

Translated Articles from JJSAM

# A survey of adverse events at acupuncture and moxibustion clinics in Japan

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# Abstract

**[Objective]** The aim of this study was to survey the current status of adverse events (malpractice and side-effects) in clinical practices of acupuncture (Acp) and moxibustion (Mox), to discuss the problems, and to suggest corrective strategies.

**[Methods]** The survey was sent by mail in October 2009 to 6,000 Acp clinics (including Mox) selected at random from the i-Town-Page telephone directory. The questions addressed the following issues: (1) respondent profile; (2) Acp adverse events; (3) Mox adverse events; (4) complaints and litigation; (5) informed consent regarding these adverse events; (6) subscriptions to publications that address the safety issues of Acp and Mox; and (7) access to free safety resources. Note that we inquired about the experiences of adverse events but did not inquire about their frequency.

**[Results]** The response rate was 21.6%. The top three adverse events for Acp were subcutaneous hemorrhage (65.8%), micro-hemorrhage (62.0%), and needle pain (52.9%). The top malpractice event was forgotten needles (32.7%). Needle breakage and pneumothorax, which are severe malpractice events, were reported by 2.2% and 2.0% of the clinics, respectively. The top three adverse events for Mox were accidental and unintentional burn injury (24.0%), singed hair (15.5%), and singed clothes (15.0%). The most severe malpractice event was suppuration of the Mox point (10.8%). The top adverse events associated with complaints and litigation were symptom exacerbation (21.8%) and pneumothorax (36.4%). Only 74.8% of respondents obtained informed consent, but of those, 61.0% reported providing adverse affect warnings orally. Subscriptions to books and periodicals on the safety of Acp and Mox were reported by less than 30.0% of the respondents.

**[Conclusion]** The most common adverse events associated with Acp were side effects caused by excessive stimulation. With Mox adverse events were more commonly attributable to negligence. The low subscription rate to safety periodicals suggests that safety information is not presently widely distributed. It is necessary to transmit safety information via the Internet as well as in books and other periodicals.

Key words: acupuncture therapy, safety, adverse events, questionnaire survey, acupuncture clinics

# I. Introduction

Actions for improving the safety of acupuncture and moxibustion therapy in Japan were prompted by notices from the Ministry of Health and Welfare (the present Ministry of Health, Labour and Welfare), namely, the 1987 notice regarding the prevention of the acquired immunodeficiency syndrome (AIS) and Hepatitis B and the 1991 notice regarding the prevention of nosocomial infection1). In the beginning, actions focused mainly on infection prevention measures. In 1992, the Acupuncture and Moxibustion Therapy Guidelines Committee (consisting of the Japan Society of Acupuncture and Moxibustion, Japan Association of Acupuncture, Moxibustion and Massage, Japan College Association of Oriental Medicine, Japan Acupuncture and Moxibustion Association and others) developed the "Guidelines of Infection Control for the Acupuncture—Moxibustion Treatment (not for sale)<sup>2</sup>)", and published the first edition<sup>3</sup> in 1993 and an expanded edition in 1997. In 1999, the World Health Organization (WHO) released the "Guidelines on Basic Training and Safety in Acupunc-

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ture,<sup>4</sup>)<sup>37</sup> and in 2003, the Ministry of Health, Labour and Welfare sent a notice to all medical institution throughout Japan to strengthen their preventive measures against medical accidents.<sup>5</sup>) These notices caused every clinic to take measures for medical malpractice and accident prevention in the same way as they had done for infection prevention. Further, in 2004, the Ministry of the Environment issued a notice about appropriate infectious waste treatment.<sup>6</sup>) In 2006 the revised Pharmaceutical Affairs Act referred to the equipment for acupuncture and moxibustion and stipulated, in particular, single use of disposal needles (filiform needles) to assure their quality.<sup>7</sup>)

