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A Multicenter Prospective Survey of Adverse Events Associated with Acupuncture and Moxibustion in Japan

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ABSTRACT

Background: There have been only a few prospective surveys on adverse events (AEs) in Japanese-style acupuncture practice, and these surveys were conducted only in a single college acupuncture clinic.
Objective: The goal of this research was to assess the safety of acupuncture and moxibustion performed in educational facilities in Japan.
Materials and Methods: This was a multicenter prospective survey, using paper reporting forms. It was conducted in eight acupuncture clinics affiliated with educational institutions. The subjects were outpatients attending the clinics. The main outcome measure was the number of reported adverse events. The study was conducted for 5–7 months at each facility between October 2014 and June 2015. Participating acupuncture practitioners were instructed to self-report AEs observed during and after treatment; patients were interviewed upon treatment completion. For returning patients, treatment was preceded by an interview survey regarding the AEs identified after the previous treatment session. A specialized 4-sheet questionnaire was used.
Results: Two hundred and thirty-two acupuncture practitioners participated, 2180 patients received treatment, and there were 14,039 sessions, overall. In total, 847 (6.03%) AEs were reported. The most common AEs included subcutaneous bleeding and hematomas (370, 2.64%), followed by discomfort (109, 0.78%) and residual pain at insertion points (94, 0.67%). No infections or serious AEs were reported.
Conclusions: Acupuncture and moxibustion performed in educational facilities in Japan were safe because most of the AEs reported were mild and transient. However, the risk cannot be defined definitely because the survey sample size was too small.

Keywords: Adverse Events, Safety, Acupuncture, Moxibustion, Japan

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INTRODUCTION

ACUPUNCTURE HAS RECEIVED MUCH ATTENTION as an important component of integrative medicine since the 1970s and has been widely used around the world, including in East Asia. For patients to receive the full benefit of acupuncture, it is important to ensure that it is practiced safely. Based on large surveys conducted in Germany[1–3] and the United Kingdom,[4,5] acupuncture is considered a relatively safe therapy. However, some serious and even life-threatening adverse events (AEs) related to acupuncture have been reported every year in Japan[6] as well as in other countries.[7,8] Furthermore, many AEs may not be reported due to publication and reporting bias.

Even though the traditional practice of Japanese acupuncture and moxibustion is derived from ancient Chinese Medicine, the practice has developed independently. The needle insertion technique and the diameter of the needles that are used are different from those used in Traditional Chinese Medicine (TCM) and dry needling therapy. Japanese acupuncturists typically use thin needles with guide tubes. In a survey of acupuncture practitioners conducted by a publisher, Ido-no-Nippon-Sha,[9] only 19.8% of the acupuncturists insert no deeper than 1 cm, which suggests that Japanese acupuncturists do not necessarily use shallow needling. In addition, many of these practitioners treat based on both Oriental and Western medicine theories.

Acupoints are selected by palpation after confirming a skin or muscle condition. According to a survey conducted by Yamashita and colleagues, the total number of needle insertions per patient on average was 21.[10] The acupuncturists used needles with diameters ranging from 0.14 to 0.3 mm with guide tubes; most of them had diameters <0.2 mm.[11] Many acupuncturists use thin needles and perform Japanese-style acupuncture by holding the needle with the bare thumb and index finger (during *Oshi-De*).[12] The *Oshi-De* issue is discussed in detail later in this article.

The current authors—the Committee for Safe Acupuncture of the Japan Society of Acupuncture and Moxibustion—have periodically searched for and reported domestic and foreign literature on AEs associated with acupuncture and moxibustion by using Medline®/PubMed and Ichushi Web (Japana Centra Revuo Medicina). Reports on these AEs are regularly published in the society's journal.[13–17] Furthermore, we conducted surveys of acupuncturists[18] and orthopedic doctors[19] about their experiences with AEs and their treatment in Japan. However, these studies were based on the respondents' retrospection with accuracy inferior to that of a prospective survey. Although there have been a few prospective surveys on AEs in Japan, like the one reported by Yamashita et al.,[10,20] these surveys were conducted only in a single college acupuncture clinic.

