| | | | |
|---|---|---|---|
| | medullary injury (1) | | hemorrhage (1) |
| | PNS<br>Peripheral neuropathy (3) | PNS<br>Needle retained in the peripheral nerve (3), occipital neuralgia (1) | |
| Skin disorders | Pigmentation<br>Localized argyria caused by an embedded needle (15), pigmentation-like change (1), tumor growth (1) | Pigmentation<br>Localized argyria (2) | Pigmentation<br>Localized argyria (1), pigmentation (1) |
| | Contact dermatitis<br>Contact dermatitis (or metal allergy) (4) | | |
| | Other skin diseases<br>Lichen planus (1), nodular lesion (1), tumor growth (1), sarcoid reaction (1) | Other skin diseases<br>Erythema nodosum (1), disease flare of Wells' syndrome (1) | |
| Other | Subcutaneous hemorrhage (2), shock symptoms (1), forgotten needles (1), severe asthma attack (1: resulting in death) | Bronchial asthma attack (2), headache and nausea (1), impaired consciousness (1: the patient died 15 days later, details unknown), aggravation of symptoms (1), retained needle (1) | Rhabdomyolysis (1) |

*: Adverse events include those that are not necessarily attributable to treatment (further details are provided in the text).

Table 2. Domestic cases of moxibustion-related adverse events reported in medical journals (The number of cases is indicated in parenthesis.)

| Classification | Late 1980s to 2002 [3, 4] | 2003 to 2006 [5] | 2007 to 2009 [6] |
|---|---|---|---|
| Skin disease | Malignant tumor<br>Basal cell carcinoma (5), verrucous carcinoma (2), squamous cell carcinoma (2, including 1 death) | Malignant tumor<br>Squamous cell carcinoma (1) | Malignant tumor<br>Granulocytic sarcoma (1), squamous cell carcinoma (identical with the case occurring from 2003 to 2006 shown to the left) |
| | Other<br>Proliferative trichilemmal cyst (1), bullous pemphigoid (5), Koebner's phenomenon (1: pruritic rash in an ATL patient) | | |
| Burn, ulcer, infection, etc. | Suppuration (cellulitis) (3), eyelid burn (2), burn ulcer (2), hospitalization for burn infection (?) (1) | Ulcer at the moxibustion site (1), blistering (1: combination of moxa needle therapy and far-infrared radiation) | Lower leg skin necrosis (1), burn (1: moxa needle therapy) |
| Aggravation of symptom/condition | Pulmonary edema attributable to excessive moxibustion in a patient with terminal cancer (1: death), induction of asthmatic attacks (2), exacerbation of rheumatoid arthritis (1: warming with a moxa stick), angina-like chest pain (1) | Bronchial asthma attack (1), low back pain (1), headache (1) | |
| Other | Induction of pain in various body parts (45), presence of dyskinesia in various body parts (11) | | |

*: Adverse events include those that are not necessarily attributable to treatment (further details are provided in the text).

ATL: Adult T cell leukemia

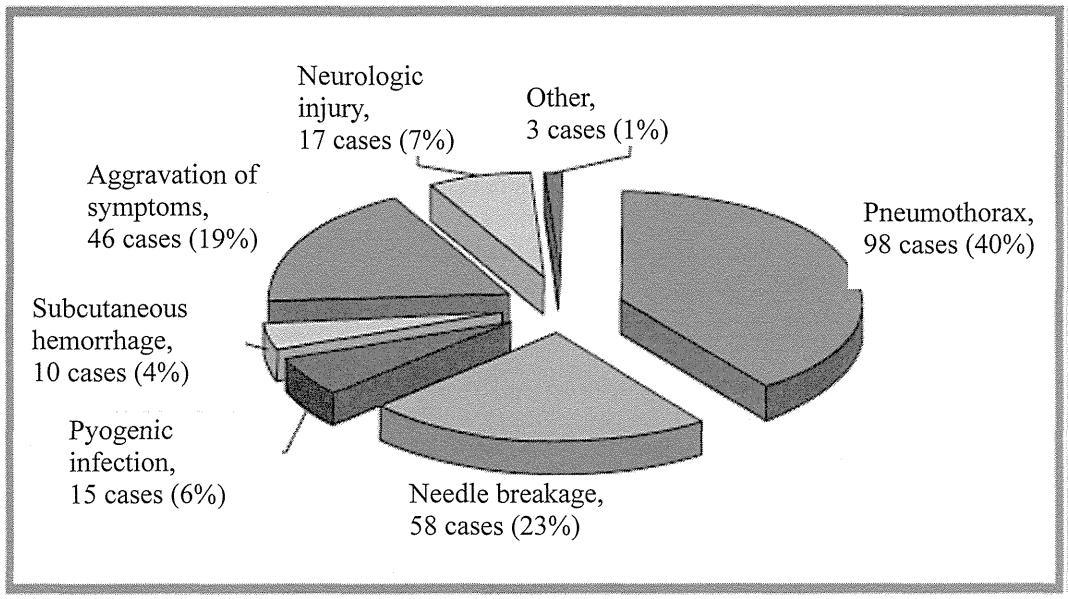


Figure 1. Adverse event claims handled by an insurer liable for damages associated with acupuncture, moxibustion, and massage from 1989 to 2002 [7)]

