

Abstracts

1ST INTERNATIONAL
SYMPOSIUM FOR
JAPANESE
KAMPO
MEDICINE

Friday, November 25, 2011

9:00 - 17:00

Hörsaal Pavillon

Hospital Klinikum rechts der Isar

Technical University of Munich

Ismaninger Strasse 22

D-81675 Munich, Germany

What is Unique in Japanese Kampo Medicine?

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Kampo medicine, literally “method from Han-period China“, is defined by the administration of herbal prescriptions and had been the established medicine in Japan for centuries until it was replaced by Western medicine towards the end of the 19th century. Recent decades saw a revival of Kampo which took place within a context dominated by modern Western medicine. Main indications today are disease patterns caused by modern industrial society, such as chronic and degenerative diseases, functional and psychosomatic disorders and the multiple diseases of the elderly. The historical development and the gradual integration of Kampo into modern medicine helped to shape unique features which are characterized as follows:

Kampo is today regarded not as an alternative treatment but as a complementary therapeutic option to enhance the quality of modern health care in defined areas. Only examined physicians are allowed in Japan to prescribe traditional medication which stands in contrast to other Asian countries. In most cases, Kampo drugs are applied in addition to a modern medical regimen. The Japanese National Health Insurance is covering ethical Kampo drugs since 1976.

With respect to clinical practice, Kampo has preserved its traditional individual and holistic therapeutic approach. The traditional multicomponent herbal prescription on the one side and the complaints of the patient and his subjective symptoms on the other side are central. The Kampo-specific abdominal palpation (*fukushin*), tongue inspection and pulse diagnosis provide further information about the stage of the disease and the constitution of the patient. This set of symptoms and bodily informations is combined to an individual symptom profile, a Kampo diagnosis (*sho*), which leads to the selection of the appropriate prescription with the corresponding efficacy profile (*ho*).

At the same time reveal recent therapeutic handbooks on Kampo medicine as well as the coming implementation of Kampo diagnostic patterns into ICD11 a trend to standardize traditional diagnostic procedures, to explain the Kampo terminology and to clearly determine indications, benefits, and risks from the viewpoint of modern medicine.

During recent decades, extensive research has been conducted in the fields of basic and clinical research and a standard regarding quality of crude drugs and extract products has been developed. Respecting tradition is not necessarily a contradiction to modernization. The ongoing modernization of Kampo medicine prepares the way for the internationalization of this form of therapy on a rational basis.

Short CV

Heidrun Reißweber-Hewel, university education at University of Bonn and at Keio-University Tokyo in Medicine (MD, PhD) and in Japanese Studies (M.A.), board specialist in Internal medicine and in Gastroenterology. 1994-1997 JSPS-Humboldt Postdoctoral Fellow at the Oriental Medicine Research Center, Kitasato University, Tokyo. 1997-2010 head of the Research Unit for Japanese Phytotherapy (Kampo) at LMU University of Munich, since 2011 Private clinic for Japanese Medicine at Gräfelfing/Munich and Associate Lecturer at the Competence Centre for Complementary Medicine and Naturopathy (CoCoNat), Technical University of Munich. Teaching of Kampo courses at the German Medical Doctors` Association for Acupuncture (DÄGfA). Since 2011 President of the International Society for Japanese Kampo Medicine (ISJKM).

Why Do Kampo Doctors Draw the Pictures They Do?

What were the motivations of Japanese (Kampo) doctors in illustrating their medical writings?

Gretchen de Soriano

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Informed by dissection of cadavers, the Italian Renaissance illustrations by Andreas Vesalius are remarkable for their anatomical precision and attention to detail. Vesalius worked with an artist to create a series of 600 woodblock prints and by graphically representing actual dissections Vesalius corrected errors physicians who preceded him. Scholars of Renaissance history describe each of the prints in *De Fabrica* as allegorical detail with covert messages accompanying the cadavers, hidden within the differing scenery, agrarian implements, poses and ornate text.

Conversely, the pictorial diagrams of the human body according to Chinese Medicine displayed inner body systems which could be known but were not visible, and could not be revealed through dissection. Understanding these invisible physiologies was imperative for physicians in the application of acupuncture and herbal decoctions. Chinese medicine was prevalent in Japan and these Chinese diagrams were localised according to unique Japanese cultural priorities. In 1775 Japanese doctors, in collaboration with Dutch and German physicians, presented a series of woodblock prints of dissected cadavers which show an immediate concern for anatomical accuracy. These Japanese were Kampo physicians, trained in the classics of Chinese Medicine.