Therefore, in order to evaluate the safety of Japanese acupuncture and moxibustion in recent years, the current authors conducted a multicenter prospective survey on AEs in acupuncture clinics located in 8 educational institutions in Japan.

According to the International Conference for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH), an AE is defined as ''any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product and which does not necessarily have a causal relationship with this treatment.''[21]

Based on this, for this study, the current authors defined an AE in acupuncture as ''any untoward medical occurrence in a patient who underwent acupuncture therapy and which does not necessarily have a causal relationship with this treatment.''

MATERIALS AND METHODS

Subjects

Subjects were outpatients visiting the following eight acupuncture clinics managed by educational institutions of acupuncture in Japan:

(1) Kansai University of Health Sciences, Osaka
(2) Kuretake School of Integrative Medicine, Kuretake College of Medical Arts & Sciences, Saitama
(3) Kuretake School of Oriental Medicine, Kuretake College of Medical Arts & Sciences, Kanagawa
(4) Meiji University of Integrative Medicine, Kyoto
(5) Morinomiya University of Medical Sciences, Osaka
(6) Oriental Medicine Clinical Laboratory, Kuretake College of Medical Arts & Sciences, Tokyo
(7) Tokyo Ariake University of Medical and Health Sciences, Tokyo
(8) Tokyo Therapeutic Institute, Kuretake College of Medical Arts & Sciences, Tokyo.

These are well-established schools that educate students in acupuncture in Japan. The surveys were conducted after approval by each clinic's or institution's ethics committee.

Survey Period

Each acupuncture clinic surveyed AEs for 5–7 months (average: 6 months) in the period between October 1, 2014, and June 30, 2015. The surveys started at different times due to the different approval dates obtained from each acupuncture clinic.

Report Forms

Four survey sheets ''Practitioner Profile Form,'' ''Patient Profile Form,'' ''General Adverse Event Report Form,'' and ''Serious Adverse Event Report Form'' were used. These forms were filled out by each practitioner who treated a patient. In this study, all participating practitioners were acupuncturists, each of whom held a national license in Japan. To ensure that no personal information was revealed, only medical record numbers were used on these report forms.

(1) Practitioner Profile Form. This included the practitioner's sex, years of clinical experience, and affiliation. This information was recorded before the start of the survey. Then, each practitioner was given a practitioner ID number to use on the forms.

(2) Patient Profile Form. This included the patient's medical record number, date of birth, sex, chief complaint, therapeutic experience (first visit or returning to the clinic), medical checklist (tendency to bleed, increased susceptibility to infection, allergies, mental disorders, hepatic disease), special instructions, and date of treatment. The Patient Profile Form was prepared at each patient's first visit after the start of the survey.

(3) General Adverse Event Report Form. This included the date of the patient's visit, medical record number, therapeutic experience (first visit or returning to the clinic), the practitioner's number, if the practitioner used medical gloves or finger cots, checklist of AEs and corresponding details, and checklist for the treatment method.

The checklist for AEs was as follows: presence or absence of AEs; pain on insertion/stimulation except pain on ''*Seppi*'' (skin penetration by vertically tapping a handle of the needle); residual pain in the insertion points; bleeding for more than 10 seconds; subcutaneous bleeding and hematomas; burn injury; aggravation of symptoms; discomfort; cutaneous and subcutaneous inflammation; forgotten needles; and others. Discomfort included nausea, vomiting, drowsiness, dizziness, feeling faint, fatigue, and malaise. Each checklist for AEs had fields to describe the relevant details (the degree, affected site, causal procedure, reason, treatment for the AE, and course of the AE). Although ''forgotten needles'' is not a patient reaction, it was included on this form because this negligence might cause serious events such as needle breakage.

The checklist for the treatment method comprised acupuncture, moxibustion, and other therapies. The acupuncture methods included filiform needle, filiform needle inserted only in the skin, electroacupuncture, moxa needle, intradermal thumbtack-type needle, intradermal granule-type needle, skin needle (scratch, contact, and press needles containing the Japanese pediatric needle), and others. The moxibustion methods included direct moxibustion, heat perception moxibustion, pedestal moxibustion, moxa stick, box moxibustion, mechanical moxibustion, and others.

