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Research on Theory, Practice and Integration

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Editorial
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Naoya Ono

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Report from Association
A Letter from the 66th General Assembly of The Japan Society for Oriental Medicine
Kazunari Ozaki

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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.

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Editorial

Background to the Emergence of Integrative Medicine in Japan

Integrative medicine began to take shape in Japan in response to the shift in the final value judgment of medical care—from the simple, subjective *cure* of diseases to health *care* that aims to enhance QOL (quality of life) by incorporating people's (patients') thoughts and subjective views—accompanying changes in disease structures as a result of the development of modern Western medicine, as well as changes in patients' awareness and actions in regard to diseases, and changes in demographics based on an aging and shrinking society.

Today, lifestyle diseases account for the majority of diseases experienced by people in Japan, and chronic diseases are most prevalent among elder care (dementia, nursing care, etc.) in today's super aging society, such that proper treatment cannot be provided alone by a single clinical department of modern Western medicine. At the same time, even when multiple departments are involved, they do not necessarily cooperate well with each other, because modern Western medicine has become further segmented and specialized through its development. In fact, the essence of holistic medicine has been lost and medicine has fallen into a state where "the forest cannot be seen for the trees." A further continuation of this situation would prevent any establishment of a strong relationship between ordinary people (patients) and medical workers, and would ultimately create a vicious cycle that leads to mistrust in medical services.

On the other hand, people who receive medical care (patients) are showing increasing interest in people's (patients') health trends and preventive medicine owing to the dissemination of knowledge about medicine and medical care by various media outlets in Japan in recent years. They are also displaying a shift from passive to active awareness. Furthermore, given today's aging and shrinking society and seamless lifestyles, people (patients) are led to value QOL over medical care that focuses narrowly on the non-ordinary event of disease cure, and seek health care, including nursing care, as a wide, ordinary event. Moreover, entangled with tax increase and national finance issues that have surfaced as a result of an increase in the burden of medical expenses in Japan's aging and shrinking society, needs for traditional medicine and complementary/alternative medicine and interest in integrative medicine have emerged beyond the existing framework of medical care comprised solely of modern Western medicine. Integrative medicine has thus begun to take shape in Japan as a new concept of health care.

In other words, it can be said that integrative medicine has emerged in Japan through the application of traditional medicine and complementary/alternative medicine in response to a shift in needs from quantity to quality medical care accompanying changes in demographics and disease structures.

Naoya Ono
Center for Lifence in 22nd Century
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Integrating Kampo and Evidence-Based Medicine – Type 1 Case

The Effects of Yokukansan on Behavioral and Psychological Symptoms of Dementia (BPSD)

Hiromichi Yasui
Japan Institute of TCM Research

Introduction

In this series, I define four types of use of Kampo medicine in daily clinical practices within Japan's unified medical system, and discuss the diseases that fall under each of these types, by giving relevant case examples. In the previous issue of this journal, I introduced four episodes, and explained that they fall under the four types of use of Kampo medicine in daily clinical practices. Let me recount them below.

Type 1: Kampo treatment is better than standard modern medical treatment

Type 2: The effects of standard modern medical treatment and Kampo treatment are both strengthened when the two are used in combination

Type 3: The side effects of standard modern medical treatment can be mitigated in combination with Kampo treatment

Type 4: Circumstances prevent the application of standard modern medical treatment, but treatment is needed

We shall take a look at type 1 in this issue. Type 1 is where Kampo treatment is more effective than standard modern medical treatment, and is used alone usually. As one case, I will introduce the effects of yokukansan and yokukansankachimpihange, a prescription that adds chimpi (Citrus Unshiu peel) and hange (Pinellia tuber) to yokukansan, on behavioral and psychological symptoms of dementia (BPSD). The application of Kampo treatment to core symptoms of dementia will be an issue I will eventually discuss later, but here I will discuss the effectiveness of Kampo medicine on BPSD, which is a important issue especially in the nursing field, through case examples.

1. An episode

A 76 year-old man living in front of my clinic is someone I have known since childhood. He took after the family joiner business that his grandfather started, and was a courteous, good-natured man with strong leadership qualities. He has been healthy all his life, but became prone to illness as he entered his seventies. He underwent surgery for thoracic and abdominal aortic aneurysms, and a coronary artery stenosis. He also started hemodialysis because of chronic renal failure from the age of 75.

From around this time, he began to display minor memory impairments, and his personality changed gradually. He would suddenly lose his temper at something that was trifle, frequently to the point where he became uncontrollable. As these episodes increased in both degree and frequency in a short time, his daughter helplessly brought him to see me.

The man who entered my office was the same man I knew since before, but according to his family, he would turn into a different person when he was angry. Upon hearing this, I prescribed yokukansankachimpihange (Kracie Pharma, Ltd., Tokyo, Japan).

The next day, his daughter came to me again and said that her father spent the previous night without anger, and that he was the person he always was. From that day, he took the prescription every day without fail, and returned to being the kind, good-natured man he used to be, without experiencing any flashes of heightened emotions.

There are countless cases like this, which have actually been triggered by the emergence of a certain paper, as will be discussed later.

2. Source and Description of Yokukansan

The original text describing yokukansan (抑肝散, Liver-Inhibiting Powder) had been said the "Hoei Satsuyo (保嬰撮要, Bao-Ying Cuo-Yao, Essentials for the Care of Infants) 1555" written by Xue Ji. In a recent study, however, the source of the prescription

was traced to *Hoei kinkyoroku* (保嬰金鏡録, Bao-Ying Jin-Jing Lu, Golden Mirror for the Care of Infants) (1550) also written by Xue Ji. Anyway, the prescription was originally a prescription for children.

This text states: "Yokukansan heals deficiency-heat of liver Meridian, the event of convulsions, or development of fever with grinding the teeth, or palpitations with anxiety; clinically irritability happens as chills and fever, or else a condition where wood over controls earth and the patient discharges phlegm and saliva, the abdomen is distended, the patient eats little and has difficulties with sleep. Use 5 fen (about 1.9g) of Bupleurum Root, 8 fen (about 3.0g) of Cnidium Rhizome, 1 qian (about 3.8g) of Angelica Root, Atractyrodes Rhizome, Poria Cocos, Uncaria Hook, and 5 fen (about 1.9g) of Licorice Root prepared in water. This decoction should be given simultaneously to both mother and child."

Nishida also reports a case similar to one written in the original text, where a mother and child both experienced an improvement after taking yokukansan[1].

3. Reports of Previous Cases

In Japan, the prescription has been known to be effective for adults as well as children since the 1700s, and has been used for cerebrovascular diseases and neurosis. In recent years, Dr. Keijiro Hara discovered it to also be effective for BPSD[2]. One of the 12 cases he reported is introduced below.

Report by Dr. Keijiro Hara
Patient: Man
Underlying disease: Senile dementia, cerebral arteriosclerosis
Chief complaint: Night wandering, self-talk
Present disease: He has been treated continuously for high blood pressure since 1963. Forgetfulness gradually set in since about two years ago, such that he frequently forgets the names and faces of acquaintances and family. After undergoing surgery (artificial head bone replacement surgery), post-surgery course was good, and walking became possible again, but he would not walk, claiming knee pain (although there was no swelling or distortion).

He had an appetite, but not in a stable manner. He experienced one bowel movement per day. Each day, he slept, woke up, talked to himself, and went outside at night and wandered the neighborhood. His family stopped on him, so he was hospitalized.
Examination findings: He was found to have a sunken and thready pulse. General weakness and a tendency for stomach palpitations were shown in a stomach examination.

Blood pressure 150/80mmHg, Red blood cells 3.46 million/mm^3, Hb 10.5g/dL, Ht 32%, white blood cells 4,900/mm^3 with no abnormal differentiation, total serum protein 6.8 g/dL, A/G ratio 1.11, GOT 14 IU/L, GPT 5 IU/L, BUN 23.4 mg/dL, creatinine 1.5 mg/dL, uric acid 7.9 mg/dL, total cholesterol 265 mg/dL, HDL-cholesterol 52 mg/dL, triglyceride 94 mg/dL, TTT 3.6 U, ZTT 5 U, HBs antigen (–), electrolytes: normal, ECG: no abnormalities, urinalysis: protein (–), urinal sugar (–), urobilinogen (+/–).
Treatment and course: After administering 7.5g of yokukansankachimpihange extract granules (Tsumura Co. Ltd., Tokyo, Japan), the patient gradually settled down, such that his self-talk completely stopped for roughly two weeks, and he slept soundly at night. His appetite and bowel movement also improved, and he began engaging in rehabilitation on his own will, so that he became able to walk. His complaints about knee pain also decreased.

4. Research by Iwasaki et al.

Following Dr. Hara's report, similar reports have been presented by many physicians. Dr. Koh Iwasaki et al. examined these previous studies and became convinced that yokukansan is effective against

BPSD. They therefore conducted the following clinical trial, and his paper revolutionized conventional wisdom about BPSD treatment.

The subjects were 52 patients (24 men and 28 women, mean +/- SD age = 80.3 +/- 9.0 years) with mild to severe dementia according to DSM-IV criteria. The trial was performed from January 2004 to March 2004. The patients were randomly divided into a group administered with yokukansan (N = 27) and a placebo group (N = 25) and treated for 4 weeks. The Neuropsychiatric Inventory (NPI) for the assessment of BPSD, the Mini-Mental State Examination (MMSE) for cognitive function, and the Barthel Index for activities of daily living (ADL) were tested at baseline and after completion of the treatment.

The frequency of extrapyramidal symptoms (EPS) and other adverse events were recorded. If patients failed to show adequate response to treatment after a week, tiapride hydrochloride, a selective dopamine D1 receptor antagonist, and L-dopa were allowed to be added to the regimen.

The result was as follows.

All patients in both groups completed the trial. In the control group, 11 patients required treatment with tiapride hydrochloride. The group administered with yokukansan showed significant improvements in BPSD compared to the control group. The NPI score showed an improvement from 37.9 +/- 16.1 to 19.5 +/- 15.6, and the Barthel Index from 56.4 +/- 34.2 to 62.9 +/- 35.2. MMSE results remained unchanged in both groups. EPS symptoms were not observed in either group, but dizziness and impaired postural sway were observed in 6 patients who were treated with tiapride hydrochloride[3].

Some papers double-checked the report by Iwasaki et al., and various reports were presented regarding yokukansankachimpihange as well.

Ikeda et al. administered yokukansankachimpihange to 23 patients with cerebrovascular dementia, so that a clear increase was observed in the scores of an intellectual function test 8 weeks and 12 weeks after administration. The patients' subjective symptoms and evaluation by caregivers also showed a high degree of improvement in the 8th and 12th weeks and a stable effectiveness of the preparation. Although there were no patients with depression at baseline, an evaluation of depression symptoms showed improvements in score in the 4th, 8th and 12th weeks, suggesting that yokukansankachimpihange has the effect of stabilizing emotions. Based on this result, Ikeda et al. reports that emotional stability appears at a relatively early stage, and regarding intellectual functions, a stable effect can be observed in the 8th week and beyond after administering the essence continuously for more than 4 weeks[4].