Subsequent graphic illustrations by Japanese Kampo physicians, however, did not produce anatomical illustrations. Instead, the Japanese Kampo physicians began to illustrate the principles of Chinese classics in pictorial form, later borrowing western pictorial formats. Kampo drawings were produced by doctors, as instruction manuals for teaching junior doctors and have, to my knowledge, not yet been the subject of academic research in the west.

This paper postulates that the messages of these Kampo drawings merge two traditions of medical illustration: the Renaissance habit of secreting allegorical messages within medical drawings, and the Chinese medical tradition of illustrating the invisible aspects of medicine. In my future research I conjecture that the illustrations of Kampo medicine are designed to capture the invisible, yet knowable aspects of Chinese medicine. These Japanese drawings, even when presented as purely Chinese in origin, provide us with unique snapshots of what aspects of human suffering were deemed curable by Kampo medicine.

Short CV

Gretchen de Soriano, Specialist for Kampo Medicine with long clinical experience in Japan. Co-Translator of “Kampo: A Clinical Guide to Theory and Practice” by Otsuka Keisetsu; President of ISJKM from 2009 – 2011, MSc in medical anthropology at Oxford University, whose current research is in medical history at SOAS University of London, United Kingdom, under the tutelage of Dr. Vivienne Lo, UCL History Department.

Learning from History: A Case of Refractory Smell and Taste Dysfunction Successfully Treated with the Formula Hochuekkito

Takayuki Hoshino, Tetsuro Oikawa, Toshihiko Hanawa

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Background: *Hochuekkito* is one of the most famous and successful Kampo prescriptions because of its wide range of applications. During the Japanese Edo period in the 18th century, as a supplement to the medicine of the Qing dynasty in China, eight additional indications of *Hochuekkito* were established as oral traditions (*kuketsu*) by Japanese doctors of the Gosei School (the Later School) of Kampo medicine. They are thought as valid even in today's Kampo clinical practice.

Case presentation: A 62-year-old woman visited our clinic with complaints of smell and taste dysfunction refractory to modern medical treatments. Firstly, to treat the chief complaint (smell dysfunction), *Reitakutsukito* was prescribed for about five months. She gained slight improvement, but additional weight loss occurred. Based on the oral tradition (*kuketsu*) of *Reitakutsukito* and *Hochuekkito*, we changed the prescription to *Hochuekkito* plus *Gardenia jasminoides* (*sanshishi*) and *Magnolia salicifolia* (*shin'i*). The patient regained half of her smell and taste function and recovered from weight loss. The indications of *Hochuekkito* were adopted from China till the early Edo period and were assembled and supplemented in the mid-Edo period in Japan.

Conclusion: This case reveals the potential of *kuketsu* even in current daily practice. We should study from our predecessors' achievements to expand the clinical options of Kampo medicine.

Short CV

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Kampo Therapy for Cancer Care: Significance as Supportive Measure

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Kampo is Japanese traditional herbal medicine and it is the most frequently used alternative and complementary medicine in Japan. The aim of Kampo therapy is to improve the patients' condition whatever their diseases are. Kampo therapy is unique because it focuses on the patient's condition not his disease. Therefore, Kampo Medicine plays a more and more important role in closing the gap between modern Western Medicine and the demand of patients. In Japan, Kampo can be used without problem for cancer patients because it is covered by the national health insurance system. It is expected to solve problems such as side effects of chemotherapy or radiotherapy, appetite loss, and various types of general fatigue or malaise. Although Kampo methodology for diagnosis and treatment is referred to as “formulation corresponding to sho”, some routine treatments have produced fruitful results which were better than expected. This led to rising expectations into Kampo Medicine.

Increasing numbers of reports or studies have been made on Kampo Medicine in cancer supportive therapy from basic research to clinical studies. We would like to introduce some formulas and recent clinical research on Kampo supportive therapy for the following complaints and symptoms of cancer patients. The concept of Kampo Medicine in supportive therapy will be shown in each subject:

1) Chemotherapy-induced nausea, vomiting, and anorexia; 2) Chemotherapy-induced diarrhea; 3) Chemotherapy-induced stomatitis; 4) Bowel obstruction; 5) Neuropathy; 6) Vasomotor symptoms associated with breast cancer therapy; 7) General fatigue; 8) Mental disorder; 9) Miscellaneous.