After careful observation of needled sites, each practitioner asked each patient treated about any AEs that the patient might have experienced after the previous visit and also asked about any AEs caused after that day's treatment. If the practitioner found or was informed of any AEs, they were recorded in the General AEs Report Form or the Serious AEs Report Form. AEs caused by previous and that day's procedures were described in the individual fields. The General Adverse Event Report Form was submitted after each treatment regardless of the presence or absence of AEs.

(4) Serious Adverse Event Report Form. If any serious AE (pneumothorax, other organ injury, central nerve injury, peripheral nerve injury, suppurative arthritis, suppurative myositis, cellulitis, hepatitis B, hepatitis C, needle breakage and/or needle migration, accidental insertion, and other symptoms that practitioners regarded as serious) occurred, the practitioner was required to describe and submit the Serious Adverse Event Report Form in addition to the General Adverse Event Report Form.

Analysis

The data from all of the participating acupuncture clinics were collected and analyzed. In addition to classification and frequency of each AE, the following parameters were analyzed:

(1) The number of times each AE occurred
(2) The number of AEs that occurred only at first visits
(3) The number of AEs that occurred at each facility
(4) Incidence of AEs in and clinical experience of groups of therapists who needle with and without finger cots or gloves (statistical analysis using a χ^2 test)
(5) Incidence of subcutaneous bleeding and hematomas in patients with or without bleeding tendency (statistical analysis using a χ^2 test).

RESULTS

The Number of Times Each AE Occurred

A total of 232 practitioners (139 men, 93 women) with 9 ± 10 years (mean $\pm$ standard deviation [SD]) of clinical experience participated in the present study (Table 1). The total number of patients was 2180 (Table 2), and the total number of treatment sessions was 14,039.

A total of 847 AEs were reported (Table 3). Of these AEs, 55 cases of small burn injuries by direct moxibustion—which means scarring moxibustion—were not included because direct moxibustion is known to be associated with small burns, and this therapy was only performed after informed consent was obtained.

The most common AEs were subcutaneous bleeding and hematomas, followed by discomfort, residual pain at insertion points, and pain on insertion/stimulation.

Table 1. Practitioners Who Participated in the Present Study

Sex	*# of practitioners*	*Years of clinical experience (mean ± SD)*
Male	139	12 ± 10
Female	93	5 ± 6
Total	232	9 ± 10

SD, standard deviation.

Table 2. Patients Who Visited the Clinics During the Study Period

Sex	*# of patients*	*Age (mean ± SD)*
Male	890	55 ± 20
Female	1288	53 ± 19
Unknown[a]	2	–
Total	2180	54 ± 19

[a]Because of incomplete patient profile form.
SD, standard deviation.

There were no serious AEs or deaths in this study. Although 5 patients consulted a doctor for aggravation of their symptoms (low-back pain, wrist pain), discomfort (feeling fatigue, dizziness) and residual pain at insertion points, these AEs were not considered serious and no patients were hospitalized.

In patients with subcutaneous bleeding and hematomas, 286 of 370 cases (77.3%) measured <1 cm in diameter. In patients with residual pain at insertion points, 75 of 94 cases (79.8%) experienced only mild pain. In patients with burn injury, 19 of 24 cases (79.2%) were first-degree burns. For cases of discomfort, 59 patients (54.1%) experienced fatigue and 23 patients (21.1%) had drowsiness. Therefore, most of the reported AEs were mild and transient.

