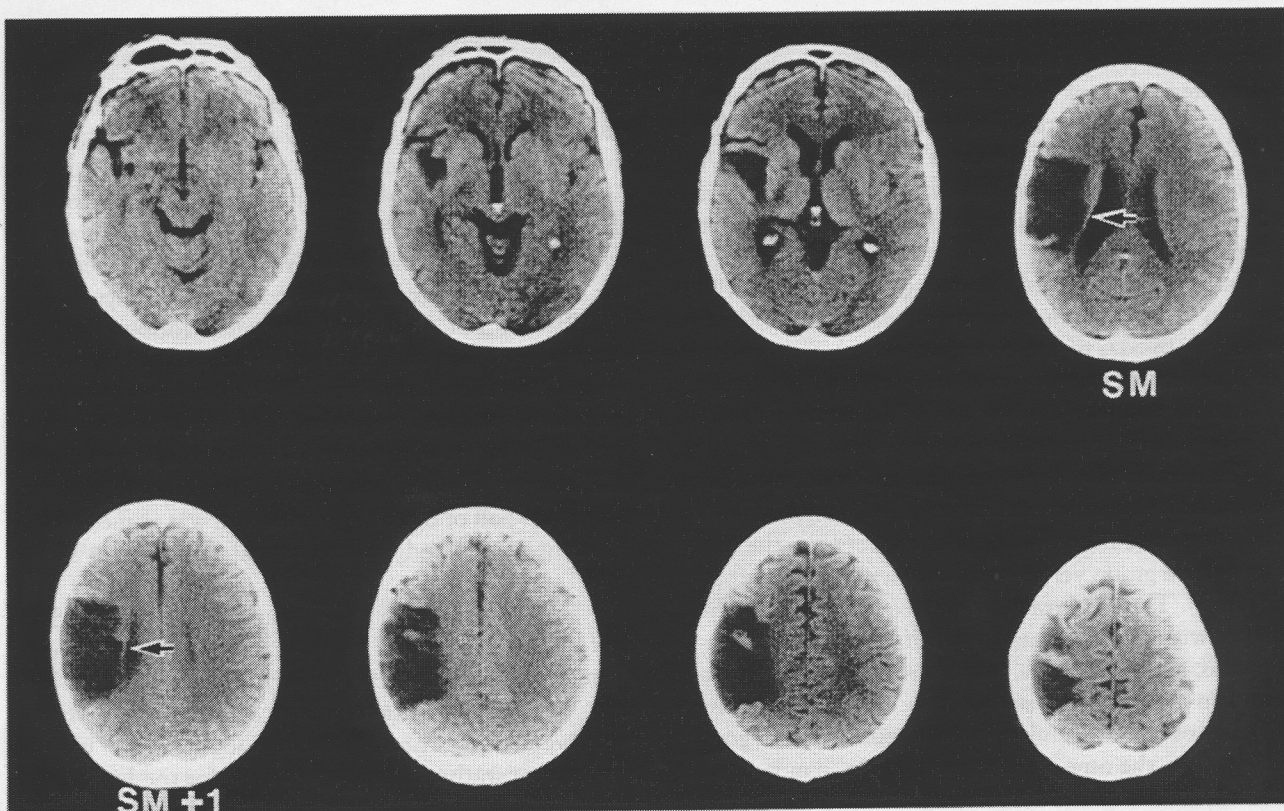
The PVWM lesion at CT scan slice SM for case SH is of particular interest (Figure 3, top). This patient had no improvement in any of the arm tests. Scores were all zero (pre- and posttests). She did, however, show improvement for three of the four leg tests. No lesion was present in the motor cortex 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

$p < .013$



at least 10 percent on at least two of the seven tests, even if there was lesion in less than half of the motor pathway areas. Lesion in more than half of the motor pathway areas apparently precludes good response to acupuncture as a treatment for paralysis. The limited case comparisons in this study suggested that extent of lesion in the subcortical PVWM area was more critical than extent of lesion in the PLIC (Case SH, Figure 3, top). The greater importance to motor recovery of lesion in the PVWM than lesion in the PLIC has been previously observed (8).

