

Editorial

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Report from WFAS Tokyo/Tsukuba 2016

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LIFENCE



College Logos

We believe it is necessary to create a new way of thinking for the total understanding of "Life, Survival, and Health". We decided to coin the world "Lifence" to express this.

Lifence means the combination of life sceince and medicine as well as other disciplines such as health science, psychology, ethics, etc.

Our college logos symbolizes the above.

The ripple effect represents the ocean and the birth of life.

The rainbow colored sphere represents a safe environment and a barrier to protect us from negative influences.

The picture by Leonardo da Vinch represents a balanced body and health.

Completing our logos is a ring which represents the unity of space fulfilling the total meanings of lifence.



The Journal of Kampo, Acupuncture and Integrative Medicine (KAIM)

Research on Theory, Practice and Integration

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MISSION

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

◇小太郎漢方製薬株式会社



KOTARO PHARMACEUTICAL introduced in 1957 the world's first Kampo extract preparations on the market. Later, in 1967, six of our preparations could be covered in Japan for the first time by the health insurance and after 1976 more than 100 of our preparations were used in hospitals and clinics. Now it is half a century since we put our Kampo extract preparations on the market and believe, we made a major contribution to this industry. In the future we intend to continue working in accordance with our company motto: "Still better Kampo for still more people" and provide pharmaceutical products of still higher quality.



Origin of the company's name

The company was named "KOTARO" by its founder Taro Ueda with reference to his birth place. Close to the ancient city of Nara. Kotaro is the name of an enormous sheer cliff, 700 m wide and about 200 m high. Mr. Ueda felt an affection rising to the heavens for this cliff and thus made it the company's name.

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Editorial Notification of Suspension of Publication of KAIM

The global spread of Oriental medicine, which began after President Nixon's visit to China in 1972, gathered strength and led to movements in various countries throughout the 1990s and 2000s to institutionalize Oriental medicine, either within or separate from their existing medical care systems, against the backdrop of conditions under which the Western countries groped for policies that might break the impasse in increasingly serious health issues and Western medicine in advanced countries, particularly in the U.S. It was the People's Republic of China, however, that pushed the global diffusion of Oriental medicine as a national policy, and as a result, Oriental medicine spread to and institutionalized in many countries around the world, where it is now regarded as Traditional Chinese Medicine.

However, countries and regions other than China, including Japan, the Korean peninsula and Vietnam, also have over 1,000 years of history using Oriental medicine, and throughout their own histories each country has made unique developments that have contributed to the maintenance and promotion of the health of its people. In Japan, over 80% of western medical doctors now uses decoction, known as "Kampo", in clinical practice, and acupuncture and moxibustion is performed as a clinical treatment that takes advantage of both modern and classical medicine theories. In addition, there are researchers who study Kampo medicine and acupuncture-moxibustion professionally from the standpoints of classical and modern medicine, respectively, and extensive excellent research has been reported. The characteristics possessed by the decoction and acupuncture-moxibustion that have become so widely used in those countries was not known, however, including even in Japan, a situation that continues in no small way even today.

Concerned about this situation, we began publishing *The Journal of Kampo Acupuncture and Integrative Medicine (KAIM)* in 2005 with the goal of telling the world about Japanese Kampo and Japanese acupuncture-moxibustion, to inform the world of the existence of Oriental medicine used broadly in Japan, which differs from Traditional Chinese Medicine, and explain the nature of Kampo to the world.

KAIM has been edited and printed in Japan, and published in the U.S. by International Institute of Health and Human Services, Berkeley. Each year we have held several editorial meetings, and over the years published 52 issues in 13 volumes, along with special feature editions on acupuncture-moxibustion and Kampo medicine.

Because of various circumstances, however, we will cease publication with this issue.

Although the extent to which we achieved our intended objectives might remain unknown, we believe we have been able to enlighten the world about the existence and characteristics of Japanese Kampo and acupuncture-moxibustion. Although our magazine has always been a work in progress, we hope that after we have ceased publication a new magazine that will continue the purposes of this publication will arise. We also hope that parties concerned with oriental medicine will be even more active in contributing articles to magazines published in Europe and America, and Asia. There are many people in Japan devoted to Oriental medicine, and we believe – and hope – these individuals will pick up the baton and carry this work forward.

In closing, we wish to thank the many doctors and acupuncturists, pharmacists who have written for us, and all of the people who worked so closely with us for the publication of this magazine, over the past 13 years.

Executive Editor: Shuji Goto Associate Editors: Hiromichi Yasui Shuichi Katai

Report from WFAS Tokyo/Tsukuba 2016

"Acupuncture for Low Back Pain and Knee Pain in Middle Age, an Anatomical Point of View"

Tomofumi Ozaki

 The Japan Conference of Clinical Acupuncture and Moxibustion
 Department of Acupuncture, Faculty of Health Sciences, Morinomiya University of Medical Sciences

1. Introduction

The Japan Conference of Clinical Acupuncture & Moxibustion started out when in 1960 Bunshi Shirota and other motivated persons attempted to put acupuncture and moxibustion on a scientific foundation and gathered for that purpose under the guidance of professor Tachio Ishikawa at Kanazawa University to found its predecessor, the "Japan Acupuncture & Moxibustion Electrical Skin Resistance Study Group", which in 1983 was then given its current name. Based on the concept of "considering all treatment forms if they are based on modern medical comprehension of pathologies" the group strove to improve the qualification of clinical acupuncturists. Up to now it has actively exchanged information pertaining to case reports and clinical studies¹⁾ mainly among members.

Improving the qualification of acupuncturists, meaning practitioners to properly comprehend enabling pathologies, acquire appropriate therapeutic skills and pedagogic techniques requires first of all the acquisition of basic knowledge about modern medical diagnostics, understanding of pathologies and therapeutics to implement the aforementioned skills. The reason for this is the necessity to be able to communicate with physicians and co-medical staff on the same level. In this context a common medical record form for diseases designated as indications for acupuncture and moxibustion like neck-shoulder-arm pain, low back and leg pain, shoulder joint pain, knee joint pain etc. has been proposed. It has already been listed in text books and is currently used in the education of acupuncture therapists^{2,3)}.

Here I would like to briefly introduce the historical development of the Japan Conference of Clinical

Acupuncture & Moxibustion and outline its goals. For this purpose I present one case report of a patient with low back pain and knee pain.

2. Historical development of the Japan Conference of Clinical Acupuncture & Moxibustion

The society was founded in 1960 under the name of "Japan Acupuncture & Moxibustion Electrical Skin Resistance Study Group". It had the purpose of building a scientific foundation for acupuncture and moxibustion based on the viscerosomatic reflex theory and the use of the dermometer proposed by doctors Hidetsurumaru and Tachio Ishikawa.

