Review

Safety of Acupuncture Practice in Japan: Patient Reactions, Therapist Negligence and Error Reduction Strategies

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Evidence-based approach on the safety of acupuncture had been lagging behind both in the West and the East, but reliable data based on some prospective surveys were published after the late 1990s. In the present article, we, focusing on 'Japanese acupuncture', review relevant case reports and prospective surveys on adverse events in Japan, assess the safety of acupuncture practice in this country, and suggest a strategy for reducing the therapists' error. Based on the prospective surveys, it seems reasonable to suppose that serious adverse events are rare in standard practice by adequately trained acupuncturists, regardless of countries or modes of practice. Almost all of adverse reactions commonly seen in acupuncture practice—such as fatigue, drowsiness, aggravation, minor bleeding, pain on insertion and subcutaneous hemorrhage—are mild and transient, although we should be cautious of secondary injury following drowsiness and needle fainting. After demonstrating that acupuncture is inherently safe, we have been focusing on how to reduce the risk of negligence in Japan, as well as educating acupuncturists more about safe depth of insertion and infection control. Incident reporting and feedback system is a useful strategy for reducing therapist errors such as forgotten needles. For the benefit of acupuncture patients in Japan, it is important to establish mandatory postgraduate clinical training and continued education system.

Keywords: adverse event-adverse reaction-forgotten needle-incident reporting-needle fainting

Introduction

Acupuncture is one of the most popular complementary and alternative therapies in developed countries. In the West, the percentages of people who have received acupuncture treatment range from 4% in the US (1) to 21% in France (2). Percentages of people who had received the treatment in the past 12 months were 2.0% in Australia (1992) (3), 1.6% in the UK (2001) (4) and 1.1% in the US (2001) (1). Based on our recent nationwide survey in 2005, acupuncture enjoys greater

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popularity in Japan with 32% of the population using acupuncture at some time during their lives, and 6.1% during a 1-year period (data being prepared for publication). In addition, data estimated from the Public Health Administration and Services reported approximately 54000 practicing licensed acupuncturists in Japan (5).

On the other hand, the number of randomized controlled trials (RCT) is higher in the West. For example, approximately 600 RCT papers on acupuncture are listed in PubMed as of the year 2006 (Keyword: acupuncture or electroacupuncture; Field: title; Limits: randomized controlled trial). Of these, the number of RCT papers from Japan is only 10 showing that Western countries are more active in producing and publishing 'evidence-based' clinical research on the efficacy of acupuncture (6,7).

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Table 1. Published cases of acupuncture adverse events in Japan (16,17)

| Туре | Diagnosis or symptom (Number of cases in parentheses) | Comments | | |
|----------------------------------|--|---|--|--|
| Organ injuries or foreign bodies | Organ injuries Pneumothorax (26), arterial injury (3), cardiac tamponade (3), renal injury (2) and pseudoaneurysm (1) | Many of the cases were caused by accidental needle breakage or prohibited embedding needles | | |
| | Foreign bodies Needle fragment(s) in the urinary tract (3), retroperitoneum (2), paravertebral muscle (2), ventricle (1), lung and diaphragm (1), liver (1), maxilla (1), cervical interspinous ligament (1), hip joint (1), abdominal aortic aneurysm (1) and nucha (1) | | | |
| Infection | Bacterial infections Abscess (6), septicaemia (6), spinal infection (4), erysipelas (3), streptococcal toxic shock-like syndrome (2: one fatal), pyothorax or pyohemothorax (2: one fatal), skull tuberculosis (1), infected atrial myxoma (1) and local redness (1) | Causal relationship with acupuncture and infection is not established | | |
| | Viral infections Acute hepatitis B (12) | | | |
| Neurological problems | Central nervous system Spinal cord injury (18), subarachnoid hemorrhage (5), subdural hematoma (1), epidural hematoma (1), and medullary lesion (1) | Many of the cases were caused by embedding needles | | |
| | Peripheral nerves Peripheral nerve injury (3) | | | |
| Dermatological problems | Pigmentation Localized argyria (15) and cutaneous chromatosis (1). | Localized argyria was caused by embedding silver needles | | |
| | Others Contact dermatitis (4), lichen planus (2), nodular lesion (2), growth of tumor (1) and skin sarcoid (1) | | | |
| Other problems | Subcutaneous bleeding (2) syncope (1) and asthmatic death (which might have been associated with emotional stress of the first-time acupuncture treatment) (1: fatal) | | | |