The second and third quarters of the PVWM area contain the descending pyramidal fibers from motor cortex. Within the second and third quarters of the PVWM area at the level of the body of the lateral ventricle, the descending pyramidal tract pathways for the leg are most medial. The descending pyramidal tract pathways for the arm are slightly more anterior and lateral within the white matter at that level. This distribution within the white matter at the level of the body of the lateral ventricle has recently been observed in an anterograde staining study with rhesus monkeys (17). One of our patients had a very discrete sparing of the most medial PVWM and good recovery of leg function after acupuncture (case SH). This is consistent with the pathway localization in monkeys. The second and third quarters of the PVWM also contain the body of the caudate nucleus and numerous other intra- and interhemispheric pathways. These pathways include: (1) the mid-callosal pathways; (2) the medial subcallosal fasciculus containing connections to the caudate from the supplementary motor area and the cingulate gyrus (18,19,20); (3) the occipito-frontal fasciculus (19); and (4) the superior lateral thalamic peduncle which includes projections from the dorsomedial nucleus and the anterior nucleus to the cingulate (21) and projections from the ventrolateral nucleus to the motor cortex. Thus, even within this small region there are numerous motor systems that might, if incompletely

damaged, respond to acupuncture. These systems include dorsal striatum, supplementary motor area, or the frontal-striatal-ventrolateral thalamic-frontal loop, as well as the descending pyramidal system.

A neurophysiological mechanism for the effect of acupuncture cannot be proposed at present. Acupuncture performed on scalp acupuncture points increases cerebral blood flow in some stroke patients but not in normal controls (5). Changes in cerebral blood flow are produced by changes in underlying neural metabolic activity. Thus, the change in blood flow may serve as a marker for the physiological processes that support the functional changes in the partially spared neural structures. [In Chinese hospitals, although acupuncture is begun as soon as possible after stroke onset in ischemic infarction cases, it is not begun until two or three weeks postonset in hemorrhage cases to protect against any possible increase in bleeding (MN, personal observation, Shanghai Medical University.)]

The electroacupuncture used in this study was done at a low frequency (1–2 Hz). When used for analgesia, this electroacupuncture technique increases central nervous system beta-endorphin levels and ACTH (22–26). The modulatory effect of neuropeptides might be particularly likely to underlie the slow, but stable improvement in motor function.