1983: Based on the concept that improving acupuncture therapist qualification will also increase the value of the medical services by these therapists and establish a position of acupuncture and moxibustion in medical care, the study group was renamed into "The Japan Conference of Clinical Acupuncture & Moxibustion".

The conduction of clinical conferences seems to be the shortest way to improve the clinical capabilities of acupuncture therapists. In other words, the group was termed Japan Conference of Clinical Acupuncture & Moxibustion, because the understanding of pathologies based on bedside interviews and examinations, judging whether a given condition is an indication or contraindication for acupuncture and moxibustion, possible referral to medical specialists, assessing the prognosis and determining the best possible treatment form can be deducted from free discussions among acupuncturists based on case studies.

3. Case study: current situation of a patient with low back pain and knee pain and the acupuncture and moxibustion treatment

The Comprehensive Survey of Living Conditions conducted in 2013 reports the ratio of the five leading symptoms among person reporting to have symptoms classified by sex (several answers possible).

The leading symptom in men is low back pain, in second place followed by shoulder stiffness, in third place by nasal congestion, in fourth place by cough and sputum. The fifth most frequent symptom was pain of joints of arms or legs. On the other hand, the leading symptom in women was reportedly shoulder stiffness, followed in second place by low back pain, in third place pain of joints of arms or legs⁴). Pain of joints of arms or legs should be understood as referring to the shoulder and knee joint. In other words, low back pain and gonalgia are considered to be a very common symptom among Japanese people.

Among the symptoms treated in acupuncture clinics many patients complain of low back pain and gonalgia and many of the patients over the age of 40 complaining of low back pain and gonalgia should be considered to suffer from osteoarthritis of either the spine or the knee (OA). Being characterized by irreversible elements these conditions chronic diseases treated with are acupuncture and moxibustion in order to slow down alleviate pain and improve disease progression, functional disorder^{5,6}.

4. Case report

Patient: dull low back pain and knee pain

Male, 60-years old, acupuncturist, height 173 cm, weight 68 kg, BMI 22.9

Chief complaint: (1) left low back pain, (2) discomfort and pain of the left knee (ST35), low back pain (left > right)

Interest: jogging

Medical history

(1) Since the age of 20 the patient experienced chronic dull low back pain and the muscle of the lumbar region often tended to be tense. The left leg was the patient's dominant leg and when he paid attention, he could feel shifting his body weight towards the left side. When tired, a table tennis ball sized muscle induration developed in the left lumbar region (BL52) and caused pain. Pressure was felt as pleasant. Since the age of 40 work related busyness gradually increased, working hours tended to be irregular and he slept only 4-5 hours, so that the chronic lack of sleep had already become the normal condition. Occasionally he experienced abdominal bloating gastrointestinal from gas accumulation and diarrhea. At times of diarrhea he suffered from marked pain and tenderness in he left BL52 region. An x-ray taken during a visit to an orthopedist showed a mild degree of scoliosis, the formation of bone spurs and the physician also pointed out a mild degree of osteoarthritis of the spine (Figure 1). Therefore the physician diagnosed "fatigue induced low back pain". Later, the patient experienced acute low back pain attacks once or twice per year. Each time the condition improved after acupuncture and moxibustion treatment.



Figure 1: x-ray findings of the lumbar region (spondylopathy)

(2) Since his time in university the patient loved to run and formerly did jog and commuted 2-3 time per week to a gym for his health management, but now he is too busy and cannot find any time for sports, rendering exercises performed once every two weeks largely insufficient. His weight gradually increased from 60 kg to 68 kg.

Since the age of 30 he participated maybe a dozen times in full marathons. The gonalgia developed because he originally planned to run 100 km per months as training starting 4 months ago. However, being busy with his work kept him from actually implementing the training schedule and when he actually started training, discomfort and gonalgia developed after running a distance of approximately 5 km. An x-ray of the knee taken during a visit to an orthopedist was normal (Figure 2). From this time onward overuse induced pain was pointed out. He did not undergo any particular treatment. He decided to observe the course while being treated with acupuncture and moxibustion. The acupuncture and moxibustion treatment provided some relief. Later he experienced some mild knee pain after excessive running. He also experienced some discomfort of the left knee while walking and jogging, aggravating after a certain distance and developing into pain during exercise. Climbing and descending stairs too resulted in mild pain. Due to injections into the thigh received during infancy there was a mild degree of quadriceps femoris muscle atrophy. Occasionally shoulder stiffness developed.



Figure 2: x-ray findings of the knee joint

General condition: The patient has appetite and excessive eating sometimes causes abdominal bloating or vomiting, sleep duration is short, about 4 hours, bowel movement frequency varies between once every 1 to 3 days.

The annual health check does not show any particular problems, but he had been advised to take precautions against hypertension and pneumonia.

• Past history

Surgery for left paranasal sinusitis, partial resection of bone because of a deviation of the nasal septum (at the age of 17), hospitalization for 17 days (at the age of 48) because of bronchiolitis obliterans organizing pneumonia, laser photocoagulation (at the age of 50) for right retinal tear, atypical pneumonia treated with Cravit, Carbocysteine (at age 58), diagnosis of hypertension (at age 58) and is since then treated with the antihypertensive agent UNISIA (Camshia) one tablet in the morning.

• General findings

Blood pressure 110/70 mmHg, pulse rate 72 bpm, brachial biceps tendon reflex, triceps tendon reflex, brachioradial tendon reflex, patellar tendon reflex, Achilles tendon reflex were all normal, abdominal percussion showed generalized tympanicity, muscle tension (left > right) in the lumbar region, loss of lumbar lordosis (Figure 3). A table tennis ball sized induration and marked tenderness were observed in the vicinity of the left BL52. Tenderness was also observed at CV12, ST25, ST26, BL17, BL18, BL25.

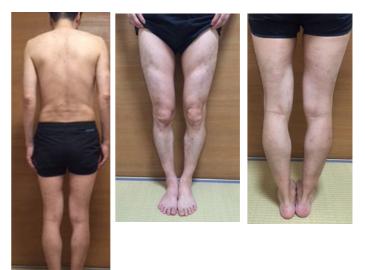


Figure 3: Findings of inspection of lumbar region and knee of a 60-year old man

• Findings of physical examinations

(1) Lumbar mobility (bending forward, backward, sideways, rotation) was normal. The finger-floor distance was 15 cm and although there was no pain, the body was stiff. SLR test (-), K-Bonnet test(-), Kemp's sign (-), walking on tip toe (possible), plantar and dorsal flexion of the first toe was normal on both left and right side, sensation too was normal on both sides, internal and external rotation test of the hip joint (-), Newton's test (-), normal pulse of A. dorsalis pedis, tibialis posterior, femoralis, no percussion tenderness, FNS test (-). Tender points: left BL22 (+), BL25 (+), left BL52 (+3), tension of the erector spinae muscles left > right⁷).

