

Safety Issue on Acupuncture and Moxibustion in Japan

Hitoshi Yamashita¹⁾, Hiroshi Tsukayama²⁾

1) Department of Acupuncture, Morinomiya University of Medical Sciences, Osaka, Japan

2) Center for Integrative Medicine, Tsukuba University of Technology, Tsukuba, Japan

1. Introduction

Evidence-Based Medicine (EBM) became popularized in the medical field in 1990s when substantial randomized control trials (RCT) on efficacy were actively performed. Against this positive trend, even in these years, methodology showed the least development in clinical research on safety of acupuncture and moxibustion. For example, although it has been publicized that “the incidence of side effects from the practice of acupuncture and moxibustion is none”, data of side effects based on well planned and systematic research have not been presented. There are, indeed, various case reports on infections that developed after acupuncture treatments. There are, however, almost no papers released that clearly show the evidence of these causal relationships.

Generally, arguments of safety of acupuncture and moxibustion often took place on the basis of anecdotal evidence, such as case reports on adverse events and various experiences of individuals. It was only after the latter half of the 1990s that clinical research other than case reports on safety of acupuncture and moxibustion, began to appear in medical journals on a full scale and actively discussed.

This report will provide case reports, prospective surveys and data from RCT on the basis of the strength of evidence and discuss safety of acupuncture and moxibustion in Japan.

2. Case reports

We have reviewed case report papers in order to grasp the incidences in Japan of adverse events associated with acupuncture treatment. Our review results showed that medical journals carried 120 articles reporting about 150 adverse events associated with acupuncture treatment in Japan during the period of the latter half of 1980s and 2002 (Table 1)^{1,2)} (Note: An adverse event is defined as an unfavorable medical event which occurred during or after the treatment *regardless of causal relationships*)³⁾. The most reported adverse event was pneumothorax. In the recent years, however, pneumothorax does not have novelty for a journal article and the number of the case reports relating to the adverse event has been reduced. In contrast, the number of cases handling liability insurance to compensate pneumothorax resulted from the acts of acupuncture and moxibustion in Japan is as highest as ever in Japan⁴⁾. As far as infections are concerned, a diversified range of infections from abscess, bacterial infections to hepatitis B were reported; although for most of these adverse events, cause-effect relationships have not been clarified..

As for “embedding needles” practiced by a few acupuncture and moxibustion therapists, the Japan Acupuncture & Moxibustion Association submitted a request to the then Ministry of Health and Welfare in 1976 to issue its directions to prohibit embedding needles. However, fragments of needles embedded before the order of prohibition (some after the order) caused unique adverse events such as organ injury, foreign body, localized argyria and others. On the other hand, many reports on accidents of needle breakage and organ or spinal injury were seen until the first half of 1990s. In recent years, reports of these cases and liability compensation cases have

decreased^{1,2,4}). It can be considered that the decrease is closely related to the wide use of disposable needles in Japan.

Cases of adverse events resulted from moxibustion are shown in Table 2^{2,5}). Moxibustion is, of course, performed by acupuncture and moxibustion therapists in Japan. However, there is a significant number of cases in Japan in which patients use moxa cones at home according to the instructions by acupuncture and moxibustion therapists or people do self-treatment by using large moxa cones (mass of moxa) according to the oral tradition without seeing acupuncture and moxibustion therapists. In many serious cases of malignant tumor or pulmonary edema, moxa cones were used excessively on patients' own judgment. It is highly controversial that self-treatment that does not have guidance from, or is not practiced by the therapist of acupuncture and moxibustion, should be called "moxibustion treatment"

3. Prospective surveys

As introduced above, it will not be appropriate from the view points of publication bias, retrospective descriptions, recall bias, and an unknown total number of treatment sessions, to argue the safety of acupuncture and moxibustion based on case reports. With these points in mind, since 1992 we have required reports on adverse events to be submitted to Tsukuba College of Technology Clinic (present Center for Integrative Medicine, Tsukuba University of Technology) in order to obtain more reliable data on safety of acupuncture and moxibustion. In this prospective information gathering system, a semi-structured report form has been used, enabling the collection of necessary information for studying cause-effect relations and recurrence prevention

measures. The total number of recipients of acupuncture and moxibustion treatments was known, which facilitated the calculation of incidence frequencies of adverse events. As a result, adverse events were reported • recorded as Table 3 shows^{6,7}). If the denominator or the total number of recipients of acupuncture and moxibustion treatments is taken into account, it can be said that serious adverse events will rarely occur in the standard acupuncture practice.

Subsequently, we conducted a thorough prospective survey over four months to gain the frequencies of mild adverse reactions (side effects) that patients can experience in daily acupuncture practice. The results are shown in Table 4⁸). Fatigue and drowsiness occurred most frequently at the initial treatment and bleeding and subcutaneous bleeding had higher rates of frequency when applying current to needles⁸). Pain when pricking was claimed at a high rate of frequency among younger subjects or women⁹). Any of these adverse reactions were transitory and no medical procedures were taken. It has been confirmed in this survey that most of the side effects, which were frequently encountered in the acupuncture treatments, were mild cases.

