THE JOURNAL OF ALTERNATIVE AND COMPLEMENTARY MEDICINE
Volume 6, Number 4, 2000, pp. 345–350
Mary Ann Liebert, Inc.

Incidence of Adverse Reactions Associated with Acupuncture

HITOSHI YAMASHITA, B.S., L.Ac.,[1,2] HIROSHI TSUKAYAMA, B.A., L.Ac.,[1]
NORIKO HORI, L.Ac.,[1] TOMOAKI KIMURA, M.Sc., L.Ac.,[2]
and YASUO TANNO, Ph.D., M.D.[1]

ABSTRACT

Objectives: To determine the type, severity, and incidence of acupuncture adverse reactions that are observed in standard practice.

Design: A survey based on observation and interview by the therapists.

Setting: Tsukuba College of Technology Clinic in Japan.

Subjects: All patients who underwent acupuncture treatment during a period of 4 months from April to July 1998.

Outcome measures: Type, severity, and incidence of acupuncture adverse reactions.

Results: A total of 391 patients were treated in 1,441 sessions, involving a total of 30,338 needle insertions. The incidence of recorded systemic reactions in individual patients was: tiredness (8.2%); drowsiness (2.8%); aggravation of preexisting symptoms (2.8%); itching in the punctured regions (1.0%); dizziness or vertigo (0.8%); feeling of faintness or nausea during treatment (0.8%); headache (0.5%); and chest pain (0.3%). The incidence of recorded local reactions, expressed as a percentage of needle insertions, was: minor bleeding on withdrawal of the needle (2.6%); pain on insertion of the needle (0.7%); petechia or ecchymosis (0.3%); pain or ache in the punctured region after the treatment (0.1%); subcutaneous haematoma (0.1%); and pain or discomfort in the punctured region during the needle retention (0.03%).

Conclusion: Although some adverse reactions associated with acupuncture were common even in standard practice, they were transient and mild compared to cases such as pneumothorax, cardiac injury, infection, or spinal lesions reported in other studies.

INTRODUCTION

Various adverse events in acupuncture treatment have been reported in the current literature (e.g. Peacher, 1975; Norheim and Fønnebø, 1995; Rampes and James, 1995; Norheim, 1996; Rosted, 1996; Ernst and White, 1997a). Some of these are serious cases such as pneumothorax, infection, or spinal lesions (Ernst and White, 1997b). We have already demonstrated that given adequately trained acupuncturists, these serious events seem to be uncommon in standard practice (Yamashita et al., 1998). We also proposed that there should be two categories of adverse events in acupuncture: the first is adverse reactions observable in standard practice and the second is therapist negligence (Yamashita et al., 1999). In our pre-

[1]Tsukuba College of Technology Clinic, Tsukuba City, Japan.
[2]Department of Family Nursing, Faculty of Medicine, The University of Tokyo, Tokyo, Japan.
[3]Department of Acupuncture, Tsukuba College of Technology, Tsukuba City, Japan.

vious study, we showed the incidence of some adverse events at our clinic (Yamashita et al., 1999). However, the incidence of less severe adverse events, most of which are adverse reactions, was not investigated because these events would not have been reported unless the therapist or patient regarded them as a problem. The primary limitation of the previous study rested on therapists' judgement, that is whether or not to report a certain event.

In the present study, for the purpose of complementing the information that we previously reported (Yamashita et al., 1999), we performed a survey on type, severity, and incidence of acupuncture adverse reaction based on thorough observation and interview.

METHODS

We performed the present survey during a period of four months from April to July 1998. Subjects were all patients who underwent acupuncture treatment at Tsukuba College of Technology Clinic. Three college instructors, one assistant, and three interns participated in the treatment and recording. All were licensed acupuncturists who use guide tubes for insertion of needles. Needle thickness ranged from 0.14 to 0.3 mm in diameter. Moxibustion or press needles (Rampes and James, 1995) were occasionally used.

The acupuncturists meticulously observed the punctured region and general condition of the patients during and immediately after treatment. The patients were asked to report any pain or discomfort caused by needle insertion. In the interview after each treatment session, the acupuncturists asked the patients, "Did you feel any discomfort during today's treatment session, or do you have now such a feeling that did not exist before the treatment session? Please tell me every slight discomfort even if you don't think it is a problem." A similar question was asked at the patient's next visit, "Did you feel any discomfort that may have had something to do with the previous treatment, after you left our clinic?" Each adverse reaction recognized by either the therapist or the patient in the process above was recorded in a structured case report form. Details recorded on the report form included date, name of the acupuncturist, patient's name, gender, age, clinic identification number, number of needles inserted, method of needle stimulation, type of adverse event, part of the body effected, severity or magnitude of symptom, and treatment for the reaction.

