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Kampo Medicine - Current Research

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Prescription (4) XXXXXXXXXX Hiromichi Yasui

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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.

Foreword XXXXXXXXXXX

1.

Naoya Ono

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Japanese Acupuncture - Current Research

Reality of Japanese Acupuncture and Moxibustion - A Review of History of Acupuncture and Moxibustion System -

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1. Introduction

The conduct of "acupuncture and moxibustion" is medical care services or medical treatment to heal diseases or relieve symptoms in humans. With its roots going back to China, it is believed to have been brought to Japan during the period between 4th and 5th century. The "Taiho Code (Taiho Ritsuyo)" enacted in 701 expressly defined acupuncture and moxibustion as a medical system in the clause to diseases¹⁾. As civilization relating was progressing in the Edo period which was under the closed door policy, acupuncture and moxibustion made their own development independent from the original style and became a representative medicine of Japan referred to as Kampo medicine.

However, the new Meiji government established in the period of Meiji Restoration decided to adopt Western medicine (German medicine) as the official medicine of Japan and radically advanced the establishment of Western medical system and its education together with the enactment of "Healthcare System and Laws" in 1874 (Year 7 of Meiji). In the situation, it was generally thought that Kampo medicine died out and similarly acupuncture and moxibustion was extinct from the Japanese society. However, in 1886 (Year 18 of Meiji) the Meiji government officially permitted the operation of acupuncture and moxibustion as business under the supervision of the authorities. In 1911 (Year 44 of Meiji), the "act regulating acupuncture and moxibustion business" (Regulatory Rules), the first national ordinance, was established. Similarly its education system was permitted by the government²).

Thereafter, with rising health consciousness of the people, needs for acupuncture and moxibustion also increased. Then the outbreak of the Second World War devastated the surroundings of acupuncture and moxibustion. After the War, the GHQ's reform drove it close to the brink of extinction. However, the "banning" was avoided by the protesting campaigns of the people who had supported acupuncture and moxibustion medicine. In 1947 (Year 22 of Showa), the original Business Law concerning Japanese Traditional Massage, Finger Pressure, Acupuncture, Moxacautery, and Judo-Orthopaedy was established in the Constitution of Japan (Act No. 217 so-called AHAKI Law).

After the War, there were no major institutional changes and stable conditions continued. In 1988 (Year 63 of Showa), substantial amendments to the AHAKI Law were made for the purpose of improving the qualifications and quality of practitioners. And then and up until today, those who want to practice acupuncture and moxibustion are required to receive unified national examinations.

In China and South Korea where traditional medicine of each country is valued given the social background of individual countries, acupuncture and moxibustion is categorized under traditional Chinese medicine (physician of traditional Chinese medicine) in China and traditional Korean medicine (physician of traditional Korean Medicine) in Korea and is accepted equally to modern Western medicine.

In the United States, it has rapidly become popular since the 1970s' media report about acupuncture anesthesia and is now being positioned as a method of primary care. In European countries, people have begun to acknowledge the value. The world surrounding acupuncture and moxibustion has also begun to make dynamic changes along with the progress of integrative medicine.

In Japan of modern age, on the other hand, acupuncture and moxibustion is not regarded as medical practice in terms of institution but is regarded as "quasi medical practice or acts similar to medical practice," so that under the medical insurance of Japan it is not provided by way of "performance in kind" and the cost of the practice is non-refundable. Some medical sociologists call this medical system as a "half-institutionalized system"³⁾.

The modern history of Japanese acupuncture and moxibustion has many unclear points, like a kind of "black box." The main contributing factors, in the first place, may be that research environment has not adequately been cultivated and there are a limited number of researchers in Japan. There has been 100 years since the enforcement of the Regulatory Rules and it is a matter of urgency to dredge up facts being buried for these 100 years or rather about 150 years after the Meiji Restoration for verification.