4. RCTs

There could be many cases of adverse events recorded in the prospective surveys that actually did not have any causal association with the acupuncture treatment. In order to assess how many specific adverse reactions to penetration of the skin are included in reported adverse events in case reports and prospective surveys, we performed a literature review of published RCTs on acupuncture for osteoarthritis of the knee (knee OA) by way of example¹⁰).

We searched for papers on RCT of acupuncture for knee OA, using two data sources: *PubMed* and *Japana Centra Revuo Medicina* (Igaku Chuo Zasshi). Of the twelve RCT papers located, seven included information on adverse events. Joint swelling, local inflammation, hematoma and back pain occurred more often in the dummy electroacupuncture or minimal acupuncture group. Therefore, it is likely that many non-specific or unconnected “adverse events of acupuncture” are reported in published case reports and prospective surveys¹⁰.

5. Conclusion

In a series of surveys introduced above, it has been confirmed that the incidence of serious side effects (adverse reactions) is rare in the acupuncture and moxibustion clinic. On the other hand, since mild side effects are common, it is essential to inform patients about information relating to these side effects. Moreover, it is fact that serious adverse events exist, such as pneumothorax and spinal injury, although limited, likely due to therapists’ negligence. Thus, as well as education and training²⁶, it is also important to develop error-prevention system, like incident reporting, to prevent avoidable adverse events³⁰.

The Japan Society of Acupuncture and Moxibustion (JSAM), a largest academic body of acupuncture and moxibustion in Japan has established the Committee for Safe Acupuncture to study safety of these treatments and promote education. We consider that a professional body like JSAM should assume roles of undertaking analyses of reported individual adverse events, verifying their causal relationships, giving feedback of the results to members, and shaping the safety education before and after graduation.

References

- 1) Yamashita H., Tsukayama H., White A.R., Tanno Y., Sugishita C., Ernst E.: Systematic review of adverse events following acupuncture: the Japanese literature. *Complement Ther Med* 2001; 9: 98-104.
- 2) Yamashita H., Egawa M., Umeda T., Miyamoto T., Ishizaki N., Katai S.: Update of adverse events associated with acupuncture and moxibustion in Japan (1998-2002) and controversy over infection control in acupuncture treatment. *J Jpn Soc Acupunct Moxibust* 2004; 54: 55-64.
- 3) Beam Jr T.R., Gilbert D.N., Kunin C.M.: General guidelines for the clinical evaluation of anti-infective drug products. *Clin Infect Dis* 1992; 15(Suppl 1): S5-S32.
- 4) Fujiwara Y.: *Shinkyu massage ni okeru Iryo Kago Genba kara no Houkoku*. San-No Shoji, Osaka, 2004.
- 5) Yamashita H., Egawa M., Miyamoto T., Umeda T., Tani M., Nabeta R., et al.: Japanese literature survey on risks and safety of acupuncture and moxibustion (4) - adverse events in moxibustion treatment -. *J Jpn Soc Acupunct Moxibust* 2000; 50: 713-718.
- 6) Yamashita H., Tsukayama H., Tanno Y., Nishijo K.: Adverse events related to acupuncture. *JAMA* 1998; 280: 1563-1564.
- 7) Yamashita H., Tsukayama H., Tanno Y., Nishijo K.: Adverse events in acupuncture and moxibustion treatment: a six-year survey at a national clinic in Japan. *J Altern Complement Med* 1999; 5: 229-236.
- 8) Yamashita H., Tsukayama H., Hori N., Kimura T., Tanno Y.: Incidence of adverse reactions associated with acupuncture. *J Altern Complement Med* 2000; 6: 345-350.
- 9) Yamashita H., Tsukayama H., Sugishita C.: Local adverse reactions commonly seen in Japanese-style medical acupuncture practice. *Clin Acupunct Orient Med* 2001; 2: 132-137.
- 10) Yamashita H., Masuyama S., Otsuki K., Tsukayama H.: Safety of acupuncture for osteoarthritis of the knee – a review of randomised controlled trials, focusing on specific reactions to acupuncture. *Acupunct Med* 2006; 24(Suppl): S49-52.

Table 1 Published case reports of adverse events associated with acupuncture in Japan^{1,2)}

Type	Diagnosis or symptom (Number of cases in parentheses)	Comments
Organ injuries or foreign bodies	<u>Organ injuries</u> 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.
	<u>Foreign bodies</u> 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	<u>Bacterial infections</u> 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.
	<u>Viral infections</u> Acute hepatitis B (12).	
Neurological problems	<u>Central nervous system</u> 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.
	<u>Peripheral nerves</u> Peripheral nerve injury (3).	
Dermatological problems	<u>Pigmentation</u> Localized argyria (15) and cutaneous chromatosis (1).	Localized argyria was caused by embedding silver needles.
	<u>Others</u> 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).	