



# KAIM

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## **Conference Report**

The First Japan-Germany Joint Symposium on Kampo Medicine and Acupuncture  
**Yoshiharu Motoo and Hiromichi Yasui**

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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

### *Having Experienced a Record Intensity Earthquake Twice*

From a global perspective, Japan is situated in a region that is subject to a high concentration of earthquakes of great magnitude. In 2011, the Great East Japan Earthquake triggered a massive tsunami that wreaked unprecedented havoc on the coastal area of the Tohoku region, but even before our memory of this disaster had begun to fade, a historical earthquake struck Kumamoto in the spring of 2016. That is, an intensity 7 earthquake, the highest seismic intensity to ever be measured, struck the area not only once but twice in a row, for the first time in recorded history. At the time, I was working at a foundation hospital in the very vicinity of the earthquake, a mere 4 kilometers from the epicenter, and took to providing care since immediately after the earthquake. As the earthquake occurred inland directly below the city, numerous houses collapsed, lifeline utilities including electricity, gas and water were damaged, and many people were forced to leave their homes. The greatest characteristic of this disaster was that an earthquake of intensity 7, the odds of which is said to occur maybe once in a hundred years, occurred twice in the same area, with the second tremor occurring a mere 28 hours after the first, and on an even greater scale. This instilled a strong sense of fear in many people's hearts that they might be hit by another large earthquake, such that even those whose homes were still livable continued to stay at an evacuation center or live out of their cars.

Under such circumstances, what role was Kampo medicine able to play? In evacuation centers, there were outbreaks of viral gastroenteritis. The malady tends to become epidemic in evacuation centers, where toilets are not sufficiently available, and is also known to be fatal at times among physically weak patients. Once it becomes epidemic due to its explosive infectability, limited medical resources, water and toilets tend to be taken up by its patients. Only symptomatic treatment is available for viral gastroenteritis, but oral administration of Goreisan was extremely effective in alleviating its symptoms in a few hours. This is widely known among those who have provided this treatment. Additionally, viral gastroenteritis is said to have strong infectability particularly during severe symptoms of vomiting and diarrhea, but Goreisan was also useful in controlling an epidemic.

When sleeping in the confined space of a car, deep venous thrombosis could occur with inadequate movement of the legs and increase the incidence of pulmonary embolism. In fact, our hospital also received many times more patients of pulmonary embolism and deep venous thrombosis than usual years. A common risk factor of deep venous thrombosis is leg edema. Using a diuretic to treat leg edema tends to cause dehydration, which readily leads to deep venous thrombosis. Elastic stockings are generally used against venous thrombosis, but wearing these stockings takes getting used to, and incorrect use could cause pain or skin damage. Leg edema that is caused by not moving the legs could be effectively treated with Boiogito in a way that differs from active diuresis.<sup>1)</sup> It is also effective against hydrarthrosis and the pain that accompanies it. Indeed, it was highly appreciated by patients who received Boiogito treatment for leg edema and osteoarthritis caused by sleeping in a car.

The common cold also tended to run rampant in evacuation centers. As people are crowded together in an open space with no walls, any coughing is easily heard and frowned upon, and the patient necessarily becomes self-conscious. For persistent nighttime coughing during the recovery phase, I mostly used Chikujountanto. Not only does it mitigate the coughing, but it is also effective against anxiety, frustration, and insomnia, so it was extremely useful in alleviating people's stress caused by the earthquake and their lack of privacy. The severe frequency of aftershocks was a rarity in the history of earthquakes, and each aftershock reminded people of the main quake. Without any signs of their situation improving, the anxiety of not knowing when they could return to their ordinary lives exacerbated anxiety disorders in many people. Benzodiazepine anti-anxiety medicine poses a risk of delirium and falling especially among elderly people, so it could not be readily used. Sleeping pills to treat insomnia stemming from anxiety were barely taken by patients who worried that they may not be able to wake up quickly when another earthquake occurs. Thus, for patients who mainly suffered from insomnia, I had them drink plenty of Sansoninto before sleeping. For patients who complained of flashbacks, I used Saikokeishikankyoto, as it was proven effective in a research conducted by the Kampo medicine department at Tohoku University, which provided Kampo treatment in the wake of the Great East Japan Earthquake even while it was itself affected by the disaster.<sup>2)</sup> Such patients who also suffered from a strong case of insomnia were effectively treated through the combined use of Sansoninto, and patients with anxiety disorder characterized by a strong sense of malaise were particularly effectively treated with Kamikihito.

Almost two months after the earthquake as I write this paper, most people are awash with a feeling of exhaustion from the countless aftershocks that are said to be the largest number ever in history, as well as from the endless tasks to restore their lives and the tension that has reached its limit. It seems there are many people who would benefit from Hochuekkito and Kososan.

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**Masayuki Kashima**

Kumamoto Red Cross Hospital  
Department of Internal Medicine

## Integrating Kampo and Evidence-Based Medicine (6) – Type 5 Cases

*Is There a Type 5?*

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

☆

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I introduced the aforementioned four types of Kampo use at a certain academic society. Among the members was Dr. Masayuki Kashima, a young friend of mine whom I respect (a physician in the internal department at Japanese Red Cross Kumamoto Hospital). After listening quietly to my presentation, he surprised me, saying "Doctor, I think there is a fifth type." He said that medicine is steadily advancing, and good drugs and new treatment methods are being developed one after the other. However, Kampo medicine is extremely useful to patients who cannot receive such expensive treatment. There are patients who are suited to Kampo not from medical reasons, but from economic

ones. These patients do not fall under any of the four types that have so far been introduced, so Dr. Kashima noted that a Type 5 category should be created. As an explanation, he then introduced a case example from among a number of cases he has personally experienced.

### Episode 1

A 37-year-old male patient began to complain of malaise, headaches, and joint aches from around August 3, 2014. On August 16, he came down with a fever of more than 39°C. As this continued for the next days, he consulted a local doctor. The results of a blood test showed aberrant values, with a WBC count of 1900/mm<sup>3</sup>, Plt of 118 × 10<sup>3</sup>/mm<sup>3</sup>, and an LDH of 942 U/l. Therefore, on August 26, the patient visited the hospital where Dr. Kashia works, with a referral letter from the local doctor.

Height: 165cm; Weight: 72kg (-4kg in 2 weeks)

Temperature: 38.4°C, with alternating chills and fever and high temperatures from early evening. The lowering of body temperature is accompanied by perspiration.

Blood pressure: 145/90mmHg; Pulse: 94/min.;

Respiratory rate: 16/min.

Slight hyperemia in the bulbar conjunctiva; No swelling of the cervical lymph node; Swollen spleen

Pulse examination: String-like and smooth

Tongue inspection: Slightly yellow tongue coating; slightly red tongue body

Abdominal examination: Intermediate abdominal strength; discomfort and distension in hypochondrium region

Examination findings were as follows.

WBC:1870/mm<sup>3</sup>; Hb13.7g/dl; Plt120,000; GOT: 111U/L; GPT: 90U/L; LDH: 1346U/L;

CRP: 4.77mg/dL; TG: 146mg/dL; Ferritin: 4420ng/mL; Soluble IL-2 receptor: 2030U/ml;

Nyelogram (8/29): M/E3.80; Megakaryocyte count: 16/c.mm; Nucleated cell count: 37950/c.mm;

Hemophagocytosis caused by histiocyte was observed in places.

Abdominal echo: Hepatosplenomegaly

General appearance indicated the patient was not in acute distress.

From the first visit, Dr. Kashima strongly suspected hemophagocytic syndrome or leukemia, and recommended inpatient examination and treatment. However, the patient did not have health insurance, and said hospitalization would pose a large economic burden and is therefore impossible.

Dr. Kashima forewent the use of a steroid, as using it before diagnosis would make accurate diagnosis and the prospect of prognosis difficult later on. Yet, the patient's symptoms were strong, and close observation was required, so based on Kampo diagnosis, Dr. Kashima administered Shosaikoto and had the patient continue to come in as an outpatient.

The patient began taking Shosaikoto from August 26, and was relieved of his fever by the morning of the 28th. A myelogram taken on the 29th affirmed the diagnosis of hemophagocytic syndrome, but because the patient's fever had already subsided and his CRP improved to 1.30 mg/dl on the same day, the same Kampo medicine was continued to be prescribed on an outpatient basis. Thereafter, the patient's cytopenia and liver disorder also gradually improved, and treatment was deemed complete on September 9 upon confirming normalization in various examinations. Regular follow-ups were performed thereafter, but no recurrence was observed over a year, so the patient was allowed to terminate his visits.

Dr. Kashima also said as follows.

“Hemophagocytic syndrome is a life-threatening disease that frequently runs a rapid course and leads to multiple organ failure. It could be caused by virus infection, drug allergy, a connective tissue disease such as SLE, or a malignant disease, but it is known to be caused mostly by intravascular malignant lymphoma. There is no single method of treatment,

but normally, chemotherapy against malignant lymphoma, administration of a large dose of immunosuppressant, or plasma exchange therapy is attempted in cases of poor reaction to massive steroid. I administered Shosaikoto in this case based on Kampo medicine diagnosis. The effect was dramatic, but even more worthy of mention is that the patient's economic burden was largely minimized.”

The patient did not have health insurance for reasons unknown. If he had been hospitalized to receive standard treatment, it would have cost him an enormous amount of medical fee.

