

# Prospective Studies of the Safety of Acupuncture: A Systematic Review

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**PURPOSE:** The objective of this review was to determine the incidence of adverse events associated with acupuncture.

**SUBJECTS AND METHODS:** A search for prospective surveys of the safety of acupuncture was conducted using computerized databases (Medline, Embase, the Cochrane Library, and CISCOM), inquiries to acupuncture organizations, and our own files. Data on sample, size, types of patients duration of study, types of acupuncture, definition of adverse events, method of evaluation, and findings were extracted systematically from the retrieved reports.

**RESULTS:** Nine surveys were located and included in the review. Their results were not uniform. The most common ad-

verse events were needle pain (1% to 45%) from treatments, tiredness (2% to 41%), and bleeding (0.03% to 38%). Feelings of faintness and syncope were uncommon, with an incidence of 0% to 0.3%. Feelings of relaxation were reported by as many as 86% of patients. Pneumothorax was rare, occurring only twice in nearly a quarter of a million treatments.

**CONCLUSIONS:** Although the incidence of minor adverse events associated with acupuncture may be considerable, serious adverse events are rare. Those responsible for establishing competence in acupuncture should consider how to reduce these risks. *Am J Med.* 2001;110:481–485. ©2001 by Excerpta Medica, Inc.

Acupuncture is among the most popular of all complementary or alternative therapies (1). Several systematic reviews have shown that acupuncture is efficacious in some conditions, such as nausea and vomiting, although not in others, such as smoking cessation and weight reduction (2). Knowledge about the safety of acupuncture, however, is largely based on anecdotal evidence, such as case reports of adverse effects (3). While such reports are important, they cannot provide information on the incidence of these events, which requires prospective studies. The aim of this systematic review was to summarize the results of such investigations to estimate the incidence of adverse events associated with acupuncture.

## METHODS

The following databases were searched: Medline, Embase, the Cochrane Library, and CISCOM (from their inception to July 1999). The search terms used were acupuncture, electroacupuncture, acupressure, moxibustion, adverse effects, side effects, and complications. We also wrote to 10 leading professional acupuncture organizations and invited them to contribute further material. Finally, we searched our own files. The bibliographies of all articles were scanned for further reports.

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There were no restrictions by language of publication. All prospective investigations of the safety of acupuncture or related techniques were selected for inclusion by agreement of the authors. Both authors read all articles and extracted and assessed the validity of data independently, according to predefined criteria (see Table column headings).

## RESULTS

Nine investigations (Table), described in 10 reports, were included in this review (4–13). Five originated in Europe (4,6–9,13) and four in the Far East (5,10–12). The setting was primary care in one study (13) and a clinical trial for another (6); the remainder involved specialized acupuncture clinics. Most reports relied on records of practitioners. For one center in Germany (7) and one in Japan (10), initial studies were repeated with a more refined method that involved detailed questioning of patients (9,12). A similar method was used to collect data in the clinical trial (6). The qualifications of the acupuncturists were not clearly stated in two reports (4,5). Two European studies involved western-trained doctors (6,13); of these, one also included nonmedically qualified practitioners (13). The remaining studies all involved acupuncturists trained in China or Japan who had no western medical qualifications.

### *Adverse Events*

Pain at the site of needling was reported by List and Helkimo (6) in 45% of patients. Yamashita et al (12) noted pain on insertion for 13% of treatments, which persisted after treatment for 2.3%. Melchart et al observed needle pain in 0.2% of patients in their first (7,8) and in 4.2% in their second (9) investigation, and Ernst et al (13) found