Under these social conditions, the Acupuncture and Moxibustion Therapy Guidelines Committee changed its name to the Acupuncture and Moxibustion Safety Committee, added new members from the Japan Association of Massage & Acupuncture Teachers, and published the "Guideline for the Treatment by Acupuncture & Moxibustion<sup>7)</sup>" in 2007 and the "Risk Management Manual for the Treatment by Acupuncture & Moxibustion<sup>8</sup>)" in 2010. Meanwhile, in 2009, the Research Section of the Safety Committee of The Japan Society of Acupuncture and Moxibustion (JSAM) published "Safety Knowledge on Acupuncture and Moxibustion Required at Clinical Practice (hereafter abbreviated as "Safety Knowledge on Acupuncture and Moxibustion.")" Today, as described above, the acupuncture and moxibustion safety covers a wide range, beginning from infection prevention measures to the prevention of adverse events (medical malpractice, side-effects and inevitable accidents) and further to the treatment of infectious waste.

According to "Safety Knowledge on Acupuncture and Moxibustion<sup>9</sup>)" mentioned above, an adverse event is defined as any unfavorable medical event that outcomes during or after a medical treatment or medical procedure regardless of whether there is a causal relationship between the outcome and the treatment or procedure. Adverse events can be categorized into three groups, namely, 1) side-effects resulting from an unfavorable biological reaction (adverse reaction) that is unintentionally caused by a medical treatment, 2) medical malpractice resulting in physical damage, which is caused by mistake or ignorance (including intentional damage), and 3) accidents caused by unavoidable events. Sideeffects are, though they can be mitigated by appropriate measures, basically unavoidable. On the other hand, medical malpractices can be avoided by enhancing education and training programs and improving preventive measures. It is assumed that, to some extent, accidents caused by unavoidable events might also be avoided or mitigated. In actual clinical practice, medical malpractice and side-effects are not obviously distinguished from each other (e.g. subcutaneous hemorrhage due to the insertion of the acupuncture needle). In this survey, we use the terms, medical malpractice and side-effect,

according to the definitions in "Safety Knowledge on Acupuncture and Moxibustion<sup>9</sup>."

Previously, we conducted a questionnaire survey on the present status of infection prevention measures at acupuncture and moxibustion clinics, presented the results at the Annual Congress of The Japan Society of Acupuncture and Moxibustion, and published a report in the Journal of The Japan Society of Acupuncture and Moxibustion.<sup>10-12)</sup> For the next stage of our survey, we attempted to investigate the current status of adverse events in acupuncture and moxibustion. Until now, many such surveys in Japan were based on public data such as published literature and litigated cases<sup>19)</sup> and there were no surveys targeting the clinics for acupuncture and moxibustion while, in some countries overseas, some reports dealt with adverse events at clinics. Therefore, in the same way as we had done for infection prevention measures, we conducted a questionnaire survey on adverse events at acupuncture and moxibustion clinics in Japan by focusing on medical malpractice and side-effects. In this paper, we report the results of our questionnaire survey about adverse events at acupuncture and moxibustion clinics.

# **II.** Methodology

### 1. Subjects and survey methods

The subjects were a sample of 6,000 clinics that were randomly selected out of the 20,454 acupuncture and moxibustion clinics throughout Japan registered in the i-Town-Page (website telephone directory published by NTT Directory Services. See http://itp.ne.jp/). Selection was made from the category (Medical, Health and Elderly Care)/subcategory (Massage, Acupuncture and Moxibustion)/subsubcategory (Acupuncture and Moxibustion). When sampling, we included acupuncture and moxibustion clinics co-registered in the subcategory of Judo Therapy and in the subcategory of Anma Massage and Finger Pressure Massage (shiatsu) but excluded overlapping registered clinics. Random sampling was conducted by using a spreadsheet (Microsoft Excel for Mac 2011, Microsoft corporation), which allowed for allocating random numbers generated by the RAND function to acupuncture and moxibustion clinics. After sorting the allocated numbers, random samples were obtained by choosing the clinics along the rows at the top of the spreadsheet. The questionnaire was anonymous. It was posted in the beginning of October 2009 with a return deadline by the end of December. The fee for posting and return was borne by the surveyors. This survey was performed after having been approved by the Research Ethics Committee of Meiji University of Integrative Medicine (Approval number 20-75-1).

