

Does Acupuncture Have Additional Value to Standard Poststroke Motor Rehabilitation?

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Background and Purpose—A significant number of patients remain severely disabled after stroke despite rehabilitation with standard treatment modalities. Acupuncture has been reported as an alternative modality. This study aims to examine whether acupuncture has additional value to standard poststroke motor rehabilitation.

Methods—A prospective randomized controlled trial (RCT) was carried out in a stroke rehabilitation unit in Hong Kong. One hundred six Chinese patients with moderate or severe functional impairment were included at days 3 to 15 after acute stroke. They were stratified into the moderate and the severe groups before randomization into the control arm receiving standard modalities of treatment, which included physiotherapy, occupational and speech therapy, and skilled medical and nursing care, and the intervention arm receiving in addition traditional Chinese manual acupuncture. A mean of 35 acupuncture sessions on 10 main acupoints were performed over a 10-week period. Outcome measures included Fugl-Meyer assessment, Barthel Index, and Functional Independence Measure, respectively, at weeks 0, 5, and 10, performed by blinded assessors.

Results—At baseline, patients in each arm were comparable in all important prognostic characteristics. No statistically significant differences were observed between the 2 arms for any of the outcome measures at week 10 or outcome changes over time.

Conclusions—Traditional Chinese manual acupuncture on the body has no additional value to standard poststroke motor rehabilitation. (*Stroke*. 2002;33:186-194.)

Key Words: acupuncture ■ rehabilitation ■ stroke

Standard treatment modalities in stroke rehabilitation are physiotherapy (PT), occupational therapy (OT), and speech therapy, in addition to skilled medical and nursing care. Despite intensive inpatient rehabilitation with these modalities in a stroke unit, 36% of acute stroke patients remain moderately to severely disabled at discharge,¹ thus imposing a great burden on the family and community. This reality drives people to search for other modalities of treatment in an attempt to further improve the outcome of stroke rehabilitation.

Acupuncture is one of the main modalities of treatment in traditional Chinese medicine (TCM) and can be traced back more than 2000 years in China. It was widely used to treat hemiplegia long before the Tang dynasty.² There are numerous reports in the Chinese literature about the efficacy of acupuncture in stroke rehabilitation. However, the result was rarely quantitatively expressed by properly validated measures, and intention-to-treat analysis was never mentioned.³ In a recent preparation for a systematic review of the efficacy of acupuncture in poststroke motor recovery, we found only 12 RCTs out of 1116 acupuncture trials in the Chinese

literature for the period of January 1981 through December 2000. We used as inclusion criteria that the trial must be a randomized controlled one having internationally or nationally recognized outcome measures. All 12 trials showed that the acupuncture group was better in functional recovery than the control group, although none had sample size calculation or used intention-to-treat analysis. Among the 12 trials, only 1⁴ compared the efficacy of acupuncture plus PT and OT with that of PT and OT alone, whereas in the English literature, 10 RCTs were found⁵⁻¹⁴ between 1966 and March 2001, using the same inclusion criteria. Excluding 2 long-term follow-up studies^{13,14} of the same sample of previously reported trials,^{5,9} 26¹² of the remaining 8 RCTs reported negative results and 27⁹ reported positive results in both impairment and disability measures. Among the 8 RCTs, 5 trials compared acupuncture plus PT and OT with PT and OT alone.

Review of these RCTs in the literature reveals that 2 issues have not been totally settled. The first issue is whether acupuncture improves motor recovery after acute stroke. The trials in Mainland China support the efficacy of acupuncture, but the quality of trials makes the results less convincing.

Received May 24, 2001; final revision received August 13, 2001; accepted September 3, 2001.

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Trials published in the English literature suggest that acupuncture may or may not be effective for motor recovery. The second issue is whether acupuncture can further improve motor recovery in addition to the standard treatment. The majority of trials in Mainland China did not include PT and OT treatment, so they could not answer this question, whereas trials in the English literature usually included PT and OT treatment in their design, but the results were inconclusive. Therefore, additional properly designed RCTs in this area are needed before conclusions can be reached. The main objective of the present RCT was to answer the second issue, whether acupuncture has additional value to standard poststroke motor rehabilitation.

