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Research on Theory, Practice and Integration

KAIM

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Clinical Report 2 (Kampo Medicine)
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Yuji Fukuma

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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.

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Editorial

Integrating NBN and EBM in Kampo Medicine

EBM is an essential concept in modern medicine. However, not all problems can be resolved using EBM methodology. It is particularly difficult to apply to diseases and pathological conditions that are deeply associated with psychological elements. The concept of NBM came to be widely known through *Narrative Based Medicine—Dialogue and discourse in clinical practice* (BMJ, 1998), edited and published by Trisha Greenhalgh and Brian Hurwitz in 1998. It introduced NBM as a complementary concept to EBM in the medical care field, and made it known that the two concepts function as the two wheels of a cart.

With regard to a certain treatment for a certain disease, it cannot be said that "no evidence exists unless its effectiveness is proven in a randomized controlled trial (RCT)." Yet, Kampo medicine is placed in this precise situation. We do not have the right to abandon Kampo prescriptions that have a history of some 1800 years for the reason that no evidence exists. This is because "no evidence means its effectiveness has not been proven yet, and is not the same as being invalid."

In Kampo medicine, physicians place importance on history taking, and make a diagnosis and provide treatment based on the patient's narrative. Needless to say, other examination methods such as visual examination, auscultation, and pulse feeling are also certainly important, but history taking, including medical history, plays an extremely important role in Kampo medicine diagnosis, and helps determine the selection of a prescription. Patients frequently say that "Kampo medicine specialists listen carefully to what patients say." However, listening carefully to a patient's narrative is nothing special. Kampo medicine specialists listen carefully because doing so is necessary for making a diagnosis and providing treatment, even if they are not aware that NBM is taking place in that process. NBM is not a new concept in traditional medicine, but has existed from ancient times.

The series on "Integrating Kampo and Evidence Based Medicine" by Dr. Yasui, which begins with this issue, is expected to shed light on the characteristics of Kampo medicine from the perspectives of both NBM and EBM. In the series, Dr. Yasui shall classify Kampo medicine as practiced under a centralized medical system into four categories, and define the role of Kampo medicine in each category.

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Integrating Kampo and Evidence-Based Medicine (Introduction)

Four Episodes About the Integration of Kampo and Modern Medicine

Hiromichi Yasui
Japan Institute of TCM Research

From this issue, the Journal provides this series in narrative form to offer a better understanding of the captioned topic.

Introduction

Kampo medicine was introduced to Japan approximately 1,500 years ago. In approximately a thousand years of history with trials and errors, it gradually took on uniquely Japanese characteristics. Then, Todo Yoshimasu established a style of Kampo medicine unique to Japan in the early-18th century.

Kampo medicine was temporarily deprived of its status as orthodox medicine during the Meiji Restoration, but owing to the efforts of many of our forefathers, it was established anew on the foundation of modern medicine in the 1940s. This movement continued even after the end of World War II. In 1972, it became possible to apply health insurance for the use of crude drugs. From 1976, we can prescribe Kampo extract preparations for medical applications in the national health insurance system.

In Japan, Kampo medicine is administered under a unified system of Western medicine. Japanese health care system is completely different from the dualistic medical system just as it is adopted in China and South Korea. Physicians who prescribe Kampo are educated in Western medical school and trained in Western medicine for a period of years after graduation, and know the natural course of almost all diseases. They know well how medical conditions change when standard treatment is administered. They also know well in what types of situations standard Western medical treatment and Kampo medicine should be used together or when they should be used separately.

In this series, I will introduce how Kampo medicine is being used in Japan. The information I provide will be practical and academic, but I will present it in narrative form to help deeper understanding of Kampo medicine used by practicing clinicians. I think it is difficult to provide an accurate understanding of the Kampo situation in Japan today, otherwise. Simultaneously, I will also introduce, as much as possible, evidences that have been confirmed to date.

Episode 1:

Let us begin with an episode that occurred to my patient.

On a certain day in October 2011, a 70-year-old man, my patient, climbed a famous mountain with 1,500 meters in height. On his way down, he became unable to walk because of a muscle spasm in both of his thighs. Even after ten minutes or more, the spasm did not abate, and he remained sitting on the side of the path not knowing what to do. Then, a stranger approached him and said, “Are you okay?” He explained what happened, and the stranger told him, “I have a good medicine for you. Here, take one,” and disappeared.

He took the medicine, and within minutes, the spasms in his thighs subsided, and the pain was also gone. He was so surprised for the effectiveness of the medicine. He said to me that he thought the stranger was a God. However, the stranger was simply an ordinary man who gave a shakuyakukanzoto extract to my patient. (The stranger was a pharmacist, as I later learned.)

This episode shows that shakuyakukanzoto is commonly used among many people as medicine for muscle spasms. It is widely known as a “silver bullet” for leg cramps, and this Kampo formula is popular not only as a medical prescription but also as an over the counter (OTC) drug. It is commonly used particularly by people who engage in sports, such as a long-distance cycling trip, hiking, and a

football match.

Katayama et al. sheds light on the roles of Kampo medicine within the health care system in Japan from various perspectives, by analyzing approximately 67 million cases extracted from the data of health insurance treatment statements governed by the Japanese Ministry of Health, Labour and Welfare[1]. They showed that shakuyakukanzoto is the most widely used prescription in Japan. As a Japanese, it makes me proud that such medicine is readily nearby and available to everyone.

Episode 2:

A 75-year-old man with trigeminal neuralgia came to my clinic on September 25, 2006. In this one month, he felt such strong pain in the right side of his face that it was painful for him even to take a bite of something or to touch his cheek. He visited a general hospital and was diagnosed as trigeminal neuralgia. He was administered Tegretol ® (carbamazepine), and his symptoms abated once after taking the drug, but the pain recurred after ten days. He said the intensity of his pain varies by the day and worsens before the weather deteriorates.

I administered goreisan (Polyporus Sclerotium 6g, Alisma Rhizome 10g, Atractylodes Rhizome 6g, Poria Cocos 6g, and Cinnamon Berk 4g) with a previous dose of carbamazepine. From the third day of goreisan, his pain subsided largely, and he rarely felt pain at night. By March 2007, his pain could be relieved only with a half of tablet (50mg) of carbamazepine. Thereafter, he got better with alternating periods of getting better and worse. On June 16, 2010, I added another 4g of Poria Cocos in consideration of the increased dampness of the rainy season. After continued administration of this prescription, his pain completely disappeared by the end of February 2011, even without carbamazepine. I continued goreisan for two years thereafter on an intermittent basis because the pain tended to come back without taking goreisan. After another two years, all medication could be stopped.

This episode describes how a trigeminal neuralgia patient with facial pain gradually recovered by taking goreisan in combination with carbamazepine. The administration of carbamazepine alone could not adequately improve the patient's pain, so goreisan was administered in combination. Therefore, carbamazepine could be lessened to the point where the pain could be controlled solely by goreisan after a while, and a drug-free condition was eventually achieved.

Standard Western medical treatment brings good results to patients usually, but when its effect is not enough, there are many cases helped by Kampo medicine. As in the above, there are various forms of treatment. For example, initial standard treatment may be combined with Kampo medicine when satisfactory results could not be obtained. The two treatments might be combined from the beginning, or temporarily. I hope the episode provided a glimpse of how modern medicine and Kampo medicine are integrated.

Episode 3:

A 53-year old woman who was diagnosed as rectal cancer in January 2010 came to my clinic. Her cancer was in Stage IV with peritoneal dissemination, meaning in terminal stage, but she decided to undergo surgery and to seek help as much as possible. I told her that the most I could do is to lessen any damage she may incur from operative stress, and to reduce the side effects of anticancer drugs to a certain extent. Then, upon gaining her understanding, I consulted with her attending surgeon, and started a decoction of a hochuekkito-based prescription from a month before the operation.