## 2. Questionnaire items

We used the questionnaire items shown below. We inquired whether or not respondents had experienced medical malpractice or side-effects (YES or NO), but did not inquire about the number of experiences (frequency). The questions were multiple-choice type unless otherwise noted.

(1) Respondent profile

1-1) Gender, 1-2) Age, 1-3) Years since an acupuncture or moxibustion license was acquired, 1-4) Years since clinic operation started, and 1-5) Membership in professional organizations relating to acupuncture and moxibustion

### (2) Adverse events for acupuncture

2-1) Adverse acupuncture events experienced during or after 2000, 2-2) Causes of needle breakage, 2-3) Causes of pneumothorax, and 2-4) Causes of infectious diseases such as dermatitis and myositis

(3) Adverse events for moxibustion

3-1) Adverse moxibustion events experienced during or after 2000, 3-2) Causes of unintentional burn injury,3-3) Degree of unintentional burn injury, and 3-4) Causes of suppuration of the moxibustion point

(4) Patients' complaints and litigation for adverse events in acupuncture and moxibustion

4-1) Patients' complaints and litigation for adverse events and 4-2) Content of patients' complaints for adverse events

(5) Informed consent regarding possible adverse events during or after acupuncture or moxibustion treatment

5-1) Status of informed consent

(6) Subscriptions to publications that address safety issues for acupuncture and moxibustion

6-1) Safety Knowledge on Acupuncture and Moxibus-

tion Required at Clinical Practice (2009), 6-2) Guideline for the Treatment by Acupuncture & Moxibustion (2007), 6-3) Guidelines on Basic Training and Safety in Acupuncture (1999), 6-4) Guidelines of Infection Control for the Acupuncture—Moxibustion Treatment, Expanded Edition (1997), 6-5) Journal of The Japan Society of Acupuncture and Moxibustion, and 6-6) Other books

(7) Free-response question relating to acupuncture and moxibustion safety (additional comments)

### 3. Data representation

Unless otherwise noted, we divided the number of responses by the total number of valid responses (percentage). Data was indicated by the mean  $\pm$  standard deviation.

# **III. Results**

#### 1. Response rate and respondent profile

The response rate was 21.6% (1,296 out of 6,000). Of those who returned the questionnaire, four of them did not fill in the questionnaire and thus the number of valid respondents was 1,292. The age of respondents was 51.5  $\pm$  12.5 years, the number of years since an acupuncture or moxibustion license was acquired was  $22.0 \pm 12.4$ years, and the number of years since the clinic began operation was  $18.2 \pm 12.7$  years (Table 1). The professional organizations in which respondents held the membership were the Japan Acupuncture and Moxibustion Association (34.0%), followed by the Japan Association of Acupuncture, Moxibustion and Massage (21.6%) and The Japan Society of Acupuncture and Moxibustion (14.5%). 57.9% of the respondents belonged to one or more of these three organizations (Table 2).

Table 1. I	Number	and	profile	of	respond	lents

	Total	Male	Female	Unknown
Number of respondents (response rate)	1,296 (21.6%)	1,097 (84.6%)	176 (13.6%)	23(1.8%)
Age	51.5±12.5 yrs old	51.3±12.3 yrs old	50.3±13.5 yrs old	57.5±13.0 yrs old
Number of years since an Acp or Mox license	22.0±12.4 yrs	22.3±12.3 yrs	19.4±12.9 yrs	28.2±13.6 yrs
Number of years since clinic operation started	18.2±12.7 yrs	18.6±12.7 yrs	15.8±12.4 yrs	20.5±13.0 yrs

The response rate was 21.6% (1,296 out of 6,000). Of those who returned the questionnaire, four of them did not fill in the questionnaire and thus the number of valid respondents was 1,292. Acp; acupuncture. Mox; moxibustion. yrs; years. Date are expressed as mean±standard deviation.