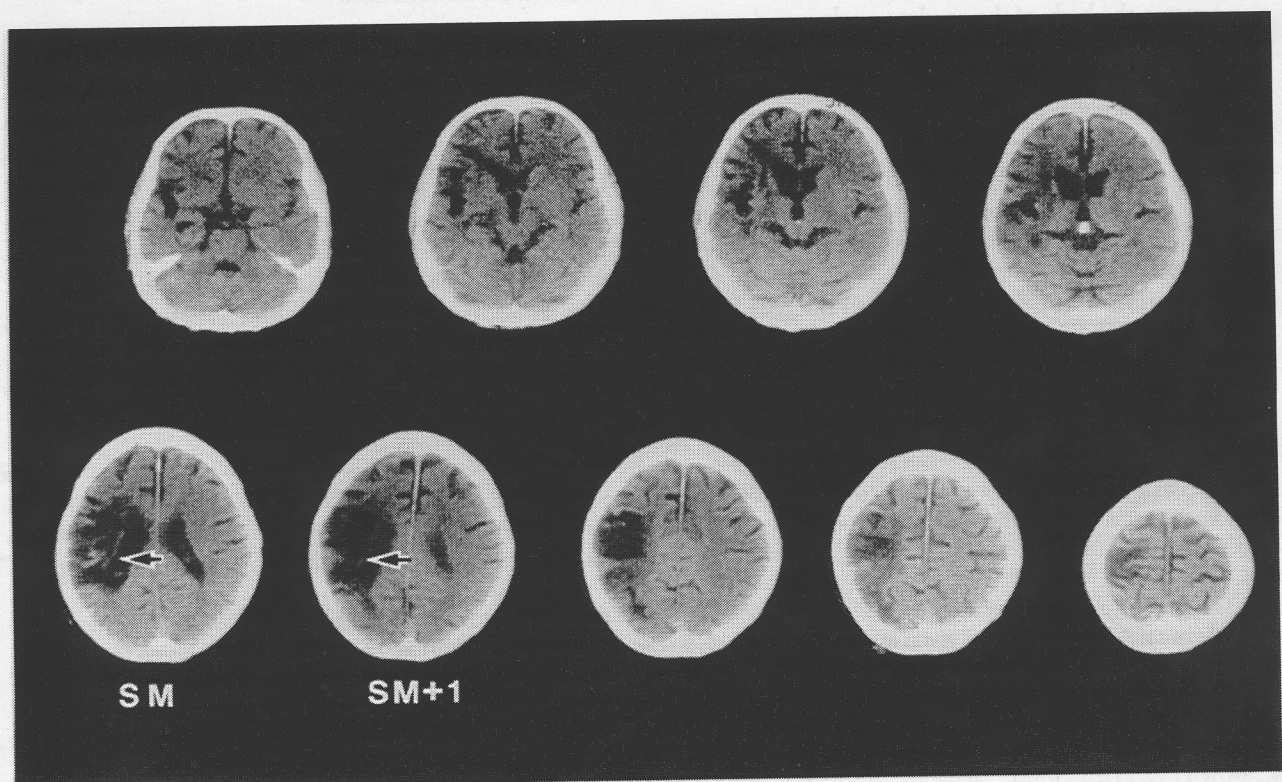
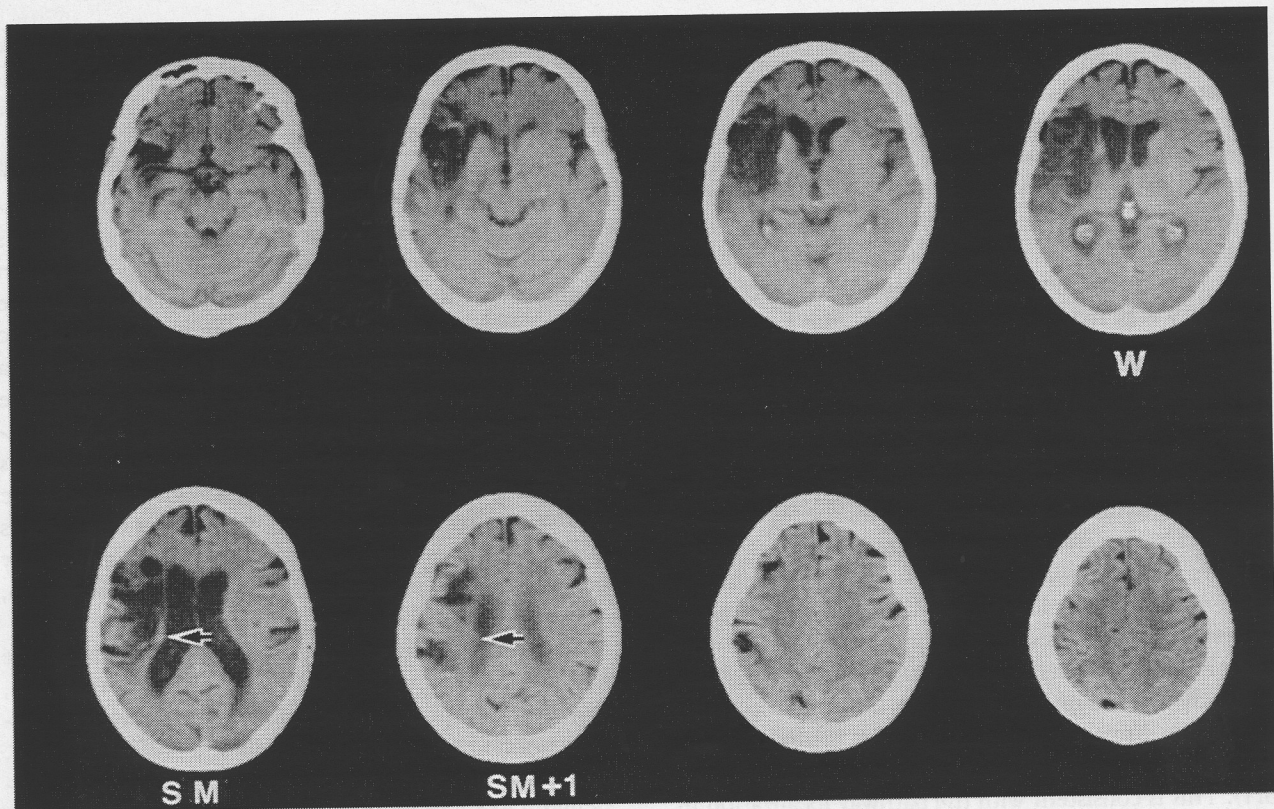
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Figure 2. Two CT scans for two patients: one who received real acupuncture (top) and one who received sham acupuncture (bottom). Each patient had similar extent of lesion in the PVWM area on CT scan slices SM and SM+1. Each patient had lesion in only about half of the PVWM area; thus they were well-matched cases for comparison of real acupuncture versus sham acupuncture.