There have also been recent reports about the effects of yokukansankachimpihange on Dementia with Lewy body, as with yokukansan. According to Sasaki et al., the MMSE score remained unchanged after 4 weeks of administration, but improvements were observed in the scores of the NPI and BPSD-International Psychogeriatric Association[5].

Aside from the above, Izumi administered the preparation to 14 patients who exhibited violent behavior or other behavioral and psychological symptoms of dementia, and reported that it had a marked effect on 5 patients, a valid effect on 7 patients, and a rather valid effect on 2 patients[6].

Kimura et al. reports that yokukansan and yokukansankachimpihange are also effective against symptoms such as insomnia, anxiety and palpitations that caregivers commonly experience, and that there have been cases where the two prescriptions have been administered simultaneously to both patient and caregiver[7].

5. Systematic Review by Matsuda et al.

Matsuda et al. conducted a meta-analysis of papers that have been presented so far on the effects of Yokukansan on dementia, and has published a systematic review[8].

The following four papers were analyzed.

1. Iwasaki K. Sato-Nakagawa T. Maruyama M. et al. A randolnized, observer-blind, controlled trial of the traditional Chinese medicine Yi-Gan San for improvement of behavioral and Psychological symptoms and activities of daily living in dementia patients. *J Clin Psychiatry* 66: 248-252. 2005
2. Mizukami,K. Asada T, Kunioka T. et al. A randomized cross-over study of a traditional Japanese medicine (kampo), yokukansan, in the treatment of the behavioural psychological symptoms of dementia. *Int J Neuropsychopharmacol* 2009, 12.191.
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4. Okahara K, Ishida Y, Hayashi Y, et al. 2010. Effects of Yokukansan on behavioral and psychological symptoms of dementia in regular treatment for Alzheimer disease. *Prog Neuropsychopharmacol Biol Psychiatry* 34: 532-536

Matsuda et al. selected 4 papers from the 46 that were in the PubMed, Cochrane Library, and Psyc INFO database as of October 2012 and retrieved using the keywords “dementia” and “yokukansan,” and conducted a systematic review of randomized controlled trials on the administration of yokukansan to dementia patients who display BPSD. The 4 papers dealt with 15 to 106 cases and a total of 236 patient-subjects, 121 of whom were administered yokukansan. They discussed various types of dementia, including Alzheimer’s disease, Dementia with Lewy body, and vascular dementia. Test periods ranged from 4 to 12 weeks (average 6 weeks). The average age of the subjects was 78.6 years of age.

The result of this review was as follows.

Yokukansan was effective in reducing the total score of NPI compared to regular treatment (p = 0.0009). About NPI subscales, significant improvements were seen regarding delusion, hallucination, and excitement/aggression, and significant improvements were also observed in ADL compared to regular treatment (p = 0.04). MMSE found no significant difference between those who were added yokukansan on regular treatment and those who weren’t. There was no significant difference in the rate of cancelling treatment between the two groups, either.

In conclusion, Matsuda et al. stated that yokukansan had a beneficial effect on improving NPI scores (BPSD symptoms such as delusion, hallucination, and excitement/aggression) and ADL, and that it was an adequately valid method of treatment.

Based on the large number of case reports and the previous papers, physicians in Japan have come to use yokukansan and yokukansankachimpihange routinely to treat BPSD in dementia patients. The use of antipsychotic drugs against BPSD must be eschewed, as there is the risk of minor to intermediate adverse effects. Under this situation, yokukansan and yokukansankachimpihange are extremely valid, and confer considerable benefits to people who work in the nursing field.

In Japan, all patients may receive this benefit, precisely because all citizens are covered by health insurance under a unified medical system. This fact is highly noteworthy.

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Note) The side-effects of licorice contained in Yokukansan

Yokukansan and yokukansankachimpihange contain licorice, which causes pseudoaldosteronism at a certain frequency. Therefore, when they are administered, it is necessary to pay special attention to physical findings (edema, rise in blood pressure), and to regularly measure potassium in the blood. There are many studies about this.

Up to now, it was thought that glycirrhetinic acid (GA), a metabolite of glycyrrhizin (GL) in licorice and produced by intestinal bacteria, is the cause of pseudoaldosteronism. However, in 1995, Kato reported that 3-Monoglucuronyl glycirrhetinic acid (3MGA) was detected only in the blood of patients who developed pseudoaldosteronism, and that the substance was not detected in the blood of patients who did not develop pseudoaldosteronism, even when licorice was used. Since then, new studies based on this report have appeared.

Makino et al. revealed that a transporter protein that appears on cell membrane is involved in the development of this side effects, judging from the facts that 3MGA in blood rises in certain types of liver diseases that 3MGA is excreted to the urine but GA is hardly excreted to the urine although it is present in the blood at high levels. This phenomenon is important because the key molecule, type 2 11β-hydroxysteroid dehydrogenase (11β-HSD2), which is a cause of pseudoaldosteronism, exists inside renal tubular cells. They then concluded that it is highly likely that 3MGA is the real cause of pseudoaldosteronism.

Before long, it will become possible to distinguish people who are inclined to develop pseudoaldosteronism by licorice.

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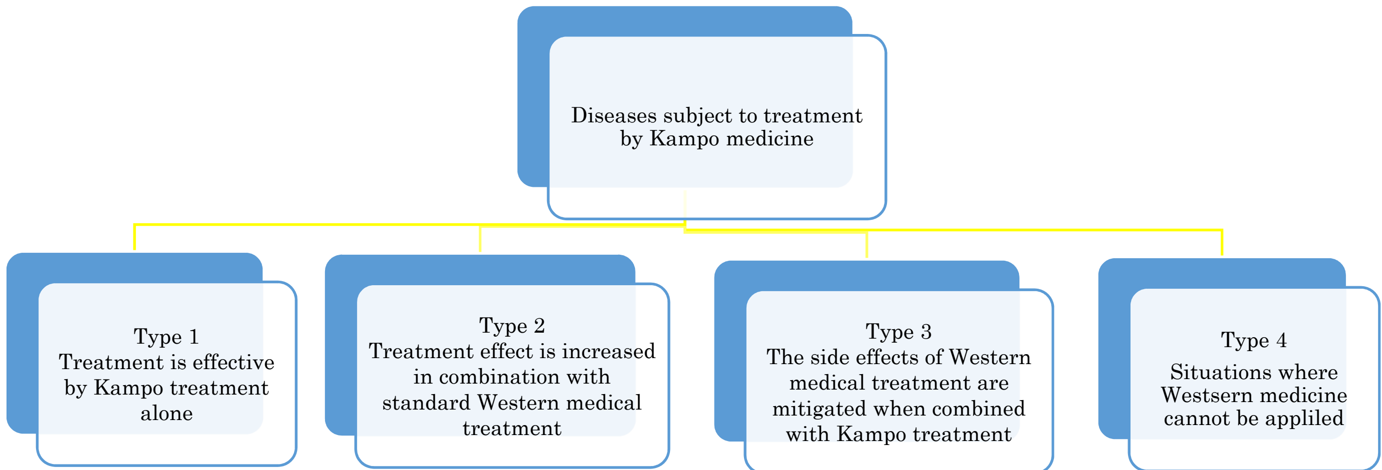
The four types and their characteristics



In this issue, cases relating to the use of yokukansan for BPSD in dementia patients were introduced as representing Type1 usage, where Kampo treatment is more effective than modern medical treatment and is thus frequently used alone, as shown below.

1) Cases where Kampo treatment is definitely better than standard treatment

Case 1: Yokukansan for behavioral and psychological symptoms of dementia (BPSD)

Case 2: Yojinkodakuto for chronic renal failure

Case 3: Goreisan for headaches associated with a drop in atmospheric pressure

Case 4: Goreisan for earaches that occur when boarding an aircraft

Case 5: Shakuyakukanzoto for muscle convulsions

Case 6: Shosaikoto, saikokeishito and saikoseikanto for recurrent upper respiratory inflammation in children

Case 7: Juzentaihoto for perianal abscess in children

Case 8: Juzentaihoto for recurrent otitis media in children

2) Cases where early healing or relief could be achieved by Kampo treatment

Case 1: A number of Kampo prescriptions for improvement of symptoms that occur before they are diagnosed as rheumatoid arthritis

Case 2: Kampo medicine represented by maoto for the early stages of influenza

Case 3: Goreisan for the early stages of vomiting and diarrhea (mostly caused by rotavirus) among children

Case 4: Kampo medicine (kakkonto, maobushisaishinto, etc.) for the early stages of a cold

Japanese Acupuncture - Current Research

Japanese Traditional Medicine Text (16) – Neurology B

Satoru Yamaguchi

Headache

1. Acupuncture Indications in Neurological Disorders

The headache symptoms commonly encountered in routine clinical practice are one thing, but there are still many challenges to its pathogenesis, diagnosis and treatment. In 1988, the International Headache Society released a "headache classification" that has been adopted by many clinicians and researchers. However, in 2003, advances in headache research led to revised classification and diagnostic criteria announced by the same society and known as the International Headache Classification Second Edition (ICHD-II) (**Table 15**)[1]. Within this classification the high prevalence of the primary headache migraine and tension-type headache was noted and within Japan accounted for 8.4% and 22.4% of migraine and tension headache sufferers. Further, this data was reported in epidemiological studies in Japan. There is evidence that clinical acupuncture and moxibustion should be considered effective for preventing migraine and tension-type headaches.

So this essay is about prospects and possibilities, and introduces the results of clinical studies of acupuncture treatment on primary headache. The author hopes to promote the current status of clinical research on acupuncture and moxibustion therapy in the pathogenesis of primary headaches both domestically and abroad.