The Number of AEs That Occurred Only at First Visits

In total, there were 984 first visits (Table 4). At these, 82 AEs were reported. The incidence of AEs at the first visit was 8.3%, higher than the 5.9% incidence of AEs at return visits. The most common AE was subcutaneous bleeding

Table 3. Reported Adverse Events

Type of adverse events	*Total # of patients*[c]	*Total # of sessions*[d]	*Details*[e]
Subcutaneous bleeding & hematoma	229 (10.50%)	370 (2.64%)	< 1 cm (286 cases), ≥1 cm (31), ≥2 cm (29), ≥3 cm (9), ≥5 cm (2), unknown (13)
Discomfort	65 (2.98%)	109 (0.78%)	Feeling of fatigue (59), drowsiness (23), dizziness (13), nausea (12), hot flash (5), faint (2), palpitation (2)
Residual pain of insertion points	77 (3.53%)	94 (0.67%)	Weak pain (75), strong pain (14), unknown (5)
Pain on insertion/stimulation[a]	59 (2.71%)	78 (0.56%)	Pain during insertion (55), pain during retaining (21), pain during electroacupuncture (3)
Bleeding[b]	50 (2.29%)	74 (0.53%)	≥ 10 sec (14), ≥20 sec (36), ≥30 sec (16), ≥60 sec (7), unknown (1)
Aggravation of symptoms	23 (1.06%)	28 (0.20%)	*Pain (15)*: low-back pain (6); knee pain (4); shoulder pain (2); headache (1); wrist pain (1); lower-leg pain (1) *Other symptoms:* shoulder stiffness (4); muscle tension & entrapment (3); others (4); unknown (2)
Burn injury	21 (0.96%)	24 (0.17%)	*Causes:* heat perception moxibustion (9); pedestal moxibustion (8); indirect moxibustion (ointment "*shiunko*" moxibustion, 2); press moxibustion (1); moxa needle (1); pedestal moxibustion with infrared radiation (1); dropped lighter (1); unknown (1) *Degree:* first degree (19); second degree (superficial, 4); unknown (1)
Others	17 (0.78%)	19 (0.14%)	Strong acupuncture sensation & heavy sensation (6), pain (4) [headache, 1], unknown, 3)], cold sensation of inserted area (2), diarrhea (2), numbness & unusual sensation (2), unknown (2), dropped needle (1)
Cutaneous inflammation & subcutaneous tissue inflammation	11 (0.50%)	12 (0.09%)	*Cutaneous inflammation (11):* itch (6); flare (3); wheal (2)
Subcutaneous tissue inflammation (1): wheal (1)			
Forgotten needles	13 (0.60%)	13 (0.09%)	—
Unknown	24 (1.10%)	26 (0.19%)	Because of incomplete report form (26)
Total	589 (27.02%)	847 (6.03%)	—

[a]Pain on "*Seppi*" (skin penetration by vertically tapping a handle of the needle) is excluded.
[b]Bleeding for less than 10 seconds is excluded.
[c]Number in parentheses represents the percentage of each adverse event for a total of 2180 patients.
[d]Number in parentheses represents the percentage of each adverse event for a total of 14,039 treatment sessions.
[e]Numbers in parentheses represent the numbers of the adverse events. Some of the details are multiple answers.
sec, seconds.

Table 4. Reported Adverse Events at 984 First Visits

Adverse events	*Total # of adverse events*[c]	*% in First visits/% in return visits*[d]	*Details*[e]
Subcutaneous bleeding & hematomas	23 (2.3%)	0.88	≥ 2 cm (4), unknown (19)
Discomfort	19 (1.9%)	2.80	Feeling of fatigue (9), drowsiness (6), dizziness (2), nausea (1), hot flash (1), faint (1), multiple (1)
Residual pain of insertion points	10 (1.0%)	1.58	Weak pain (7), strong pain (3)
Pain on insertion/stimulation[a]	10 (1.0%)	1.95	Pain during insertion (5), pain during retaining (3), pain during electroacupuncture (2)
Bleeding[b]	10 (1.0%)	2.07	≥ 10 sec (3), ≥20 sec (4), ≥30 sec (3)
Aggravation of symptoms	3 (0.3%)	1.59	*Pain (2):* low-back pain (2) Other symptoms (1)
Burn injury	1 (0.1%)	0.58	*Cause:* heat perception moxibustion (1) *Degree:* second degree (superficial) (1)
Others	2 (0.2%)	1.56	Strong acupuncture sensation & heavy sensation (1), diarrhea (1)
Cutaneous inflammation & subcutaneous tissue inflammation	3 (0.3%)	4.42	*Cutaneous inflammation (3):* itch (2), flare (1)
Forgotten needles	0 (0.0%)	0.00	—
Unknown	1 (0.1%)	0.53	Incomplete form (1)
Total	82 (8.3%)	1.42	—