2. Research background

2-1 Suggestions from medical sociology

Medical sociologist Prof. Junichi Sato, says about acupuncture and moxibustion: [Although "medical care with acupuncture and moxibustion" is legally bounded and regulated by "AHAKI Law," etc., its definition is made partially and very ambiguously in a polysemous and arbitrary way compared to modern medicine, and it is "institutionalized partially and to a limited extent" on the premise that modern medicine has been institutionalized in advance, so that it can be said that it is a half institutionalized non-modern medicine.] He further pointed out that [it exists as "one system for giving treatment" in the modern Japanese society and it functions as the second largest medical sector after modern medical care.] He suggests [the necessity of conducting medical sociological analysis of acupuncture and moxibustion practice from the institutional and structural points of view ³.]

2-2 Contradicting interpretations - inside or outside the medical system

Concerning acupuncture and moxibustion, the Ministry of Health & Welfare's understanding shown in the 50-Year History of the Ministry of Health & Welfare (50-Year History) published in 1988 is [...in view of the fact that Japanese traditional massage, etc. having a long history play a certain role in health care, four types of business including Japanese traditional massage (note by the author: acupuncture, moxibustion, Judo-Orthopaedy, etc. are referred to herein) are institutionally granted only outside the medical system⁴⁾.] Accordingly, in reference to the understanding of the Ministry that governs the nation's healthcare, the author has presented 'acupuncture and moxibustion' until now as a healthcare that is outside the healthcare system," which is like aniethesis, SUZUMURA, who was an official and a technical officer of the Ministry of Health & Welfare, and Mr. Teizo ASHIDA gave their interpretation of acupuncture and moxibustion in their co-authored book [Anma, Hari-Kyu, Jyudo Seifuku, nado Eigyou Hou no Kaisetsu] that [...that is to say, licensing referred to herein is the act of the nation which lifts a partial banning of medical business and those who have been licensed will be allowed to conduct a part of medical business within the range of individual business⁵).]

In short, from this interpretation, acupuncture and moxibustion was a "part of medical care" and placed "inside." Their interpretation was made almost in real time, no time lag from the establishment of the law. Moreover, this book carries the recommendation from Yutaro AZUMA. then Director General of the Ministry of Health & Welfare, at the beginning of the book. Forty years after Suzumura and Ashida published their interpretation, the Health & Welfare Ministry's understanding was expressed in printed form in the 50 Year History. It is no wonder that there might have been some arbitrary manipulation as the medical sociologist Jyunichi SATO said. In a sense, the institutional double standards were applied to official the standing of acupuncture and moxibustion in the Japanese society. And the author thinks it a problem that the level of awareness regarding the inside interpretation is low in the acupuncture and moxibustion world.

3. Consideration concerning the history of acupuncture and moxibustion legal system

3-1 Summary of changes in the acupuncture and moxibustion system

The major changes in the acupuncture and moxibustion system that were made during the period from the "enactment of Healthcare System and Laws" in 1874 (Year 7 of Meiji) (which was the Meiji government policy) to the current days are summarized in Table 1.

Since the decision by the Fukuoka District Court of 1998 for the "case of request for reversal of non-resignation of the training school of Judo-orthopaedic practitioners" (hereafter Fukuoka Court decision), vocational colleges have newly been established one after another and new departments have been increasingly set up, which, if not institutional innovations or restructuring, is a phenomenon reflecting the social conditions and a significant fact in the institutional history⁶).

Table 1 Summary of changes in the acupuncture and moxibustion system

1874 (Meiji era 7) Enactment of Healthcare System and Laws

 \rightarrow Principles of westernization of medical care of modern Japan, and prohibition of acupuncture and moxibustion practice outside medical care management

1885 (Meiji ear 18) Regulatory measures for acupuncture and moxibustion business (Interior Ministry's notification Ko 10-go)

 \rightarrow supervision was transferred to local governors

1911 (Meiji era 44) Regulatory rules for acupuncture and moxibustion business (Interior Ministry's notification Ko 11-go)

 \rightarrow Enactment of the first national law. Education system was explicitly described in statutory form for the first time.