Short CV

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Clinical Use of Kampo Medicine in Gastroenterology

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Kampo Medicine has a long tradition in the prevention and treatment of gastrointestinal diseases. The inspection and examination of the abdomen (*fukushin*) has been introduced during the 18th century (Yoshimasu Todo). It is central to the determination of the body constitution (*sho*) and helps to select the appropriate drug formula. Especially in gastroenterology, the abdominal diagnosis points to the underlying disease whilst indicating pressure pain, the state of nutrition, the tonus of the abdominal muscles, skin temperature, gas formation and bloating, peristalsis as well as aortic pulsation.

As in Western medicine, the patient-reported symptoms as well as the clinical examination lead to a specific treatment. But whilst in Western medicine the term for the diagnosis is leading the treatment, in Kampo medicine, it is secondary. Herbal applications are immunomodulatory, have anti-oxidative effects, and support the microcirculation and the neurovegetative nerve system. As prescriptions have multiple active ingredients, their mode of action uses different targets, which together treat the underlying disease.

Gastrointestinal diseases are multifactorial themselves. Especially functional disorders like nausea and emesis (*Shohangekabukuryoto*), chronic gastritis (*Shikunshito*, *Rikkunshito*), irritable colon (*Keishikashakuyakuto*) and chronic obstipation (*Daikenchuto*, *Bofutsushosan*), or abdominal pain (*Shakuyakukanzoto*, *Shokenchuto*) – to name a few - are good targets for Kampo medicines. Also chronic inflammatory bowel diseases can be treated with Kampo medicine, in particular to prevent flairs. Kampo medicine can also help to prevent side effects of conventional drugs, such as chemotherapy-induced diarrhea (*Hangeshashinto*), to improve the body constitution after chemotherapy and to help normalize the bowel movement after long-term treatment with antibiotics (*Hochuekkito*, *Juzentaihoto*). Furthermore there are prescriptions which attenuate viral liver diseases (*Shosaikoto*, *Saikokeishito*, *Juzentaihoto*) and ameliorate the flow of gall juice (*Inchinkoto*).

The choice of Kampo medicines has to be well-documented and the prescription might need to be adapted during treatment by a doctor trained in Kampo medicine. In general, herbal remedies – as conventional prescriptions - have to be taken over a longer time period. These requirements are not always easy to implement into the current medical system, but they should be accounted for.

Short CV

Silke Karolin Cameron, university education in Medicine (MD, PhD) and in German Literature (M.A.), board specialist in Internal medicine and in Gastroenterology. 2000-2002 JSPS-Humboldt Postdoctoral Fellow at the Oriental Medicine Research Center, Kitasato University and at Keio-University Tokyo. Currently head physician at the Department of Gastroenterology and Endocrinology, University of Göttingen.

The Value of Kampo Medicine in Geriatric Patients

Kenji Watanabe

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In recent decades, patients in the increasingly aging societies of the world ask for new perspectives and answers by modern medicine. Japan is the foremost aged society in the world and Kampo medicine is challenged to meet these requests.

There are several reasons why Kampo is frequently used for geriatric patients. First of all, aged patients have many problems and complicated problems at the same time. In Western medicine, the treatment is based on pathological diagnoses and many different drugs are necessary for an aged patient. In Kampo, principally one drug (a combination product) may be selected for one patient. This specific feature of Kampo medicine is expected to reduce national medical expenditure.

Secondly, aged patients have many health problems and complaints without clear diagnoses. In this case, Western medicine can provide only limited treatment. Kampo is applied on the basis of the subjective complaints of the patients and can directly meet them.

Thirdly, Kampo is of natural origin and has less side effects than synthetic drugs. In the presentation, I will show some typical case examples.

Short CV

Kenji Watanabe, MD, PhD, FACP; 1984-1990 Department of Internal Medicine, Keio University School of Medicine; 1990-1991 Department of Immunology, Tokai University; 1991-1995 Department of Genetics, Stanford University, USA; 1995-2001 Oriental Medicine Research Center, Kitasato Institute; since 2001 Associate Professor and Clinical Director, Center for Kampo Medicine, Keio University, School of Medicine, Tokyo.

Effects of Kampo Therapy for Refractory Immuno-Allergic Diseases

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Introduction: Some immuno-allergic diseases are hard to cure by conventional therapy. In order to judge the efficacy of Kampo therapy for the treatment of these diseases, several cases are examined and presented here.