(2) No rubor, warmth or swelling of the knee joint, no varus deformity, but there is a distance of 4 cm between both knees, no valgus deformity (Figure 3), no flexion deformity, atrophy of the left and right thighs. The circumference of the thighs (15 cm above the patella at sites of marked indentations) was 47.4 cm on the right and 47 cm on the left; at a distance of 10 cm above the patella these values were 42 cm on both left and right; circumference at the level of the patellar base was 37.4 cm on the right and 37 cm on the left, patellar ballotment (-), patella grinding test (-), varus / valgus stress test of the knee (-), Steinman test (-), McMurray's test (-), anterior drawer test (-), posterior drawer test (-), Lachman test (-), flexion impairment (-), quadriceps femoris power (-). Tender points: ST31, GB31, ST34, SP10, particularly marked at medial Ex21⁸⁾.

• Identifying the pathology

(1) The x-rays of the lumbar vertebrae showed some minor osteophyte development and based on the presence of scoliosis and rotation of the lumbar vertebrae as well as the medical history and the absence of positive pathologic findings, the condition was considered to be mainly due to age-related spondylophathy. Constant strain on the left lumbar region then led through overuse to hypertonic stress of the erector spinae muscles etc., which then probably resulted in myofascial low back pain.

(2) Knee x-rays were normal. Medical history and pathologic examinations allowed to rule out meniscus damage or lesions of either the anterior crucial ligament or the collateral ligaments. Injections the patient received during infancy into the thigh caused a mild degree of quadriceps femoris atrophy, but muscle testing did not reveal any problems. Exercises like walking and running etc. likely strained the patient's knee. A mild degree of soft tissue inflammation induced by overuse is also conceivable⁹⁾.

• Treatment plan

Being very busy with his work, a chronic lack of sleep, paired with irregular meal times and excessive eating and drinking caused gastric bloating or nausea. The gastrointestinal functioning was not really well and the patient occasionally developed diarrhea, disrupting the regularity of his daily life. His current condition conceivably developed before this background. The low back pain and gonalgia were conceivably caused by these various forms of stress. The low back pain was also brought about by an accumulation of muscle fatigue, but is basically due to some minor degree of spondylopathy and muscle fatigue. Here I decided to alleviate the individual symptoms with acupuncture and moxibustion treatment and add some general conditioning.

(1) Relief of muscle tension in the low back area and over the back, administering some comfortable needle sensation at the point of maximal tenderness (BL52). I also added treatment to regulate the gastrointestinal function.

(2) Treatment to achieve relief of muscle tension in the thigh and lower leg to alleviate pain, administering some comfortable needle sensation at the point of maximal tenderness (Ex-LE4).

• Treatment

I used 40 mm No. 18 Seirin disposable needles and needled mostly sites of tenderness or indurations¹⁰⁾.

Needling sites were BL10, GB21, SI14, BL43, LI10, ST36, Ex-HN5. Each of these points were needled applying some thrusting and lifting manipulation to obtain a pleasurable needling sensation. Treatment duration was about 20 minutes.



Figure 4: Left BL52 needling and needling sensation 50 mm disposable needles, No. 24, insertion depth 4 cm perpendicular to the body surface, with maximal needling sensation

At GV20 a needle was retained until the end of the treatment to raise the pain threshold and promote sleeping. To regulate gastrointestinal function I made singular insertions at CV12, ST27 and ST36.

(1) On the back thrusting and lifting manipulation at BL17, BL18, BL20, BL22, BL25. Application of a pleasurable needling sensation at BL52¹¹⁾.

(2) Singular insertions on the thigh at ST31, SP10, ST34, Ex-LE4, ST36, GB31; on the posterior side BL37, BL40, KI10 and BL56. Needles were retained at ST31, ST34, Ex-LE4, ST36, GB31 and on the posterior side at BL37, BL40, KI10 and BL56.

Needle retention for 7 minutes at ST31, SP10, ST34, Ex-LE4, ST36, GB31¹²⁾. Later acupuncture and moxibustion treatment was continued for maintenance at a rate of twice a week. During the treatments the quiet breathing of the sleeping patient could be heard and after the treatments he reportedly felt very refreshed. Even though he complained generally about occasional low back pain and stiff shoulders, acupuncture and moxibustion treatment administered early after the onset of those symptoms usually led to an early improvement. He is still very busy with his work and sleeps only about 5 hours, but since the acupuncture and moxibustion

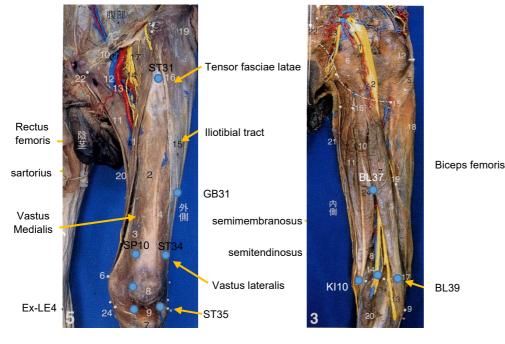


Figure 5: Basic acupoints for the treatment of gonalgia Seiichiro Kitamura et al.: Color Atlas of Local Anatomy for Acupuncturists and Judo Therapist; Nanzando; 101-111

Results

The muscle tension in the lumbar and femoral regions decreased after the acupuncture and moxibustion treatment and the patient reported a VAS $10 \rightarrow 1$ improvement for the low back pain and a VAS $10 \rightarrow 5$ improvement for the knee pain. The treatment effects lasted for 2-3 days. After 3 days a similar treatment resulted in a VAS $5 \rightarrow 1$ improvement for the low back pain and a VAS $5 \rightarrow 1$ improvement for the knee pain. After the third session the VAS score improvement of $3 \rightarrow 0$ was achieved for both low back pain and knee pain.

treatment has improved his general condition, the treatment frequency was changed from twice a week to once a week. Even though the sleep duration has not changed, he reported to sleep better recently and both appetite and bowel movements are well regulated. This gives the impression of a good health management.