Thus, until the late 1990s, discussions about the safety of acupuncture and moxibustion were based on the weak evidence presented in case reports of adverse events. Instead of concluding based on the case reports of adverse events, prospective surveys to record, collect, and analyze all data from clinical practice were commenced after the mid-1990s. Independent prospective surveys of Japanese acupuncture and moxibustion [8)], modern medical acupuncture and moxibustion in the UK [9)], and traditional Chinese acupuncture and moxibustion in the UK [10)] found that most cases of adverse events were mild. Furthermore, results of a large-scale survey of acupuncture treatment-related adverse events published in Germany (**Table 3**)[11–13)]. These data have made it possible to show the evidence that standard acupuncture treatment is associated with a very low incidence of serious adverse events.

### 3. Adverse effects (adverse reactions) and communication

**Table 4** shows systemic frequently observed adverse effects (or adverse reactions), and **Table 5** shows frequently observed local adverse effects (or adverse reactions) [14)]. Post-treatment tiredness, malaise, and drowsiness occur most commonly at the time of initial presentation. Minor bleeding and subcutaneous hemorrhage occur more frequently after electroacupuncture, and needle insertion pain occurs more frequently in younger persons and women [15)]. All of these adverse effects are transient.

Drowsiness and poor concentration can be great risks to patients who drive a vehicle or operate

machinery after treatment. Therefore, it is necessary to notify patients that drowsiness and/or poor concentration may occur after treatment and may lead to an accident. In other words, transmission of information on adverse effects (or adverse reactions) is essential in order to protect patients. In oriental medicine, transient worsening of symptoms after treatment, followed by improvement of the chief complaint, is often called " *Mengen* (瞑眩)." It is important, however, to notify patients that post-treatment drowsiness, malaise, or poor concentration may occur whether or not it is a healing crisis.

Ideally, written informed consent should be obtained from patients after provision of such information about acupuncture and moxibustion practice. To be truly informed, however, detailed information on efficacy, risk, or cost is lacking. Therefore, research and case series data are now being collected and accumulated.

**4. Protection of personal information**

As with informed consent, patients should be notified of the personal information protection policy before treatment. Personal information should be handled with extreme care, based on the perception that medical records and information in the records belong to patients, not the institution. The institution should at least stick a document of protection policy up.

**5. Error prevention system**

As mentioned above, the incidence of serious adverse events is low in the practice of acupuncture/moxibustion. However, events such as organ injury occur at a certain frequency. If adverse effects are risks inherent in acupuncture/moxibustion procedures, then errors may be regarded as risks not included in acupuncture/moxibustion itself but posed by the practitioners of acupuncture/moxibustion. Therefore, to minimize errors, training and preventive measures need to be improved.

The current concept of medical malpractice prevention is based on the report entitled "To Err is Human" [16] published in 1999 by the Committee on Quality of Health Care in America, Institute of Medicine (U.S.). Preventive measures are now considered systematically, with the system anticipating the inevitability of errors and focusing on "why an error occurred" rather than "who made it". An incident reporting system is an effective means of preventing errors focusing on "why" and "how" they occur. Information should be collected, with care not to overlook the near-misses. Although it is important to learn from past errors, more information can be obtained from the many near-misses (or close-call incidents) than from the few serious accidents in the past. Such information enables us to learn a valuable lesson before an actual error occurs. Near-misses (or

close-call incidents) and actually occurring adverse events are collectively called “incidents” in Japan.

The frequency of errors such as forgotten needles can be reduced by reporting and analyzing incidents and providing feedback [17]. This routine, however, does not prevent all errors, and its effect gradually decreases as it becomes a habit. The style of reporting has to be changed periodically to keep the mind fresh. It goes without saying that basic training systems (including systems that provide practitioners with basic knowledge of safe practice and error prevention) are as essential as the incident reporting system.

