

Needle Acupuncture in Chronic Poststroke Leg Spasticity

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ABSTRACT. Fink M, Rollnik JD, Bijak M, Borstädt C, Däuper J, Guergueltcheva V, Dengler R, Karst M. Needle acupuncture in chronic poststroke leg spasticity. *Arch Phys Med Rehabil* 2004;85:667-72.

Objective: To determine whether needle acupuncture may be useful in the reduction of leg spasticity in a chronic state.

Design: Single-blind, randomized, placebo-controlled trial.

Setting: Neurologic outpatient department of a medical school in Germany.

Participants: Twenty-five patients (14 women) suffering from chronic poststroke leg spasticity with pes equinovarus deformity (Modified Ashworth Scale [MAS] score, ≥ 1), aged 38 to 77 years (mean $\pm$ standard deviation, 58.5 ± 10.4 y), were enrolled in the study. The mean time from stroke to inclusion in the study was approximately 5 years (mean, 65.4 ± 48.3 mo; range, 7–180mo).

Interventions: Participants were randomly assigned to placebo treatment ($n=12$) by using a specially designed placebo needling procedure, or verum treatment ($n=13$).

Main Outcome Measures: MAS score of the affected ankle, pain (visual analog scale), and walking speed.

Results: There was no demonstrated beneficial clinical effects from verum acupuncture. After 4 weeks of treatment, mean MAS score was 3.3 ± 0.9 in the placebo group versus 3.3 ± 1.1 in the verum group. The neurophysiologic measure of H-reflex indicated a significant increase of spinal motoneuron excitability after verum acupuncture (H-response/M-response ratio: placebo, $.39 \pm .19$; verum, $.68 \pm .41$; $P < .05$).

Conclusions: This effect might be explained by afferent input of A delta and C fibers to the spinal motoneuron. The results from our study indicate that needle acupuncture may not be helpful to patients with chronic poststroke spasticity. However, there was neurophysiologic evidence for specific acupuncture effects on a spinal (segmental) level involving nociceptive reflex mechanisms.

Key Words: Acupuncture; H-reflex; Motor neurons; Muscle spasticity; Rehabilitation; Spasticity; Stroke.

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ALTHOUGH ACUPUNCTURE HAS been used for more than 2000 years in China and Japan, traditional Chinese medicine (TCM) has just begun to gain influence in Western civilizations in the last decades. In Europe, 12% to 19% of the population report using acupuncture,¹ and the US Food and Drug Administration estimates that 9 to 12 million acupuncture treatments are performed annually in the United States.² Although acupuncture has captured the public interest and has come to be widely practiced, there is an obvious lack of rigorous research in this field: acupuncture literature is dominated by articles from China that are positive but often of poor scientific quality.³

Only a few studies have investigated the use of acupuncture systematically in central nervous system conditions such as stroke. Johansson et al⁴ performed a randomized study on 78 patients with severe hemiparesis within 10 days of stroke onset. Forty patients in the control group received daily physiotherapy, and 38 received acupuncture, in addition, twice weekly for 10 weeks. Patients given acupuncture recovered both faster and to a greater extent than did the control group and had significant differences in improvement of balance, mobility, activities of daily living (ADLs), quality of life (QOL), and lengths of stay in hospital.⁴ That study has been substantially criticized because the control group did not receive any placebo treatment. Another randomized controlled study, involving 45 patients, was performed in the subacute stage of stroke.⁵ Sallstrom et al⁵ examined hemiparetic patients 40 days (median) after stroke. All participants had individually adapted rehabilitation therapy, and the 24 who were randomized to acupuncture received 20 to 30 minutes of classical acupuncture treatments 3 to 4 times a week for 6 weeks. Although both groups improved significantly in motor function and ADLs, the improvement was significantly greater among the acupuncture group.⁵ In another study by the Johansson group,⁶ acupuncture and transcutaneous nerve stimulation were applied in stroke rehabilitation, starting 5 to 10 days after stroke, totalling 20 treatments during a 10-week period. Johansson could not find any beneficial effects on functional outcome or life satisfaction.⁶

So far, no controlled randomized studies are available that concentrate on the effects of acupuncture in the chronic stage of poststroke spasticity; in particular, there are no studies including neurophysiologic techniques. Our study was devoted to examining the efficacy and safety of needle acupuncture in chronic poststroke leg spasticity.