**Table.** Prospective Studies of the Safety of Acupuncture

First Author (Year)	Sample Studied (Period)	Type(s) of Acupuncture	Definition of Adverse Event and Method of Evaluation	Most Commonly Reported Events (% of Consultations Unless Stated)
Umlauf (1988)	All 14,340 patients treated in a hospital acupuncture clinic in Czechoslovakia (10 years): 139,988 treatments	Needle acupuncture (99%), electroacupuncture (38%), cupping (38%), moxibustion (4%), laser acupuncture (0.5%), indwelling needles (1.5%)	Not stated; recorded by acupuncturists	“Pre-collapse faintness” 7% Vasovagal collapse 0.3% Hematoma 1.6% Pneumothorax 0.0014% Needle fracture requiring surgical removal 0.0014%
Chen (1990)	All patients treated in a veteran’s hospital acupuncture clinic in Taipei (8 months): 28,285 treatments	Needle acupuncture, electroacupuncture (100%)	Only fainting episodes that were recorded by acupuncturists	Fainting 0.19%
List (1992)	29 subjects included in a therapeutic trial in Swedish dental institute: (not stated) about 174 treatments	Needle acupuncture	Standardized patient questionnaire, listing 18 symptoms and “other”	(% of patients) Relaxation 86% Aggravation of pain 59% Pain after needling 45% Abnormal tiredness 41% Hematoma 38% Dizziness 38%
Melchart (1995/6)	1,507 consecutive inpatients receiving acupuncture in Chinese medicine hospital in Germany: (5 months)	Needle acupuncture	Routine inquiry by orthodox physician on discharge	(% of patients) Pain 0.2% Tension and dizziness, skin eruptions/edema, cyanosis with breathlessness, and nausea, all 0.001%
Melchart (1998)	121 consecutive inpatients receiving acupuncture in Chinese medicine hospital in Germany (6 weeks): about 1,200 treatments	Needle acupuncture	Standardized patient questionnaire, listing 14 specified symptoms and “other”	(% of patients: 28% experienced at least one adverse event) Needle pain 4.2% Fatigue or exhaustion 2.3% Aggravation of symptoms 1.8% Hematoma 0.33% Faintness or dizziness 0.25% Nausea 0.25%
Yamashita (1999)	All patients seen in a training clinic in Japan (6 years): 65,482 treatments*	Japanese needle acupuncture with or without electric stimulation, moxibustion, press- needles	Any unfavorable medical event during or after treatment regardless of causation, recorded by acupuncturists	Total of 94 adverse effects, all minor (0.14%) Failure to remove needle 0.04% Ecchymosis or bleeding 0.03% Faintness or dizziness 0.02% Burn injuries (moxibustion) 0.01% Nausea or vomiting 0.01%

*(continued)*

Table.—Continued

First Author (Year)	Sample Studied (Period)	Type(s) of Acupuncture	Definition of Adverse Event and Method of Evaluation	Most Commonly Reported Events (% of Consultations Unless Stated)
Yong (1999)	All 1,128 patients treated in a hospital research acupuncture clinic in Singapore (15 months): 12,172 treatments	Mostly needle acupuncture, some moxibustion and cupping	Not stated; recorded by acupuncturists	'Near syncope' 0.02% "Local complications . . . not observed"
Yamashita (2000)	All 391 patients seen in a training clinic in Japan (1 month): 1,441 treatments <sup>†</sup>	Japanese needle acupuncture (99%), electroacupuncture (30%), moxibustion (2%), press-needles (1%)	Standardized patient questionnaire and open question, plus observation by acupuncturists	Local: bleeding 38% Needle insertion pain 13% Petechiae, ecchymosis or hematoma 7.6% Tiredness 3.3% Pain after treatment 2.3%
Ernst (2000)	409 acupuncture patients of German acupuncturists (12 months): 3,535 treatments <sup>‡</sup>	Needle acupuncture	Standardized questionnaire for acupuncturists, listing 9 specified symptoms and "other"	Slight bleeding 2.9% Hematoma 2.2% Dizziness 1% Fainting 0.14% Other vegetative symptoms 2.7% Pain on needling 0.9% Nausea 0.2%

\* Therapists consisted of 13 experienced teachers and 73 recently qualified interns

† Therapists consisted of 3 teachers, one assistant and three interns

‡ Therapists consisted of 13 general medical practitioners and 16 non-medically qualified acupuncturists

pain on needling in 0.9% of treatments. Pain due to aggravation of the presenting complaint was reported in 59% of patients by List and Helkimo (6) and in 3% by Yamashita (12).

Tiredness was reported by 41% of patients in the List study (6) and by 8.2% of patients in the study by Yamashita et al (12). Melchart et al (9) noted fatigue or exhaustion in 2.3% of their patients.

Bleeding was reported in different ways. Yamashita et al (12) reported bleeding in 38% of treatments in their second survey, and petechia, ecchymosis, or hematoma in 7.6%. A total of 38% of patients noted hematomas in the study by List and Helkimo (6), and Ernst et al (13) observed hematomas or slight bleeding in 5.1% of treatments. Hematomas occurred in 1.6% of treatments in the Czech study (4), whereas Melchart and colleagues (9) found this problem in 0.33% of their patients. Yamashita et al (10) noted ecchymosis or bleeding in 0.03% of all treatments in their first study.

Feelings of faintness were reported by Umlauf (4) in 7% of patients treated in a sitting position. Syncope occurred in 0.28% of patients. Melchart et al (9) reported faintness or dizziness in 0.25% of patients. Chen et al (5) reported syncope in 0.19% of consultations. Three patients fainted twice, and fainting was more likely after the

first treatment than after subsequent treatments. Ernst and colleagues (13) observed fainting in 0.14% of their patients and other vegetative symptoms in 2.7%. Yamashita et al (10) observed faintness or dizziness in 0.02% of treatments with Japanese (shallow) acupuncture. Yong et al (11) reported faintness with "near syncope" in 0.02% of consultations with acupuncture in a Singapore outpatient clinic.