On February 17, 2010, she was performed surgery to remove her rectal cancer. From March 9, intravenous injections of an anticancer drug

(FOLFOX) were begun. On this day, she had a CEA of 7.2 ng/dL and CA19-9 of 887.9 U/mL. Side effects were expected from the surgery and administration of the anticancer drug, she did not develop loss of appetite, diarrhea, nor aphthous stomatitis. Actually, her good appetite while the anticancer drug was surprising.

On May 25, her CT scan showed hepatic metastasis and peritoneal metastasis, and the anticancer drug regimen was changed. From June 9, she began receiving an administration of irinotecan hydrochloride, but as this caused diarrhea, she was given hangeshashinto extract (Kracie Pharma, Ltd., Tokyo, Japan), which eased her symptoms. On June 21, she developed aphthous stomatitis, which subsided after administering unseiin extract (Kracie Pharma, Ltd., Tokyo, Japan). Diverse symptoms, however, gradually appeared thereafter. She showed signs of temporary recovery by using shikonboreito in combination with her other treatments, but passed away on September 13, 2011.

This episode does not claim that Kampo medicine is effective against malignant tumors. It shows that Kampo medicine relieves the adverse effects from the standard treatments against malignant tumors. The standard treatments include surgery, anticancer drug treatment, or radiation therapy, but they are all invasive to the body, and the side effects are common.

The previous patient first received surgery to remove her tumor, immediately followed by chemotherapy. The administration of Kampo medicine from a month before her surgery mitigated the expected side effects of her following chemotherapy, and allowed her to live comfortably, albeit temporarily, to the point where she could prepare herself to bring down the curtain on her life. With the support of many friends, she passed away and went to heaven surrounded by her friends. She was alone about the fact that she did not have a family, but after her death, her friends worked for her as her family members. I learned later how blessed she was to have such wonderful friends.

Episode 4:

A 54-year-old man visited me with complaints of a fever, sluggishness, and subtle pain in all his joints since the previous day. His fever would not go down even after a day, and moreover, he said he suddenly developed lower back pain and could not walk properly. Although his lower back aches, he said he came to my clinic seeking Kampo treatment primarily for his cold, as he is allergic to non-steroidal anti inflammatory drugs (NSAIDs) and Calonal ® (acetaminophen). His body temperature was 37.7°C. He seemed to have tremendous difficulty walking because of his lower back pain, and entered my office holding onto the wall.

He explained as follows. Last May and June, he was underwent surgery for anal fistula. He took Voltaren ® (diclofenac sodium) and Loxonin ® (loxoprofen) as part of his treatment, but stopped taking those medications on the third day, as he developed a rash and experienced swelling throughout his body. He underwent another surgery in November, and was cured of his anal fistula. Again, he was administered Loxonin, and again, he developed a rash. When he caught a cold at the end of the last year, he took an OTC drug, and again developed a rash throughout his body. Thereafter, he developed lower back pain and went to an orthopedic clinic. When he took the Calonal, he developed a rash again. After all, he wished to treat his cold with Kampo medicine because he could not take NSAIDs or acetaminophen any more.

I combined 2.5g of keishito extract (Kotaro Pharma, Ltd., Osaka, Japan) extract and 1.5g of eppikajutsuto extract (Kotaro Pharma, Ltd., Osaka, Japan) extract to prepare a prescription similar to keishinieppiichito, and told him to take it every two hours. I also told him to stop taking it when he

begins to sweat. He took the Kampo formulas four times, sweated, and brought his fever down. The next day, his body temperature was 36.6°C, and he said his sluggishness, sensation of heat, and joint pains were gone.

After the episode of common cold, he wished treatment for his lower back pain, which has gotten much better since the previous day but still aches. I therefore began treating his lower back pain.

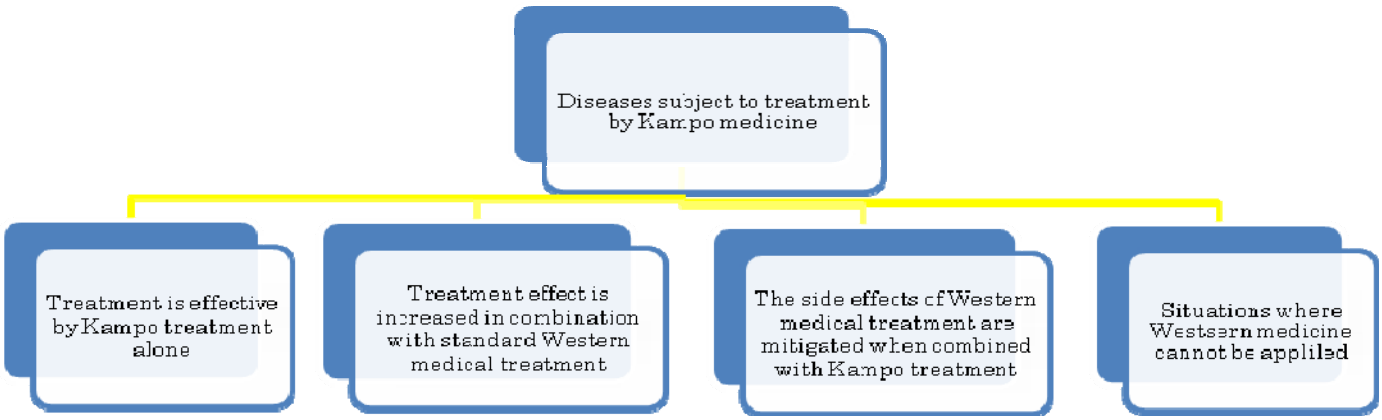
This episode shows that Kampo medicine can be used to easily cure diseases even in a patient who is allergic to standard treatment. As introduced above, he was allergic to many antipyretic analgesics. It is disputable whether antipyretic analgesics are required for common cold or influenza that begins with a chilly sensation. In Kampo medicine, it should be avoided to adopt the medications which "cool down heat" for the diseases because of "the invasion of coldness".

Kampo medicine is extremely effective against many disease conditions that normally require the use of an antipyretic analgesic. Even if the above patient were not allergic to antipyretic analgesics, I would still have administered the above prescription without hesitation. This is because treatment of acute febrile illnesses is one of the greatest specialties of Kampo medicine.

What the four episodes convey

Did you gain any new information from the above four episodes? To those who are well versed in Kampo medicine and Chinese medicine, they are not particularly rare cases. Actually I introduced them to show the roles that Kampo medicine could play in medical systems that are based on modern medicine. Furthermore, it should be noted that they each represent one of four types in the use of Kampo medicine in daily clinical practices.

The characteristics of each type are shown in the figure below[2].



Type 1: Kampo treatment is better than standard Western medical treatment, and is thus used alone

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

Case 1: yokukansan for behavioral and psychological symptoms of dementia (BPSD)
Case 2: yojinkodakuto for chronic renal failure
Case 3: goreisan for headaches associated with a decrease of atmospheric pressure
Case 4: goreisan for earaches that occur when boarding an aircraft
Case 5: shakuyakukanzoto for muscle spasms
Case 6: shosaikoto, saikokeishito and saikoseikanto for recurrent upper respiratory inflammation in children
Case 7: juzentaihoto for perianal abscess in children
Case 8: juzentaihoto for recurrent otitis media in children

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

Case 1: A number of Kampo prescriptions for improvement of symptoms that occur before they are diagnosed as rheumatoid arthritis
Case 2: Kampo medicine represented by maoto for the early stages of influenza
Case 3: goreisan for the early stages of vomiting and diarrhea (mostly caused by rotavirus) among children
Case 4: Kampo medicine (kakkonto, maobushisaishinto, etc.) for the early stages of a cold

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

Case 1: Combination of triptan and goshuyuto for migraine headaches
Case 2: Combination of carbamazepine and goreisan for trigeminal neuralgia
Case 3: Combination of MTX and Kampo medicine for rheumatoid arthritis
Case 4: Combination of antibacterials and daiobotampito for colonic diverticulitis
Case 5: Combination of kakkontokasenkyushin'i and standard treatment for purulent rhinorrhea
Case 6: Combination of inhaled steroids and Kampo medicine for bronchial asthma and COPD
Case 7: Administration of daikenchuto for bowel movement after intra-abdominal procedures

