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Foreword
Kampo Medicine: A Systems Approach
Hiromichi Yasui

Japanese Acupuncture - Current Research
Effects of Acupuncture Treatment on Osteoarthritis of the Knee
Masato Sato

Kampo Medicine - Current Research
Effects of *Boiogito* on Osteoarthritis of the Knee
Hiromichi Yasui

Clinical Report 1 (Japan)
Case Report: Treatment of a Patient with Peripheral Facial Palsy Associated with Sequelae Low Frequency Electoacupuncture
Keishi Yoshikawa, et al.

Clinical Report 2 (Japan)
A Case in which *Shakanzoto* Proved Markedly Effective in a Patient with Arrhythmia
Takao Namiki

Clinical Report 3 (Japan)
Treatment of Obesity with *Bofutsushosan*: Obesity is Inflammation
Yoshiyuki Ishizuka

Clinical Report (Europe)
Case Report: Menopausal Syndrome
Ulrich Eberhard

Introduction of Japanese Acupuncture
Considering the Therapist's Hand (3)
Shuichi Katai

Medical History in Japan
Japanese Acupuncture and Moxibustion under the Rule of GHQ after World War II (3)
Takako Okutsu

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Quality Of Life
OMINEDO

A good motive creates a selfless devotion.

"I just want my customers to feel better, body and soul. Just to see their faces light up with hope and happiness, I'd do anything," remarks Masao Tsuji, President of Ominedo Pharmaceutical Industry Company. He visits various sites where raw herbs and substances for use in their Kampo products are picked. And he believes this is the tradition Ominedo had maintained for over a century now since the company was founded in 1900.

The same philosophy is applied in handling the numerous high-quality formulas created at their labs where highly advanced scientific and pharmacological researches are conducted. The company's state-of-the-art facilities that comply with GMP standards turn out various extracts to be incorporated into their pride products.

"Every merchandise is the by-product of our sincere devotion to delivering a lineup of products that not only work for the customers' body, but also bringing peace of mind as well," Tsuji concludes, "delivering the right product to customers who appreciate our knowledge and devotion is our ultimate goal."

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TABLE OF CONTENTS

1 **Foreword**
Kampo Medicine: a Systems Approach Hiromichi Yasui

2 **Japanese Acupuncture - Current Research**
Effects of Acupuncture Treatment on Osteoarthritis of the Knee Masato Sato

8 **Kampo Medicine - Current Research**
Effects of Boiogito on Osteoarthritis of the Knee
Hiromichi Yasui

14 **Clinical Report 1 (Japan)**
Case Report: Treatment of a Patient with Peripheral Facial Palsy Associated with Sequelae Low Frequency Electoacupuncture Keishi Yoshikawa, et al.

20 **Clinical Report 2 (Japan)**
A Case in which Shakanzoto Proved Markedly Effective in a Patient with Arrhythmia
Takao Namiki

23 **Clinical Report 3 (Japan)**
Treatment of Obesity with Bofutsushosan: Obesity is Inflammation Yoshiyuki Ishizuka

27 **Clinical Report (Europe)**
Case Report: Menopausal Syndrome Ulrich Eberhard

29 **Introduction of Japanese Acupuncture**
Considering the Therapist's Hand (3) Shuichi Katai

31 **Medical History in Japan**
Japanese Acupuncture and Moxibustion under the Rule of GHQ after World War II (3)
Takako Okutsu

MISSION

To disseminate peer-reviewed information on the use of acupuncture and herbs, and integration with western medicine, based on research from an international perspective; thereby stimulating further research, application of documented therapeutic measures; and facilitating dialogue among health care practitioners worldwide.

Foreword
Kampo Medicine: A System Approach

In Japan, the national health insurance program covers the use of 148 types of Kampo extract formulations. More than half of these prescriptions are formulated as described in the classic medical texts *Shang Han Lun* (On Cold Damage) and Jin *Gui Yao Lue* (Synopsis of Prescriptions of the Golden Chamber).

The Japanese people have traditionally used these prescriptions to treat a wide range of diseases. In contrast to Chinese TCM, which provides specific prescriptions for individual conditions, Japanese Kampo medicine has always used the classical prescriptions as the basis for treating a wide range of diseases, and then adjusted that treatment for specific situations. This pattern is still being followed today. Conditions that did not respond to these prescriptions have been handled by using prescriptions that were developed or augmented later. Experience with this model of medical treatment has been highly influential in Japan, and is well-documented through research and case reports.

One of the most predominant characteristics of Kampo medicine is the Japanese system that includes this accumulated experience, centering around the classic prescriptions. This paradigm is very different from specific instances or series of instances. For example, the effectiveness of ginkgo in preventing and treating cerebrovascular disease by improving peripheral blood flow. A variety of physical abnormalities are recognized under Kampo medicine, and appropriate treatment methods have been developed in response. But although the methodology of this approach differs from that of Chinese or Korean medicine, Kampo medicine operates within the same system as these two other forms of Asian medicine.

Research into the preparation of extracts of Kampo drug formulations began in Japan in the 1940s. This research was completed in 1950, and sales in the general marketplace began in 1957. Products include the sources for some of the extract formulations sold at present in the US. Extracts for medical use were subsequently developed in Japan in 1976, and qualified for health insurance coverage. Such Kampo extract formulations are prescribed by physicians in Japan today.

All Japanese physicians are currently educated under a system based on Western medicine and they provide medical treatment within that context. In terms of the practice of Kampo medicine, this situation has both advantages and drawbacks. One advantage is that by viewing the patient and disease from the perspective of Western medicine, we can verify the position of Kampo therapy in comparison to Western medical standards. A drawback is that actual clinical practice may not adhere closely enough to the traditional philosophy of this very traditional form of medicine. Thus, Japanese physicians who practice Integrative Medicine must be proficient in both Western and Asian medical systems.

It is not necessary for the U.S. to take a path identical to the one followed in Japan. However, I believe that the Japanese model can create a useful new perspective for U.S. practitioners who choose not to limit themselves to traditional Chinese and Korean medicine. This broader perspective can result in more effective medical treatment in this country.

Hiromichi Yasui
Japan Institute of TCM Research

Japanese Acupuncture - Current Research

Effects of Acupuncture Treatment on Osteoarthritis of the Knee

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Introduction

Today, Japan boasts one of the longest average lifespans in the world, but only 60 years ago it was considered an accomplishment in Japan to live to the age of 50. This recent sudden increase in average lifespan, both in Japan and around the world, means that the profile of disease in our modern age is very different from that when the ancient medical texts on acupuncture were written. It seems likely that diseases associated with joint deformation, muscle atrophy, and a general reduction in the capacity to heal were less common at that time than they are in modern society. That being the case, we need to take a new look at the degenerative diseases that we see so often around us today.

In these pages we will discuss osteoarthritis of the knee, a typical example of degenerative disease that acupuncturists are often asked to treat. We will present research that offers perspectives for effective treatment regimens, and provide information on indications for acupuncture treatment and the limitations of that treatment.

Research to date

Across the ages, both in Asia and in the West, there have been numerous books and articles stating that acupuncture is "very effective." However, frank and objective commentary is rare.

Among the relatively recent reports on treating osteoarthritis of the knee in Japan, we have Hirohisa Yoneyama's comments. In the 1980s he stated, "Conditions such as osteoarthritis require prolonged medical treatment, and in such cases, acupuncture treatment can sometimes be used as adjunct therapy. However, from the viewpoint of medical management, chronic disease is very difficult to cure completely, and only after the acupuncturist and the patient have developed a relationship of trust and mutual cooperation should acupuncture therapy be initiated for joint pain." Yoneyama offers an objective assessment of treatment methods and of the limitations of acupuncture treatment.

Masato Nakao noted that, "Acupuncture is often quite effective in relieving pain ... and can be extremely useful in treating pain that does not respond to drug therapy. However, acupuncture appears to be almost completely ineffective in preventing or relieving muscle atrophy and joint contracture, which is probably one of the reasons for the generally poor therapeutic outcome for acupuncture in the treatment of advanced osteoarthritis of the knee. There are thus some situations in which other treatment options should be aggressively pursued." Nakao, while supporting the usefulness of acupuncture, believes that therapeutic effectiveness is reduced by the presence of advanced osteoarthritis and muscular atrophy, and recommends countermeasures involving the concomitant use of rehabilitation medicine and other indicated therapies.

The report by Hideki Ochi and colleagues, presented in this issue, describes their tests to determine the scientific validity of the opinions expressed by acupuncture practitioners.

1. The importance of adjunct use of exercise therapy

Research design

(*Fig. 1 Treatment administered, treatment period, diagram of acupuncture points*)

Ochi and colleagues found that the effectiveness of acupuncture treatment for osteoarthritis of the knee was increased by the adjunct use of exercise therapy (quadriceps training). They proved this by performing the comparative study described below. Subjects were patients who had been diagnosed with osteoarthritis of

the knee. Enrolled subjects were divided into three groups: one group receiving acupuncture only, one group receiving acupuncture in combination with exercise therapy, and one group receiving exercise therapy without acupuncture. Researchers compared the effects of each of these treatments, using the indicators of extended muscle strength and joint function. They scored joint function in four different categories: ability to walk on a flat surface, ability to climb stairs, angle of knee flexion, and swelling of the knee joint, from 100 points (normal) to 0 points.

Subjects: Patients diagnosed with primary osteoarthritis of the knee.

48 patients (48 joints) in whom the extent of joint deformation was considered early-stage or mid-stage on the basis of x-ray findings.

Mean age was 64 ± 7.0 years.

Of these patients, 18 were treated with acupuncture alone, 20 with acupuncture and exercise therapy, and 10 with exercise therapy alone; and results were analyzed.

(Fig. 2 Bar Graph of Joint Function, Fig. 3 Bar Graph of Muscle Strength).

The results showed a statistically significant increase in extended muscle strength in the groups treated with exercise therapy, but not in the group treated with acupuncture alone.

The groups treated with acupuncture showed obvious improvement in overall knee function, while the group treated with exercise alone showed no clear improvement in this area.

Those findings indicated that a combination of acupuncture and exercise therapy provides a more favorable prognosis for osteoarthritis of the knee than either acupuncture treatment or exercise therapy alone.

2. Extent of knee defromation and the effectiveness of acupuncture therapy

Research design

After determining that a combination of acupuncture treatment and exercise therapy was effective for osteoarthritis of the knee (see above), Ochi and colleagues suspected that treatment effectiveness might vary for different levels of joint deformation. To confirm this, they performed the following comparative study. Their selected subjects were patients diagnosed with osteoarthritis of the knee, in whom knee joint x-ray findings showed initial deformation ranging from barely detectable to visible loss of tibial joint surface. Knee joints were classified by disease stage in order of severity ("early stage", "mid stage", and "late stage"). Therapeutic effects were investigated and compared for each of those stages.

Subjects: 25 patients with primary osteoarthritis of the knee (25 joints).

Mean age was 66 ± 9.0 years.

The subjects were early stage in 10 cases, mid stage in 7 cases, and late stage in 8 cases. Major findings were analyzed.

(Fig. 4 Bar Graph of Joint Function, Fig. 5 Bar Graph of Muscle Strength)

Results confirmed that knee function and strength were both reduced with increasing deformation. Acupuncture treatment in combination with exercise therapy produced some improvement in both strength and function, regardless of the extent of deformation present. However, the more severe the deformation, the greater the extent of loss of function and muscle strength at treatment baseline. The severe cases showed some improvement, but not enough to allow the patients in that category to return to daily activities. This makes it particularly important to explain the limitations of acupuncture therapy to patients who show pronounced joint deformation (informed consent) before initiating treatment.

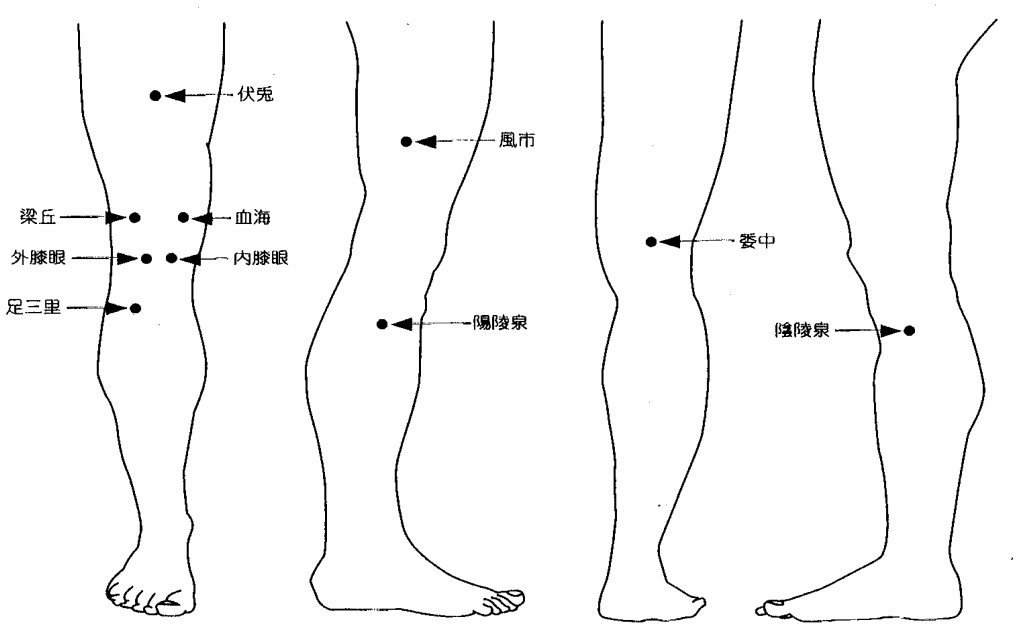
Analysis of results

This report is based on the results of treatment performed for only one month, a relatively short period for research on a chronic condition. However, the study illustrates the following points regarding the

treatment of osteoarthritis of the knee:
(1) The combination of acupuncture treatment and exercise therapy (quadriceps training) appears to be more effective than acupuncture alone, and
(2) In cases of pronounced deformation of the knee, it is unlikely that acupuncture will provide clinically significant improvement in either joint function or muscle strength.

Ochi and colleagues emphasized the importance of obtaining fully informed consent before giving acupuncture treatment to patients with advanced deformation of the knee joint. They do not specifically discuss methods of obtaining informed consent.

We understand that while acupuncture treatment can be useful for managing degenerative diseases associated with aging, acupuncture is rarely curative for such conditions. It is important to explain this clearly to patients. In Japan the middle-aged and elderly account for a high percentage of acupuncture patients, many of whom continue acupuncture treatment for 10 or 20 years, or even longer, as part of their personal self-care program. Fumihiko Shirota stated that, "Health usually deteriorates with age, and patients come in with the objective of not getting any worse after their first visit. But actually that is an unrealistic goal."



Treatment interval: In general, once or twice a week
Needle used: 40 mm 18 gauge stainless steel
Needling locations and techniques
Points: Sparrow-pecking technique at ST32, SP10, ST34, EX-LE4, Outer Eye of the Knee, GB31, ST36, SP9, GB34, and BL40.
・10 minutes of SSP (silver spike point) therapy (compression wave, 3 to 20 Hz) applied to the rectus femoris muscle and the medial joint space.
Note: (SSP therapy): A form of low frequency electrotherapy in which conical shaped silver-plated electrodes (SSP electrodes) are positioned on the surface of the skin, secured with adhesive tape, and used to deliver a low frequency electrical current.
Exercise therapy
Quadriceps training (patella setting exercise and straight leg raises), performed in sets of 20 to 30 repetitions, using 1 to 2 kg weights, 3 sets per day.
Treatment period: 4 weeks. In general, treatment is performed one to two times a week.

