Effects of Acupuncture Treatment on Daily Life Activities and Quality of Life

A Controlled, Prospective, and Randomized Study of Acute Stroke Patients

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Background and Purpose—A number of studies have indicated that acupuncture might improve the functional recovery of stroke patients. These studies vary in inclusion criteria, sample size, and evaluation methods. The present study was designed to investigate whether electroacupuncture treatment favorably affects stroke patients’ ability to perform daily life activities, their health-related quality of life, and their use of health care and social services.

Methods—One hundred four consecutive patients >40 years of age admitted to hospital because of an acute stroke were randomized to 3 groups: deep, superficial, and no acupuncture treatment. The acupuncture treatment given by 4 physiotherapists started 4 to 10 days after randomization and was given twice a week for 10 weeks. All patients underwent conventional stroke rehabilitation as well. Two occupational therapists, blinded regarding the patients’ allocation, evaluated the treatment effects. The assessments were performed 4 times during the first year after randomization by means of interviews and observations.

Results—There were no differences between the groups with reference to changes in the neurological score and the Barthel and Sunnaas activities of daily living index scores after 3 and 12 months. Regarding the Nottingham Health Profile, the no acupuncture group had somewhat fewer mobility problems. No differences in health care and social services were found between the groups.

Conclusions—The present study does not give support to the previous studies, which indicates that acupuncture treatment may have a beneficial effect on acute stroke patients’ ability to perform daily life activities, their health-related quality of life, and their use of health care and social services. (Stroke. 1998;29:2100-2108.)

Key Words: activities of daily living ■ acupuncture ■ cerebrovascular disorders ■ quality of life ■ stroke outcome

A number of Chinese studies have indicated that acupuncture might improve patients who have had a stroke. However, with a few exceptions, these studies have not been randomized and properly controlled. Formally randomized studies in this area have been performed mainly in the Scandinavian countries and the United States. One of the randomized studies was small and was not properly controlled, because it used the treated patients as their own controls. None of the studies were placebo controlled. Johansson et al found significant improvement in a group of stroke patients who received acupuncture during the acute phase, compared with an untreated group, regarding assessments of walking, balance, activities of daily living (ADL), quality of life, mobility, and emotional state. The acupuncture group also spent fewer days in nursing homes and rehabilitation wards compared with the control group. In a follow-up study by Magnusson et al, it was shown that the acupuncture treatment had enhanced recovery of the postural function, an improvement that was still evident after 2 years. In a study by Sällström et al in subacute stroke patients, the acupuncture group improved significantly more than the control group, as assessed by motor function, ADL, and quality of life. The follow up-study after 1 year states that the improvement remained. Naeser et al have done smaller controlled studies. In one, a randomized, controlled study, real and sham acupuncture were compared in subacute stroke patients. All subjects were given conventional treatment in addition to acupuncture. Four of 10 patients who received real acupuncture showed a good response, and those who received sham acupuncture showed a poor response. However, because of

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the small sample sizes, the results are inconclusive, as there are considerable risks for type I and II errors. Hu et al. studied 30 acute stroke patients and found that the improvement was greatest in patients with a poor neurological score at baseline. Zhang et al. studied the use of acupuncture in 94 patients with limb paralysis after stroke. Although both the acupuncture treatment group and the control group showed improvement, that in the acupuncture group was significantly greater.

In summary, the cited studies comprise small numbers of patients, and the inclusion criteria vary as well as the time from the stroke onset to the start of acupuncture treatment. In addition, the type of acupuncture treatment, as well as the evaluation methods and criteria used to define improvement, differs from study to study.

The present study was designed with the specific purpose of examining possible placebo components of acupuncture treatment. It can be assumed that the extra time and attention given to the patients, in combination with the expectation effects associated with acupuncture treatment, may confer an unspecific beneficial effect that has nothing to do with the specific effect of deep acupuncture. It is important to clarify such a specific effect of acupuncture, from both the perspective of understanding the underlying mechanism and that of making decisions whether to use such time-consuming treatment in clinical practice. Thus, the aim of the present study was to compare the effects of deep acupuncture, superficial acupuncture, and no acupuncture in the acute stage of stroke with respect to ability in ADL, quality of life, and use of health care and social services.