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

Case 1: juzentaihoto, hochuekkito, etc. for loss of appetite caused by anticancer drugs
Case 2: ninjin'yoeito for mitigation of the side effects of anticancer drugs (mFOLFOX6 therapy)
Case 3: goshajinkigan for the neurotoxicity of anticancer drugs (FOLFOX therapy)
Case 4: shakuyakukanzoto for the neurotoxicity of anticancer drugs (taxane agents) and neuralgia
Case 5: hangeshashinto for diarrhea caused by anticancer drugs (irinotecan hydrochloride)
Case 6: ninjin'yoeito for anemia developed during ribavirin therapy for treatment of Hepatitis C
Case 7: juzentaihoto for anemia during interferon + ribavirin therapy for treatment of Hepatitis C
Case 8: saikokaryukotsuboreito for tachycardia caused by tocolysis (ritodrine hydrochloride) used in the treatment of threatened miscarriage or premature delivery
Case 9: bakumondoto, etc. for dry mouth caused by the administration of psychotropic drugs

Types 4: Treatment is needed, but standard Western medical treatment cannot be applied

Case 1: Cases where standard treatment cannot be applied due to a drug allergy

Case 2: Cases where standard treatment cannot be applied due to its side effects

Case 3: Cases where standard treatment is difficult due to age constraints

From the next issue and on, I will introduce each of the above patterns in detail, for case examples.

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[List of prescriptions]

shakuyakukanzoto：芍薬甘草湯

goreisan：五苓散

hochuekkito：補中益気湯

hangeshashinto：半夏瀉心湯

unseiin：温清飲

shikonboreito：紫根牡蛎湯

keishito：桂枝湯

eppikajutsuto：越婢加朮湯

keishinieppiichito：桂枝二越婢一湯

Japanese Acupuncture - Current Research

Japanese Traditional Medicine Text (15) – Neurology A

Ikuro Wakayama

General Neurology

1. Acupuncture Indications in Neurological Disorders

The World Health Organization (WHO) presented a list of 43 disorders treatable by acupuncture in 1979. The list was amended to 49 disorders in 1996. Current research on these disorders will be presented here. Each neurological disorder category contained various symptoms and diseases, such as headache, migraine, tension-type headache, sciatic neuralgia, post-herpetic neuralgia, and hemiplegia. However, rigorous clinical trials have not been conducted to prove the effectiveness of acupuncture for these conditions. The 1979 list of conditions was clearly not based on clinical evidence. Therefore, reflection on the 1996 draft led to the conclusion that future amendments of acupuncture indications should be adapted based on rigorous clinical evidence[1]. Work began in 1996, and was eventually published by the WHO in 2002 as "Acupuncture: Review and analysis of reports on controlled clinical trials"[2]. As the title of this book indicates, clinical acupuncture research designed as randomized controlled trials (RCT) and controlled clinical trials (CCT) has demonstrated that 28 conditions have been shown to be effectively treatable with acupuncture. An additional 63 conditions may be effectively treatable but further evidence is required, 9 conditions warrant clinical trials as the current Western treatment has proven difficult, and 7 conditions seem promising but still require an appropriate method of evaluating current clinical results. Even though clinical trials are the basis for this book, it should be noted that a majority of the research presented is still of low quality. Since 1996, when these results were first collared, neurological disorders confirmed to be effectively treatable by acupuncture included facial pain, headaches, sciatica, and stroke.

On the other hand, in 1997, the National Institutes of Health (NIH) issued a Consensus Statement that the effectiveness of acupuncture was based on scientific evidence, and it included the relief of nausea and vomiting caused by surgery and/or chemotherapy, hyperemesis gravidarum, and toothache following surgery. Also cited were conditions related to pain, drug addiction, stroke, headache, menstrual pain, tennis elbow, fibromyalgia, low back pain, carpal tunnel syndrome, and asthma; of these, only headache and stroke are neurological disorders. Concerning the 2002 statement by the NIH, there have been recent publications on the Internet indicating that the statement may no longer be valid[3].

Although most of the fundamental results were based on poorly designed clinical research, the WHO and NIH, internationally recognized agencies, announced which conditions can be treated by acupuncture. However, very few neurological disorders were mentioned. This has been the situation regarding acupuncture therapy for neurological disorders until just recently. Concerning the future of moxibustion therapy, high-quality, integrated clinical trials are eagerly awaited, with it only occasionally being reported in clinical trials at the present time. For this reason, the current volume focuses on acupuncture therapy.

2. Review of Acupuncture for Neurological Disorders as Presented in the Cochrane Collaboration

The Cochrane Collaboration was founded in 1993, and it assists people involved in health care by referring them to online information. It currently consists of over 4,000 Cochrane reviews, helping patients obtain accurate information so that they can make informed health decisions. Cochrane reviews are based on systematic reviews of primary research in human health care. Reviews are posted on some neurological disorders, such as stroke, Bell's palsy, dysphagia due to stroke, epilepsy, prevention of migraine, restless legs syndrome, stroke rehabilitation, tension-type headache, and vascular dementia[4].

Reviews of the results for the neurological disorders are displayed in Table 11. They have yet to draw conclusions or post prospects for the future

because most current reviews are based mostly on low-quality clinical trials. However, reviewers suggested that, for the prevention of migraine and tension-type headache, acupuncture treatment is effective[5, 6]. In addition, for these 2 notable diseases, by adding a new clinical trial in the 2008 Edition, for which evidence was insufficient in 2001, reviews of the effectiveness were verified. That is to say, the quality of clinical trials for the conditions listed in Table 11, as well as other diseases, or diseases not listed here, will confirm the effectiveness of acupuncture for neurological disorders once large-scale, high-quality clinical research can be conducted. Additionally, there are some neurological disorders for which trials have not yet been conducted but protocols for them have been established. They are Guillain-Barre syndrome, multiple sclerosis, Parkinson's disease, post-herpetic neuralgia, and diabetic neuropathy.

Regarding whether or not acupuncture is effective for specific neurological disorders, there are currently few studies and little evidence besides migraine and tension-type headaches. However, this article refers to the Cochrane reviews as a potential source of evidence for the validation of acupuncture's effectiveness for neurological disorders: (1) migraine, (2) tension-type headaches, (3) epilepsy for functional disorders; (4) Parkinson's disease, (5) stroke, and (6) multiple sclerosis for central nervous system disorders; and (7) diabetic neuropathy, (8) Bell's palsy, (9) Guillain-Barre syndrome, and (10) post-herpetic neuralgia for peripheral nerve disorders. Here, we introduce international and domestic research results on acupuncture treatment for these 10 conditions.

Table 11. Neurological disorders for which the effectiveness of acupuncture has been assessed by the Cochrane Review

Disorders	Year	No. of trials	No. of patients	Evidence
Acute stroke	2004	14	1,208	No evidence*
Bell's palsy	2010	6	537	Inconclusive**
Dysphagia due to acute stroke	2008	1	66	Inconclusive**
Epilepsy	2008	11	914	No evidence*
Prevention of migraine	2008	22	4,419	Similar or superior to drug treatment
Restless legs syndrome	2008	2	170	Inconclusive**
Stroke rehabilitation	2006	5	368	Inconclusive**
Tension-type headache	2008	11	2,317	Reduced frequency of headaches
Vascular dementia	2007	0	0	No data***

*: No evidence suggesting the effectiveness of acupuncture treatment. Further, larger scale research would be desirable.
**: The quality and the scale of trials were inadequate. The effectiveness of acupuncture cannot be determined.
***: No randomized controlled trials available.