Case presentation: One case with food-dependent, exercise-induced anaphylaxis: a 28-year-old woman consulted the Kampo clinic in order to get improvement of her attacks induced by wheat, apple, aspirin etc. She also hoped to get her necessary hospitalization days reduced and her whole constitution changed. After the administration of *Shoseiryuto* as extract powder, she now has been in good condition without emergent hospitalization for 8 years. Two cases with interstitial pneumonia: a 67-year-old woman visited the Kampo clinic expecting her recovery from a condition with shortness of breath, reinforced cough and sputum after she had caught a cold. A 66-year-old woman with dermatomyositis under steroid therapy accompanied by Kampo decoction for 9.5 years had a complication of interstitial pneumonia after she caught a cold. Both cases are in good controlled condition treated with *Ryokankyomishingeninto*. Two cases with scleroderma: a 72-year-old woman visited our Kampo clinic after 15 years of diagnosed scleroderma. A 77-year-old woman wished to get reduced her finger pain after one year of diagnosed scleroderma. Both cases were treated with a Kampo decoction, which resulted in relative recovery of quality of life.

Discussion: Autoimmune diseases and some severe allergic diseases are hard to cure by contemporary therapy. Steroid and/or immuno-suppressive therapy normally help to control these conditions, but sometimes patients suffer from side effects. By the additional administration of Kampo therapy, the disadvantages and side effects of contemporary treatment are being reduced and the quality of life of the patients can be increased. This efficacy was not only experienced in our cases, but there are also many effective cases by Kampo therapy reported in the literature.

Short CV

Takeshi Sakiyama, MD, PhD, specialist in Kampo Medicine, previously assistant professor of Pediatrics, associate professor of Pathology, currently guest professor of St Marianna University School of Medicine; Kampo clinic, and Liaison Director of the Japan Society for Oriental Medicine (JSOM).

The Treatment of Acute Episodes of 'Flushing up Distress' during Menopause - a Case Discussion

Ann Bradford

Westminster University, London, United Kingdom

Background: Menopause is not an illness, however it describes a time of life when hormonal changes bring on symptoms, which can be very distressing for many women. Menopausal complaints are a good and common indication for the use of Kampo medicine, famous prescriptions are *Kamishoyosan* and *Keishibukuryogan*.

Case: This case discussion will address a patient who had been having menopausal symptoms which included night sweats, insomnia, facial flushing and also acute episodes of a rushing and flushing upward accompanied by sensations of panic and cardiac discomfort.

Treatment: Initial treatments helped with the night sweating and the insomnia, however the remaining upward surging feelings and the panic and distress remained. Listening to the patient's description of the symptoms and by the 'Sho' led to the use of *Ryokeikansoto* (Hoelen Licorice and Jujube)

Results: The use of this prescription stopped the distressing symptoms within 48hours. The patient felt calmer and the flushing up sensations stopped as did the panic and cardiac discomfort. This prescription has since been used on two other patients with a similar 'Sho' with similar results.

Conclusion: It may be useful to consider the use of *Ryokeikansoto* for cases with a similar 'Sho'.

Short CV

Ann Bradford, Specialist for Kampo Medicine, Senior Lecturer in the Department of Chinese Medicine, Westminster University and a member of the East research group at Westminster University, with research interests in menopause and also appetite and satiety.

Effectiveness of the Kampo Formula *Maobushisaishinto* against Ofloxacin-resistant Bacterial Infections

Tsutomu Kamei

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Maobushisaishinto (Chinese name: *Ma-Huang-Fu-Zi-Xi-Xin-Tang*) has long been used in Japan and other East-Asian countries for the treatment of common cold, and was previously reported to be effective for a patient with recurrent bacterial pneumonia. However, there are still serious problems of newly-acquired resistance in certain bacteria against various kinds of antibiotics. I examined the effectiveness of *Maobushisaishinto* against such resistant bacterial infections.

I administered 600mg/day of dried extract of the following mixed crude drugs for seven days: 2.0g of ephedra herb, 1.5g of asiasarum root and 0.5g of processed aconite root, to seven elderly patients with fever due to bacterial infection, and to one decubitus ulcer patient. All had failed to respond to ofloxacin (OFLX) 300mg/day for three days. The extract volume I administered was approximately half the standard dose of *Maobushisaishinto* components.

Body temperature in all seven bacterial infection patients fell below 37.0° and C-reactive protein (CRP) levels decreased from an average over 3mg/dl to normal range average ($p < 0.02$). In the decubitus patient, body temperature fell from 38.3° to 37.1° and CRP level decreased from 5.54mg/dl to 3.03mg/dl.

In cases where fever does not respond within three days to a normal dosage of ofloxacin, administration of a half-dose of the standard dose of *Maobushisaishinto*, for one week, should be considered as an alternative or complementary therapy.