**Subjects and Methods**

One hundred four consecutive patients admitted to the hospital because of acute stroke were included in the study. After their informed consent had been obtained, the patients were randomized to 3 different treatment groups.

**Inclusion Criteria**

Patients ≥40 years with an acute focal ischemic nonhemorrhagic lesion were invited to take part in the study. The stroke onset had to be less than 1 week before the randomization. The extent of the paresis had to be such that the patient could not walk without support and/or could not eat and/or dress without assistance. The patient had to be able to cooperate mentally and be willing to participate in the study.

**Exclusion Criteria**

These criteria included other severe disease necessitating hospital or nursing home care; severe aphasia or unconsciousness; an earlier cerebral lesion, with a documented need of care; and treatment with a cardiac pacemaker.

**Overall Design, Sample Size, and Randomization**

The design was a multicenter, randomized, open and prospective study, with 3 parallel groups followed for 1 year. The sample size calculation was based on the results from a previous study. Thus, it was assumed that in comparison with the control group, treatment with deep acupuncture would lead to a 20% improvement in the Barthel ADL Index and that 30% of the patients would not participate in the 1-year follow-up. The calculations revealed that 32 patients had to be recruited to each of the 3 groups (α=0.05 and β=0.80).

The computer-generated randomization was stratified for side of cerebral lesion (right/left), diabetes mellitus (yes/no), and hospital (Möln达尔/Sahlgrenska/Ostra). The responsible doctor called the randomization center and gave stratification data. At the randomization center, the list with the combination of stratification variables specific for the individual patient was defined. The patient obtained the consecutive number on this list, which resulted in allocation to 1 of 3 groups—deep acupuncture, superficial acupuncture, or no acupuncture—as previously generated by the computer.

All patients received conventional stroke rehabilitation as well. The acupuncture, deep and superficial, was performed by 4 physiotherapists (PTs), trained together to give the same information and to use the same techniques. The treatment started in both groups 4 to 10 days after randomization and was given twice a week for 10 weeks.

**Deep Acupuncture**

Ten acupuncture points, according to traditional Chinese medicine, were used: LI 4, LI 11, ST 38, and EX mob on both the paretic and the nonparetic sides; SJ 5 on the nonparetic side; and DU 20 on the scalp. (The point SJ 5 is currently called TE 5, and the point DU 20 is called GV 20.)

The needles were 30 mm long. The needles on the nonparetic side were stimulated manually, every 5 minutes, each time until the “de chi” sensation was achieved. Electrical stimulation at a frequency of 2 Hz was applied to the needles on the paretic side. The intensity of stimulation was increased until pronounced muscle contractions were achieved. Each treatment was given for 30 minutes.

**Superficial Acupuncture**

Four short needles (15 mm) were used, 1 in each extremity. The needles were placed superficially just under the skin, where they were left for 30 minutes. The points used were LI 11 bilateral and EX mob bilateral. No electrical or manual stimulation was applied to the needles.

**No Acupuncture**

The no acupuncture group received conventional stroke rehabilitation only.

**Evaluation Method**

Two occupational therapists (OTs), who were blinded to patient allocation after randomization, evaluated the treatment effects on ADL, health-related quality of life, and use of health care and social services.

The assessments were performed 4 times during the first year; 3 days after randomization and at 3 weeks, 3 months, and 12 months. The assessments were done by means of interviews and observations at the hospitals, nursing homes, and/or in the patients’ homes. If there was any doubt about patients’ abilities, they were asked to perform the activity. The occupational therapist did all the scoring and followed the same patients at the 4 assessment times.

The study was approved by the Ethics Committee of the Faculty of Medicine, University of Göteborg, Sweden.

**Measurement Instruments**

Functional outcome was based on the neurological score according to the Scandinavian Stroke Study Group, including motor function of the arm, hand, and leg; ambulation; orientation; and speech. The maximum score is 48 points.