Subjects and Methods

Patients

One hundred six consecutive patients admitted to the stroke rehabilitation unit from June 2000 through February 2001 were included in the study after informed consent. Inclusion criteria were the following: (1) Chinese patients with hemorrhagic or ischemic stroke (either CT scan confirmed or CT scan normal but clinically consistent with the World Health Organization's definition of stroke), (2) admission within 15 days of stroke, (3) Glasgow Coma Scale¹⁵ of 15, and (4) ability to follow simple commands. Exclusion criteria were the following: (1) admission Barthel Index (BI)^{16,17} <3 or ≥15, (2) no motor deficit, (3) hemodynamic instability, (4) history of dementia, and (5) inability to give consent because of impaired cognition or receptive aphasia. Among the very severe stroke patients (admission BI ≤5), patients with admission BI <3 were virtually totally dependent in activities of daily living (ADL), most likely with occasional urinary and fecal incontinence, requiring long-term institutional care. On the other hand, patients with admission BI ≥15 were usually quite independent in ADL except bathing and climbing stairs, and they usually requested to be discharged to an outpatient rehabilitation setting in a week or so. Therefore, to make sure all participants could comply with the same treatment protocol of 10 weeks of inpatient and outpatient rehabilitation, we excluded patients with admission BI <3 or ≥15.

Design and Setting

A prospective, single-blinded RCT was carried out in an inpatient stroke rehabilitation unit with day hospital service in Hong Kong, China. Ethics Committee approval was granted, and the trial was performed in accordance with the Declaration of Helsinki.

Sample Size Calculation

According to a previous study on 20 hemiplegic stroke patients¹⁸ receiving standard stroke rehabilitation, the Fugl-Meyer Assessment of Physical Performance—Motor subsection (FMAM) median score change at 8 weeks was 3.7 points, with clinically noticeable motor improvement. In other words, a change of ≈3 points on the FMAM scale was associated with clinically noticeable motor improvement. Therefore, we assumed that the FMAM median score change in the acupuncture arm should be 3 points more than the FMAM median score change in the control arm over the same period of time to demonstrate that acupuncture produced additional motor improvement. Assuming equal variance of FMAM scores in the 2 arms, to detect such a difference required 40 patients in each arm ($P=0.05$, power=0.8, 2-sided test). This was based on a moderate-effect size of 0.5¹⁹ (PASS 2000, NCSS Statistical Software). Taking into consideration a 15% dropout rate, at least 47 patients in each arm were needed.

Stratification and Randomization

After inclusion, patients were stratified into group I, if admission BI was <11, and group II, if admission BI was ≥11. Stratification was used to avoid chance imbalance of severity of disability between the

intervention arm and the control arm, and also because the severe group required longer inpatient rehabilitation than the moderate group. Patients in groups I and II were then separately randomized to the intervention arm and the control arm according to random permuted blocks of 4, with consecutively numbered sealed envelopes for each group. The research assistant opened envelopes consecutively on a patient's enrollment and informed the acupuncturist if he or she was in the intervention arm. She also informed the attending physician and the therapists about the enrollment but not who belonged to which arm. In addition, she reminded patients receiving acupuncture not to tell the attending physician or therapists whether they were being treated with acupuncture. Therapists who performed outcome assessment did not provide daily care to any particular patients and did not know who belonged to which arm. The principal investigator did not directly provide care to the participating patients, but would be called in to assess a participating patient when the attending physician thought any problem related to the trial had occurred. The principal investigator would then decide whether to continue the trial or to break the code and terminate the trial.

Duration of Intervention and Intention-to-Treat Analysis

Group I patients received 5 weeks (±1 week) of inpatient rehabilitation, followed by 5 weeks (±1 week) of day hospital rehabilitation. Group II patients received 3 weeks (±1 week) of inpatient rehabilitation, followed by 7 weeks (±1 week) of day hospital rehabilitation. The total intervention duration was 10 weeks. All dropout cases were documented with reasons, and analysis was based on intention to treat.

Intervention

Control Arm

Patients received standard treatment. For inpatients, standard treatment included PT 5 sessions per week and 60 minutes per session, OT 5 sessions per week and 45 minutes per session, speech therapy and psychological counseling as indicated, and skilled nursing care and a daily medical round. For day hospital patients, standard treatment included attendance at a day hospital 3 days a week up to 8 weeks from inclusion, and then 2 days a week for the remaining 2 weeks. There were 60 minutes of PT and 45 minutes of OT per attendance day. Drug therapy was not prespecified, and antiplatelet agents and anticoagulants were allowed at the discretion of the attending physician.

Intervention Arm

Patients received the same standard treatment as described for the control arm, together with traditional Chinese acupuncture 5 sessions per week for inpatients, 3 sessions per week up to the end of 8th week, and then 2 sessions per week for the remaining 2 weeks for day hospital patients. The acupuncture session was arranged randomly either before or after the OT session in the same half-day, lasting for 30 minutes.

Physiotherapy

In our PT department, as in many PT departments around the world, stroke rehabilitation was mainly based on the Bobath approach²⁰ in an attempt to restore normal movement and improve strength. The treatment modalities used in the present study included manual facilitation, mechanical facilitation using tilt table, Arjo walker, Balance Master (NeuroCom) and similar equipment, functional electric stimulation (FES), and transcutaneous electric neuromuscular stimulation (TENS). Each patient received certain modalities of treatment as decided by the supervising senior physiotherapist according to the patient's need at different stages of recovery. FES and TENS were avoided if possible; if the therapist thought FES or TENS must be given, he or she must document in the research record the indication, the sites applied, the electric frequency and intensity, and the total number of treatments. The principal investigator would check, and cases violating this condition would be treated as protocol violators.