An evidence-based approach to acupuncture safety, however, has been slow to appear in both the West and the East. Without well-designed surveys on adverse events, acupuncture safety was only discussed based on retrospective and anecdotal case reports until the late 1990s. After that time, some prospective surveys on acupuncture safety were conducted and published (8-13). Another problem was that the researchers paid little attention to the difference between Japanese-style (14) and traditional Chinese-style acupuncture (15). Although Japanese acupuncturists have a wide variety of methods of diagnosis and treatment, they basically use thinner needles (usually 0.16-0.2 mm in diameter) with a guide tube and do not necessarily seek Degi (or Teh-Chi) sensation (specific needle sensation). Until recently, these differences made it difficult to understand whether the risks of acupuncture were homogenous for each country or not.

Focusing on 'Japanese acupuncture', we review relevant case reports and prospective surveys on adverse events in Japan, assess the safety of acupuncture practice in this country, and suggest specific methods to reduce risks.

Published Case Reports on Adverse Events in Japanese Acupuncture Practice

Literature Review

Between the 1980s and 2002, approximately 120 published articles reported 150 adverse events in acupuncture practice in Japan (Table 1) (16,17). Adverse event is defined as an unfavorable medical event that occurs during or after the treatment *regardless of causal relationship* (18). The most reported adverse event is pneumothorax. Various types of infections including two fatalities have been reported, but the causal relationship is unclear in most of these cases. Ten cases of injury were from self-treatment (16).

One of the most characteristic adverse events in Japan is embedded needles due to intentional needle breakage. With this method, a silver or gold needle is inserted, and the exposed part is cut off. Then the needle fragment left in the body is pressed further and retained permanently. Subsequently some needles cause organ injuries and localized argyria. In patients of more than 60 years of

age, it was not a very rare event in some areas of Japan to find countless needle fragments with X-ray photographs (19). In 1976, Japan Acupuncture & Moxibustion Association recommended that the embedding needle method be curtailed with a consequent decrease in this practice.

The frequency of reports of pneumothorax is similar in the West (20) and Japan. While the transmission of viral hepatitis is reported less frequently in Japan, bacterial infections have similar frequency, and chondritis caused by auricular acupuncture is reported more often in the West, perhaps because the needle used for auricular acupuncture is substantially smaller and shorter (1.3 mm long and 0.22 mm in diameter) in Japan.

Limitation of Case Reports

As suggested earlier, assessing the safety of acupuncture based on published case reports pose some problems. First, there is a publication bias. Since only papers of serious cases or rare adverse events are submitted and published by medical doctors, the frequency and severity of adverse events seen daily by acupuncture practitioners is unknown. Second, there is also a recall bias because relevant case studies are retrospective. Since it is difficult to describe the details around an adverse event, it is also difficult to assess the causal relationship between the event and acupuncture treatment. Third, we cannot assess the incidence of each adverse event because it is impossible to accurately calculate the total number of treatment sessions (i.e. denominator in calculating incidence).

Reviewing retrospective case reports does not provide enough evidence, making it important to assess the safety of acupuncture based on prospective surveys.

Prospective Surveys conducted in Japan

A Six-Year Survey on Adverse Events

From 1992 through 1998, we required all acupuncturists at the national Tsukuba College of Technology Clinic to report any adverse event occurring during acupuncture treatment (8). (Note: in 2005, the Clinic was renamed as a Center for Integrative Medicine, Tsukuba University of Technology). The acupuncturists recorded events in semi-structured case report forms immediately upon recognition.

