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Findings by SBU Alert

Acupuncture is an established method of pain relief. Acupuncture has also been tested in Sweden and other countries to treat stroke paralysis, with a focus on improving patients' mobility and abilities to manage activities of daily living (ADL).

Nine small, randomized (or pseudo-randomized) scientific studies were identified, four of which were conducted in Sweden. Seven of the nine studies reported positive effects from acupuncture, at least in some outcome variables, eg, motor-function, ADL ability, and/or well being. Both of the studies that reported no effects were conducted in Sweden and included 39 percent of all patients studied. Both were judged to be of high quality. In this context, they are relatively large studies and have – in contrast to most of the other studies – adequate control groups, independent evaluators of outcomes, and long followup times.

Hence, there is moderate* scientific evidence on the use of acupuncture for stroke, but study findings diverge and the conclusions are uncertain. The costs are substantial, in the range of 10 000 SEK per patient treated. Therefore, acupuncture should not be used routinely in rehabilitation after stroke except in randomized controlled studies aimed at further assessment.

*This assessment by SBU Alert uses a 4-point scale to grade the quality and evidence of the scientific documentation. The grades indicate: (1) good, (2) moderate, (3) poor, or (4) no scientific evidence on the subject. For further information please see "Grading of evidence".

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Technology

Traditionally, for thousands of years, acupuncture has been used to treat stroke in China and other Asian countries [4]. The scientific literature includes numerous reports regarding the positive effects on motor skills, speech, and function in patients who are affected by stroke [overview 1,5]. With few exceptions, these reports address series of patients without control groups. Many different mechanisms have been suggested as reasons for the favorable effects reported. [4,15,16,19,20].

In traditional Chinese medicine, and in Western applications, a range of variations can be found in acupuncture treatment of stroke. Treatment can begin within 1 week following onset, but it is more common to start treatment after 2 to 4 weeks. Treatment late in the course has also been reported. Case studies on successful acupuncture therapy as late as 6 years following onset have been presented [14]. Often needles are used in both the paralyzed and the nonparalyzed sides. These are applied in the classic acupuncture sites in the scalp, arm, and leg. The needles are either manipulated manually or by electrostimulation. Treatment sessions last approximately 30 minutes and are repeated up to five times per week over several weeks.

During the 1990s, post-stroke acupuncture was introduced into the health services in Sweden. The method has been used mainly by geriatric clinics and in ambulatory care programs late in the course. Treatment is provided by physicians, physiotherapists, or nurses having different types of training in acupuncture.

Target group

Each year, approximately 30 000 people in Sweden are affected by stroke. Of these, close to 20 percent die within 3 months and another 30 percent improve spontaneously to the extent that specific treatment at a late stage is not needed. For other reasons (eg, practical and ethical) acupuncture treatment is not an option in some of the remaining stroke patients. However, after subtracting these cases, over 10 000 patients per year remain to constitute a potential target group for acupuncture in the subacute phase following stroke. The target group would be larger if patients received repeated treatment sessions late in the course.

Relation to other technology

Compared to conventional care, the care provided at dedicated stroke units has positive, documented effects on the course in stroke patients. The effects are found both in units linked to emergency departments and those associated with geriatric or rehabilitation medicine departments [2]. Although it is uncertain which of the care components have the greatest influence on the favorable course, the common denominator in stroke units is the emphasis placed on early, intensive reactivation and rehabilitation.

There are many specific rehabilitation methods to treat motor, speech, perception, and cognitive disturbances. It is unclear whether any specific method is superior to another. Weak statistical power and/or low quality characterize most of the studies.

Patient benefits

Most of the studies on acupuncture after stroke involve uncontrolled series of patients and describe improvements during acupuncture treatment [5]. Improvements appear more often in patients treated early after onset than in those where treatment was started late in the course. This agrees with the natural course, and the uncontrolled studies provide little guidance on the benefits of the method.

Eight randomized studies have been conducted, whereof three were in Sweden. In addition, a smaller pseudo-randomized trial was conducted in Sweden which used a predetermined schedule of acupuncture in every second patient [8]. In total, 644 patients were included in these studies. Only summaries are available in English for some of the Chinese studies. Most of the studies must be viewed as having low or very low quality, and the presentation of methods and results is unclear. The table presents the study designs and the main findings.

Of the nine randomized/pseudo-randomized studies, seven present some type of positive result, usually in motor function and/or ADL ability. Both of the negative studies come from Sweden. These studies are larger than the other randomized trials and include 39 percent of all patients, but none of them had sufficient statistical power to reveal small differences among the treatment groups. Only three studies (whereof two were Swedish) specifically report that independent evaluators were used in the assessment (blinded assessment).

It is not apparent why the different studies yielded such different results. In many of the smaller studies, remarkable effects with statistically significant differences were shown even though only 14 to 24 patients had been included in the acupuncture groups. The extremely limited number of patients in these studies also means that the groups often were not comparable at the start of the study, and dropout in the groups was unevenly distributed. All of these factors contribute toward making the effects of treatment difficult to assess. Likewise, it cannot be ignored that publication bias may exist in this field of research, ie, small studies with negative outcomes are not published or are discontinued prematurely without being presented in a scientific context.

A particular problem in these studies is related to the selection of control groups. In one model, the control groups received routine, individualized therapy with a physiotherapist, occupational therapist, and speech therapist, while the treatment group received the same basic rehabilitation with the addition of acupuncture. This means that the acupuncture groups received substantially more attention. In an attempt to compensate for this, the Swedish multicenter trial used subliminal skin stimulation via TENS electrodes on the acupuncture sites and provided an equal number of treatment sessions using the same therapists. Furthermore, in this study, another trial group received low frequency, high-intensity electrical stimulation via conventional TENS. The intended purpose here was to distinguish specific acupuncture stimulation with needles from more non-specific, deep muscle stimulation [3].