METHODS

Participants

Twenty-five patients (14 women), aged 38 to 77 years (mean $\pm$ standard deviation [SD], 58.5 ± 10.4 y), were enrolled in a single-blind study and randomly assigned to placebo ($n=12$) or verum treatment ($n=13$). The mean time from ischemic stroke to inclusion in the study was approximately 5 years (mean, 65.4 ± 48.3 mo). Time from stroke onset was at least 7 months (range, 7–180mo). All patients had hemiparesis and spastic equinovarus deformity of the affected leg. Causes for the recent stroke were identified as (1) cerebral thrombosis, mostly of the

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Table 1: Demographic Data of Placebo and Verum Group (at study entry)

	Placebo	Verum	Statistics*
Age (y)	61.3±8.4	56.0±11.8	NS
Gender (F/M)	6/6	8/5	NS
Time from stroke (mo)	64.2±48.3	66.5±50.2	NS
Height (cm)	170.6±11.6	170.8±10.0	NS
Weight (kg)	78.6±19.3	75.1±15.2	NS

NOTE. Values are mean ± SD.

Abbreviations: F, female; M, male; NS, not significant

*Mann-Whitney *U* tests resp. χ^2 test for sex distribution.

middle cerebral artery (14 cases); (2) brain hemorrhage (8 cases); and (3) other causes (3 cases). Both groups did not differ with respect to age, sex, severity of spasticity, and time from stroke at baseline (table 1). Patients were informed about the purpose of the research study and gave written informed consent to the experimental procedure. The study was approved by a local ethics committee. Main exclusion criteria were anticoagulation, pregnancy, history of epileptic seizures, acute or chronic infectious diseases, and autoimmune diseases (eg, multiple sclerosis, collagenosis). Concomitant medication (eg, baclofen) was allowed during the study and was documented carefully, but patients were required to keep the dose stable throughout the whole study. Threshold Modified Ashworth Scale (MAS) score required for admittance to this study was 1 or more.

Acupuncture Treatment

After randomization, the patients underwent 2 treatments a week for a total of 8 treatments. The initial treatment was performed by a well-experienced acupuncture teacher (MB) from the Ludwig-Boltzmann-Institute for Acupuncture, Vienna, Austria. Further treatments were performed by well-trained acupuncturists (MF, MK) from the Medical School of Hannover, Germany. The acupuncture points used at study entry did not vary throughout the study (table 2). Most frequently, verum needles (Seirin B-type needle no. 8 [0.3×0.3mm] and no. 3 [0.2×0.15mm]) were inserted at acupoints GB34 (in the depression anterior and inferior to the head of the fibula), GB39 (3 cun above the tip of the external malleolus, in the depression between the posterior border of the fibula and the tendons of the peroneus longus and brevis muscles), LR3 (first interosseus muscle of the lower limb), and LI4 (first dorsal interosseus muscle of the upper limb) of the affected limbs, and, depending on additional symptoms, according to TCM criteria, at ST36 (lateral to the tibia at the level of the tuberositas tibiae) and LI10 (2 cun below the lateral end of the elbow fold) of the affected limbs, and at SP6 (3 cun directly above the tip of the medial malleolus, on the posterior border of the medial aspect of the tibia) and LU9 (at the radial end of the transverse crease of the wrist, in the depression on the lateral side of the radial artery), bilaterally. In addition, GV20 was needled in 10 of 13 patients. The needles (maximum of 15 needles per patient and treatment) were left in place for 30 minutes after insertion without further manipulation. The exact localization of the acupoints used in our study is described in table 3.

