

Is acupuncture safe?: evidence from Germany

Klaus Linde

Centre for Complementary Medicine Research, Department of Internal Medicine II, Technical University Munich, Germany

Background: Since 2001 data on safety have been collected prospectively in three major reimbursement and research projects sponsored by German statutory sickness funds. The author was involved in one of these three projects and reports on the findings.

Methods: Between July 2001 and June 2003 basic data on characteristics, treatments, outcomes and side effects of all 503.397 patients with chronic pain treated with acupuncture by one 9.918 accredited physicians were documented on a one-page form. This documentation was mandatory for reimbursement and filled in by the treating physicians. After completion of the treatment cycle physicians had to document whether a side effect occurred or not. In case a side effect had occurred the severity had to be rated and the type of side effect had to be reported. Answer options (based on previous surveys) were bleeding, needling pain, haematoma, infection, cardiovascular problems, forgotten needles and other (with a free text describing the side effect). Severe adverse events in which a causal relationship seemed possible to the physician had to report on a separate more detailed form. In addition, a sample of 6.140 patients were asked about side effects within a more detailed questionnaire.

Results: On average, patients received 8.4 acupuncture sessions, thus the total number of acupuncture sessions covered by the study exceeds 4 million. Physicians reported side effects in 7.8% of the patients. Needling pain was reported in 3.95% of patients, a hematoma in 3.3%, bleeding in 1.6%, cardiovascular problems in 0.4%, forgotten needles in 0.3% and other side effects in 0.6%. The number of side effects reported varied strongly between physicians with many reporting none and a limited number reporting side effects in a relevant proportion of patients. This suggests that physician varied strongly in what they considered a side effect. In the questionnaire given to the sample of 6.140 patients 9.3% reported that they had experienced a side effect. Of these 10.4% reported that side effects were not bothersome at all, 65.1% that they were slightly bothersome, and 14.5 that they were truly bothersome. The most frequently reported side effects were fatigue (116 cases), headache (57), pain in general (57), and dizziness (45). A total of 13 severe adverse effects were reported to the coordinating study centre (6 cardiovascular problems such as fainting, 3 pneumothoraces, 2 skin infections, 1 severe asthma attack, 1 deterioration of depression).

Conclusions: The findings of this large study confirm findings from other studies that acupuncture is a safe therapy and that severe adverse effects are rare events. Patients and physicians tend to consider different events as side effects.