Table 3. Large-scale prospective surveys on the adverse events of acupuncture treatments carried out in Germany

| (% in population) | Berlin (2009)[11] | Munich (2004)[12] | Bochum (2004)[13] |
|---|---|---|---|
| | 229,230 (2000 to 2004) (Total of 2.2 million times) | 97,733 (until 2002) (Total of 0.76 million times) | 190, 924 (2001 to 2002) (Total of 1.77 million times) |
| Common adverse events | Bleeding/hematoma: 6.1%<br>Headache: 0.5%<br>Other pain: 1.2%<br>Aggravation of symptoms: 0.3%<br>Inflammation: 0.3%<br>Fatigue: 0.2%<br>Vertigo: 0.2%<br>Swelling: 0.15%<br>Nausea: 0.1% | Needling pain: 3.3%<br>Hematoma: 3.2%<br>Bleeding: 1.4%<br>Orthostatic problems: 0.5% | Hematoma: 5.2%<br>Aggravation of symptoms: 1.3%<br>Vasovagal reactions such as dizziness, nausea, and collapse: 0.7%<br>Perceptual disturbance during treatment: 0.08%<br>Severe pain at the site of needling: 0.05% |
| Adverse events probably caused by errors | Burns after moxibustion: 0.006%<br>Needle forgotten: 0.005%<br>Needle broken: 0.001%<br>Pneumothorax: 0.001% (n=2) | Forgotten needles: 0.25%<br>Pneumothorax: 0.002% (n=2) | Blisters following moxibustion: 0.0005% (n=1)<br>Broken needle: 0.0005% (n=1) |
| Other | Local infection: 0.01%<br>Unconsciousness: 0.03%<br>Nerve injury/paresis: 0.03% | Acute hypertensive crisis, exacerbation of depression and suicide attempt, asthma attack with hypertension and angina, unconsciousness due to vasovagal reaction (n=1 each) | Local skin infection: 0.045% |
| Remarks | Of 4,963 patients (2.2%) who were treated for adverse events, none died. | None died. | During the survey period, nine patients died (4 from heart disease, 2 from cancer, 1 from stroke, 1 from pneumonia, and 1 from motor vehicle accident injury), and none were considered to be directly related to acupuncture. The number of deaths was much smaller than 180, which is the number of deaths estimated to occur in the same population during the same survey period based on demographics. |

Table 4. Common systemic adverse reactions to acupuncture[14)]

| Symptoms | Incidence* (number of patients with adverse reactions/number of patients who received acupuncture) | Remarks |
|---|---|---|
| Tiredness | 8.2% (32 / 391) | Occurs most frequently after the initial treatment. |
| Drowsiness | 2.8% (11 / 391) | Occurs most frequently after the initial treatment. |
| Aggravation of the preexisting symptom | 2.8% (11 / 391) | Sciatica, neck -shoulder pain, low back pain, tinnitus, etc. |
| Itching in the punctured regions | 1.0% (4 / 391) | |
| Dizziness or vertigo | 0.8% (3 / 391) | |
| Feeling of faintness or nausea | 0.8% (3 / 391) | Occurs more commonly when patients receive acupuncture while sitting or standing. |
| Headache | 0.5% (2 / 391) | |

*: Incidence of acupuncture-related adverse reactions is the number of patients who report adverse effects if 100 patients receive the treatment.

Table 5. Common localized adverse reactions to acupuncture[14,15)]

| Local symptoms | Incidence* (number of needles that caused adverse reactions/number of needles inserted) | Remarks |
|---|---|---|
| Minor bleeding on withdrawal of the needle | 2.6% (781 / 30, 338) | Amount of blood was < 1 drop in 86% and ≥ 2 drops in 1% of all cases of bleeding. Bleeding was stopped within 5 minutes in all cases. |
| Pain on insertion of the needle | 0.7% (219 / 30, 338) | Pain subsided immediately after needle withdrawal in 81% and persisted for a while in 7%. |
| Petechia or ecchymosis | 0.3% (100 / 30, 338) | Diameter was < 20 mm in 68% and 20 to 30 mm in 8%. |
| Pain or ache in the punctured region after treatment | 0.1% (38 / 30, 338) | |
| Subcutaneous hematoma | 0.1% (31 / 30, 338) | Hematoma was painless with a diameter of < 10 mm in 74% and 10 to 20 mm in 13% of all cases. Painful hematoma was observed in 6% of all cases of hematoma. |

*: Incidence is the frequency of the adverse reaction when 100 needles are inserted.

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## B. Prevention of individual adverse events

### 1. Organ injury

Hitoshi Yamashita

As previously indicated, various organ injuries, including pneumothorax, have been reported as adverse events of acupuncture (Table 1 of the previous section). Therefore, practitioners of acupuncture/moxibustion must have sufficient knowledge of the safe depths of needle insertion to prevent organ injury. **Table 1** shows the safe depths to which a needle may be inserted into major acupuncture points based on findings of autopsy, tomography, etc. [1]. There may be a sternal foramen at the Danzhong point (CV17) of the sternum; in some cases, a needle passed through the foramen during chest center needling can cause cardiac tamponade [2, 3]. Care should be taken to insert needles to safe depths in order to prevent potential risks even in the presence of an anatomical variant (破格).