Placebo Condition

To avoid transdermal stimulation, placebo needles were inserted at defined nonacupoints (middle of the ventral surface of the affected thigh, middle of the medial side of the affected

lower leg, middle of the affected foot, and middle of the back of both hands). The tip of the needle is blunt, and when it touches the skin patients feel a pricking sensation, simulating puncturing of the skin.⁷⁻⁹ To place the needle, we used a cube-shaped elastic foam fixed on the skin. Therefore, it is not visible that the blunt placebo needle is not inserted into deeper tissue layers, but the blunt tip on the skin may be felt by the volunteers. Further, the needle appears to be shortened because of the elasticity of the foam. The investigator (who performed outcome measures), as well as the patients, was blind to treatment condition (placebo vs verum). Blinding the acupuncture practitioner was impossible, for methodologic reasons. None of the patients was able to distinguish between verum and placebo

Table 2: Treatment Scheme of Verum-Treated Patients

Patients	Age (y)	Spastic Hemiparesis	Sex	Acupuncture Points
1	46	Right	F	Bilaterally: HT4, SI3, LI4, KI3, GB39 Right only: ST36
2	51	Left	F	GV20 Bilaterally: GB20, GB39, LR3, LI4 Left only: SI3, LI15, GB 34, ST36, SP6
3	44	Left	F	GV20 Left only: LI10, GB34, GB39, KI6, BL62, SP6, SP9, ST36, LI3
4	54	Right	F	GV20 Bilaterally: KI3, LR3, LR9, ST36 Right only: GB34, GB39, LI4, LI10, LI15
5	45	Right	M	Right only: LI4, LI10, SI3, GB34, GB39, LR3, SP6, ST36
6	60	Left	M	GV20 Bilaterally: BL10 Left only: LI10, LU9, GB34, GB39, LR3, SP6, ST36
7	63	Left	F	Bilaterally: KI6, LU7, GB39, LR3 Left only: LI4, ST36; GB34
8	74	Right	F	GV20 Bilaterally: LU9, LR3, KI3, GB39 Right only: ST36, GB34, LI4
9	51	Left	M	GV20 Bilaterally: LR3, ST40, SP6 Left only: GB39, ST36, LU9, LI4
10	77	Left	M	GV20 Bilaterally: KI3, LR3, LU9 Left only: ST36, GB34, GB39, LI4, SI3
11	38	Right	F	GV20 Bilaterally: LI4, LU7, LR3 Right only: GB34, GB39, ST36, SP6
12	65	Left	F	GV20 Bilaterally: SP6, ST36, LI4, LU7, GB3 Left only: LR3, GB34, GB39
13	60	Right	M	GV20 Bilaterally: SP6, ST36, LI4, LU7, GB3 Right only: LR3, GB34, GB39

Table 3: Abbreviations, Meridians, and Acupuncture Point Localization Used in Our Study²³