3. International Research on Acupuncture Treatment for Neurological Disorders

Most of the international clinical research on the above-mentioned neurological disorders, including stroke, migraine, and tension-type headache, involve relatively *common* diseases. Regarding stroke, the effect of acupuncture for stroke rehabilitation in the Cochrane review was inconclusive as shown in Table 11, but later, a systematic review (SR) indicating acupuncture as effective treatment was reported (Table 12)[7, 8]. In addition, an SR has been reported on the effectiveness of moxibustion for stroke rehabilitation (Table 13)[9]. Thus, it cannot be stated that there is sufficient SR-based evidence for either acupuncture or moxibustion; however, it could be confirmed if more RCT are conducted and integrated as SR in the near future.

Concerning other disorders, for example Parkinson's disease, there are 2 SR, and only one or at most 2 RCT available. Both of these Parkinson's disease SR were presented in 2008. However, the first SR reported on the significant effectiveness of acupuncture treatment. The second SR included an RCT on scalp acupuncture within the effectiveness of acupuncture therapy, and a meta-analysis provided further evidence of its efficacy, although the overall effectiveness of acupuncture treatment for Parkinson's disease was not conclusive (Table 14)[10, 11]. Thus, at present, convincing evidence for the effectiveness of acupuncture treatment on neurological disorders is definitely lacking, but, recently, there has been a gradual increase in reliable evidence.

Table 12. Systematic reviews of acupuncture combined with rehabilitation in patients with stroke

	No. of databases searched	Year of searches	Inclusion criteria	No. of RCTs	Evidence
Kong JC (2010)	25	~Sep. 2009	Sham controlled RCT	10	No evidence*
Wu P (2010)	9	~Sep. 2009	RCT	9	Likely effective**

Table 13. Systematic reviews of moxibustion combined with rehabilitation in patients with stroke

	No. of databases searched	Year of searches	Year of searches	No. of RCTs	Evidence
Lee MS (2010)	14	~Nov. 2009	RCT	9	Effective with some limitations**

*: No evidence suggesting the effectiveness of acupuncture treatment. Further, larger scale research would be desirable.
**: Acupuncture treatment appears effective; however, large-scale, high-quality research is still desirable.

Table 14. Systematic review of acupuncture for Parkinson's disease

	No. of databases searched	Year of searches	Inclusion criteria	No. of RCTs	Evidence
Lam YC (2008)	13	～July 2007	Sham or waiting list controlled RCT	10	Appears to be effective*
Lee MS (2008)	17	～Sep. 2007	RCT	11	Inconclusive**

*: Acupuncture treatment appears effective; however, large-scale, high-quality research is still desirable.
**: The quality and scale of trials were inadequate. The effectiveness of acupuncture cannot be determined.

This concludes our overview of the results of the Cochrane review with references to SR and RCT in foreign countries. Gradually, evidence for the effectiveness of acupuncture in some neurological diseases such as migraine and tension-type headache has been increasing. In addition, as I indicated in Parkinson's disease and stroke, the quality of trials improved, the scale of the trials increased, and the SRs integrated those trials, and so the effectiveness of acupuncture will be more strongly supported.

4. Domestic Research on Acupuncture Treatment for Neurological disorders

a. Clinical Trials

Of the 10 conditions listed above, unfortunately, no RCT have been from Japan. Among comparative studies using multiple subjects, one report involved 38 patients suffering from diabetic neuropathy treated with acupuncture[12], and another study treated 113 patients with peripheral facial palalysis (Bell's palsy or Hunt syndrome)[13]. Three comparative studies reported on the clinical effects of acupuncture and moxibustion treatment for stroke patients combined with rehabilitation[14-16]. Also, there was a report on the n-of -1 trial method for Parkinson's disease[17]. Comparative research in Japan has not been conducted for other neurological disorders. Therefore, as discussed above, there are very few comparative studies investigating acupuncture intervention for neurological disorders conducted in Japan.

b. Case Series

There are case series studies demonstrating the effect of acupuncture treatment for tension-type headache (86 patients)[18] and refractory cases of Bell's palsy/Hunt syndrome (29 patients)[19]. Results from these studies showed almost or complete clinical improvement at rates of 19.7 and 17.2%, respectively, indicating the reliable effects of acupuncture treatment for these conditions. Also, successful acupuncture treatment for 48 subjects with cervical dystonia [20] was reported. High-quality, comparative clinical trials in the future are desirable.

c. Case Reports

As for case reports, especially treatment results of acupuncture interventions, it has generally been the case that reports of these results focus primarily on atypical treatment courses or unexpected favorable results. Case reports suggesting special mechanisms of action of acupuncture that were not previously reported are also important. Unfortunately, those kinds of case reports are very rare among Japanese clinical reports; instead, most reports merely mention that acupuncture could be used to successfully treat the presenting symptoms.

Acupuncture case reports within the field of neurological disorders in Japan usually focus on the

10 disorders addressed above. However, recently, acupuncture treatments are being increasingly reported for specific central nervous system neurological disorders, such as Parkinson's disease and cervical dystonia in which muscle tone increases pathologically.

d. Acupuncture Treatment for Neurological Disorders in Japan

Regarding acupuncture treatment methods in Japan for functional headache, including both tension-type headache and migraines, the treatment generally centers on acupoints and tender points of the neck and shoulders [18]. For Parkinson's disease, acupuncture points were selected based on visceral pattern identification, and the acupuncture session will also include points for local tenderness and induration[21]. For diabetic neuropathy, the needle retention method or electro-acupuncture generally utilizes distal extremity acupoints[12, 22]. Treatment for facial paralysis usually includes the 6 acupoints on yang channels of the face combined with peripheral acupoints of the upper extremities[13, 19].

5. Future Perspective

With the current development of medicine, we are seeing the era of a team approach in health care. Acupuncture was introduced from China in the 6th Century, and later developed as Japanese acupuncture during the Edo era; however, medical teams integrating acupuncture and other forms of medicine have not yet been realized. The medical system in Japan has only recently started to emphasize the importance of a team approach.

The development of clinical research without the consolidation of the team approach is impossible. That is to say, for conducting good clinical research, research team composed of more than several kinds of professionals, such as supervisor, physicians, clinical epidemiologists, statisticians, and others, are necessary, and good study designs are also needed. This type of research system was developed in Western countries, but has not yet been fully developed in Japan. Why have clinical trials of acupuncture not been well-developed in East Asian countries such as China, Korea, and Japan where acupuncture originated? It is because the team approach as seen in Western countries has not been practiced. Large-scale trials of acupuncture conducted in the West have been, as mentioned above, extremely precise, co-authored, and carried out by multi-talented teams of professionals from different fields. In addition, there is the possibility that because acupuncture and moxibustion developed gradually since ancient times in Japan, there was never any doubt about their clinical validity or effectiveness, so clinical trials did not develop. However, as a more significant factor, acupuncture was not considered appropriate in a hospital setting where large-scale trials conducted by qualified research teams took place, so acupuncture and acupuncturists were largely left unexplored and under-utilized.

Most clinical trials of acupuncture involving Japanese interventions include just low number and small-scale clinical trials on low back pain[23]. Considering international clinical trials for low back pain, relatively reliable evidence for the effectiveness of acupuncture is readily available. However, establishing evidence may not be desirable even for low back pain if the current research system in Japan does not change, being much less desirable for neurological disorders.

As mentioned above, high-quality, large-scale clinical trials are thought to be necessary to verify the clinical effect of acupuncture in Japan. However, we cannot have high hopes for the relevancy of acupuncture research in Western hospitals until an established system of team research develops, and acupuncture is used as a matter of course within that system.