Thanks to Dr. Kashima's appropriate judgment, the patient's symptoms were ameliorated by taking Kampo, and his medical fee was able to be minimized. In sum, the patient improved owing to an inexpensive treatment method, without depending on expensive standard treatment. For reference, the price of a day's dose of Shosaikoto is approximately 230 yen. The patient took the prescription for 15 days, so it cost him 3,450 yen in total.

Such cases are not necessarily few, but they are hardly taken up, because most are simply reported as an isolated case. For treatment of serious diseases, many people do not believe there are any cases in which inexpensive Kampo medicine can be superior to expensive standard medicine. However, this is not necessarily true in all cases.

Shosaikoto will not always improve the symptoms of hemophagocytic syndrome. Dr. Kashima was able to prescribe it in this case, because he has abundant experience in the emergency outpatient and outpatient internal medicine departments, as well as deep knowledge of Kampo medicine theory.

It is sufficiently worth discussing whether or not this represents a case in which treatment by inexpensive Kampo medicine due to economic reasons improved the patient's symptoms compared to standard treatment. In a sense, it does, but as there are too many uncertainty factors, it might be somewhat too early to conclude that this case



represents Type 5. In terms of the four conventional types, this case would fall under Type 4.

## Episode 2

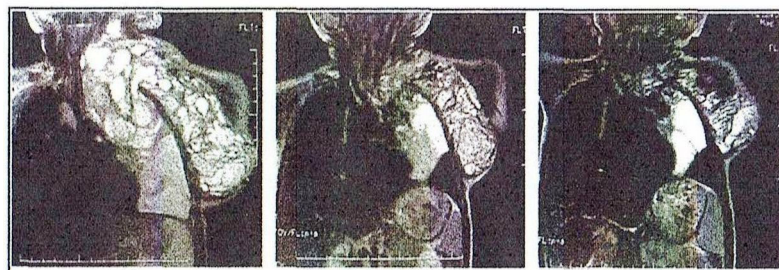
Let us look at another case, the “Case of Mediastinal Lymphangioma Successfully Treated with Kampo Medicine”<sup>1)</sup>, which was published in the *Journal of Alternative and Complementary Medicine* by Dr. Keiko Ogawa, a discussion partner of mine who is in charge of outpatient Kampo medicine at Kanazawa University Hospital.

The patient is a two-year-old boy who was born with a tumors mass in his left axillary fossa. At an age of 1 year and 9 months, he was referred to a children’s hospital in the region, and was diagnosed with a mixed type of lymphangioma in the region from his left axillary fossa and left mediastinum to his pleural cavity. He was treated at the hospital by OK-432 sclerotherapy, but to no effect.

The patient’s parents thus requested Kampo treatment, and took the patient to see Dr. Ogawa as an outpatient when he was 2 years and 10 months old.

lymphangioma from the left cervix to the mediastinum. The MRI findings were as follows. The left mediastinum was almost wholly affected by lymphangioma, causing a displacement of the liver and trachea and a deviation of the trachea.

The clinical course was as follows. First, marked sweating was interpreted as an exterior pattern, and the patient was prescribed Eppikajyutsuto. The MRI taken three months after the first visit did not show any reduction in the size of the lymphangioma. Five months later, the patient developed repeated bronchial asthma triggered by an infection and accompanied by hives, and sweated, so Ogikenchuto was also administered along with Eppikajyutsuto. A reduction in the lymphangioma was observed in the MRI that was taken after 9 months, and further reduction after 15 months. The cyst in the cervix almost wholly disappeared, and a clear reduction in size of the polycystic area, in particular, was observed (Figure 1). The cross section also showed a reduction of the tumor mass, as well as a return of the displacement of the trachea to normal condition (Figure 2). The number of coughing and frequency of asthma attacks declined, and the same prescription is still being continued at present.



Before first visit 15 months later 9 months later  
Figure 1: Changes in MRI findings (1)



Before first visit 9 months later 15 months later  
Figure 2: Changes in MRI findings (2)

An MRI examination of the chest immediately before the first visit to Dr. Ogawa indicated a partly cavernous to mixed polycystic

This case report was written in English. Thus, people around the world were able to read it. A while after the journal was published, Dr. Ogawa received an email written in English. It was from the U.K. A father of a child with the same disease wrote to inquire how he could acquire the drug, because although Japan's Kampo prescriptions for medical use are highly superior, they are not approved as medicinal drugs in countries other than Japan.

Infantile lymphangioma is caused by a congenital anomaly of a lymphatic vessel. It is a benign tumor, but it develops by indistinctly infiltrating the surrounding organs, and displaces the surrounding organs. There is no known standard treatment, and treatment by sclerotherapy using various drugs has become the first choice of treatment today. Depending on the nature of the lesion, sclerotherapy is not effective, and surgical treatment is then considered. However, because its boundary is unclear, as mentioned above, removal by surgery runs the risk of damaging normal tissues around it. For this reason, it is difficult to completely remove the tumor in such cases, and treatment runs into a brick wall, so to speak, in many cases.

In this case, sclerotherapy using OK-432 was already performed, without effect. There was still a number of possible Western medical treatment methods, but Dr. Ogawa succeeded in dramatically ameliorating the young patient's lymphangioma using Kampo medicine.

After Dr. Ogawa's report was published, a number of pediatricians and pediatric surgeons submitted additional reports one after the other to the effect that the disease was ameliorated by using Eppikajyutsuto. Representative of these is the "Clinical Efficacy of Herbal Medicine for Pediatric Lymphatic Malformations: A Pilot Study"<sup>2)</sup> by Dr. Naoki Hashizume et al. of Kurume University Hospital, published in *Pediatric Dermatology*.

#### **Pilot Study by Dr. Hashizume et al.**

Dr. Hashizume et al. monitored the progress of eight children (four boys and four girls) with lymphatic malformations after applying Eppikajyutsuto (TJ-28; Tsumura, Tokyo, Japan).

The result was as follows.

Four of the eight patients had a macrocystic type of lymphatic malformation, and the other four had a micro-macrocystic mixed type. They were observed over a period of 75 months, from January 2009 to May 2014, and were administered the drug over  $7.2 \pm 2.9$  months (a scope of  $5 \pm 12$  months). After administering Eppikajyutsuto to these patients, their magnetic resonance imaging (MRI) results showed a reduction ratio of  $54.5 \pm 38.3\%$  ( $73.6 \pm 27.0\%$  among macrocystic types,  $35.4 \pm 41.5\%$  among micro-macrocystic mixed types). Among the four patients with a macrocystic lymphatic malformation, a considerable reduction was observed in one patient, and a moderate degree of reduction was observed in two patients. Among the four patients with a micro-macrocystic mixed lymphatic malformation, a noticeable improvement was observed in three patients. No reaction was observed in the other patient. There were no advanced adverse events.

The presentation of this paper after Dr. Ogawa's case report further demonstrated that Eppikajyutsuto is effective against lymphatic malformations in a significant number of patients. Other case reports presented at a number of academic societies held in Japanese also conspicuously show the drug's effectiveness against lymphatic malformations.

In the case of this disease, pediatricians and pediatric surgeons who possess accurate knowledge of modern medicine can use this prescription under their own supervision and obtain results relatively easily, without making a precise Kampo medicine diagnosis as in the previous case example. Kampo medicine is inexpensive. A single day's dose of Eppikajyutsuto is around 85 yen, so even a year's

worth costs only approximately 31,000 yen. It is far more inexpensive and easier to use compared to sclerotherapy and operative treatment.

When focusing on the fact that in these examples Kampo was able to ameliorate the patient's symptoms at a lower cost to the patient than standard treatment, they could perhaps be classified under Type 5. However, with regard to the fact that Kampo provided effective treatment without standard treatment, many might say that they rather fall under Type 1.

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The episodes by Dr. Kashima and Dr. Ogawa, and the pilot study by Dr. Hashizume associated with Dr. Ogawa all characteristically demonstrate that Kampo medicine was able to ameliorate patients' diseases in an inexpensive manner, where Western standard treatment would have cost a large amount of medical fee. Kampo medicine is taken orally, so it is non-invasive, and is simple and easy for the patient to take.

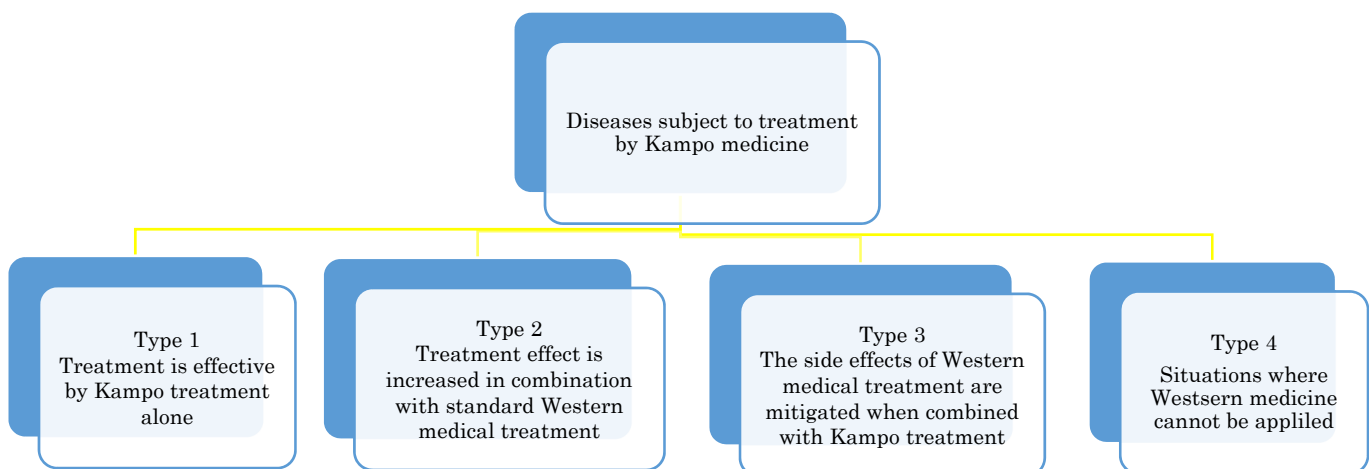
Ogawa's experience as a pediatric surgeon and outstanding capabilities as a Kampo doctor led her to prescribe Eppikajyutsuto and Ogikenchuto. Furthermore, Dr. Ogawa's case report led to the study by Dr. Hashizume et al., and generated an even larger number of case reports.