Traditional Chinese Acupuncture

All cases in the intervention arm were given acupuncture by a well-qualified and experienced acupuncturist (X.Y.). The main acupoints were the following: (1) Jianyu-LI15, (2) Quchi-LI11, (3) Shousanli-LI10, (4) Hegu-LI4, and (5) Waiguan-TE5 (upper limb), and (6) Huantiao-GB30, (7) Yanglingquan-GB34, (8) Zusanli-S36, (9) Jiexi-S41, and (10) Kunlun-B60 (lower limb). Selection of the 10 main acupoints was based on the TCM theory. The large intestine and stomach meridians are meridians full of "essence and blood." Stimulating the acupoints along these meridians can facilitate the restoration of free flow of essence and blood. Therefore, traditional Chinese acupuncture often chooses acupoints along the large intestine meridian, such as LI15, LI11, LI10, and LI4, and the stomach meridian, such as S36 and S41, for the treatment of hemiplegia after stroke. The following acupoints could be added by the acupuncturist as auxiliary acupoints: (1) Zhongwan-CV12, (2) Xiawan-CV10, (3) Qihai-CV6, (4) Guanyuan-CV4, (5) Huaroumen-S24, and (6) Wailing-S26 on the abdominal wall. CV12 and CV10 govern the acquired essence, whereas CV6 consolidates the congenital essence. S24 and S26 also belong to the stomach meridian and are used to facilitate the free flow of essence. For each case, omission of any main acupoints or addition of any acupoints not mentioned above should not exceed 3 and should be documented in the research record with a good reason. The principal investigator would check, and cases violating this condition would be treated as protocol violators. In the present study, Kingli sterile, disposable No. 30 (0.3 mm) and 32 (0.25 mm) needles, 40 mm in length, were used. Once a characteristic aching, tingling sensation (known as "te-chi," meaning "obtained essence") was elicited, the needle would be kept in situ for 30 minutes without continuous or intermittent stimulation either manually or by electric means. Needling was based on the TCM principle of "neither augmentation nor depletion [of essence],"²¹ and was performed on the paretic side.

Evaluations

Adverse reactions that occurred during acupuncture sessions were reported to the principal investigator, who would decide whether the trial should be terminated. Patients who had defaulted for 3 times would be treated as having dropped out of the trial. Causes of death and other reasons for withdrawal were also recorded. Baseline characteristics and comorbidity of the enrolled patients, impairments and complications of stroke, and duration of inpatient rehabilitation and day hospital rehabilitation were all recorded.

Measurements

Fugl-Meyer Assessment of Physical Performance (FMA)

FMA¹⁸ is a well-validated instrument assessing motor recovery after stroke,²²⁻²⁴ and has been widely used for both clinical and research purposes.^{25,26} FMA is a 3-point ordinal scale and has a maximum score of 226 points in 5 subsections, namely the motor (100 points), balance (14 points), range-of-movement (44 points), sensation (24 points), and pain (44 points) subsections. The reliability coefficients for the 5 subsections varied from 0.61 for the pain measurements to 0.97 for the upper extremity items.²⁷

Barthel Index

BI¹⁶ is a validated and widely used instrument to measure disability in ADL.^{16,17} In the present study, we used the version described by Wade and Collin in 1988,¹⁷ which has a total BI score of 20. The severity of disability is classified as mild (BI \geq 15), moderate to severe (5<BI<15), and very severe (BI \leq 5).²⁸

Functional Independence Measure (FIM)

FIM²⁹ is a more comprehensive assessment of disability not only of self-care activities and mobility as measured by FIM-motor (FIM-m), but also communication and cognitive function as measured by FIM-cognition (FIM-c). FIM-m contains 13 items, and FIM-c contains 5 items. Each item has 7 points with a total score of 126. FIM is well validated, and the interrater reliability is high.³⁰

Abbreviated Mental Test (AMT)

AMT³¹ is a validated instrument for screening cognitive impairment. It measures concentration, new learning, and fixed knowledge. It is composed of 10 items with 1 point scored for each item, and the maximum score is 10. Cognitive impairment is defined as AMT<7. AMT was recorded on admission for comparison of baseline cognitive function between the 2 arms.

NIH Stroke Scale (NIHSS)

NIHSS^{32,33} is widely used to measure the severity of neurological impairment, and its validity and reliability have been studied. In the present study, we used the modified version,³³ which is composed of 13 items with each item scoring 0 to 2 or 0 to 3, with a maximum score of 31. NIHSS was recorded on admission for comparison of the severity of neurological impairment between the 2 arms.