Fig. 1 Treatment Method

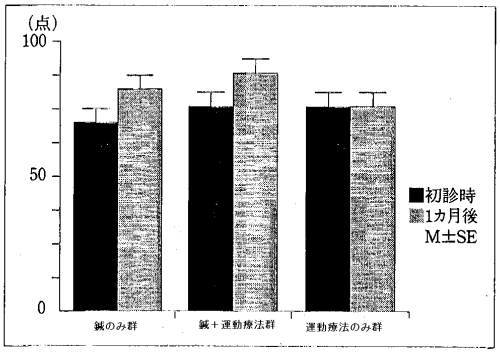


図２　膝関節機能

Fig. 2 Knee Joint Function
Group treated with acupuncture only
Acupuncture + Exercise therapy
Exercise therapy only
Initial visit
After 4 weeks

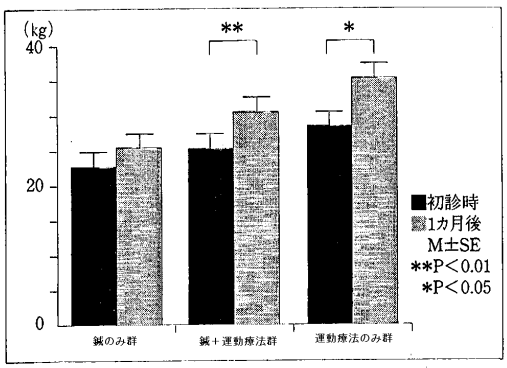


図３　膝伸展筋力

Fig. 3 Knee Extension Strength
Group treated with acupuncture only
Acupuncture + Exercise therapy
Exercise therapy only
Initial visit
After 4 weeks

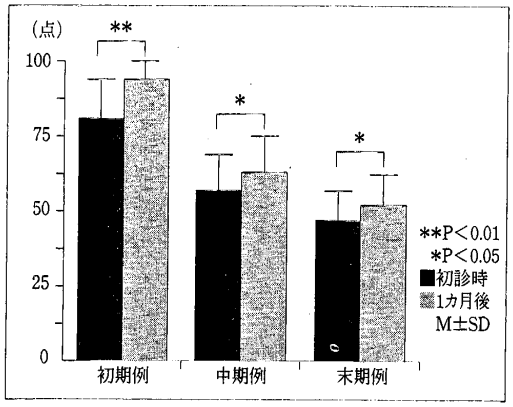


図４　膝関節機能

Fig. 4 Knee Joint Function
Early stage group
Mid stage group
Late stage group
Initial visit
After 4 weeks

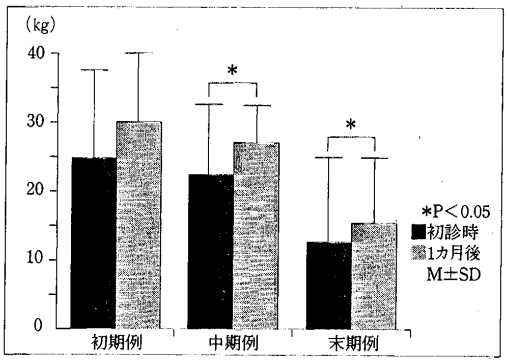


図５　膝伸展筋力

Fig. 5 Knee Extension Strength
Early stage group
Mid stage group
Late stage group
Initial visit
After 4 weeks

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- Literature cited
  Title: Clinical study of genicular osteoarthritis: Investigation into pathology and indications for acupuncture treatment
  Author: Hideki OCHI
  Affiliation: Clinical Acupuncture Medicine Dept. II, Meiji Acupuncture University
  Published in: Acupuncture OSAKA, p. 33-39, Vol. 18 No. 4, 2002

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1. Pain, ability to walk	
Able to walk a distance of 1 km or more. Ordinarily no pain, experience of pain on exercise acceptable.	30 points
Able to walk a distance of 1 km or more, pain present.	25 points
Able to walk at least 500 m but less than 1 km, pain present.	20 points
Able to walk at least 100 m but less than 500 m, pain present.	15 points
Able to walk indoors, or less than 100 m, pain present.	10 points
Unable to walk.	5 points
Unable to stand.	0 points
2. Pain, ability to go up and down stairs	
Able to go up and down stairs freely, no pain.	25 points
Able to go up and down stairs freely, no pain. Need to use handrail, no pain.	20 points
Need to use handrail, pain present. Need to go step by step, no pain.	15 points
Need to go step by step, pain present. Need to use handrail and go step by step, no pain.	10 points
Need to use handrail and go step by step, pain present.	5 points
Cannot go up and down stairs.	0 points
3. Angle of knee flexion and ankylosis/extreme joint contracture	
Able to sit in a kneeling position with legs folded under the body.	35 points
Able to sit in a kneeling position with legs to the side, or to sit cross-legged.	30 points
Knee can bend at an angle of at least 110°.	25 points
Knee can bend at an angle of at least 75°.	20 points
Knee can bend at an angle of at least 35°.	10 points
Knee can bend less than 35°, or ankylosis/extreme joint contracture present.	0 points
4. Swelling	
No swelling or fluid	10 points
Occasional needle aspiration required	5 points
Frequent needle aspiration required	0 points

Table Clinical Course of Osteoarthritis of the Knee (according to Koshino)

Extent of deformation	No. of cases	Assessment method	Initial visit	→	4 weeks	Difference
Early stage group	10 patients	JOA score	82.0 points	→	94.5 points	12.5 points improvement
		Knee extension strength	25.7 kg	→	29.7 kg	4.0 kg improvement
Mid stage group	7 patients	JOA score	57.9 points	→	65.5 points	7.6 points improvement
		Knee extension strength	22.4 kg	→	27.3 kg	4.8 kg improvement
Late stage group	8 patients	JOA score	43.8 points	→	53.1 points	9.3 points improvement
		Knee extension strength	11.3 kg	→	15.9 kg	4.6 kg improvement

Early stage: Images show only bone spurs and osteosclerosis, with weight-bearing x-ray showing no narrowing of the joint space.
Mid stage: Narrowing or elimination of the joint space can be observed.
Late stage: Friction wear or loss of tibial joint surface evident.

Table

Extent of deformation	No. of cases	Assessment method	Initial visit	→	4 weeks	Difference
Group treated with acupuncture only	18 patients	JOA score	71.1 points	→	85.6 points	14.4 points improvement
		Knee extension strength	22.6 kg	→	24.8 kg	2.2 kg improvement
Acupuncture + Exercise therapy	20 patients	JOA score	81.0 points	→	92.3 points	11.3 points improvement
		Knee extension strength	25.3 kg	→	31.5 kg	6.2 kg improvement
Exercise therapy only	10 patients	JOA score	80.0 points	→	81.0 points	1.0 points improvement
		Knee extension strength	28.7 kg	→	34.9 kg	6.2 kg improvement

* All groups except for those receiving acupuncture alone showed a statistically significant increase in knee extension strength ($p < 0.05$ - 0.01).

Kampo Medicine - Current Research

Effects of Boiogito on Osteoarthritis of the Knee

Hiromichi Yasui
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Osteoarthritis of the knee is a generative disease that occurs with age and an extremely large number of people suffer from this disease, not only in the U.S., but also in other countries. The disease is treated with many different therapies according to the severity of impairment. In recent years, herb medication has been in the spotlight as an effective treatment for the disease. In Japan, clinical research with the use of herb medicines has been carried out for several decades to treat osteoarthritis of the knee and there are some papers already released. Among the medicines studied, *boiogito,* is now gaining attention.

Boiogito is one of prescription of a holy scripture, Jin Gui Yao Lue (Essentials from the Golden Cabinet), and is described as it is effective for "Fushitsu (Wind-Damp). "Fushitu (Wind-Damp)" means a group of diseases, such as articular rheumatism and neuralgia with pain as a main symptom in the body. The book does not mention that *boiogito* is specially responsive to pain in the knee joints, but people of later age have referred to this book and used this formula for pain in knee joints.

Most recently, the research on the effect of *boiogito* on osteoarthritis of the knee has emerged, in which a clinical epidemiological method was used. The research will be introduced below with citations of preceding research.

Experience of Keisetu OTSUKA

It was Keisetsu OTSUKA (1900-1983) that used the formula of *boiogito* for knee diseases for the first time. In his paper published in 1954, "About *boiogito,*" accurate therapeutic uses of *boiogito* were mentioned, including the application to pain in knee joints. The descriptions in the paper are as follows[1]:

> The case of using *boiogito* is seen more often in "so-called" rich women of leisure than in men. This is also true of women flabby with water. Many of these women have the desire to get thinner. These women feel heavy themselves, are languid in motions, such as standing up, sitting down, etc., and do not like to do cleaning and cooking, or rather think it too much trouble to do these things. When going out, these persons use a car without physical activities and thus they gain more fat. They eat a small amount of food and can go without having one meal. Many of these persons like hot tea. They have bowel movements almost every day but often have a small amount of menstrual discharge, or complain of irregularity. They have hyperhidrosis and dripping sweat during the summer.
>
> A large proportion of women of this type start complaining of pain in the knee joints when exceeding the age of 50. In the evening, they have edemas in the lower extremities and their shoes or Japanese socks become too tight. Abdominal examinations reveal swelling of the abdomen, which is flaccid with no resistance and pain.

Otsuka came to the above conclusion from his own clinical experience and used *boiogito* for many cases of osteoarthritis of the knee. In later years, he said that he found a clue in the writing of the doctor who was active 150 years ago and arrived at a conclusion, that is, "Patients have the soft and lax skin. This is not an edema but water flown into the surface of the body. [snip] Many of these patients are women who became obese before or after the age of 20 years [omit the rest.][2] Then Otsuka continued: "I interpreted this writing as "effective for women flabby with water" and used *boiogito*." He further said: "This is my own thinking and other people will get other hint from the writing. So, I want people of later days not to adhere to my interpretation and want them to find something new from the original writing."

Despite Otsuka's desire, the interpretations made later of *boiogito* have not deviated from this category. *boiogito* has been used for osteoarthritis of the knee on the basis of Otsuka's interpretation. There has been some research conducted on the effect of *boiogito* on osteoarthritis of the knee and many cases have been reported. *Boiogito* was shown to be clinically beneficial. Typical cases will be introduced below.

Sample of preceding research

Otani, et al. reported[3] that they administered *boiogito* alone to 137 patients with osteoarthritis of the knee (male 20, female 117) and followed up for 6 months. Pains were assessed in 5 stages by visual analogue scale with the results showing improvement in 45 patients (32.8%) after 4 weeks and in 59 patients (43.1%) after 6 months.

Konari, et al. reported as follows[4]: They performed an analysis of 2,886 patients out of 7,088 patients with osteoarthritis of the knee that visited Konari's medical institution during January 2001 to March 2006. *Boiogito* was used in 1,009 patients. The breakdown of these patients was 330 females and 679 males with an age range from 25 to 95, an average of 64.1 years old. The duration of the use of *boiogito* was 0.5 to 75 months with an average of 4.4 months. The treatment effects showed improvement in 753 cases (74.6%), remained unchanged (7.5%) and not-known (10.6%). There was no difference in the improvement ratio among age, sex and duration.

Noguchi, et al. reported the following[5]. They made a controlled study with the subjects being 84 patients with primary osteoarthritis of the knee who were diagnosed as having edemas and whose roentogenographic images within 6 months after the enrollment were assessed as not over Stage III using the Hokudai Scale. The subjects were divided into the following three groups and administered the assigned medication for a period of 8 weeks: a group of *boiogito*, a group of *boiogito* in combination with NSAIDs, and a group of NSAIDs.

Improvements in floating patella were observed with 80.0% in the *boiogito* group, 96.4% in the *boiogito* and NSAIDs group, and 57.9% in the NSAIDs. The concomitant group of *boiogito* with NSAIDs showed a better improvement ratio than the NSAIDs alone group. Similar levels of improvement were shown in swelling in soft parts of the knee and a sensation of heat.

There was a study conducted on the use of *boiogito* for knee disease other than osteoarthritis of the knee. Otsuka, et al. released a report that they performed arthroscopic meniscectomy for symptomatic discoid lateral meniscus and used *boiogito* for the patients who then had hydrarthrosis, and the results were favorable[6].

New study by Mizuno, et al.

With the above studies of the past, Mizuno et al. conducted an epidemiological study using multivariate analysis in order to objectively grasp the effects of *boiogito* on osteoarthritis of the knee. The results were quite different from common knowledge and had clear indicators that can be used directly at clinical sites.

1. Subjects and methods

The subjects of the study were patients aged 60 or above who were complaining of persistent knee pain for 3 months or more, diagnosed as having osteoarthritis of the knee, and started the therapy of *boiogito*. The period of the treatment was four weeks.

With consent from each patient prior to the commencement of the treatment, questions were asked about patients' living habits, general symptoms before and after the treatment, and symptoms of the herb medicine to make investigations of symptoms and signs. General questions asked of patients (general questionnaire sheet) included 66 items about systemic condition: mood, sleep, cephalic symptom, thoracic symptom, dermal condition, dietary habit, oral condition, drinking and eating, hand and feet, lumbar, shoulders, muscles, abdominal symptom, urine and stools, and menopausal syndrome. And 24 questions were made to the attending physicians concerning physical findings, pulsation, abdominal findings, tongue condition, complexion, and complications.

Before and after the treatment, semiquantitative questions specific to the knee condition were provided to the patients, using a written questionnaire. The questions covered 11 items: severity of pain (visual analog scale: VAS), region of pain, duration of pain, presence of swelling, history of drainage of fluid from the knee, motion to cause pain, whether to able to sit on the heels or not, walking distance, necessity of supporting tool for walking, whether able to descend steps, analgesic now in use, etc.

The attending physicians made semiquantitative examinations (4 steps) on the five items, i.e., presence

of a sensation of heat, presence of edema, varus deformation (distance between both knees), and angle of knee extension.

Treatment was performed with *boiogito* at 7.5g / day in two doses in principle. Antiphlogistic analgesic was used as needed as far as possible. For serious cases, regular administration of NSAIDs was given orally, for which case the evaluation of the herbal effect was focused on whether the amount of NSAIDs could be reduced or not. Before the start of the administration (within a month) and during the course of the herb administration, new therapy had not been given (cool compress, rehabilitation, manipulative treatment, intraarticular injection, etc.).

The subjects were 64 patients (male 7, female 57) with a larger proportion of female (89.1%). Patient profile is shown in Table 1 below. With regard to BMI, the values before and after the administration were indicated.

Age	72.9±8.9 years
Height	152.7±7.5 c m
Weight before	58.1±9.1 k g
Weight after	57.9±9.1 k g
BMI-before	24.9±3.2kg/㎡
BMI-after	24.8±3.2kg/㎡
Systolic BP	132.9±15.2mmHg
Diastolic BP	76.3±9.7mmHg
Pulse	72.8±9.5/min

Table 1 Patients Profile

2. Efficacy Assessment and rates

Similarly with general accumulation case studies, one of the objectives of this study was to see the efficacy rates of *boiogito* in osteoarthritis of the knee. The other objective was to identify the effectiveness.

Effectiveness was graded as “markedly effective”, “moderately effective”, “slightly effective”, and “poor.” This was administered by persons who were not involved in the treatment on the following three points: 1) Visual Analog Scale (VAS) records taken by the patient for the knee pains before and after the treatment, 2) self-assessment on improvements in the knee condition, and 3) physician’s assessment.

The results are shown in Table 2. Moderately effective or above was 31.3% with 57.8% indicating slightly through markedly effective. These results are not greatly different from those of other studies above and it has been confirmed that this medication has certain levels of effects on this disease that occurs with age.

Markedly effective	9.3%
Moderately effective	21.9%
Slightly effective	26.6%
Poor	42.2%

Table 2 Efficacy ratio of *boiogito* in osteoarthritis of the knee

3. Effective factors and ineffective factors

The other purpose of the study was to identify the factors that allow effective functioning or ineffective functioning of the medication using a multivariate analysis. The materials used for the analysis were vast volumes of investigational items, VAS recorded by patients, degree of improvement in subjective symptoms, and findings of physical examinations by the attending physicians. These symptoms and signs were investigated to find the factors in the group with effectiveness and the group without effectiveness.