**Table 2. Organizations of respondents** 

Organizations	Number of respondents	Total
The Japan Society of Acupuncture and Moxibustion	188 (14.5%)	
The Japan Acupuncture and Moxibustion Association	440 (34.0%)	751(57.9%)
The Japan Association of Acupuncture, Moxibustion and Massage	280 (21.6%)	
Others	382 (%)	
Independents and nonrespondents	250 (19.3%)	

B. Causes of needle breakage (n=28, multiple answers)



A. Adverse events for acupuncture (n=1,292, multiple answers)

### Figure 1. Experiences of adverse events with acupuncture

The most common adverse event for acupuncture, which respondents had experienced since 2000, was subcutaneous hemorrhage (65.8%)(A). Of the causes of needle breakage, needle failure was the most common (57.1%) (B). Of the causes of pneumothorax, deep needle insertion was most common (59.3%) (C). Of the causes of infectious diseases such as dermatitis or myositis, "not known" was the most common response (62.5%) (D). Note that we inquired whether or not respondents had experienced medical malpractice or side-effects (YES or NO), but did not inquire about the number of experiences (frequency).

# 2. Experiences of adverse events with acupuncture or moxibustion

The most common adverse event for acupuncture, which respondents had experienced since 2000, was subcutaneous hemorrhage (65.8%), followed by microhemorrhage (62.0%), needle pain when inserted (52.9%), retained needles (32.7%), pain after removing needles (23.8%), cerebral anemia and fainting (17.7%), discomfort (17.6%) and symptom exacerbation (14.2%) (Fig. 1-A). Of the causes of needle breakage, needle failure was the most common (57.1%) (Fig. 1-B). Of the causes of pneumothorax, deep needle insertion was most common (59.3%) (Fig. 1-C). Of the causes of infectious diseases such as dermatitis or myositis, "not known" was the most common response (62.5%) (Fig. 1-D).

The most common adverse event for moxibustion, which respondents had experienced during or after 2000, was accidental and unintentional burn injury (24.0%), followed by singed hair (15.5%), singed clothes (15.0%) and suppuration of the moxibustion point (10.8%) (Fig. 2-A). Of the causes of accidental and unintentional burn injury, falling Moxa was the most common (28.4%), followed by excessive stimulation (23.9%) and dropping of the Moxa ball off the acupuncture needle (22.2%) (Fig. 2-B). Of the degrees of burn injury, superficial (first degree) was the most common (52.9%), followed by superficial partial thickness (second degree) (32.9 %) and deep partial thickness (second degree) (6.1%) (Fig. 2-C). Of the causes of suppuration of the moxibustion point, patient's inappropriate self-handling of the moxibustion point after treatment was the most common



#### Figure 2. Experiences of adverse events with moxibustion

The most common adverse event for moxibustion, which respondents had experienced since 2000, was accidental and unintentional burn injury (24.0%)(A). Of the causes of accidental and unintentional burn injury, falling Moxa was the most common (28.4%)(B). Of the degrees of burn injury, superficial (first degree) was the most common (52.9%)(C). Of the causes of suppuration of the moxibustion point, patient's inappropriate self-handling of the moxibustion point after treatment was the most common (30.9%)(D). Note that we inquired whether or not respondents had experienced medical malpractice or side-effects (YES or NO), but did not inquire about the number of experiences (frequency).

(30.9 %), followed by "unknown" (27.6%), elderly patient (23.7%) and diabetic patient (21.7%) (Fig. 2-D).

# 3. Complaints and litigation from patients regarding adverse events

As for the status of complaints and litigation from patients, "nothing in particular" was the most common response (66.8%), followed by "a complaint was filed" (18.5%), "litigation was about to be filed" (1.6%), and "litigation was filed" (0.8%) (Fig. 3-A). The most common complaint was symptom exacerbation (21.8%), followed by fatigue or discomfort (13.1%), subcutaneous hemorrhage or hematoma (13.1%), retained needles (11.1%), pain or numbness at the needle insertion site (10.3%), and burn injury or moxibustion scar (10.3%) (Fig. 3-B). The causes of the cases of filed litigations (11 cases in total) were pneumothorax (4 cases), infectious diseases caused by needle insertion (2 cases), and retained sensation of acupuncture (1 case) in addition to the responses "other" (3 cases) and "not clear" (1 case).