5. Discussion

1) Necessity for an accurate assessment of the pathology

Acupuncture and moxibustion is a treatment form with a long history and has been handed down as an unbroken tradition. When acupuncturists practice based on modern medical examination methods and with an understanding of pathology, they can accurately assess the pathology of their patients, assess whether acupuncture and moxibustion treatment is indicated or contraindicated, the question of whether the patient should be referred to a specialist, and holding discussions with physicians and co-medical staff enables them to cooperate in medical care. Also, in case the condition is considered or suspected to be a contraindication for acupuncture and moxibustion treatment, it is necessary to recommend seeing a specialist¹³⁾.

2) Tender points and needling points

The needling sensation elicited at the left BL52 induced in this patient marked improvement. Acupuncture and moxibustion comprises many different techniques. We as acupuncture therapists use tender points or indurations, motor points, trigger points etc. for therapeutic purposes based on an anatomical point of view. Treatment point locations often coincide with acupoints, but their selection is not restricted to oriental medical examinations, but local tender points also constitute useful sources of information for an assessment of the condition at hand and the actual needling requires a search for the point of maximal tenderness and identification of its accurate anatomical location¹⁴⁾.

3) Acupuncture and moxibustion treatment for local and general symptoms

Three years ago this patient had suffered from pneumonia and thus was worried about his health. While being in general confident about his health, he was kept very busy and thus had to deal with chronic feelings of fatigue. On this occasion an extended period of acupuncture and moxibustion treatment led to improved sleep and bowel movements, helping to relief accumulated fatigue. The treatment also increased the patient's awareness pertaining to health management and daily efforts related to health maintenance. Clinical acupuncture and moxibustion is characterized according to Hirohisa Yoneyama¹⁰⁾ and Sakae Yoneyama¹⁴⁾ not only by treatment form for diseases, but also as a form of health management, in other words for regular maintenance (reconditioning treatment) and the author too is convinced, that this is where the real value of

acupuncture and moxibustion treatment lies. However, the therapists should inform the patient prior to the acupuncture and moxibustion treatment of the importance of a regular daily life. Medical care basically strives to bring about improvement of symptoms or healing, but the essence of acupuncture and moxibustion treatment does not restrict its attention to specific body regions or conditions, but rather aims at health management (maintenance) and the prevention of diseases. Health is sleeping well, eating well and pleasant bowel movements. Acupuncture and moxibustion treatment can maintain these three health factors¹⁰⁻¹⁴.

5. Conclusions

Above I briefly described The Japan Conference of Clinical Acupuncture & Moxibustion and offered my opinion about the merits of Japanese acupuncture and moxibustion by presenting a case report. The basis for a correct understanding of pathologic conditions by acupuncturists is the acquisition of knowledge pertaining to modern medical examination techniques, assessment of pathologies and available therapies as well as the careful observation of tender spots and indurations on the body surface. Acupuncture and moxibustion treatment is not restricted to local treatment, but can treat the whole body and thus presents a holistic medical care allowing to include health management and maintenance (reconditioning treatment).

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Clinical Report (Acupuncture)

A Case of Low Back Pain Akio Manabe Acupuncture & Moxibustion Care Unit of East Asian Traditional Medicine, Ehime Prefectural Central Hospital

Introduction

When we diagnose and treat our patients, we emphasize on the time series data obtained from patient's life and medical history. By writing the information in the Chronological Chart (Fig.1), we can find the relation between patient's life events and their chronic health problems and will be able to understand them structurally. This understanding is comprehensive and useful for planning MITATE (diagnosis, treatment and prognosis) that we emphasize.

Case Study

75 year old man

First visit:

May 11th of X year

Chief complaint:

Left lumbago, right buttock pain, stiff neck (started from June of X-1 year)

Past History:

Otitis media operation and tonsillectomy in his childhood, decompression surgery for trigeminal neuralgia in his 49 year old, hemorrhagic operation in his 60 year old, treatment of hypertension in his 69 year old, shingles on the right front forehead in his 71 year old.

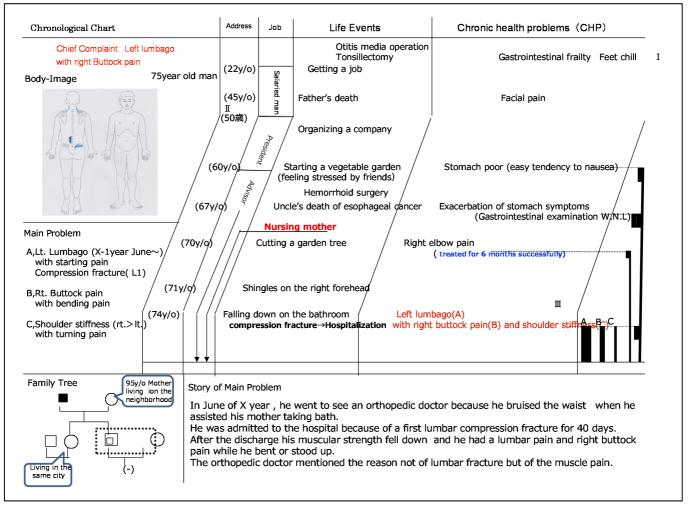


Figure 1

Present illness:

In June of X year, he went to see an orthopedic doctor because he bruised the waist when he assisted his mother taking bath. He was admitted to the hospital because of a first lumbar compression fracture for 40 days. After the discharge his muscular strength fell down and he had a lumbar pain and right buttock pain while he bent or stood up. The orthopedic doctor mentioned the reason not of lumbar fracture but of the muscle pain. He remembered that he was treated well his right elbow pain in our acupuncture and moxibustion care unit, so he decided to come to see us again.

Living conditions:

He was running a company with wife and taking care of a 95 year old mother living in the neighborhood in the same town.

Present status:

His height is 167cm and his weight is 67kg. His blood pressure is 137/84mmHg(pulse 71c/s) and controlled well with telmisartan 40mg/day.

Subjective problem:

Severe coldness in his toes

Objective findings:

Straight leg raising and femoral nerve stretching tests are within the normal range

Oriental medical findings: (Fig.2)

Tongue diagnosis;

purple colored, extended sublingual veins, swelling tongue and tooth impression

Pulse diagnosis;

sunken pulse

Abdominal diagnosis;

umbilical tenderness and resistance near ST27, weakness of the lower abdominal region. This means Kidney qi deficiency

Back diagnosis;

Small superficial vessels near GV4.

This means traumatic blood stagnation also his many operations history.