Daily life activity outcome was evaluated with the Barthel Index and Sunnaas Index of ADL. The Barthel Index is an instrument with a maximum of 100 points that includes 10 personal activities: feeding, personal hygiene, bathing self, dressing, toilet, bladder control, bowel control, chair/bed transfer, ambulation/wheelchair, and stair/climbing. The Sunnaas Index includes 12 daily life activities, personal as well as instrumental, including eating, continence, indoor mobility, toilet management, transfer, dressing and undressing, hygiene, bath/shower, cooking, housework, outdoor mobility, and communication. The maximum score is 36 points. A higher score indicates fewer problems in both of these ADL indexes.

Health-related quality of life was estimated by means of the Nottingham Health Profile (NHP), part I. It reflects the patient’s degree of discomfort or distress within 6 dimensions (emotional relations, sleep, lack of energy, pain, physical mobility, and social
isolation), in a total of 38 yes/no questions. The ratings on each item are weighted to give a score of 0 to 100; a higher score indicates more problems.

The NHP questionnaire, a self-instructive instrument, was given to the patient and collected on the assessment occasion by the occupational therapist. In a few cases, the patient needed assistance to fill in the questionnaire. Most often help was needed because of a visual deficit or writing problems. The interviewer then read the questions aloud and, if necessary, wrote down the answers. Structured questionnaires were used to collect data about the patient’s clinical picture, marital status, and social and living conditions. Social services were defined as formal care, and assistance from relatives was designated informal care.

### Statistical Methods

The analyses were planned to be performed in 2 steps. In the first step, the superficial acupuncture group and the no acupuncture group were compared. If no differences were observed between these groups, they were combined. In the next step, comparisons were made between the deep acupuncture group and the combined superficial acupuncture/no acupuncture group. Comparisons were thereafter carried out for entry characteristics and changes from entry to follow-up after 3 and 12 months. The changes within each group (follow-up minus baseline) were then used to calculate the net effect (change in the deep acupuncture group minus change in the combined superficial acupuncture/no acupuncture group). The analyses were performed according to the intention-to-treat principle. Loss of data on neurological score and ADL indexes in patients who had died before the 12-month follow-up assessment were not adjusted for in additional analyses unless there was a difference in mortality rates between the groups.

The Fisher permutation test was used in the statistical analyses for the outcome. The χ² test and Kruskal-Wallis test were used in the statistical analyses for the entry characteristics. The proportional hazards model was used to calculate whether either of the 2 acupuncture treatments was associated with a change in mortality risk compared with the group with no acupuncture treatment. Confidence intervals (CIs) were calculated for the main variables. The mean age among the deceased patients was 81 years and among the others 76 years.

### Results

One patient initially randomized to the deep acupuncture group was dropped from the study immediately because of refusal to participate. Further, 1 patient receiving deep acupuncture dropped out of the evaluation program. This 86-year-old man was referred to geriatric rehabilitation and left the hospital after 2 months. Nine months after the first stroke, he died of pneumonia. Three patients did not complete the deep acupuncture treatment and withdrew for various reasons (2 disliked the acupuncture treatment; 1 developed an erysipelasoid arm infection). All 3 patients had received most of their treatment (14, 15, and 18 sessions, respectively). In the superficial acupuncture group, 1 patient did not want to continue the treatment after completing 4 sessions. These 4 patients are all included in the analyses according to the intention-to-treat principle. Nine women and 10 men died during the study. All patients except 1 among the survivors were completely assessed, leaving 82 patients at the 12-month follow-up (Figure 1).

Within the groups, 4 patients died in the deep acupuncture group; the causes of death were cardiac death (n=2), pneumonia (n=1), and cerebral infarction (n=1). In the superficial acupuncture group, 10 patients died of cardiac death (n=6), cerebral infarction (n=2), renal insufficiency (n=1), and gastrointestinal bleeding (n=1).

In the no acupuncture group, 5 patients died of cardiac death (n=3), cerebral infarction (n=1), and pneumonia (n=1).

The mean age among the deceased patients was 81 years and among the others 76 years.