To prevent organ injury caused by deep insertion, it should be noted that there are static safe depths of needle insertion obtained from anatomical analyses (**Table 1**) as well as dynamic safe depths of needle insertion that vary according to the hand-pressure applied to the needling site. That is, it should be noted that the greater the hand-pressure applied to the needling, the shallower the safe depth of needle insertion becomes [4].

In practice, whether a needle is inserted to a safe depth depends on the needling technique of the practitioner. If practitioners insert needles more deeply than they intend, their acupuncture/moxibustion treatment cannot be safe even though they are fully aware of the safe depths of needle insertion and the pressure exerted by their hand-pressure. Practitioners with many years of clinical experience do not necessarily insert acupuncture needles to their accurate depths [4]. According to a report by an insurer liable for acupuncture-, moxibustion-, and massage-related damages, the company most frequently pays for pneumothorax caused by practitioners in their 40s [5]. Practitioners should thoroughly learn basic acupuncture techniques in the earliest stage of their education, and evaluation of the techniques should be repeated voluntarily even after graduation.

Table 1. Safe depths for needle insertion [1)]

| Acupoints | | Safe depth (except for severely underweight patients) | Organ that may be injured |
|---|---|---|---|
| Yamen | GV15 | <30 mm | Spinal dura mater |
| Tianzhu | BL10 | <35 mm | Vertebral artery |
| Jianjing | GB21 | <20 mm | Lung |
| Gaohuang | BL43 | <19 mm | Lung |
| Danzhong | CV17 | <10 mm | Heart |
| Zhongwan | CV12 | < 5 mm | Peritoneum |
| Liangmen | ST21 | <10 mm | Peritoneum |
| Shenshu | BL23 | <40 mm | Kidney |
| Zhishi | BL52 | <20 mm | Kidney |

**2. Needle breakage**

Takashi Umeda

Needle breakage refers to accidental breaking and retention of a needle inserted in the body during acupuncture treatment. Possible causes include the use of an inappropriate needle (wrong thickness, length, etc.), abnormality of the needle (corrosion/erosion defects due to low-frequency or direct-current electroacupuncture, flaws such as cracks, pits, etc.), and reduction in strength due to uneven composition of the needle.

A review of Japanese literature published before 1996 found 61 cases of needle breakage, mainly occurring in the 1970s [6)]. The breakage may have been caused by reduction in tensile strength due to erosion or corrosion of the needles, because, in the 1970s, silver needles were commonly used and frequently autoclaved for reuse. Fujiwara [5)] reported on 58 cases of needle breakage that occurred from 1989 to 2002. Since the implementation of the revised Pharmaceutical Affairs Law in April 2005, single-use filiform needles stipulated in Japanese Industrial Standards (JIS) T9301 [7)] have been commonly used. Now that the quality of needles has been improved, cases of needle breakage are expected to decrease.

In acupuncture treatments, low-frequency electroacupuncture is often performed to induce analgesia, muscle-relaxation, and bloodstream-improvement. Acupuncture needle manufacturers have pointed out that practitioners may be responsible for needle breakage during electroacupuncture in some cases, because single-use filiform needles are not intended for use as electrodes in electroacupuncture [8)]. Stainless steel needle No. 20 (0.20 mm in diameter) or greater is recommended for low-frequency electroacupuncture [9)]. No safety standards for low-frequency electroacupuncture have been established and there is an urgent need for national safety standards.

At our institution, needle breakage occurred at the 6$^{th}$ cervical Jiaji point (EXB2, 第6頸椎横夾脊部) after low-frequency electroacupuncture (1 Hz, 15 min) using a single-use filiform needle (50

mm, No. 20) in a patient whose major complaint was neck stiffness. The needle fragment, extending approximately 20 mm from the tip, was retained in the body.

**B. Prevention of individual adverse events**

The needle fragment was then removed [8]. To determine the cause of the accident, the low-frequency electroacupuncture device was examined for signs of degraded operation, and factors in the patient's environment were evaluated. Results showed that none of the factors were causative. Fragments of the needle, including the part removed from the body, were investigated by electron microscopy, analyzed by transmission electron microscopy to determine metal composition, and tested to determine tensile strength. Results showed irregularities in the crystalline structure of the metal and reduced tensile strength (toughness) compared with that of other products. However, evidence showing that these were the causes of the needle breakage was inconclusive. If single-use filiform needle breakage occurs, it will be necessary to develop a system that allows for analysis by a public agency and investigation of the cause by a third-party committee.

Retained needle fragments can migrate [6]. Notably, migration of embedded and intradermal needles cause neurologic damage, and the biological reaction around the needle has been reported to lead to paresthesia, pain, impaired motor function, and dysuria [10].

Muscle fibers at the site of needle insertion may suddenly contract in response to obtaining qi (鍼のひびき) or insertion pain, making it difficult to insert or withdraw the needle smoothly. In such cases, some procedures (e.g., *Fukushigekijutsu* [副刺激術], *Jishidaho* [示指打法], *Mukaebari* [迎え鍼]) should be performed to relax the muscle. If it is still difficult to withdraw the needle, additional needles should be placed around the site of insertion and retained until the muscle is relaxed, instead of attempting a forcible withdrawal.