Pressure sensitive hardening near BL17, Pressure sensitive depression near GV11 • GV12. This means somatoform disorders caused by the life stress of taking care of his mother. Treatment: (Fig.2)

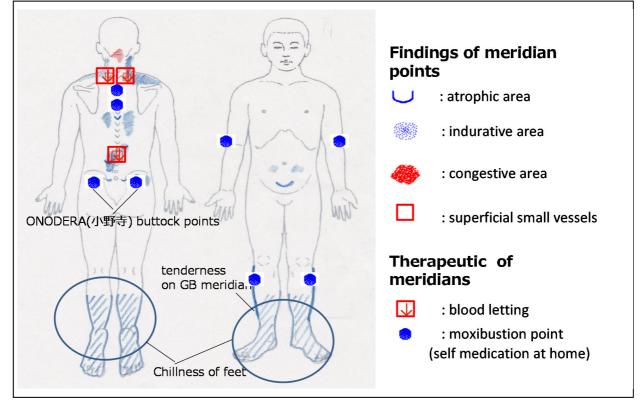


Figure 2

Our treatment for this patient is mainly as follows.

- The traumatic blood stagnation was treated by bloodletting of small superficial veins near 命門(GV4).
- 2) The Kidney qi deficiency was treated by moxibustion on the top of needle near CV4.
- 3) The somatoform disorder was treated by direct moxibustion on GV11 · GV12.
- 4) Moxibustion to right buttock pain, The pint of ONODERA buttock points. The pint of ONODERA buttock points are good for lumbago as well as stomach pain.
- 5) The herbal medicine *keishibukuryogan* was used because of the traumatic blood stagnation.

Clinical course:

The patient was treated every 2-4 weeks. Four weeks after the first visit, left lumbago pain decreased from 10 to 5 in numeric rating scale (NRS) and right buttock pain decreased from 10 to 5.

After 3 months, the degree of left lumbago pain decreased from 5 to 1, the right buttock was painless and only dull feeling.

After treating for about a year, patients were able to continuing self medication of moxibustion at home, so treatment was terminated.

Conclusion

When we treat our patient we emphasize on their constitutional condition such as; traumatic stagnation, qui deficiency, and somatoform disorder. These basic treatment prevent the recurrence of their disease. As for this kind of diagnosis, treatment and prognosis (or prevention) we call them together MITATE.

Research Review

Adverse Effects of Kampo Medicine Toshiaki Makino¹⁾ and Hiromichi Yasui²⁾ 1) Department of Pharmacognosy, Graduate School of Pharmaceutical Sciences, Nagoya City University, Nagoya, Japan 2) Japan Institute of TCM Research

In the past in Japan, when unexpected incidents the administration of Kampo occurred by prescriptions, those are not recognized as adverse effects but the drugs used are prescribed under incorrect diagnosis in the patient's symptom or the essential worse reaction to make a full recovery. However, now the adverse effect of Kampo prescriptions are well recognized, and when it happens, the medication should be stopped and suitable treatment is needed. The most frequent adverse effect occurred by Kampo prescriptions is gastrointestinal disorders, and rehmanniae radix. gypsum, ephedrae herba, and angelicae radix sometime cause. In addition, drug eruption and cystitis due to allergy sinetunes occur with several kinds of crude drugs. Furthermore, various symptoms caused by the sympathetic stimulation of ephedrine contained in ephedrae herba. pseudoaldosteronism caused by glycyrrhizae radix, aconitine poisoning caused by aconiti radix processa, interstitial pneumonia and drug-induced liver injury caused bv scutellariae radix. mesenteric phlebosclerosis caused by gardeniae fructus has been reported.

Keywords: Kampo prescriptions, adverse effects, drug allergy, pseudoaldosteronism, interstitial pneumonia, drug-induced liver injury, mesenteric phlebosclerosis

Japan has a centralized medical system centered on Western medicine, and Japanese traditional Kampo medicine is also used in this system. In recent years, with the spread of Kampo medicines, it has been found that Kampo prescriptions also have considerable side effects $[1]_{\circ}$ In the past, when unexpected incidents occurred by the administration of Kampo medicine, those are not recognized as adverse effects but the drugs used are prescribed under incorrect diagnosis in the patient's symptom or the essential worse reaction to make a full recovery. However, now the adverse effect of Kampo medicines are well recognized, and when it happens, the medication should be stopped and suitable treatment is needed.

Kampo formula is a mixture of several crude drugs, and their adverse effects can be explained by the crude drugs contained therein. The side effects that can be caused by each crude drug are described below.

1. Gastrointestinal disorders

The most frequent side effects of Kampo medicines are gastrointestinal disorders. Typical crude drugs that induce gastrointestinal disorders include ground rehmanniae radix, gypsum, ephedrae herba, angelicae radix, cnidii rhizoma, and zizyphi spinosi semen. Among them, rehmanniae radix often causes anorexia, epigastric discomfort, epigastric pain, diarrhea, etc. Ephedrae Herba also causes anorexia and epigastric pain.

Most of these symptoms usually relieve if the drugs are stopped. Kampo prescriptions are basically administered before meals, but administration after meals may avoid to cause such symptoms.

2. Drug allergy

It is known that some crude drugs easily cause allergic reactions to the living body. The most common symptom is on the skin (drug eruption). Rash or pruritus is sometimes caused by cinnamomi cortex, ginseng radix, astragali radix, rehmanniae radix, tritici fructus, oryzae fructus, dioscoreae rhizoma, and perillae herba [2; 3]. In addition to these crude drugs, there are reports on crude drugs

<Case report>

The patient is a 56-year-old man. A few years ago, renal function was pointed out, but a doctor at a visiting hospital told him that his serum creatinine level was so high that hemodialysis would be needed soon. Then, he visited my clinic on May 6, 20XX. The serum creatinine level was 5.78 mg/dl. I prescribed him for yojinkodakuto. Astragali radix was 20 g. Creatinine continued to fall as expected, reaching 2.16 mg/dl on July 31. However, at this point, a strong pruritic rash appeared on his entire body, and I was forced to discontinue the prescription. His serum creatinine level began to rise gradually, reaching 3.85 mg/dl on November 28, but when I administered the same prescription instead of astragali radix, the rash appeared two weeks later, serum creatinine dropped to 3.21 mg/dl.

In addition, drug-induced cystitis has been reported for saireito, shosaikoto, saibokuto. saikokeishito, seijobofuto, and unseiin. It has been reported that the administration of these Kampo prescriptions caused cystitis-like symptoms, such as dvsuria. dysuria, pollakiuria, pusuria. and hematuria [2; 3]. The pathological condition is druginduced cystitis, *i.e.*, eosinophilic cystitis with eosinophil infiltration. Some allergic mechanism has been speculated. As of 2011, 90 cases of cystitis were reported due to Kampo prescriptions in Japan, and among these prescriptions, 80 cases are using prescriptions including scutellariae radix [4]. These are rare side effects, and withdrawal of the drug often improves the symptoms promptly, but care must be taken.