Abbreviation	Meridian	Localization of Points
LU	Lung	LU7: 1.5 cun above the most distal transverse crease of the wrist, above the styloid process of the radius LU9: on the most radial end of the transverse crease of the wrist, lateral border of the radial artery
LI	Large intestine	LI3: on the dorsum of the hand, at the radial side of the proximal part of the second metacarpal bone LI4: first dorsal interosseus muscle of the upper limb LI10: brachioradialis muscle, 2 cun below the external end of the elbow transverse crease (when elbow is flexed) LI15: at the antero-inferior part of the acromion
ST	Stomach	ST36: tibialis anterior muscle, lateral to the tibia at the level of the tuberositas tibiae ST40: 8 cun above the anterior part of the lateral malleolus
SP	Spleen	SP6: 3 cun directly above the tip of the medial malleolus, on the posterior border of the medial aspect of the tibia SP9: under the medial condyle of the tibia, on the medial side below the knee
HT	Heart	HT4: 1.5 cun above HT7 (along the most distal skin crease of the wrist, on the radial side of the flexor carpi ulnaris muscle)
SI	Small intestine	SI3: on the ulnar side proximal to the metacarpophalangeal joint of the little finger, at the end of the transverse crease of the palm
BL	Bladder	BL10: right on the natural line of the hair at the back of the head, on the lateral part of the margin of the trapezius muscle BL62: in the depression below the lateral malleolus
KI	Kidney	KI3: in the depression between the tip of medial malleolus and tendocalcaneus KI6: in the depression directly below the medial malleolus
GB	Gallbladder	GB3: on the anterior part of the ear and the upper margin of the zygomatic branch GB20: below the occipital bone, in the depression on the outer part of the trapezius muscle GB34: in the depression anterior and inferior to the head of the fibula GB39: 3 cun above the tip of the external malleolus, in the depression between the posterior border of the fibula and the tendons of the peroneus longus and brevis muscles
LR	Liver	LR3: on the depression distal to junction of the first and second metatarsal bones LR9: 4 cun above the medial epicondyle of the femur, in between the sartorial and vastus medialis muscles
GV	Governor vessel	GV20: at the highest tip of the skull

acupuncture. This was controlled by a questionnaire (credibility of treatment), used in earlier studies by our group.^{8,10}

Clinical and Psychologic Outcome Measures

The patients were carefully examined at baseline (assessment 0); reexamined immediately after the first acupuncture treatment (assessment 1); again immediately after the last treatment (4wk after first acupuncture; assessment 2); and finally, some of the efficacy variables were recorded about 3 months after completion of the study (assessment 3). Patients were examined neurologically (cranial nerves, motor and sensory system). The date of the current stroke, stroke etiology, leg affected, and number of falls the patient had experienced during the previous 4 weeks were recorded.

In addition, a 2-minute walk test (2MWT) was performed.¹¹ Patients were asked to walk continuously for 2 minutes, using their regular aids or orthoses, but with no support from the investigator. The walk took place over a distance of 10m, and patients were required to change direction of their own accord. The distance walked in a 2-minute interval was recorded. If the patient was not able to walk for 2 minutes, the distance and time walked was recorded.

A Rivermead Motor Assessment (RMA) test (leg and trunk section) was performed to evaluate motor function.¹¹ In addition, an assessment of patients perceived function (Rivermead Mobility Index [RMI]) was documented.¹¹

Step length, cadence, and mode of initial foot contact were also documented.¹¹ Step length was defined as the distance

between initial foot strike of 1 lower limb and the initial foot strike of the opposite limb. Cadence was defined as the number of steps per minute. The mode of initial foot contact of the affected side was classified as follows: fore-foot versus sole versus heel.

A goniometry for the affected ankle was performed (based on the neutral-0 method), with the knee flexed and straight, and angles of active and passive movement were recorded.

Spasticity present at the ankle (spastic pes equinovarus) was rated clinically using the MAS. This scale allows a rating from 0 (no increase in muscle tone) to 4 (affected part rigid in flexion or extension).¹¹ A 2MWT, step length, and cadence was measured to obtain gait measures. Pain intensity (visual analog scale [VAS]: range, 0–10cm; 0, no pain; 10, strongest pain) and pain localization (pain due to spasticity) were documented. Furthermore, patients and investigator were required to give a rating of their impression of improvement on a Clinical Global Impressions (CGI) scale¹² when followed up. To evaluate QOL parameters and coping strategies, subjects were asked to complete the Nottingham Health Profile,¹³ the Everyday Life Questionnaire¹³ (ELQ), the Freiburg Questionnaire of Coping with Illness,¹⁴ and the von Zerssen Depression Scale.¹³

Neurophysiologic Measures

For the quantitative neurophysiologic assessment of spasticity, H-reflex measurements of the affected and unaffected leg were obtained by using a Nicolet Viking II device.^a The Hoffmann reflex, or H-reflex, is the neurophysiologic correlate of