During 6 years, a total of 84 acupuncturists participated in the study, and the total number of acupuncture treatment sessions was 65 482. (Note: we define 'acupuncture' as a combined treatment of acupuncture and moxibustion because these two therapies are inseparable in actual Japanese practice). A record of adverse events (Table 2) (8), showed no serious adverse

events such as pneumothorax or organ injuries during the survey period. Interestingly, the incidences of 'significant' adverse events, defined as 'unusual, novel, dangerous, significantly inconvenient, or requiring further information' (10), that were actually minor events were similar to those reported in other countries or schools: 14 per 10 000 treatment sessions in medical acupuncture performed mainly by physicians (10), 13 in traditional acupuncture performed mainly by traditional Chinese medicine acupuncturists (11), and 14 in Japanese acupuncture performed at our clinic (8). Although some cases may have been underreported, serious adverse events were rare in standard acupuncture practice regardless of school or mode of practice.

A Four-Month Survey on Adverse Reactions

In our prospective survey (8), less severe adverse events such as minor bleeding and fatigue after treatment went unreported if neither acupuncturist nor patient regarded them as a problem. Most of these underreported events are 'adverse reactions', often called 'side effects'; negligent cases not included, observable even in standard practice. To record type, severity and incidence of adverse reactions, we conducted another observation and interview-based survey during the 4months from April to July of 1998 at Tsukuba College of Technology Clinic (9).

Seven acupuncturists meticulously observed the punctured region and general condition of patients during and immediately after treatment. The patients were asked to report any pain or discomfort caused by needle insertion. Also at the next visit, the acupuncturists asked the patients about any feeling of discomfort after their treatment sessions. Recognized adverse reactions were recorded in a structured case report form.

The total number of treatment sessions was 1441, and the total number of needle insertions was 30 338 (an average of 21 insertions per visit). The actual number of individual patients was 391 with ages ranging from 12 to 88 years. The most frequent stimulation method was simple needle retention (13 187 insertions): needles were retained for 10–20 min after insertion, and then removed. The second most frequent method was electroacupuncture (9249 insertions), followed by manual stimulation of the needle (7668 insertions): needle tips were moved up and down approximately 10 times in the muscle, and then removed. Moxibustion was performed 642 times, and press tack needles were used a total of 234 times (9).

Our data on the frequency of adverse reactions (Table 3) included itching in the punctured regions in the category of systemic reactions because patients complained of itching at almost all punctured regions on the body. All reactions were mild and transient, and no medical care was required.

Table 2. 'Significant' adverse events recorded in prospective surveys (8,10,11)

| Туре | Licensed acupuncturists in Japan (Reference 8) (65 482 sessions in total) | Doctors and physiotherapists in the UK (Reference 10) (31 822 sessions in total) | Traditional acupuncturists in the UK (Reference 11) (34 407 sessions in total) |
|---|--|--|---|
| Autonomic, cardiovascular or gastrointestinal reactions | Discomfort (7 cases) | Fainting (6 cases) | Nausea (5 cases) |
| | Dizziness (6 cases) | Nausea (2 cases) | Fainting (4 cases) |
| | Nausea or vomiting (6 cases) | Vomiting (1 case) | Dizziness and feeling faint (1 case) |
| | | | Sweating and needle shock (1 case) |
| | | | Vomiting (1 cases) |
| Neurological, psychological, or psychiatric reactions | Malaise or fatigue (3 cases) | Drowsiness or falling asleep (3 cases) | Tired or exhausted feeling (4 cases) |
| | Numbness in the upper extremities (1 case) | Disorientation (2 cases) Lethargy (2 cases) | Emotional outburst and anger (1 case) |
| | | Anxiety and panic (2 cases) | Panic (1 case) |
| | | Headache (2 cases) | Emotional confusion (1 case) |
| | | Euphoria (1 case) | |
| | | Hyperesthesia with numbness (1 case) | Depression with anxiety (1 case) |
| | | Seizure (1 case) | Headache (1 case) |
| | | Slurred speech (1 case) | Drowsiness (1 case) |
| Allergic reactions | Itching or erythema (3 cases) | Needle allergy (2 cases) | |
| Negligence | Forgotten needles (27 cases) | Forgotten needle (5 cases) | Forgotten needles (2 cases) |
| | Burn (7 cases) | Forgotten patient (2 cases) | Moxibustion burn (1 case) |
| | | Cellulitis in the leg (1 case) | |
| | | Blister after moxibustion (1 case) | |
| Others | Subcutaneous bleeding (17 cases) Pain at punctured site (6 cases) Minor bleeding (4 cases) | Exacerbation of symptoms (5 cases) Needle site pain (3 cases) | Aggravation of symptoms (7 cases) Pain at needled site (3 cases) |
| | Aggravation of symptoms (4 cases) Fever (3 cases) | recent site pain (5 cases) | Rash (2 cases) Heavy bruising (2 cases) Unspecified (2 cases) Hematuria (1 case) Weak knee (1 case) |