The items in Table 1 were divided into an effective group of markedly effective + moderately effective (20 patients, 31.2%) and an ineffective group of slightly effective + poor (44 patients, 68.8%) for statistical analysis. The results indicated that effective factors of significance were “less than 1 year of pain duration” (odds ratio 3.2) and “presence of swelling in the knee joints” (odds ratio 3.2). Although significant differences were not observed statistically, the effective factors had a tendency of “**supporting tool is necessary for walking”** (odds ratio 8.0) and “free from insomnia” (odds ratio 4.2) (Table 3).

Study items	p value	Odds ratio	95% confidence interval
Duration of knee pains - less than one year	0.037	3.2	1.08～9.81
Presence of swelling in knee joints	0.037	3.2	1.07～9.62
Supporting tool necessary for walking	0.054	8.0	0.96～65.87
Can sleep	0.078	4.2	0.85～20.61

Table 3 Effective factors
(Markedly effective + Moderately effective vs. Slightly effective + Ineffective)

Meanwhile, ineffective factors of significance were "no sensation of heat" (odds 0.19), "BMI 25 or above before the treatment" (odds ratio 0.25), "have nocturnal urine" (odds ratio 0.28), "fatigable" (odds ratio 0.3), "BMI 25 or more after the treatment" (odds ratio 0.3). (Table 4)

Study items	p value	Odds ratio	95% confidence interval
No sensation of heat	0.009	0.19	0.06～0.66
BMI25 or more before treatment	0.023	0.25	0.08～0.82
Have nocturnal urine	0.024	0.28	0.09～0.84
Fatigable	0.037	0.3	0.10～0.93
BMI25 or more after treatment	0.047	0.3	0.09～0.98
Stomach feels heavy r stuck	0.069	0.14	0.02～1.17
Not have dry mouth	0.081	0.33	0.10～1.15
Often eat miso-soup	0.094	0.35	0.10～1.19

Table 4 Ineffective factors
(Markedly effective + Moderately effective vs. Slightly effective + Ineffective)

Conditions of age, pulsation, tongue and abdominal did not work either as an effective factor or an ineffective factor.

Table 5 shows symptoms associated with osteoarthritis of the knee that develops with the probability of 40% or above. Many of these symptoms are the targets of *boiogito*. "Feeling short of breath" and "getting hot flashes in hands and feet" accounted for 70% of all the patients. Accounting for 60% were "hands and legs/feet become numb", "sensitive to heat and cold", "mouth gets dry", "shoulders get stiff easily", "muscles cramp", "have nocturnal urine", "have a chill in the lower back", etc. Analysis was carried out on these factors, but the result showed that they are neither effective factors nor ineffective factors.

Symptoms	Symptom ratio (%)
Get short of breath	76.6
Get hot flashes in hands and feet	76.6
Hands and legs/feet become numb	68.8
Sensitive to heat and cold	67.2
Mouth gets dry	64.1
Shoulders get stiff easily	64.1
Muscle cramp	62.5
Have nocturnal urine	60.9
Have a chill in the lower back	60.9
Prefer something cold	56.2
Fatigable	54.7

Table 5 Rates of symptoms associated with osteoarthritis of the knee (40% or more)

4. Discussion by Mizuno, et al.

Gaining the results above, Mizuno, et. al. have added the following considerations: Efficacy rates of *boiogito* in osteoarthritis of the knee in this study were 57.8% for slightly effective or above and 31.3% for moderately effective or more. These results were similar to those reported in the past, not greatly different from those of other clinical studies. What was made clear in this study we4.re effective factors and ineffective factors.

In Kampo therapy of osteoarthritis of the knee, bibliographic effective factors of *boiogito* were: traditionally fair-complexioned, soft flesh, obesity trend or so-called flabby with water, fatigable, and

tend to perspire a lot. This study, however, has revealed that *boiogito* is less responsive to obesity with BMI25 or above. This result is decisively different from what was believed to be effective in patients with the constitution of flabby-with-water. It has also been revealed that it is difficult to get effectiveness of the medication in patients with the condition of lack of qi, such as fatigue and nocturnal urine. On the contrary, since either of "no mouth dry" or "no sensation of heat" are a significant ineffective factor, condition with heat could be considered as an effective factor.

It is reasonable to consider from the above results that effective factors of *boiogito* are symptoms peculiar to osteoarthritis of the knee and not *boiogito* itself.

It was also revealed that *boiogito* is effective if the duration of the disorder is within one year. If the duration becomes longer, it is less responsive. In short, *boiogito* is effective in the case of osteoarthritis of the knee with a short duration and mild severity, whereas the medication is less effective in the case of the disease which becomes serious in a short period. This is probably because joint destruction progresses and great organic changes take place.

As far as knee conditions are concerned, swelling and heat sensation are greatly benefited by *boiogito*, whereas conditions without heat were less responsive. In other words, it has clearly been shown that only swelling, like hydrarthrosis, is less effective and obvious heat conditions such as heat in joints and dry mouth are more responsive.

It has been said that weight loss can be expected as *boiogito* has an aquaretic function. In fact, there were some cases that weight was lost together with an increase in urine volume after the administration[7]. However, it is not clear if there were variances in weight before and after the use of the medication. It seems difficult to expect strong aquaretic function.

In regard to the profiles of pulsation, tongue and abdomen, effective factors or ineffective factors of significance were not observed. Age was neither an effective factor nor an ineffective factor.

What can be derived from the study

From the above, prediction can easily be made if *boiogito* is beneficial or not, from the following elements: "duration of the disease is within one year" and "BMI is 25 or below" (these were from the interview with the physician), and "a sensation of heat and swelling in knee joints" from findings of physical examinations. As the author, et al. say, the results of this study will offer substantial benefits to the scenes of actual clinical practice that have time constraints.

At the clinical sites, there are many cases in which this formula is used with an addition of prepared aconite tuber or ephedra, or in combination of Cassia Twig Tuckahoe Pill. Many clinicians say that the combination use of *boiogito* brings excellent benefits. Especially an addition of prepared aconite tuber gives further effects[8]. Nagao, et al. reported that *boiogito* added by prepared aconite tuber showed an efficacy ratio of 87.8% and is a safer and effective therapy, compared to the results of nonsteroid anti-inflammatory agents[9].

It is expected that further research on *boiogito* will be conducted. With the use of the methodology of clinical epidemiology in the research of Kampo medicine, this paper has opened a new page to clinical applications of the formula of *boiogito*. This research will greatly contribute to future development of this field.

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Clinical Report 1 (Japan)

Case Report: Treatment of a Patient with Peripheral Facial Palsy Associated with Sequelae Low Frequency Electoacupuncture

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Key words: peripheral facial palsy, acupuncture, low frequency electoacupuncture, thermography

Summary

The department of physiotherapeutics at Tsukuba University was established for the purpose of training teaching staff in acupuncture and moxibustion skills, to conduct research into physiotherapy, as well as preparation of teaching faculty. At the same time, an acupuncture and moxibustion outpatient department was established, for patients who express their wish to undergo acupuncture treatment are treated. The chief complaints of the patients are very diversified. Here we report the effects of acupuncture and moxibustion. treatment of a patient with peripheral facial palsy associated with sequelae.

Among patients with peripheral facial nerve palsy, the most frequent type is Bell's palsy. Generally, this is a condition with a favorable prognosis marked by ratio of spontaneous healing in about 70% of the cases. In this patient more than 2 years had elapsed since the onset and the patient was diagnosed in many different medical facilities with Bell's palsy, which is difficult to heal completely. A facial nerve palsy score of 24 points, pathological associated movements, facial spasms, the crocodile tears phenomenon and similar sequelae were observed. Thermography showed a temperature difference between the paralyzed and the healthy side of 0.9°C, showing a lower temperature on the paralyzed side. The purpose of the acupuncture treatment was to achieve an improvement in facial circulation and activation of the facial nerve. The method of treatment used was low frequency electroacupuncture that had been developed at this department and specifically applied for stimulation of the facial nerve (nerve pulse) and facial muscles (muscle pulse).

The facial nerve palsy score and thermography served as the means for the evaluation. The results revealed an improvement in the facial nerve palsy score and the disappearance of the temperature difference between the paralyzed and healthy sides. Further, subjectively the patient reported that she seemed to be able to move the mimic musculature more easily and experienced some relief of the crocodile tears phenomenon. Following prolonged application of low frequency electroacupuncture, improvement in facial circulation was observed, suggesting the possibility that it improves the patient's QOL.

I. Introduction of the Tsukuba University

Tsukuba University is a center, housing more than 20 joint research projects. This facility was established for the training of the teaching personnel in acupuncture and moxibustion skills and research into physiotherapy (Photo 1). Pedagogic organizations that allow their students to take the state examination for acupuncture and moxibustion skills include vocational schools, schools for the blind, centers for persons with visual impairments and universities. Since these are in charge of education other than that provided at universities, a teaching staff licence is required. This is the only facility of its kind in Japan that is authorized to issue teacher licences for people in charge of the teaching of acupuncture and moxibustion skills.

The curriculum in this facility requires two years. Each class has 20 students that are taught by four university teachers and 65 part-time lecturers. Also, in the past a large number of foreign students have been accepted.

Photo 1: Tsukuba University, School for the training of teachers of physiotherapy

The subject of the research in this facility are the basics and clinical application of low frequency electroacupuncture (Photo 2), research conducted in fields like circulatory and autonomic functions, muscle physiology etc. In this facility there is an acupuncture ambulatory practice for the practice of acupuncture and moxibustion clinics. Approximately 40 patients are treated here per day (about 8000 per year). Our concept regarding acupuncture and moxibustion is to perform acupuncture from the standpoint of western medicine. Accordingly, in cooperation with neighboring university hospitals, manual acupuncture and moxibustion treatment are performed. The center of this therapy is the low frequency electroacupuncture that was developed in this facility 30 years ago for clinical application in acupuncture anesthesia. With this technique, frequency and needling depth are determined depending basically on the pathophysiology. As a means of objective assessment of the therapeutic effects an infrared thermography device (Photo 3), a polygraph, a myograph (Photo 4) and electrocardiographs are used.

Photo 2. Low frequency electroacupuncture treatment

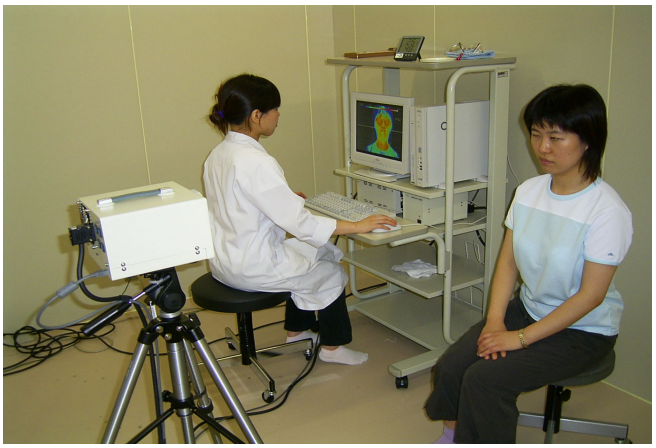


Photo 3. Scene showing thermographic measurements

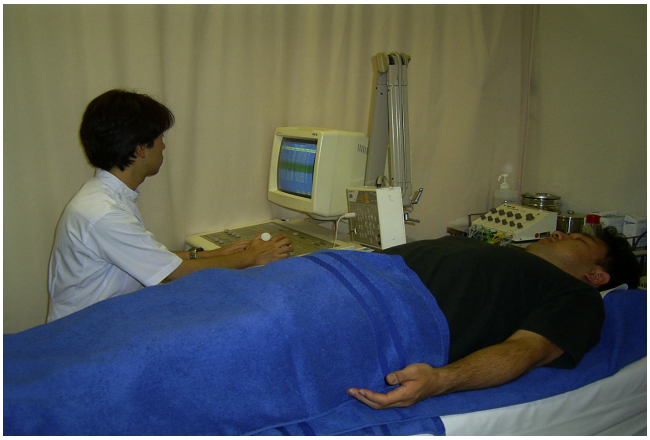


Photo 4. Scene showing electromyographic measurements

II. Case report

1. Introduction

Among the forms of peripheral facial nerve palsy, Bell's palsy is the most frequent type. Generally, this is a condition with a favorable prognosis marked by a ratio of spontaneous healing of about 70%[1]. The 40-point method established by the Japan Society of Facial Nerve Research defines cure as an improvement of more than 36 points within 6 months after onset and no obvious late effects[2]. Yet, in about 30% of the cases, pathological associated movements and other late effects remain and the approach to these symptoms has recently become a focus of attention. Sequelae include pathological associated movements, facial spasms, and the crocodile tears phenomenon. When Waller degeneration occurs during the process of regeneration of the nerve fibers, there may be excessive regeneration. This occurs because the regenerating axons do not follow the original course and is said to be irreversible[3].

We performed low frequency electroacupuncture on a patient with Bell's palsy more than 2 years after onset in the presence of clear late effects. Evaluation was based mainly on the facial paralysis score.

2. Case

Patient: 29-year old female
First visit: August 1, 2000
Chief complaint: left facial paralysis
Diagnosis: Bell's palsy
Anamnesis: The patient noticed in July 1998 that water spilled from her mouth during gargling after

rising in the morning. Upon consultation at a local neurosurgical clinic, the results of MRI and CT examinations did not show any anomalies, so that a peripheral facial nerve palsy was diagnosed. Therapeutically, prednisone was prescribed and taken over a period of 4 months. Later the patient visited the department of neurology at a university hospital. The results of the examination showed dysgeusia, auditory hypersthesia, positive testing for virus (type of virus uknown). In October of the same year, consultation was given at a nearby clinic of internal medicine. The results of the examination showed a negative seroconversion for the previously positive testing for virus. At that point low frequency treatment current therapy and mecobalamin was prescribed. The low frequency treatment was continued over a period of 7 months. In July 1999, consultation at the department neuro-otology of a university hospital. Gustation tests and hearing tests were performed, but the results of both tests were judged to be normal. In 2000, the patient started commuting to the current local clinic of neurology, performed facial massage at home, and was prescribed vitamins. At the time of onset, the patient reported the inability of left eyelid closure, spilling of water spilled from her mouth and similar symptoms, which gradually improved with the low frequency current therapy. Yet, since mild paralytic sequelae remained, she requested acupuncture treatment and thus visited our facility.

Past history: nothing particular
Family history: nothing particular
Current status: hight = 159 cm, weight = 53 kg, blood pressure = 122/68 mmHg, pulse = 68 bpm, general health status = good.
Medications: mecobalamin (vitamin B12), ascorbic acid (vitamin C), fursultiamine (vitamin B1).

Findings during first visit:
Facial paralysis score (40-point method): 24 points (Table 1)
Electroneurography (below abbreviated ENoG) value: 25.1%, gustatory anomalies (+), auditory hypersensitivity (-) pathological associated movements (+), facial spasms (+), crocodile tears phenomenon (+)

	Almost normal (4 points)	Partial paralysis (2 points)	Severe paralysis (0 points)
Asymmetry during rest	●		
Wrinkling of the forehead		●	
Lightly closing the eyelids	●		
Tightly closing the eyelids		●	
Closing one eye	●		
Wrinkling the root of the nose		●	
Puffing the cheeks			●
Show teeth saying "eee"		●	
Whistling		●	
Turn down the corners of the mouth		●	
Subtotal	12	12	0
Total	**24/40 points**		

Table 1. 40-Point method (on first examination)

Thermographic measurements:

A Fujitsu INFRA-EYE 1200 was used, the room temperature adjusted to 26±1.0°C and after a resting period of 20 minutes frontal thermographs of the face and from both sides obtained. Based on these images, the core temperature was deducted from three points: forehead, eyelids and, anterior buccal region. The average temperature of the face was calculated. This was then compared between corresponding regions on the affected and the healthy side. The results showed a temperature difference between the affected and the healthy side of 0.9°C, the temperature being lower on the paralyzed side.