Table 15　International Headache Classification (ICHD–II)

1. Migraine
2. Tension ― type headache (TTH)
3. Cluster headache and other trigeminal/ autonomic nerve type headaches
4. Other primary headaches
5. Headache attributable to head or neck trauma/ injury
6. Headache attributable to vascular disorder in the head and neck
7. Headache attributable to non-vascular intra-cranial disorder
8. Headache attributable to substance abuse or withdrawal
9. Headache attributable to contagious diseases
10. Headaches attributable to homeostatic disorders
11. Headache attributable to other cranial or facial pain (cranium, neck, eyes, ears, nose, sinuses, teeth, mouth or other location in the face or head)
12. Headache attributable to neurological disorders
13. Cranial neuralgias and facial pain attributable to the central nervous system
14. Other headache, cranial neuralgia, central or primary facial pain

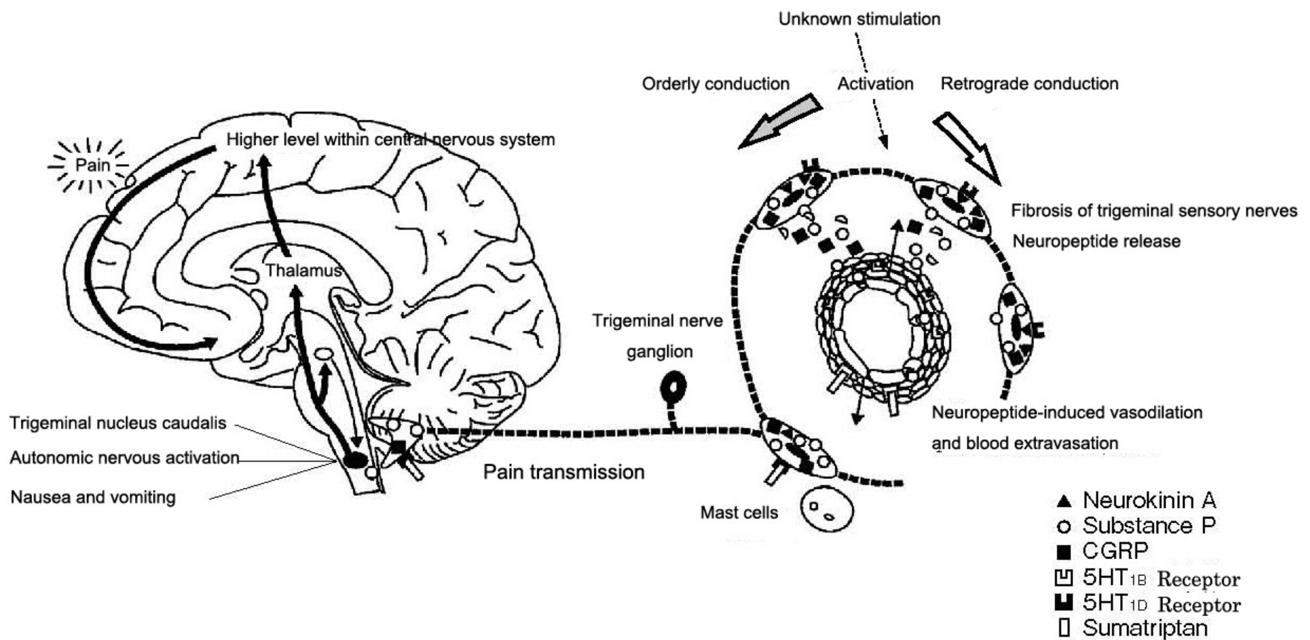


Figure 12 Patient condition of migraine headache (The author altered the figures of Moskowitz and Goadsby)

1. Pathogenesis of primary headaches

a Migraine headache

A study of cerebral blood flow in patients with migraine found decreased cerebral blood flow during the prelude and an increased blood flow during the headache phase. This phenomenon became known as "vascular theory". However, Olesen et al. suggested vascular changes during migraines are not unique, reportedly caused by neurological changes in their cerebral cortex, they are collectively referred to within the "neural theory". On the other hand, Moskowitz et al. investigated the relationship between the trigeminal nerve and vascular intracranial blood vessels, especially blood vessels of the Dura mater. The trigeminal ganglia from un-myelinated C fibers are distributed to the blood vessels of the Dura. Further, they clarified that when the trigeminal nerve was stimulated electrically or chemically, dural vessels showed "neurogenic inflammation" (degranulation of mast cells, vasodilation and plasma protein leakage). This "trigemino vascular system" was thought to mediate "neurogenic inflammation" as a model of migraine headache pathway, thereby reinforcing the trigeminal vascular theory (trigeminovascular theory (**Figure 12**). That is to say, some stimulation in the axons of the trigeminal nerve in vicinity of the Dura blood vessels, cause the release of neuropeptide (substance P, neurokinin A, CGRP etc.), in turn causing "neurogenic inflammation". It is thought that this process results in trigeminal nerve anterograde and retrograde conduction. The former results in the trigeminal nuclei, at the same site where the c-Fos production is stimulated, the latter is more conducive to the release of neuropeptides that promote blood vessel activity. Until recently, these theories, vascular and neuronal, are considered to be organically combined[2]. Further, in recent years, central nervous system irritability and instability reflected in the blood vessels, has changed the main concept of pain in the central nervous system. In other words, there apparently exists a "migraine generator", activation of this site in some way causes headaches to occur[3]. Areas listed as migraine generator locations include nuclei of the thalamus and hypothalamus, raphe nuclei of the brainstem, locus coeruleus and mesencephalic aqueduct within the gray matter.

b Tension headaches

Tension-type headaches result following sustained physical and mental stress leading to contraction of cranial musculature and decreased blood flow. Further, lactic acid and pyruvic acid, by-products of this continued stress are created, exacerbating the pain cycle. This type of pain is due to sympathetic nervous excitation, which allows sustained muscle contraction and a relative insensitivity to pain (elevated pain threshold). This type of headache is also stressful to the body, so once the vicious cycle is established these headaches are often prolonged.

Muscle tension was shown to be involved with tension headaches in 1963, when Wolff used an EMG to show muscle contraction, he then used local anesthetic, relaxing the musculature and relieving the headache. Sakuda[4] observed lying prone decreased blood flow to muscles and muscle discharge. Further, Sakai at al.[5] used a muscle hardness method and observed a high level of hardness in the Trapezius and posterior neck muscles. Results of a study[6] using plethysmography, EMG and thermography revealed that, rather than muscles of the head, tight neck, shoulder and proximal upper back muscle groups play an important role in tension-type headache pathogenesis. These results show, daily clinical examination findings often confirmed the significance of tenderness or induration in muscles of the neck, upper back and shoulder. In 2003 the International Headache Society revised the tension-type headache classification reiterating the importance of pressure pain findings. There are a wide variety of underlying factors causing people to become susceptible to tension-type headache, but tight neck, shoulder and proximal upper back muscle are thought to be deeply involved in the pathogenesis of these headaches.

Kitagawa et al.[7] suggested that pathogenesis of tension-type headache included not only sustained muscle tension but also mental and emotional stress that triggers abnormal experience of central nervous system sensations. Anxiety, depression and stress affect the limbic system lowering the pain threshold, leading to spinal inhibitory system disorders, abnormalities in central nervous system neurotransmitters, and decrease in endorphins, etc., critical factors in central and peripheral nervous system pain hypersensitivity contribute to headache and also biochemical factors such as serotonin may be related as well. There are reports of central sensitization related factors of the central nervous system, especially in chronic tension-type headache, the pain threshold was found to be extremely low. Suppression of the temporalis and masseter muscles are related to interneuron in the pons, as seen in the surface EMG potentials (extero-ceptive suppression of temporal muscle: ES2) in chronic tension-type headache patients, the brainstem mechanisms point to central sensitization.

2. Clinical studies abroad

Using a PubMed literature search for acupuncture treatment of foreign research on primary headache, we used ”acupuncture”, ”metaanalysis”, ”migraine” and ”tension-type headache” as keywords. Eighty-eight reports were retrieved, however excluding non-drug and alternative therapies for pain, there were only 30 remaining reports. As for acupuncture for migraine headaches, 21 appropriate reports were extracted, and there were 3 appropriate reports discussing migraine treatment for children. Evaluation methods included VAS scale, number of days with headaches and SF — 36 (a multi-purpose, patient-reported short-form health survey) etc. Only one report utilized an economic (treatment cost-effectiveness) evaluation. Acupuncture treatment results for migraine headache showed short term, results were good compared to a standard preventive drug. However, 6 months later the effects were comparable but acupuncture patients reported fewer side effects and no significant difference compared to Sham acupuncture was confirmed. Acupuncture effects on tension-type headache were drawn from 9

reports with 1 of these focusing on children with chronic tension headaches, 1 for adults with chronic tension headaches and the remaining 7 were general tension-type headaches. Evaluation methods were VAS scales, reported number of days with headaches, SF—36 survey, etc. Only one reports included a cost-effectiveness evaluation. Acupuncture treatment results for tension-type headache suggested its usefulness and improved results compared to the standard treatment, although compared with the placebo group, a clear result was not reached. Economic evaluation showed acupuncture to be highly cost-effective for both tension-type and migraine headaches. Also we have already reviewed the effects of acupuncture treatment for pregnancy migraine sufferers when a non-drug therapy is highly desirable. In the future, it will be necessary to consider what effects and limits to treatment will be admitted to any subgroup as we create and design future projects.

3. The condition of domestic clinical research

We carried out a domestic literature search for acupuncture effects on primary headache in Japan and published in major medical journals. Keywords included “headache”, “tension-type headache”, "migraine", "cluster headache" and "acupuncture treatment". One- hundred twenty-five original reports of headache treated with acupuncture and moxibustion treatment were extracted; 15 tension-type headache, 12 migraine, duplicate studies were excluded. Also only primary headache research was included, research on secondary headaches was excluded from the clinical review. Therapeutic intervention was considered: acupuncture treatment only, combinations with other alternative medical techniques or modalities were excluded. Terms such as muscle tension headache or vascular headache, which did not fit ICHD-Ⅱ categories of migraine, tension-type headache, and cluster headache, were categorized as "headache" because mixed or multiple symptoms could not be determined from the article.

Literature references on acupuncture treatment for headaches, included 12 for migraine, 14 for tension-type headache, 1 for cluster headache and 19 for headache. Case studies were most common with 14 references, integrated reviews of case studies accounted for 8 reports and only 4 comparative studies were available and these were only concerning acupuncture treatment for patients with tension-type headache. Studies based on RCT or meta-analysis were not available. On the effect of acupuncture treatment for migraine, Liu's[8) treatment method was found to be significantly effective within certain limits.

Although none of the published clinical research denied the effectiveness of acupuncture and moxibustion therapy for headache, evidence from higher level, well thought-out RCT or CCT studies are desirable.

4. Results of clinical studies in Oriental Medical Center from Saitama Medical University

a Migraine headache

1) Effects of acupuncture treatment

Seventy patients who met the ICHD-II classification standards for migraine were given acupuncture treatments for 2 months before the effects were evaluated. Greater than moderate results were reported, patients experienced significantly fewer days with headaches and correlated reduced tenderness of the muscles of the neck and shoulders with their acupuncture treatments.

2) Acupuncture treatment mechanism

Comparing the influence of cerebral blood flow in acupuncture for migraine patients with that of normal subjects, acupuncture was found to be safe and non-invasive even without the use of contrast agents and with repetitive inspections using arterial spin-labeling (ASL) MRI. Results showed migraine patients treated with acupuncture stimulation had increased cerebral blood flow in the thalamus, hypothalamus and pars opercularis, cingulate gyrus and insula during and after the acupuncture

stimulation. On the other hand, a transient increase in blood flow during acupuncture stimulation was confirmed in the healthy subjects. Given these results, while acupuncture on healthy individuals whose cerebral circulation increased in response to the stimulation, preventative acupuncture for migraine attacks may involve stimulating higher levels of the central nervous system.

b Tension-type headache

1) Effects of acupuncture

Other medical department occasionally make clinic requests for acupuncture. Ninety-two tension-type headache patients whose symptoms met the ICHD-II classification criteria were given acupuncture and analysis of the effects of these treatments showed an 82.3% efficacy rate. Also, regarding factors related to the improvement rate of other related symptoms following acupuncture, multiple regression analysis results confirmed satisfaction with the improvement rate for stiff neck and shoulders[9].