Short CV

Tsutomu Kamei, MD, PhD in medicine, specialist of Kampo medicine, currently professor at the Meiji University of Integrative Medicine, Kyoto and at Nagasaki University. Guest professor at Leipzig University, Germany.

Evidence Reports on Kampo Treatment (EKAT)

Yoshiharu Motoo^{1,2}, Ichiro Arai^{1,3}, and Kiichiro Tsutani^{1,4}

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As of November, 2009, there were 345 randomized controlled trials (RCT)s on Kampo medicine in Japan. The evidence-based medicine (EBM) Special Committee of the Japan Society for Oriental Medicine (JSOM) published the “Evidence Reports on Kampo Treatment (EKAT) 2010” in June 2010, which consist of a structured abstract (SA) of one page for each RCT.

Such a structured abstract includes reference, objectives, design, setting, participants, intervention, main outcome measures, main results, conclusions, from Kampo medicine perspective, safety assessment in the article, abstractor's comments, name of abstractor and date.

We analyzed how Kampo diagnosis was applied to inclusion and exclusion criteria (pre-randomization) and subgroup analysis (post-randomization). Linking the EKAT to the CENTRAL of the Cochrane Library is undergoing.

Short CV

Yoshiharu Motoo, MD, Ph.D., graduated from Faculty of Medicine, Tokyo Medical and Dental University in 1980; Fellow of the American College of Physicians (FACP) in 2000; Professor and Chairman, Department of Medical Oncology, Kanazawa Medical University; Director of the Multidisciplinary Cancer Center, Kanazawa Medical University Hospital since 2005.

Comparative Effectiveness Research and Implications on Kampo Clinical Studies

Claudia M. Witt

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To date, most clinical studies on Kampo focused on efficacy by comparing Kampo compounds with a placebo. The results from those RCTs can be summarized in systematic reviews and meta-analyses, which could be used to inform policy makers for decision-making. Efficacy studies evaluate if a treatment works under ideal conditions, thus a homogenous patient population is included. Noncompliant participants and those with conditions, which might reduce the effect are often excluded from the study. The treatment protocol is standardized, the compliance is monitored closely and objective or surrogate parameters are preferred used to measure the treatment success. The previous studies do indeed have relevance; however for valid decision-making, clinical trials on effectiveness and cost-effectiveness are required to provide realistic benefit estimates for future health care. Effectiveness studies look at whether a treatment works when used in routine care. There is less pre-selection of the patients, often resulting in substantial heterogeneity, representative of the population under investigation. Furthermore, the treatment protocol is close to routine care and patient-centered outcomes are used to determine the effectiveness. Comparative Effectiveness Research (CER) can include single interventions such as Kampo medication or complex interventions such as Kampo medication and life style advice in combination with conventional care. There is a need for CER in Kampo research to follow the current movement within conventional medicine where decision makers have expressed an urgent need for CER, which allows for comparing real treatment alternatives in a usual care setting. This presentation will provide guidance on the underlying concepts of both efficacy and effectiveness studies and in particular outline the relevant aspects of the efficacy-effectiveness continuum when designing trials.

References

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Witt CM. Clinical research on acupuncture - Concepts and guidance on efficacy and effectiveness research. *Chin J Integr Med.* 2011 Mar;17(3):166-72. Epub 2011 Feb 27. Review.

Short CV

Claudia M. Witt, MD in medicine, epidemiologist, MBA (Master of Business Administration); since 2008 Professor for complementary medicine at the University Medical Center Charité in Berlin and Vice Director of the Institute for Social Medicine, Epidemiology and Health Economics at the Charité Berlin. 2011 Visiting Professor at the University of Maryland School of Medicine and Visiting Scholar of Institute of integrative Health. She is the president elect of the International Society for Complementary Medicine Research (ISCMR).

Image Analysis of Tongue Inspection in Kampo Medicine

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Tongue diagnosis is important in Kampo medicine and gives us much information about patient's physical and mental imbalance. However, tongue diagnosis, which requires much training, may differ among Kampo experts because it is based on each expert's subjective experience.

Tongue diagnosis should be standardized even among primary care doctors in an objective way using a new imaging system and algorithm for the quantitative analysis of tongue. We have developed a tongue image acquisition system with a 3-band camera and integrating sphere, an algorithm for the color management. We are able to acquire images without specular reflection and process with valid color, and it can be expected to prove useful for future studies of the tongue.