1947 (Showa 22) "The business law of anma-massage, acupuncture, moxibustion and Judo-Orthopaedics, etc." (Law number 217-go referred to as AHAKI Law in shortened form)

 \rightarrow Passage of the bill after GHQ's reform challenges.

Later, the law was revised into the law of status "concerning anma-massage-shiatsu therapists, acupuncturists, moxibustionists, etc."

1988 (Showa 63) Major revisions were made to the AHAKI Law designed to enhance qualifications.

 \rightarrow The examination system in which examinations were held by prefectural governors was changed to the system of uniform national examinations.

3-2 An aspect of the acupuncture and moxibustion system in modern Japan

The Meiji Restoration was the transition period to the modern country from the period of shogunate and han (domain) system and to the era of opening up Japan. The Meiji government had the overriding imperative of joining the ranks of powerful advanced countries and was engaged in the country's modernization process with the slogans of cultural enlightenment, prosperous country and strong army. However, the domestic scene was devastating; the Boshin War broke out, then the Seinan War followed and a cholera epidemic was raging (Meiji 11).

When Sensai NAGAYO who took the office of Deputy General of Medical Affairs of the Education Ministry in 1873 (Meiji 6), he issued an order for nationwide investigations concerning health and medicine and submitted a draft medical law consisting 76 articles prepared based on the research results to the central government (equivalent to the present cabinet) in 1874 (Meiji $(7)^{7}$). The Law of Medical System and Laws was the Japan for guidelines to undergo drastic westernization and introduce Western ideas of healthcare as the modernized country. Article 53 of the law stipulated that the practice of acupuncture and moxibustion was only allowed in effect under a doctor's supervision. If this clause is viewed from a different angle, it may be said that the Law was the official document that recognized the existence of the people who were engaged in acupuncture and moxibustion as their business - the business of acupuncture and moxibustion was documented for the first time in the modern system of Japan. At the same time, this indicates the fact that acupuncture and moxibustion treatment was continuously being practiced during and after the period of Meiji Reformation. The Law of Healthcare System and

Laws did not have a strong binding and it is not a fact that acupuncture and moxibustion was controlled under the Article 53⁷).

In 1877 (Meiji 10) and onward, individual prefectures began to maintain statistical records of the number of practitioners who was doing the business of acupuncture and moxibustion in Japan. In 1885 (Meiji 18), the Internal Ministry issued the "Regulatory for acupuncture measures and moxibustion business" to prefectural offices. entrusting them to permit and regulate or control the business of acupuncture and moxibustion. In fact, the original intent and purpose of the law to place the practice of acupuncture and moxibustion under a doctor's supervision were not achieved. In the meantime, the Meiji government issued a government policy, ordering local governments to adopt the permission system in which they checked applications and evaluate gualifications of those who wanted to do the business of acupuncture and moxibustion and if qualified, issued permission.

Table 2 Number of acupuncturists and physicians in modern Japan

	Acupuncturists	Physicians
1887 (Meiji 20)	12,145	40,343
1897 (Meiji 30)	24,393	39,392

Prepared by the author based on the statistical data of NDL (National Diet Library) Modern Digital Library and data from 50-Year History of the Ministry of Welfare & Health. (The total number of physicians in 1887 includes 32,839 physicians who were traditionally on their own business. The total number of physicians in 1897 includes 23,596 physicians who were traditionally on their own business.)

The 12,145 acupuncturists of 1887 (Meiji 20) include those who started practice before the

notification of the "Regulatory measures for acupuncture and moxibustion business". After the notification, the number of acupuncturists steadily increased to 24,393 in 1897 (Meiji 30). The number of acupuncturists almost doubled during these 10 years, whereas physicians remained at the same level. It is more interesting to note that the number of the traditionally independent physicians focusing mainly on Kampo medicine decreased by about 9,000 in these 10 years. In other words, although the reduced number of physicians went into Western medicine, the number of acupuncturists increased.