A break between the handle and shaft of the needle (fixed) (*Nukebari* [抜け鍼]) may occur when the shaft of the needle is suddenly forced deeper into the body as a result of obtaining qi, movement of the patient, and strong muscle spasm caused by coughing or sneezing. In extreme cases, the needle may be broken in the middle. Special care must be taken when inserting needles at points located on the waist, buttock, and back of the thigh, where needles are inserted deeper. Needles should be of appropriate length, and at least one-third of the shaft should always extend above the skin.

**3. Infection control**

Takashi Umeda

Fujiwara [5] reported that 25 cases of suppuration/infection occurred from 1975 to 2002, and the

patients claimed compensation for their injuries. In a review of the Japanese literature on the safety of acupuncture/moxibustion[11] (between 1998 and 2006), 21 cases of bacterial infection were reported and 16 articles reported viral infection. There were also anecdotal reports from other countries[12, 13]. The review of the Japanese literature[11] suggested that the association between acupuncture treatment and infection (though possible) was not conclusive and that infection is prevalent in patients who may be immunocompromised due to diabetes, the long-term usage of corticosteroids, etc. These cases of infections are usually caused by indigenous bacteria, such as *Pseudomonas aeruginosa*, *Staphylococcus aureus*, and streptococci. A case of toxic shock-like syndrome (TSLS) caused by group A streptococci has also been reported [14]. Many patients who come for acupuncture treatment complain of joint symptoms, such as shoulder and knee joint symptoms, and therefore are often treated near the affected joint. There is also a report on a case of purulent shoulder arthritis resulting from infection with methicillin-resistant *Staphylococcus aureus* (MRSA) caused by needle insertion into the shoulder joint [15]. For acupuncture near joints, a disinfection technique should be used to prevent infection.

According to the World Health Organization (WHO) Guidelines on Basic Training and Safety in Acupuncture[16] (hereinafter referred to as the WHO Guidelines), avoidance of infection in acupuncture requires a clean working environment, clean hands of the practitioner, preparation of the needling sites, sterile needles and equipment, and their proper storage, aseptic technique, and the careful management and disposal of used needles and swabs, as with any subcutaneous or intramuscular injection. For infection control in clinical practice, the Standard Precautions and Transmission-based Precautions of the Centers for Disease Control and Prevention (CDC)[17] should be used. Specifically for infection control in acupuncture clinics, a comprehensive approach should include handwashing and disinfection, disinfection of needling sites, disinfection and sterilization of medical equipment, and a clean working environment.

**A. Handwashing and disinfection**

Acupuncture/moxibustion treatments require hygienic handwashing. Alcohol-based hand rubs are the most convenient and efficacious agents for reducing the number of bacteria on the hands and the most commonly used handwashing method in acupuncture/moxibustion settings. Alcohol-based hand rubs are recommended in the CDC guideline [18] and used as the standard method of handwashing in everyday practice. When visibly dirty, hands must be washed off with soap and water. In emergencies, fingers may be cleaned with cotton balls moistened with alcohol to remove dirt and disinfect them.

**B. Disinfection of needling sites**

For disinfection of needling sites, the WHO guidelines [16] recommend the use of 70% ethanol or 70% isopropyl alcohol. In Japan as well, the use of ethanol for disinfection (76.9% to 81.4%) or 70% isopropyl alcohol is recommended [19]. In addition, 0.5% chlorhexidine gluconate may be added to ethanol for disinfection to prolong the disinfectant effect.

Disinfection may be affected by factors such as the type and concentration (%) of the disinfectant and contact time (sec), the chemical composition of the disinfectant cleaner in cotton balls, disinfection technique/method (pressure, frequency, and direction of scrubbing [e.g., one-way, swirling, and in the direction opposite to the hair flow]), and material on the skin (e.g., sweat, grease) [19].

However, few studies explore these factors. For alcohol, the skin disinfection time is reported to be 30 seconds [20] or from 30 seconds to 1 minute [21]. Vigorously scrubbing the skin for 15 seconds is also reported to be effective [22].

According to the WHO guidelines for disinfection techniques/methods [16], the point to be needled should be swabbed from the center to the surrounding area using a rotary scrubbing motion, and alcohol should be allowed to dry. According to the textbook entitled "Theory of Acupuncture and Moxibustion" [23], the point should be swabbed unidirectionally or from the center to the surrounding area in a swirling manner. Another article has reported that the site of needle insertion should be swabbed using different surfaces of cotton balls and then swabbed again with a new cotton ball [20].