Complications and side effects

Several of the randomized studies on stroke reported that information on potential side effects was systematically collected. Dizziness [9] and difficulty in tolerating electrostimulation [3] were reported in some isolated cases, but the main impression is that treatment is remarkably free from side effects even in this patient group. Many of the studies included patients who received ongoing treatment with anticoagulant or thrombocyte inhibitors. However, no bleeding complications were noted.

A systematic literature review that reported serious side effects from acupuncture (regardless of study type and indication) until 1996 found that infections were the most common: hepatitis B and C, HIV, and bacterial infections [6]. Complicated infections were reported mainly when acupuncture needles were used. In Sweden, probably disposable needles are used exclusively. Next to infection, puncture of a lung is the most commonly reported side effect. Also heart tamponades, spinal cord injury, and disrupted pacemaker function caused by electrostimulation from the needles are described [6].

Costs and cost-effectiveness

A treatment session takes approximately 45 minutes (including preparation time). The Swedish acupuncture studies have included 20 such sessions per patient, which means a staff cost around 3000 to 3500 SEK per patient. Additionally, there are equipment costs, material costs, and facility costs. Travel costs are substantial for the patient group since patients usually need to be transported by taxi or ambulance. If treatment is provided in the home in the most severe cases, there are major costs for travel and transport time for the therapist. For 20 sessions, travel costs are approximately 5000 to 7000 SEK. The total costs for 10 weeks treatment can therefore reach between 10 000 and 13 000 SEK per patient.

Since scientific literature is contradictory regarding possible effects of treatment, the calculations of cost effectiveness are not meaningful. This is illustrated by elementary sensitivity analysis. If one would assume that the most favorable Swedish results (the Lunda study) with a reduction in the percentage of those receiving institutional care among the survivors was 73 percent to 42 percent at 3 months and from 34 percent to 11 percent at 12 months following onset, the savings to society would reach hundreds of millions SEK annually. If, instead, one applies the results from Göteborg and the Swedish multicenter trial to the entire potential target group, society would incur costs in the range of 100 million SEK per year without benefiting stroke patients.

Structure and organization of health services

Currently, an unknown share of rehabilitation resources in Swedish stroke care goes to acupuncture treatment. At least a smaller percentage of these resources could be used for careful assessment. Most could be redistributed to other inputs with better-documented benefits in stroke care.

Ethical aspects

In most of the randomized studies, the acupuncture patients received substantially more attention than did those in the control groups. The absence of effects in the largest trial, the Swedish multicenter study, can possibly be the result of the control groups receiving as much attention by the same staff and that their expectations on treatment effects were equally great [3]. A positive interpretation of the results is therefore that the involvement of the environment and patients' expectations can be of critical importance in the long-term course following stroke. Likewise, the favorable effects from stroke units are partly the result of the fact that patients are cared for by particularly knowledgeable and motivated staff [2].

Diffusion in Sweden

Largely unknown. Reports, mainly from all geriatric clinics, suggest that activity is extensive. A survey would be desirable.

Current evaluation research

A systematic literature review of different rehabilitation methods after stroke, including acupuncture, is being conducted within the Stroke Module of the Cochrane Collaboration.

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Year	Study	Number patients	Treatment start (time after onset)	Treatment time	Type of acupuncture	Intervention in control- group(s)*	"Blinded" assess- ment **	Main findings
1990	Zou et al, China [21]***	63	?	6 weeks	Needles	0	?	"Better treatment outcomes in the the acupuncture group."
1993	Hu et al, Taiwan [9]	30	Within 36 hours	4 w.	Needles, some with electro- stimulation	0	Not reported	Significantly better neurological function, no significant difference in ADL function.
1993– 94	Johansson et al, Lund [10,11,13]	78	Within 10 days	10 w.	Needles with some electro- stimulation	0	Not reported	Significantly better motor function, balance, ADL skills, and quality of life. Reduced need for institutional care. Effects remained after 1 yr.
1996– 97	Kjendahl et al, Norway [12,17]	45	Average 40 days	6 w.	Needles some combined with electrostimulation or moxibustion (burning of growths on the skin)	0	Yes	Significantly better motor function, ADL skills, well being, and social adaptation. Effects remained after 1 yr.
1998	Gosman- Hedström et al, Göteborg [7]	104	4–10 days	10 w.	Needles, some with electro- stimulation	A. Needles surface in the skin B. 0	Yes	No difference in neuro- logical deterioration, ADL skills, well being, or resource utilization.
1998	Si et al, China [16]***	42	?	?	Electrostimulation	0	?	Significantly better function ?no timepoint given.
1998	Gustafsson [8]****	14	5–12 days	10 w.	Needles some with electro- stimulation	0	Yes	Significantly better ADL function (but the groups were not comparable at study start).
1999	Wong et al, Taiwan [18]	118	10–14 days	2 w.	Electrostimulation via surface electrodes	0	Not reported	Significantly better mobility and ADL skills upon discharge from hospital.
1999	Multicenter, Sweden [3]	150	5–10 days	10 w.	Needles, some with electro- stimulation	A. Subliminal skin stimulation with TENS B. Low fre- quency, high intensity muscle stimulation with TENS	Yes	No differences in motor skills, walking ability, ADL skills, or well being.

In addition to conventional rehabilitation and drugs
Evaluator without knowledge of the group to which patients belonged
Only English abstract available for assessment
Pseudorandomized study (every second patient active treatment, every second control)