These case reports and studies show that Kampo medicine, under certain conditions, is extremely cost-effective. However, it is too early yet to decide whether a Type 5 category should be created, based on their data alone. The views of an even greater number of people shall be obtained before making a decision.

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### The four types and their characteristics



In the case in Episode 1, Dr. Kashima's advanced diagnostic capability regarding Kampo medicine led him to prescribe Shosaikoto. In Episode 2, Dr.

## Japanese Acupuncture - Current Research

*Japanese Traditional Medicine Text (20) Palliative Care*

Masanori Takashi

Cancer is the number one cause of death in Japan since 1981. With the addition of the rapid aging of society as another major factor, these are times when one in every two people has cancer and one in every three people dies of cancer in Japan.

Given that cancer has become a serious issue to people's lives and health, the Japanese government established the Cancer Control Act in June 2006 and put it into force in April 2007. Article 16 of the Act, titled "Maintenance and Improvement of the Quality of Recuperation by Cancer Patients," stipulates that "medical care to relieve pain and other suffering should be implemented early and appropriately." Thus, education to develop dedicated cancer specialists is now being promoted among healthcare professionals in various fields.

### **1. Definition of Palliative Care**

Palliative care refers to specialized medical care given to cancer patients, from the point they are told they have cancer and begin treatment, through to their receiving terminal care. WHO defines palliative care as "an approach that improves the quality of life of patients and their families facing the problem associated with life-threatening illness, through the prevention and relief of suffering by means of early identification and impeccable assessment and treatment of pain and other problems, physical, psychosocial and spiritual." Cancer patients face various types of pain and distress that disrupt their ability to live humanly. Based on this understanding, it is important for health workers to actively help cancer patients live their one and only precious life as a unique human being by relieving them of their pain and distress while respecting their will,

values and dignity to the greatest extent. The meaning of cancer treatment is thus to prolong life, provide cure, alleviate symptoms, and improve QOL. Providing treatment may have the effect of prolonging life, but it causes QOL to decline in many cases. Palliative care, on the other hand, neither hastens nor delays death, but improves QOL by alleviating the patient's various pains and distress. Therefore, palliative care and cancer treatment are not contradictory, but rather supplement each other, and the two combined could perhaps deliver "ideal cancer treatment" that aims to both improve QOL and prolong life.

The role of acupuncture therapy in palliative care must be considered not from a one-directional approach to treatment, but from a multi-dimensional perspective of the situation at hand. It could be classified into therapy for (1) prevention of recurrence after Western medical treatment, (2) management of the physical condition of patients, (3) alleviation of symptoms among cancer patients, (4) mitigation of side-effects produced by Western medical treatment, and (5) terminal care.

### **2. Overview of Studies in Japan and Overseas**

Below is an introduction of publications on symptoms of cancer patients that are expected to benefit from acupuncture, based on "Acupuncture guidelines based on palliative evidence of cancer treatment using acupuncture" presented in a study report published by Shimoyama<sup>1)</sup>.

#### **a. Publication search conditions and evaluation (Table 20)**

Publications (study designs) were classified into systematic reviews (SR) and meta-analyses (MA), randomised controlled trials (RCT), non-randomised controlled trials, studies with no control group, and others.

A total of 261 publications were adopted from

among a list of 1,757 English publications composed of database search results and other related publications, obtained after eliminating all duplications. They included 15 systematic reviews and meta-analyses, 30 randomised controlled trials, 5 non-randomised controlled trials, 140 studies with no control group, and 71 others.

To evaluate research quality, systematic reviews were evaluated according to 11 items of the Quality of Reporting of Meta-Analyses (QUOROM) Checklist. Those that satisfied 7 or more items were considered to be high in quality, and those that satisfied 6 or less items were considered to be low. Randomised controlled trials were evaluated using the van Tulder scale (11 items). Those that satisfied 7 or more items were considered to be high in quality, and those that satisfied 6 or less items were considered to be low.

Table 20 Publication search conditions

November 2006 & October 2007

	Search Engine	Condition
English publications	PubMed	Publications on acupuncture and cancer.
Japanese publications	Ichushi-Web (service provided by the Japan Medical Abstracts Society)	Publications on acupuncture and cancer.

January 2008 & January 2009

	Search Engine	Condition
English publications	MEDLINE, EMBASE, AMED, COCHRANE LIBRARY, PubMed	Publications on acupuncture and cancer
Japanese publications	Ichushi-Web (service provided by the Japan Medical Abstracts Society)	Words related to acupuncture. Words related to cancer

## b. Symptoms that are expected to benefit from acupuncture

Symptoms that emerged included aching pain, hiccups, diarrhea, vasomotor disturbance, xerostomia, nausea, poor feeding, dysuria, leukopenia, fatigue and malaise, anxiety,

insomnia, edema, abdominal fullness, constipation, numbness, and acupuncture anesthesia. Of these symptoms, five with the largest number of references are discussed below.

1) Aching pain (including both cancerous pain and pain unrelated to cancer)

The search yielded 47 English papers and 39 Japanese papers. They consisted of 4 systematic reviews, 9 randomised controlled trials, 51 case reports, and 11 studies with no control group.

Among these, “Acupuncture for the relief of cancer – related pain – a systematic review” by Lee, H. et al., a publication that discusses acupuncture treatment, scored high on the Quality of Reporting of Meta-Analyses (QUOROM) Checklist. The evaluation of “Efficacy of complementary and alternative medicine therapies in relieving cancer pain: a systematic review” by Bardia, A. was such that “acupuncture treatment may be valid, but as there are too few studies that have been carefully designed, it cannot be said to be useful to relieving pain.” The Japanese papers were all case reports, and included a report by Kobayashi et al., which discusses 7 cases of treatment that combined EAP and an analgesic.

In terms of clinical applicability, evidence level was 1a, and recommendation level was C.

2) Nausea, vomiting, poor feeding

The search yielded 21 English publications and 6 Japanese publications. They consisted of 6 systematic reviews, 7 randomised controlled trials, 6 studies with no control group, and 8 case reports.

“Cochrane systematic reviews examine P6 acupuncture – point stimulation for nausea and vomiting” by Ezzo, J., Streitberger, K. et al. scored relatively high on the Quality of Reporting of Meta-Analyses (QUOROM) Checklist, and was judged as a substantial systematic review. The Japanese publications were all case reports, and included a report on the improvement of cancer symptoms by Yoshikawa.

In terms of clinical applicability, evidence level was 1a, and recommendation level was A (conditional). The condition was that electroacupuncture is effective against vomiting after chemotherapy.

All Japanese papers were case reports.

### 3) Vasomotor disturbance (hot flashes)

The search yielded 12 English papers and no Japanese papers. They consisted of 2 systematic reviews, 2 randomised controlled trials, 6 studies with no control group, and 2 case reports. Most literature was about breast cancer patients.

In terms of clinical applicability, evidence level was 1b, and recommendation level was B.

There were no relevant Japanese papers.

### 4) Fatigue and malaise

The search yielded 8 English papers and 11 Japanese papers. They consisted of 1 systematic review, 1 randomised controlled trial, 4 studies without a control group, and 12 case reports.

“The management of cancer – related fatigue after chemotherapy with acupuncture and acupressure: A randomised controlled trial” by Molassiotis, A., Sylt, P., and Diggins, H. scored a high 8/11 on the van Tulder scale. In it, the feeling of fatigue and malaise is compared among an acupuncture group, a shiatsu finger-pressure therapy group and a sham shiatsu therapy group, with the result that all groups showed significant improvement in general fatigue, physical fatigue, activity and motivation, and the acupuncture group showing particularly greater efficacy compared to the other groups.

All case reports were Japanese papers, with 10 out of 12 papers showing a positive result.

In terms of clinical applicability, evidence level was 1b, and recommendation level was A, on the condition that it is recommended only to cancer patients who complain of fatigue after chemotherapy.

The Japanese papers were all case reports, with the exception of 2 studies without a control

group. They were “Acupuncture and moxibustion therapy for cancer patients” and “Cancer care – Pain relief provided to cancer patients – The reality and efficacy of acupuncture and moxibustion” by Yokokawa et al.

### 5) Edema

The search yielded 4 English papers and 4 Japanese papers.

Evidence level was low, as they were all studies without a control group. Acupuncture is not recommended, due to scattered results.

Of the 8 papers, 4 showed a positive result.

In terms of clinical applicability, evidence level was 5, and recommendation level was C (precaution needed). Due to the scattered results presented in the papers, no conclusion was able to be reached at the present stage.

