

Systematic review of adverse events following acupuncture: the Japanese literature

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SUMMARY. Context: Many Japanese cases of adverse events after acupuncture are not listed in medical databases such as Medline. Therefore, they are not easily accessible to researchers outside Japan. Objective: To complement existing reviews of adverse events after acupuncture in the West and to provide more detailed discussion and analysis. Data sources: Literature search using 'Igakyo Chuo Zasshi (Japania Centra Revuo Medicina) CD-ROM version' covering the period of 1987-1999. Study selection: Case reports of adverse events, which were suspected to be due to acupuncture treatment, were included. Experimental studies, surveys, and news articles were excluded. Data extraction: Two independent reviewers extracted data from located articles in a pre-defined structured way, and assessed likelihood of causality in each individual case. Data synthesis: 89 articles which reported 124 cases were located. The most frequent adverse events were: pneumothorax (25 cases), spinal cord injury (18 cases), acute hepatitis B (11 cases), and localized argyria (10 cases). There were two fatalities from infections. Forty-eight events were caused by needle breakage including 26 cases of intentionally embedded needle and 16 cases of accidental breakage. There were also 10 cases of injury from self-treatment. Conclusion: Although it has already been demonstrated that severe adverse events seem to be uncommon in standard practice, many serious cases of negligence have been found in the present review, suggesting that training system for acupuncturists (including medical doctors) should be improved and that unsupervised self-treatment should be discouraged. © 2001 Harcourt Publishers Ltd

INTRODUCTION

In recent years adverse effects of acupuncture have been discussed more intensively than ever before.¹⁻³ The basis for this discussion has originated mainly from two sources: the review of case reports of adverse events⁴⁻⁶ and the determination of their frequency.⁷⁻¹⁰ In the reviews of case reports, literature searches are performed using medical databases such as Medline, which have a clear

dominance of publication in the English language. Many Japanese cases of adverse events after acupuncture are not listed in such databases. Therefore, they are not easily accessible to researchers outside Japan.

There are approximately 137 000 licensed acupuncturists who finished 3-year or more authorized courses in Japan.¹¹ In comparison, the estimated numbers of acupuncture practitioners are 30 000 in Germany, 20 000 in the USA, and 5600 in

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Table 1. Adverse events of acupuncture in the localized Japanese literature

Type of event	Diagnosis or symptom (Number of cases)	Likelihood of causality judged by	Comments
Organ injuries or foreign bodies (42 cases)	two reviewers (Number of cases)		
	<i>Organ injuries</i> Pneumothorax (25), arterial injury (3), cardiac tamponade (2), and renal injury (2). (Nerve injuries see below.)	Definite (12), probable (12), possible (1), and inconclusive (7).	Cardiac tamponade: 1 case of embedded needle; 1 case of an insertion from the epigastric area.
	<i>Foreign bodies in internal organs</i> Needle fragment(s) in the urinary tract (3), the retroperitoneum (2), the lung and the diaphragm (1), the liver (1), the maxilla (1), the cervical interspinous ligament (1), and the hip joint (1).	Definite (10).	
	<i>Bacterial infections</i> Abscess (6: one overlap with septicæmia), septicæmia (4), spinal infection (4: one overlap with septicæmia), erysipelas (3), streptococcal toxic shock-like syndrome (2: one fatal), pyothorax or pyohemothorax (2: one fatal), skull tuberculosis (1), and local redness (1).	Probable (17), possible (3), and inconclusive (1).	4 patients with diabetes mellitus, 2 patients aged 80 years or more, and 1 patients with lymphatic edema. In 1 case of erysipelas, the treatment method was scarification.
	<i>Viral infections</i> Acute hepatitis B (11).	Probable (10) and possible (1).	2 groups of patients (2 and 8) had received acupuncture in the same clinic in the same period, respectively.
Neurological problems (29 cases)	<i>Central nervous system</i> Spinal cord injury (18), subarachnoid hemorrhage (5), medullary lesion (1), epidural hematoma (1), and subdural hematoma (1).	Definite (20) and probable (6).	Spinal cord injury: time period of onset after embedding needles ranged from 'during treatment' to 17 years.
	<i>Peripheral nervous system</i> Peripheral nerve injury (3).	Definite (3)	
	<i>Pigmentation</i> Localized argyria (10) and cutaneous chromatosis (1).	Definite (11).	All cases of argyria were caused by embedded silver needles.
Dermatological problems (17 cases)	<i>Others</i> Contact dermatitis (2), nodular lesion (2), growth of tumour (1), and skin sarcoid (1).	Definite (5) and possible (1)	Skin sarcoid (silicone granuloma51: see text) was observed also in the patient's injection scars.
Other problems (4 cases)	Subcutaneous bleeding (2), syncope (1), and burn injury (1).	Definite (3) and probable (1).	Burn injury was caused by burning moxa on the handle of the needle.