The method of computing total PVWM lesion extent with a 0–5 point rating scale is explained as follows: A lesion extent value of 5 reflects total solid lesion in a given area drawn on the CT scan templates at the bottom of Figure 1. If solid lesion (rating of 5) was present in the second and third quarters of the PVWM area on slices SM and SM+1 (four quarters), a total lesion extent value of 20 represented complete lesion in the PVWM area. A total lesion extent value of 10 represented lesion in approximately half of the PVWM area. Each patient in this figure had a total PVWM lesion extent value of 10. Additionally, for each patient in this figure, the PVWM lesion was not immediately adjacent to the body of the lateral ventricle; there was a thin area of sparing within the PVWM area immediately adjacent to the body of the lateral ventricle (arrows).

TOP: This patient (CR, 67 yr. M) received real acupuncture beginning at three months postonset and had good response. CT scan is twelve months postonset.

BOTTOM: This patient (LH, 70 yr. M) received sham acupuncture beginning at one month postonset and had poor response. CT scan is six months postonset. See Appendix A for specific pre- and posttreatment scores for each patient.



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Note: Information regarding the status of acupuncture in the various states and names of Certified Acupuncturists may be obtained from the American Association of Acupuncture and Oriental Medicine, 4101 Lake Boone Trail, Raleigh, NC 27607, (919) 787-5181.

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Figure 3. Two CT scans for two patients who received real acupuncture. The patient in the top CT scan (SH) had lesion in less than half of the PVWM area at slices SM and SM+1; she had good response. The patient in the bottom CT scan (GJ) had lesion in more than half of the PVWM area at slices SM and SM+1; he had poor response.

TOP: Case SH, 65 yr. F, who began receiving real acupuncture treatments at two months postonset. The total PVWM lesion extent for this patient was computed as follows: second quarter PVWM: Slice SM = 5; Slice SM+1 = 1; third quarter PVWM: Slice SM = 3; Slice SM+1 = 0; total PVWM lesion extent = 9. This patient had lesion in less than half of the total PVWM area (total PVWM lesion extent < 10), and there was good response following real acupuncture. The PVWM lesion was not immediately adjacent to the body of the lateral ventricle (arrows). Note that this patient with lesion in less than half of the PVWM area had good response following the acupuncture treatments, despite presence of some lesion in the PLIC (slice W). CT scan is five months postonset.