The Japanese papers included a study without a control group titled “An experience in acupuncture and concoction combined treatment against leg edema after radical hysterectomy or radiation therapy” by Takashi and a case report on 40 cases by Yokokawa et al.

## **3. Summary**

Judging by the numbers of Japanese papers published in the last 10 years, there is increasing interest in palliative care, but most papers are case reports, and do not discuss the efficacy of acupuncture treatment or present any evidence of its scope of application. Recently, however, an increasing trend has begun to be seen in papers on moxibustion, such as “Leukokinetic analysis of moxibustion therapy applied in combination with chemotherapy for peritoneal cancer” by Nakamura, and papers on the mitigation of the side effects of Western medical treatment, such as “Acupuncture therapy against the side effects of cancer treatment – The safety and efficacy of acupuncture therapy against peripheral neuropathy caused by cancer chemotherapy” by Fukuda et al. and “Cancer and integrative

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## Clinical Report 1 (Acupuncture)

### *Chinese Acupuncture and Moxibustion in Japan - Constipation*

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#### Introduction

Constipation is among adults not a particularly rare complaint, but as the author has stated during a round-table discussion held by the “The Journal of Kampo Medicine” (Japanese Version), this complaint is rather rare among patients visiting acupuncture and moxibustion clinics with gastrointestinal symptoms and its presence is often discovered first during anamnesis or the course of the treatment when confirming symptoms, subsequently leading to its treatment<sup>1)</sup>.

On this occasion the patient visited our clinic with a chief complaint of low back pain, but since she complained during treatment also of constipation, I administered acupuncture and moxibustion treatment and report its effectiveness here.

#### Case

[Case] 37-year-old woman, office work

[Chief complaint] Constipation

[Present illness]

She tended to have constipation since her twenties, but did not consult any medical institution and instead relied on dietetics and a combination of commercial laxatives and enemas to control the condition. She regularly visited our clinic since one year earlier for the treatment of low back pain, but at that point did not complain about constipation. However, three months after treatment begin the tendency towards constipation increased, so that the patient requested treatment, because she had not had any bowel movements for several days. She had bowel movements only once every 3-4 days, which were thin and short and did not really bring her relief. Also, a feeling of abdominal distension rated as high as 75 mm on a VAS tended to be relieved by

passing winds and belching. The low back pain was a painful tension extending from the low back towards the flank(s) and changed location while fluctuating in intensity. Treatment based on my pattern identification as liver Qi stagnation decreased the VAS value from 80 to 45 mm. After that the acupuncture and moxibustion treatment focused mainly on the constipation.

Otherwise the patient complained of shallow sleep with much dreaming, lack of appetite, a feeling of a blocked throat, easy fatigability, irregular, short interval menstruation, premenstrual breast tenderness and menorrhagia, which was particularly strong during the first half of the menstruation.

[Past history]

Eczema (at age 20), duodenal ulcer (at age 33), low back pain (at age 35)

[Present status]

Height: 145 cm; weight: 37 kg; pulse: deep, wiry; tongue: red with cracks, white coat; abdomen shows much gas and is generally distended, but fecal masses could not be palpated. The extremities showed reversal cold.

[TCM diagnosis]

Liver Qi stagnation

[Therapeutic principle] Promote orderly Qi flow and relieve stagnation

[Acupoint selection]

ST-25, SJ-6, St-37, BL-25, LIV-3, BL-18, BL-23 (Figure)

Used needles:

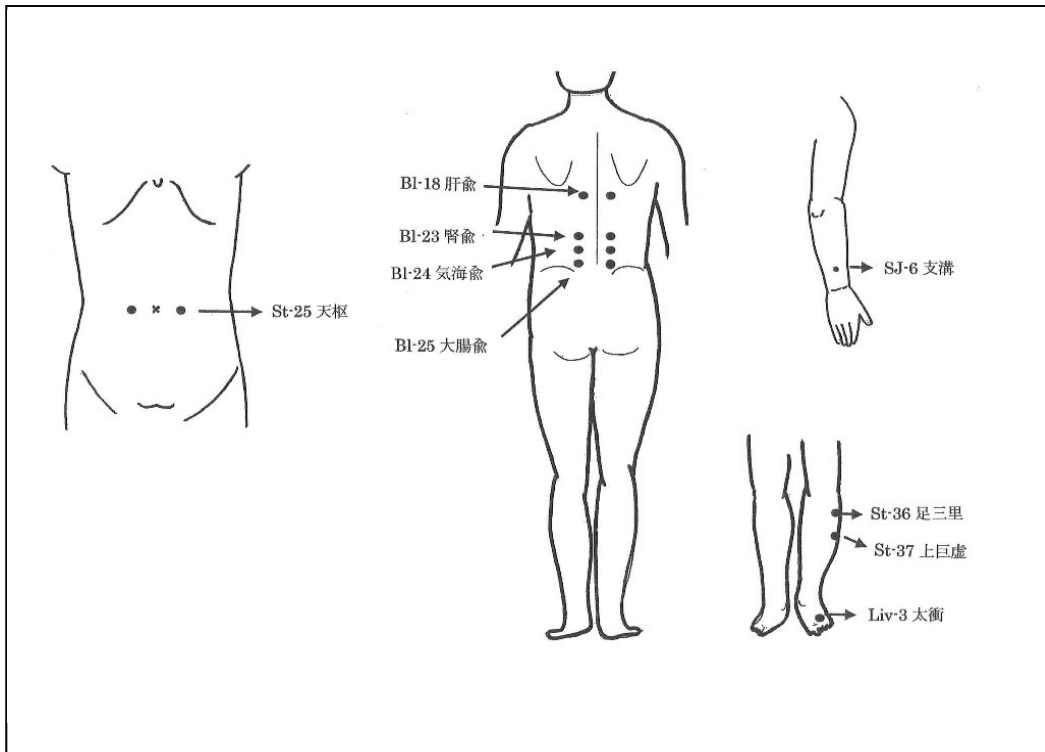
Disposable sterilized Seirin needles, length: 1 cun 6 fen, No.1 and No.3

[Explanation]

I used reduction by twirling the needles at BL-18 and LIV-3 to disperse stagnated liver-energy and regulate energy<sup>2)</sup>. Application of reducing techniques to the back shu point of the large intestine channel BL-25 and the alarm point ST-25 was intended to free the Qi movement of the large intestines, relax the bowels and regulate congestion<sup>3)</sup>.



had increased. For that reason I applied a somewhat



**Figure**

Also, since the lower sea point ST-37 of the large intestines is a place where the channel Qi of the six bowels meet, reactions to diseases of the six bowels appear here. Since the chapter 4 of the Ling-Shu "Visceral Diseases Caused by Evil Qi" states: "the He points are for treating the viscera"<sup>4)</sup>, I chose ST-37 and ST-25 and used a reducing method to free the bowels and regulate Qi<sup>5)</sup>. Since the low back is the house of the kidneys, I used BL-23 for neutral supplementation and drainage<sup>6)</sup> to treat the low back pain.

[Course] Treatments were administered once a week.

First session:

Following the treatment an urge to defecate developed and while the bowel movement was small, she could pass it by herself and it decreased the feeling of abdominal distension. At this point she discontinued the OTC laxative.

Second session:

Because the patient had no bowel movements on the day prior to the treatment session, the low back pain

stronger reducing stimulation using twirling at BL-25. Third and fourth session: Bowel movements occurred after the treatment and subsequently in intervals of once every 3 days. The thickness of the stool increased from pencil to small banana size and the patient reported the bowel movements now being comfortable.

Fifth session:

The patient had now bowel movements every other day. Expression of the abdominal distension on the VAS was now 40 mm. For the low back pain I combined the treatment with cupping at BL-25 and BL-24.

Sixth session:

Expression of the low back pain on the VAS was 15 mm and did not bother the patient any longer.

Eighth session:

Expression of the feeling of distension on the VAS was 20 mm. To regulate abdominal Qi movement I added Zu Sanli to the treatment.

Tenth session:

Since the low back pain had been alleviated and the patient had bowel movements every other day without discomfort the treatment was ended.

## Discussion

Constipation is classified according to its causes into idiopathic simple constipation and secondary constipation.

The condition can be classified into idiopathic simple constipation, referring to temporary simple constipation caused by environmental factors, dietary changes as well as stress and similar mental factors. Little food intake may result in a lack of stimulation of the intestinal mucosa, decreasing peristaltic movements and thus cause atonic constipation, or else the sensitivity of the wall of the rectum may decrease and thereby decrease the defecation reflex in rectal constipation. In spastic constipation the feces do not move forward to the anus when the sigmoid colon is spastic.

Moreover, secondary constipation may be further classified into obstruction constipation due to colon tumors obstructing the intestinal lumen. A variety of endocrine or systemic disorders can cause constipation, as well as relaxation of smooth muscles induced by antipsychotic agents or muscle relaxants, resulting in drug induced constipation<sup>7)</sup>.

While the cause is not clear in this case, I presumed it to be idiopathic simple constipation.

In the second volume of the "Textbook of Acupuncture and Moxibustion" constipation is classified into the four forms of heat constipation caused by dryness-heat of stomach and bowels, Qi constipation caused by liver depression and Qi stagnation, constipation due to both Qi and Blood deficiency as well as cold constipation due to kidney yang deficiency. For the treatment I used ST-25 and SJ-6. To the basic treatment point ST-37 LI-11 and LU-5 were added for heat constipation, LIV-3 and GB-34 for Qi constipation, ST-36, BL-20 and SP-6 for deficiency type constipation and for cold constipation BL-23 and BL-24<sup>8)</sup>.