The incidence of systemic reactions was obtained by dividing the number of relevant patients by the total number of patients. The incidence of local adverse reactions, which were recognized at a specific insertion site, was obtained by dividing the number of reactions by the total number of the insertions. The number of treatment sessions in which an adverse reaction occurred was expressed as a percentage of total sessions.

RESULTS

The total number of treatment sessions was 1,441 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; ages ranged from 12 to 88 years. The most frequent stimulation method applied was simple needle retention (13,187 insertions); needles were retained for 10–20 minutes after insertion, and then removed. The second most frequent method was electroacupuncture (9,249 insertions), followed by manual stimulation of the needle (7,668 insertions); needle tips were moved up and down approximately 10 times in the muscle, and then removed. Moxibustion was performed 642 times, and press needles were used a total of 234 times.

Nine episodes of failure to remove the needle were recorded as obviously negligent cases. No sequelae were observed after removal of the needles. These nine cases due to negligence were excluded from the category of adverse reaction in accordance with our proposed definition (Yamashita et al., 1999).

Table 1 shows the type, number, incidence, and severity of recorded acupuncture adverse reactions. Of the systemic reactions, the most common was tiredness (*Hiro-kan*). Its incidence was 8.2% in the total of 391 patients. The second most common reaction was drowsiness (*Nemuke*) and aggravation of the preexisting

Table 1. Recorded Acupuncture Adverse Reactions

Type of adverse reaction	*Number of patients*	*Incidence (% of total number of 391 patients)*	*Number of sessions*	*% of total number of 1441 sessions*	*Comments*
Systemic Reactions					
Tiredness (*Hiro-kan*)	32	8.2%	48	3.3%	Duration: less than 1 day: 21 patients (44%), 1–3 days: 8 (17%), 3–6 days: 3 (6%), unknown: 16 (33%)
Drowsiness (*Nemuke*)	11	2.8%	17	1.2%	Disappeared within a day.
Aggravation of the preexisting symptom	11	2.8%	16	1.1%	Sciatica (5 sessions), neck and shoulder pain (4), low-back pain (2), tinnitus (2), pain in the extremities (1), knee pain (1), abdominal pain (1). Recovered to the previous level within a maximum of 3 days.
Itching in the punctured regions	4	1.0%	13	0.9%	Disappeared within a day.
Dizziness or vertigo (*Memai*)	3	0.8%	5	0.3%	Disappeared within a day.
Feeling of faintness or nausea (*Kiban-furyo*) during treatment	3	0.8%	3	0.2%	No loss of consciousness or falling down. No vomiting. Disappeared within 30 minutes with patient resting in recumbent position.
Headache	2	0.5%	2	0.14%	Disappeared within a day.
Chest pain	1	0.3%	1	0.07%	Lasted for 1 day. Pneumothorax and ischemic heart disease were ruled out after a chest x-ray and an electrocardiogram.
		(% of total number of 30,338 insertions)			
Local Reactions					
Minor bleeding on withdrawal of the needle	781	2.6%	546	38%	Less than one drop: 675 insertions (86%), 1 to 2 drops: 72 (10%), more than 2 drops: 11 (1%), unknown: 23 (3%). The time required for stopping the bleed was no more than 5 minutes.
Pain on insertion of the needle	219	0.7%	184	13%	177 (81%) disappeared immediately after withdrawal of the needles, 15 (7%) remained for a while after withdrawal, 27 (12%) unknown.
Petechia or ecchymosis	100	0.3%	82	5.7%	Diameter: less than 10 mm: 26 (26%), 10–20 mm: 42 (42%), 20–30 mm: 8 (8%), unknown 24 (24%). One patient reported pain.
Pain or ache in the punctured region after the treatment	38	0.1%	33	2.3%	Duration: less than 1 day: 10 (26%), 1–2 days: 1 (3%), unknown: 27 (71%).
Subcutaneous haematoma	31	0.1%	27	1.9%	Diameter: less than 10 mm: 23 (74%) without pain and 1 (3%) accompanied by pain, 10–20 mm: 3 (10%) without pain and 1 (3%) accompanied by pain, unknown 3 (10%).
Pain or discomfort in the punctured region during the needle retention	10	0.03%	10	0.7%	Disappeared immediately after withdrawal of the needles.

symptom with an incidence of 2.8%. Itching in the punctured regions, dizziness or vertigo (*Memai*), feeling of faintness or nausea (*Kibun-furyo*) during treatment, headache, and chest pain followed in decreasing order of incidence. Itching in the punctured regions was included in the category of systemic reactions because the patients complained of itching of almost all punctured regions in the whole body.