BOTTOM: Case GJ, 58 yr. M, who began receiving real acupuncture treatments at three months postonset. The total PVWM lesion extent for this patient was computed as follows: second quarter PVWM: Slice SM = 4.25; Slice SM+1 = 4.8; third quarter PVWM: Slice SM = 3.75; Slice SM+1 = 4.8; total PVWM lesion extent = 17.6. This patient had lesion in more than half of the PVWM area (total PVWM lesion extent > 10), and there was poor response following real acupuncture. The PVWM lesion (arrows) was immediately adjacent to the body of the lateral ventricle on slice SM+1. This patient had also had poor response following twenty sham acupuncture treatments, which had been initiated at one month postonset. CT scan is eight months postonset. See Appendix A for specific pre- and posttreatment scores for each patient.

Appendix A Lower Extremity and Upper Extremity Pre- and Posttreatment Test Scores for Acute Stroke Patients with Right-sided Paralysis Who Received Either Real Acupuncture or Sham Acupuncture. GR = Good Response PR = Poor Response

Lower Extremity Tests—Percent Isolated Active ROM										
	Age	MPO	Hooklying		Knee		Knee		Ankle	
	Enter	Enter	Abd./Add.		Flexion		Extension		Dorsiflexion	
	Study	Study	Pre- Tx.	Post 20 Tx's	Pre- Tx.	Post 20 Tx's	Pre- Tx.	Post 20 Tx's	Pre- Tx.	Post 20 Tx's
Real Acupuncture										
Acute Cases:										
Cases, Lesion < 1/2										
Motor Pathways										
HN	74	1	100	100	0	0	17	95	0	0
SA	61	1	100	100	0	0	56	70	0	0
SH	65	2	33	100	7	31	11	44	27	18
CR	67	3	100	100	23	85	100	100	90	90
Cases, Lesion > 1/2										
Motor Pathways										
CL	44	1	0	100	0	0	0	17	0	0
GD	68.5	2	100	100	0	0	0	0	0	0
SS	56	3	100	100	0	0	22	22	0	0
EH	65	3	0	0	0	0	0	0	0	0
GJ*	58	3	100	100	0	0	0	0	0	0
RJ*	54	3	100	100	0	0	100	100	0	0
Sham Acupuncture										
Acute Cases:										
Cases, Lesion < 1/2										
Motor Pathways										
MJ	72	1	100	100	0	0	0	0	0	0
LH	70	1	100	100	0	69	92	100	58	42
CP	54	2	75	75	0	0	0	0	0	0
Cases, Lesion > 1/2										
Motor Pathways										
GJ*	58	1	100	100	0	0	0	0	0	0
HJ	58	2	100	100	0	0	61	40	0	0
RJ*	54	2	100	100	0	0	100	100	0	0

*Cases who originally received 20 sham acupuncture treatments over a 1 month period, then 20 real acupuncture treatments over the next 1 month period.

Upper Extremity Tests—Percent Isolated Active ROM

Shoulder Abduction		Forearm Supination Elbow Flexed		Forearm Supination Elbow Extended		Total Number Tests Improved by > 10%	Total Lesion Extent in PVWM (Slices SM + 1 and SM) 20 = Complete Lesion 10 = Half Lesion
Pre-Tx.	Post 20 Tx's	Pre-Tx.	Post 20 Tx's	Pre-Tx.	Post 20 Tx's	Post 20 Tx's	
0	0	0	50	0	50	3 GR	7.5
0	0	0	0	0	0	1 PR	8
0	0	0	0	0	0	3 GR	9
66	78	100	100	44	78	3 GR	10
0	0	0	0	0	0	2 GR	17.5
50	50	44	55	5	11	1 PR	(Leg and Arm Motor Cortex Area Lesions)
0	11	0	0	0	0	1 PR	(Leg and Arm Motor Cortex Area Lesions)
0	0	0	0	0	0	0 PR	14
0	0	0	0	0	0	0 PR	17.6
22	22	0	0	0	0	0 PR	19.3
0	0	0	0	0	0	0 PR	7.25
0	0	0	0	0	0	1 PR	10
0	0	0	0	0	0	0 PR	(Cerebral Peduncle)
0	0	0	0	0	0	0 PR	17.6
0	0	0	0	0	0	0 PR	(Leg and Arm Motor Cortex Area Lesions)
22	22	0	0	0	0	0 PR	19.3

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