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Clinical Report 1 (Acupuncture)

A Case of Acupuncture and Moxibustion Treatment for Insufficient Lactation Following Premature Birth

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【Introduction】

Obstetrics and pediatrics in Japan promote breast-feeding in infancy. "Breast-rearing" is defined as the promotion of infant growth through breast-feeding with breast milk (the mother feeds the infant directly from her own breast). Even if only a small amount of breast milk is fed to the infant, one can speak in this case of breast-rearing, but ideally the proportion of breast milk should be increased. On the other hand, "maternal feeding" refers to feeding breast milk to provide nutrition where administering mother's milk in other ways than direct breast-feeding also covers the definition of maternal feeding. This feeding form is called "maternal feeding" when the proportion of mother's milk is higher than 80%, while at a proportion of less than 20% it is called "artificial (bottle) feeding" and the range from 20% to 80% is labeled "mixed feeding". Accordingly, even if artificial feeding the proportion of mother's milk which is less than 20% still constitutes breast-rearing[1].

Yet, while in the "Investigation of infant feeding (2005)" conducted every 10 years by the Ministry of Health, Labor and Welfare[2] 96% of the pregnant women responded during pregnancy, that they would like to provide maternal feeding, three months after delivery 20% of the mothers did not breast-feed. Further, if the infant's suckling power is weak because of premature birth, making oral feeding impossible, breast-rearing will become difficult.

Here I will report in a case insufficient lactation following premature birth, where the administration of acupuncture and moxibustion treatment made breast-rearing possible.

【Case】

1. Profile

The patient was a 37-year old woman, height 159cm, weight 59kg, wishing mainly to improve the insufficient lactation after the birth of the second child. Asthma and buckwheat allergy were complications. The asthma the patient had been suffering from during her childhood had been alleviated, but recurred after the birth of her first child and can currently be controlled with inhalation twice daily of Pulmicort. The family history shows that her father had hypertension and her mother arrhythmia.

Following the 20th gestational week the patient took tocolytic agents 4 times a day and rested at home, but on the third day of the 35th week her waters broke and on the 5th day of the 35th week she gave birth to a 2210-g boy through vaginal delivery. Both mother and child were later discharged after the usual length of hospitalization.

2. Postpartum course

Since direct breast-feeding immediately postpartum was not possible as shown in Figure 1, she received breast-feeding instructions 30 days after delivery from the practicing midwife S and thus became able to directly breast-feed by the 42nd day after delivery. Also, because of insufficient lactation the patient received by the 61st day a breast massage from the practicing midwife S, but since this did not promote lactation as expected, she visited this clinic by the 81st day after delivery, asking to promote lactation because she strongly wished to provide maternal feeding.

3. Present status

The mother's abdomen on the whole lacked strength, in particular the area around CV4

appeared to be concavity, but the adequate tension of the mother's breasts and engorgement of blood vessels was not observed. Moreover, excessive tension of the neck and back muscles was observed. The infant on the other hand gained about 10g body weight during the week prior to the clinic visit and drank about 280ml of powdered milk, divided into 7 portions over the day. On an acupuncture and moxibustion examination I judged the condition of the mother being a deficiency pattern and recovery after childbirth being doing poorly. Also, the weight gain of the infant appeared to be insufficient. The amount of powdered milk for an infant of the given age of the moon of the first visit would have been 720-960ml, so that I judged the feeding to be mixed feeding with a ratio of 29.2%-38.9% of powdered milk.

4. Acupuncture and moxibustion treatment

The acupuncture and moxibustion treatment had the goal to improve the deficiency pattern of the mother, in other words recover from the fatigue of delivery and increase the amount of lactation. Based on the examination of the mother and the condition of her breasts the amount of powdered milk was decreased over several steps. At first visit I treated the stiffness of neck, shoulder and back muscles, using KI4, KI7, KI9, HT3, PC4, SP4, SP7, inserting needles to a depth of about 5 mm and retaining them there for about 12 minutes. I used 40-mm stainless steel needles with a diameter of 0.16mm (Seirin product). To improve the concavity around CV4, the lack of abdominal tension and promote lactation I applied moxa sticks at KI3, SP6 and CV17 until the lack of abdominal tension and concavity around CV17 had disappeared. I used the moxa sticks "SennenQ Bokyu (moxa sticks)" manufactured by Senefa. Also, I instructed the patient to apply these moxa sticks as self-care at home once or twice daily for about 5 minutes at KI3, SP6 and CV17.

5. Evaluation

I evaluated the following parameter: (1) concavity around CV4 and general abdominal tension as body surface findings, (2) improvement of shoulder and back muscle tension, and (3) the development of an appropriate tension of the breasts and engorgement of the blood vessels, set the weight gain of an average infant of 25-30 g/day as a target, and (4) decreased in the amount of powdered milk. Further, I had the patient weigh the infant's body weight at home and report back, upon which the amount of powdered milk was decreased over several steps.

【Results】(Figure 2)

The acupuncture and moxibustion treatment was performed a total of 5 times. Treatment interval was 3 days between the first and second session and after that once a week.

At the first visit the same amount of powdered milk of 280ml was used and the number of feedings per day decrease by 2 times from the 7 times.

Since at the second visit (3 days after the first visit) still neither an appropriate tension of the breasts and engorgement of the blood vessels nor any other changes in physical condition were observed, I repeated the same treatment given during the first session. From the second session the patient realized an until that point not present increase in lactation resulting in permeation of breast milk into her underwear and a daily weight increase of the infant of 35g. For those reasons the daily amount of powdered milk was decreased 7 days after the first visit to 200ml administered in sitting. Following the 13th day after the first visit, however, the amount of powdered milk administered per day was returned to 280ml, because the weight gain of the infant later fell short of the expectations.

On the fourth visit (17 days after the first visit) the concavity around CV4 had decreased in depth

and both a general increase in abdominal tension and an appropriate tension of the breasts and engorgement of the blood vessels were observed. Yet, because these improvements were still insufficient, the same treatment administered during the first session was continued. Also, the mother had observed her child without administering powdered milk, but since the infant's weight decreased, she administered 21 days after the first visit 160ml of powdered milk per day.

By the fifth session (24 days after the first visit) the concavity around CV4 had disappeared, the abdominal wall showed elasticity, the breast an appropriate tension and engorgement of the blood vessels. For this reason the treatment in this clinic was terminated and the patient instructed to continue the self-moxibustion at home. Even after the end of the acupuncture and moxibustion treatment the patient reported the body weight of the infant and continued to adjust the amount of powdered milk.

The amount of powdered milk per day was 38 days after the first visit 160ml and the infant gained about 25g weight per day. When the amount of powdered milk used per day was 140 ml the weight gain of the infant dropped to 18.6g, so that 52 days after the first visit the amount of powdered milk per day was returned to 160ml. The weight gain of the infant stabilized as a result of feeding 160ml of powdered milk per day. I concluded that the mother was capable of continuing the management independently and we agreed to terminate the treatment, but she would continue to feed the infant powdered milk once a day.

【Discussion】

Lactogenesis and lactatin are according to "Standard Science of Obstetrics and Gynecology"[3] a processes where "postpartum stimulation of the nipples by suckling releases prolactin, which then promotes lactation. The prolactin secretion is highest immediately after delivery and gradually decreases after that, but each time the nipples are stimulated temporarily increases again, resulting in the establishment of periodic lactation upon suckling by the ninth day postpartum independent of the prolactin or oxytocin concentration. After a 3-month postpartum period the prolactin value settles to the same level as in non-lactating women and even after suckling increases are no longer observed. Promotion of sufficient lactation requires adequate sleep, avoidance of mental stress and the performance of breast massage." On the other hand, the Ministry of Health, Labor and Welfare reported "Examination of fluctuations in the proportion of infant feeding methods (Figure 3) shows, that 1 month postpartum 42.5% used maternal feeding, 52.5% mixed milk feeding and 5.1% artificial feeding. Three months postpartum the ratio of maternal feeding had decreased by 4.4% to 38.0%, while the ratio of mixed milk feeding had fallen by 11.5% to 41.0%. However, the ratio of artificial feeding had increased by 15.9% to 21.0%. This indicates insufficient lactation and an increase of mothers not feeding the infants with mother's milk. It also reveals that during pregnancy mothers may wish to breast-feed their children, but during the lactation period this may in reality not work out so well.