3. Treatment

1) Treatment method

To improve circulation and the mimic musculature on the side of the facial nerve palsy the following treatment was performed.

(1) Facial nerve pulse

Stimulation of the facial nerve with low frequency electroacupuncture using a frequency of 1 Hz for a period of 15 minutes at TE17 and ST7. The needle at

TE17 was directed obliquely upward and inserted to a depth of about 10-15 mm, while the needle at ST7 was inserted perpendicular for about 10 mm.

(2) Muscle pulse

For stimulation of the orbicular muscle of eye GB1, for the orbicular muscle of mouth ST4 and for the venter frontalis GB14 low frequency electroacupuncture with a frequency of 1 Hz was applied for a period of 15 minutes.

Otherwise, "Taiyo", ST2, ST3 were added as required. The used needles were disposable 50-mm, No. 18 needles (Seirin Inc.). Initially treatment frequency was twice a month, which was later changed to one a week.

2) Treatment duration

August 1, 2000 to March 25, 2001 (total: 28 sessions)

4. Treatment course

Subjectively the movement of the forehead on the paralyzed side and buccal stiffness were improved and the crocodile tear phenomenon decreased occasionally on some days. Objectively, the score of 24 points obtained at the beginning of the treatment with the 40-point method (August 1, 2000) had improved by the 27th treatment (February 19, 2001) to 30 points (Figure 1). Among the 40 points for the item "puff the cheek," the initially leaking air had stopped leaking, an improvement from 0 to 2 points, and "whistling" had improved from 2 to 4 points.

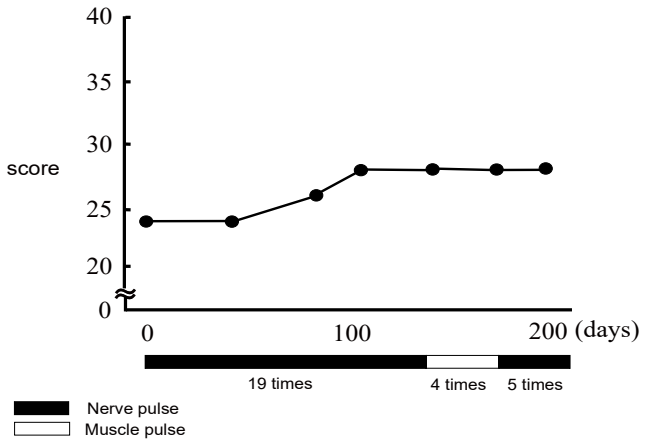
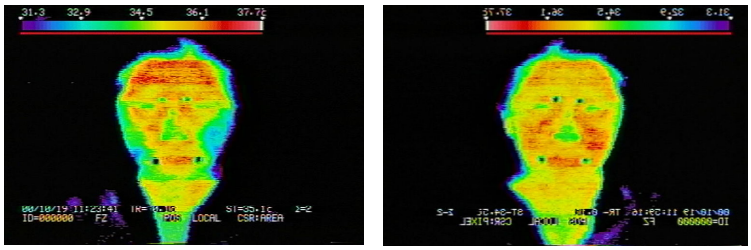


Figure 2 Variations in the score for the facial paralysis

Thermography showed that the initially measured temperature difference between the paralyzed and the healthy side of 0.9°C had improved to 0.7°C. By the 15th treatment session the temperature difference had improved to 0.8°C before treatment, so that almost no differences to the first session were observed, but after the treatment the left-right difference had disappeared (Photo 5).



Before treatment After treatment

Photo 5 Thermography of the face

Thermography of the face during the 15th treatment. During the application of facial nerve pulse stimulation a decrease in the temperature difference between the healthy and paralyzed sides before and after the treatment were observed.

5. Discussion

This was a case in which more than 2 years had elapsed since the onset and associated with clear manifest pathological associated movements. A score of 24 was obtained with the 40-point method and the ENoG value was 25.1%. Based on these symptoms we concluded that a complete denervation had occured, rendering the prognosis unfavorable. The ENoG value allows to objectively quantify the degree of the Waller degeneration and is thus significant regarding the prediction of the prognosis. Based on the relevant values obtained between the 8th and 14th day after onset of the paralysis it is possible to assess the duration probably required until recovery[4]. Since in this patient more than 2 years had elapsed since the onset of the paralysis, the score obtained with the 40-point method being 24 and the ENoG value 25.1%, we concluded that in this patient a complete recovery would be difficult[5].

The patient had, in particular, problems moving the forehead and complained of a feeling of buccal stiffness. Following the acupuncture treatment an improving tendency was reported subjectively for these symptoms. Also, among the 40 points, the item "puff the cheek" had improved from 0 to 2 points and "whistling" had improved from 2 to 4 points.

Previously air had leaked during puffing the cheeks but now air did not leak any more and the patient improved so far as to be able to whistle.

Eighty days after treatment began (the 15th treatment session) thermography showed a left-right temperature difference between the paralyzed and the healthy side before treatment, but following the low frequency electroacupuncture this left-right difference had disappeared. The correlation between peripheral facial paralysis and thermography has been examined, but reports vary widely depending on the researcher. Okamura et al. reported on the correlation between skin temperature and paralysis and indicated regarding the correlation with the prognosis, that in cases presenting with low temperature during the acute phase, a conservative treatment should lead to recovery, while patients presenting with high temperature often require surgical intervention[5]. Ishikawa et al. reported that complete recovery is unlikely in cases where the left-right temperature difference of the entire face during the first visit was more than 1°C, or else the temperature difference in the preotic buccal region 0.4°C, and moreover the score for the mimic musculature less than 20 points. Furthermore, even on the same paralyzed side skin facial temperature may be in comparison to the healthy side either high or low depending on the region[6]. In healthy people the left-right temperature difference ranges between 0.12 and 0.18°C. Any temperature difference that exceeds this range should be viewed as a pathological finding[7]. In this case the temperature difference between the paralyzed and healthy sides was 0.9°C, in the prebuccal regions even a laterality of 1.3°C was observed, so that this may clearly be identified as a pathologic finding. Moreover, Uchino et al. suggested that based on the sympathetic skin response (SSR) and thermography it may be possible to derive minimal microcircular disturbances, which may serve as an important factor affecting the prognosis[8]. The patient's thermography showed a decrease in the average temperature difference between the paralyzed and healthy sides immediately following the low frequency electroacupuncture, which allows to infer an improvement in microcirculation. Moreover, with an increasing number of treatments, this reactivity improved.

A low frequency electroacupuncture device was used for the low frequency electroacupuncture treatment method for this patient to treat the pathologically affected tissues and organs with electroacupuncture[9,10]. The stimulation was, depending on the treated areas, classified into muscle pulse, nerve pulse, intervertebral joint pulse and subcutaneous pulse; but the authors used for the treatment of peripheral facial paralysis facial nerve pulse and mimic musculatur pulse. Elsewhere "following regeneration of the synapses in the muscles electrical stimulation inhibits axon regeneration"[11,12], "low frequency stimulation may trigger pathologic associated movements"[13] has been reported. Thus, concerns have been voiced regarding the treatment of facial paralysis with low frequency electroacupuncture, but Kasuya et al. have reported that treatment of peripheral facial paralysis with low frequency electroacupuncture initiated within three weeks after onset did not delay the improvement on the paralysis[14]. In this patient no tendency towards further aggravation of the sequelae was observed, but instead, a reduction in facial stiffness and the crocodile tear phenomenon was subjectively reported. This allows one to presume that the acupuncture treatment probably improved the QOL of this patient. We think, that in the future it will be necessary to examine how such sequelae should be approached by acupuncture, increase the number of treated patients, and investigate the effectiveness of acupuncture treatment based on the results of electrophysiologic examinations as well as its effects on the patient's QOL.

6. Conclusions

We performed low frequency electroacupuncture in a patient more than 2 years after the onset of peripheral facial paralysis, in whom pharmacotherapy did not improve the symptoms. The obtained results were as follows.

1. The facial paralysis score improved from 24 points to 28 points.
2. Following low frequency electroacupuncture, the difference in the average temperature as observed with thermography between the paralyzed and healthy side, decreased.
3. Subjectively the feeling of buccal stiffness and the frequency of crocodile tear phenomenon decreased.

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Clinical Report 2 (Japan)

A Case in which Shakanzoto Proved Markedly Effective in a Patient with Arrhythmia

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Introduction

Arrhythmia is a medical condition that manifests as irregularities in the heart rhythm. It involves abnormal pulse rate and abnormal or irregular signal transmission. It is common for the patient to be aware of arrhythmia when it occurs, and for the irregular or intermittent beat to be detectable when taking the pulse at the radial artery, etc. However, there are also cases in which this condition involves other symptoms apparently unrelated to the pulse, such as chest pain or dizziness. When the patient is subjectively aware of palpitations, a characteristic symptom of arrhythmia, this awareness is most commonly experienced at the heart, on the left side of the chest, and sometimes in the abdomen. In some cases the condition is asymptomatic. On ECG, tachycardiac arrhythmia includes extrasystole, tachycardia, and atrial fibrillation, while bradycardiac arrhythmia includes sick sinus syndrome and atrioventricular block. Among these conditions, treatment with Kampo medicine is currently used in cases in which there is symptomatic arrhythmia and the patient is subjectively aware of palpitations.

In particular, Kampo medicine is the first choice for the treatment of patients who are subjectively aware of their heartbeat or complain of palpitations, and without abnormal ECG. Western medicine generally receives priority if the ECG is abnormal.

Recently we had a case in which ECG findings were abnormal and Western drug therapy was initiated, but treatment was discontinued because of adverse drug reactions. The patient was then switched to a Kampo medication, and arrhythmia was reduced. Our findings are reported below.

Patient: 63-year-old man

Occupation: farmer

Past history: hyperlipidemia

Familial history: Unremarkable

Present history: In March 1993 the patient developed chest pain unrelated to exertion. He came to the hospital for extensive cardiovascular examination. In addition to chest pain, the patient reported symptoms of occasional palpitations and of tiring rather easily.

Chest x-ray and ECG findings were normal. Echocardiogram showed slight calcification of the aortic valve, but no other abnormal findings. Holter ECG recordings showed supraventricular extrasystoles (Fig. 1) and ventricular extrasystoles (Fig. 2) occurring primarily during the day (Fig. 3, Table).

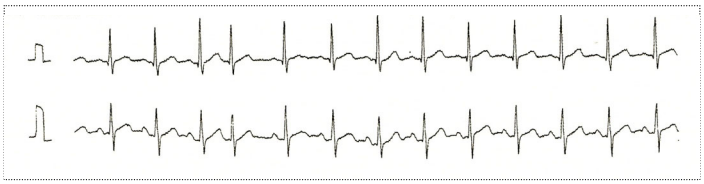


Fig. 1 Supraventricular extrasystole before treatment with *shakanzoto*

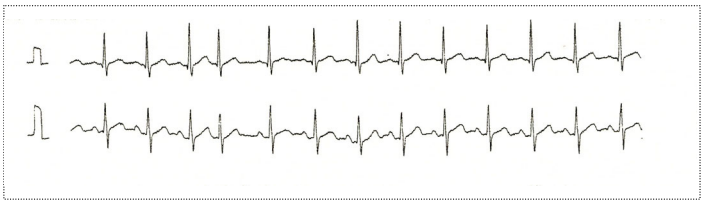


Fig. 2 Ventricular extrasystole before treatment with *shakanzoto*

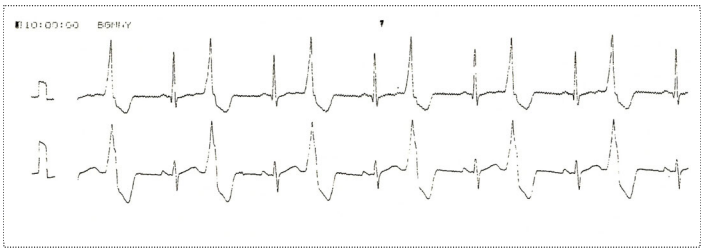


Fig. 3 Holter ECG records for heart rate and number of irregular beats (before taking *shakanzoto*)
(Upper row: supraventricular extrasystole; Lower row: ventricular extrasystole)
Horizontal axis: time; Vertical axis: heart rate or number of irregular beats

Table Results of Holter ECG findings before and after treatment with *shakanzoto*

	Before	After	Reduction rate
Total heart beats	105600/day	110771/day	
SVE	3382/day	202/day	94%
VE	12947/day	1228/day	90%
couplets	145 episodes	49 episodes	
run	103 episodes	0 episode	

SVE: supraventricular extrasystole VE: ventricular extrasystole

Present status:

Height: 162 cm
Weight: 72 kg
Blood pressure: 164/80 mmHg
Heart rate: 72 beat /min irregular beat
Conjunctiva bulbi: No anemia, no jaundice
Cardiac sounds: Systolic murmur 2LSB Levine II/IV
Respiratory sounds: No rales
Abdomen: Liver and spleen not palpable
No edema of the lower limbs

Present Status from the perspective of Oriental medicine

Pigment deposits on the face, dry skin
Pulse: Knotted, lanquidus relaxed, somewhat deep and weak, somewhat congested
Tongue: Somewhat dark red, no fur on tongue, no tooth marks, no fissures
Abdomen: No fullness of the hypochondrium, moderate resistance and tenderness on the lower right abdomen, soft lower abdomen below navel.

Clinical course

Disopyramide 300 mg/day was initially used for the treatment of arr. However, this treatment was discontinued when the patient developed thirsty of parasympathetic symptom. At that point the patient was started on 9 g/day of *shakanzoto* , a formulation considered to be effective in the treatment of conditions such as knotted pulse, palpitations, and fatigue. After taking the decoction, the patient reported that symptoms such as chest pain and fatigue had vanished. Holter's ECG, performed 1 month later, showed at least 90% reduction in both supraventricular and ventricular arrhythmia (Fig. 4, Table).

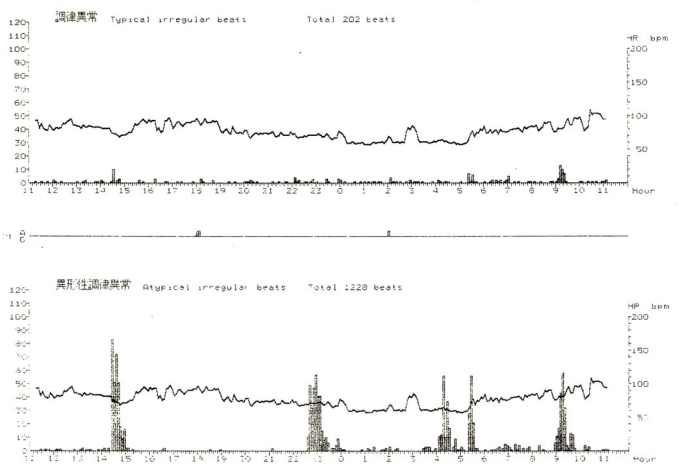


Fig. 4 Holter ECG records for heart rate and number of irregular beats (after taking *shakanzoto*)

Upper row: supraventricular extrasystole
Lower row: ventricular extrasystole)
(Horizontal axis: time; Vertical axis: heart rate or number of irregular beats)

Discussion

In this case *shakanzoto* was administered when the patient developed an adverse drug reaction to the Western drug treatment. The roasted licorice formulation proved to be remarkably effective.