I considered the condition in this case to be a constipation caused by liver depression and Qi stagnation. That is why LIV-3 among the above mentioned basic treatment points was effective.

There is a tendency to consider pain caused by diseases of the locomotor system to be an indication for acupuncture and moxibustion treatment, but idiopathic or secondary constipation due to the side

effects of opioids like in this case are also good indications.

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\* This report was published in the "The Journal of Kampo Medicine" (Japanese edition) Vol. 55; No.12 and has been translated after slight modifications.

## Clinical Report 2 (Kampo Medicine)

### *Clinical Experiences and Practices of hainosankyuto for Suppurative Diseases*

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### Abstract

**Aim:** Hainosankyuto is called as an “antibiotics of traditional Japanese medicine”, but in current status on development of western antibiotics, its effect is limited. In this report, clinical experiences and practices of hainosankyuto for suppurative diseases in our hospital were reviewed.

**Methods:** Thirty three patients including sixteen men and seventeen women were treated by hainosankyuto between July 2012 and August 2014. These cases were retrospectively researched in views of clinical backgrounds, western medical diagnosis, treatment period, concomitant drugs and clinical outcomes.

**Results:** Most of diseases are cellulitis of extremity, colonic diverticulitis, and herpes zoster-induced skin erosion. Mean treatment period was about 30 days. About 90% patients were also treated with antibiotics, anti-viral drug or anti-fungal drug. In clinical outcomes, about 90% were healing or nimble, but remaining about 10% were immutable or worsening.

**Conclusion:** As a target for “penetrating with the outside-world, that is superficial and open”, hainosankyuto may be more effective, but not useful to cases of poor general conditions and intractable situations. Several kinds of suppurative diseases

that hainosankyuto may be beneficial were recognized.

**Key words:** hainosankyuto, suppurative diseases, antibiotics

### Introduction

Hainosankyuto is mixed traditional Japanese medicine that Todo Yoshimasu devised in Edo period on Japanese history. According to source book, that is, “Kinkiyoryaku”(1), hainosan (mixture of Kijitsu, Kikyo and Shakuyaku) using at mature stage of inflammation and hainoto (mixture of Kanzo, Kikyo, Shokyo and Taiso) using at early or post-drainage end stage of inflammation, were mixed for treating suppurative diseases during all over the stage of inflammation.

In views of current status on development of western antibiotics, its effect is limited and poorer than that of western antibiotics. Its drug adaptation of the attached documents in Japan are painful lesions such suppurative diseases as carbuncle, furuncle, facial furuncle and other furunculosis with their reddish and swollen conditions from early stage to post-drainage end stage.

In this present report, clinical experiences and practices of hainosankyuto for suppurative diseases in our hospital were reviewed.

### Patients and Methods

Thirty three patients including 16 men and 17 women (mean age 75 y.o., 41~93 y.o.) were treated by hainosankyuto (Tsumura & Co., Tokyo, 7.5g/day, or Kotaro & Co., Tokyo, 7.5g/day) in our hospital between July 2012 and August 2014.

These cases were retrospectively researched in views of clinical backgrounds, western medical diagnosis, treatment period, preceding or concomitant drugs and clinical outcomes by three-

step evaluation (healing, nimble and immutable or worsening).

Results

Most diseases of western medical diagnosis are cellulitis of extremity, colonic diverticulitis, herpes zoster-induced skin erosion (Fig. 1). Mean treatment period was about 30 days (median 14 days, range 3~180 days).

Fig. 1 : Hainosankyuto and its origin

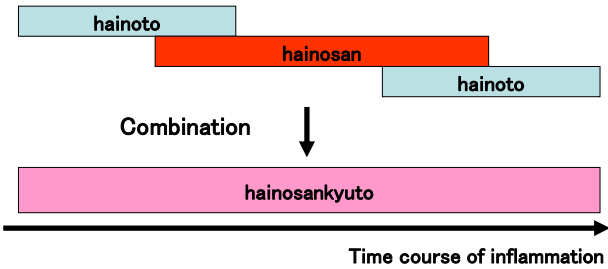
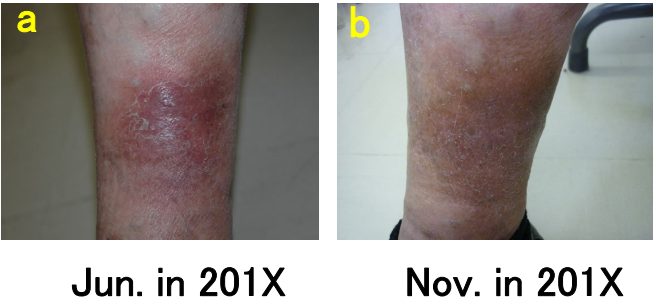


Fig. 1: Hainosankyuto and its origin

12.1% of patients were only treated by hainosankyuto. 87.9% of patients precedingly or simultaneously treated with antibiotics, anti-viral drug or anti-fungal drug. Honestly, 66.6% of patients simultaneously treated with antibiotics, anti-viral drug or anti-fungal drug.

In clinical outcomes, 84.4% of patients were healing or nimble, but remaining 15.2% were immutable or worsening because of translocation physician, operation or basic illness-related death (Fig. 2).

Fig. 2 : Right pretibial cellulitis



- Fig. 2: Case 1 Clinical course of pretibial cellulitis
- a. On the anterior side of right lower leg, reddishness and swelling with partially skin peeling were observed.
  - b. Reddishness and swelling were almost disappeared leaving the pigmentation

Remarkable adverse effects were not detected. They belonged to either “Kyo-sho” meaning subjects who have weak constitutions and low vital energy or “Jitsu-sho” meaning subjects who have strong constitutions and high vital energy. “Sho” means universal proof in Oriental medical sense.

Table 3 demonstrated all 33 cases in detail. In addition, more meaningful three cases were presented for clinical significance as following.

Table 3	Age	Sex	Western medical diagnosis	Treatment periods	Clinical outcome	Prescribed drug	Concomitant drug	SI
1	63	Male	Cellulitis of extremity	10	Cure	-	Cefazolin Sodium Hydrochloride Hydrate	JH
2	41	Male	Cellulitis of extremity	7	Cure	-	Levofloxacin Hydrate	JH
3	71	Female	Subcutaneous abscess	8	Immutable	-	Cefazolin Sodium	JH
4	47	Male	Cellulitis of extremity	7	Cure	-	Levofloxacin Hydrate	JH
5	66	Female	Pharyngitis	49	Cure	Piperacillin Sodium	Ceftriaxone Sodium Hydrate	KI
6	93	Female	Cellulitis of extremity	30	Cure	Levofloxacin Hydrate	-	KI
7	74	Male	Cellulitis of extremity	7	Cure	-	Cefazolin Sodium Hydrochloride Hydrate	JH
8	67	Female	Infectious paronychia cyst	12	Cure	-	Levofloxacin Hydrate	SH
9	63	Male	Pressure ulcer	180	Worsening	Cefazolin Sodium	Vancomycin Hydrochloride	KI
10	62	Male	Cellulitis of extremity	55	Worsening	Cefazolin Sodium Hydrochloride Hydrate	Cefazolin Sodium Hydrochloride Hydrate	KI
11	62	Male	Cellulitis of extremity	7	Cure	-	Cefazolin Sodium Hydrochloride Hydrate	KI
12	77	Female	Herpes zoster induced skin erosion	11	Cure	Valacyclovir Hydrochloride	-	JH
13	62	Female	Cellulitis of extremity	3	Cure	-	Fucidic Acid Sodium	JH
14	79	Male	Peritonsillar abscess	14	Cure	-	Cefazolin Sodium Hydrochloride Hydrate	KI
15	60	Male	Herpes zoster induced skin erosion	4	Cure	Valacyclovir Hydrochloride	-	KI
16	66	Female	Cellulitis of extremity	14	Cure	-	Ceftriaxone Sodium Hydrate	KI
17	72	Female	Cellulitis of extremity	140	Worsening	-	-	SH
18	62	Male	Cellulitis of extremity	7	Cure	Levofloxacin Hydrate	-	KI
19	61	Female	Pressure ulcer	180	Cure	Pseudoephedrine Hydrochloride	Vancomycin Hydrochloride	KI
20	77	Female	Liver Abscess	14	Cure	Mercaptopurine Hydrate	Mercaptopurine Hydrate	SH
21	62	Male	Cellulitis of extremity	21	Cure	Levofloxacin Hydrate	-	JH
22	76	Male	Cellulitis of extremity	28	Immutable	Cefazolin Sodium Hydrochloride Hydrate	Miconazole Hydrochloride	JH
23	66	Female	Skin erosion after laser treatment	3	Immutable	-	-	KI
24	61	Male	Cellulitis of extremity	14	Cure	-	Levofloxacin Hydrate	JH
25	62	Female	Herpes zoster induced skin erosion	27	Cure	Valacyclovir Hydrochloride	Cefazolin Sodium Hydrochloride Hydrate	KI
26	66	Female	Alveolar pyorrhea	63	Worsening	-	-	SH
27	60	Female	Cellulitis of extremity	21	Worsening	Levofloxacin Hydrate	Cefazolin Sodium Hydrochloride Hydrate	JH
28	66	Female	Pressure ulcer	7	Immutable	-	-	KI
29	63	Male	Cellulitis of extremity	7	Cure	Levofloxacin Hydrate	Cefazolin Sodium Hydrochloride Hydrate	JH
30	60	Male	Cellulitis of extremity	7	Cure	-	Levofloxacin Hydrate	JH
31	62	Female	Cervical flow and urinary infection	25	Cure	-	Fluconazole	KI
32	66	Female	Herpes zoster induced skin erosion	14	Cure	Levofloxacin Hydrate	-	KI
33	60	Male	Infectious spondylitis	14	Worsening	-	Cefazolin Sodium Hydrochloride Hydrate	SH

Table 3 List of all 33 cases

Case 1 (No.17): 72-year-old woman (Fig. 2)

She was medicated for rheumatoid arthritis. On June in 201X, she was diagnosed as cellulitis of right lower extremity (right pretibial cellulitis) and was taken therapy by Dermatologist. Although only ointment made her not enough to be recovery, hainosankyuto (Tsumura & Co., Tokyo, 7.5g/day) was started. 140 days later, reddish and swollen lesions were recovered with leaving only the pigmentation.