End Points

The primary end points were the FMAM median score at 10 weeks and FMAM median score change over time. FMAM was assessed at 0, 5, and 10 weeks by a blinded physiotherapist who was unaware of the arm to which a given patient had been assigned.

Secondary end points were FMA, FIM, and BI median scores at 10 weeks and FMA, FIM, and BI median score changes over time. FIM and BI were assessed at 0, 5, and 10 weeks by a blinded occupational therapist who was also unaware of the arm to which the patient had been assigned.

Statistical Methods

χ^2 test, χ^2 exact test, Mann-Whitney test, and *t* test were used to compare the demographic characteristics and other variables of the 2 arms where appropriate. Mann-Whitney test was used to assess any difference in baseline FMAM, FMA, FIM, and BI median scores and median score changes between the 2 arms. Statistically significant or near-significant ($P<0.15$) covariates, identified by Mann-Whitney test to be associated with FMAM, FMA, FIM, and BI scores at 10 weeks, were further subjected to the generalized additive models (the nonparametric regression method) for multivariate analysis.

Analyses were performed using SPSS for Windows statistical software (version 10.0), and S-Plus statistical program (version 4.3, MathSoft Inc). The level of significance was set at 5% in all comparisons, and all statistical testing was 2-sided.

Results

A total of 106 Chinese patients were enrolled at days 3 to 15 after acute stroke. Thirty-one patients each were randomized to group IA and group IB, and 22 patients each were randomized to group IIA and group IIB. Patient baseline characteristics (Table 1), comorbidity (Table 2), and impairments and complications of stroke (Table 3) were comparable between the intervention arm and the control arm. The baseline scores of FMAM, FMA, BI, and FIM were comparable between the 2 arms, except that the baseline FMAM and FMA scores of group IIB were significantly lower than those of group IIA (Table 4).

Fourteen patients dropped out during the trial, accounting for a 13% dropout rate. There were no deaths or protocol violators during the trial. Among the 14 dropouts, 3 patients had recurrent stroke; 5 defaulted on treatments; and 4 withdrew as a result of congestive heart failure, newly diagnosed hepatocellular carcinoma, fracture of tibia, and bleeding gastric ulcer, respectively. One patient withdrew because he thought acupuncture did not help, and another withdrew because she could not be discharged within the defined period because of a social problem. There was no statistical difference in dropouts between the 2 arms.

TABLE 1. Baseline Characteristics of the Stroke Patients

Characteristics	BI 3–10				P	BI 11–14				P
	Intervention (N=31)		Control (N=31)			Intervention (N=22)		Control (N=22)		
	n	%	n	%		n	%	n	%	
Age, y*	69.3±9.6		71.9±7.5		0.226†	69.7±11.0		72.5±6.8		0.321†
Sex										
Male	14	45.2%	16	51.6%	0.611‡	14	63.6%	12	54.5%	0.540‡
Female	17	54.8%	15	48.4%		8	36.4%	10	45.5%	
Stroke status										
First stroke	23	74.2%	22	71.0%	0.776‡	17	77.3%	12	54.5%	0.112§
Recurrent stroke	8	25.8%	9	29.0%		5	22.7%	10	45.5%	
CT scan										
Normal	2	6.5%	0		0.221§	1	4.5%	1	4.5%	0.112§
Infarct	23	74.2%	19	61.3%		16	72.7%	14	63.6%	
Lacunar infarct	3	9.7%	7	22.6%		2	9.1%	6	27.3%	
Hemorrhage	3	9.7%	5	16.1%		3	13.6%	1	4.5%	
Lesion site										
Normal	2	6.5%	1	3.2%	0.583§	1	4.5%	1	4.5%	0.425§
Cortical	6	19.4%	2	6.5%		2	9.1%	4	18.2%	
Basal ganglion	15	48.4%	19	61.3%		11	50.0%	12	54.5%	
Cerebellar	1	3.2%				1	4.5%			
Brain stem	3	9.7%	3	9.7%		2	9.1%	3	13.6%	0.796§
Multiple	4	12.9%	6	19.4%		5	22.7%	2	9.1%	
Discharge place										
Home	22	71.0%	22	71.0%	0.632§	19	86.4%	22	100.0%	0.233§
Old aged home	6	19.4%	8	25.8%		2	9.1%	0		
Readmission	3	9.7%	1	3.2%		1	4.5%	0		
Duration of inpatient rehabilitation*	35.5±3.2		34.5±3.2		0.250†	20.2±4.2		21.2±1.7		0.289†
Duration of DH rehabilitation*	34.1±5.6		32.4±2.5		0.162†	46.6±4.5		45.6±2.9		0.398†

*Mean ±SD.

†t-test, P value.

‡ χ^2 test, P value.§ χ^2 test exact, P value.