As for local reactions, the most common reaction was minor bleeding on withdrawal of the needle. Its incidence was 2.6% in the total of 30,338 insertions. The second most common reaction was pain on insertion of the needle, with an incidence of 0.7%. Petechia or ecchymosis, pain or ache in the punctured region after the treatment, subcutaneous haematoma, pain or discomfort in the punctured region during needle retention followed in decreasing order of incidence.

All reactions were mild and transient. No medical care was required for any of these reactions. As for the case of chest pain, which lasted for one day after the treatment, both pneumothorax and ischemic heart disease were ruled out after a chest x-ray and an electrocardiogram.

DISCUSSION

Limitation of the present study

In the present study, the quality of the main data depends on how honestly and faithfully the patients informed the therapists of the reactions they experienced; older Japanese patients are apt to conceal any problems if they think it might sound critical of their therapist. Although we tried to discover every minor adverse reaction by interview as described above, there are at least three problems which affect the accuracy of the data.

First, the acupuncturists themselves could not recognize reactions that occurred after the patients left the clinic if they did not return. For example, subcutaneous hematoma might have appeared after a treatment session. Second, we cannot judge whether a symptom reported by a patient is actually related to the acupuncture treatment or not. For example, some reported cases of aggravation may not be due to acupuncture. At the same time, there may have been some unreported cases which were caused by acupuncture. Third, any delayed reactions, such as histologic changes in a frequently punctured point or endocrinologic changes throughout the body, were not included in the present survey.

Thus, the present study mainly covers relatively immediate reactions. We therefore need to perform long-term surveys to address these problems. Despite these limitations, we believe that the accuracy of the data, especially on minor adverse reactions, has considerably improved compared to the previous study (Yamashita et al., 1999) that depended only on the therapists' judgement.

Frequency of acupuncture adverse reactions

In showing the incidence of systemic reactions, we used the percentage occurring in the total of 391 patients because our concern is how many percentages of different patients experienced this type of reaction. On the other hand, in showing the incidence of local reactions, we used the percentage occurring in the total of 30,338 insertions. The reason for this is that we are interested in how often a needle insertion causes a reaction. In this way, we shall be able to inform patients of the risk of adverse reactions, for example: "Approximately 8% of patients may experience transient tiredness." "On average, patients experience pain on insertion of the needle 7 times per 1000 insertions." We also showed the percentages of sessions in which any reaction occurred. This will be useful for knowing how many percentages of treatment sessions an acupuncturist will encounter each reaction.

In accordance with the standard category of frequency of adverse drug reactions recommended by the Council for International Organizations of Medical Sciences (CIOMS, 1995), an estimate of frequency for each systemic acupuncture adverse reaction is expressed as follows: tiredness, drowsiness, aggravation of the preexisting symptom and itching in the punctured regions are "common (or frequent, $\geq 1\%$ and $< 10\%$)"; dizziness or vertigo, feeling of faintness or nausea during treatment, headache and chest pain are "uncommon (or infrequent, $\geq 0.1\%$ and $< 1\%$)." If we apply percents of total number of sessions, then itching in the punctured regions shifts to the category

Table 2. Incidence of Tiredness and Drowsiness by Visit at Different Stages of Acupuncture Treatment

	Number of events	
	Tiredness	*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%)

of "uncommon," and chest pain shifts to that of "rare ($\geq$0.01% and $<$0.1%)." A causal relationship between recorded reactions and acupuncture, though not definite, is highly likely, in view of the short time elapsed between treatment and recognition of the reaction.

Systemic adverse reactions

It has been our impression that the frequency of tiredness or drowsiness in a given patient gradually decreases with repeated treatments. Table 2 shows the acupuncture experience of the patients who complained of tiredness or drowsiness. As we would expect, the incidence tended to be higher on the first visit. Although this trend is consistent with the report by Brattberg (1986), incidence of drowsiness in his report is extremely high (65%) compared with that in the present study (2.8%). The reason for this discrepancy may be due to differences in the patients' characteristics and stimulation methods. In Brattberg's study (1986), all the subjects were patients at a pain clinic and DEQI was sought as a matter of course, in every patient. Stronger stimulation and transient relief from chronic pain may have caused the much higher incidence of drowsiness. Thus, the incidence of drowsiness after acupuncture may range widely between individual patients and according to strength of stimulation.

Regarding the cause of itching in the punctured region, most of the present cases did not appear to be allergic contact dermatitis. Suspected allergic contact dermatitis caused by stainless steel needles was observed in much lower incidence (0.005%) in our previous survey (Yamashita et al., 1999).

A feeling of faintness or nausea is the same as the category of "needle-fainting" (syncope without loss of consciousness) reported by Chen et al. (1990), and the reported incidence (0.194% of sessions) is consistent with our result (0.2% of sessions). Because this reaction is probably due to transient hypotension, treatment in a recumbent position should reduce the incidence of fainting (Chen et al., 1990; Yamashita et al., 1999).