Oriental medical findings: “Chukan-sho” (meaning subjects between “Kyo-sho” and “Jitsu-sho”, previously described). Pulse finding was slightly precipitation. Tongue finding was pink. Abdominal finding was moderate.

#### Case 2 (No.19): 81 year-old woman (Fig. 3)

She was medicated for Hypertension. Years ago, she was pointed out collagen disease, but had taken no therapy. On January in 201Y, she was admitted to our hospital because of bone fracture of left femur. On admission, pressure ulcer on her left heel was detected. Next month, operation was done. One week later, good clinical course made her remaining stitches take off, but serum C-reactive protein (CRP) did not normalized. After then, culture of pressure ulcer portion revealed Methicillin resistant *Staphylococcus aureus* (MRSA). Blood culture at high fever state also revealed MRSA sepsis. A sensitive antibiotic, vancomycin, was used for therapy. At the same periods, hainosankyuto (Tsumura & Co., 7.5g/day) was started. 90 days later, her pressure ulcer was almost healing, and 180 days later, was almost cured.

Oriental medical findings: “Kyo-sho”. Pulse finding was precipitation. Tongue finding was crimson. Abdominal finding was mild.

Fig. 3: Case 2 Clinical course of left heel pressure ulcer  
c. Skin ulcer with purulent change.  
d and e. Skin ulcer were shrinkened with approaching epithelialization.  
f. Epithelialization and almost scarring.

#### Case 3 (No.9): 84-year-old man (Fig. 4)

He was medicated for Hypertension, diabetes and chronic renal failure. On October in 201Z, he was taken operation for bone fracture of left femur. Next month, he was transferred to our hospital for rehabilitation. At the same time, sacral pressure ulcer was detected. On February in next year, cutaneous flap was constructed. But, MRSA-induced flap necrosis (wound infection) occurred unfortunately. Then, other therapies of continuous pus aspiration and plastic sheet therapy (so-called, Japanese original technique, Wrap therapy), were started. But, blood culture at high fever state revealed MRSA induced bacteremia. A sensitive antibiotic, vancomycin, was used for therapy. At the same periods, hainosankyuto (Kotaro & Co., Tokyo, 7.5g/day) was started. 180 days later, his sacral pressure ulcer was closed and almost cured.

Oriental medical findings: “Jitsu-sho”. Pulse finding was slightly floating. Tongue finding was pink. Abdominal finding was moderate.

**Fig. 3: Left heel pressure ulcer**



**Fig. 4: Sacral pressure ulcer**



**Fig. 4: Case 3 Clinical course of sacral pressure ulcer**

- g. Pressure ulcer on right buttock.
- h. After skin flap procedure.
- i. Opened state after flap infection
- j. Skin wound was shrinkened and progressing to epithelialization.
- k. Skin wound was completely closed and scarring.

## Discussion

Hainosankyuto is mixed traditional Japanese medicine. According to source book, “Kinkiyoryaku” (1), hainosan and hainoto were mixed. It has a lot of quality indicating “qing heat-detoxification”, “expectoration-drainage”, “pain-kill” and “stomach calm”. Its clinical target is wide for treating suppurative diseases during all over the stage of inflammation. Namely, hainoto was used for absorption at early condition under not so highly uplifting from skin surface. On the other hand, hainosan was used for drainage at stonely swollen condition under uplifting hemispherically. It was originated from “Kinkiyoryaku”(1), and was effective for suppurative diseases such as carbuncle and furuncle. “Kinkiyoryaku”(1) also showed only “Ho” meaning drug orientation, but not “Sho”. In source book of Todo Yoshimasu, “Ruijyuhō”(2), it has virtuosity in senses of combining “Kikyo” having drainage effect with “Kijitsu” having exclusive effect of inflammatory mass.

In community medicine including our hospital, a lot of suppurative diseases are found if clinicians are consciously careful for them. As hainosankyuto is well-known to be effective against sinusitis, otitis media, mastitis, carbuncle and furuncle, a target for “penetrating with the outside-world, that is, superficial and open” may be more effective during all over the stage of inflammation. But it was not useful to the cases of poor general conditions and intractable ones implicating “kyo-sho”.

In our clinical experiences and practices, not only to many diseases based on classic Bible, but also to colonic diverticulitis, herpes zoster-induced skin erosion, pressure ulcer (namely bed sore),

periodontal abscess, alveolar pyorrhea, candida flow, urinary infection, infectious pancreatic cyst and liver abscess, adapted diseases were trying to become wider. Subsequently, clinical outcome were good. Although most of them simultaneously took antibiotics or anti-viral drug, pure effect of hainosankyuto did not be evaluated.

By the way, though the meaningful 3 cases (Case 1, 2 and 3) had unfortunately inconvenient past history and basic illness such as collagen diseases, diabetes and chronic renal failure, significance of its long-term use is deeply valuable.

There are many clinical reports as to usefulness of hainosankyuto. In area of pediatric surgery, perianal abscess is well-known to its effectiveness on decreasing operation(3,4). In area of dermatology, there are a few effective reports to palmoplantar pustulosis(6,7,8,9). In area of ophthalmology, there is an effective report to hordeolum, which is sole paper with randomized controlled trial that Japanese Eastern Medical Society certified as “Kampo Evidence report 2013”. In area of gynecology, there is an effective report to pyometra(11). In reference to this report, it was used for candida flow and urinary infection and resulted in good clinical course.

In basic research about periodontal diseases, anti-inflammatory reaction of hainosankyuto was researched in vitro model, indicating that it increased amount of interleukin-6 and interleukin-8 by stimulating lipopolysaccharide(12). In reference to this paper, it was used for two cases trying to therapy for periodontal abscess and alveolar pyorrhea. In mouse model(13), while Group A-beta streptococcus was infected to mice, promoting interferon- $\gamma$  and interleukin-12 by enhanced macrophage phagocytosis. This remarkable approach except using antibiotics may be promising. It is well-known that Streptococci are inducible to bacterial cellulitis, so cellulitis of extremity was entered in our clinical experiences with promising strategy in purpose.



In addition, viral infection such as mumps virus(14), common wart(14), hand-foot and mouth disease(15), subacute thyroiditis(16) and others were sporadically reported indicating hainosankyuto may have a role on interferon induction.

According to Nojima's report(17) about analysis of 68 cases of sacral pressure ulcer, the treatment period was average 6.2 months. As the cases of them received an additional therapy after surgery, as the treatment period was longer. Compared bacteria positive group in culture of pressure ulcer with bacteria negative group, the latter had better clinical course. In Case 3 suffered from sacral pressure ulcer, four months later since admission, cutaneous flap was performed. After then, more 4 months later, MRSA-infected flap necrosis was detected. Under such condition, hainosankyuto after surgery considered that intractable sacral pressure ulcer was almost cured as significance of combined therapy.

Ishino's reference(18) highlighted differential diagnosis from another medication on usage of hainosankyuto as following. Senkinaitakusan is suitable to the delicate and easily tired person ("kyo-sho") with pulurent chronic diseases. Jyumihaidokuto is suitable to the nervous person with epigastric discomfort for changing constitutions. Hakushusan is mainly fit to be transiently used at early chronic phase, but not acute phase. Keibohaidokusan is preferable to the local reddishness and swelling together with headache repeatedly. Keigairengyoto is suitable to the person whose skin is swarthy with distension of rectus abdominis muscle to make better constitution in middle-aged periods.

## Conclusion

As a target for "penetrating with the outside-world, that is, superficial and open", hainosankyuto may be more effective, but not useful to the cases of poor general conditions and intractable ones. In community medicine, some suppurative diseases that hainosankyuto may be beneficial including

long-term prescription were recognized, and wider indication of it has to be researched further.

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## Conference Report

### *The First Japan-Germany Joint Symposium on Kampo Medicine and Acupuncture*

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Opening remarks by Dr. Yoshiharu Motoo

### Introduction

The First Japan-Germany Joint Symposium on Kampo Medicine and Acupuncture was held on April 15, 2016 in Okinawa, Japan. This symposium was aimed to promote mutual understanding of Japanese traditional medicine, Kampo, and acupuncture. Although this was a semi-closed symposium, there were over 50 observers in addition to the designated discussants (18 from Japan and 9 from Germany).

The symposium was started with opening remarks by Dr. Yoshiharu Motoo and Dr. Heidrun Reissenweber-Hewel at 14:00.