DH, day hospital.

All patients receiving acupuncture tolerated it well without side effects, except 1 patient on warfarin for atrial fibrillation developed some bruising at the acupuncture site, but acupuncture continued uneventfully. The total number of acupuncture sessions ranged from 34 to 44 for group I patients, and from 26 to 39 for group II patients, with a mean of 35 sessions per patient (SD 4.2).

Acupoints LI11, GB34, and S36 were not omitted in any patient receiving acupuncture. Acupoints LI15, LI10, and LI4 were omitted in only 1 patient; TE5 in 2 patients; GB30 in 3 patients; B60 in 4 patients; and S41 in 6 patients. These omissions were mainly due to severe paralysis causing difficulty in maintaining a needle at such sites throughout the session. Three main acupoints were omitted in only 1 patient.

Twenty-five patients received acupuncture at 1 additional acupoint besides the 10 main and 6 auxiliary

acupoints, 17 patients at 2 additional acupoints, and 8 patients at 3 additional acupoints. The most commonly added acupoints were Qiuxu-G40 and Weizhong-B40, and S32, S40, SP10, K3, L5, Liv3, P6, SI3, and TE14 were occasionally added. These acupoints were added to treat other stroke complications or to strengthen motor recovery according to the TCM theory. The 6 predefined auxiliary acupoints were used in 25 of the 53 acupuncture patients. Of the 53 patients receiving acupuncture, 41 were reported to have *teh-chi* (“obtained essence”).

Three patients in the acupuncture arm and 5 patients in the control arm received TENS for shoulder pain at a frequency of 200 Hz and an intensity of 4 to 5 mA. Two patients in the acupuncture arm and 3 patients in the control arm received FES, considered as necessary for their limb paralysis by the senior physiotherapist without knowing who was in the

TABLE 2. Comorbidity of Stroke Patients

Comorbidity	BI 3–10				<i>P</i>	BI 11–14				<i>P</i>
	Intervention (N=31)		Control (N=31)			Intervention (N=22)		Control (N=22)		
	n	%	n	%		n	%	n	%	
Diabetes mellitus	10	32.3%	17	54.8%	0.073*	5	22.7%	7	31.8%	0.498*
Hypertension	20	64.5%	26	83.9%	0.082*	12	54.5%	17	77.3%	0.112*
Hypercholesterolemia	11	35.5%	6	19.4%	0.155*	1	4.5%	5	22.7%	0.185†
Atrial fibrillation	5	16.1%	5	16.1%	1.000*	0		0		
Valvular heart disease	1	3.2%	1	3.2%	1.000†	0		0		
Ischemic heart disease	4	12.9%	4	12.9%	1.000†	1	4.5%	1	4.5%	1.000†
Myocardial infarction	1	3.2%	0		1.000†	0		0		
Smoking	1	3.2%	4	12.9%	0.354†	4	18.2%	4	18.2%	1.000†
Transient ischemic attack	0		2	6.5%	0.492†	0		1	4.5%	1.000†

* χ^2 test, *P* value.† χ^2 test exact, *P* value.

intervention group. FES was given at a frequency of 30 to 50 Hz and intensity of 20 to 35 mA.

No differences were seen between the intervention arm and the control arm in either group I or group II, when comparing impairment scores of FMAM and FMA, or disability scores of FIM-c, FIM-m, FIM, and BI at 10 weeks (Table 4). The median score changes of FMAM, FMA, FIM-c, FIM-m, FIM, and BI over 10 weeks from baseline also did not show statistical difference between the 2 arms (Table 4). In fact, both arms showed similar improvement in motor impairment and disability, and the improvement was faster in the first 5 weeks (Figure 1).

Discussion

Our present study failed to show additional improvement in motor impairment or disability in patients receiving acupuncture as compared with the control. We will discuss whether any factors might have confounded the study and led to a negative result.

Firstly, patient characteristics, comorbidity, and impairments and complications of stroke in the 2 arms were comparable, except that the baseline FMAM (motor) and FMA (total) scores in group II control were significantly lower than those in group II intervention. Obviously, this would not lead to a false-negative result. However, the comparability assessment between the 2 arms was based on