2) Mechanism of Acupuncture [6, 10, 11]

As previously mentioned, results from plethysmography, EMG, and thermography shed some light on the mechanisms behind tension-type headache pathogenesis. Rather than muscles of the head or scalp, tight neck, shoulder and proximal upper back muscles play an important role. Published reports suggest acupuncture treatment relaxes these tight muscle groups and improves circulation contributing to the improvement of the headache. Also, using a quantitative measurable open loop video pupillography, a non-invasive inspection method of examining autonomic nervous function, we investigate the mechanism of acupuncture. As a result, acupuncture therapy in patients with tension-type headache, caused pupil dilation greater than pupil constriction showing dominant parasympathetic stimulation. Such reactions to acupuncture are not simply a local reactions (axis axon reflex), higher central nervous system influence is also apparent (Edinger-Westphal nucleus and Central gray matter) suggesting systemic physiological influences contribute to the improvement of the headache. Also pupillary reaction to acupuncture in normal subjects, created no significant changes, unlike the reaction to acupuncture for tension-type headache patients. Because reactions to acupuncture were different between the healthy individuals and the headache patients it was concluded that acupuncture treatments improve the body's homeostasis.

5. Future prospects

Results of acupuncture treatment for headaches, a large clinical study from Europe indicated (n=15,056, RCT or non-randomized cohort), (treatments were continued for 3 months) daily reports of headache frequency decreased from 8.4 days to 4.7 days per month. In comparison, the control group reported headache reduction from 8.1 to 7.5 days, a significant difference in reduction of headaches (p<0.001). Additionally, QOL indexes improved more within the acupuncture group[12]. Also in terms of health care cost economy, evaluation shows acupuncture costs to be about € 11,657 a year, QOL compensation and life extension's cost-effect ratio by acupuncture is sufficiently effective and economical[13]. In the update report of the Cochrane review of acupuncture for migraine headache, acupuncture has yet to be proven more or less useful than sham acupuncture (placebo) however, acupuncture treatment cost-effect ratio and QOL compensation were positively confirmed. Importantly, compared with the established effectiveness of preventive drug therapy, acupuncture treatment is equally effective with fewer adverse side-effects. Additionally, patients with tension-type headache confirmed that their headache frequency and severity improved even with sham acupuncture. As expressed above, authors investigating the mechanism of tension-type headache and, over a fixed period, the continued effects of acupuncture treatment continued to reduce the frequency of headaches, and within each health

parameter the authors reported the patient's conditions were approaching normal. Also, the analgesic mechanism of these simple local reactions (axon reflex) and the higher central nervous system have an effect, and clearly the autonomic nervous system plays an important role, acupuncture has a homeostatic reaction, which can scientifically confirm characteristics of traditional medicine[14].

In the future, the purpose of acupuncture treatment should be clarifying the mechanism of action, and even the pathophysiology of these headaches. In recent years, brain hypersensitivity has been introduced, so we should be willing to consider in detail the effects of acupuncture treatment on lowering the pain threshold in the "migraine generator" pain sites (thalamus, hypothalamus, midbrain aqueduct, gray matter, coeruleus and raphe magnus etc.) using ASL and MRI etc., these findings should be involved in clarifying acupuncture treatment effects on higher levels of the central nervous system. In addition, I want to thoroughly clarify and export Japanese acupuncture and the effects of acupuncture and moxibustion for treating migraine with or without an aura and tension-type headache paying special attention to classifying repetitive, frequently recurring and chronic conditions using RCT or CCT.

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Clinical Report 1(Acupuncture)

Make Moxibustion Work – Moxibustion at LR1 for Vertigo

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Keywords: vertigo, moxibustion, Acupuncture points analysis, chronological analysis

【Introduction】

In this clinic I attempt to holistically comprehend the condition of my patients through chronological analysis[1] and analysis of the reactions at point locations and carried out my moxibustion treatment following the Sawada and Fukaya styles. The Fukaya style comprises 10 basic clauses[2] of which the first says "moxibustion does not work, it has to be made to work". To that end he describes ways of how to find the reactive points and determine the degree of heat penetration. In clinical practice the acupoint locations are not only identified via inspection or palpation, but the sensitivity to the heat of actually performed moxibustion and the acupoint sensitivity at reactive points seems also to be important.

Here I describe the application of heat penetrating moxibustion at central LR1, one of the specifically effective points for vertigo, and correlated the degree of heat penetration to the symptoms and report its effectiveness.

【Fukaya style】

The essence of the Fukaya moxibustion method has been summarized in 10 basic clauses[2] of which the first says "moxibustion does not work, it has to be made to work". It further says, "this first clause shows the basic approach of the Fukaya moxibustion method, while the second and following clauses describe the details." Regarding these details the second clause describes the types of reactive points and how to find them, subsequently the third clause describes how to combine these points for treatment purposes and some ways of how to perform moxibustion at these reactive points. In the ninth clause then it says "adjust the size and number of the moxa cones to the physical constitution of the patient (<u>apply moxa at points where the patient does not feel the heat until s/he does</u>)" and as supplementary explanation in the section about the performance of moxibustion "as for moxibustion it is always normal that the heat is not felt at pathological reactive sites. Even if the moxibustion is felt hot, the penetration of the heat produces a rather pleasant heat-pain sensation." The text further says, that "The number of moxa cones should not be determined according to any specific pattern. Ideally the penetration of the heat determines the limit of the number of moxa cones."

With reference to these descriptions Yamami et al. proposed[3] some ways based on imagining the moxibustion heat at the reactive points regarding the size and density of the moxa and treated their patients while confirming the degree of moxa heat penetration (Figure 1).

【Case study】

A 54-year old woman, nurse (deputy manager of a nursing department), chief complaint was rotatory vertigo. (No tinnitus or hearing impairment, she had not been otorhinologically diagnosed, but based on the symptoms the vertigo was considered to be non-vestibular vertigo). In relation to ADL she reported "I have the feeling it may occur even in my sleep and thus prevents me from sleeping, I also lack concentration and vitality and fear, this may interfere with my work".

The present illness started around X-25, when the chief complaint vertigo occurred approximately 2-3 times/year and later subsided by X-15. In the same year the patient underwent surgery for bilateral ovarian cysts and because of continuing profuse menstrual periods she started hormone therapy in X-9, artificially inducing menopause. However, because the patient considered the risk of breast cancer, she thought it would be better not to continue

the hormone therapy over a prolonged period, but when she discontinued it in X-2, the vertigo recurred. In July of X she underwent surgery for right-sided breast cancer (breast-conserving surgery). She was discharged after 2 weeks and scheduled to return to work, but the vertigo exacerbated under these conditions when the future treatment plan was about to be determined. That is why the patient visited my clinic following recommendation by her superior 4 days prior to her reinstatement.

(Chronological analysis; Figure 2)

She originally suffered from menstrual pain and after giving birth to two children developed stiff shoulders and headaches, so that her complaints were considered to be manifestations of the condition 'blood stagnation' characteristic for women. In her forties menopause was artificially induced when she underwent surgery for bilateral ovarian cysts and climacteric symptoms developed as side effects of a hormone therapy. After a surgery for breast cancer the chief symptom vertigo developed, suggesting the development of blood stagnation in addition to the trauma of the surgery. Further, in X-25 the vertigo developed when she was reassigned from the outpatient service to the ward nursing staff. The associated change in the pressure of her work triggered the symptoms, which later continued even during work in the outpatient service, but were probably also influenced by sickness and death in the family causing a decreased stress tolerance. In X she not only underwent surgery for breast cancer, but also was promoted to nursing department deputy manager. This conceivably led to an aggravation of the chief complaint as well as dizziness that may also have been triggered by the lowered stress tolerance.

(Analysis of the reactions at point locations; Figure 3)

Pressure hypersensitive indentations (GV12, BL15, BL17, BL23), pressure hypersensitive indurations (BL27, ST27, SP6), pressure hypersensitive edema/congestion (GV20), fine floating vessels (GV14, GV11, GV3) were observed. Based on the main indications for the relevant point locations at BL17, BL27, ST27, SP6, GV3 I considered these to be blood stagnation reactions, while the reactions at GV14, GV12, GV11, BL15, GV20, CV17 indicated a decreased stress tolerance.

(Treatment; Figure 3)

Based on a chronological analysis and an analysis of the reactions at the various point locations I concluded that blood stagnation and a lowered stress tolerance had led to health impairment and administered a treatment at the reactive points.

As a treatment I used micropuncture to led blood at GV3, GV14, direct moxibustion at GV12, BL15, BL27, CV4 and SP6. For the vertigo I tried moxibustion at GV20, but because the patient reported "I am under the impression this makes the dizziness only worse", I switched to micropuncture to led blood and instead performed direct moxibustion at central LR1. During the moxibustion treatment it took quite a number of moxa cones until the heat penetrated. After that I instructed the patient to perform this kind of moxibustion at home until heat penetration is achieved. Among Kampo medicines mainly Shigyakusan (Frigid Extremities Powder) and Keishibukuryougan (Cinnamon Twig and Poria Pill) were used.

(Course; Figure 4)

Already early after treatment begin the vertigo was alleviated to a degree, that it did not interfere any longer with her work. Following improvement of the symptoms I shifted the focus of the treatment to health care management and have continued this for about 6 years now. Figure 4 shows an excerpt from the time the patient was in poor physical condition, recording the number of moxa cones required to achieve heat penetration. After the first session the patient returned to work. When the vertigo did aggravate slightly after the start of radiation therapy, I increased the number of moxa cones burnt at central LR1. Yet, later she did not need to take time off from work even when initiation of the hormone therapy caused some aggravation. The

patient reported "when I feel vertigo is about to start, this feeling disappears when I administer moxa at central LR1". Regarding the performance of moxibustion at home, she was treated on the back about once or twice a week, but treated central LR1 almost daily. (However, since she did not record the changes in the number of moxa cones applied at home, these are unknown.) In January of X+1 she started to feel pain deep inside the scar of the breast surgery and a mild degree of vertigo and dizziness developed. At that time I increased the number of moxa cones applied at central LR1 and heat penetration was not achieved unless almost 50 cones were burnt. Also, on the occasion of her retirement in X+6 her work load increased for a while drastically related to handing over her duties to her successor, requiring temporary hospital admission. Overall, the symptoms related to the breast cancer as well as the vertigo exacerbated on occasions when she was very worried and very busy with her work (physical and mental busyness as a nursing department deputy manager). On those occasions the sensitivity at central LR1 decreased, so that I increased the number of moxa cones until heat penetration was achieved. Again, at the same time heat penetration at central ST45 was achieved with just one cone.

【Discussion】(Figure 5)

Central ST45 is an extraordinary point used according to the Fukaya moxibustion method[4] for vertigo and motion sickness. It is selected according to the aforementioned reference as a variant of the ST45 (stomach channel) a tenth of an inch from at the center of the nail plate of the second toe. The cases of motion sickness described in the book "Episodes of how I cured diseases with moxibustion[5]" apparently did not feel the heat of the moxa treatment and a large number of cones were applied until heat penetration had been achieved. The point is said to be effective for motion sickness induced vertigo in the presence of stomach troubles.