On the other hand, a number of studies have suggested that the site of injection should be swabbed from the center to the surrounding area in a swirling manner [24]. One study examined three swabbing methods (swabbing from the center outward in a swirling manner, downward swabbing, and upward swabbing) on the inner side of the elbow joint, and reported that there was no difference in disinfectant effect between the three methods [25].

Umeda et al. [26] evaluated the effects of swabbing pressure (2 conditions) and swabbing frequency (3 conditions) on the degree of forehead skin disinfection using cotton balls with the same alcohol content. Results showed that swabbing with 50% isopropyl alcohol reduced the bacterial count by only 82.1–88.6%, whereas 70% isopropyl alcohol and ethanol for disinfection reduced it by 87.0–97.6% and 90.9–99.6%, respectively; that is, of the three disinfectants, ethanol for disinfection was the most effective in reducing the number of bacteria. Therefore, for effective disinfection, it is recommended that ethanol be used, swabbing pressure be high, and swabbing frequency be 2 or 3 times.

How high the level of disinfection needs to be remains unknown. For prevention of infection, skin disinfection should minimize bacterial counts.

Acupuncture points are located all over the body, from head to toe. For effective disinfection of the head, swabbing frequency and alcohol content in cotton balls for disinfection should be increased

because of the number of skin bacteria is larger on the head than on other parts of the body [27]. Disinfection of other regions including the pinna requires further investigation.

**C. Disinfection and sterilization of acupuncture equipment**

The WHO Guidelines on Basic Training and Safety in Acupuncture [16] stipulate that sterilization is required for all needles, cups, and other equipment (culture dishes, forceps, guide tubes for needles, cotton balls, cotton swabs, etc.).

Some acupuncture devices require sterilization and some require only washing. For proper management of objects, it should be clearly understood whether washing, disinfection, or sterilization is required [28]. Spaulding's classification scheme has been used to select the appropriate disinfection method [29]. Accordingly, instruments and other items are divided on the basis of use into critical, semi-critical, and non-critical. Disinfection methods should be determined according to this classification. Critical items should be sterilized, semi-critical items require intermediate- to high-level disinfection, and non-critical items require only washing. Items that come in contact with intact skin require low-level disinfection, alcohol disinfection, or wiping with a damp cloth [30].

Sterilization methods include autoclaving, ethylene oxide gas sterilization (EOG sterilization), low-temperature hydrogen peroxide gas plasma sterilization (plasma sterilization) [31], dry heat sterilization, and radiation sterilization. Autoclaving is the most common sterilization method in acupuncture/moxibustion settings. Some institutions use low-temperature methods such as EOG and plasma sterilization. Plasma sterilization is preferred to EOG because of the toxicity of EOG, and its use is increasing [31].

The former sterilizers are more commonly used in acupuncture/moxibustion treatments. Materials that tolerate high temperatures and high pressures, including metal, glass, porcelain, rubber, fiber, and paper products, should be sterilized. Sterilization exposure time varies depending on the temperature in the sterilizer. According to the Japanese Pharmacopoeia Fourteenth Edition [32], the sterilization temperature and exposure time should be 115°C–118°C for 30 minutes, 121°C–124°C for 15 minutes, and 126°C–129°C for 10 minutes. Sterilizers designed to operate at 132°C or 134°C (these are not mentioned in the Japanese Pharmacopoeia) are also commercially available. Both the WHO Safety Guidelines [1] and ISO /DIS17665 [33] stipulate that the exposure time should be 3 minutes at a sterilization temperature of 134°C and measured from the moment when the sterilization temperature is actually reached, not when the power is turned on.

Sterilizers must be inspected and maintained on a regular basis. A sterilizer should be loaded with enough air space between packages to permit the proper circulation of steam and air. Items should be placed in a sterilizer in such a way that steam and air can circulate between their packages. The water level in the reservoir should not be below the lowest line, and the reservoir tank should be

refilled with fresh water once weekly. The sterilization temperature and pressure in the sterilizer should be checked during operation, and completion of sterilization should be confirmed by indicators.

**D. Aseptic technique**

The Clean Needle Technique is the standard. Needles should be inserted in such a way that the practitioner's fingers do not touch the shaft. In acupuncture practice, the pressing hand (a technique unique to Japanese acupuncture) can pose a hygiene problem [34)] because the hand presses the area of puncture to facilitate insertion of thin needles. It fixes the location of the acupuncture point on the skin, helps to prevent needle insertion pain, and prevents bending of the needles. Also, the pressing hand can feel the body's subtle reaction to needle insertion, and therefore can promptly respond to accidents such as the patient's movement.

For prevention of infection, finger stalls and surgical gloves are used, and the shaft of the needle is wrapped with a sterilized cotton ball prior to insertion. These problems have been solved by a new needle product on the market. The product has a slightly rigid guide sleeve on the outside of the needle shaft, enabling the shaft to smoothly move in the sleeve. Because the guide sleeve is held by the pressing hand, the practitioner can insert and withdraw the needle without touching the needle shaft. This product will ensure that the needles remain clean during needle insertion, and that infections caused by the pressing hand technique will decrease drastically. Also, its use is expected to become more widespread (**Figures 1 and 2**).