Dr. Heidrun Reissenweber-Hewel

### Session 1.

Originally, Dr. Masayuki Kashima was supposed to be the first speaker, but he was late due to a big earthquake in Kumamoto on the previous day. Therefore, the original Session 2 was moved to Session 1, and Dr. Toshiaki Makino addressed a keynote lecture, entitled “Concept on active

ingredients of crude drugs used in Kampo



Medicine”.



Commentator: Dr. Hans Rausch

## Session

### 2.

Dr. Masayuki Kashima addressed his keynote lecture, entitled “Structure and characteristics of Kampo Medicine”. He arrived at the Okinawa Convention Center during the Session 1, after taking care of people suffering from the earthquake at the emergency room of Kumamoto Red Cross Hospital without sleep. He explained the characteristics of Kampo Medicine showing some examples. His perspectives on “Hosho-sotai (Formula-Diagnosis Correspondence)” clearly showed the structure of



Chair: Dr. Sven Schroeder

Commentators: Dr. Kuchta (left) and Dr. Cameron (right)

Keynote lecture by Dr. Masayuki Kashima

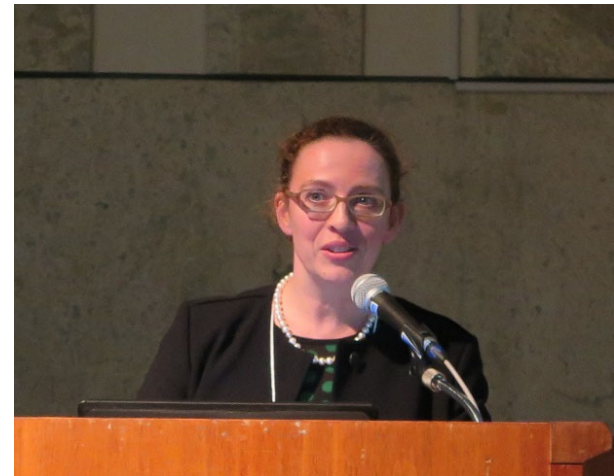
Kampo Medicine.



Chair: Dr. Klaus Hambrecht

Dr. Klaus Hambrecht, chair of this session, mentioned the differences in clinical effects between single herbs and formulas.

Dr. Kostner, one of the



commentators of this session, asked to Dr. Kashima whether he had difficulty in using Kampo Medicine and modern medicine at the same time. Dr. Kashima answered “It is as if I use my right brain (hemisphere) and the left one, integrating the all items as a whole”. Another commentator, Dr. Ulrich Eberhard, talked about the history of clinical practice of Kampo Medicine in Japan. During the general discussion, several participants repeated the beneficial role of Kampo Medicine as unitary medical system.



**Session**

**3.**

Dr.  
Claudia  
Witt



addressed her keynote lecture, entitled “Clinical research on acupuncture – What can we learn from the efficacy effectiveness gap?”. She provided an overview about the evidence from clinical research perspective. Dr. Witt addressed factors that moderate the treatment outcome, discussed advantages and limitations of previous studies and made suggestions for future research. Furthermore, she introduced comparative effectiveness research (CER), showing examples from acupuncture research. Her talk greatly impressed the audience with its high-level contents based on evidence as well as her wonderful English.

Commentator: Dr. Hitoshi Yamashita

Dr. Denichiro Yamaoka summarized this session, together with his perspectives on the history of Japanese acupuncture.



Dr. Yamashita pointed out that the differences in cultural or contextual factors among countries affect the interpretation of “effectiveness” of traditional medicine.

Keynote lecture by Dr. Claudia M. Witt



Commentator: Dr. Takashi Seki

traditional medicine, especially acupuncture, to face evidence-based medicine in terms of efficacy and effectiveness. Her presentation was very instructive and favorable to Japanese acupuncturists.

Thus, the three sessions were successfully completed. The symposium was closed by remarks by Dr. Motoo and Dr. Reissenweber-Hewel at 18:00.

### Acknowledgments

We would like to thank Goto College of Medical Arts and Sciences for the support of this symposium.

### Discussions

The symposium was well-controlled and discussions were fruitful.

Dr. Makino's keynote lecture at the Session 1, characteristics of Japanese Kampo products for ethical use and how to evaluate their quality assurance would have been quite fresh to Japanese clinicians, and also have been very helpful to German researchers. Utilization of the characteristic chemical compounds in the crude drug as the marker compounds to identify the origin and to maintain the quality of the crude drugs seemed understandable to German doctors.

Dr. Kashima's presentation was epoch-making, showing the comprehensive framework covering Japanese Kampo Medicine and Traditional Chinese Medicine (TCM). He suggested the methodology to understand Traditional Medicines originating from ancient Chinese Medicine, answering the questions from all over the world "what is the difference between Kampo Medicine and TCM?".

Dr. Witt's lecture was important for researchers of

## ABSTRACT

### Session 1.

#### Concept on active ingredients of crude drugs used in Kampo medicine

**Toshiaki Makino, PhD**

**Professor**

*Dept. Pharmacognosy, Grad. Sch. Pharm. Sci., Nagoya City University, Japan*

Since ancient times, human beings have used natural substances as crude drugs to treat various diseases. In modern pharmaceutical sciences, chemists have isolated the active ingredients (compounds) from these natural substances used as medicines, and these ingredients (compounds) have developed as chemical drugs. For example, morphine, a chemical compound that has 285.34 g/mol molecular weight, was isolated from opium poppy in 1803, and has been used as narcotic drug to reduce severe pain in cancer patients. Digoxin, another compound that has 780.938 g/mol molecular weight, was isolated from the leaves of *Digitalis purpurea* (foxglove) in 1875, and has been used as a cardiotonic drug to prevent e atrial fibrillation and atrial flutter. Instead of the use of active ingredients (compounds) as chemical drugs, original natural substances have not been used as crude drugs. We can not find opium or digitalis leaf but can find morphine or digoxin In the present pharmacopoeia.

However, in traditional medicine, we are still using crude drugs as medicines. Although ephedrine was isolated from the stem of *Ephedra sinica* (*Ephedra Herba*, 麻黄) in 1885 and has been used as bronchodilator in modern medicine, we have still been using *Ephedra Herba* as a crude drug in traditional Oriental medicine to dispel the exterior evil in body surface with pungent taste and warm nature (辛温解表薬). In the textbook of pharmacognosy (生薬学), *Ephedra Herba* is used as a bronchodilator, and its active ingredient is ephedrine, since pharmacognosy belongs to modern science (Western medicine). Indeed, ephedrine is one of the active ingredients (compounds) of *Ephedra Herba* to treat bronchial asthma, *Ephedra Herba* may contain other active ingredients than ephedrine to dispel the exterior evil in body surface. In another example, we knows the active ingredient of Rhubarb (the rhizome of *Rheum palmatum*, 大黄) exhibiting laxative is sennoside A, but in traditional Oriental medicine, 大黄 is used not only as a laxative but we use to activate blood to dissipate blood stasis (活血化瘀) and to remove interior heat (清热). When we use Rhubarb to dissipate blood stasis, we can recognize that sennoside A is not the active ingredient but the causative agent of diarrhea as an adverse effect.

When we use the term “active ingredients”, the meaning of the term should contain both information of the names of chemical compounds and some efficacies. In usual, the pharmacognosists find the active ingredients of crude drug extracts by activity-guided fractionation using some pharmacological experiments. Although we can confirm the pharmacology

in modern

medicine (薬理), such as antipyretic, cardiogenic, bronchodilator, or laxative, by conducting pharmacological experiments, it is very difficult to confirm the pharmacology in traditional medicine (薬能), such as dispelling the exterior evil or activating blood and dissipating blood stasis, or removing interior heat, by experimental pharmacology, because the experimental animals do not exhibit about their symptoms in traditional medicine, and we can not measure or analyze the term “evil” or the efficacies by mechanical instruments. Unless the philosophy of the pharmacology in traditional medicine is translated into modern science, we can not use the term “active ingredient” of crude drugs in traditional medicine.

Why we have to learn the ingredients (chemical compounds) in crude drugs? The reason is to maintain the quality of crude drugs. Since crude drugs have higher values of medicinal efficacies than foods in natural substances, and since general people can not recognize or identify the quality of crude drugs, it is easier to distribute the counterfeits or shoddy goods. Indeed, crude drugs are derived from natural substances that usually have large individual differences and diverseness. As the drug, the pharmacists have to prepare crude drugs with the stable qualities, and the individual differences of crude drugs should be regulated in the minimum levels all of the time. Then, we can use the characteristic chemical compounds in the crude drug as the marker compounds to identify the origin or to maintain the quality of the crude drug. Though sennoside A is not the active ingredient of Rhubarb in traditional medicine, this compound is one of the characteristics of Rhubarb and can be used as the marker of Rhubarb, i.e. the stable content of sennoside A among a number of batches of Rhubarb can warrant the quality of Rhubarb, though we do not know the genuine active ingredient of Rhubarb in traditional medicine.

In summary, in the textbook of pharmacognosy or Materia Medica describing crude drugs or herbal medicines from natural substances, the chemical compounds in crude drugs are not always described as the active ingredients. Especially in traditional Oriental medicine, we can not determine the active ingredients in crude drugs. We have to recognize the differences of the concepts of active ingredients and marker compounds in pharmacognosy, and the most of ingredients of crude drugs described in the textbook of traditional Oriental medicine are not the active ingredients but the marker compounds.