### 4. Status of informed consent regarding adverse events in acupuncture or moxibustion

Of the respondents, 74.8% required informed consent regarding possible adverse events with acupuncture and moxibustion, and, of those who required informed consent, 61.0% obtained it orally, 12.4 % both in writing and orally, and 1.4% in writing (Fig. 4). Of the remaining 25.2% respondents who did not require informed consent, 16.0% answered "do not provide adverse effect warnings" and 9.2% did not answer. As for whether or not having obtained informed consent is a way to avoid litigation, 75.0% of those who had obtained informed consent experienced "actually litigated" or "about to be litigated" while 73.2% of those who had not provide adverse event warnings did not experience a problem of litigation (no figure).

# 5. Status of subscriptions to publications that address the safety issues for acupuncture or moxibustion

The expanded edition of Guidelines of Infection Control for the Acupuncture—Moxibustion Treatment



A. Patients' complaints and litigation for adverse events (n=1,292, multiple answers)

# Figure 3. Complaints and litigation from patients regarding adverse events

As for the status of complaints and litigation from patients, "nothing in particular" was the most common response (66.8%)(A). The most common complaint was symptom exacerbation (21.8%)(B).



### Figure 4. Status of informed consent regarding adverse events in acupuncture or moxibustion

Of the respondents, 74.8% required informed consent regarding possible adverse events with acupuncture and moxibustion, and, of those who required informed consent, 61.0% obtained it orally, 12.4% both in writing and orally, and 1.4% in writing. Of the remaining 25.2% respondents who did not require informed consent, 16.0% answered "do not provide adverse effect warnings" and 9.2% did not answer.



Figure 5. Status of subscriptions to publications that address the safety issues for acupuncture or moxibustion

The expanded edition of Guidelines of Infection Control for the Acupuncture—Moxibustion Treatment (1997) had the most subscribers among the respondents (27.9%), followed by the Guideline for the Treatment by Acupuncture & Moxibustion (2007) (22.9%) and the Journal of The Japan Society of Acupuncture and Moxibustion (21.3%).

(1997) had the most subscribers among the respondents (27.9%), followed by the Guideline for the Treatment by Acupuncture & Moxibustion (2007) (22.9%) and the Journal of The Japan Society of Acupuncture and Moxibustion (21.3%). However, the number of subscribers was low, below 30% for each of these publications (Fig. 5).

# **IV. Discussion**

The intent of this questionnaire was to inquire about experiences of adverse events at acupuncture and moxibustion clinics (practitioners) without specifically targeting individual cases. Therefore, there is a possibility that the survey results miss obvious causal relationships (lacking objective evidence) between the adverse events and the acupuncture and moxibustion treatments.

The most common adverse events for acupuncture that respondents experienced since 2000 were side-effects such as subcutaneous hemorrhage, micro-hemorrhage, needle pain during insertion, and pain after removing needles. Moderately common adverse events included cerebral anemia or fainting, difficulty in removing needles, and other adverse events such as development of fever caused by excessive stimulation. On the other hand, serious adverse events such as needle breakage and pneumothorax were only moderately common. Of the causes of needle breakage, needle failure and muscle contraction accounted for more than half. Of the 28 respondents who had experienced needle breakage, 32.1% (9 respondents) were using disposal needles, 17.9% (5) non-disposal needles or reusable needles, 35.7% (10) the both, and 14.3% (4) did not answer (no figure). Of the respondents, 62.5% (807) were using disposal needles, 6.5% (84) non-disposal needles or reusable needles, 24.1% (311) the both, and 7% (90) did not answer. This implies that the use of reusable needles could increase the possibility of needle breakage. Needle breakage was regarded as the major cause of pneumothorax as well as the cause of damage to the peripheral or central nervous systems and other organs (no figure). It is strongly recommended to implement education and training programs for students before graduation and for clinical practitioners after graduation, thus allowing them to acquire and maintain appropriate hand skills.

