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Prospective Investigation of Adverse Effects of Acupuncture in 97 733 Patients

Acupuncture is practiced by about 40 000 physicians in Germany and has been reimbursed by statutory sickness funds (social health insurance companies) in the past on an informal basis. Since October 2000, acupuncture treatment can only be reimbursed for a limited number of conditions within the framework of so-called trial phases ("Modellvorhaben"). During these trial phases randomized trials are performed in a limited number of patients to evaluate effectiveness. However, reimbursement of acupuncture is possible on a nationwide scale within the trial phase if (1) the treatment is provided by a licensed physician trained in acupuncture and (2) the physician reports data on patient characteristics, treatment, outcome, and adverse effects on a standardized form. We report herein the preliminary results on adverse effects from the trial phase of a group of statutory sickness funds (Ersatzkassen) covering roughly a quarter of the German population (about 20 million persons).

Methods. A total of 9429 German physicians with at least 140 hours of formal acupuncture training (19% had >350 hours) have been accredited to the trial phase, which started in July 2001. Fifty-three percent

Table 1. Nonserious Adverse Events of Acupuncture Reported in 97 733 Patients

Event	No.	% of Total	99% Confidence Interval
Needling pain	3202	3.28	3.13-3.43
Hematoma	3114	3.19	3.04-3.34
Bleeding	1346	1.38	1.28-1.48
Orthostatic problems	447	0.46	0.40-0.52
Forgotten needles	242	0.25	0.21-0.29
Other	674	0.69	0.62-0.76
Local skin irritation	173		
Deterioration of symptoms	118		
Headache	38		
Fatigue	26		
Any nonserious adverse event	6936	7.10	6.88-7.32

were general practitioners, 20% orthopedic surgeons, 9% internists, and 18% various other specialists. Patients insured by one of the participating statutory sickness funds are eligible if they have chronic headache, low back pain, or osteoarthritis pain. After each last treatment session, physicians had to report whether an adverse effect (defined as any adverse event possibly related to acupuncture) occurred. If this was the case, the adverse effect had to be specified. Predefined categories were bleeding, needling pain, hematoma, infection, orthostatic problems, forgotten needles, and any other events. Serious adverse effects (defined as any adverse effects possibly related to acupuncture making treatment necessary or severely interfering with the patient's well-being, eg, a pneumothorax or a nerve injury) must be reported to the study center within 24 hours.

Results. By April 15, 2002, data for 97 733 patients (mean \pm SD age, 55.0 \pm 15.5 years; 80.5% female) reported by 7050 physicians were available for analysis. The mean \pm SD number of acupuncture sessions per patient was 7.8 \pm 2.4; thus, the total number of sessions exceeded 760 000. The mean (SD) number of inserted needles per session was 12.6 (5.1). Mild adverse effects were reported in 6936 patients (7.10%; 99% confidence interval, 6.88%-7.32%). The most frequently reported adverse effects were needling pain and hematoma (**Table 1**).

There was considerable variability among physicians regarding the proportion of patients with adverse effects: 58.4% of the physi-

cians did not report a single case, 22.7% recorded adverse effects in up to 10% of patients, 15.0% in 10% to 50% of patients, and 3.9% in more than 50% of patients (analysis restricted to 2900 physicians who had documented at least 10 patients).

Five potentially serious adverse effects were noted in 6 patients (**Table 2**). A 47-year-old, slender woman received acupuncture on her back at the level of the third thoracic vertebra. Feeling cold, she asked for a blanket to be wrapped around her. Through this action, a needle was pushed deeper, causing the pneumothorax. The patient was immediately referred to a hospital and treated with Bülow drainage. She made a complete recovery within 4 days. The second patient was a 73-year-old, slim woman needed at a thoracolateral trigger point. A small subpleural pneumothorax resulted from the needle accidentally puncturing her lung. The patient was referred to a hospital but specific treatment was not considered necessary and subsequent x-ray control films showed spontaneous recovery. The 4 other adverse events reported were an exacerbation of depression, an acute hypertensive crisis, a vasovagal reaction, and an acute asthma attack with angina and hypertension (**Table 2**).

Comment. Our results confirm the findings of earlier reports¹⁻⁴ that acupuncture, in the hands of qualified practitioners, is safe. Contrary to these smaller studies, the present investigation also reports serious adverse effects, which previously have been noted only as case reports without incidence figures.⁵ Despite the

Table 2. Potentially Serious Adverse Events of Acupuncture in 6 of the 97 733 Patients

Events	No. of Patients	Description (Causality)
Exacerbation of depression	1	A 36-year-old man with chronic depression became acutely suicidal immediately after acupuncture (possible)
Acute hypertensive crisis	1	A 66-year-old woman with history of stroke developed blood pressure of 200/100 mm Hg (possible)
Vasovagal reaction	1	A 51-year-old man developed hypotension 10 min after needle insertion and was briefly unconscious (likely)
Asthma attack with hypertension and angina	1	A 62-year-old woman with a history of asthma had an asthma attack with hypertension and angina after acupuncture (possible)
Pneumothorax	2	(1) A 47-year-old woman who wrapped a blanket around her shoulder thus making the acupuncture needle penetrate her lung, required hospitalization (certain) (2) A 73-year-old woman became acutely dyspneic during treatment, diagnosis confirmed radiographically, no treatment required (certain)

large sample size, our results should be interpreted with caution. The routine documentation in this trial phase cannot be compared with that in a clinical trial. Participation in this trial phase is a precondition for reimbursement. Because of the large number of physicians, the documentation and definitions of adverse effects and serious adverse effects had to be extremely simple. The variation in reporting indicates that the opinion of German physicians as to what constitutes a minor adverse effect vastly differs. Simple discriminative definitions should be developed to facilitate future research. For severe adverse effects, underreporting is a potential problem. Although it was mandatory for all participating physicians to report severe adverse effects, we had no way of checking.

The trial phase includes only German physician acupuncturists. The type and frequency of minor adverse effects are similar to those found with medical doctors, physiotherapists, and traditional acupuncturists in other countries.¹⁻⁴ Comparable data on serious adverse effects do not exist.

We conclude that serious adverse effects of acupuncture seem to be true rarities. This renders acupuncture a safe intervention. The real incidence of minor adverse effects is difficult to assess because of difficulties in establishing a simple discriminative definition.

Dieter Melchart, MD
Munich, Germany and
Zurich, Switzerland
Wolfgang Weidenhammer, PhD
Andrea Streng, PhD
Susanne Reitmayr, Dipl Oec Troph
Andrea Hoppe, MD
Munich
Edzard Ernst, MD, PhD
Exeter, England
Klaus Linde, MD
Munich

This study was funded by a group of German statutory sickness funds, including the Deutsche Angestellten-Krankenkasse, Barmer Ersatzkasse, Kaufmännische Krankenkasse, Hamburg-Münchener Krankenkasse, Hanseatische Krankenkasse, Gmün-

der Ersatzkasse, HZK Krankenkasse für Bau- und Holzberufe, Brühler Ersatzkasse, Krankenkasse Eintracht Heusenstamm, and Buchdrucker Krankenkasse.

The authors have no relevant financial interest in this article.

Corresponding author: Dieter Melchart, MD, Centre for Complementary Medicine Research, Department Internal Medicine II, Technische Universität München, Kaiserstr 9, D-80801 München, Germany (e-mail: Dieter.Melchart@lrz.tu-muenchen.de).

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