In this case the patient took tocolytic agents during the pregnancy, but based on the premature delivery I surmise that her body was not ready to maintain the pregnancy until full term (from the 37th GW to less than the 42nd GW). Also, the first visit for acupuncture and moxibustion treatment was on the 81st day after delivery and the treatment was completed on day 103 after delivery. The condition of mother and breasts, the time of lactation onset had already reached the stage of non-lactating women, so that it can be anticipated that without treatment she would gradually have switched to artificial nutrition.

Searching for reports about insufficient lactation in magazines about Chinese medicine I found only one report about supporting lactation while hospitalized after full-term delivery by Fujiwara et al.[4].

Causes for insufficient lactation include (1) decreased lactation volume because of low milk production, (2) sufficient production, but problems with the milk discharge, (3) poor holding of the baby, (4) the infant cannot take hold of the nipple because of inverted nipples, or (5) there is a problem of how the infant suckles[5]. In the present case (1), (4) and (5) conceivably could have caused the insufficient lactation. Again, (6) decreased suckling drive, (7) suckling difficulties and (8) exhaustion of the mother may be factors impeding direct breast-feeding. Suckling difficulties include (a) malformation of the nipples (sunken, flat, hypertrophic hypotrophic), (b) anomalies of the breasts (breast tension, secretion), (c) medical conditions like cleft-palate), (d) functional factors like immature infant, low-birth-weight newborn and (e) medical factors[8]. The items (6), (8) and a., b. and d. applied in the present case.

Tatsunami et al. reported about the effects of combined Ringheaded thumbtack needles and breast massage[6], while Fujiki et al. reported about the effects on lactation in a SSP treatment group compared with an untreated group[7], where either of these reports had been limited to a period of one month from immediately after delivery. Yano used the following acupoints GV20, LU1, LU2, CV6, CV12, CV17, ST18, ST36, SP6, LR3, SI11, BL17, BL18, BL20[5], Tatsunami et al. used LU1, CV17, ST36 etc.[6], while Fujiki et al. listed LU1, ST18, CV17, SI11, GV12, LU10[7]. Common acupoints are LU1 and CV17, but the reports did not detail the reactions at the acupoints. In my case, however, I chose and treated CV17, because I felt a depression there (state of deficiency) upon palpation and also treated this point for postpartum convalescence of the mother. With the convalescence of the mother and disappearance of the depression at CV17 the mother started to provide maternal feeding and an appropriate tension of the breasts and engorgement of the blood vessels were observed. The acupuncture and moxibustion treatment promoted lactation in spite of the prolactin dropping to a level similar to that of non-lactating women. Achieving improvement of the postpartum exhaustion of the mother the treatment thus conceivably led to maternal feeding.

The first author has a license as a midwife and as such examined the condition of the mother and her breasts, adjusting the amount of powdered milk several times, but as Figure 2 shows, the infant did not reach the target weight gain line. Adjustment of the amount of powdered mild, not only in this particular case, may determine, whether the infant's weight gain will reach the expected level or not. Yano recommends that pregnant women should receive appropriate guidance from a midwife already during pregnancy. He recommends that the guidance by the midwife should be continued postpartum and a combination with acupuncture and moxibustion treatment would be desirable[5]. As Yano already pointed out, cooperation with the midwife during acupuncture and moxibustion treatment results in a still more appropriate treatment. Moreover, receiving acupuncture and moxibustion treatment already during pregnancy helps to prepare the expecting mother's body and may guide the women towards a normal delivery. A normal delivery reduces the physical burden and leads to a good start of the child rearing. Reducing the physical burden associated with pregnancy, delivery, child rearing by acupuncture and moxibustion treatment helps mothers to enjoy childcare and the author would like to recommend using acupuncture and moxibustion treatment for many pregnant women.

【Conclusion】

In a woman with insufficient lactation after giving prematurely birth in the 35th GW 5 acupuncture and moxibustion treatments starting on the 81st day after delivery and reduction in the amount of powdered milk made maternal feeding possible.

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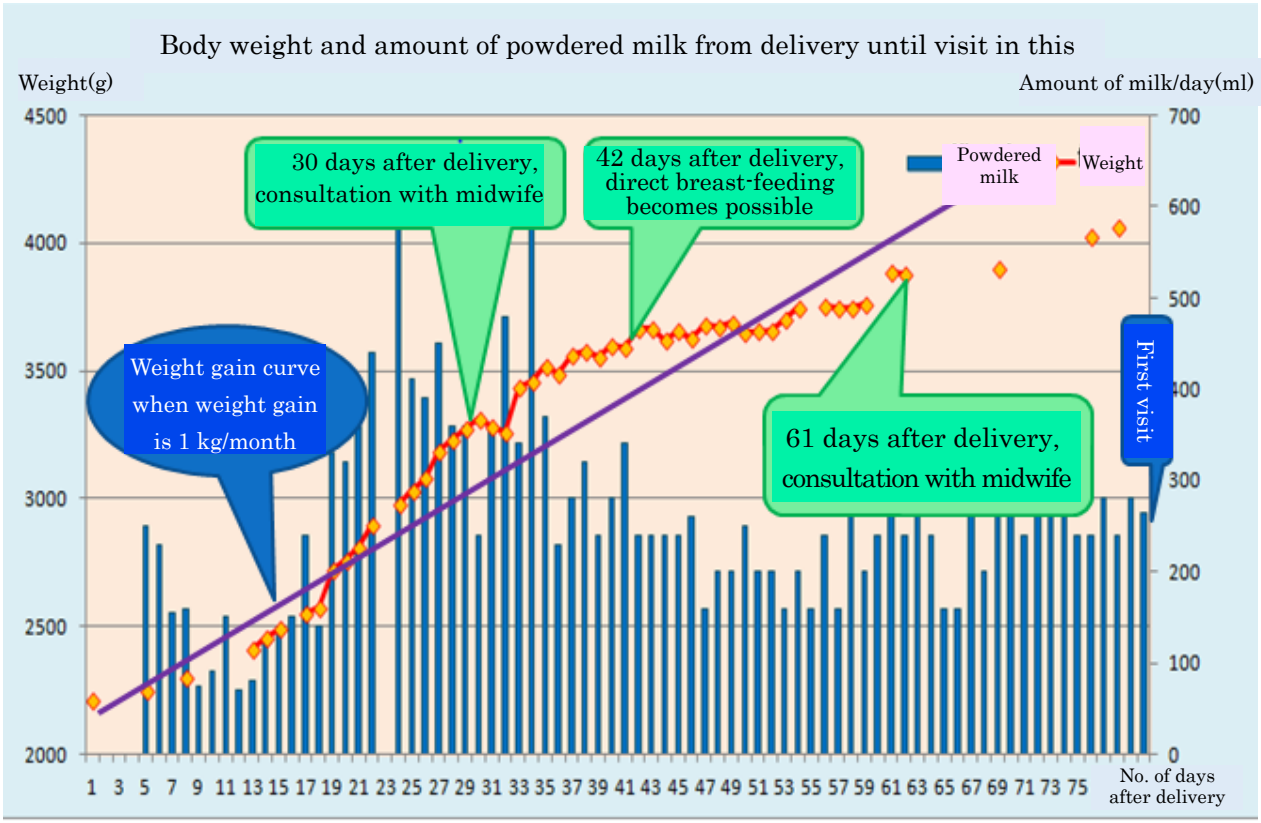