Almost all of the collected data reflect reactions that occurred during a relatively short-term period. So far there are no data based on a long-term prospective survey.

Common Adverse Reactions to Acupuncture

Fatigue and Drowsiness

Some patients complained of fatigue or drowsiness (Table 4) with a higher incidence on the first visit. Although this trend is consistent with a report by Brattberg (21), the incidence in his report was extremely high (65%) compared with ours (2.8%). In Brattberg's study, all the subjects were patients at a pain clinic and *Deqi* was sought in every patient while Japanese acupuncture does not necessarily seek this specific needle sensation, showing that drowsiness after acupuncture depends on treatment style and each patient's condition.

Mengen: Transient Worsening of Condition

Japanese acupuncturists often regard transient aggravation, fatigue, drowsiness or dizziness as the 'Mengen (or Menken)' phenomenon, which is a kind of 'healing crisis'. Some acupuncture practitioners insist that these symptoms should not be included in the category of 'side effects' because transient worsening of the condition is followed by improvement in some cases. In the context of patients' safety, however, it makes little difference whether or not the Mengen phenomenon leads to healing. For example, for a patient who intends to drive home after an acupuncture treatment, we have to inform him/her that drowsiness or dizziness might cause a car accident (22).

Needle Fainting

Needle fainting, syncope or feeling faint, is probably mostly due to vasovagal reflex during or after needling.

| Systemic reactions | | Local reactions | | |
|---|---|--|---|--|
| Type of reaction | Incidence (number of patients with reaction/total number of patients) | Type of reaction | Incidence (number of insertions with reaction/total number of insertions) | |
| Fatigue | 8.2% (32/391) | Minor bleeding on withdrawal of the needle | 2.6% (781/30 338) | |
| Drowsiness | 2.8% (11/391) | Pain on insertion of the needle | 0.7% (219/30 338) | |
| Aggravation of the existing symptom | 2.8% (11/391) | Petechia or ecchymosis | 0.3% (100/30 338) | |
| Itching in the punctured regions | 1.0% (4/391) | Pain or ache in the punctured region after the treatment | 0.1% (38/30338) | |
| Dizziness or vertigo | 0.8% (3/391) | Subcutaneous hematoma | 0.1% (31/30338) | |
| Feeling of faintness or nausea during treatment | 0.8% (3/391) | Pain or discomfort in the punctured region during the needle retention | 0.03% (10/30 338) | |

Table 3. Common adverse reactions in standard Japanese-style acupuncture practice (9)

Table 4. Incidence of fatigue and drowsiness by the different number of visit (9)

| | Number of events | 1 |
|----------------------|------------------|------------|
| | Fatigue | Drowsiness |
| First visit | 10 (20.8%) | 6 (35.3%) |
| Second visit | 7 (14.6%) | 5 (29.4%) |
| Third visit | 5 (10.4%) | 5 (29.4%) |
| Fourth visit or more | 26 (54.2%) | 1 (5.9%) |
| Total | 48 (100%) | 17 (100%) |

During the period between April 2000 and June 2004, 53 events (51 patients) of needle fainting or an incidence (% of total number of 39 691 sessions) of 0.13% were observed at our clinic. This incidence is nearly the same as that of our 4-month prospective survey above (0.2%) (9) and a study in Taiwan (0.194%) (23). Loss of consciousness, between 30 s and 2 min, occurred in 3 patients, but epilepsy was diagnosed or suspected in these cases. In 27 cases (51%), fainting occurred at the first, second or third visit. Fainting occurred during needling in a sitting or standing position in 22 cases (42%), and while sitting or standing up immediately after treatment in 10 cases (19%). The patients recovered within 5 min in 22 cases (42%), and 6–60 min in 20 cases (38%).