TABLE 3. Impairments and Complications of Stroke

Impairment/Complication	BI 3–10				<i>P</i>	BI 11–14				<i>P</i>
	Intervention (N=31)		Control (N=31)			Intervention (N=22)		Control (N=22)		
	n	%	n	%		n	%	n	%	
Dysphasia	5	16.1%	3	9.7%	0.707*	0		0		
Dysphagia	11	35.5%	9	29.0%	0.587†	1	4.5%	2	9.1%	1.000*
Hemiparesthesia	17	54.8%	14	45.2%	0.446†	8	36.4%	13	59.1%	0.131†
Sensory inattention	5	16.1%	2	6.5%	0.425*	1	4.5%	2	9.1%	1.000*
Apraxia	2	6.5%	1	3.2%	1.000*	0		0		
Cranial nerve palsy	20	64.5%	16	51.6%	0.303†	5	22.7%	9	40.9%	0.195†
Hemiplegia										
Right	9	29.0%	10	32.3%	0.783†	14	63.6%	9	40.9%	0.131†
Left	22	71.0%	21	67.7%		8	36.4%	13	59.1%	
Cerebellar dysfunction	0		3	9.7%	0.238*	4	18.2%	2	9.1%	0.664*
Incontinence on admission	7	22.6%	6	19.4%	0.755†	0		2	9.1%	0.488*
AMT score on admission‡	9.0 (8.0–10.0)		8.0 (6.1–9.9)		0.121§	10.0 (8.6–10.0)		9.0 (8.0–10.0)		0.235§
NIHSS on admission‡	7.2 (4.8–10.0)		6.2 (4.8–9.0)		0.351§	3.0 (1.6–4.0)		3.0 (2.0–5.4)		0.565§

* χ^2 test exact *P* value.† χ^2 test *P* value.

‡Values are median (interquartile range).

§Mann-Whitney test *P* value.

TABLE 4. Outcome Changes Between the Two Arms

Outcome Measure	Week	BI 3–10		<i>P</i> *	BI 11–14		<i>P</i> *
		Intervention (N=31)	Control (N=31)		Intervention (N=22)	Control (N=22)	
		Median (Interquartile Range)	Median (Interquartile Range)		Median (Interquartile Range)	Median (Interquartile Range)	
BI	0	7.2 (5.0–9.0)	6.2 (3.7–9.0)	0.270	12.0 (11.0–13.0)	12.0 (11.0–13.0)	0.881
	5	14.8 (9.0–16.0)	12.8 (8.1–17.0)		18.0 (16.0–19.4)	18.0 (17.0–19.4)	
	10	16.2 (10.1–18.0)	14.7 (8.7–18.0)		19.0 (15.9–20.0)	19.0 (18.0–20.0)	
	Change in median score†	8.0 (4.0–10.9)	7.8 (3.0–10.9)	0.596	7.0 (3.9–7.4)	7.0 (5.6–8.0)	0.469
FMAM(motor)	0	29.7 (14.0–46.4)	38.7 (14.1–64.5)	0.251	81.0 (61.4–90.0)	65.0 (49.3–78.8)	0.029
	5	40.8 (21.4–66.8)	46.8 (17.4–75.5)		86.5 (74.6–94.3)	79.0 (67.5–90.7)	
	10	51.2 (23.8–76.8)	53.3 (23.1–82.4)		89.8 (80.8–95.6)	84.0 (68.8–92.8)	
	Change in median score†	18.8 (6.2–26.9)	14.5 (4.0–26.4)	0.280	9.8 (4.2–19.8)	12.7 (8.6–26.3)	0.200
FMA(total)	0	133.3 (108.5–155.4)	137.5 (115.6–168.9)	0.367	199.5 (177.5–208.3)	182.8 (160.0–193.6)	0.036
	5	150.0 (115.4–178.4)	152.3 (124.1–193.1)		208.3 (193.0–216.4)	198.3 (187.5–210.0)	
	10	164.5 (121.4–188.8)	158.0 (133.3–204.4)		210.5 (200.4–218.6)	204.5 (187.3–214.8)	
	Change in median score†	27.3 (6.3–38.9)	24.3 (0.2–40.4)	0.463	14.7 (5.0–22.6)	18.7 (6.5–33.6)	0.372
FIM(cognition)	0	31.2 (26.0–34.3)	30.0 (21.5–33.0)	0.219	32.0 (27.9–34.0)	33.0 (29.0–35.0)	0.553
	5	33.0 (28.5–35.0)	30.0 (24.1–35.0)		34.5 (30.0–35.0)	35.0 (33.6–35.0)	
	10	34.2 (29.1–35.0)	31.2 (29.1–35.0)		34.5 (30.6–35.0)	35.0 (34.6–35.0)	
	Change in median score†	1.3 (0–6.3)	1.0 (0–6.3)	0.977	1.0 (0–4.6)	1.0 (0–5.6)	0.923
FIM(motor)	0	39.0 (31.4–47.0)	36.3 (28.2–42.0)	0.226	55.5 (51.6–64.5)	59.0 (52.8–64.6)	0.445
	5	68.5 (44.6–77.3)	58.5 (38.3–76.5)		80.5 (71.5–87.1)	83.0 (77.0–87.8)	
	10	78.7 (49.2–82.4)	69.7 (45.5–84.0)		84.8 (72.8–89.0)	88.5 (82.8–89.8)	
	Change in median score†	32.8 (12.5–43.4)	34.7 (12.1–43.5)	0.893	26.8 (18.3–35.6)	26.5 (18.6–33.0)	0.760
FIM(total)	0	68.8 (60.1–81.4)	65.3 (50.4–74.4)	0.159	89.5 (79.0–96.0)	89.8 (82.8–97.0)	0.698
	5	97.5 (78.1–111.3)	86.8 (67.8–108.0)		113.5 (102.1–119.6)	118.0 (111.6–122.6)	
	10	109.3 (80.8–116.9)	96.5 (74.3–118.3)		118.0 (103.6–124.0)	123.5 (116.0–124.8)	
	Change in median score†	33.3 (16.3–45.4)	35.5 (13.1–48.3)	0.860	29.0 (16.9–37.4)	28.5 (19.9–38.0)	0.655