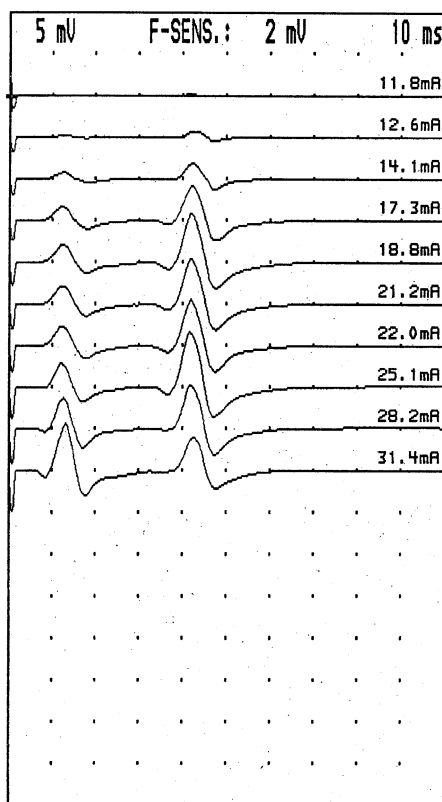


Fig 1. Recording of H-reflexes: electric stimuli of increasing intensity are applied to the tibial nerve in the hollow of the knee (stimulation intensities are displayed in microamperes). CMAPs are recorded from the ipsilateral soleus muscle by using conventional surface electromyography electrodes. The H response appears after 35 to 40ms (after submaximal stimulation). Then, with increasing intensities, the M response can be evoked and the H response decreases.

the Achilles' tendon reflex. Electric stimuli of increasing intensities are applied to the tibial nerve in the hollow of the knee with conventional surface electrodes (starting with 10mA stimulus intensity, increasing in steps of 1–2mA until the H response disappears; duration of the electric stimulus, 0.3ms). Compound muscle action potentials (CMAPs) were recorded from the ipsilateral soleus muscle by using conventional surface electromyographic electrodes (different electrode in between the lateral and medial head of the gastrocnemius muscle, indifferent electrode on the Achilles' tendon). The H response appeared approximately 30ms after submaximal stimulation. With increasing intensities, the M response was evoked (CMAP evoked by orthograde nerve stimulation) and the H response decreased (fig 1). The relation between maximal H response and M response is called Hmax/Mmax ratio and reflects the excitability of the spinal alpha motoneuron. The higher the state of excitability (and the more severe the leg spasticity), the higher the Hmax/Mmax ratio.⁹ The schedule of clinical and neurophysiologic assessments can be found in table 4.

Statistics

Statistical analyses used Mann-Whitney *U* tests. Outcome parameters (MAS, VAS, CGI, 2MWT, RMA, RMI, step length, cadence, goniometry, QOL measures, depression scale) were used as dependent variables, and treatment condition (placebo vs verum) was used as independent variable. Differences were regarded as significant at *P* less than .05. Results are reported as means and SDs. Further, bivariate Pearson correlations were done to correlate neurophysiologic measures with MAS score.

RESULTS

MAS scores (as a clinical measure of spasticity) did not show significant differences between placebo and verum in any of the follow-up examinations. The MAS scores at baseline were 3.1 ± 0.8 in the placebo group and 3.0 ± 1.2 in the verum group. At the first follow-up (immediately after the first treatment), the MAS score remained unchanged (placebo: 3.3 ± 0.8 ;

Table 4: Schedule of Assessments

Assessment	0 Baseline	1 After First Treatment	2 Immediately After End of Treatment	3 3 Months After Completion
Informed consent	X			
Inclusion/exclusion criteria	X			
Demographics	X			
Physical examination	X		X	
Medical and recent stroke history	X			
2MWT	X	X	X	
RMA	X		X	
Step length, cadence	X	X	X	
Goniometry	X	X	X	
MAS	X	X	X	
Pain score (VAS)	X	X	X	X
RMI	X		X	
CGI		X	X	X
Adverse events	X	X	X	X
QOL (NHP, ELQ, VAS)	X		X	X
Freiburg Questionnaire	X			
Depression scale	X		X	X
Credibility of treatment			X	
Neurophysiologic examination	X	X	X	