[a]Pain on "*Seppi*" (skin penetration by vertically tapping a handle of the needle) is excluded.
[b]Bleeding for less than 10 seconds is excluded.
[c]Number in parentheses represents the percentage of each adverse event for a total number of 984 first visits.
[d]Number of occurrences in the first visit percentage/Number of occurrences in return visit percentage.
[e]Some of the details are multiple answers. Numbers in parentheses represent the number of the adverse events.
sec, seconds.

and hematoma, followed by discomfort, residual pain at insertion points, pain on insertion/stimulation, and bleeding.

The Number of AEs That Occurred at Each Facility

The AEs that occurred at each clinic are indicated in Table 5. The incidence of AEs at each clinic was 7.10% ± 3.07 (mean ± SD), with the minimum being 1.51% and maximum being 11.67%. The occurrence of subcutaneous bleeding and hematomas had the largest difference (0.41%–7.57%), followed by discomfort and residual pain.

Comparison Between the Groups With and Without Finger Cots or Gloves

The total number of treatments during which practitioners wore medical gloves or finger cots was 6252, while the total number of treatments during which practitioners did not wear them was 7787. There was a significant difference in clinical experience between these groups (7.4 years ±7.9 versus 15.9 years ±10.9, respectively [mean ± SD]; $P < 0.001$). The number of occurrences of subcutaneous bleeding and hematomas (257 [4.11%]), discomfort (61 [0.98%]), and residual pain of insertion points (66 [1.06%]) in the group treated by practitioners who wore gloves or finger cots was significantly larger than patients treated by practitioners in the non–glove wearing group (113 [1.45%], 48 [0.62%] and 28 [0.36%]; $P < 0.001$, 0.05, and 0.001, respectively).

Comparison Between Patients With and Without Bleeding Tendency

One hundred and thirty patients had potential bleeding tendencies. The details were: taking a blood anticoagulating agent (71 patients); hemorrhagic disease (2); unknown (36); and others (21: with hypertension, atrial fibrillation, plethora, taking ifenprodil, and other conditions). No statistically significant difference was found in the occurrence of subcutaneous bleeding or hematoma between patients with and without potential bleeding tendencies. For bleeding that lasted 10 seconds or more, there was a significant difference between patients with potential bleeding tendencies (1.00%) and patients without that tendency (0.48%), if the current authors calculated the number of events per session, but no significant difference was found in events per patient (2.31% and 2.21%, respectively).

DISCUSSION

Occurrence of Serious AEs

To the best of the current authors' knowledge, this study is the first multicenter prospective survey of AEs related to acupuncture conducted in Japan. The International