All dropouts were analyzed regarding survival. One man died of pneumonia 9 months after inclusion. Two of the female dropouts were still alive when the study was completed, the one who refused to participate and the one who dropped out after 3 months.

The proportional hazards model showed that neither deep nor superficial acupuncture was associated with any differences in mortality risks compared to the no acupuncture group (relative risk, 1.1 [95% CI, 0.29 to 4.1] and 2.5 [95% CI, 0.8 to 7.9], respectively).

### Entry Characteristics

There were no statistically significant differences in the entry characteristics between the groups (Table 1). There were no differences between the groups in the systolic and diastolic blood pressures (data not shown). The women as a group...
were older than the men, and they also more often had a history of treated hypertension (n = 30 [52%] versus n = 14 [30%]; P = 0.029).

Changes During Follow-Up
No differences were seen between the superficial acupuncture and the no acupuncture groups when comparing the changes in the neurological score and the Barthel and Sunnaas index scores.

For the ADL index scores after 3 and 12 months (Table 2), no differences were seen between the deep acupuncture and the combined superficial/no acupuncture groups making the same comparisons (Table 3).

In all 3 groups, the neurological score and the Barthel and Sunnaas ADL index scores showed that most of the improvement occurred between 3 days and 3 weeks. After that time, the improvement continued but leveled off, as expected. At the 12-month assessment, 5 patients in the deep acupuncture group, 5 in the superficial acupuncture group, and 6 in the no acupuncture group had Barthel Index scores of 100 points.

Regarding the Nottingham Health Profile, the no acupuncture group scored significantly lower in the dimension “physical mobility” (P = 0.048) compared with the deep acupuncture group after 12 months. This indicates that the no acupuncture group had somewhat fewer mobility problems. In the other 5 dimensions in NHP (emotional reactions, sleep, lack of energy, pain, and social isolation), no significant differences were found between the groups (Table 4).

After 3 months 35% of the patients in the deep acupuncture group still remained at the rehabilitation units compared with 24% in the superficial acupuncture group and 15% in the no acupuncture group. After 12 months the proportion of patients living in their own homes was 73% in the deep acupuncture group, 53% in the superficial acupuncture group, and 82% in the no acupuncture group. After 12 months there were no differences between the groups regarding acute hospital care, nursing home care, living and social conditions, use of formal/informal care and need of personal assistance, or help with instrumental ADL. It was found that all 3 groups had more informal than formal care. Spouses and children

### TABLE 1. Characteristics of the Patients (n=104) at Entry, by Group

<table>
<thead>
<tr>
<th></th>
<th>Deep Acupuncture (n=37)</th>
<th>Superficial Acupuncture (n=34)</th>
<th>No Acupuncture (n=33)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female gender, n (%)</td>
<td>17 (46)</td>
<td>17 (50)</td>
<td>24 (73)</td>
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<tr>
<td>Age, y</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Women</td>
<td>75</td>
<td>82</td>
<td>78</td>
</tr>
<tr>
<td>Men</td>
<td>77</td>
<td>76</td>
<td>74</td>
</tr>
<tr>
<td>Neurological score</td>
<td>26</td>
<td>26</td>
<td>28</td>
</tr>
<tr>
<td>Barthel ADL Index score</td>
<td>24</td>
<td>26</td>
<td>33</td>
</tr>
<tr>
<td>Sunnaas ADL Index score</td>
<td>7</td>
<td>8</td>
<td>10</td>
</tr>
<tr>
<td>Previous stroke, n (%)</td>
<td>4 (11)</td>
<td>8 (24)</td>
<td>6 (18)</td>
</tr>
<tr>
<td>Central nervous sensibility loss, n (%)</td>
<td>17 (46)</td>
<td>15 (44)</td>
<td>14 (42)</td>
</tr>
<tr>
<td>Neglect, n (%)</td>
<td>7 (19)</td>
<td>7 (21)</td>
<td>8 (27)</td>
</tr>
<tr>
<td>Previous myocardial infarction, n (%)</td>
<td>4 (11)</td>
<td>5 (15)</td>
<td>1 (3)</td>
</tr>
<tr>
<td>Intermittent claudication, n (%)</td>
<td>3 (8)</td>
<td>1 (3)</td>
<td>2 (6)</td>
</tr>
<tr>
<td>Aspirin use, n (%)</td>
<td>6 (16)</td>
<td>10 (29)</td>
<td>9 (27)</td>
</tr>
<tr>
<td>Chronic heart failure, n (%)</td>
<td>5 (14)</td>
<td>3 (9)</td>
<td>1 (3)</td>
</tr>
<tr>
<td>Diabetes mellitus, n (%)</td>
<td>6 (16)</td>
<td>7 (21)</td>
<td>5 (15)</td>
</tr>
<tr>
<td>Hypertension, n (%)</td>
<td>17 (46)</td>
<td>16 (41)</td>
<td>13 (39)</td>
</tr>
<tr>
<td>Current smoking, n (%)</td>
<td>8 (22)</td>
<td>7 (21)</td>
<td>6 (18)</td>
</tr>
</tbody>
</table>