Although most cases of needle fainting were mild and transient, this reaction may lead to secondary injury. Special care should be taken when inserting needles in a standing or sitting position or when a patient stands or sits up quickly after a treatment if the patient has little or no experience receiving acupuncture.

Minor Bleeding and Subcutaneous Bleeding

The incidence of bleeding reminds us that acupuncture has the potential hazard of blood-borne infections.

Table 5 shows different incidences of minor bleeding and subcutaneous bleeding (petechia or ecchymosis) associated with different modes of acupuncture stimulation (9). The highest incidences recorded during application of electroacupuncture are probably due to needle tip movement during an associated muscle twitch. Reasons for decreased incidence of bleeding in manual stimulation compared with needle retention were unclear in this study.

Although both acupuncturists and patients take little notice of minor subcutaneous hemorrhage in Japan, this local reaction is sometimes recognized as a problem from the cosmetic point of view. Approximately 85% of the subcutaneous bleeding reportedly disappears within 14 days and the average period for disappearance is approximately 12 days (24).

Based on the survey of adverse reactions, we calculated the incidence in each individual patient (9). The incidence of minor bleeding was <15% (with insertion) in 96% of the patients, and the highest incidence was 33.3% in one patient. The incidence of subcutaneous bleeding (petechia, ecchymosis or hematoma) was <10% in 97% of the patients, and the highest incidence was also 33.3% in one patient (25). Although we could not find any particular commonality of disease or medication in the patients with frequent bleeding, this possibility needs further investigation. Acupuncturists should advise such patients to seek further testing at a hospital.

Pain on Insertion of the Needle

In Japan, 'pain' on insertion may include *Deqi* sensation as well as a sharp, tingling or pinching pain. Some Japanese patients refer to *Deqi* as a comfortable stimulation while others express a dislike for it. The highest incidence of pain on insertion was 50.0% in one patient, but in 84% of the patients the incidence was 0% (25). The incidence of pain on needle insertion differed

Table 5. Incidence of minor bleeding and subcutaneous bleeding (petechia or ecchymosis) by modes of stimulation (9)

| Reactions | Mode of stimulation | Number of events | Total number of insertion | Incidence |
|----------------|---------------------------------|------------------|---------------------------------|-----------|
| Minor bleeding | Electroacupuncture | 312 | 9249 | 3.37% |
| | Needle retention ^a | 372 | 13 187 | 2.82% |
| | Manual stimulation ^b | 49 | 7668 | 0.64% |
| Subcutaneous | Electroacupuncture | 44 | 9249 | 0.48% |
| bleeding | Needle retention ^a | 31 | 13 187 | 0.24% |
| | Manual stimulation ^b | 21 | 7668 | 0.27% |

^aNeedle retention: needles are retained for 10-20 min after insertion, and then removed.

according to age category (Table 6) (25): Patients 10–19 years old tended to have a higher incidence while 80–89-year-olds had a lower incidence of pain. In a gender comparison (Table 7) (25), female patients complained of pain on insertion more often than male patients. Thus, younger generations and the female genders may be more sensitive to needle stimulation, although older Japanese patients might hesitate to tell their therapists if they are experiencing pain.

Common Negligence by Acupuncturist

Forgotten needles

Forgotten needles or failure to remove acupuncture needles after needle retention for 10–20 min is obviously caused by the acupuncturist's negligence. Although no sequela has occurred during our investigation, forgotten needles can lead to serious organ injury or infection. At our clinic, in spite of occasionally reminding acupuncturists to check the number of needles during removal, the frequency of forgotten needles did not decrease until we introduced the incident reporting and feedback system, indicating that this problem was probably due to lapses of memory rather than insufficient education. Details are reported subsequently.