3. Licorice-induced pseudoaldosteronism

Glycyrrhizae radix is the dried root and stolon, with (unpeeled) or without (peeled) the periderm, of Glycyrrhiza uralensis Fischer or Glycyrrhiza glabra Linné (Leguminosae), and it is commonly called as licorice root. This causes pseudoaldosteronism with some frequency. Therefore, it is necessary to pay attention to physical findings (edema, increased blood pressure) during the administration and to measure potassium in the blood regularly. In Europe, where licorice is used as a food additive sweetener, this side effect has long been reported [5-8]. In Japan, the incidence of pseudoaldosteronism due to Kampo prescriptions was said to be higher rate among elderly women. However, this is not true, and although there are large individual differences in the onset, it occurs in all generations regardless of gender at a fixed rate [9]. The onset of pseudoaldosteronism depends to some extent on the amount of licorice intake, and when using Kampo prescriptions containing 2.5 g or more of licorice per day, be sure to pay attention to the onset of this side effect. In addition, licorice is the most commonly prescribed crude drug in Japanese Kampo prescriptions. There is a possibility that the combination of Kampo prescriptions may not be noticed, or exceed amount when combined with the use of licorice as a food additive.

Symptoms of pseudoaldosteronism include hypokalemia, increased blood pressure, sodium/body fluid retention, edema, and weight gain. In severe cases, it causes myopathy and rhabdomyolysis. Therefore, attention should also be paid to weakness, muscle pain, limb spasms and paralysis, CK (CPK), etc. When licorice is used, serum potassium levels should be measured sufficiently. If abnormalities are observed, the administration should be discontinued. appropriate treatments such the and \mathbf{as} administration of potassium agents should be taken as necessary. It also improves when used in combination with aldosterone antagonists such as eplerenone [10].

The component that causes pseudoaldosteronism caused by licorice is glycyrrhetinic acid (GA), a metabolite of glycyrrhizin contained in licorice by intestinal bacteria. GA inhibits type 11*B*hydroxysteroid dehydrogenase (11 β -HSD) 2 present in renal tubular epithelial cells, and the accumulated cortisol activates mineralocorticoid receptors, thereby excreting potassium to promote reabsorption of sodium and sodium, resulting in hypokalemia [7; 8]. However, since GA appears as a metabolite in the blood of all patients who take licorice, it cannot explain the individual differences in the occurrence of pseudoaldosteronism, so a search for a true causative substance instead of GA was conducted, At present, glycyrrhetinic acid-3-Osulfate, another metabolite of glycyrrhizin, is estimated to be the causative substance [11], and hypoalbuminemia is considered as one of the risk factor to cause pseudoaldsteronism [12].

4. Palpitations, tachycardia caused by Ephedrae Herba

Ephedrae herba is the dried terrestrial stem of *Ephedra sinica* Stapf. This crude drug contains ephedrine that is a similar chemical structure to adrenaline and has a mixed sympathetic nervous system effect. The bronchodilating activity resulting therefrom can be said to be a scientific basis for the medicinal effects of ephedrae herba, but adverse effects sometimes occur including hypertension, tachycardia, palpitations, insomnia, and urinary retention.

<Case report>

68-year-old man. Two days ago, he arrived my clinic due to severe pain accompanied by swelling at the first toe of his right foot. Until now, it was pointed out that the uric acid level was high, but he said that he had left it alone. I diagnosed a gout attack, and prescribed eppikajutsuto extract. The patient came to my clinic the next day, and although the pain in the left first toe was alleviated, the patient said that after taking this prescription, urine was flowing only once. I thought this was a adverse effect of ephedrae herba and stopped it immediately, and i changed my prescription to ryutanshakoto. The dysuria disappeared, and the pain of the first toe of the left foot gradually resolved.

When administering Kampo prescriptions containing ephedrae herba to patients with circulatory disorders such as angina pectoris and myocardial infarction, with severe hypertension, renal disorder. hyperthyroidism, prostatic hypertrophy, prone to insomnia, careful observation and discretion should be taken not to exacerbate these diseases and conditions. The incidence of this side effect has individual differences and dosedependency to some extent.

5. Aconite poisoning

Aconiti radix processa is the dried tuberous root of Aconitum carmichaeli Debeaux or Aconitum *japonicum* Thunberg (Ranunculaceae) prepared by the following processes. 1: Autoclaving. 2: Heating or autoclaving after rinsing in salt or rock salt solution. 3: Treating with calcium hydroxide after rinsing in salt solution. Before processing, contains aconitine, mesaconitine, etc., has strong analgesic activity, but also has strong toxicity [13; 14]. By heat-processing, aconitine and mesaconitine were hydrolyzed to become benzoylaconine and benzoylmesaconine, respectively, and their toxicity were reduced about 1,000-fold [14]. The Japanese Pharmacopoeia describes the upper limits on the contents of aconitine and mesaconitine in aconiti radix processa, that makes it relatively safe to use, but may still cause poisoning in sensitive patients. The initial symptoms of sticking poisoning are numbress and palpitations, and the patients with those symptoms need to stop using or reduce the dosage. Among the preparations of aconiti radix processa marketed in Japan, some manufacturers produce the contents of aconitine and mesaconitine near the upper limit to

have high analgesic effect, but these products may easily cause side effects. On the other hand, the active ingredient of aconiti radix processa for neuropathic pain is not the highly toxic alkaloid, but neoline, an alkaloid that does not hydrolyze. [15]. Therefore, even if the heat treatment is performed well to completely decompose highly toxic alkaloids, it is also useful for neuropathic pain.

<Case report>[16]

The patient is a 78-year-old woman. Since X-31 year ago, she has suffered from rheumatoid arthritis. She visited my clinic in the year X. Administration of daibofuto decoction containing 4.5 g of unprocessed aconiti radix markedly improved her joint pain and laboratory findings. However, the joint pain was exacerbated on October 7th, X+2 year. Then, the drug was changed to uzuto decoction containing 4.5 g of unprocessed aconiti radix. On October 11th, one hour after the oral administration, she developed blurred eyes and pharyngeal strangulation, and vomited three times. Since the heart rate dropped to 60/min and the blood pressure dropped to 90 mmHg, blood vessels were secured and the electrocardiogram was monitored. Although he did not receive any special treatment, it improved as it was.