Values are mean; numbers in parentheses are percentages.

### TABLE 2. Changes from Baseline: Comparison of the Superficial Acupuncture Group and the No Acupuncture Group

<table>
<thead>
<tr>
<th></th>
<th>Changes After 3 Months</th>
<th>Changes After 12 Months</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Superficial Acupuncture Group (n=34)</td>
<td>No Acupuncture Group (n=33)</td>
</tr>
<tr>
<td>Neurological score</td>
<td>9.17±7.37</td>
<td>11.07±6.88</td>
</tr>
<tr>
<td>Barthal ADL Index score</td>
<td>32.0±27.34</td>
<td>40.17±20.02</td>
</tr>
<tr>
<td>Sunnaas ADL Index score</td>
<td>10.23±8.33</td>
<td>13.37±6.66</td>
</tr>
</tbody>
</table>

*Values are subtractions from baseline (baseline examinations were performed within 3 days after randomization).
TABLE 3. Changes from Baseline (3 Days): Comparison of the Deep Acupuncture Group and the Combined Superficial Acupuncture/No Acupuncture Group

<table>
<thead>
<tr>
<th></th>
<th>Changes After 3 Months</th>
<th>Changes After 12 Months</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Deep Acupuncture Group*</td>
<td>Combined Superficial Acupuncture/No Acupuncture Group*</td>
</tr>
<tr>
<td></td>
<td>(n=37)</td>
<td>(n=67)</td>
</tr>
<tr>
<td>Neurological score</td>
<td>9.27±9.23</td>
<td>10.12±7.13</td>
</tr>
<tr>
<td>Barthel ADL Index score</td>
<td>38.15±24.77</td>
<td>36.08±24.11</td>
</tr>
<tr>
<td>Sunnaas ADL Index score</td>
<td>12.21±7.27</td>
<td>11.80±7.64</td>
</tr>
</tbody>
</table>

*Values are subtractions from baseline (3 days).

assisted more frequently in personal ADL than persons from the social services (Table 5).

Discussion

This randomized, controlled study in elderly patients with acute stroke was unable to demonstrate that deep acupuncture, given twice weekly for 10 weeks, was associated with any beneficial effect as measured in different dimensions. Thus, neither ADL scores, neurological scores, use of health care and social services, nor quality of life showed more improvement in the deep acupuncture group than in the other groups.

However, these findings have to be considered from the perspective of four methodological issues, eg, design, treatment program, evaluation methods, and representativity of the patient sample.

In regard to the first issue, ie, the design of the study, we chose a randomized parallel group study with 3 arms. The rationale for having both a superficial acupuncture group and a no acupuncture group was to clarify whether the acupuncture treatment situation per se was associated with any effect. As no such effect was found, these 2 groups were used as a combined control group in the following comparisons with the deep acupuncture group. The power of the study is largely dependent on the sample size, which was calculated through use of the results of a recently published study. Further, more, to make the present and the previous studies comparable, similar patient inclusion criteria and acupuncture methods were applied.