Figure 1 Present illness

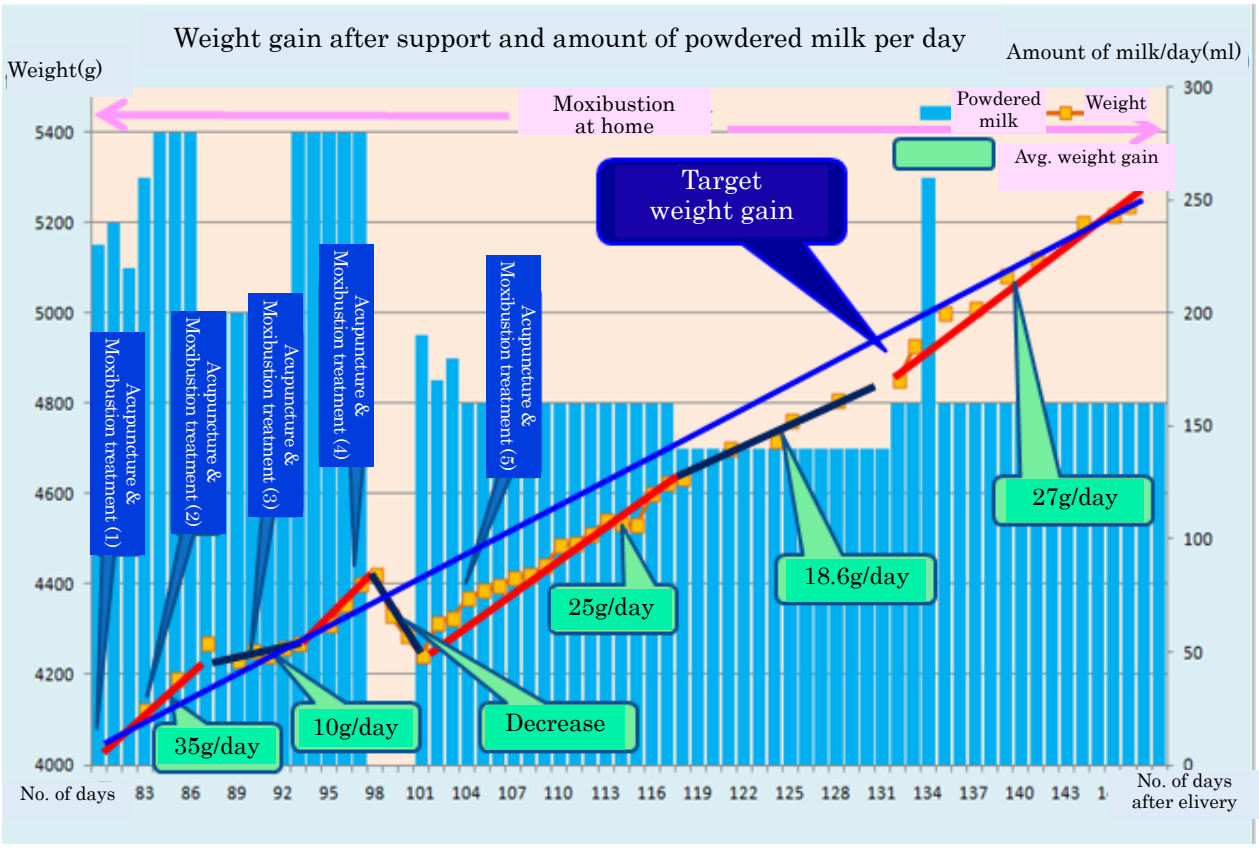
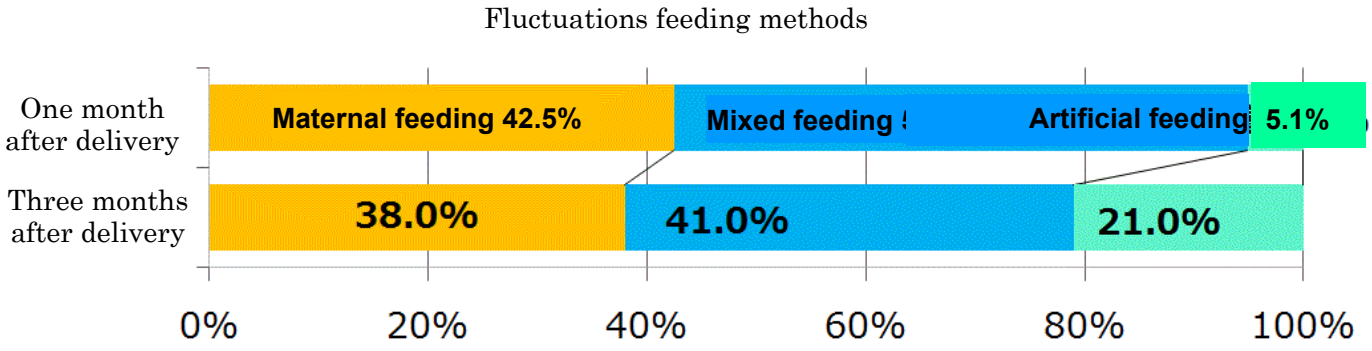


Figure 2 Course



Source: Ministry of Health, Labor and Welfare "Investigation of infant feeding in 2005"

Figure 3 Fluctuations in infant feeding methods

Clinical Report 2 (Kampo Medicine)

A Case Where Ryokyojutsukanto was Effective for Hyperactive Bladder

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The number of patients with hyperactive bladder, a pathological condition marked by pollakiuria and urinary urgency, is steadily rising in conjunction with the increasingly aging population in Japan. Therapy is based mainly on anticholinergic drugs or beta-3 adrenergic receptor stimulants, but the effect cannot always be described as sufficient, rendering treatment in many cases difficult. Further, while prescription of these western medications may cause an increase in residual urine volume after voiding and urinary retention, the use of Kampo medicines has the advantage of carrying a low risk of these effects, allowing the physician to use them unworriedly.

On this occasion I would like to present one case difficult to treat with western medication in which ryokyojutsukanto was effective.

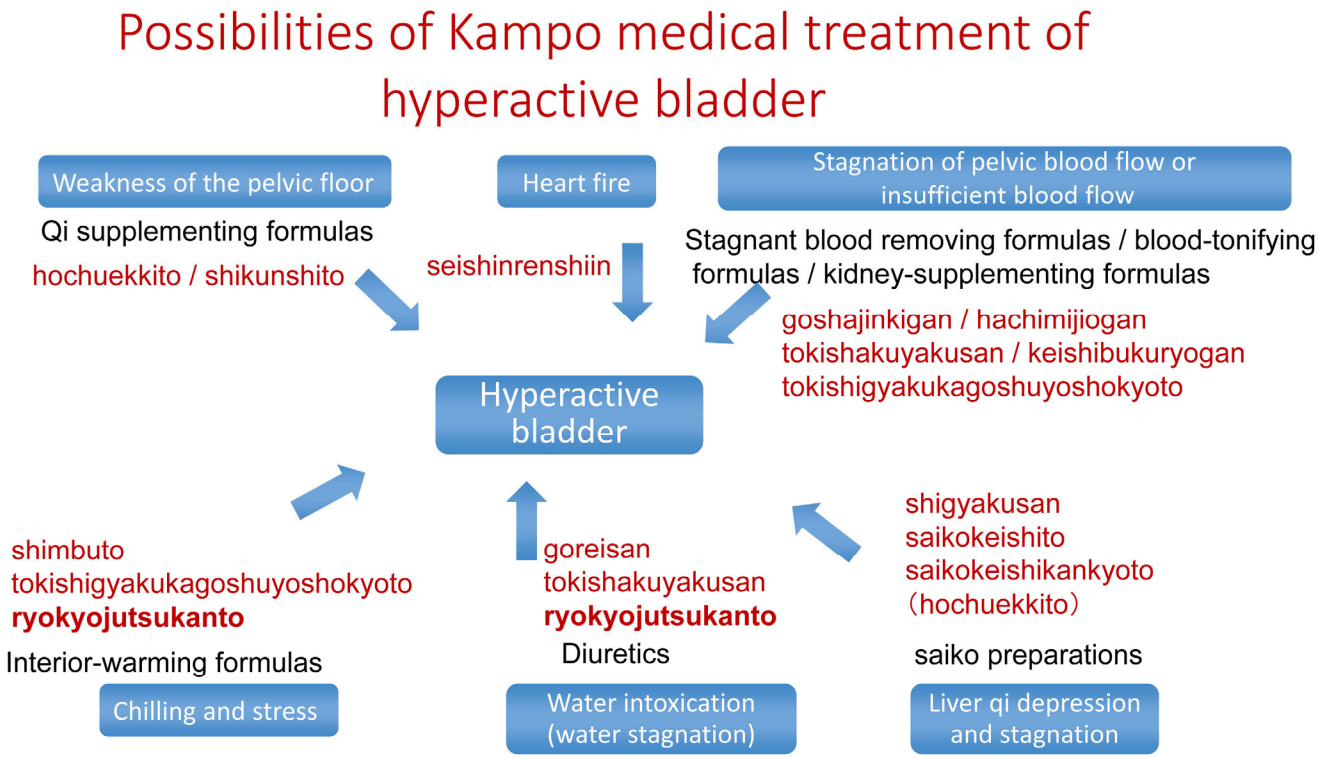
The patient was a 68-year old man. He has a history of diabetes, lipid anomalies and hypertension. In August of XXXX nocturia and urinary urgency developed for which he consulted the department of urology of another hospital. The patient was diagnosed with hyperactive bladder, but the prescribed anticholinergics (solifenacin, propiverine) were not effective. Even just hearing the sound of running water induced the desire to urinate. Low temperatures on November 11 of the same year causing an aggravation of the nocturia and urinary urgency/incontinence motivated the patient visited our department. At the time he visited our department he experienced urinary urgency/incontinence 2 to 4 times a day and the voiding frequency at night was 5 times. The overactive bladder symptom score (OABSS) was a total of 12 points and the residual urine volume following voiding 59 ml. He was of slender physique and had a violet-red tongue with dental impressions. Sublingual veins were only slightly engorged. The pulse was deep and choppy. On his abdomen only a mild degree of palpitations above the umbilicus were observed. He complained about chilling and weariness of low back and legs and his lower legs tended to become edematous in the evening. Based on these signs ryokyojutsukanto was prescribed. Without any increase in the residual urine volume following voiding the urinary incontinence disappeared after about one month and the OABSS improved by 4 points. The prescription was chosen to target not only the voiding related symptoms, but also accessory symptoms and proved to be effective in this one case.