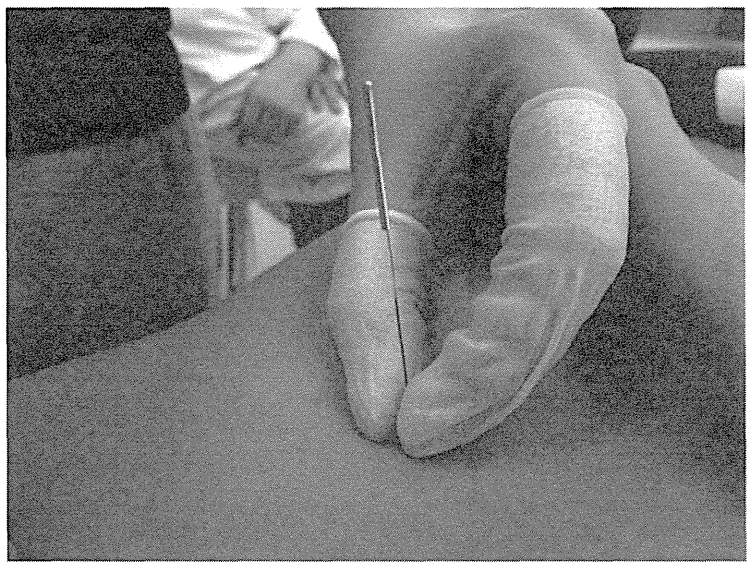

Figure 1. A filiform needle for the Clean Needle Technique

The needle is covered by the sheath made of a solid material, which enables the needle to be inserted preventing practitioner's fingers from directly touching it.

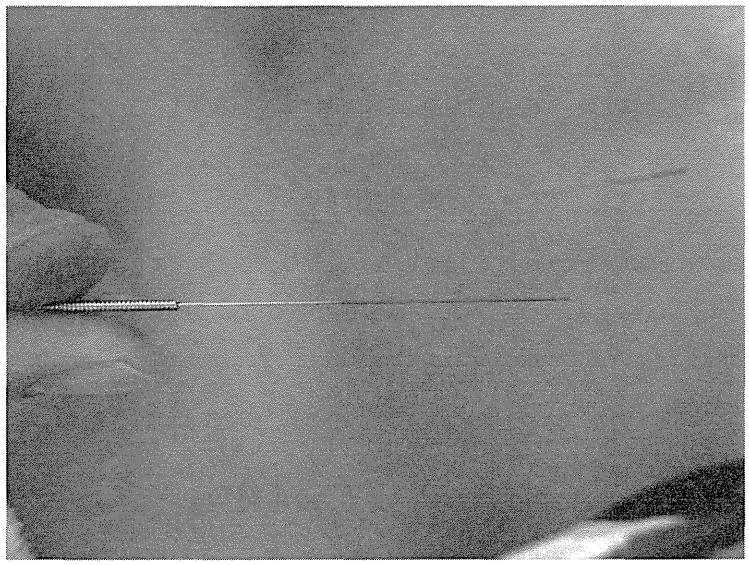

Figure 2. A filiform needle for the Clean Needle Technique

### E. Other infection control measures

Routes of transmission include direct infection (contiguous infection), droplet infection (dust-borne infection), and indirect transmission (by fomites). Preventive measures should include the use of masks when needed, timely replacement of white coats and curtains, disinfection of the patient's environment, and timely disinfection of the dials and electrodes of measuring instruments and low-frequency therapy apparatuses. Used needles, cotton balls, and other equipment should be placed in a special container for medical waste immediately after use and discarded. Kidney basins and culture dishes contaminated with blood should be washed, soaked in an enzymatic detergent solution, rinsed, and then sterilized. It is recommended that disposable products, such as kidney basins, culture dishes, sheets, and pillowcases, should be used wherever possible and changed and discarded for each patient.

Before receiving acupuncture or moxibustion treatment, patients take off their socks and wear slippers. The number of bacteria on the surfaces of slippers, where their soles come in contact, is larger than generally recognized. Slippers that are not washable should be disinfected with alcohol or ultraviolet light.

Practitioners should be vaccinated against hepatitis B as a preventive measure, receive regular monitoring of their hepatitis B antibody titer, and if necessary, receive a booster dose.

## 4. Management of equipment

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With advances in technology, a large number of medical engineering devices have been developed for treatment and measurement. For optimal use of such devices, proper understanding of the principles, and proper handling, maintenance, and management are necessary.