the UK.^{12,13} Thus, more acupuncture treatments are being performed, and more adverse events may be occurring in Japan than in most other countries. Although the Japanese-style acupuncture differs somewhat from Western or Chinese-style,¹⁴ reviewing case reports published in the Japanese literature might help to understand better the adverse events after acupuncture. The present review is aimed at systematically evaluating case reports of adverse events of acupuncture in the Japanese medical literature.

METHODS

Data sources

We searched for the relevant literature using 'Igaku Chuo Zasshi (Japana Centra Revuo Medicina) CD-ROM version' in the period of 1987–1999. This database contains approximately 3 million articles from 2357 medical journals issued in Japan.¹⁵ We did not perform cross-referencing or scanning the references of located articles because they referred to many essay-like unauthorized reports, which might render our inclusion criteria vague.

Study selection

We used the Japanese keywords 'Hari', 'Hari-Chiryō' and 'Shinkyū', which mean acupuncture or acupuncture needle. Case reports of adverse events, which were suspected to be due to acupuncture treatment, were subsequently selected by title. We defined adverse event as an unfavourable medical event which occurred during or after the treatment regardless of causal relationships. Our definition is in accord with the definition in the clinical evaluation of drugs.^{16,53} Only case reports of adverse events were included. Experimental studies, surveys, and news articles were excluded. If a full text paper and a conference abstract reporting the same case existed, the abstract was excluded.

Data extraction

Data from all articles thus located were extracted in a pre-defined, structured way by the first two authors independently. The likelihood of causality between the event and acupuncture was assessed in each individual case. The causality assessment was based on the following four criteria: 1) Time period until the onset of symptom, 2) Locational correspondence between the needled region and the affected region, 3) Presence of needle fragment, and 4) Condition treated by acupuncture. The likelihood was classified as 'definite', 'probable', 'possible', 'doubtful' and 'inconclusive'. Disagreements between the reviewers were settled by discussion and a consensus could be reached in all cases.

In order to find how many articles or cases are listed in Medline, we used PubMed on the Internet

and searched duplicate cases, using MeSH Terms ('acupuncture/adverse effects') and author name, event ('pneumothorax' for example) and journal title of each located case report.

RESULTS

Data synthesis

Eighty-nine articles (56 full papers and 33 conference abstracts) reporting 124 cases of adverse events were located. Eighty-six articles were from journals in orthodox medicine and three articles were from journals in oriental medicine. Nineteen of these articles^{17–35} (five of which were parallel publications) were also listed in PubMed. In other words, 70 articles which reported 105 cases were not listed in PubMed.

In all cases, the affiliations of the first authors were medical facilities such as medical schools, hospitals, research institutes or private clinics, suggesting that the authors were medical doctors. Patients in the reported cases were 55 males and 68 females (one unknown). Their age ranged from 14 to 85 and peaked around the age of 50. Most of the practitioners, involved in the adverse events, were suggested to be licensed acupuncturists from the context of each article, with the exception that five medical doctors were also involved.

The reported adverse events were classified into five categories: injuries or foreign bodies in internal organs (42 cases), infections (32 cases), neurological problems (29 cases), dermatological problems (17 cases), and other problems (four cases) (Table 1).

The most frequent adverse event was pneumothorax. Of the 25 cases, 11 occurred during or immediately after needling. One case was accompanied by cardiac arrest. In a case of a 33-year-old female,³⁶ the patient began to cough when the acupuncture needle was inserted in the scapular region. The acupuncturist told her 'It may be pneumothorax, but you will recover within 3 days' and sent her home. About 6 hour later, she became dyspneic and was admitted to a hospital. After drainage of the pleural cavity and conservative management she was discharged about 2 weeks later.