Nausea was noted in 7 (0.2%) of treatments by Ernst and colleagues (13) whereas Yamashita et al (10) observed nausea or vomiting in 0.01% of treatments. Nausea was mentioned as an adverse effect in the first study of Melchart et al (7,8) but the incidence was not stated.

Other minor adverse effects (Table 1) included unusual feelings of relaxation in 86% of patients (6), and tension, skin eruptions or edema, cyanosis with breathlessness (9), and dizziness (13). Reported practitioner error included 27 episodes in which the acupuncturist failed to remove a needle (0.09%) (10).

Potentially serious adverse effects were observed in two studies. Umlauf et al (4) reported 2 cases of pneumothorax and 2 cases of needle fracture requiring surgical removal of the fragment (incidence of 0.001% for both). Yamashita and colleagues (10) reported 1 case of burn injury after moxibustion (0.01%). In none of the studies

were there any reported cases of infectious complications or transmission of disease through needling.

## DISCUSSION

Considering the remarkable popularity of acupuncture and its invasive nature, the paucity of prospective investigations of its safety is disappointing. We located only nine studies, although they included nearly a quarter of a million treatments. Minor complications may be more common than previously appreciated: 38% of all patients experienced some bleeding (12), 28% reported an adverse event on at least one occasion (9), and 45% reported an aggravation of pain (6). Serious events are much more rare. Pneumothorax, for example, occurred only twice. Infections, another life-threatening complication (3), were not reported. This suggests that serious adverse consequences of acupuncture are rare, confirming the tentative appraisal in a systematic review of case reports of life-threatening adverse events (3). The surveys in the present review, however, were mostly conducted in hospitals or teaching clinics, at which the standards of training and supervision are likely to be higher than average.

Unfortunately, this evidence is not conclusive. There was no uniform definition of adverse events for all studies. Moreover, a degree of underreporting is likely. This is suspected and commented on by one author (9), and appears likely in the case of Yong (11), who reported no local complications in more than 12,000 treatments. Few studies commented on loss to follow-up; thus long-term complications, such as nerve injury or hepatitis, may have been underestimated.

The incidence of adverse events varied substantially among studies. There may be three sources of this variation. First, the methodology for defining, identifying, and reporting data differed among studies. Direct questioning of patients is likely to produce a higher incidence than spontaneous reporting by practitioners. Three studies did not state the method that they used to ascertain adverse events (4,9,11). Second, the style of acupuncture differs between cultures. Chinese-style acupuncturists tend to insert needles deeply into muscle and to stimulate them manually. This method appears to have been the predominant one in the studies included in this review. Two surveys (10,11) involved Japanese-style acupuncture, in which needles are usually inserted only into subcutaneous tissues and are not stimulated. The risk of direct trauma as well as systemic reactions may be less with this style of treatment. Third, the incidence of adverse events may vary according to the part of the body being treated, which may explain the particularly high incidence of adverse events in the study of craniomandibular disorders that involved treatment to the face and head (6).

There have also been two retrospective surveys of the

incidence of adverse events (14,15). Norheim and Fonnebo (14) estimated that a pneumothorax could be expected to occur once in every 120 years of full-time acupuncture practice. Based on the rate of pneumothorax in another study (15), we estimate that a pneumothorax would be expected to occur once in every 41 years of full-time practice. The two retrospective studies also considered the indirect adverse events of treatment by practitioners who are not trained in orthodox medicine, particularly failure to detect underlying pathology or recommend conventional treatment of known effectiveness. In the Norwegian survey (14), doctors reported 10 cases of delayed doctor contact.

Adverse events can be categorized as avoidable or not. Several adverse events are likely to be unavoidable, including hematoma, nausea and vomiting, and aggravation of symptoms. Others adverse events, including pneumothorax and moxa burns, fainting of a patient treated while seated, and failure to remove a needle, are clearly avoidable. Our results constitute a challenge to the acupuncture field to improve standards of training and practice.

According to the principle of informed consent, patients who are considering receiving acupuncture must be given accurate information about the possibility of adverse events. Our results confirm that the true incidence of serious complications is low (3). Minor events should not be ignored, however, as they may lead to serious complications. For example, hematomas may become infected, and drowsiness may lead to road accidents.

Further research should confirm that both serious and minor adverse events are rare in clinical practice in different settings and determine how rates of adverse events relate to standards of training. We recommend that the methodology for such studies be standardized, perhaps using symptom checklists (6,9).

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