## Session 2.

### Structure and characteristics of Kampo Medicine

Masayuki Kashima, MD

*Department of General Internal Medicine, Japanese Red Cross Kumamoto Hospital*

emphasized of Kampo medicine are HOUSYOU-SOUTAI (方証相對) system (prescription directly links to symptoms and signs), more detailed analysis of pathophysiology and medical action in traditional Chinese medical words than Chinese, and the Unitary medical service system that a doctor having one license uses Kampo and Western medicine. HOUSYOU-SOUTAI system which was established by Toudo Yoshimas(吉益東洞) in the Edo period, is that the prescription is directly leaded from symptoms and sings, without using theory of etiology, pathophysiology or pharmacology. If the arbitrary combination choice was from a plurality of symptoms and signs, there are the large amounts of choices of prescription in this way. To solve the problem, the abdominal finding is placed to the key diagnostic valuable sign. The abdominal examination (腹診) has been developed highly. In the complicated or including a lot of systems disorder case, when there are some choices of prescription, the method is frequently used that the classifications which are consisted of some symptoms and signs, are linked to some prescriptions, are intervened between clinical findings and prescriptions, and help to choice the prescription. In this method, using some classifications, it is able to narrow downs the choice of prescription belonging to plural classifications. HOUSYOU-SOUTAI system let to accumulate experiences limited number prescriptions therapy the various conditions, discover the new using way of the prescription unlimited by traditional theory, prompt to verify the traditional Chinese medicine's theories. There is another the way of thinking in Kampo medicine, which is more detailed analysis of pathophysiology and medical action in traditional Chinese medical words than Chinese, being located in the opposite pole of HOUSYOU-SOUTAI.

Traditional Chinese medicine has the character summarizing and explaining, the concrete biological phenomenon by the highly abstractive concepts, for example, In-Yan (陰陽), surface-inside (表裏) etc. This type thinking is difficult to understand for not only another culture area member feeling about disregarding the abstraction level, but also Japanese who had long term to acquire Chinese culture. The way of thinking in Japan which uses traditional Chinese medical theory shows more concretely “where is”, “what is”, “how to” play the role closely connected to each symptoms in the pathophysiology or the pharmacology than Chinese and points out the contradict points of the modern Chinese medicine. These Kampo styles play a good navigator of learning the traditional Eastern oriental medicine for not Chinese culture area people. Kampo medicine which is based on these styles is practiced by the doctor who acquired the the Western medicine in the Unitary medical system. Today, over 90% Japanese doctor use the Kampo prescription based on the wide range thinking styles form only the western medicine style diagnosis to the Kampo theory, therefore, the Kampo medicine is the most established alternative and complemental medicine. In addition, the Kampo medicine used by a doctor, can play the interactive role of the Western medicine beyond only an alternative or complemental role, and provides the tight-knit medical system.



**Session 3.****Clinical research on acupuncture – What can we learn from the efficacy effectiveness gap?****Claudia M. Witt, MD, MBA****Professor and Chair***Institute for Complementary and Integrative Medicine, University of Zurich and University Hospital Zurich, Switzerland, claudia.witt@uzh.ch*

To date, most clinical studies on acupuncture have focused of the specific effects of single treatment components such as point location, needling and needle stimulation.

However, acupuncture can be viewed as a multi-component treatment that also includes many other aspects such as palpation of the points and patient doctor interaction. Furthermore, most clinical trials included highly selected patients and applied standardized treatment protocols with the aim to exclude as much bias as possible. These studies have contributed important information on the efficacy of acupuncture; however, their results are only marginally helpful to understand the value of acupuncture in a more usual care context. The current movement to Comparative Effectiveness Research (CER) in conventional medicine fosters the generation and synthesis of evidence that compares the benefits and harms of different treatments in a more typical setting. CER has considerable potential to help health care providers as well as patients and clinicians to choose among currently available therapeutic options including acupuncture. CER compares two or more health interventions in order to determine which of these options works best for which types of patients in settings that are similar to those in which the intervention will be used in practice. This evidence, more generalizable than the evidence generated by traditional randomized controlled trials, is better suited to inform real-world care decisions. CER uses a broad spectrum of methodologies including randomized pragmatic trials. Creating a modern, strategic research framework that takes into account the stakeholders' perspectives, follows a patient-centered approach, uses mixed methods research methodologies, and combines modern scientific techniques such as systems-biology-based 'omics technologies would be beneficial for bridging the gap between traditional medicine theory and modern clinical research methodologies.

In most areas of integrative medicine data on comparative effectiveness is scarce, but available acupuncture research already contributes to CER evidence. This presentation will provide an overview about the evidence from clinical research perspective. It will address factors that moderate the treatment outcome, discuss advantages and limitations of previous studies and make suggestions for future research. Furthermore it will introduce CER, show examples from acupuncture research and make suggestions for future research.

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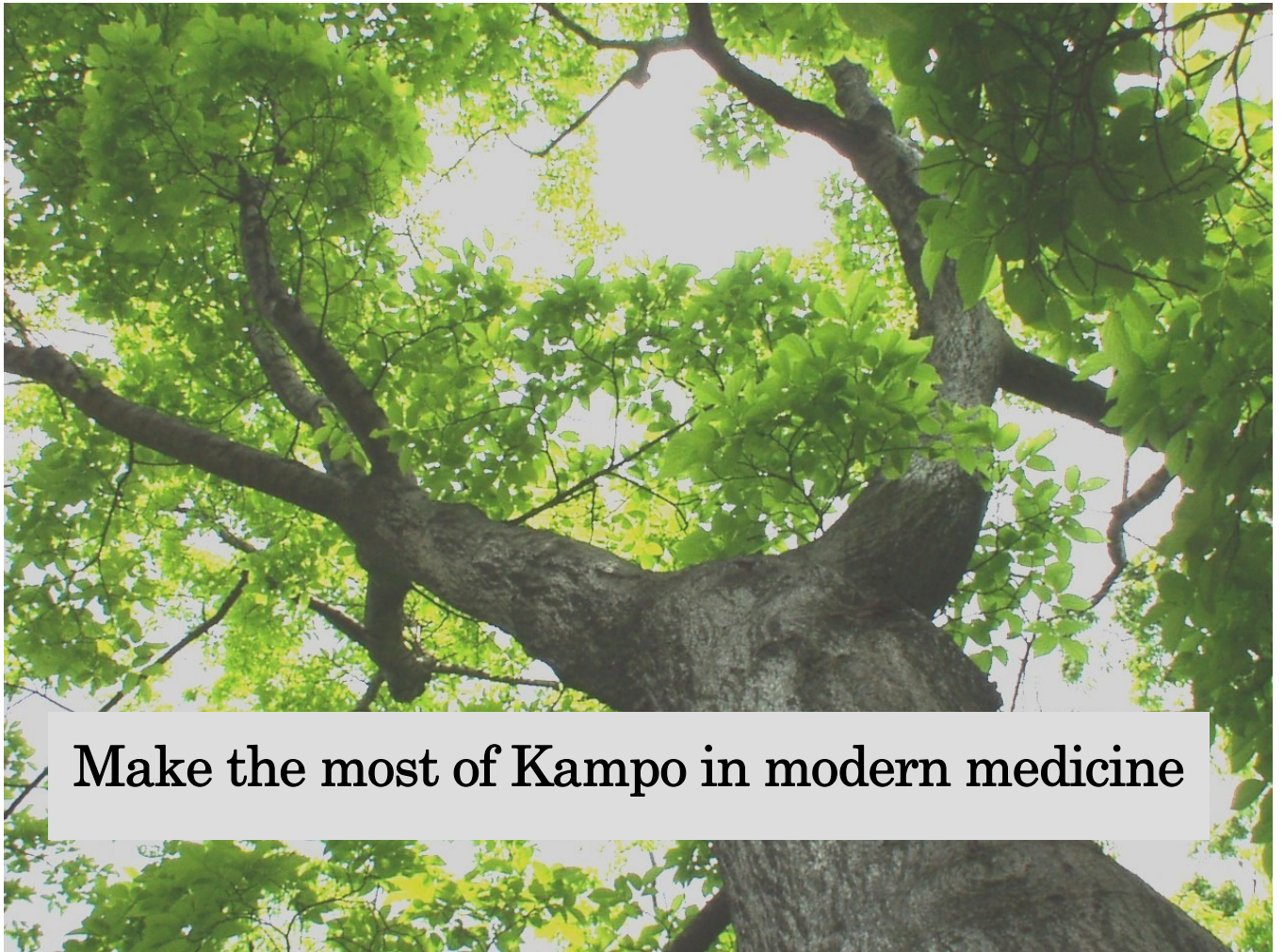
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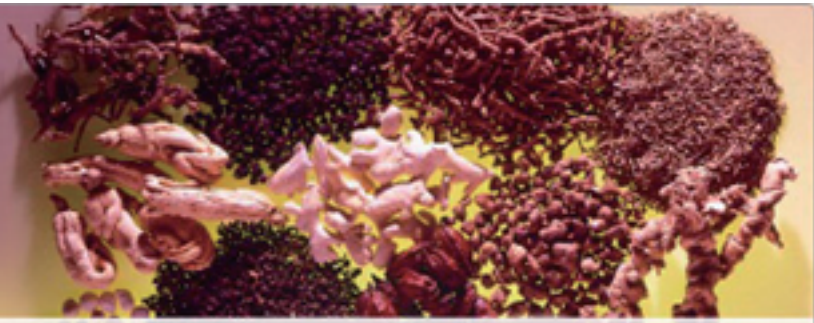
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