The second most frequent adverse event was spinal cord injury. Of the 18 cases, 10 were caused by accidental needle breakage, six were caused by intentional needle breakage (embedded needle), and in two cases there was no description whether the breakage was intentional or accidental. In one case, several hundreds of acupuncture needles were intentionally broken and permanently embedded in the patient's body during 3 years of treatment.²⁰

The third most frequent adverse event was acute hepatitis B. Eleven cases were reported in three articles. Two groups of patients (two and eight, respectively) had received acupuncture in the same clinic during the same period.^{17,38}

Table 2. Adverse events caused by needle breakage.

Events	Number of the cases of embedded needles (Intentional breakage)	Number of the cases of accidental breakage of needles	Uncertain whether intentional or accidental	Total
Spinal cord injury	6	10 (6*)	2	18
Foreign bodies in organs	2	4 (2*)	4	10
Localised argyria	10			10
Peripheral nerve injury	1	2		3
Arterial injury	2			2
Cardiac tamponade	1			1
Cutaneous chromatosis	1			1
Medullary lesion	1			1
Pneumothorax	1			1
Subarachnoid hemorrhage	1			1
Total	26	16	6	48

* Number of the cases of self-treatment.

The fourth most frequent diagnosis was localized argyria caused by embedded silver needles. In all 10 cases, granules consisting mainly of silver were observed by X-ray microanalysis.

There were two fatalities after infections associated with acupuncture. One was a case of a 41-year-old male who suffered from streptococcal toxic shock-like syndrome.²⁵ The authors of this report presumed the infection to be 'probably caused by acupuncture' mainly based on the history of the patient. The other fatality was seen as a postmortem case only. The 59-year-old female was found to have a phlegmon around the right side of the 7th cervical vertebra, and a right pyohemothorax, from which *Streptococcus agalactiae* and *Pseudomonas fluorescens* were identified.³⁹ The authors of the report considered that the infection was probably due to acupuncture with incompletely disinfected needles because the patient had been receiving acupuncture for the last 1 month as a treatment of the right neck/shoulder stiffness. Of the 21 cases of infection, four patients were diabetic, two patients were aged 80 years or older, and one patient was suffering from lymphatic oedema after mastectomy.

Forty-eight adverse events were caused by needle breakage. Twenty-six of these cases were caused by embedded needles, 16 by accidental needle breakage, and in six cases no details were described (Table 2). Of the 16 cases of accidental needle breakage, eight occurred during or after self-treatment. There were also two cases of self-treatment which resulted in subarachnoid haemorrhage and myelitis. In only one case of self-treatment, which caused spinal cord injury, the patient was a licensed acupuncturist.

The number of cases of embedded needles peaked in 1990 (seven cases), and that of accidental needle breakage peaked in 1991 (three cases). Few articles described when embedded needles were inserted, but at least nine cases were performed after 1976, when an acupuncturists' society in Japan recommended that the embedding needle method should no longer be applied.

Most of the infection cases (27 out of 32 cases, including two fatalities) were judged to be 'probable'

in our causality assessment. In most of the cases of neurological problems (23 out of 29 cases), dermatological problems (16 cases out of 17 cases), and all cases of foreign bodies in internal organs (10 cases), causality was judged to be 'definite' because of the existence of needle fragments.

DISCUSSION

Six articles reporting Japanese cases of adverse events could be retrieved by PubMed searches within the reporting period of our study (1987–1999). These were not located by our search strategy because they were written in English and published in countries other than Japan. Those articles reported six cases: the death of an asthmatic which might have been associated with emotional stress of the first-time acupuncture treatment,⁴⁰ spinal cord injury,⁴¹ delayed cardiac tamponade and hemothorax caused by self-treatment,⁴² pseudoaneurysm,⁴³ needle in the paraspinous muscle,⁴⁴ and retroperitoneal hematoma due to rupture of a pseudoaneurysm.⁴⁵

If we combine the six cases found through PubMed with the present results, we find that at least 130 significant adverse events including three fatalities were associated with acupuncture treatment during the past 13 years in Japan. In order to understand the characteristics of adverse events of acupuncture in Japan, it is useful to compare the present results with those of Norheim.⁵ He classified the adverse events of acupuncture by their country of origin. According to these findings, the total number of the events reported in Europe and America during 1981–1994 is 162. Compared with Norheim's data, the frequency of pneumothorax reported here is similar (25 vs 22). The transmission of viral hepatitis seems to be less frequent in Japan (11 vs 100). Although bacterial infections have been reported with similar frequency (21 vs 21), chondritis caused by auricular acupuncture accounted for two-thirds of cases in Europe and America (14 of the 21 cases). No adverse event related to auricular acupuncture has been reported perhaps because a

needle used for auricular acupuncture in Japan is substantially smaller and shorter than needles used in the West. If we exclude auricular chondritis, bacterial infection has been reported more often in Japan (21 vs 7).