*Mann-Whitney test *P* value.

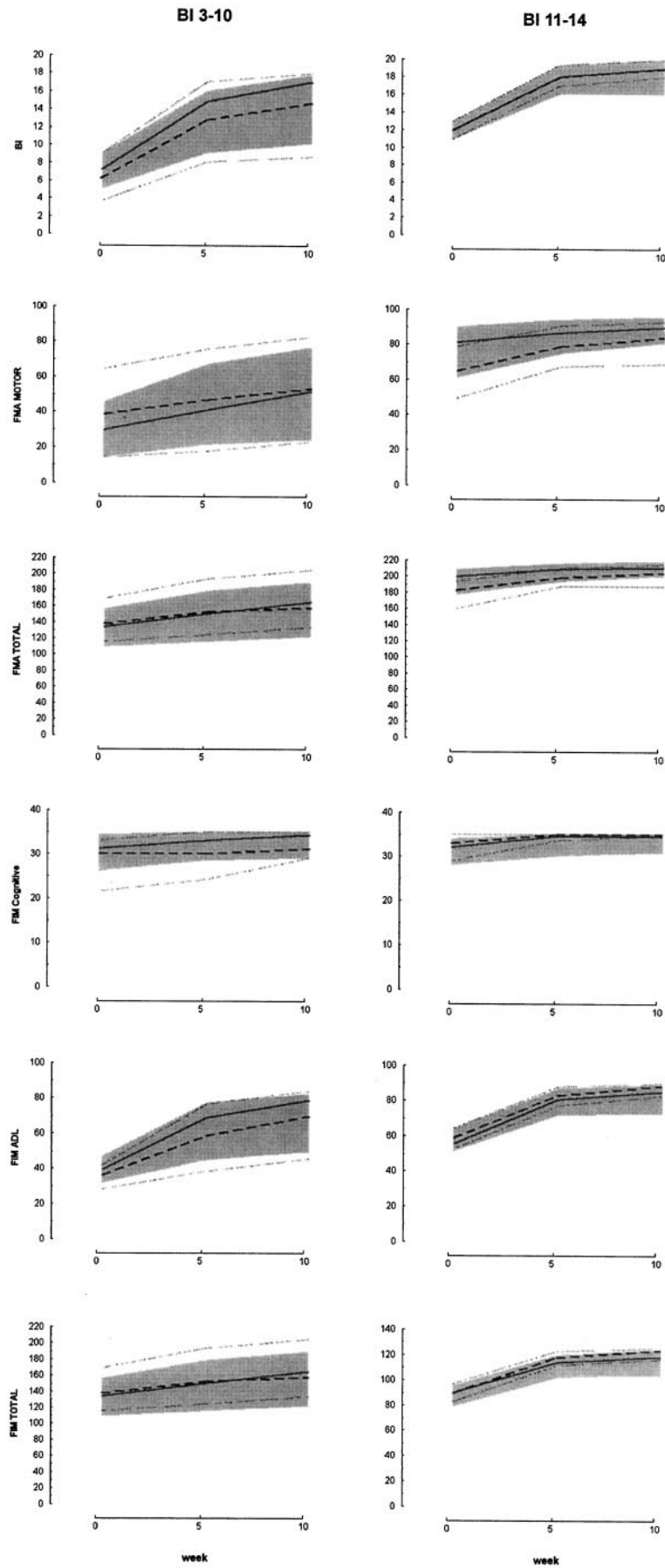
†Change in median scores at 10 weeks from baseline; higher values indicate greater improvement.

Western medicine, and not on the TCM classification of stroke and its characteristics. This should be borne in mind in interpreting the result.