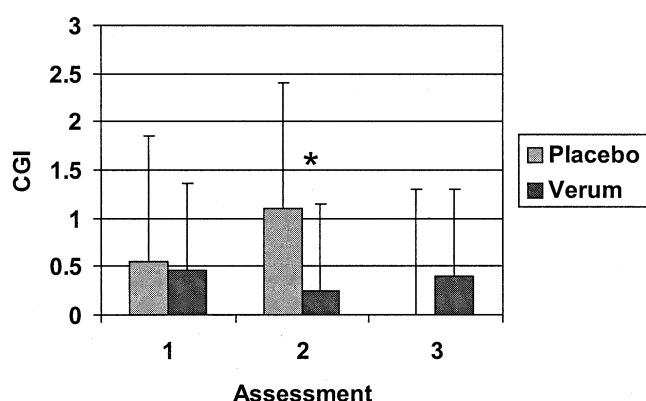


Fig 2. The CGI patient rating. There is a significant difference only in assessment 2 (immediately after end of treatment), which indicates a significantly worse result for the patients treated with verum acupuncture. NOTE. Values are mean $\pm$ SD. * $P < .05$.

verum: 2.9 ± 1.3). After the last treatment (4-wk follow-up), there was no significant difference between placebo and verum groups, either (placebo: 3.3 ± 0.9 ; verum: 3.3 ± 1.1).

The CGI patient rating indicated significantly worse results at assessment 2: although placebo-treated patients gave a mean rating of 1.1 ± 1.2 points (equal to a "slight improvement"), verum-treated subjects reported only a mean of 0.3 ± 0.6 points (equal to "no change"; $z = -1.98$, $P < .05$; fig 2).

From analyzing the neurophysiologic data, we found that the Hmax/Mmax ratio of the spastic leg indicated significant differences between both groups in assessment 2 (fig 3), but no significant differences at baseline or assessment 1. Baseline assessment (assessment 0) was $.59 \pm .28$ for placebo-treated patients versus $.75 \pm .52$ for verum-treated patients. Assessment 1 was $.68 \pm .37$ for placebo group versus $.87 \pm .61$ for verum group. Assessment 2 was $.39 \pm .19$ for placebo subjects versus $.68 \pm .41$ for verum subjects ($z = -2.11$, $P < .05$). The Hmax/Mmax ratio of the unaffected leg did not show any significant differences between the 2 groups. Bivariate Pearson correlations did not reveal any significant correlation between Ashworth score and Hmax/Mmax ratio at baseline or at assessment 2.

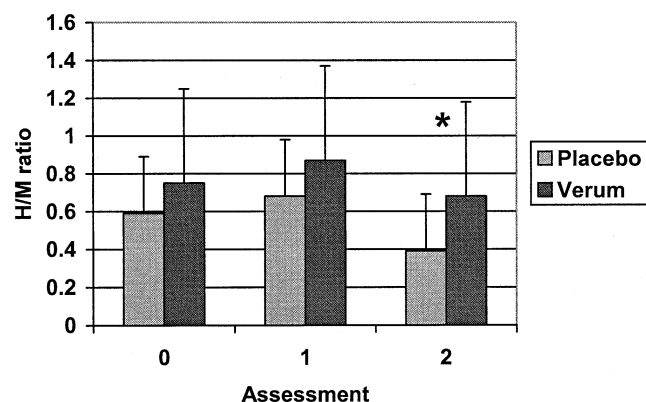


Fig 3. Hmax/Mmax ratio of the affected (spastic) leg indicates significantly higher values in assessment 2 for verum-treated patients. NOTE. Values are mean $\pm$ SD. * $P < .05$.

None of the other efficacy variables indicated significant differences between placebo and verum conditions at any of the follow-ups.