6. Interstitial pneumonia and drug-induced liver injury

These side effects of Kampo medicines have been reported since 1989. Prior to that, it may have been, but never mentioned. Of particular note was the report that 88 patients who took Shosaikoto developed interstitial pneumonia in the three years since 1994, of which 10 died. However, its frequency is extremely low, and according to Homma's research, the frequency of occurrence is almost 100,000 per 4 people / year [17]. Among them, most of the patients had chronic hepatitis B and C, and interferon was used in almost all patients. Therefore, the concomitant use of shosaikoto and interferon preparations is currently contraindicated. In a survey of Tsumura ethical shosaikoto extract preparations from October 1995 to March 1997, 69 cases (2.8%) out of 2,495 patients were reported to have adverse effects including abnormal laboratory test.

<Case report>[18]

A 71-year-old woman was hospitalized with a diagnosis of pneumonia. She had fever, cough, dyspnea, and diffuse granular reticular shadows in both lung fields on chest X-ray. I suspected summertype hypersensitivity pneumonitis, but I chose no medication since the condition is not but. However, her condition had been further exacerbated, I suspected drug-induced pneumonia, and all medications were discontinued and prednisolone was administered. Chest X-rays improved markedly. Transbronchial lung biopsy showed interstitial pneumonia, and lymphocyte stimulation test showed positive for shosaikoto. The challenge test revealed fever, hypoxemia, and the appearance of interstitial pneumonia on chest X-ray. This case report appears to be the first of drug-induced pneumonia caused by shosaikoto.

Following this report, the similar adverse effects were seen in more than 15 Kampo extract formulations including scutellariae radix that is the dried root of *Scutellaria baicalensis* Georgi (*Labiatae*), from which the periderm has been removed. Then, it was speculated that this adverse effect was probably due to scutellariae radix. It is predicted baicalin, which is contained in scutellariae radix in relatively large amounts binds to albumin to become hapten, and that the sensitization is established. However, this is only a prediction and future research is required.

Scutellariae radix has also been suspected to cause drug-induced liver injury. Some patients have increased ALT/AST in a short time after taking scutellariae radix [19]. Although the frequency is extremely low, it is often asymptomatic. Therefore, it is desirable to conduct a liver function test within a few weeks after administration of the preparation. In addition, the cases of fever have been reported. Fever is also a subjective symptom, and is relatively easy to find. It is reported by Terashi et al. [20].

At present, about 40 kinds of Kampo formulas that caused liver disorders, and about 30 kinds of Kampo formulas that caused lung disorders have been reported. It is said that these cases are relatively common in the elderly, but this is not always the case, and the cause is thought to be due to a specific constitution such as allergy. Therefore, the only way to prevent these adverse effects is to carefully detect and respond to the history of drug or food allergies at the time of drug administration.

Formulas reported to cause interstitial pneumonia: Shosaikoto, daisaikoto, saikokeishito, saibokuto. saireito. saikokeishikankyoto, saikokarvukotsuboreito, hangeshashinshinto. shoseiryuto, bakumondoto, hochuchuekkito, goshajimkigan, seihaito, shin'iseihaito, junnchoto, seishinreshiin, boiogito, bofutsushosan, otsujito, orengedokuto, yokukansan, keigairengyoto, nijutsuto, unseii, gorinsan, sanoshashinto, shakuyakukanzoto, daikenchuto, ryuchoshakoto.

Formulas reported to cause drug-induced liver injury and jaundice: Otsujito, daisaikoto, shosaikoto, shosaikotokakikyosekko, saikokeishito, saikokaryukotsuboreitoto, saikokeishikenkyoto, saibokuto, saireito, orengedokuto, sanmotsuogonto, shakuyakukanzoto, hangeshashinto, unseiin, shoseiryuto, maobushisaishinto, kakkonto, seihaito, seijobofuto, shin'iseihaito, bakumondoto, nyoshinsan. keishibukuryogan, kamishoyosan, rikkunshito, hochuekkito, ninjinyoeito, daikenchuto, nijutsuto, juzentaihoto, boiogito, bofutsushosan, junchoto. inchinkoto. goshajinkigan, keigairengyoto, seishinrenshiin, yokukansan, ryutanshakanto, sanoshashinto, goshuyuto, goreisan.

Although interstitial pneumonia and druginduced liver injury caused by Kampo prescriptions are not so frequent, these adverse effects should be noted. When fever, cough, dyspnea, or abnormal lung sounds (fine crackles) appears, the administration of Kampo prescriptions should be discontinued, chest X-rays should be immediately examined, and the appropriate treatment such as the administration of corticosteroids should be performed. It is also necessary to conduct liver function tests regularly to prevent drug-induced liver injury.

7. Mesenteric phlebosclerosis caused by gardeniae fructus

It has been reported that mesenteric phlebosclerosis caused by Kampo prescriptions. In 2013, the Research group funded from Ministry of Health, Labor and Welfare conducted national survey, and reported that over 80% of mesenteric phlebosclerosis patients took Kampo prescriptions containing gardeniae fructus. More than 90% of the patients had taken the drugs more than 5 years [21].

Gardeniae fructus is the dried fruit of Gardenia jasminoides Ellis (Rubiaceae). There are many Kampo formulas containing gardeniae fructus, but the special attention is needed for eight formulas such as kamishoyosan and orengedokuto. If the patients who have been taking these prescriptions for 5 years or more have repeated abdominal pain, diarrhea. constipation, abdominal bloating. nausea/vomiting, or have positive fecal occult blood (asymptomatic), it is necessary to conduct colonoscope and CT inspection. If there are characteristic symptoms such as dark purple or bronze color on the mucous membrane at the right colon, linear or dotted calcification along the colon wall or mesenteric vein on CT, the calcification of venous wall and the increased collagen fibers in the histopathology, the drugs should immediately be discontinued. The prognosis is generally good by the withdrawal of Kampo prescription, but it takes a long time to improve fibrosis and calcification. In the case of long-term administration of Kampo prescription containing gardeniae fructus, it is desirable to conduct a fecal occult blood test, regular colonoscopy once every 1 to 2 years, simple abdominal CT test, etc. [22].