Pulse diagnosis is said to have originated in Asia, spreading through the Islamic world to the West, and ancient Chinese texts on pulse diagnosis have many entries on the pulse. For example, there are entries on Rapid Pulse, corresponding to tachycardia, and on Slow Pulse, corresponding to bradycardia, as well as entries on lost beat (Irregularly Intermittent Pulse and Regularly Intermittent Pulse). The entries regarding the pulse are more detailed than in Western medicine, and possibly as a result of this detailed focus on the pulse, Kampo medicines have been formula for the treatment for the arrhythmias.

Shakanzoto was first documented in Shang Han Lun (Discussion of Cold-induced Disorders)", which offered a typical prescription for deficiencies of both ki and yin elements in the heart, including conditions such as knotted pulse, palpitations, shortness of breath, and fatigue. This extract formulation contains

the following ingredients(g):

Glycyrrhizae Radix Praeparata	3.0g
Zingiberis Rhizoma Processum	3.0 g
Cinnamomi Cortex	3.0g
Cannabis Fructus	3.0g
Ziziphi Fructus	3.0g
Ophiopogonis Radix	3.0g
Ginseng Radix	3.0g
Asini Corii Collas	2.0 g
Rehmanniae Radix	6.0g

This prescription, also known as the “shakanzoto”, is considered to build up the blood and restore the pulse. In the Shang Han Lun (On Cold Damage), in the second volume on *Greater Yang Disease*, the text states that, "After cold damage is relieved, knotted pulse and palpitations are present," and the Jin Gui Yao Lue (Synopsis of Prescriptions of the Golden Chamber), in the volume on Asthenic Disease, notes that, "For deficiency and sweating, relieves knotted pulse and palpitations, indicating treatment for arrhythmia.”

There are no definitive reports of anti-arrhythmic effects of individual ingredients of herbal medicines. From a Kampo perspective, *Rehmanniae* Radix, *Ophiopogonis* Radix, and *Asini Corii* Collas have the effects of moisturizing and cooling of the body ,lubricating dry skin, improving nutrition, relieving heat, and acting indirectly to strengthen the heart. *Glycyrrhizae* Radix and *Cinnamomi* Cortex are known to reduce palpitations, and in combination with ginseng, to show cardiotonic and stomachic effects. These pharmacologic effects suggest that *shakanzoto* acts to regulate the autonomic nervous system. The arrhythmia-improving effects noted in this case indicate that the effects of this decoction may extend to sympathetic nervous system activity. Further investigation will be required.

Conclusion

When a patient who had experienced frequent arrhythmia was treated with *shakanzoto* , Holter ECG findings showed arrhythmia to be reduced to 10% or less. It is hoped that this mechanism can be clarified in further research.

Clinical Report 3 (Japan)

Treatment of Obesity with Bofutsushosan: Obesity is inflammation

Yoshiyuki Ishizuka
Ishizuka Clinic

Introduction

C-creative protein (CRP) identified by *Tilet* and *Francis* in 1930 in the plasma of pneumococcus-infected patients with pneumonia is a member of the class of acute phase proteins that precipitate with C-polysaccharide. As is well known, CRP has been widely used as a marker for the presence of inflammation and its activity factor, especially in infectious diseases among inflammatory diseases. With the recent development of a high-sensitive technique for CRP determination, however, the levels of as low as 0.02mg/dl can be traced, leading to disclosure of sub-clinical inflammatory conditions. Thus, disorders that previously were not in the category of inflammation, like hypertension, hyperlipidemia, diabetes, and obesity, and even metabolic syndrome that is a complex of these disorders, are now regarded as chronic inflammation of vascular endothelium and adipose tissue. In fact, it has been demonstrated that high-sensitive CRP (hsCRP) correlates with BMI, waist circumference measurement, and amount of visceral fat. The hsCRP is also considered as an independent risk factor in the events of cardiovascular diseases and type 2 diabetes mellitus, and is associated with the onset of hypertension. The hsCRP level is an important indicator in managing lifestyle-related diseases inclusive of metabolic syndrome. Meanwhile, *bofutsushosan,* a herbal medicine Liu wuan-su originally prescribed to "rid of stagnation and depression of all the wind-heat" is now often used for the treatment of obesity rather than for that of infectious diseases. In this paper, I would like to take up the theme of "obesity is inflammation" through the therapy of *bofutsushosan* for the treatment of a patient who was obese with fatty liver.

Clinical Report

Patient: Male, 44-years old (school teacher for handicapped children)

Chief complaint: Obesity and fatty liver

Present illness

The patient had been identified with liver function abnormalities (ALT67IU/L) in the medical examination of July, 2004 and made his first visit to us. In his initial visit, obesity (weight 85 kg, BMI 29.4) and moderate fatty liver were observed, and the extract of *bofutsushosan* was administered, resulting in no reduction in weight. Three months later, the treatment was discontinued on his own judgment. On July 2005, the patient had a weight increase by 3 kg with the elevated ALT to 85IU/L and returned to the clinic.

Physical findings

The patient's height was 170cm, weight 88kg (BMI30.4), and blood pressure 142/92mmHg. There were no abnormalities in cardiopulmonary auscultation. Pulse palpitation was somewhat empty but deep at the rate of 76/min. The tongue was bright red colored, engorged, and somewhat excessively wet without no scars of teeth, spots and dilation of sublingual veins. The coating of the tongue was yellowish white and moderately thick. There were no resistance and tenderness in the abdomen. The waist circumference measured 94cm and obesity of visceral fat type was observed.

Laboratory findings

Laboratory tests revealed the following values: peripheral erythrocyte count $470x10^6/mm^3$, Hb 14.1g/dl, Ht 41%, total bilirubin 0.4mg/dl, AST 41 IU/L, ALT 85 IU/L, γ-GTP 48 IU/L, total cholesterol 204mg/dl, LDL cholesterol 105mg/dl, HDL cholesterol 62mg/dl, triglyceride 94mg/dl, uric acid 7.5mg/dl, FBS 90mg/dl, HbA_{1c} 4.8%, hsCRP 0.158mg/dl, HBs antigen (-), and HCV antibody (-).

Clinical Course

The patient was not eager to play sports/do workout. He liked sweet goods although he did not drink alcohol. The therapy of *bofutsushosan* was resumed under his usual diet and living habit. As previously, no decreases were observed in weight and ALT levels for three months after the resumption of the treatment. Meanwhile, the levels of hsCRP

dropped sharply. Subsequently, the oral administration was continued, resulting in gradual decreases in the weight and ALT levels. In July 2006, improvement was achieved in the weight to 84kg, ALT to 31 IU/L and hsCRP to 0.039mg/dl (Chart 1).

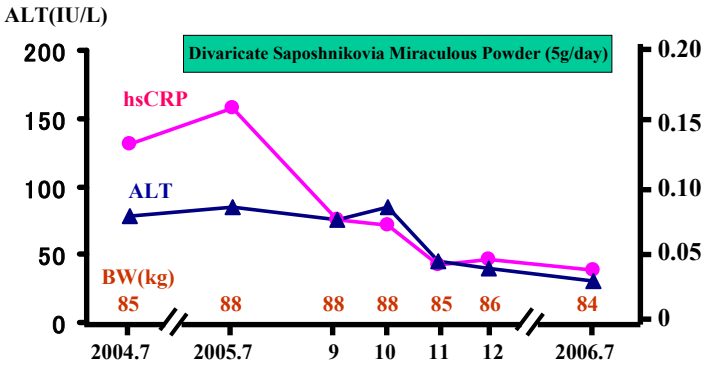


Chart 1: Clinical course (Male, 44 years old)

Discussion

Obesity is a condition in which excessive fat is accumulated in the body. As well as storing energy surplus in cells in the form of triglycerides, enlarged adipocytes in obese subjects secrete inflammatory cytokines (TNFα, etc), kemokines (monocyte chemoattractant protein-1: MCP-1, etc.) and hormones (adiponectin, leptin, etc.). Adipose tissue is comprised of mature adipocytes and stromata (stromal-vascular fraction: SVF). SVF contains monocytes, macrophages, preadipocytes, blood vessel components, and fibroblasts, presumably regulating reproduction / differentiation of adipocytes, and inflammation in the adipose tissue. In fact, Anty et al.[1] have reported that in obese patients there is a positive relation between the amount of IL-6 and the amount of CRP mRNA and that IL-6 and CRP exist in both mature adipose cells and SVF, more of them existing in the latter five to eight folds. It is assumed that in obese subjects, TNFα and MCP-1 secreted from enlarged adipocytes allow monocytes/macrophages to infiltrate into adipose tissue, where IL-6 is released. And I consider that the released IL-6 enhances CRP secretion from preadipocytes at local adipose tissue and from liver cells at remote organs (Chart 2). There is a recent report that CRP mediates LDL uptake by macrophages; attenuates synthesis of NO while increasing production of endothelin-1 (ET-1) and plasminogen activator inhibitor-1 (PAI-1) from vascular endothelium; and induces secretion of IL-6 and MCP-1 from endothelium. CRP is not merely an inflammation marker but also one of important factors directly linked to the events of atherosclerosis and thrombosis.

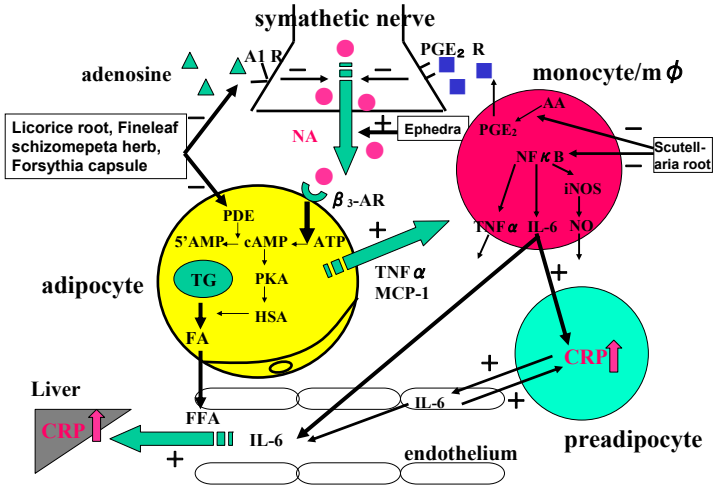


Chart 2: Mechanism of CRP increase in obesity (assumption)

To prevent cardiovascular events in patients with obesity, losing 5% of the current weight is the initial treatment goal to be achieved. It should, however, be remembered to reduce the levels of hsCRP. It is beyond any doubt that weight control by diet/exercise therapy alone can lower the hsCRP concentration. This is probably because burning of tryglycerides accumulated in adipocytes contributes to lower the secretion of TNFα and MCP-1 from adipose tissue, accompanying the reduced secretion of IL-6 from monocytes/macrophages. For middle-aged working people who are busy and have no exercise habit, like the subject case in this report, however, weight reduction through diet/exercise is often extremely difficult. In this case with obesity, treatment was performed only with *bofutsushosan* without employing diet/exercise, and the reduced hsCRP/ALT and weight loss were encountered. The ingredients making up the *bofutsushosan* are *Ephedorae* Herba, *Saposhnikoviae* Radix, *Schizonepetae* Spica, and wild mint to expel heat that does not diffuse from the body surface; *Rhei* Radix and *Natrii Sulfas* that are excreted in stool; *Kasseki*(talc) that is excreted in urine; *Gypsum* Fibrosum, *Scutellariae* Radix, *Gardeniae* Fructus, *Forsythiae* Fructus, and *Platycodi* Radix for internal

heat to subside; *Angelicae* Radix, *Peoniae* Radix, *Cnidii* Rhizoma, *Atractylodis* Rhizoma, *Zingiberis* Processum Rhizoma, and *Glycirrhizae* Radix to increase Qi and blood. Ephedorine in *Ephedorae* Herba promotes the release of noradrenaline (NA) from sympathetic nerve terminals[2]. When NA binds to β_3-adrenaline receptors present in the surface of adipocytes, the concentration of cAMP in adipocytes is elevated and hormone sensitive lipase is activated by catalytic PKA to decompose triglycerides. When adenosine A1 receptors and PGE_2 receptors in the sympathetic nerve terminals are stimulated, the release of NA from nerve terminals is suppressed. Xanthine derivatives included in licorice, fineleaf schizonepeta herb, and forsythia capsule work to inhibit adenosine A1 receptors, and scutellaria root works to inhibit synthesis of PGE_2 through mediation of COX_2 in monocytes/macrophages (aspirin-like action). These two functions indirectly serve to facilitate NA releases from sympathetic nerve terminals. Moreover, since Xanthine derivatives (licorice, fine leaf schizonepeta, and forsythia capsule) inhibit breakdown of cAMP in adipocytes through the inhibition of phosphodiesterase (caffeine-like action)[2], *bofutsushosan* can yield the effect of fat burning even in Japanese people who often have β_3-AR gene mutation. The menthol in wild mint possibly stimulates TRPM8, one of cold receptors, in peripheral nerves and activates the sympathetic nerves through the hypothalamus to promote catabolic action.

In the subject case, however, lowering levels of CRP were observed soon after the start of the administration of *bofutsushosan* and subsequently weight loss and improvement in ALT value were encountered. This cannot be explained sufficiently by the breakdown of triglycerides being accelerated in adipocytes and hepatocytes. Piao et al. [3] have reported that in a rat reperfusion model of focal cerebral ischemia, scutellaria root suppressed the release of TNFα, IL-6 and NO from activated microglia (intracerebral macrophages) by inhibiting the NF-κB signaling pathway. *Daisaikoto*, also frequently used for the treatment of obesity or fatty liver, includes *Scutellariae* Radix. I consider that the reduced levels of CRP induced by the *bofutsushosan* in obesity may be significantly attributed to an important role in direct anti-inflammatory activity of *Scutellariae* Radix against monocytes/macrophages.

Presently for *Natrii* Sulfas, mostly hydrous sodium sulfate ($Na_2SO_4 \cdot 10H_2O$) is used, whereas it is shown by Masutomi [4] that mirabilite is hydrous magnesium sulfate ($MgSO_4 \cdot 7H_2O$). Both compounds have potent purgation, but hydrous sodium sulfate is not desirable to the obese patients who are frequently predisposed to an accompanying hypertension due to a sodium load. Meanwhile, lowered levels of blood magnesium (Mg^{2+}) cause aggravation of the pathologic status of hypertension, hyperlipidemia, and atherosclerosis. In fact, low levels of blood magnesium are observed in obese patients and there is a report that magnesium supplementation can achieve weight reduction. Magnesium is necessary for activating lipoprotein lipase to decompose tryglycerides. Magnesium deficiency can develop hypertriglyceridemia. Presently, magnesium oxide, a laxative agent has been given as an attempt to the obese patients with normal renal function at low dosages. In this sense, it is preferable that mirabilite in the *bofutsushosan* is hydrous magnesium sulfate.

The *bofutsushosan* used this time was an extract drug and administered twice a day, in the morning and at night. At the time of the first treatment, the dosing schedule was conveniently set for the patient due to difficulty taking medication during working hours. It was amazing that the doses in two-thirds of the regular amount yielded sufficient decreases in the levels of hsCRP, ALT and weight with no complementary diet/exercise therapy. Meanwhile, for the initial three months after the administration was started, completely no weight loss was observed regardless of the amount of dosage. Although I had doubts temporarily about the efficacy of the *bofutsushosan*, the observation of a decrease in hsCRP prompted me to continue the treatment.