The most distinct characteristic of adverse events of acupuncture in Japan is the frequency of cases caused by 'Umebari' or 'Maibotsu-Shin', which means embedding needles by intentional needle breakage (also termed implanted needles, indwelling needles or retained needles; the word 'Okibari', which actually means needle retention for only 10–20 minutes, is wrongly used in some articles). With this method, a silver or gold needle is inserted, and the exposed part is cut off. The needle fragment left in the body is subsequently pressed further and retained permanently. The number of needles embedded varies by therapist between several and hundreds. This technique is used for almost every part of the body. The embedded needles twist and migrate to other parts of the body propelled by repeated muscle contraction.^{46–48} Eventually some needles may cause organ injuries and localized argyria. Finding countless needle fragments with X-ray photographs⁴⁹ is not a very rare event in Japanese patients of more than 50 years of age.

Adverse events as a result of self-treatment seem relatively frequent in Japan. People who treat themselves with acupuncture may not be satisfied with the magnitude of stimulation by acupuncturists they have consulted, and they may wish to receive stronger needle stimulation. They may also feel it wasteful to receive acupuncture, for example, only for occipital pain in acupuncture clinic. Pharmacies or other stores usually do not have acupuncture needles for sale, but people can easily obtain them by directly contacting distributors. The important point, we believe, is the people's attitude: they may think that acupuncture does not require much medical knowledge. To reduce the frequency of adverse events of acupuncture by self-treatment, the Japanese public might require educating.

Some of the adverse events, particularly bacterial infection, may not be causally related to acupuncture treatment. A fatal case of bacteremia after acupuncture, in which an autopsy suggested opportunistic infection from chronic otitis media, has been reported.⁵⁰ In some cases, acupuncture may have been employed to improve the symptom of infection – thus the infection would be the cause rather than the result of acupuncture. Nevertheless, two independent reviewers judged 17 cases (81%) of bacterial infections as 'probable' in terms of causality. These reviewers had practiced acupuncture for more than 10 years and were aware of many problems with the safety of acupuncture in Japan, which include poor hygienic condition of some acupuncture clinics, poor aseptic procedure for needle insertion, and poor medical knowledge about infectious disease in some acupuncturists.

Adverse events of acupuncture can be classified

into those seen in spite of good clinical practice, and others where therapists' negligence is an important element. Some adverse reactions are inevitable in standard practice. In pharmacotherapy, adverse drug reactions are clearly distinguishable from negligence. If we evaluate the present results under this aspect, we find only eight cases of adverse reaction: two cases of contact dermatitis, two cases of nodular lesion, two cases of subcutaneous bleeding, one case of skin sarcoid (this case has recently been published as 'silicone granuloma'⁵¹ after we finished our review), and one case of syncope. As for the case of tumour growth, we tentatively categorise it as negligence because skin tumours should not be needed. Excluding the eight cases of adverse reaction and 10 cases of self-treatment, 106 reported cases (85%) can (and perhaps should) be classified as negligence, ignorance, or malpractice of the therapists.

None of the cases included in this systematic review was reported by an acupuncturist. In our experience, Japanese acupuncturists rarely access the medical journals which carried the articles located in the present study. It is therefore likely that most acupuncturists in Japan do not know what kind of adverse events have occurred after their treatments. This may be one of the reasons why similar cases of negligence have been reported repeatedly. An effective feedback system on adverse events of acupuncture is lacking in Japan. The Committee for Safety of Acupuncture established by the Japan Society of Acupuncture and Moxibustion (JSAM) has recently launched a review of relevant cases and is planning to inform its membership about potential adverse events.

We have previously demonstrated that severe adverse events seem to be uncommon in standard practice performed by adequately trained Japanese acupuncturists.^{52,53} Nevertheless, many cases of negligence, such as pneumothorax or spinal cord injury, have been found in the present review. We therefore suspect that many acupuncturists would benefit from more adequate training such as internship after acquisition of the license. We also emphasize that unsupervised self-treatment should be discouraged. In the interest of the patients, these should be the challenge for Japanese acupuncture, and perhaps acupuncture also in other countries, in the years to come.

(A full list of articles and the results of reviewing are available by contacting the first author.)

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