The most common adverse events for moxibustion were accidental and unintentional burn injury, singed hair and clothes, and suppuration of the moxibustion point. The causes of accidental and unintentional burn injury were falling Moxa, excessive stimulation and dropping of the Moxa ball off the acupuncture needle, all of which could have been avoided if practitioners had taken sufficient care. As for the degree of burn injury, 1st degree burns and superficial dermal 2<sup>nd</sup> degree burns accounted for 85.8%, implying that most burn injuries were not so serious. The occurrence of infectious diseases associated with moxibustion, such as suppuration of the moxibustion point, was higher than that associated with acupuncture, such as dermatitis and myositis. However, not many respondents answered that the causes of infectious diseases for both acupuncture and moxibustion were because of the practitioner (e.g. disinfection and sterilization processes being insufficient or incomplete). There were many answers saying that the causes were unknown or because of the patient (inappropriate self-handling of the moxibustion point, age, underlying diseases, etc.). The exact cause of each case was not obvious though practitioners are required to take the greatest care when doing disinfection and sterilization as well as when treating compromised patients who are less than normally able to resist infection. They are also required to give patients sufficient explanation and guidance regarding self-handling of the moxibustion point after treatment.

Of patients' complaints about adverse events, sideeffects were the most common reason, which is the same result for practitioners' experiences in performing acupuncture and moxibustion. Of the complaints about sideeffects, symptom exacerbation was dominant. Meanwhile, there were cases where patients complained that the therapy was not effective, demanded refund of the treatment fee or even asked for consolidation money. There was one case where a practitioner, in fear of harmful rumors, settled with money. There was another case where a patient believed that the pain he suffered was due to acupuncture despite the fact that he had not been given acupuncture treatment (his misguided belief came from other medical practitioners). Concerning cases of retained needles, there were no cases that resulted in any serious medical accident. However, any case of retained acupuncture needles not only reduce patients' trust in the practitioner who has done it, but also the whole image of acupuncture and moxibustion therapy. While keeping this in mind, every practitioner must address ways to prevent the occurrence. Of the cases of litigation from patients for adverse events, 1.6% responded that "litigation was about to be filed", and 0.8% responded that "litigation was filed" was, which implies that 2.4% of the respondents were involved in serious problem and this rate does not seem to be small. The most common cause of litigation was pneumothorax (4 cases). One respondent settled out of court for three million yen because he had not taken out a liability insurance policy. His problem seems to be that he neglected adverse events or assumed such events would not occur. Needless to say, it is important not only to develop prevention measures for adverse events, but in addition, to prepare for occurrences, namely, by taking out a liability insurance policy, developing post-occurrence measures, creating manuals and so on. As described above, many adverse events experienced by practitioners can be mitigated or prevented by controlling side-effects the amount of stimulation, sufficiently massaging before treatment, re-counting the number of the needles that was used after treatment, and so on. However, so long as adverse events (especially side-effects) do occur, whatever preventive measures are taken, obtaining informed consent beforehand is important in order to prevent problems with patients and their families not only about treatment content but also about possible adverse events. However, this survey indicates that only 74.8% of the respondents "obtained informed consent", and of those 74.8% respondents, 61.0% obtained consent orally. Then, in order to understand whether obtaining informed consent was effective to avoid litigation, we compared the respondents who answered "litigation was about to be filed" and "actually filed" with those who answered "no litigation problem. Contrary to our expectations, the rates of YES and NO responses were almost the same (YES was 75.0% and NO was 73.2%). This implies that obtaining informed consent is not a sure way to prevent litigation. However, obtaining informed consent not only orally but also in writing would seem to be good practice as such consent could be used as critical evidence, similar to using medical records<sup>7-9</sup>) to cope with possible litigation. As seen in a comment written by one respondent, there are patients, though few in number, who resort to blackmailing as a claim for damages. At the same time, some respondents commented that they prevented problems from growing larger by taking a rapid and

sincere action when handling accidents. This suggests that a business-like attitude may not be desirable. One respondent answered that he solved a problem by consulting a lawyer who was introduced by the Japan Acupuncture and Moxibustion Association, which may imply that seeking opinions from experts and appropriately handling cases at an early stage are ways to successfully avoid litigation.