Burns induced by Moxibustion

There are two types of moxibustion in Japan: direct and indirect. Burn injury caused by indirect moxibustion belongs to the category of negligence because acupuncturists do not intend to make burns with indirect moxibustion, such as that done with a moxa stick. Some elderly Japanese, however, especially in western Japan, prefer direct moxibustion which induces small burns. This is one of the cultural characteristics of acupuncture clients in Japan. Whether or not the small burn is recognized as therapist negligence depends on

Table 6. Different incidence of pain on insertion by age (25)

| Age | Number of patients | Pain on insertion of the needle | | |
|----------|--------------------|--|------------------------------|--|
| category | | Incidence (%) ^a in each patient (mean with ranges in parentheses) | Number of patients with pain | |
| 10–19 | 8 | 4.7 (0–22.2) | 2 (25%) | |
| 20-29 | 28 | 2.3 (0-37.5) | 4 (14%) | |
| 30-39 | 41 | 1.1 (0-13.3) | 7 (17%) | |
| 40-49 | 74 | 1.7 (0-26.7) | 13 (18%) | |
| 50-59 | 84 | 2.0 (0-50.0) | 15 (18%) | |
| 60-69 | 96 | 1.4 (0-19.2) | 13 (14%) | |
| 70-79 | 49 | 1.4 (0-13.3) | 8 (16%) | |
| 80-89 | 11 | 0.0 (0-0) | 0 (0%) | |

^aPercentage indicates how frequent the reaction occurred in each patient. For example, in patients aged 10–19 years, pain on insertion was experienced 4.7 times on average per 100 insertions in each patient.

Table 7. Different incidence of pain on insertion by gender (25)

| Gender | Number of | Pain on insertion of the needle | | |
|--------|-----------|--|------------------------------|--|
| | patients | Incidence (%) ^a in each patient (mean with ranges in parentheses) | Number of patients with pain | |
| Male | 159 | 1.1 (0–19.2) | 20 (13%) | |
| Female | 232 | 2.0 (0-50.0)* | 43 (19%) | |

^aPercentage indicates how frequent the reaction occurred in one patient on average.

whether or not the burn was a result that the patient expected (8).

Incident Reporting and Feedback System

Tackling Frequent Forgotten Needles

After repeated failure to decrease the occurrence of forgotten needles at Tsukuba College of Technology Clinic, we, inspired by the activity of risk management in the field of nursing, introduced an incident reporting and feedback system (26). This was commenced from April, 2000 after a pilot trial period of several months. We defined an 'incident' as 'any occurrence which is not consistent with the professional standards of care of the patient' (27). Also near misses—incidents which nearly occurred—were regarded as incidents and had to be reported.

Acupuncturists involved in incidents spoke in detail about the circumstances in everyday evening

^b#Manual stimulation: needle tips are moved up and down approximately 10 times in the muscle, and then removed.

^{*}P = 0.088 (unpaired t-test), compared with male patients.

staff meetings. They also filled in a semi-structured 'Incident Report Form'. We summarized these reports at monthly meetings, based on the analysis of the accumulated Incident Report Forms for the current month. Especially, we focused on 'how' the forgotten needles occurred (or nearly occurred), as well as the details of other reported incidents. Based on an idea that punishment does not prevent reoccurrence (28), we firmly maintained the 'blame-free' rule and did not discipline acupuncturists who reported the incidents.

Analysis of Incident Report Forms on Forgotten Needles

During 4 years, 87 incidents (including near misses) of forgotten needles involving 154 acupuncture needles were reported. Twenty-nine acupuncturists out of 67 who had worked for our clinic were involved in the incidents. In 14 of the 87 incidents, needles were actually left *in situ* after the treatment session within half a day. The needles in these cases were found and removed by the patients, and no further harm was reported. In 73 near misses, forgotten needles were noticed by acupuncturists or patients in the treatment booth, and removed before the treatment session finished.

Needles tended to be forgotten mainly in the lower extremities, the head or the back, where they were hidden by a towel, hair or clothes. In 34% of all incidents, the acupuncturists who removed the needles were acting on behalf of the acupuncturist who had inserted them. The incidence of forgotten needles tended to be less frequent during the period of students' vacation (July, August and March) when the acupuncturists had no teaching duties.