<Case report>[22]

The patient is a 65-year-old woman. In July in X year, she visited my hospital to take Kampo medication for hepatitis C. Initially, hochuekkito had been administered, and then changed to saikokeishikankyoto, keishibukuryogan, etc. Thereafter, the dosage of gardeniae fructus was temporarily reduced to 5 g/day, but had been soon returned to 15 g/day and continued. At X+13 year, her cumulative intake of gardeniae fructu was 5,379 g for 9.4 years. There were no findings such as abdominal pain, abdominal distension, abdominal tenderness, etc., but under the patient's consent, colonoscopy was performed in May in X+17 year. Blue pigmentation and mild edema were observed on the mucosa of the cecum, ascending colon, and transverse colon. Histopathological test also showed increased submucosal collagen fibers in the cecum, ascending, and transverse colon. This confirms the diagnosis of mesenteric venous sclerosis

8. Lactose allergy and intolerance

Drug adjuvants such as excipients are contained in Kampo extract prescriptions. Commonly used excipients are lactose, starch, cellulose and so on. Among these, lactose contained only a small amount of milk-derived protein as an impurity, which could be a problem for milk allergy patients. However, even patients with relatively severe milk allergy have no abnormalities in the results of oral lactose tolerance test [23]. Lactose intolerance has been reported to be less than 1% in ethical Kampo prescriptions using lactose as an excipient [24]. Therefore, it is considered to be of little concern clinically. However. since secondary lactose intolerance such as after gastroenteritis in infants

and children is clinically experienced, it is better to use lactose-free Kampo preparations for the symptoms of prolonged diarrhea after gastroenteritis.

9. Aristolochic acid-induced kidney injury and cancer

It was reported in Belgium that people who took weight-loss herbal preparations developed kidney injury that required dialysis and transplantation between 1990 and 1992 [25]. In this preparation, *Aristolochia fangchi* (Aristolochiaceae) that contains aristolochic acid, which are nephrotoxic and carcinogenic, was found. In Japan, there have been some case reports of kidney injury caused by Tokishigyakukagosyuyushokyoto preparation using the stem of *Aristolochia manshuriensis* as an ingredient instead of akebiae caulis, the dried stem of *Akebia quinata* Decaisne or *Akebia trifoliata* Koidzumi (Lardizabalaceae), and herbal dietary supplements containing aristolochic acid [26; 27].

At present, the distribution of crude drugs containing aristolochic acid is banned not only in Japan but also in other countries. Therefore, it is thought that the toxicity of aristolochic acid will not occur with regular drugs. However, the possibility to use the products distributed in unregulated internet market or the old herbal product before ban is undeniable, care must be taken account.

Conclusion

As descried above, Kampo medicines also have many adverse effects. Diarrhea caused by rhei rhizoma, the dried rhizome of *Rheum palmatum* Linné (Legminozae), etc. or sal mirabilis, a mineral substance, mainly composed of sodium sulfate hydrate (Na₂SO₄•10H₂O) is not adverse effect but the excessive mistaken dosage. However, in clinical practice, a wide variety of adverse effects from very slight allergies to severe liver damage has been experienced. These can be can be led quickly in a short period without any serious situation if the physician and pharmacist find it and perform appropriate treatment immediately. Careful observation is the best way to deal with adverse effects.

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Book Review

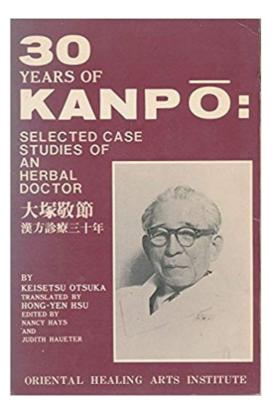
Dr. Otsuka's "30 Years of KAMPO" Hiromichi Yasui Japan Institute of TCM Research

Dr. Keisetu Otsuka summarized his case reports and wrote a book entitled "Kampo Shinryo 30 Nen (30 Years of Kampo)" in 1959 following 30 years of practice in Kampo medicine treatment. There is no TCM (Traditional Chinese Medicine) theory mentioned in any case report out of a total number of 374 cases in this book. In each case, only the symptoms and signs of the patient and the prescription used are described. He did not write down anything about pathological theories or reasons for choice of the prescriptions on each case. One day, I asked him, "Why did you not write down the reasons for using the prescriptions?" Then he answered, "Such a thing will be considered by the latter person."



"30 Years of Kampo" Japanes original Such clinical style of Dr. Otsuka takes over the tradition from the Edo period. System1 with Clinical Pearls as its background is emphasized, on the other hand, System2 which needs theory such as TCM is rarely used in that book. Providing only description of facts without theory. This is fresh even from the viewpoint of modern medicine, due to its objectivity. There are also Clinical Pearls created by Dr. Otsuka himself some sections of the book, and some very interesting descriptions.

This book conveys the wonderfulness of treatment of Kampo medicine around the late 1920s to the late 1950s when Western medicine was not yet producing sufficient results. What we can get from this book is bigger than what we imagine. I sincerely thank Dr. Hong-Yen Hsu from Taiwan who translated this book into English.



"30 Years of Kampo" English version



Foundation: 1905

A century of tradition ———

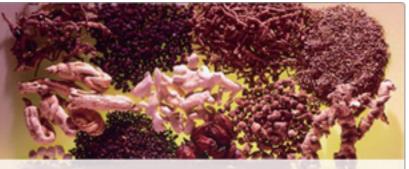
We are a manufacturer consistently controlling the entire process from the import of crude herbs to the manufacture of Kampo extracts and as such have contributed to the development of Japanese Kampo.

We sincerely hope to continue in the future with our contribution to modern medicine through "Kampo".



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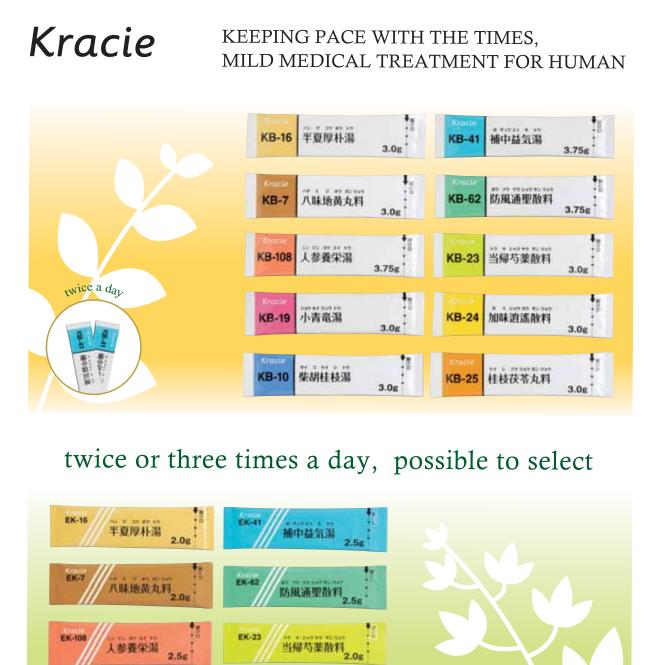


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