Among the adverse events, serious malpractice is not only a problem between a practitioner and a patient, but is also a problem that adversely affects the whole medical community of acupuncture and moxibustion. Every practitioner is required to contentiously remember to prevent the occurrence of malpractice. Toward this goal, it is necessary to make efforts to continuously acquire new and updated knowledge and information on the safety of acupuncture and moxibustion. However, the number of subscriptions to books and periodicals that deal with safety issues for acupuncture and moxibustion was low, and the number of memberships in professional organizations for acupuncture and moxibustion was only 57.9% of the respondents. Nowadays, the way to acquire this kind of information is limited to commercially available books and periodicals or academic journals. In the future, in order to widely distribute such kind of knowledge and information, the internet will play a central role, as well as continuing to use traditional printed matter. In addition, it will be useful to provide a place to exchange information on each website. In view of the intent of the foundation of the following associations, it would be appropriate for the Japan Acupuncture and Moxibustion Association and Japan Association of Acupuncture, Moxibustion and Massage to take principal positions and distribute information via their websites and email. At the same time, The Japan Society of Acupuncture and Moxibustion and the Foundation for Training and Licensure Examination in Anma-Massage-Acupuncture, Acupuncture and Moxibustion are committed to conducting investigations and research that are the basis for acquiring knowledge and information, and they are required to maintain even closer relations than before with the two associations mentioned above. We are going to continue to conduct investigations and make presentations on the safety of acupuncture and moxibustion, and, by feeding back the results obtained, contribute to the construction of a system for safe acupuncture and moxibustion therapy.

### V. Conclusion

The following results were obtained from a questionnaire survey about adverse events at acupuncture and moxibustion clinics.

 The most common adverse events for acupuncture were side-effects such as subcutaneous hemorrhage, micro-hemorrhage and needle pain during insertion.

- (2) For acupuncture malpractice on the whole, the most common adverse effect was "retained needles" while, for severe acupuncture malpractice, the most common adverse effects were needle breakage and pneumothorax, which were caused by needle failure and deep needle insertion, respectively.
- (3) The most common adverse events for moxibustion were accidental and unintentional burn injury, singed hair and singed clothes. Causes of many of these adverse events for moxibustion, including excessive stimulation and dropping of the Moxa ball off the acupuncture needle, were due to the negligence of the practitioner.
- (4) The most common causes of suppuration of the moxibustion after treatment were due to the patient, inappropriate self-handling of the moxibustion point after treatment, old age, underlying diseases, and so on.
- (5) The most common complaints for adverse events were side-effects such as symptom exacerbation, fatigue or discomfort, and subcutaneous hemorrhage or hematoma.
- (6) The most common malpractice event associated with complaints was retained needles, while the most common malpractice associated with litigation was pneumothorax.
- (7) Obtaining informed consent about possible adverse events orally was the most common practice.
- (8) The number of subscriptions to both books and periodicals about the safety of acupuncture and moxibustion was low, which implies that safety information is not widely distributed. It may be necessary to introduce a new system to transmit information using the internet.

## Acknowledgement

We sincerely thank the respondents for their cooperation in this questionnaire survey. We also deeply thank our research students, Mr. NAKAJIMA Chiharu, Mr. YOSHIMATSU Keitaro, and Mr. KAIZUKA Kohei and our seminar students, Mr. KOIZUMI Takehiro, Mr. MATSUOKA Soichiro, and Mr. YAMAGATA Haruka for their help in sending out the questionnaire.

We express considerable thanks to the graduate student of the Department of Health Promoting and Preventive Acupuncture and Moxibustion, Mr. MIYAHATA Masato for his cooperation in tallying the questionnaire results.

This survey was funded by the FY 2009 Grant-in-Aid for Scientific Research (KAKENHI) of the Ministry of Education, Culture, Sports, Science and Technology (research subject No. 21790510).

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