TABLE 5. ADVERSE EVENTS ACCORDING TO EIGHT ACUPUNCTURE CLINICS

Adverse event	*A*	*B*	*C*	*D*	*E*	*F*	*G*	*H*	*Total*
Subcutaneous bleeding & hematomas	17 (0.41%)	16 (0.92%)	68 (4.18%)	66 (3.09%)	55 (4.26%)	23 (4.20%)	31 (2.41%)	94 (7.57%)	370 (2.64%)
Discomfort	1 (0.02%)	16 (0.92%)	45 (2.77%)	12 (0.56%)	3 (0.23%)	2 (0.36%)	23 (1.79%)	7 (0.56%)	109 (0.78%)
Residual pain of insertion points	4 (0.10%)	10 (0.58%)	16 (0.98%)	17 (0.80%)	23 (1.78%)	1 (0.18%)	6 (0.47%)	17 (1.37%)	94 (0.67%)
Pain on insertion/stimulation[a]	9 (0.22%)	18 (1.04%)	5 (0.31%)	5 (0.23%)	26 (2.01%)	2 (0.36%)	4 (0.31%)	9 (0.72%)	78 (0.56%)
Bleeding[b]	10 (0.24%)	17 (0.98%)	23 (1.41%)	14 (0.66%)	8 (0.62%)	0 (0.00%)	1 (0.08%)	1 (0.08%)	74 (0.53%)
Aggravation of symptoms	1 (0.02%)	8 (0.46%)	6 (0.37%)	4 (0.19%)	0 (0.00%)	1 (0.18%)	5 (0.39%)	3 (0.24%)	28 (0.20%)
Burn injury	13 (0.31%)	1 (0.06%)	0 (0.00%)	2 (0.09%)	1 (0.08%)	0 (0.00%)	2 (0.16%)	5 (0.40%)	24 (0.17%)
Others	3 (0.07%)	6 (0.35%)	1 (0.06%)	1 (0.05%)	3 (0.23%)	0 (0.00%)	1 (0.08%)	3 (0.24%)	18[c] (0.13%)
Cutaneous inflammation & subcutaneous tissue inflammation	0 (0.00%)	4 (0.23%)	0 (0.00%)	3 (0.14%)	2 (0.15%)	0 (0.00%)	0 (0.00%)	3 (0.24%)	12 (0.09%)
Unknown	5 (0.12%)	1 (0.06%)	2 (0.12%)	1 (0.05%)	6 (0.46%)	5 (0.91%)	3 (0.23%)	3 (0.24%)	26 (0.19%)
Total	63 (1.51%)	97 (5.60%)	166 (10.21%)	125 (5.85%)	127 (9.84%)	34 (6.20%)	76 (5.92%)	145 (11.67%)	833 (5.93%)
Total number of treatment sessions	4181	1732	1626	2135	1291	548	1284	1242	14039

Notes: A–H represent the eight clinics. The underlined part is the minimum. The double underlined part is the maximum.

[a]Pain on "*Seppi*" (skin penetration by vertically tapping a handle of the needle) is excluded.

[b]Bleeding for less than 10 seconds is excluded.

[c]Except for one case of a needle dropping (in clinic D).

Conference for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH) defines a serious AE as "any untoward medical occurrence that at any dose: - results in death, - is life-threatening, - requires inpatient hospitalization or prolongation of existing hospitalization, - results in persistent or significant disability/incapacity, or - is a congenital anomaly/birth defect."[21]

In the present survey, there were no serious AEs, such as infection, pneumothorax, or other organ injuries. Most of the reported AEs were mild and transient. Therefore, serious AEs seem to be rare in Japanese acupuncture clinics affiliated with educational institutions.

Assessment of Each Adverse Event

The most frequent AE was subcutaneous bleeding and hematomas (2.6%). These events were also commonly observed in earlier studies.[1–5] Given that acupuncture is a treatment that requires needles to be inserted into the body, it is impossible to completely avoid microbleeding and hematomas. Acupuncturists must therefore take standard precautions to prevent bloodborne infections via microbleeding.

For subcutaneous bleeding, hematoma, and bleeding, no clinically significant difference was found between patients with and without potential bleeding tendencies. However, there are some articles that report AEs, such as bleeding from the inferior epigastric artery,[22] acute spinal subdural hematomas,[23] and hematomas on the buttocks.[24] Therefore, acupuncturists should avoid unnecessary deep needling and crude procedures regardless of their patients' bleeding tendencies.

There were 94 cases (0.67%) of residual pain at insertion points and 78 cases (0.56%) of pain on insertion/stimulation. The incidence of these events was reported at a constant rate in earlier studies.[1–5] Pain is probably caused by both the acupuncturist's poor technique and the patient's susceptibility to the stimulation. Thinner acupuncture needles should be used to help with patients' susceptibility and needle-insertion techniques should be improved.

Although 19 of 24 patients reported first-degree burns, most of these were mild. The details of the treatment are not known, but it is recommended that the practitioner should not leave the patient alone so that the burning moxa can be removed as soon as the patient complains of the heat.

In the present survey, no serious AEs occurred. However, bleeding and burn injuries could harm the aesthetic impression of a certain body region, even if the event is mild. In addition, it is important to pay attention to patient fatigue and drowsiness because the patient might need to drive after the treatment. Therefore, even if it is not a serious AE, the consequences need to be explained to the patient and obtaining informed consent is necessary.