Attention should be paid to electrical, mechanical, chemical, thermal, and optical safety. In particular, measures to prevent the flow of electric current from equipment into the human body are necessary, and safety standards for facilities and equipment have been established [35].

### A. Protection against electric shocks

The use of a hospital grade mains socket outlet for protective grounding and mains plug (3P plug) is essential. In acupuncture and moxibustion treatments involving the use of electroacupuncture therapy devices and electrodes, it is necessary to take protective measures against electric shocks (macro-shock and micro-shock). Electroacupuncture therapy devices connected to the mains are well

designed to prevent current leakage, and current flows through an earthing electrode when and if an accident occurs. Therefore, to use a device connected to the mains (i.e., not battery-operated), it is essential to use a 3P plug and ensure that the device is connected to earth [35]. Electroacupuncture therapy, which is performed with needles directly inserted into the body, is more likely than transcutaneous electrical stimulation to cause micro-shock (current flow into the body) if the device is faulty. If there is no hospital grade mains socket outlet (3P) built in the wall and the device is connected to an outlet for a plug with two identical flat prongs (2P), the earth conductor must be grounded through the earth terminal of the 3P-2P relay.

**B. Classification of medical devices**

The revised Pharmaceutical Affairs Law, which went into effect in 2005, classifies medical devices into general medical devices (Class I), controlled medical devices (Class II), and specially controlled medical devices (Class III and IV), based on the risk to the human body if an adverse effect or dysfunction occurs. The risk to the human body is lowest with Class I devices and highest with Class IV devices, with adverse events due to Class IV device malfunction being potentially life-threatening [36].

Medical devices that require special expertise and skills in their management are designated as "medical devices requiring special maintenance and management" by the Ministry of Health, Labour and Welfare (MHLW), regardless of classification. These include 4,044 medical devices (Class I, 1,195; Class II, 1,785; Class III, 1,064) in MHLW Notification No. 71 and 1,182 medical devices in MHLW Notification No. 78.

General medical devices classified as Class I include acupuncture and moxibustion devices such as reusable filiform needles, non-active contact needles, single-use finger protectors, reusable finger protectors (fingertips), and natural/synthetic rubber gloves for tests and examinations.

Controlled medical devices classified as Class II include many medical devices such as electronic sphygmomanometers, sterilizers (e.g., autoclaves), phototherapy devices (e.g., infrared therapy devices), low-frequency therapy devices, acupuncture point locators, single-use filiform needles, and acupuncture kits. Specially controlled medical devices classified as Class III or IV include semiconductor laser devices and helium-neon laser devices.

**C. Inspection and repair of equipment**

If abnormal operation of a device is detected in routine maintenance and inspection, the device should not be used especially if a fault, breakage, or deterioration is thought to be the cause of the abnormality, and operation should be checked again after inspecting the items recommended in the

instruction manual. If the device still does not operate normally, a repair is needed. To repair such a medical device, the device must first be classified as "a medical device requiring special maintenance and management" or "medical device other than those requiring special maintenance and management". Therefore, the repair of the device should be contracted out to a repairer that has been certified under the Pharmaceutical Affairs Law. An attempt must not be made to repair or improve a medical device based on one's own judgment because it may make the device less safe and lead to an accident.

**5. Needle quality** [37)]

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Under the revised Pharmaceutical Affairs Law [38)], which went into effect in 2005, single-use filiform needles have been classified as Class II medical devices (controlled medical devices). With the revision of the law, JIS T 9301 [7)] (March 25, 2005) established the performance standards for these needles.

This standard specifies the various requirements for single-use, disposable filiform needles such as physical requirements (needle shaft materials, lubricants, appearance, cleanliness), chemical requirements (limits for acidity and alkalinity of extracts, limits for extractable metals), dimensional tolerance (appearance, wire diameter tolerance, needle length tolerance), performance (pull-out strength), validation of sterilization, packaging, and labeling. Although the quality of needle products varies from manufacturer to manufacturer, the quality of JIS-certified, single-use filiform needles is assured within a specified range. Moreover, single-use filiform needles have been designated "controlled medical devices (MHLW Notification No. 112 of 2005)". As a general requirement, controlled medical devices are required to meet both performance standards and risk management standards. Therefore, the medical devices must be certified by a third-party certification body registered to the MHLW (third-party certification system), instead of by MHLW itself. For manufacturers of the medical devices, the certification requirement is to meet the standard for the quality management system (QMS). For marketing authorization holders, good quality practice (GQP) specifies the appropriate handling of complaints and ensures the maintenance of the quality assurance system in the company. In addition, the post-marketing safety management standard (good vigilance practice: GVP) requires the manufacturers to determine whether or how product-related malfunction occurs, for proper use of the product. Thus, the manufacturers of single-use filiform needles already on the market, including imported products, are supposed to be responsible for their quality and safety as JIS-certified controlled medical devices, under the revised Pharmaceutical Affairs Law.