It may still be argued that the present study was underpowered and that important beneficial effects of acupuncture have remained undetected. However, the 95% CIs of the net effects on the main variables do not indicate that this is the case.

The second methodological issue to be addressed relates to treatment. Acupuncture has been used in Sweden for the treatment of chronic pain conditions during the past decade. Some trials also address the possibility of improving the rehabilitation outcome after stroke. However, in contrast to the fairly good scientific support for pain treatment with acupuncture, the scientific rationale for treating different diseases is still poorly substantiated.

In the present study, the acupuncture treatment was similar to that performed in the study by Johansson et al (personal communication, B.B. Johansson, 1992). The only difference between that study and ours was that the locations chosen for the needles were strictly formalized in our study, because the treatment was given by more than one PT. This was considered important to make easier deductions for future practical use in stroke treatment and care. The occurrence of sensory deficits was limited, and only a minority of patients failed to perceive the typical “de chi” sensation from the paralyzed extremities. The choice of placebo treatment with a few superficial needles close to acupuncture points was based on

TABLE 4. Health-Related Quality of Life by Group as Assessed by NHP at 3 and 12 Months

<table>
<thead>
<tr>
<th></th>
<th>Deep Acupuncture (n=30)</th>
<th>Superficial Acupuncture (n=20)</th>
<th>No Acupuncture (n=27)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>3 mo 12 mo</td>
<td>3 mo 12 mo</td>
<td>3 mo 12 mo</td>
</tr>
<tr>
<td>Emotional reactions</td>
<td>19.3 14.8</td>
<td>23.9 12.8</td>
<td>15.8 14.2</td>
</tr>
<tr>
<td>Sleep</td>
<td>29.5 23.2</td>
<td>28.3 23.6</td>
<td>25.3 24.0</td>
</tr>
<tr>
<td>Lack of energy</td>
<td>34.0 34.6</td>
<td>29.1 36.0</td>
<td>30.4 30.8</td>
</tr>
<tr>
<td>Pain</td>
<td>15.8 19.4</td>
<td>13.4 11.8</td>
<td>18.5 16.7</td>
</tr>
<tr>
<td>Physical mobility</td>
<td>47.2 53.5</td>
<td>46.1 43.2</td>
<td>39.6 36.0*</td>
</tr>
<tr>
<td>Social isolation</td>
<td>13.0 15.4</td>
<td>16.6 11.7</td>
<td>10.7 14.6</td>
</tr>
</tbody>
</table>

Values are mean (ranging from 1 to 100 in each specified dimension); data are longitudinal.

*P<0.05 versus the corresponding value in the deep acupuncture group. Otherwise, there were no significant changes between the groups.
previous experience. This type of treatment does not influence acute (B. Olausson, J. Sagvik, unpublished data, 1997) or chronic pain conditions. It may still be argued that even superficial needles may have an effect when applied to acupuncture points. However, when comparing the outcome in the superficial and the no acupuncture groups, there was not the slightest indication of a better effect in the former group. If anything, the reverse was observed. Placebo has been widely used as a control procedure for a number of different symptoms and treatments, including acupuncture. Regarding acupuncture, a number of different control measures have been used; for instance, needles in points other than true acupuncture points, needles placed superficially, needles glued to the skin, and mock transcutaneous nerve stimulation. Preferably, the psychological impact of the placebo treatment should be of the same magnitude as that of the true treatment. Superficial acupuncture (ie, needles inserted superficially into the skin, using classical Chinese acupuncture points) has been used as placebo in studies on pain and usually found to have less effect than manual acupuncture or electroacupuncture. In the present study, deep acupuncture (10 classical acupuncture points) was compared with superficial acupuncture (4 classical acupuncture points) to minimize the treatment effect and maintain a psychological impact. The 2 acupuncture groups were compared with a control group receiving no acupuncture, thus taking into account that both acupuncture treatments could be effective. The patient’s expectancy of the efficacy of treatment may influence the result. Coller et al found, however, that neither attitudes nor knowledge of acupuncture influenced the response to acupuncture. The use of a credibility scale is one way of ascertaining the strength of the patient’s expectations of improvement. Such a scale was not used in this study. Status, behavior, and attitudes of the therapist may also influence the size of the treatment effect. The therapists in the present study were all carefully instructed to maintain a neutral attitude so as not to influence the patient’s view of the treatment in any way.