Central LR1 is not an extraordinary point, but rather selected as the so-called well point of the liver channel. In the book "Episodes of how I cured diseases with moxibustion[6]" the description reads: "in the middle of the toe from the external edge of the nail plate of the great toe and at a distance from the tuft of hair". It does not lie opposite from the point SP1 on the spleen channel (Shinkyu Setsuyaku = Summarized explanation of acupuncture and moxibustion), but the text says: "at the edge of the great toe, a little distance from the nail plate, in skin folds shaped like Chinese chives, among three-colored hairs" (Jushi Kei Hakki = Elaboration of the Fourteen Meridians). This description can be interpreted as the point being selected in the center of the dorsal aspect of the large toe, 1/10 of an inch (bu = fen) rearwards from the nail plate. Moreover, in case of dizziness a variant point can also be selected at the tip of the large toe. Its main indications according to the Fukaya moxibustion method are heart pain or fainting and similar convulsive disorders and the description says, there are no differences in effectiveness between the central point and the point at corner of the nail plate. The use of LR1 is also mentioned in Shinkyu Shinzui[7]. This reference does not describe any cases treated with multiple moxa cones at central LR1 for the treatment of vertigo, but based on experience with the use of central ST45 I have administered multiple cone moxibustion to achieve heat penetration in my clinic for a long time already.

Based on the chronological analysis and point reaction analysis I diagnosed the condition as blood stagnation, a disease associated with dizziness and vertigo and the patient's impression expressed as "when I feel vertigo is about to start, this feeling disappears when I burn moxa (at central LR1)" I believe, the use of central LR1 of the liver channel has been effective. The sensitivity of central LR1 and central ST45 are clearly different and there is a correlation between the severity of the symptoms and the number of moxa cones until heat penetration is achieved. Thus, the use of this central LR1 and the administration of an adequate number of moxa cones seems to have been effective.

Through the here presented case study I reconfirmed, that not only reactions like tenderness, indurations or indentations, the degree of heat

penetration also was an important reaction at the point location.

【Conclusion】

Both alleviation of symptoms and aggravation cause changes in the degree of heat penetration and central LR1 is considered to be effective for the kind of dizziness and vertigo observed in this case.

Upon identifying the point reactions the degree of heat penetration should be included. Performance of moxibustion adjusted to this sensitivity is important and considered to be one of the characteristics of Japanese acupuncture and moxibustion.

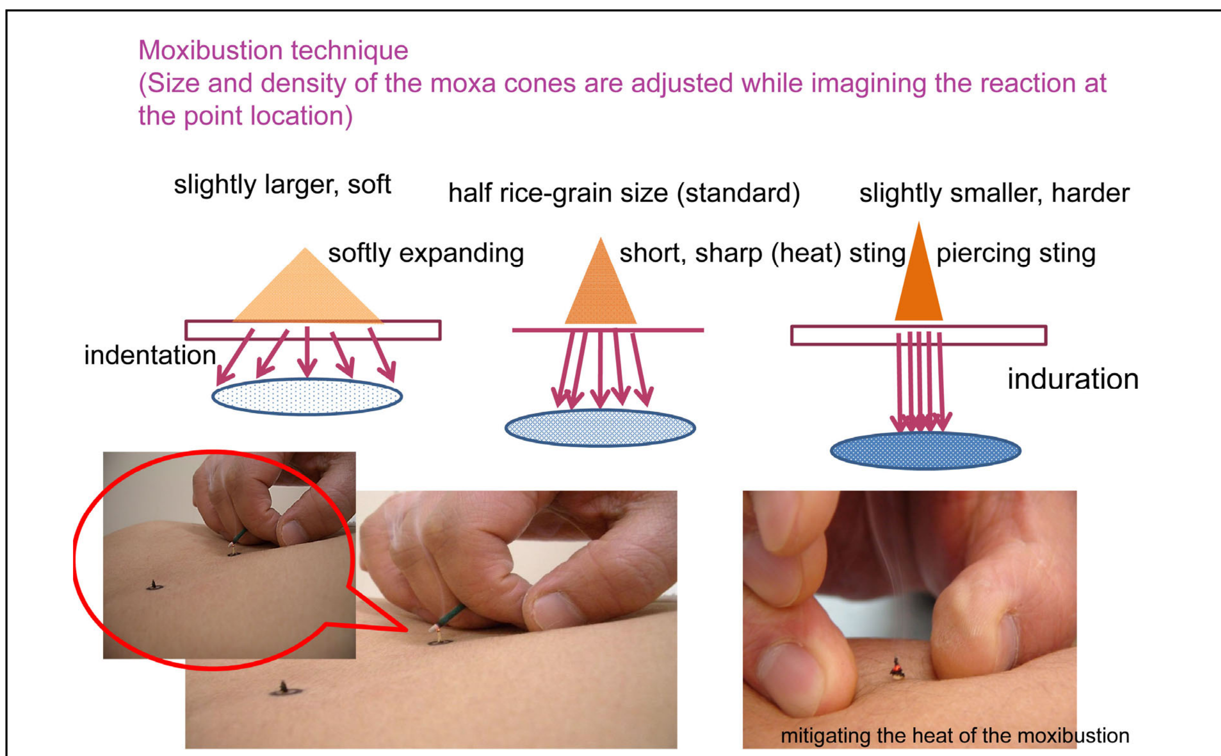

Figure 1

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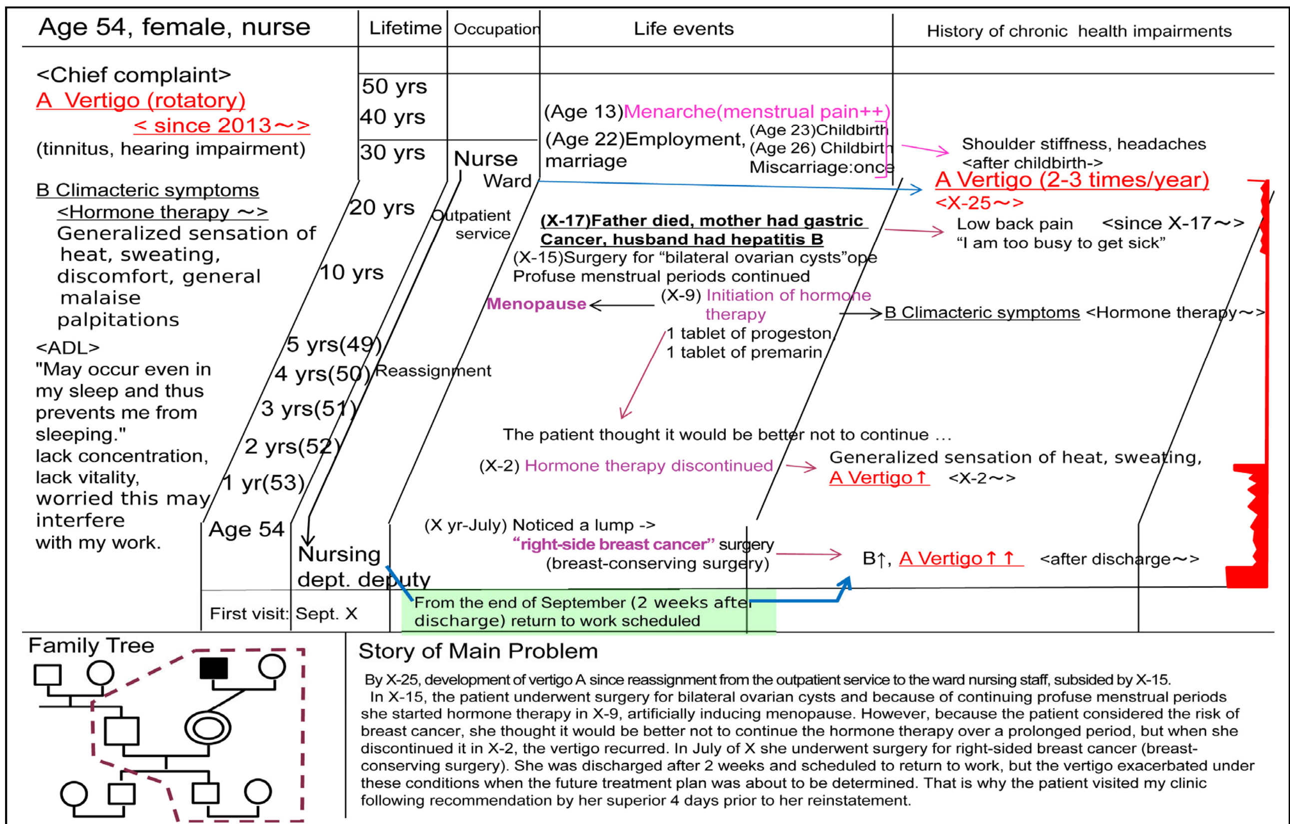