Kampo medical interpretation of hyperactive bladder allows classification by several causes.

Weakness of the pelvic floor, stagnation of pelvic blood flow or insufficient blood flow, liver qi depression and stagnation, heart fire, water stagnation (water intoxication), chilling and stress are the main etiologic causes for hyperactive bladder and allow to understand the rationale for using the relevant formulas. In cases of weakness of the pelvic floor qi supplementing formulas like hochuekkito or shikunshito are used. For stagnation of pelvic blood flow or insufficient blood flow mainly formulas for overcoming blood stagnation like keishibukuryogan, hachimijiogan or tokishakuyakusan are used, or else kidney-supplementing or blood supplementing formulas. When the condition is caused by liver qi depression and stagnation Saiko preparations like shigyakusan are used, for water stagnation (water intoxication) goreisan or tokishakuyakusan and similar diuretics are used. For chilling or stress induced conditions interior-warming formulas like shimbuto or ryokyojutsukanto are used. It is important not only to identify the nature of pollakiuria and urinary urgency in cases of hyperactive bladder during interviews with the patient, but also focus on accessory symptoms.

Both the number of patients with urological diseases and the number of cases refractory to western pharmacological therapy are expected to increase. Skillful integration of Kampo medicines may possibly broaden the therapeutic spectrum. The author considers focusing not only on dysuria and urinary incontinence, but also accessory symptoms to be a shortcut to the selection of appropriate formulas.

ryokyojutsukanto: 苓姜朮甘湯
hochuekkito: 補中益気湯
shikunshito: 四君子湯
keishibukuryogan: 桂枝茯苓丸
hachimijiogan: 八味地黄丸
tokishakuyakusan: 当帰芍薬散
shigyakusan: 四逆散
goreisan: 五苓散
shimbuto: 真武湯



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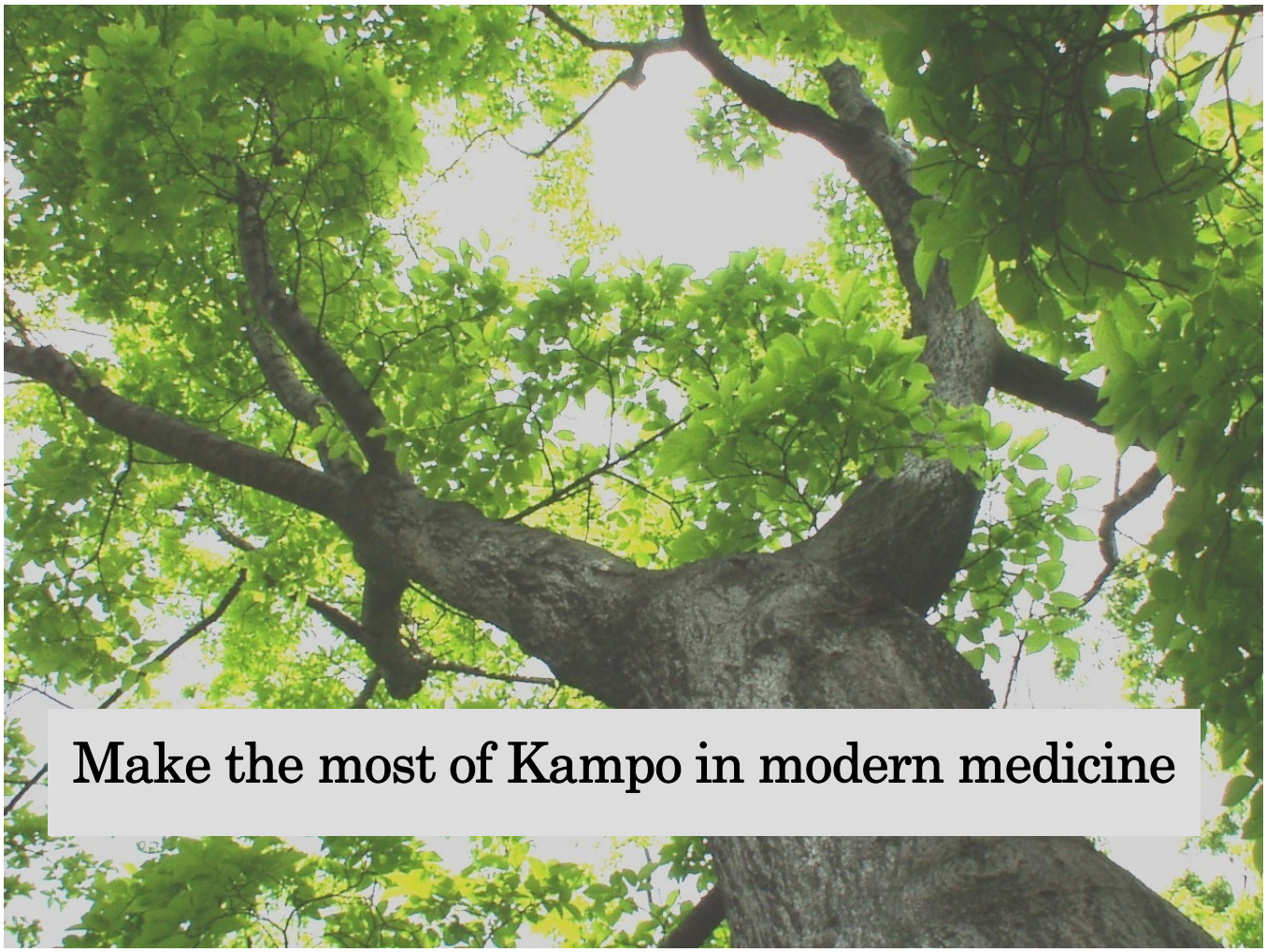

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