The other reported systemic reactions are discussed more extensively in our previous report along with the notion of Menken phenomenon (Yamashita et al., 1999).

Local adverse reactions

It is obvious from the present results that acupuncture needles injure blood vessels, although in most cases only slightly. The incidence of bleeding reminds us that aseptic procedure is crucial in acupuncture treatment. Acupuncturists need to be equally cautious about the hazard to themselves as well as to their patients. Table 3 shows different incidences of minor bleeding and petechia or ecchymosis associated with different modes of acupuncture stimulation. The highest incidences recorded during application of electroacupuncture are probably due to needle tip movement during the associated muscle twitch.

Table 3. Incidence of Minor Bleeding and Petechia or Ecchymosis by Modes of Stimulation

Adverse 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%
Petechia or ecchymosis	Electroacupuncture	44	9249	0.48%
	Needle retention[a]	31	13,187	0.24%
	Manual stimulation[b]	21	7668	0.27%

[a]Needle retention: needles are retained for 10–20 minutes after insertion, and then removed.
[b]Manual stimulation: needle tips are moved up and down approximately 10 times in the muscle, and then removed.

Pain on insertion of the needle may include DEQI (Streitberger and Kleinhenz, 1998) (or Teh-Chi) sensation as well as a sharp, tingling, pinching pain. DEQI is a characteristic sensation induced by insertion of an acupuncture needle, which involves a sensation of dull pain or numbness. Some patients refer to it as a comfortable stimulation while others will express a dislike for it. For this reason, establishing a universal incidence of pain on insertion seems difficult.

Petechia or ecchymosis and subcutaneous haematoma was discussed in our previous report (Yamashita et al., 1999).

Clinical safety information on acupuncture

Medical consumers should be fully informed of potential adverse reactions before receiving treatment, whether it be conventional or acupuncture therapy. Apart from cases due to negligence, a distinction should be made with respect to adverse reactions observed in standard practice. From the point of view of informed consent, preparing information on the type, severity, and incidence of acupuncture adverse reactions in standard practice is imperative.

In conclusion, some acupuncture adverse reactions are common even in standard practice. However, these reactions are very mild compared to reported cases of gross negligence such as pneumothorax, cardiac injury, infection or spinal lesion (Rampes and James, 1995; Ernst and White, 1997b). We believe that, for some adverse reactions, there will be wide differences in incidence due to treatment style or cultural familiarity with acupuncture. Thorough surveys such as the present study should be performed in many countries and schools in order to establish more comprehensive clinical safety information on acupuncture.

ACKNOWLEDGMENTS

We wish to thank Itsuro Hirasawa, Norikazu Sugiyama, and Satoko Hirachi who assisted in the treatment and recording of data, and Dr. Adrian R. White, Department of Complementary Medicine in University of Exeter, for comments on the text.

REFERENCES

Brattberg G. Acupuncture treatments: A traffic hazard? Am J Acupunct 1986;14:265–267.

Chen FP, Hwang SJ, Lee HP, Yang HY, Chung C. Clinical study of syncope during acupuncture treatment. Acupunct Electrother Res 1990;15:107–119.

CIOMS. Guidelines for preparing core clinical-safety information on drugs. Geneva: WHO, 1995:28.

Ernst E, White A. Life-threatening adverse reactions after acupuncture? A systematic review. Pain 1997a;71:123–126.

Ernst E, White A. Acupuncture: Safety first. BMJ 1997b;314:1362.

Norheim AJ, Fønnebø V. Adverse effect of acupuncture. Lancet 1995;345:1576.

Norheim AJ. Adverse effects of acupuncture: A study of the literature for the years 1981–1994. J Altern Complement Med 1996;2:291–297.

Peacher WG. Adverse reactions, contraindications and complications of acupuncture and moxibustion. Am J Chin Med 1975;3:35–46.

Rampes H, James R. Complications of acupuncture. Acupunct Med 1995;13:26–33.

Rosted P. Literature survey of reported adverse effects associated with acupuncture treatment. Am J Acupunct 1996;24:27–34.

Streitberger K, Kleinhenz J. Introducing a placebo needle into acupuncture research. Lancet 1998;352:364–365.

Yamashita H, Tsukayama H, Tanno Y, Nishijo K. Adverse events related to acupuncture. JAMA 1998;280:1563–1564.

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.

Address reprint requests to:
Hitoshi Yamashita, B.S., L.Ac.
Tsukuba College of Technology Clinic
4-12-7, Kasuga, Tsukuba City
305-0821, Japan

E-mail: yamashita@k.tsukuba-tech.ac.jp