Figure 2

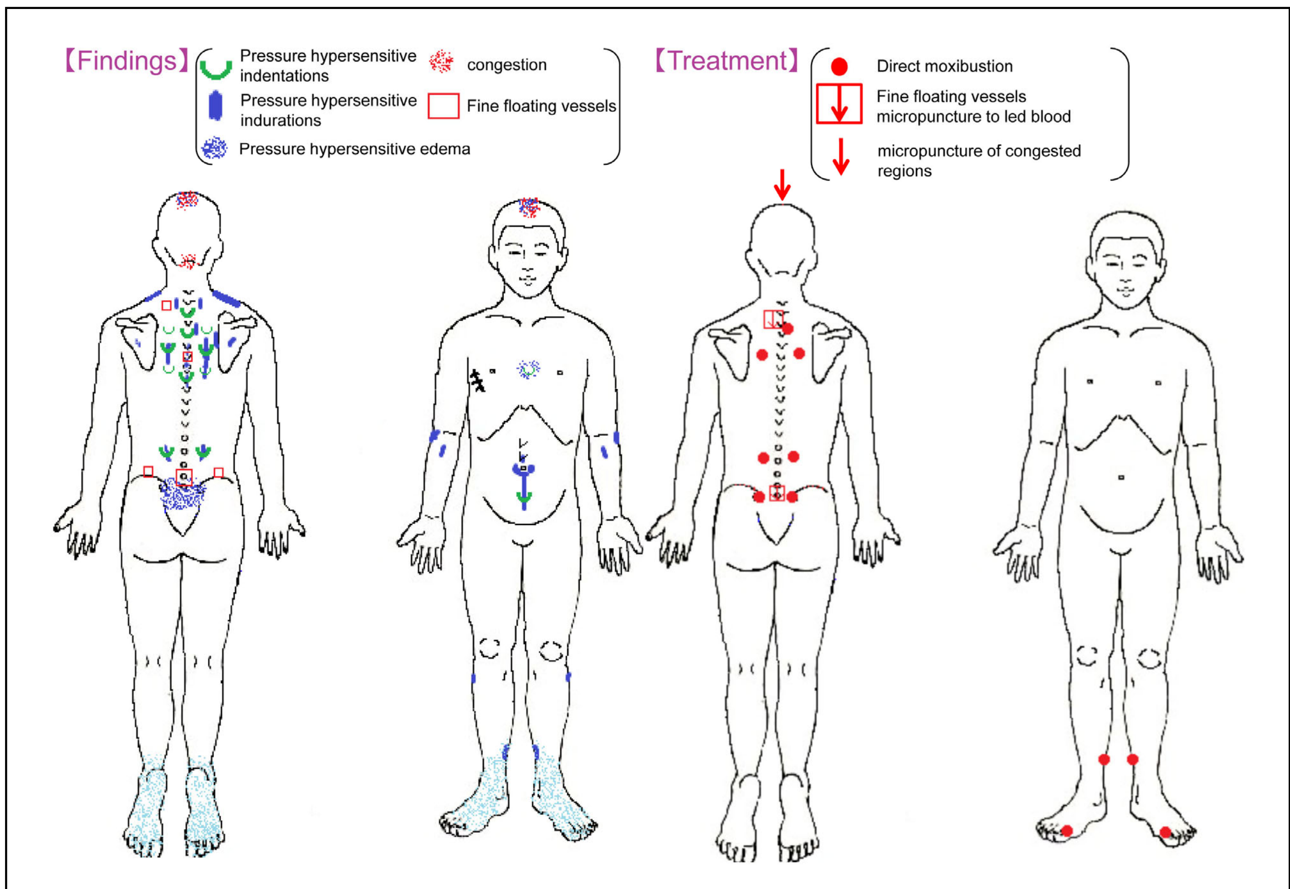


Figure 3

	Life events	Vertigo	Dizziness	Central LR1 R / L	
Sep. X (first visit)		mild	+	3	3
Oct. X	Return to work scheduled for September October: radiation therapy	occasionally	+	12	12
Nov. X	Start hormone treatment in November	++	+	5	3
Dec. X	"When I feel vertigo is about to start, this feeling disappears when I administer moxa at central LR1"	↓	mild	7	3
7	Pain felt deep in the surgical scar; consultation days of the physician in charge do not fit her schedule	mild	↑	13	8
X+1 year, Feb.	The patient consults a breast surgeon. No urgency, observing course until examination by the physician in charge is possible. Continued	++	++	45	50
X+1 year, Mar.	After treatment examination by the physician in charge	mild	mild	5	5
X+5 year, Jan.	Hospitalization for 3 days because of vertigo	++	—	12 central ST45 1	9 central ST45 1
X+5 year, Feb.	Transition	+	—	15 central ST45 1	9 central ST45 1
X+5 year, Mar.	Retirement	—	—	3	3

Figure 4

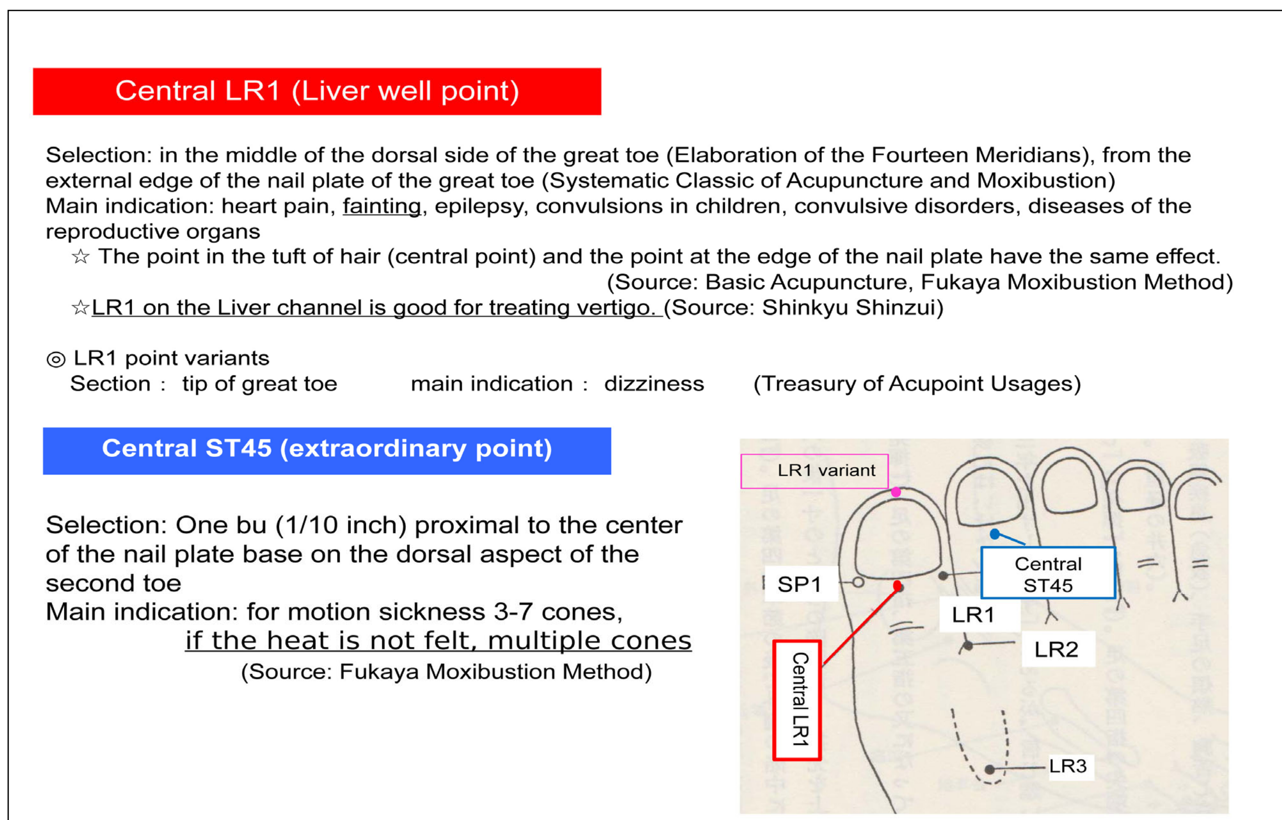


Figure 5

Clinical Report 2 (Kampo Medicine)

Case Studies from Ehime Prefectural Central Hospital (1)

– From the Rural Bedside to the Global Podium –

Genki Shimizu, Hiroshi Kakuto, Den-ichiro Yamaoka
The Internal Departement of East Asian Traditional Medicine of Ehime Prefectural Central Hospital

【Introduction】

At Ehime Prefectural Central Hospital, we have two young, developing Kampo clinicians. They are Drs. Genki Shimizu and Hiroshi Kakuto. Dr. Shimizu is in his eighth year of clinical practice. After graduating from Tokushima University, he completed a two-year post-graduate clinical training program, and thereafter commenced Kampo, acupuncture and moxibustion treatment while receiving specialized training in our hospital's general department. Dr. Kakuto is in his twelfth year as a practicing physician after graduating from Jichi Medical University and completing a post-graduate training program for new physicians at our hospital. He spent roughly nine years engaging in community healthcare while also receiving guidance on Kampo medicine once a week at our hospital, and now practices both Kampo medicine and integrative internal medicine. Both doctors are Kampo specialists in addition to being a certified physician and general medicine specialist. Today, they provide treatment in the Internal Department of East Asian Traditional Medicine while also serving as emergency physicians and ward physicians of the department of general medicine in our hospital.

Below, the two doctors' clinical experience is summarized according to the four types of Kampo medicine application as proposed by Dr. Hiromichi Yasui.

Type 1: Case examples in which Kampo treatment is effective by itself

Type 2: Case examples in which the effectiveness of Kampo treatment is increased when combined with standard Western medical treatment

Type 3: Case examples in which the side effects of Western medical treatment is alleviated when combined with Kampo treatment

Type 4: Case examples in situations where Western medicine cannot be applied

Photos: Ehime Prefectural Central Hospital and personnel at the Internal Department of East Asian Traditional Medicine

Type 1 Case Example: Kampo treatment is effective by itself

[Case example 1 (Dr. Shimizu's case)]

27-year-old man

[Chief complaint] Fever

[History of present illness]

In the late afternoon on July 9 of a certain year, the man came down with a high fever of 40 degrees. He also developed a sore throat and aching joints, and was thus referred to our hospital on July 11. A blood test indicated minor leukopenia, thrombopenia and increased CRP, and the man proved positive for jolt accentuation, so he was subject to various examinations. However, the cause of his fever could

not be identified, and the man was immediately admitted for intensive examination and treatment.

[Development after admission]
Once admitted, the man's condition was closely followed while replacing his fluids and administering an antipyretic analgesic. By the next day, the man's fever tentatively declined, but on the third day of hospitalization, his headache, chills, neck and back pain, and joint pain worsened, and he experienced vomiting. He had no appetite, and had diarrhea whenever he did eat. His pulse was floating, fast, and tense. The man was prescribed 7.5g/day of Kakkonto extract, and by the next day, his headache, chills, and joint pain disappeared and he also regained his appetite. The post-meal diarrhea he had been experiencing for close to a month also stopped, and he was thus discharged on the fifth day. From the above, the man was diagnosed with severe virus infection.

[Observation] The *Shokanron* contains a passage that says, "those who display a combination of early yang and middle yang symptoms necessarily develop spontaneous diarrhea, but this can be cured with Kakkonto." The above case example may have been a combination of the early yang and middle yang stage types.

[Case example 2 (Dr. Shimizu's case)]
32-year-old lactating woman
[Chief complaint]
Breast pain
[History of present illness]
In the middle of the night on October 12 of a certain year, the woman began to feel pain in her right breast. She also had a shaking chill, so she called an ambulance and was brought to our hospital.

[Development after arriving at hospital]
The woman had a fever of 39.9 degrees and an induration in her right breast, and was thus diagnosed with acute mastitis. She displayed delirious speech, rigidity of her neck and back, and strong chills when she arrived at the hospital, but her blood test did not indicate any increase in inflammatory response. She was given fluid replacement and 5g of Kakkonto in the emergency outpatient unit, and color returned to her face, also her shaking chills stopped. After returning home, the woman took Kakkonto only and brought her fever down. The next morning, she visited the gynecology department in our hospital, where she was instructed to continue taking Kakkonto and make a return visit if the condition worsens, but she has not made a visit since.

[Observation]
The experience of this case example, in which Kakkonto responded effectively to acute mastitis, indicated the possibility of applying Kampo medicine to emergency medical care.

[Case example 3 (Dr. Shimizu's case)]
86-year-old man
[Chief complaint] Abdominal pain
[History of present illness] On October 1 of a certain year, the man began to experience pain in his stomach after supper. He developed a sense of abdominal fullness and came to the emergency unit in our hospital. He has surgery in the past for stomach cancer, and has experienced a repeated occurrence of ileus.

[Present condition]
The man had a blood pressure of 121/64 mmHg and a pulse of 61/min. His stomach was slightly swollen but soft, and had pressure pain on the left side of his navel. There was no rebound tenderness. His bowel sounds were accelerated.

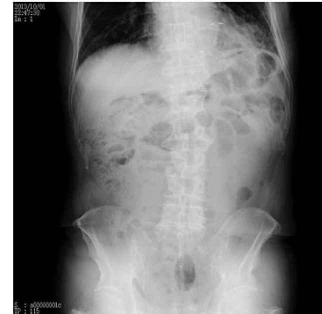
[Examination findings] No blood count or biochemical abnormalities.