The information before randomization was also held in as neutral a form as possible. Though placebo effects seem fairly well controlled in this study, such mechanisms cannot be excluded. Even in double-blind drug trials, therapists obtain results in accord with their respective expectations, which means that the therapist may have more subtle influences on the placebo response.

Since there was no difference between any of the groups, the results of this study do not reinforce the need for acupuncture as additional treatment for patients with acute stroke.

Regarding the third methodological issue, optimally objective evaluation methods are of particular importance in this type of study. In our study, 2 OTs not participating in the treatment program evaluated the results. They were blinded with respect to patient allocation after randomization. They were aware of the importance of not discussing the kind of acupuncture treatment with the patients. If the patient mentioned having had acupuncture, neither the patient nor the occupational therapist would know whether it had been deep or superficial acupuncture. All patients were approached in the same way, and the OTs strictly adhered to the procedures related to the evaluation instruments. The OTs were trained together and experienced assessing ADL both from neurological clinics and primary health care. Most of the examinations were done by interviews in the patients’ homes. Ability to perform ADL is to a certain extent dependent on the environment and acts to enable or to constrain engagement in some activities. If the OT had any doubt about a patient’s ability, the patient was asked to perform the activity under observation. This

<table>
<thead>
<tr>
<th>TABLE 5. Living and Social Conditions by Group at 3 and 12 Months</th>
</tr>
</thead>
<tbody>
<tr>
<td>Deep Acupuncture (n=37)</td>
</tr>
<tr>
<td>------------------------</td>
</tr>
<tr>
<td><strong>3 mo</strong></td>
</tr>
<tr>
<td>Own home*</td>
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<tr>
<td>Formal care</td>
</tr>
<tr>
<td>Informal care</td>
</tr>
<tr>
<td>Rehabilitation unit</td>
</tr>
<tr>
<td>Nursing home/Old peoples home</td>
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<tr>
<td>Acute hospital</td>
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<tr>
<td>Marital status</td>
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<tr>
<td>Married</td>
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<tr>
<td>Single</td>
</tr>
<tr>
<td>Widow/widower</td>
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<tr>
<td>Divorced</td>
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<tr>
<td>Missing</td>
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<tr>
<td>Dead</td>
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</tbody>
</table>

*Formal assistance is defined as community-based social services; informal assistance is given by spouses and children. Values in parentheses indicate personal assistance.
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could be the case, for instance, for patients with neglect problems. Each patient was followed by the same OT, which probably kept both the variability and the dropout rate low.

When choosing instruments for evaluation, it is important to look at the responsiveness, ie, whether the instrument has the sensitivity to detect sufficiently small differences both in terms of differences between groups and changes over time. The Barthel ADL Index was chosen because it has widely been used in other stroke studies and tested for interrater reliability. The Sunnaas Index was chosen because other studies have shown that ADL dependence in elderly populations generally occurs in instrumental activities. However, such a finding was not made in our study. According to earlier validation of these instruments, sum scores were used. No differences between the groups were seen in either of the ADL indexes.

However, it should be pointed out that sum scores do not reveal in which activities the problems occur. Certain activities are more essential to independence than others. Thus, not being able to go to the toilet means that the patient is much more dependent on personal assistance several times a day, whereas not being able to take a bath corresponds to personal assistance a couple of times a week. Objections have been raised against sum scores and the way in which assessments on an ordered categorical level are treated like interval scores. Using a sum score therefore has its limitations but gives the reader the opportunity to compare the result with those in previous studies. To assess health-related quality of life in this study, a self-instructive instrument, NHP, was used to examine some specific aspects. A few patients had problems with reading/writing. In these cases, the OT read the questions or/and wrote down the answers. In addition, some patients were unable to fill in the NHP questionnaire for various reasons, such as perception of illness, fatigue, a language problem, or a psychological problem. If it had been possible to include these patients in the assessment, a further decrease in the quality of life would probably have been found. Hypothetically, the mean score would have been even higher, indicating a still lower quality of life, if these patients had been able to complete the questionnaires.