The subject case of the report is on the borderline of metabolic syndrome from the Japanese criteria for

metabolic syndrome. Among the patients on the borderline, however, some have increased levels of hsCRP. The subject case had the history of no alcoholic drinks with fatty liver, which cannot be discriminated between simple fatty liver (steatosis) and nonalcoholic steatohepatitis (NASH) since liver biopsy was not performed. Even nonalcoholic fatty liver disease (NAFLD), a disease concept covering from non-progressive simple steatosis to progressive NASH, poses a variety of problems of hypercytokinemia, oxidative stress, and insulin resistance with accumulation of visceral fat. Chart 3 and 4 exhibit results of the treatment with the *bofutsushosan* in 6 cases of obesity (5 males and 1 female) with NAFLD, inclusive of the subject case. With the consent of all the patients, they received only *bofutsushosan* without concomitant diet・exercise therapy. In the third month since the therapy started, the levels of hsCRP in blood significantly dropped from 0.237±0.060mg/dl to 0.140±0.065mg/dl ($p < 0.05$), and other profiles indicated decreases but were not statistically significant; weight 86.1±3.0kg to 84.3±3.4kg, blood AST values 37±4IU/L to 30±IU/L, and blood ALT values 56±4IU/L to 50±10IU/L. It can be expected that *bofutsushosan* calms inflammation in the adipose tissue, vascular endothelia and liver not only by the effect of weight reduction as previously mentioned but also by lowering the levels of hsCRP, which prevent progression of atherosclerosis and liver cirrhosis. In the obese patients whose hsCRP values are 0.1mg/dl or more with metabolic syndrome and/or NAFLD, the herbal therapy with *bofutsushosan* as well as diet and or exercise therapy should be attempted in a positive manner.

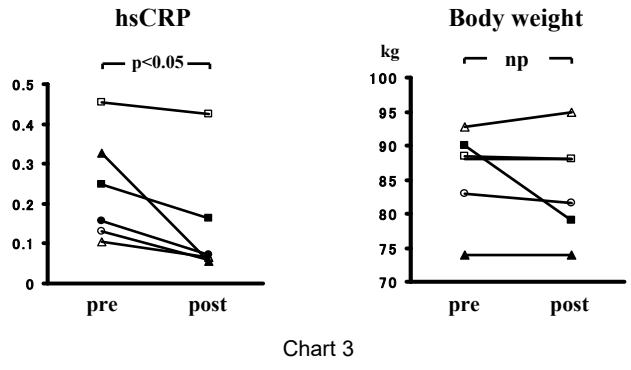


Chart 3

■:Case 1 □:Case 2 ●:Case 3 ○:Case 4 ▲:Case 5 △:Case 6

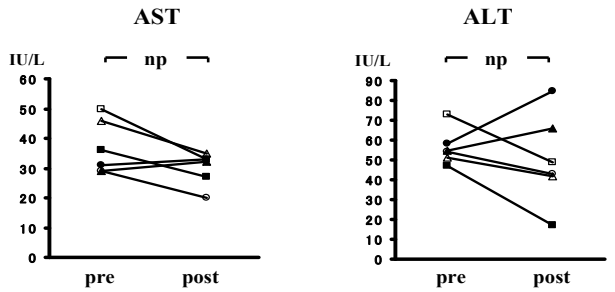


Chart 4

Chart 3, 4: Efficacy of *bofutsushosan* in obesity with nonalcoholic fatty liver disease (NAFLD)

Author's remarks

I have reported the case in which *bofutsushosan* was effective for the obese patients with fatty liver. It was interesting that *bofutsushosan* afforded a decrease in hsCRP levels during an early stage of administration, which, I consider, suggests that obesity is persistent systemic inflammation focused on adipose tissue even if it is at low level. Excessive nutrition becomes "evil *(jya)*" in the body. This evil turns out to be "flame *(hi)*" or "inflammation" that Liu wuan-su refers to. "Obesity is nothing less than inflammation."

Reference

1) Masutomi Y.: Shosoin yakubutsuwo chushintosuru kodaisekki no kennkyu *[Study of ancient stone medicines, mainly focused on Shosoin medicines]*, Nihon kobutsu shumi no kai *[Japan Mineral Hobbyists Group]* 1957

Clinical Report (Europe)

Case Report: Menopausal Syndrome

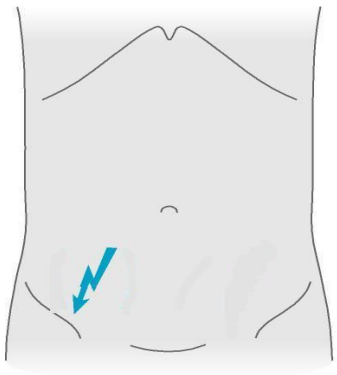
Ulrich Eberhard

A 48-year old female patient had been referred by a gynecologist and presented climacteric symptoms (hot flashes with a feeling of uprising heat from the chest through the neck into the head, sweating, at the same time cold feet, irritability, suddenly succumbs to feelings of sadness and complains about easy fatigability). These complaints had been present for about 6 months and were associated with irregular menstruations. Occasionally spontaneous nose bleeding did develop simultaneously. Other symptoms that follow from the anamnesis are: paroxysmally occurring attacks of pruritus affecting the entire body, frequently upset stomach, in particular following rich meals.

Kampo diagnosis:

Slim, sporty stature, strikingly dry skin, anemic appearance, spider nevi on the legs.

Tounge: dry, thin white coating, dental impressions
Pulse: deep and wiry
Abdomen: tenderness in the right lower abdomen



Shô identification: stage: lesser yang, status between excess and deficiency (ki-intermedio), liver qi stagnation, *oketsu**, Blood
deficiency and temporary Blood heat (also „erratic Blood movements"), indications of spleen weakness.

*(*oketsu* – Kampo term for a constitutional symptom complex, characterized by a stagnation of *ketsu blood*)

Kampo prescription:

unseiin

Rp.	
Rad. Angelica acutilobae	4.0 g
Rad. Rehmanniae	4.0 g
Rad. Paeoniae	3.0 g
Rhiz. Cnidii	3.0 g
Rad. Scutellariae	3.0 g
Fruct. Gardeniae	2.0 g
Rhiz. Coptidis	2.0 g
Cort. Phellodendri	2.0 g
miste fiat species	(for 7 days)

Course:

The initial prescription was given for 7 days. During the second consultation the patient complained about a feeling of fullness and pressure in the pit of the stomach following ingestion of the decoction. These complaints were clearly indicative of an intolerance of this Kampo prescription, since they did not only occur during the first two days, but persisted throughout the entire treatment period. A re-examination of the abdomen revealed weak pulsation around the area of the naval. This led to the decision to change the prescription:

New Kampo prescription:

kamishoyosan

Rp.	
Rad. Angelica acutilobae	3.0 g
Rad. Paeoniae	3.0 g
Rhiz. Atractylodis ovatae	3.0 g
Pachyma Hoelen	3.0 g
Rad. Bupleuri	3.0 g
Rad. Glycyrrhizae	2.0 g
Cort. Moutan	2.0 g
Fruct. Gardeniae	2.0 g
Herba Menthae	1.0 g
Rhiz. Zingiberis viridis	1.0 g
Miste fiat species	(für 7 Tage)

Further progress:

The new prescription again was prescribed only for 7 days. During the following visit the patient reported

a good tolerance of the prescription and that no gastrointestinal symptoms occurred. Subsequently, prescription of this preparation for a 14-day period. Next visit: good tolerance of the prescription, the patient felt subjectively better (less nervous). Findings: the tongue was moist, there were still signs of dental impressions, a thin white coat; the pulse was stronger, no longer wiry; abdomen: periumbilical pulsations were no longer palpable, while the tenderness in the right lower abdomen persisted. Subsequently, continued treatment with the prescription *kamishoyosan* for 28 days each. After 2 months of therapy hot flashes had been, except for some mild residual complaints, mostly alleviated and the patients reported feeling psychologically more stable and no longer so "sensible". Similarly the condition of the pruritus had improved and regarding the gastrointestinal sensitivity, the patient reported a 100% improvement, stating she never suffered from stomach troubles again.

The therapy was continued over a period of 7 months.

Remarks:

For the first prescription the focus had been on the signs of Blood-Heat (nosebleeds, pruritus) and thus the relevant prescription *unseiin* selected. Less attention had been paid to the qi deficiency of the spleen. That was a mistake. Stomach trouble developed promptly following the ingestion of the decoction. In patients with this type of constitution hypersensitive reactions of the stomach are frequently observed with prescriptions containing Rad. Rehmanniae.

Thus, a change of the prescriptions was in this case was absolutely necessary and verified by the prompt improvements observed following the ingestion of *kamishoyosan.*

Incidentally, the prescription *kamishoyosan* is the **drug of first choice** for **menopausal syndrome**.

Reference:

Eberhard U.: Guideline Kampo Medicine, Japanese Phytotherapy, Elsevier (Urban&Fischer) 2003

Introduction of Japanese Acupuncture

Considering the Therapist's Hand (3)

Shuichi Katai

III. Training of the therapist's hands

From the author's perspective the role of palpation in current acupuncture and moxibustion should be revised and the training of clinicians who have acquired excellent palpation skills remains an important task. The "training of the hands" that traditionally has been emphasized in Japanese acupuncture and moxibustion should be subject of re-education during clinical acupuncture and moxibustion training. To this end, solutions to the below listed tasks are urgently needed (table).

Tasks pertaining to the improvement of palpation skills
1. Organization of the biological responses identified through palpation
2. Establishment of palpation skills to identify responses
3. Establishment of appropriate stimulation methods to modify these responses
4. Establishing the theoretical role of responses, response identification and induction of modifications within acupuncture and moxibustion theory
5. Establishment of educational methods and practices to acquire the above mentioned

1. Organization of the biological responses identified through palpation

There are an infinite number of biological responses. Attempts at identifying these responses through palpation inevitably are marked by pronounced subjective trends. Doubtlessly, efforts are made to identify the findings in an "objective" manner and reported accordingly. It cannot be denied that these are nevertheless extremely subjective. Information pertaining to acupuncture and moxibustion (not restricted to acupuncture and moxibustion) is gathered for specific purposes based on advanced determined therapeutic theories or medical systems; in other words, following the yin-yang or five phase patterns, and then classified according to purpose.

Moreover, the contents of the medical treatment and the identified findings are strongly regulated by therapeutic methods. Depending on whether you use acupuncture, moxibustion, manipulation or any combination of these, determines which findings are gathered. It is meaningless to gather findings for parameters that cannot be changed and findings that are not subject to therapeutic intervention or evaluation. That is because findings and therapies will become organized in a system of mutual correlations. Identification of findings that will not be the subject of therapeutic interventions for some time is still not meaningless, but rather needs to be incorporated as a reaction within the system.

Muscle tonus is a representative palpatory finding observed during acupuncture and moxibustion treatment and emphasized in Japan. In association with it indurations and similar changes are also mentioned as well as: swelling, feeling of warmth, pain and other signs of inflammation, and of course their respective opposites like feeling of cold, muscle atrophy and similar responses. These findings reflect the strong integration of physical therapy in current Japanese acupuncture and moxibustion.

However, if palpation is performed based on classical theory, findings that need to be mentioned include muscle tonus, indurations, stiffness etc. that would be classified as "excess" conditions; contrasted with "deficiency" conditions marked by findings like lack of muscle elasticity, popularly termed lack of strength. Moreover, when based on classical theory, there are problems preceding the level of muscles that need to be emphasized. This refers to a lack of skin tension and elasticity, tonus of subcutaneous (connective) tissues and indentations due to a lack of strength. These are essential when considering "acupoints" and may be regarded as an extension of the body surface reactions presented in the "Lin Shu" (Spiritual Pivot). When these findings are classified according to the Yin-Yang concept, they are inseparable from the concepts of tonification and sedation in clinical acupuncture and moxibustion and in this sense may require to be arranged anew.

2. Establishment of palpation skills to identify responses

The technique of palpation varies depending on the kind of reaction that is sought. During the establishment of the palpation skills, the reactions to be identified must be classified and systematically organized. Attempts at the palpation of the above described reactions raise the question as to how to develop the relevant technical skills. For the palpation performed during acupuncture and moxibustion treatment it is ultimately important to find and determine the sites that are to be stimulated. The sites eligible for acupuncture stimulation include the skin or connective tissue and muscles (occasionally the bones). Moreover, stimulation methods for the various sites differ, so that the needle stimulation techniques for the pathologies manifesting at those various sites also need to be classified accordingly.

Thus, target pathologies are classified and the palpation skills for their determination established. During this procedure, patient stress (pain or discomfort) should be kept at a minimum, while maximum efforts should be made to avoid subjective evaluations. Occasionally, when only the pathology is identified without troubling oneself with any further details, a possibly increased burden of the patients with pain or discomfort tends to be neglected. This possibility should be kept in mind and not forgotten.

For example, when considering treatment for increased muscle tonus, the condition of muscles, tendons, and bones should be well understood and an appropriate palpation should allow one to discriminate between them. Also, inducing contractions or extensions of muscles may make it easier to determine their status. Thus, considerations of patient position and exercise instructions must be integrated into the theory.

For the establishment of palpation based on deficiency-excess, tonification-sedation the palpation should be performed based on the correlation between skin - connective tissue - muscles - bones in order to determine the condition of the respective tissues. Palpation in Japanese acupuncture and moxibustion concentrating on locomotor organs like muscles or bone and tendons are, as has already been described, is strongly influenced by physical therapy. The performance of treatments using contact acupuncture or extremely shallow needle stimulation, also represent an important field of Japanese acupuncture and moxibustion. Therefore, organization of body surface information from tissues located shallower than muscles or bones is also essential.

Yet, most importantly, it is necessary to carefully first pick up the individual physical reactions (actually observing the body) in order to establish a system of palpation without restricting oneself to the above mentioned therapeutic aims or theories.

Medical History in Japan

Japanese Acupuncture and Moxibustion under the Rule of GHQ after World War II (3)

Recommendation by the Public Health and Welfare Section for the prohibition of moxibustion and acupuncture, and the response of those in the moxicautery and acupuncture fields in Japan

Takako Okutsu

Acupuncture Continuation Movement for the visually impaired

On October 27, 1947, the LMAMP (League of Moxa-cautery, Acupuncture and Massage practitioners) submitted a petition calling for legislation to secure acupuncturist credentials. Meanwhile, the Acupuncture Continuation Committee for the visually impaired had met on October 19 at the Tokyo Metropolitan School for the Visually Impaired to discuss a response to the recommendation. Instructors at that school had just completed two documents (*Theory of Efficacy of Acupuncture and Moxabustion*, and *Feasibility of Acupuncture Treatment by Visually Impaired Practitioners*), and on October 20 the committee members paid visits to the GHQ (General Headquarters for the occupying forces), the Ministry of Health and Welfare, the Ministry of Education, the House of Representatives, and the House of Councilors. They then proposed action based on these two documents.

On October 27, the Japanese Association of Principals of Schools for the Visually Impaired and the Provisional Committee for the Visually Impaired Education Alliance of Japan convened a meeting at the Tokyo Metropolitan School for the Visually Impaired, where they dissolved the Acupuncture Continuation Committee, to be replaced by the newly formed League for the Continuation of Acupuncture, and agreed to work together and intensify their activities. Activity was not limited to school principals and teachers. Students were also concerned, and became involved in the movement. At the center were students of the Normal School Division of Tokyo Metropolitan School for the Visually Impaired, who felt that the future occupation of visually impaired students across the country was at risk.

On November 14, students from schools for the visually impaired convened the All-Japan Congress for Visually Impaired Students at the Tokyo Metropolitan School for the Visually Impaired. They pleaded for the continuation of acupuncture from the student's perspective, petitioning the GHQ, the Ministry of Health and Welfare, and the Ministry of Education. They also presented the Petition Opposing the Prohibition of Visually Impaired Acupuncture Practitioners to the National Diet, (Petition No. 714, submitted by the Student Union of the Tokyo Metropolitan School for the Visually Impaired). Clearly, the students considered this to be a "life and death" issue.

Activities were not limited to the LMAMP and to students, families, and staff of schools for the visually impaired. Movements also developed around Japan, initiated by visually impaired acupuncturists whose livelihood depended on their profession. On October 30, the All-Japan Congress Advocating the Right to Work for the Visually Impaired (chairman Hideo Imazeki) held a demonstration at the plaza in front of the Imperial Palace in order to appeal to public opinion about the sad plight of the visually impaired, after which the group petitioned the Ministry of Health and Welfare, the House of Representatives, the House of Councilors, and the Prime Minister to withdraw the prohibition of acupuncture practice by the visually impaired (Materials 1).