Blood test

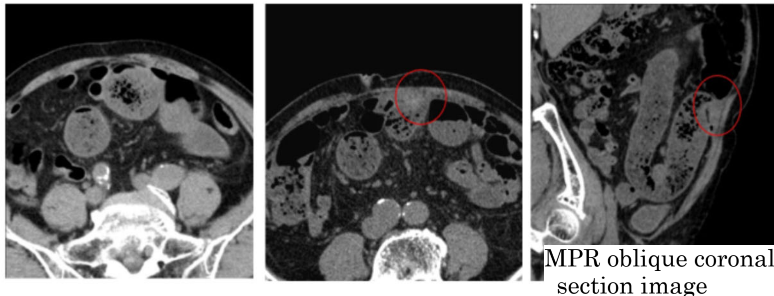
WBC	6780	/μl
RBC	346	10*4/μl
HGB	11.3	g/dl
HCT	32.7	%
PLT	21.5	10*4/μl
AST	21	U/l
ALT	16	U/l
T-Bil	0.4	mg/dl
LDH	194	U/l
γ−GTP	13	U/l
CK	76	U/l

BUN	12.5	mg/dl
CREA	0.85	mg/dl
AMY	70	U/l
CRP	0.06	mg/dl

Simple photo of the abdomen



Simple CT of the abdomen



MPR oblique coronal section image

There is a localized expansion to the small intestine along the midline of the abdomen. It is thought to be caused by an adhesion at the junction below the abdominal wall. A large amount of residue is pooled near the constricted part.

[Findings from the images] No niveau is seen in the simple photo of the abdomen.

[Progress] In the emergency outpatient unit, the man was administered 5g of Daikenchuto extract dissolved in plain hot water to replace his fluid, and was closely monitored. Waste gas increased, but his abdominal pain would not go away, so he was administered 5g of Daikenchuto dissolved in plain hot water again after 15 minutes. 10 minutes thereafter, waste gas was released from his body with a large sound and the man's abdominal pain subsided somewhat, so he was sent home. After returning home, the man's abdominal pain disappeared as more stomach gas was released, and he was cured of the pain.

[Observation] In this case example, an abdominal examination detected gas in the intestinal tract. Determining this to be a sub-ileus condition, Daikenchuto was effectively prescribed.

[Case example 4 (Dr. Kakuto's case)]
77-year-old woman with frequently recurring postoperative adhesive ileus

[Chief complaint]
Postoperative adhesive ileus

[Past medical history]
Gastric resection due to stomach cancer (approx. 10 years ago), Parkinson's disease

[Medicine]
Daikenchuto extract 15g, oxidized Mg, levodopa, cilostazol, ferrous citrate

[History of present illness]
After receiving surgery for stomach cancer, the woman's condition had been stable, so she was put in a care facility. However, in XXXX, she was hospitalized after experiencing a frequent occurrence of ileus, in February, May, and September. She suffered an ileus again in October of that year, and was treated in our hospital. She was discharged the following month, but three days later, she suffered another recurrence and was admitted to a local hospital. A week after she was discharged from the local hospital, she developed ileus once again and was referred to our hospital for emergency hospitalization.

[Progress]
The woman was kept fasting and put on an IV drip after admission while closely monitoring her condition. Eventually, her general condition improved.
Given the woman's frequent occurrence of ileus, a surgeon was consulted concerning surgical indications. However, the surgeon noted that there were no indications, so a policy of conservative treatment was taken. The woman had been continuously taking Daikenchuto prescribed at her previous clinic, but it did not seem to go down well. In fact, she would develop vomiting, and could not continue to take the prescription.

[Observation]
Bed-ridden, thin and frail elderly woman. Able to communicate. Lack of interest or enthusiasm.
Anemic.
Tongue: Rather dry
Stomach: Soft, no pressure pain. Accumulation of stomach gas.
Bowel movement has been observed after hospitalization.

[Progress]
Daikenchuto was discontinued and replaced with 5g each of Hangekobokuto and Hochuekkito. Rehabilitation was also begun. As a result, there was no recurrence of ileus even after resuming meals, so the woman was transferred to a referred hospital.

[Assessment]
Japanese surgeons routinely use Daikenchuto to prevent occurrence of postoperative ileus. However, we sometimes experience ileus cases with qi stagnation or qi deficiency.
Hangekobokuto regulates qi, on the other hand, Hochuekkito tonifies qi.We diagnosed this case as the trouble of qi.

Case 5 (Dr. Kakuto's case)]
86-year-old woman with stasis dermatitis in her lower leg
[Chief complaint]
Suspected stasis dermatitis in right lower leg

[Past medical history]
Currently receiving outpatient care at our department for pain from left hip to leg.
High blood pressure, osteoporosis, recent surgery for breast cancer
Internal medicine: Hochuekkito, amlodipine

[History of present illness]
The woman had been receiving continuous acupuncture and moxibustion treatment for her low back pain and other pain, but since bruising her right front tibia in mid-May, swelling and

redness came to be observed on the front of both her lower legs in the late afternoons. Cellulitis appeared negative, so 10mg of prednisolone was administered, but with no improvement. An antibiotic was also used, but no marked improvement was observed.

Around three days after prescribing 7,5g of Eppikajutsubuto extract + 7.5g of Jidaboku-ippo extract, a gradual improvement was observed, and the woman's edema had disappeared by her return visit ten days later.

[Assessment]

Dr. Shu-an KAGAWA (1683-1755) in Edo era created a Kampo formula which is effective for blood stagnation because of a bruise or a sprain and named Jidaboku-ippo. "Ji" means treatable , "daboku" means bruise and sprain, and "ippo" means Kampo formula. If the affected area was swelling with heat, the combination of ephedra and gypsum is suitable. Eppikajutsuto is appropriate to this condition if we use extract drug. Even if the patient showed the skin problem, the therapist has to think about other problems such as his or her medical history in order to find out a suitable treatment for the patient.

Report from Association

A Letter from the 66th General Assembly of The Japan Society for Oriental Medicine

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1. Introduction

Kampo medicine is a medical system that has been traditionally practiced in Japan, based on ancient Chinese medicine. The Japan Society for Oriental Medicine (JSOM) is the largest and one of the most active medical societies on *Kampo* medicine in Japan. At the time the JSOM was founded in 1950, the number of member was only 99. As of June, 2015, the JSOM has a total of more than 9000 members. It was established to improve the quality of life (QOL) of the people by sharing research results on health, medicine and welfare, functioning as a worldwide network to achieve the goal. It became a member of the Japanese Association of Medical Sciences in 1991[1].

The 66th General Assembly of the Japan Society for Oriental Medicine took place June 12-14, 2015 at Toyama International Conference Center, Toyama Shimin Plaza, and ANA Crowne Plaza Toyama in Toyama, Japan[2]. The General Assembly was organized by JSOM and supported by the Toyama prefectural government, the Toyama city government, the Toyama Shimin Plaza, the ANA Crowne Plaza Toyama, the Japan Pharmaceutical Association, the Toyama Pharmaceutical Association, the Japan Acupuncture and Moxibustion Association and the Japan Society of Acupuncture and Moxibustion. The conference was attended by 2548 researchers and physicians from all over the world – primarily from Japan – who exchanged opinions and presented studies on diverse *Kampo* medical research fields in over 80 sessions including 11 symposiums and 13 seminars[3].

2. Sessions

This General Assembly is designed for researchers and scholars to present various studies on its theme, that is "Traditions passed on to succeeding generations and new development in medicine——Let's go back on track". The conference was a great success with some standees on the section of general lectures and of acupuncture and moxibustion. There were some educational seminar on *Kampo* for physicians, acupuncturists and pharmacists.

In the afternoon session on June 12th, there was a clinical seminar on traditional medicine, which theme was "Master's secret oral teachings passed on to succeeding generations on *Kampo*". Prof. Toshihiko HANAWA (Oriental Medicine Research Center, Kitasato University, Tokyo, Japan) has given a speech on "Traditions passed on to succeeding generations at Oriental Medicine Research Center, Kitasato University". Prof. Tadamichi MITSUMA (Department of Kampo (Japanese traditional) Medicine, Aizu Medical Center, Fukushima Medical University, Fukushima, Japan) has made a lecture on "Traditions passed on to succeeding from Dr. Fujihira and Dr. Ogura". Prof. Keigo NAKATA (Seikoen Hosono Clinic, Kyoto, Japan) has made a presentation on "Traditions passed on to succeeding from Dr. Hosono and Dr. Sakaguchi". There were some meetings including the General Assembly of Partners and board of directors.

In the morning session on June 13th, there was a presidential lecture on traditional medicine, which theme was "Attempts to find a therapeutic guide into tomorrow by taking lessons from the past on *Kampo* medicine ---Studies on *chotosan* (釣藤散<jp>, Uncaria Powder) and *keishibukuryogan* (桂枝茯苓丸<jp>, Cassia Twig and Tuckahoe Pill)---". Prof. Yutaka SHIMADA (Department of Japanese Oriental Medicine, Graduate School of Medicine and Pharmaceutical Sciences (Faculty of Medicine), University of Toyama, Toyama, Japan) has given

a lecture on *chotosan* in the treatment of vascular dementia: A double blind, placebo-controlled study, which was originally reported by Dr. Katsutoshi TERASAWA et al. [4], and on effects of *keishibukuryogan* on erythrocyte aggregability [5], erythrocyte deformability [6], and endothelial function [7].

At "The World is watching *Kampo* medicine" symposium, Dr. Toshinori ITO (Department of Integrative Medicine, Osaka University Graduate School of Medicine, Suita, Japan) has introduced on "Status Quo and Prospect of Integrative Medicine in Japan.", Dr. Toshiaki MAKINO (Department of Pharmacognosy Graduate School of Nagoya City University, Nagoya, Japan) has made a lecture on 'New Challenge for Drug Information on "single crude drug for prescription", "OTC crude drug product", and "crude drug" to Become Internationalized', Dr. Shin TAKAYAMA (Department of Education and Support for Community Medicine, Tohoku University Hospital, Sendai, Japan) has made a presentation on "Status Quo of Kampo Medicine in Germany", and Dr. Masayuki KASHIMA (Department of General Internal Medicine, Japanese Red Cross Kumamoto Hospital, Kumamoto, Japan) has given a speech on 'What is *Houshousoutai* (Diagnosis and planning of treatment with "symptoms and syndrome" of each diseases in Kampo)? ---A Brief Survey of Historical Studies and Prospect of *Houshousoutai* in Japan.---'.

At "The Japan-Korea academic symposium on *Kampo* medicine and traditional Korean medicine", Prof. Motoko FUKUZAWA (Omotesando Fukuzawa Clinic, Tokyo, Japan) has made a lecture on "Characteristics of Traditional Japanese Medicine Viewed from the Aspect of Frequent Prescription", and Prof. Kyuseok KIM (College of Korean Medicine, Kyung Hee University, Seoul, Korea) has made a presentation on "Major Insured Herbal Preparations in Korean Medicine".