This system can be a milestone toward standardizing Kampo diagnosis in an objective way and elucidating Kampo medicine scientifically.

Short CV

Takao Namiki, MD, Ph.D., graduated from Chiba University, School of Medicine; Specialist in cardiology and Kampo medicine; Research Fellow at Emory University GA, USA 1996-1998. Since 2005 visiting associate professor at the Department of Frontier Japanese-Oriental (Kampo) Medicine, Graduate School of Medicine, Chiba University. Since 2010 Associate Professor at the Department of Japanese–Oriental (Kampo) Medicine, Graduate School of Medicine, Chiba University.

Does Kampo Medicine Cause Drug-Induced Liver Injury? – a Case Analysis

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Background: Japanese Kampo medicines are in general well tolerated and safe with only few and mild side effects. Nevertheless, there are reports about cases of drug-induced liver injury which are suspected to be due to TCM or Kampo medicines. Since scientific literature on this topic is still rare, we conducted an analysis of cases in our Kampo clinical setting.

Methods: Between the years 2000 and 2009 approximately 22000 new patients were treated with a huge variety of Kampo medicines in our institute. During this period, 21 cases of drug-induced liver injury were reported which were suspected to be due to Kampo medicines. We analyzed the clinical features of these cases.

Results: The mean age of the 21 cases was 55.2±13.4 years. They were 5 males and 16 females. In 17 of the 21 cases, drug-induced liver injury occurred within 3 months after treatment start with Kampo medicines. 11 cases reported no subjective symptoms, while the other 10 patients complained about various symptoms including high fever. In liver function tests, 9 cases showed a hepatocellular injury type and another 9 cases a mixed type. In 19 of the 21 cases Kampo prescriptions which contain *Scutellariae Radix* (ogon) were administered. DLST (drug-induced lymphocyte stimulation test) was examined in 5 cases. It tested positive for Kampo medicines in only one of the 5 cases. The reported liver injury improved or normalized in 18 cases (85.7%) after termination of the causative Kampo prescription. In 3 cases, the liver injury normalized after removing *Scutellariae Radix* from the prescription.

Conclusion: These results suggest that especially in the case of prescribing Kampo formulae which contain *Scutellariae Radix*, it is recommended to check the liver function by blood tests within 3 months of medication intake to facilitate the early diagnosis of any drug-induced liver injury.

Short CV

Tetsuro Oikawa, MD, PhD; 1986 Graduated from Hamamatsu University School of Medicine, Japan; 2011 Vice director general, Oriental Medicine Research Center, Kitasato University, Tokyo, Japan.

On the Logistics to Import Kampo Crude Drugs from Japan to Europe

Ulrich Eberhard

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As of 1986, Kampo crude drugs (*Kampo shoyaku*) were directly imported from Japanese manufacturing companies to various pharmacies in Munich. In the mean time, the number of Kampo-trained therapists increased steadily as well as the amount of imported Kampo crude drugs. Nevertheless, the difficulties to introduce Kampo as a complementary therapy were considerable as Kampo was largely unknown in Western countries. One of the difficulties was to organize a logistic system to import the herbal drugs from Japan and to keep them in stock in a pharmacy in order to maintain the availability of each drug.

In 2004, the situation changed radically with the amendment of a new drug law by the German government, which renewed the existing pharmaceutical law („Arzneimittelgesetz“) by establishing new regulations for pharmacies dealing with herbal drugs („Apotheker-Betriebsordnung“). This new regulation requires fundamental changes for the import and dispensing procedures. A certification procedure is now obligatory:

- Each drug has to be certified by the Government Authority prior to the importation
- The producer has to possess the qualifications of GMP
- The importer has to meet the official requirements („Herstellererlaubnis“)
- Each imported drug (lot) has to be checked for residuals (chemical, heavy metal, biological) through an independent laboratory after importation

The obvious beneficial effect of the new law is to prevent the import of contaminated or low-quality-drugs of dubious provenance. On the other hand, the high costs of laboratory testing for each lot makes it difficult to establish and ensure a stable Kampo business.

Short CV

Ulrich Eberhard, MD, PhD, board specialist in general medicine, studied Kampo medicine at the Oriental Medicine Research Center of the Kitasato Institute, Tokyo; since 1987 private Kampo clinic in Munich, since 2002 in Madrid, Spain. Author of the German Kampo book: Leitfaden Kampo Medizin, Urban & Fischer 2003, teaching Kampo courses at the German Medical Doctors` Association for Acupuncture (DÄGfA).