ハリ灸の禁止にアンマの反対

Material 1: "Traditional massagers protest against banning acupuncture and moxibustion" The Mainichi Newpaper (October 31,1947) Commentary: It was recorded that on October 30, 1947, visually-impaired persons in business

gathered in the square in front of the Imperial Palace, marching to advocate the contined use of anupuncture and moxibustion and the right of performing the business. Their action was appealed through mass media on a massive scale.

In addition, large numbers of visually impaired acupuncturists from across Japan joined in submitting petitions to permit the continuation of acupuncture practice by the visually impaired.

With strong protests from around the country, urging that the visually impaired be allowed to continue learning and practicing acupuncture, the GHQ began to modify its position. This process is recorded in the memoirs of Brigadier General Crawford Sams, the Director of the Public Health and Welfare Section (PHW) of the GHQ, written after he returned home to the United States. The change in attitude shows how shocking these movements were to the GHQ, who had absolute authority in Japan during the postwar Occupation.

General Sams' decision

As a result of the series of demonstrations and related activities by the visually impaired, the GHQ began to understand the importance of acupuncture as an occupation for the visually impaired in Japan. They realized that barring the visually impaired from the profession of acupuncture would place the livelihood of many visually impaired Japanese at risk, and would inevitably result in social turmoil. The GHQ, which was using the Japanese occupation government to display American credibility and prestige in the international community, definitely wanted to avoid any such turmoil. To that end, the GHQ gave full permission for visually impaired practitioners to perform acupuncture treatment, while at the same time requiring that acupuncturists act quickly to establish laws and regulations regarding public qualifications. This compromise from the GHQ to allow the visually impaired to provide acupuncture treatment was promptly communicated to the Ministry of Health and Welfare. The MHW, which represented the Japanese government in this area, undoubtedly played an active part in this change of position, but the fundamental motivating force was the desperately relentless activity by acupuncturists and their supporters across Japan.

The Ministry of Health and Welfare drafted this compromise proposal into a bill, and forwarded it as draft legislation to the National Diet.

Negotiations between the Ministry of Health and Welfare and the GHQ

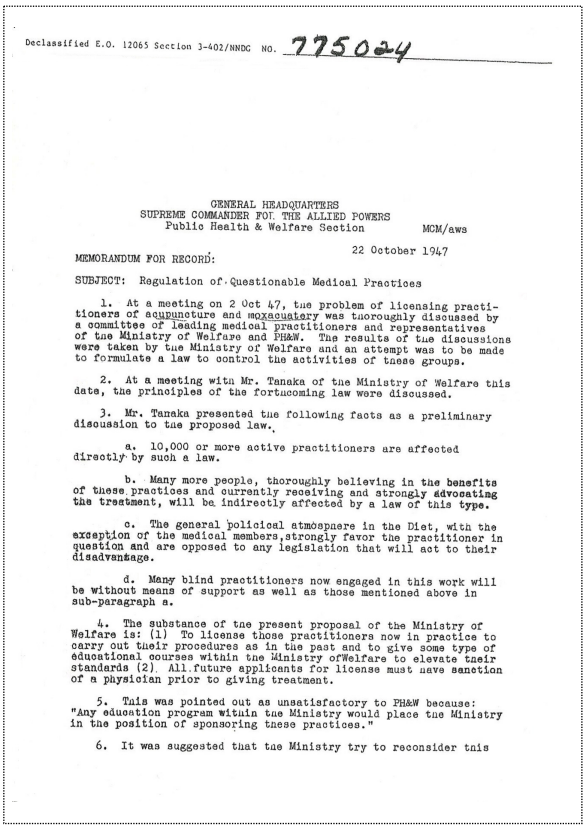
Negotiations on legislation between the Ministry of Health and Welfare and the GHQ actually started after the MHW report on October 2, as the movement for the future of the acupuncture industry was beginning to take shape. The contents of those negotiations are available from the archives of the U.S. National Archives and Records Administration (GHQ/SCAP Records).

The discussions between the Ministry of Health and Welfare and the GHQ covered a number of areas, including scientific proof of acupuncture effectiveness, educational reform, and appropriate dealings with the visually impaired. But the fundamental question was on legislation pertaining to the Asian medicine that formed the theoretical basis for acupuncture. At that time, Japan considered Western medicine to be "standard medicine," so the idea of legislating the status of practitioners engaged in Asian medicine seemed both epoch-making and a violation of common sense. The absence of precedent necessitated a careful and deliberate discussion of these issues between the Ministry of Health and Welfare and the GHQ.

The gist of those discussions can be inferred from a memorandum "Regulation of Questionable Medical Practice," dated October 22, 1947 and written by Milton C. Morton, MD, who at that time was the Assistant Chief, Medical Service Division, PHW. (Materials 2)

This title makes it clear that the GHQ initially considered acupuncture to be mysterious and inscrutable. The memo records the three-party negotiations among the Ministry of Health and Welfare, the Council for the Medical System, and the GHQ following the report on October 2 by the Council for the Medical System. Particularly notable are his comments on the " ... opposition of the GHQ to the proposal by the Ministry of Health and Welfare to create a reeducation

program for acupuncturists. This is because within the Ministry of Health and Welfare the creation of a reeducation program is connected to support for (certification of) acupuncture by the MHW."



Declassified E.O. 12065 Section 3-402/NNDC NO. 775024

GENERAL HEADQUARTERS
SUPREME COMMANDER FOI THE ALLIED POWERS
Public Health & Welfare Section MCM/aws

22 October 1947

MEMORANDUM FOR RECORD:

SUBJECT: Regulation of Questionable Medical Practices

1. At a meeting on 2 Oct 47, tue problem of licensing practitioners of acupuncture and moxacuatary was thoroughly discussed by a committee of leading medical practitioners and representatives of tne Ministry of Welfare and PH&W. The results of tue discussions were taken by tne Ministry of Welfare and an attempt was to be made to formulate a law to control the activities of tnese groups.

2. At a meeting with Mr. Tanaka of the Ministry of Welfare this date, tne principles of the fortncoming law were discussed.

3. Mr. Tanaka presented tne following facts as a preliminary discussion to tne proposed law.

a. 10,000 or more active practitioners are affected directly by such a law.

b. Many more people, thoroughly believing in the benefits of these practices and currently receiving and strongly advocating the treatment, will be indirectly affected by a law of this type.

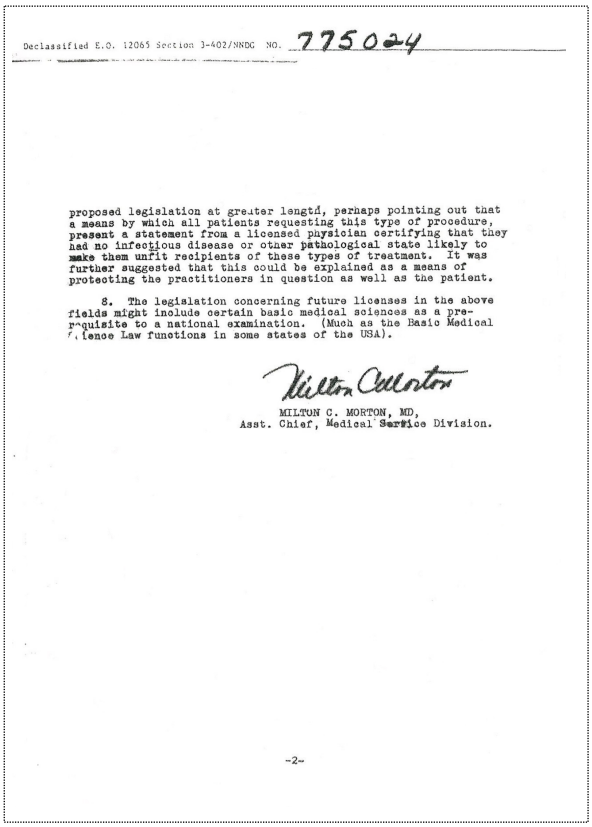
c. The general policical atmosphere in the Diet, with the exception of the medical members, strongly favor the practitioner in question and are opposed to any legislation that will act to their disadvantage.

d. Many blind practitioners now engaged in this work will be without means of support as well as those mentioned above in sub-paragraph a.

4. The substance of tne present proposal of the Ministry of Welfare is: (1) To license those practitioners now in practice to carry out their procedures as in the past and to give some type of educational courses within tne Ministry ofWelfare to elevate tneir standards (2). All future applicants for license must nave sanction of a physician prior to giving treatment.

5. Tnis was pointed out as unsatisfactory to PH&W because: "Any education program within tne Ministry would place tne Ministry in tne position of sponsoring tnese practices."

6. It was suggested that tne Ministry try to reconsider tnis



Declassified E.O. 12065 Section 3-402/NNDC NO. 775024

proposed legislation at greater lengtd, perhaps pointing out that a means by which all patients requesting this type of procedure, present a statement from a licensed physician certifying that they had no infectious disease or other pathological state likely to make them unfit recipients of these types of treatment. It was further suggested that this could be explained as a means of protecting the practitioners in question as well as the patient.

8. The legislation concerning future licenses in the above fields might include certain basic medical sciences as a prerequisite to a national examination. (Much as the Basic Medical Science Law functions in some states of the USA).

Milton C. Morton

MILTON C. MORTON, MD,
Asst. Chief, Medical Service Division.

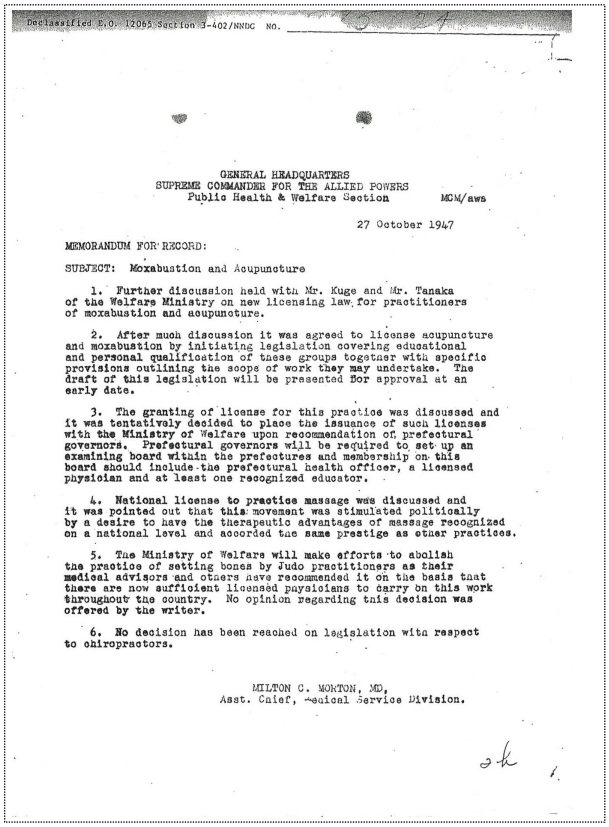
-2-

Material 2: "Regulation of Questionable Medical Practice" (GHQ/SCAP) U.S. National Archieves and Records Administration; Japan National Diet Library (October 22, 1947)
Commentary: The contents of the talks made when the then Ministry of Welfare's submitting the report on October 2 were recorded. At the time, the enactment of a legislation concerning the status of acupuncture and moxibustion practitioners and principles of the contents were discussed, and Koun Takada, Kacho of Imu-ka (Manager of Medical Section) gave explanations of the then current condition of the industry to GHQ. It can be considered that the author, Dr. M.C. Morton attended the meeting.

(Note) A name called "Mr. Tanaka" appears in the record as a person from the Ministry of Welfare, but there is no relevant person found in the list of its public officers. From the circumstance of the time, it must be Mr. Takata, Manager, instead of Mr. Tanaka.

The contents of this memorandum show that the GHQ, which intended to build a new Japanese medical system based on Western medicine, saw the MHW's proposal to create a reeducation program for acupuncturists as being tied to the recognition of "another form of medicine" in addition to Western medicine. That idea was unacceptable to the GHQ. A later memorandum by Dr. Morton ("Moxabustion and Acupuncture," dated October 27, 1947) shows how this problem was resolved. (Materials 3)

That memorandum records discussions between MHW Deputy Director Kuge, Section Director Takada, and the GHQ from October 2 onwards. It states that,
1. If the MHW will add sections that clearly summarize the range of services to be covered, the GHQ will permit legislation to be initiated.
2. Advisory committees are to be established in every prefecture of Japan, and are required to have at least one civil servant from the prefectural health office or department, one licensed physician, and one person recognized as having received higher education.[6)]



Declassified E.O. 12065 Section 3-402/NNDC NO. _____

GENERAL HEADQUARTERS
SUPREME COMMANDER FOR THE ALLIED POWERS
Public Health & Welfare Section MCM/aws

27 October 1947

MEMORANDUM FOR RECORD:

SUBJECT: Moxabustion and Acupuncture

1. Further discussion held with Mr. Kuge and Mr. Tanaka of the Welfare Ministry on new licensing law for practitioners of moxabustion and acupuncture.

2. After much discussion it was agreed to license acupuncture and moxabustion by initiating legislation covering educational and personal qualification of these groups togetner with specific provisions outlining the scops of work they may undertake. The draft of this legislation will be presented for approval at an early date.

3. The granting of license for this practice was discussed and it was tentatively decided to place the issuance of such licenses with the Ministry of Welfare upon recommendation of prefectural governors. Prefectural governors will be required to set up an examining board within the prefectures and membership on this board should include the prefectural health officer, a licensed physician and at least one recognized educator.

4. National license to practice massage was discussed and it was pointed out that this movement was stimulated politically by a desire to have the therapeutic advantages of massage recognized on a national level and accorded the same prestige as other practices.

5. The Ministry of Welfare will make efforts to abolish the practice of setting bones by Judo practitioners as their medical advisors and others have recommended it on the basis that there are now sufficient licensed physicians to carry on this work throughout the country. No opinion regarding this decision was offered by the writer.

6. No decision has been reached on legislation with respect to chiropractors.

MILTON C. MORTON, MD,
Asst. Chief, Medical Service Division.

Material 3: "Moxibustion and Acupuncture" (GHQ/SCAP) U.S. National Archieves and Records Administration; Japan National Diet Library (October 27, 1947)

Commentary: Records were kept on the contents of the talks toward the establishment of the legislation between the Ministry of Welfare (Katsuji Hisashita, Jicho of Imukyoku {Deputy Director of the Medical Bureau} and Koun Takada, Manager of the Medical Section) and GHQ

This appears to indicate that the GHQ was instructing the Ministry of Health and Welfare to create legislation that would involve the presence of physicians. The Japanese government was at that time looking into establishing legislation under the National Medical Treatment Law (1942), which formed part of the basis for the current medical system, so on this point there was mutual agreement between the Japanese government and the GHQ.