In the afternoon session on June 13th, there was a symposium, which theme was "Clinical Practice Guidelines and *Kampo* medicine". Prof. Takeo NAKAYAMA (Department of Health Informatics, Graduate School of Medicine and Public Health, Kyoto University, Kyoto, Japan) has introduced on "Status Quo of Clinical Practice Guidelines in Japan", Dr. Yoshiharu MOTOO (Department of Medical Oncology, Kanazawa Medical University, Uchinada, Japan) has made a lecture on "Coverage of *Kampo* medicine in the Clinical Practice Guidelines in Japan", Prof. Takaki MIWA Department of Otorhinolaryngology, Kanazawa Medical University, Uchinada, Japan) has presented on "How to treat the inclusion of *Kampo*-related information in Western medicine Clinical Practice Guidelines developed in Japan. --- Guidelines for diagnostics and treatment smell and taste disorders---", Prof. Ichirou ARAI (Department of Kampo Medicines, Nihon Pharmaceutical University, Ina, Japan) has given a speech on "How to reflect the *Kampo* medical evidences in the clinical practice guidelines in Japan. --- A methodology of how to write dissertations, thesis or other academic papers and to refer documents related to evidence based medicine---", and Prof. Ikurou WAKAYAMA (Graduate School of Kansai University of Health Sciences, Kumatori, Japan) has made a presentation on "Surveys on how clinical practice guidelines in Japan reflect evidences of acupuncture".

In the morning session on June 14th, there was a symposium, which theme was "New Developments and Possibilities in *Kampo* Medical Research". Prof. Youichirou ISOHAMA (Faculty of Pharmaceutical Sciences, Tokyo University of Science, Tokyo, Japan) has introduced on "Pharmacological and pharmaceutical aspect of *goreisan* (五苓散<jp>, Poria Powder with Five Herbs) for nonsurgical management of chronic subdural hematomas. --- Aquaporins play some important roles for water homeostasis and inflammatory response.---", Dr.

Chihiro TOHDA (Division of Neuromedical Science, Department of Bioscience, Institute of Natural Medicine, University of Toyama, Toyama, Japan) has presented on "Therapeutic potency of *Kampo* medicine for neurodegenerative diseases", Dr. Takako FUJIMOTO (Faculty of Human development, University of Toyama, Toyama, Japan) has made a lecture on "The effects and mechanisms of *Kampo* medicine on insulin-resistance and metabolic syndrome", Dr. Teruhiko MAKINO (Department of Dermatology, Graduate School of Medicine and Pharmaceutical Sciences, University of Toyama, Toyama, Japan) has introduced on "Effectiveness and mechanism of *Keishibukuryogan* on chronic inflammatory disease of the skin", Dr. Haruka FUJINAMI (Department of Endoscopy, Toyama University Hospital, Toyama, Japan) has presented on "Spraying of *Shakuyakukanzoto* (芍薬甘草湯<jp>, Peony and Licorice Decoction) onto the Duodenal Papilla: A Method for Preventing Pancreatitis following Endoscopic Retrograde Cholangio-Pancreatography (ERCP)", Dr. Makoto FUJIMOTO (Department of Japanese Oriental Medicine, Toyama University Hospital, Toyama, Japan) has given a speech on "Effectiveness of *Keishibukuryogan* for treatment of nonalcoholic fatty liver disease (NAFLD)", and Dr, Yutaka NAGATA (Center of Japanese Oriental Medicine, Suwa Central Hospital, Chino, Japan) has made a presentation on "A New Study on Endothelial Function --- Beneficial Effect of *Keishibukuryogan* on Endothelial Function in Patients with metabolic syndrome-related factors---".

In the afternoon session on June 14th, there was a symposium, which theme was "Standardization of *Kampo* medicine--- Issues and response to the international movement on standardization of traditional medicine". Prof. Toshihiro TOGO (Tokyo Ariake University of Medical and Health Sciences, Tokyo, Japan) has introduced on "A report on the sixth general meeting of ISO/TC 249---The Latest Trends in International Standardization of traditional medicine ---", which details on the International Organization for Standard (ISO) and Technical Committee (TC) will be available later. Prof. Takao NAMIKI (Department of Japanese-Oriental (Kampo) Medicine, Chiba University Graduate School of Medicine, Chiba, Japan) has presented on 'Term Standardization at WHO/ICD-11 on Traditional Medicine in the East Asian Region and its Influence on "Japanese Standard Nomenclature of Oriental Medicine (*Tōyō igaku yōgoshū*) [8] [9]"', Dr. Hiromichi YASUI (Yasui Clinic, Yokkaichi, Japan) has introduced on "Standardization of information on traditional medicine at ISO/TC249/WG5 (Informatics of Traditional Chinese Medicine)", Prof. Kenji WATANABE (Faculty of Environment and Information Studies, Keio University, Fujisawa, Japan) has given a speech on "A study of questionnaire for *Kampo* medicine and development of decision support system with computer-aided diagnosis", Mosaburo KAINUMA (Community Medicine Education Unit, Graduate School of Medical Sciences, Kyushu University, Fukuoka, Japan) has made a presentation on "The association between objective tongue color and endoscopic findings: Analysis of tongue color with Tongue image analyzing system (TIAS)", Dr. Shuji YAKUBO (Department of Medicine, Nihon University School of Medicine, Tokyo, Japan) has introduced on "A Project of Standardization of Abdominal Diagnosis with an Abdominal Diagnosis Teaching Simulator", and Dr. Hiroshi ODAGUCHI (Oriental Medicine Research Center, Kitasato University, Tokyo, Japan) has presented on "A Project of Standardization of *Kampo* Medical Findings and Diagnosis".

3. About the presentation of "A report on the sixth general meeting of ISO/TC 249".

I would like to draw attention to an important issue in the 66th General Assembly of The Japan Society for Oriental Medicine, namely the presentation of "A report on the sixth general meeting of ISO/TC 249---The Latest Trends in International Standardization of traditional medicine ---", not only because of shortage of space but because the "standardization of traditional medicine" issue requires urgent attention and collective actions from the international community. An independent, non-governmental organization, ISO is one of the world's largest developer of voluntary international standards. Established in 2009, ISO/TC249 convenes annual plenary meetings to discuss standardization on traditional medicine in the Western Pacific Region. The work of ISO/TC249 consists of the setting up of international quality standards for acupuncture needles and tools, traditional medicine on pharmacognosy and its products, medical equipment, and medical informatics.

As already mentioned, Prof. Toshihiro TOGO has introduced on "A report on the sixth general meeting of ISO/TC 249---The Latest Trends in International Standardization of traditional medicine ---". One of the most important report was: "At the sixth plenary meeting of ISO/TC 249 in Beijing, Traditional Chinese Medicine (TCM), which had been treated as the provisional name for the committee, was finalized and officially written into the meeting resolution through negotiations and the committee voting". In the first round of voting, the provisional title-name of "Traditional Chinese Medicine" got eight votes, "Traditional Medicine: Chinese Medicine, *Kampo* and Korean Medicine" got three, "Traditional Medicine" got one, and "Traditional Chinese Medicine and other medical systems derived from ancient Chinese Medicine" got one. On the final runoff ballot, "Traditional Chinese Medicine" edged out "Traditional Medicine: Chinese Medicine, *Kampo* and Korean Medicine" eight to three. Further information will be forthcoming, but for more context please visit the homepage of ISO/TC249 (10). Dr. Togo emphasized in the last part of his speech that it was important for the Japanese delegation to take the policy of international cooperation that cooperated with America and Europe and to develop the qualification of international standards.

4. Concluding remarks and about the upcoming congresses.

All the participants agreed that the General Assembly was an academic event of *Kampo* medicine with high level and standard. The researchers and physicians of the *Kampo* Medicine have obligation to improve the quality of life (QOL) of people all over the world by sharing study results on health, welfare, and medical science.

There will be the 67th General Assembly of The Japan Society for Oriental Medicine (JSOM) in Takamatsu, Japan (June 3-5, 2016) (11). The theme of this future conference will be "The inheritance of *Kampo* paradigms and its paradigm-shift ---Bridging *Kampo*, Science, and Practice". In view of JSOM's long experience in organizing key events and of the city's main congress facilities, the 67th General Assembly of The JSOM 2016 will be sure not to disappoint.

[1] Homepage of the Japanese Association of Medical Sciences. http://jams.med.or.jp/members-s/87.html.pdf [the last date of access Sep30,2015]

[2] Homepage of the 66th General Assembly of The Japan Society for Oriental Medicine. http://www.pcojapan.jp/jsom66/ [the last date of access Sep30,2015]

[3] Abstracts of the 66th General Assembly of the Japan Society for Oriental Medicine. Kampo Medicine (extra issue), 2015; 66: 1-367. (第66回日本東洋医学会学術総会　講演要旨集. 日本東洋医学雑誌, 2015; 66: 1-367.)
The 10th International Association of Gerontology and Geriatrics - Asia/Oceania 2015 Congress, Final Program, 19-22 October, 2015 (Chiang Mai, Thailand), 1-130, 2015.

[4] Terasawa K, Shimada Y, Kita T, et al. Choto-san in the treatment of vascular dementia: A double blind, placebo-controlled study. Phytomedicine, 1997; 4: 15-22.

[5] Kohta K., Hikiami H., Shimada Y., et al.: Effects of Keishi-bukuryo-gan on erythrocyte aggregability in patients with multiple old lacunar infarction. J. Med. Pharm. Soc. WAKAN-YAKU, 1993;10: 251-259.

[6] Hikiami H., Goto H., Sekiya N., et al.: Comparative efficacy of Keishi-bukuryo-gan and pentoxifylline on RBC deformability in patients with "oketsu" syndrome. Phytomedicine. 2003;10(6-7):459-66.

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[10] Homepage of ISO/TC249. http://www.iso.org/iso/standards_development/technical_committees/other_bodies/iso_technical_committee.htm?commid=598435 [the last date of access Sep30,2015]

[11] Homepage of the 67th General Assembly of The Japan Society for Oriental Medicine. http://www.med-gakkai.org/jsom67/ [the last date of access Nov21,2015]

Dedication to Crude Drugs

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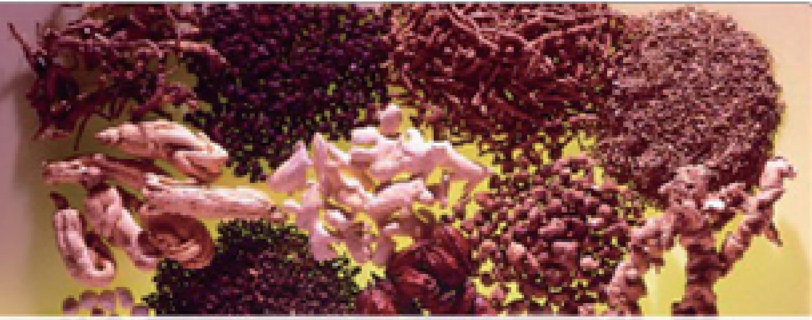

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