DISCUSSION

Needle acupuncture may be beneficial in the rehabilitation of poststroke patients in an acute or subacute phase.⁵ Although many patients and acupuncturists believe in the beneficial effects of needle acupuncture in chronic poststroke leg spasticity, there are no controlled trials. This lack of data inspired us to perform a study focusing on the effects of acupuncture in the chronic state after stroke. From a methodologic point of view, it was essential to use a placebo method of needling with the same psychologic impact as verum needling. Streitberger and Kleinhenn,⁷ Park et al,¹⁵ and our own group^{8,10} have developed and introduced a placebo needle in which a mounted blunt needle strikes the skin without penetrating it. This placebo needle permits a valid control of the placebo effect in acupuncture studies.^{7,8,10,15}

As a major result, we did not find any beneficial, spasticity-reducing effect from verum acupuncture. Indeed, verum-treated patients reported significantly worse CGI after the end of treatment (assessment 2).

An explanation for these poor clinical results may be derived from the neurophysiologic data. Hmax/Mmax ratio as an objective measure of the severity of spasticity⁹ indicated a higher value for verum-treated than placebo-treated patients after 4 weeks of acupuncture (assessment 2). This ratio reflects spinal alpha motoneuron excitability⁹ and indicates that verum acupuncture induced a facilitation of the lower motoneuron, probably on a spinal (segmental) level. How can this facilitation be explained? Among other mechanisms, segmental analgesic effects of needle acupuncture are based on a stimulation of A delta or group III small myelinated primary afferents and C fibers.¹⁶ Hori et al¹⁷ have examined synaptic actions of cutaneous A delta and C fibers of primate hindlimb alpha motoneurons (as a model of the so-called withdrawal or nociceptive reflex). They found that A delta volleys caused motoneurons to fire in several instances, and some motoneurons discharged repetitively during the depolarizations evoked by activities in C fibers.¹⁷ Very similar results have been reported by Cook and Woolf,¹⁸ which suggests that activation of A beta, A delta, and C fibers produce excitatory postsynaptic potentials at progressively longer latencies in alpha motoneurons. Woolf and Swett¹⁹ studied the responses of these efferents to stimulation of A beta, A delta, and C fiber cutaneous afferents in the sural nerve. Short latency reflexes were elicited in all efferents by A beta inputs, longer latency reflexes were elicited in 64% by A delta inputs, and very-long latency responses with long after-discharges were found in 73% of the units to C inputs.¹⁹

Thus, a higher Hmax/Mmax ratio (indicating a higher excitability of spinal motoneurons) might be explained on a segmental level by nociceptive reflex mechanisms involving A delta and C fiber input. Because motoneuron excitability was elevated in verum- (vs placebo-) treated patients, one might conclude that this finding delivers evidence of a specific needle acupuncture effect (modulated by nociceptive reflex mechanisms). This neurophysiologic effect might also account for the worsening of clinical symptoms (CGI), which could be observed in the verum-treated group.

Another explanation for the negative results of our study could be the technique of needle acupuncture. It should be noted that acupuncture per se is not one entity and that there are several other acupuncture techniques—for example, electroacupuncture²⁰ and auricular acupuncture.²¹ In particular, electroacupuncture is an interesting technique, which combines acu-

puncture and transcutaneous electric nerve stimulation.²⁰ Thus, the negative results reported in this article (focusing on needle acupuncture only) do not imply that all acupuncture techniques would induce the same negative effects.

CONCLUSIONS

Needle acupuncture may be helpful in a variety of chronic diseases and pain conditions, for example, chronic epicondylitis.²² However, the results from our study suggest that needle acupuncture in the chronic state after stroke may not reduce spasticity. Although clinical effects were rather discouraging, neurophysiologic examinations revealed specific segmental acupuncture effects mediated through nociceptive reflex mechanisms. Because we have very little scientific evidence for specific modes of action, further studies focusing on these neurophysiologic effects of needle acupuncture are strongly encouraged.

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