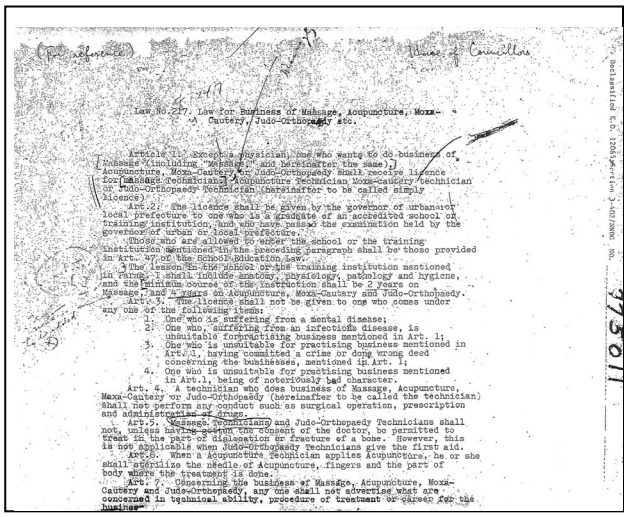
It was finally decided that even though they were not licensed physicians, and not allowed to diagnose patients, Japanese acupuncturists would be allowed to maintain an independent practice as they had in the past, rather than being required to work under the supervision of a physician. This was because Asian and Western medicine are based on such fundamentally different theories that, as the previous report noted, it would at present create an extremely difficult working environment to require acupuncturists to practice under the supervision of a physician. The GHQ and the MHW were in agreement on this point. Both parties also agreed that an acupuncturist's credentials would not be considered legally equivalent to a physician's license, but that Asian medicine had benefits in its own right even though its theoretical foundations were incomplete. Since even today there continues to be heated debate over the value and position of Asian medicine, it is interesting that these same questions were also addressed by the United States and Japan during the Occupation.

Proceeding by trial and error, the MHW and the GHQ finally agreed that, while the current status of Western medicine would be maintained, legislation would also be implemented to cover Asian medicine. The Law for Business of Massage, Acupuncture, Moxa-Cautery, Judo-Orthopaedy, Etc., which laid the groundwork for present-day regulation, was born out of this dilemma over the position of Asian medicine, both within Japanese society and in the US government. It would be accurate to say that the law realistically represented the social status of Asian medicine in Japan at that time.

At the end of these negotiations, the MHW began the process of drafting the proposed legislation. However, there was not much time available. This was because the MHW at the time was dealing with a number of medical reforms, including the revision of the National Medical Treatment Law, and all of the industry regulations that had been established under the old imperial constitution (the Meiji Constitution) were soon to become null and void under the new postwar Constitution of Japan. If new legislated status for acupuncturists could not be put into place quickly, they were concerned that acupuncture might vanish from the Japanese medical system. Section Director Takada, who was responsible for generating many pieces of legislation related to medical treatment, including the Law for Business of Massage,

Acupuncture, Moxa-Cautery, Judo-Orthopaedy, Etc., later reminisced about the difficulties in his memoirs. He and his staff consulted with numerous physicians in order to prepare that legislation, and the work caused him to be late with another law for which he was personally responsible (the Medical Service Law, 1948). These episodes illustrate how difficult it was for the Ministry of Health and Welfare to establish the legislated status of acupuncture.

Next, the Ministry of Health and Welfare submitted to the GHQ an advance copy of the draft in Japanese, with an English translation (LAW No.217. LAW FOR BUSINESS of Massage, Acupuncture, Moxa-Cautery, Judo-Orthopaedy Etc.), as a courtesy to the "indirect government" of Occupation forces. (Materials 4) (Materials 5) (Materials 6) That draft was submitted to the Katayama cabinet on November 8, where it was discussed, and was then deliberated on the floor of the Diet. (Materials 7)



Law No.217. Law for Business of Massage, Acupuncture, Moxa-Cautery Judo-Orthopaedy etc.

Article 1.1. Except a physician, one who wants to do business of Massage (including "Anmo" and hereinafter the same), Acupuncture, Moxa-Cautery or Judo-Orthopaedy shall receive licence for Massage Technician, Acupuncture Technician Moxa-cautery Technician or Judo-Orthopaedy Technician (hereinafter to be called simply "licence").

Art.2. The licence shall be given by the governor of urban or local prefecture to one who is a graduate of an accredited school or training institution, and who have passed the examination held by the governor of urban or local prefecture.

(Those who are allowed to enter the school or the training institution mentioned in the preceding paragraph shall be those provided in Art. 47 of the School Education Law.)

2 The lesson in the school or the training institution mentioned in Para. 1 shall include anatomy, physiology, pathology and hygiene, and the minimum course of the instruction shall be 2 years on Massage, and 4 years on Acupuncture, Moxa-Cautery and Judo-Orthopaedy.

Art. 3. The licence shall not be given to one who comes under any one of the following items:

1. One who is suffering from a mental disease;
2. One who, suffering from an infectious disease, is unsuitable for practising business mentioned in Art. 1;
3. One who is unsuitable for practising business mentioned in Art. 1, having committed a crime or done wrong deed concerning the business, mentioned in Art. 1;
4. One who is unsuitable for practising business mentioned in Art.1, being of notoriously bad character.

Art. 4. A technician who does business of Massage, Acupuncture, Moxa-Cautery or Judo-Orthopaedy (hereinafter to be called the technician) shall not perform any conduct such as surgical operation, prescription and administration of drugs.

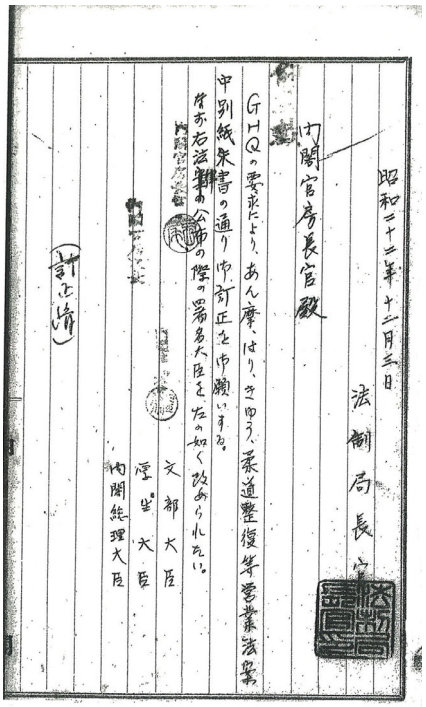
Art.5. Massage Technicians and Judo-Orthopaedy Technicians shall not, unless having gotten the consent of the doctor, be permitted to treat in the part of dislocation or fracture of a bone. However, this is not applicable when Judo-Orthopaedy Technicians give the first aid.

Art.6. When a Acupuncture Technician applies Acupuncture, he or she shall sterilize the needle of Acupuncture, fingers and the part of body where the treatment is done.

Art. 7. Concerning the business of Massage, Acupuncture, Moxa-Cautery and Judo-Orthopaedy, any one shall not advertise what are concerned in technical ability, procedure of treatment or career for the business.

Material 4: "Law No.217: Law for Business of Massage, Acupuncture, Moxa-Cautery, Judo-Orthopaedy etc." (GHQ/SCAP) U.S. National Archieves and Records Administration; Japan National Diet Library

Commentary: Under American occupation, each ministry of the government of Japan was required to submit English translations of draft legislations to GHQ for their examination when submitting them to the Cabinet. This material must be the one prepared by the Ministry of Welfare and submitted to GHQ.



昭和二十二年十二月三日

法制局長官

内閣官房長官殿

GHQの要求により、あん摩、はり、きゅう、柔道整復等営業法案中別紙条書の通り修訂正を申願いますね。

尚右法律案の公布の際の署名大臣を左の如く改められたい。

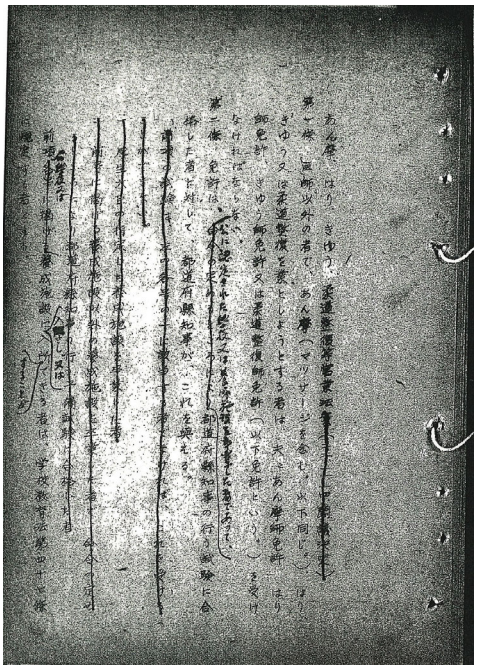
内閣総理大臣

厚生大臣

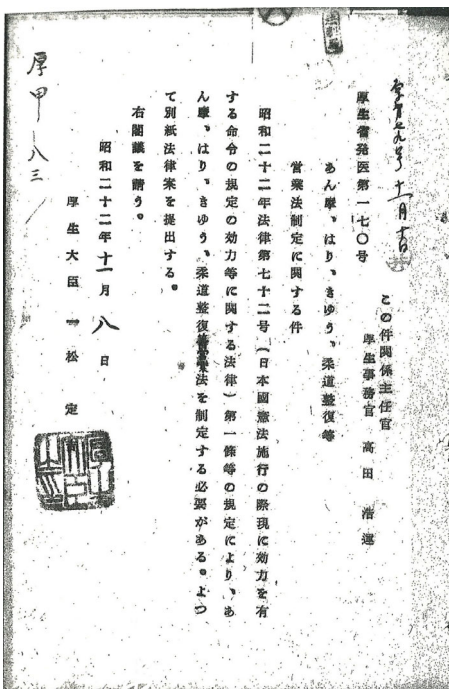
文部大臣

訂正済

Material 5



Material 6



厚甲一八三

発第一七〇号

昭和二十二年十二月八日

厚生事務官 高田浩運

この件関係主任官

あん摩、はり、きゅう、柔道整復等営業法制定に関する件

昭和二十二年法律第七十二号（日本国憲法施行の際現に効力を有する命令の規定の効力等に関する法律）第一條等の規定により、あん摩、はり、きゅう、柔道整復等営業法を制定する必要がある。よつて別紙法律案を提出する。

右閣議を請う。

昭和二十二年十一月八日

厚生大臣 一松定

Material 7

The above materials are: "Law No.217: Law for Business of Massage, Acupuncture, Moxa-Cautery, Judo-Orthopaedy, etc." Japan National Diet Library. Material 5: A document from Chokan of Hosei Kyoku (Director of the Legislative Bureau) of the Cabinet to Chief Cabinet Secretary requesting to make corrections to the draft legislation according to the demand by GHQ. It seems from the document that GHQ involved itself in drafting the legislation. Material 6: In compliance with the demand by GHQ (Ref. Drawing 5), corrections were made in red. Material 7: Kosei Sho Hatsu I No. 170 {Medical No.170 published by the Ministry of Welfare} relating to the matter of enacting the legislation concerning traditional massage, acupuncture, moxibustion, Judo-Orthopaedics. After the examination by GHQ, the Ministry of Welfare submitted the draft legislation to the Cabinet led by Tetsu Katayama as of 8th of November, requesting the presentation to the ministerial meeting for passing to the Diet. The name of Koun Takada, Manager, who was engaged in negotiations with GHQ was described.

Establishing the Law for Business of Massage, Acupuncture, Moxa-Cautery, Judo-Orthopaedy, etc. (Law No. 217)

The contents of deliberations on this bill are available from the records of the National Diet.

The Diet began its deliberations on acupuncture in the Health and Welfare Committee of the House of Councilors on November 13, and the bill was first introduced into the Health and Welfare Committee of the House of Representatives on November 17. On December 3, the bill was formally submitted by the Cabinet, and the process of enacting the legislation was initiated.

The majority of Diet members supported acupuncture as a form of traditional Japanese medicine at that time, and they approved the legislation of practitioners' status. Particularly instrumental in this process were Councilor Kobayashi, who threw his strong support behind this legislation, and MHW Minister Hitotsumatsu, who made a direct plea to the GHQ for the continuation of acupuncture. As a result of the previous recommendation from GHQ for the prohibition of acupuncture and moxibustion, lawmakers were keenly aware of the questions of inadequate disinfection, treatment safety, scientific rationale, educational reform, and appropriate dealings with the visually impaired who accounted for more than half of all practicing acupuncturists at the time.

The Diet members thus engaged in vigorous debate to resolve those questions through legislation.

The legislation was passed by the House of Representatives on December 6, and by the House of Councilors on December 7. On December 20 the Law for Business of Massage, Acupuncture, Moxa-Cautery, Judo-Orthopaedy, Etc. (Law No. 217) was made public, to go into effect January 1 of the following year.

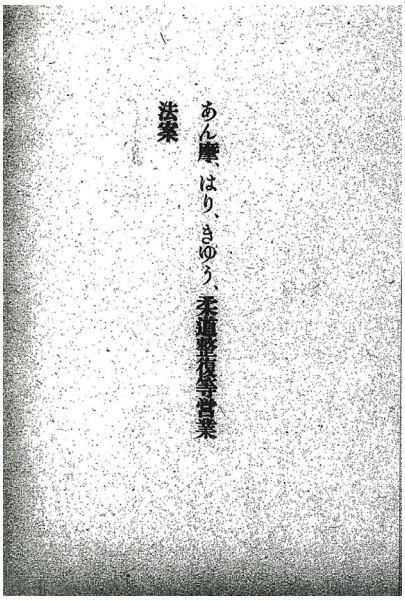
The law includes the following points:
(1) The traditional "business license" will be changed to "license/qualifications" (the category used for medical licenses).
(2) No new licenses will be granted except to graduates of publicly accredited schools or training facilities who have passed a prefectural examination.[7)]

This legislation raised the stature and social standing of acupuncturists, while also making it clear that the occupation would now be regulated by legislation for medical treatment, rather than by legislation for business as had been the case in the past. (Materials 8) (Materials 9)

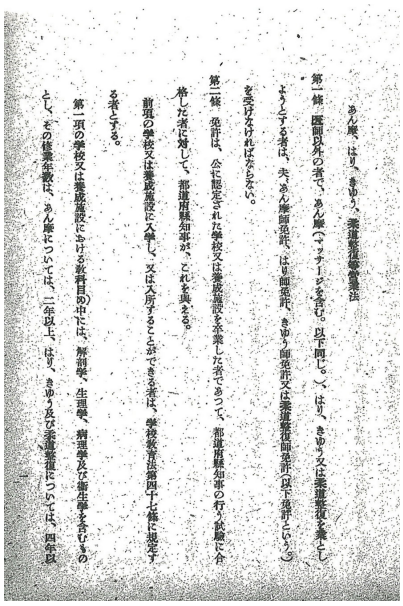
References

6) U.S. National Archives and Records Administration and Japan National Diet Library, GHQ/SCAP documents, Moxabustion and Acupuncture. 27 October 1947

7) Ministry of Health and Welfare Fifty Years of History Editorial Committee: Ministry of Health and Welfare -- Fifty Years of History (commemorative edition). Kosei Mondai Kenkyukai Foundation. 1988: 671


あん摩、はり、きゆう、柔道整復等営業
法案

Material 8


あん摩、はり、きゆう、柔道整復等営業法

第一條　医師以外の者で、あん摩（マッサージをいう。以下同じ。）、はり、きゆう又は柔道整復を業としようとする者は、夫々あん摩師免許、はり師免許、きゆう師免許又は柔道整復師免許（以下「免許」という。）を受けなければならない。

第二條　免許は、公に認定された学校又は養成施設を卒業した者であつて、都道府縣知事の行う試驗に合格した者に對して、都道府縣知事が、これを與える。

前項の学校又は養成施設に入學し、又は入所することができる者は、学校教育法施行四十七條に規定する者とする。

第一項の学校又は養成施設における教育課目のうちには、解剖学、生理学、病理学及び衛生学を含むものとして、その修業年數は、あん摩については、二年以上、はり、きゆう及び柔道整復については、四年以

Material 9

"Law No.217: Law for Business of Massage, Acupuncture, Moxa-Cautery, Judo-Orthopaedy, etc." Japan National Diet Library.

Commentary

Material 8: It was the legislation concerning the status that the industry of acupuncture and moxibustion long desired and marked the start after the War.

Material 9: Article 2 stipulates that the related license is given only to the person who graduated from one of the publicly accredited schools and passed the examination given by the governor of each metropolitan and city government. It is shown that this legislation was designed to improve through education quality and social position of acupuncture and moxibustion practitioners.

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Excerpted from National Park Service