Secondly, we followed a RCT design as rigorously as we could. Various sham acupuncture treatments^{6,11–12} have been used as placebo controls, but sham acupuncture cannot exactly simulate true acupuncture, especially an acupuncture performed in a traditional way rather than on certain fixed acupoints only. Because we followed the traditional method of acupuncture by allowing the acupuncturist to add or omit a certain number of acupoints from a set of agreed-upon classical acupoints, we could not use sham acupuncture in the control arm. Vincent and Richardson³⁴ thoroughly discussed the pros and cons of using fixed acupoints in acupuncture trials. We selected 10 main acupoints through consultation with experienced acupuncturists and making reference to the textbooks²¹ of acupuncture in Mainland China. At the same time, we allowed the acupuncturist to add some auxiliary acupoints or omit a maximum of 3 main acupoints according to each patient's need from the point of view of TCM. In analyzing

the data, we did not find any violation of the design, and omission from the set of main acupoints was not common; omission of 1 main acupoint occurred in 16.9% of the patients, 2 in 5.6%, and 3 in only 1.9%. In contrast, a significant number of patients (47%) received acupuncture at 1 additional acupoint, and the auxiliary acupoints were also frequently used (47%). We think this flexibility of selecting a certain number of acupoints in addition to the agreed-upon acupoints has met the unique need of traditional Chinese acupuncture and, at the same time, has not jeopardized the quality of the study. Our present study's duration of intervention, duration of each acupuncture session, and frequency of acupuncture sessions were comparable with those of previous trials (our study had even greater frequency of sessions than some others).^{5–14} A significant number of patients (77%) had *teh-chi*; this is considered to be as important as the sites of acupuncture used in TCM. Therefore, we think the negative result could not be due to any of these factors.

In terms of selection of outcome measures, as our objective was to examine the efficacy of acupuncture on motor recov-



Comparison of outcome changes over time between the 2 arms. Bold lines and upper and lower boundaries of shaded areas indicate 50th, 75th, and 25th percentiles of the intervention arm, respectively; dashed lines and their upper and lower boundaries (indicated by dotted lines), 50th, 75th, and 25th percentiles of the control arm.

ery, selection of FMAM score at 10 weeks as the primary end point was appropriate. Improvements in motor power and ADL over 10 weeks were well detected by FMAM, FIM, and BI, respectively, in all groups, which suggests that these outcome measures were properly chosen. We believe, therefore, a clinically meaningful difference in motor recovery between the 2 arms was unlikely to have been missed.

A true double-blinded acupuncture trial would be very difficult, as discussed by Vincent and Richardson.³⁴ In the present study, we used independent, blinded assessors for outcome measurement in an attempt to avoid assessor bias. Therapists were also blinded as to which arm the patient belonged to, to avoid therapist bias. Nevertheless, in interpreting the present negative result, we should take into consideration the limitations of a single-blinded control study.

Thirdly, statistically significant or near-significant ($P < 0.15$) covariates associated with FMAM, FMA, FIM, and BI scores at 10 weeks had been identified by Mann-Whitney test and subjected to the generalized additive models for multivariate analysis. Factors such as age, stroke status, dysphagia, dysphasia, AMT, NIHSS, and urinary incontinence on admission, which would affect the outcomes over time, had been taken into consideration in statistical analysis. Therefore, we believe the negative result could not have been confounded by these factors.

Fourthly, a meta-analysis³⁵ on FES trials suggests that FES promotes recovery of muscle strength after stroke. We did post hoc analyses of the data by excluding the 5 patients who received FES or excluding the 13 patients who received either FES or TENS, but all of the results remain negative. We believe, therefore, the negative result was not due to FES or TENS procedures that were performed in a small number of our patients.

We did not use continuous or intermittent stimulation either manually or by electric means once the needle was put in situ. We cannot answer whether strengthening stimulation during the session could have yielded a positive result. Nor can we answer whether acupuncture on sites such as the head or ear could have had a different result. Among the 12 RCTs with positive results in the Chinese literature, 5 did not use continuous stimulation, 3 used intermittent manual needling, 2 used continuous electric stimulation, and another 2 did not report the details. Five trials used body acupuncture as we did, 6 trials used head acupuncture, and another trial used body-plus-head acupuncture. As for the 8 RCTs⁵⁻¹² in the English literature, they all used continuous electric stimulation with body acupuncture in 3 trials and body-plus-head acupuncture in 5 trials. The results of these RCTs in the literature do not suggest that strengthening stimulation during acupuncture or performing acupuncture on sites other than the body really matter.

From the above discussion, we conclude that traditional Chinese manual acupuncture on the body has no additional value to standard poststroke motor rehabilitation.

Acknowledgments

This study was funded by the Hong Kong Association for Health Care Ltd. We are particularly indebted to Jin-ling Tang, PhD, for

providing us with 6 original Chinese papers or abstracts that were referred to in his paper, Review of Randomized Controlled Trials of Traditional Chinese Medicine. We also thank Edith M.C. Lau, MD, for her valuable comment on the study; Yeung Fai, MSc, for research assistance; and Stephanie Lam, PTI; Ricky Lau, PTI; Amy Chan, OTI; and Teresa Leung, OTI for their independent assessment of the patients.

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