Incident Reporting and Feedback System Decreased Incidence

The data of reported forgotten needles were gathered for 4 years after the introduction of the incident reporting and feedback system. Our previous survey (9), in which the incidence of forgotten needles was also recorded, provides the baseline data for comparisons. The frequency of forgotten needle incidents decreased after introducing the incident reporting and feedback system, and tended to decrease year by year until FY2002. In FY2003, the number of near misses increased again, while the number of actual occurrences decreased. (Table 8)

Based on the analysis of the Incident Repot Forms, the main reasons for frequent incidence are:

- (i) Lack of confirmation (regarding the exact number of needles actually inserted): After needle retention, some of the needles were hidden by a towel, the hair or clothes.
- (ii) Lack of communication: In the clinic where treatment is performed by teams of acupuncturists,

- a needle inserter often differs from a needle remover in one session.
- (iii) Lack of concentration: preceptor acupuncturists tend to become distracted when their students attended the treatment sessions.

We occasionally reminded the acupuncturists to check the number of needles removed even before the introduction of the incident reporting and feedback system, but this precaution proved ineffective. Apparently the precaution was not specific enough for the actual treatment sessions. What we focused on after FY2000 was to record, analyze and convey to the acupuncture team members 'how' the incidents occurred. Specifically, we emphasized the above three reasons for forgetting needles.

Thus, the incident reporting and feedback system may, if not perfect, be a useful strategy to reduce negligence (at least in the case of forgotten needles). Especially, in reporting near misses, we can collect more data before mishaps actually occur. Another advantage of incident report 'writing' in general is that a reporter can methodically reflect on 'how' an incident happened and systematically reassess how it could be prevented in the future, facilitating learning from past mistakes. Recently some, not many so far but gradually, other clinical facilities of acupuncture in Japan have introduced an incident reporting and feedback system.

Conclusions

Prospective surveys (8–13), although more large-scale and long-term prospective surveys should be performed in the future, show that serious adverse events are rare in standard practice by adequately trained acupuncturists, regardless of country or mode of practice. After demonstrating that acupuncture is inherently safe, we should focus on how to reduce the risk of negligence. In Japan, we have attached primary importance to educating acupuncturists more about safe depth of insertion, aseptic procedure, incident reporting and so forth.

In our experience, Japanese acupuncturists do not frequently access medical journals that carry articles regarding the safety of acupuncture. It is therefore likely that most acupuncturists in Japan do not know what kind of negligence occurs after their treatments. An effective feedback system on adverse events of acupuncture is still lacking in Japan. Societies and associations of acupuncture and moxibustion in Japan have recently launched collecting information, analyzing relevant data, assessing solutions and distribute the updated knowledge for their members. However, there are many acupuncturists who do not belong to such professional bodies. For the benefit of acupuncture patients in Japan, we believe it important to establish mandatory postgraduate clinical training as well as continued education

Table 8. Change in frequency of incidents of forgotten needles during 4 years

| Fiscal year | April to July, 1998 ^a (Baseline data for comparison) | 2000 (Incident reporting and feedback system started) | 2001 | 2002 | 2003 |
|---|---|--|------|------|------|
| Number of sessions | 1441 | 10 437 | 8849 | 8872 | 9353 |
| Number of actual occurrences | 1 | 5 | 5 | 3 | 1 |
| Frequency of occurrences (%) | 0.07 | 0.05 | 0.06 | 0.03 | 0.01 |
| Number of near misses | 8 | 34 | 15 | 7 | 17 |
| Frequency of near misses (%) | 0.56 | 0.33 | 0.17 | 0.08 | 0.18 |
| Number of incidents (actual occurrence + near misses) | 9 | 39 | 20 | 10 | 18 |
| Frequency of incidents (%) | 0.62 | 0.37 | 0.23 | 0.11 | 0.19 |

^aIn this period of 4 months, a prospective survey was conducted by seven acupuncturists, and nine episodes of forgotten needles were recorded (9). These included one actual occurrence and eight near misses (9).

system to further improve undergraduate education for acupuncture students.

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