NHP is a sum score organized into 6 dimensions, each of which consists of 3 to 9 questions. The only dimension that showed a significantly better result was physical mobility in the no acupuncture group, at the 12-month assessment, compared with the deep acupuncture group. This is probably a chance finding, as it was a single observation that, in addition, favored the group that received no acupuncture treatment. Since we had no baseline values from NHP (only those after 3 and 12 months), we could not present a comparison of change from baseline as was done with the other outcome variables. The reason for not trying to establish a prestroke baseline is that such an estimate would be very unreliable by the acute stroke phase. A comparison of the NHP scores at 12 months with a 76-year-old reference population shows that the scores were higher in most of the dimensions among our patients, indicating a lower quality of life. However it must be taken into consideration that this group of stroke patients is not representative of all stroke patients, because the inclusion criteria excluded the less disabled patients.

A confounding factor when evaluating ability to perform ADL and quality of life among elderly patients is the high comorbidity rate. Thus, many 80-year-old patients who have had a stroke are also suffering from a variety of other dysfunctions and diseases, which might influence all of the dimensions in NHP. Moreover, in this age group, there is a high incidence of other negative events, such as the loss of a spouse, which also affects the quality of life.

The last methodological issue deals with the representativeness of the patients. Although they were consecutively recruited among acute patients at 3 hospitals, they are not representative of the total stroke population, because specific recruitment criteria were used. However, the method of selection was similar to that in a previous study.

The majority of patients were living in their own homes at the 12-month assessment (Table 5). Many of them were dependent on formal or informal care, or a combination of both. In this study, as well as in previous reports, informal care was predominant. More attention is now being paid to this problem, and studies have shown the importance not only of assessing the patient’s ability in performing ADL but also of having assessment instruments to identify the relatives at risk of high levels of burden and problems related to caregiving. Considering the burden of care that stroke might give rise to, it is of greatest importance that caregivers and care planners in the Health and Social Welfare System involve the relatives in patient care and give them information and support.

Acupuncture might influence intrinsic cortical circuits in the focally damaged brain. Thus, the brain tissue could tentatively modify itself through changes at the cellular level, including neuronal and glial cell extensions and synapses. Such neocortical plasticity should possibly be tested on a higher level than motor function. Accordingly, the evaluation was focused on the disability level instead of a motor function level. The reason for this choice is that it is very important to evaluate whether acupuncture has an effect not only on an impairment level but also on the patient’s ability to manage ADL. If this is not the case, such treatment would be of less value to both the individual and society. The evaluations showed, as expected, that all 3 groups recovered from stroke onset up to the follow-up assessment after 12 months, but the recovery in the deep acupuncture group was not superior to that in the other 2 groups.

The question is why our study showed so consistently that acupuncture has no discernible effect on the outcome after stroke, whereas previous studies have shown favorable results. Apart from differences in patient selection or design, several of the previous studies may be criticized for their limited sample size and lack of independent evaluation procedures, factors that may affect study results. In 2 of the studies, selection of patients for a rehabilitation center was probably made with consideration of age and rehabilitation potential, which might influence the result. It is probable that different ages and different subtypes of stroke, including different localizations of the brain damage, could influence the potential for brain plasticity. Thus, it is not possible to
generalize the results from the present study to all types of clinical settings.

Nevertheless, it can be concluded that the present study does not confirm the findings in previous studies which have indicated that acupuncture treatment may have a beneficial effect on acute stroke patients in terms of functional ability, quality of life, and use of health care and social services. The costs for stroke rehabilitation are high, and it is important that every component of the rehabilitation program has well-documented effects regarding clinical outcome, particularly with respect to effects on the ability to perform ADL and on health-related quality of life.

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Effects of Acupuncture Treatment on Daily Life Activities and Quality of Life: A Controlled, Prospective, and Randomized Study of Acute Stroke Patients
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