Analysis of the First Visit

Of the 847 cases of AEs that were reported, 82 (8.3%) occurred at the first visit. The incidence of AEs at the first

visit was higher than the incidence at any return visit (5.9%), and this was true for all AEs except subcutaneous bleeding/hematoma and burn injury. One possible reason for this could be that first-time patients respond to the treatment more strongly than someone who is accustomed to it on a more regular basis. For patients receiving acupuncture for the first time, it is necessary to explain potential adverse reactions, and treat these patients with relatively less stimulation depending on their susceptibilities and constitutions.

A Controversial Issue Particular to Japanese-Style Acupuncture

In Japan, as already mentioned, many practitioners who perform Japanese-style acupuncture hold the body of the needle with their bare thumb and index finger (during *Oshi-De*). *Oshi-De* may be regarded as being unsanitary[12] although the present survey did not report any infections. Japanese law requires acupuncturists to swab the skin with alcohol before inserting needles. Also, it is generally instructed that acupuncturists should cover the needle body with alcohol cotton or not touch the needle body when removing the needle from the patient's body. In addition, the hygienic status of patients tends to be high in Japan. Nevertheless, these facts do not support an assertion that *Oshi-De* is completely safe. This issue should be discussed further, extensively based on data from prospective surveys with larger sample sizes, involving not only university or school acupuncture clinics but also general acupuncture practitioners.

In the present survey, the total number of treatments during which practitioners wore medical gloves or finger cots was 6252 while the total number of treatments during which they were not worn was 7787. It was found that the clinical experience, in terms of practicing years, of the practitioners who wore finger cots or gloves was significantly less than those who did not (7.4 versus 15.9 years on average). This might be because educational methods have been changing, and more practitioners in the younger generation have acquired the habit of using medical gloves or finger cots during needle insertion with *Oshi-De*. The difference of clinical experience may also be a likely explanation for the increased incidence of bleeding and pain in the finger cot/glove group. Although infections were not reported to be associated with or without the use of finger cots or gloves in the present survey, due to the small sample size, the current authors cannot draw any firm conclusions.

Limitations of the Present Study and Future Challenges

There were large differences in the incidence of AEs among each clinic, especially for subcutaneous bleeding and hematoma (Table 5). Because AE reporting often depends on the subjective judgment of each participant, a large observation bias could have existed in the present survey. Also, it is possible that the incidence the current authors calculated was slightly different from that in general acupuncture clinics. This was because the participating therapists in the present survey worked for acupuncture clinics affiliated with educational institutions, and many of the therapists were not only licensed acupuncturists but also professors or teachers.

The total number of treatment sessions recorded in this survey was 14,039. These numbers are much smaller than those reported in earlier surveys.[1–5] Based on the ''rule of three''[25] (the upper limit of the 95% confidence interval [CI; = maximum risk] for occurrence is $3/n$ when no events occurred in n patients), the upper limit of the 95% CI for the occurrence of a significant AE would have been 0.02% (3/14,039, per session) in the present survey. Although this was a very low incidence, pneumothorax did occur in a larger-scale survey,[1] with an incidence of 0.001% per patient. Even if serious AEs are very rare, once one occurs, it is unacceptable for the patient who experienced it. Therefore, recording AEs in a multicenter large-scale survey and updating safety information regularly should be performed in each country.

CONCLUSIONS

Most of the AEs that occurred in the present multicenter prospective survey were mild, and no serious AEs were reported. These findings suggest that the practice of acupuncture and moxibustion in educational facilities in Japan is safe, although a definitive conclusion cannot be reached due to the insufficient number of surveyed patients and the possibility of a reporting bias in each facility.

In the future, if an AE reporting system were established using the worldwide web, it would be easier to conduct a much larger-scale and longer-period survey. Furthermore, it may be necessary to require all acupuncture practitioners to register and report all designated AEs.

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AUTHOR DISCLOSURE STATEMENT

No competing financial interests exist.

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