In those days, Western medicine was not an easy access for the people of Japan from economic and limited institutional standpoints. With roughly 40,000 physicians of Western medicine, needs and demands for healthcare services from the people could not be met. In the situation, it may be said that acupuncture and moxibustion absorbed the unmet requirements. The Meiji government certainly kept a tally of the number of people who were engaged in acupuncture and moxibustion and regulated and controlled them. It can be gathered that because the government took a national policy of adopting Western medicine with the intention of Kampo medicine fading away, the Meiji government had to grant acupuncture and moxibustion as "business" instead of medical practice.

The momentum led to the establishment of the first nationa1911 (Meiji 44) ordinance of the "Regulatory rules for acupuncture and moxibustion business." Then the education system for acupuncture and moxibustion was put in statutory form for the first time and the acupuncture and moxibustion education stood at the dawn of a new era.

3-3 Westernization - Modern Japan's imperative

In line with the objectives of the "Medical System and Laws" of 1874 (Meiji 7), the Meiji government steadily carried out the modernization process by enacting decrees, in rapid succession, of the "Rules for the National Medical Practitioners Qualifying Examination" in 1879 (Meiji 12), "General Rules and Regulations for Medical Schools" in 1882 (Meiji 15), and "Regulations concerning Doctor Licenses in 1883⁸).

In formulating the acupuncture related law of "Regulatory measures for acupuncture and moxibustion business," no descriptions were made concerning matters relating to Western medicine in the regulatory. However, it is not correct to say that acupuncture and moxibustion was not involved in the westernization at all. Movements in concert with the westernization were seen.

In 1889 (Meiji 22), "Tokyo Shinkyu Chi Kai (Toyo Acupuncture Moxibustion Treatment Association) was inaugurated for the purposes of organizing an association for practitioners engaged in the business of acupuncture and moxibustion in Tokyo-fu and for the enhancement of their qualifications. The key persons in setting up the organization were Shouzou HIROSE and Genshi OKAMOTO who were doctors of the Imperial Household Ministry. The opening ceremony was attended by 1,500 people including Shokichi TAKE (medical officer of Tokyo-fu) who delivered a speech and Noritami KAWASAKI (anatomical physiologist of Medical School) who gave a lecture⁹⁾. After that, the association provided voluntary education in the form of lecture or speech through workshops of Western medicine in order to improve qualifications of practitioners.

When referring to the purpose of the enactment of the 1911 (Meiji 44) Regulatory Rules, Noda, who was then a technician of the Internal Ministry, expressed his opinion that it was necessary to urgently prepare school educational environment and its substantiation, and that it was important to conduct research to study mechanisms of acupuncture and moxibustion in the (Western) medical method¹⁰). The Regulatory Rules had the provisions concerning examinations for obtaining license/license tag for conducting the business of acupuncture and moxibustion. The examination subjects provided in the Rules were related to Western medicine such as "human body structure, functions of main organs, and relations between muscles and neurovasculars" and "synopsis of sterilization." It was the end of the Meiji era that Western medicine was also standardized institutionally in acupuncture and moxibustion.

4. Unrealized enactment of "Medical Law for acupuncture and moxibustion physicians"

With the establishment of the institutional system at the end of the Meiji period, acupuncture and moxibustion began to be recognized by the society. Then in the Taisho period, acupuncture and moxibustion also began to satisfy needs of the people with their increasing health consciousness. At the end of the Taisho era, "Shinkyu Ihou Kisei Doumei (Association)" was organized. Ryosai YAMAZAKI, an acupuncturist of Osaka, who was the main player for organizing the association, invited Ichiro KIYOSE (who was a lawmaker of the House of Representatives) as Adviser of the association. About lobbying activities and schemes of modern acupuncturists and moxibustionists in order to advance reforms through correcting institutional disparities and enhancing their status, the then "Nippon Shinkyu Zasshi (Journal of Acupuncture and Moxibustion of Japan) made detailed reports.

Table 3 From "Nippon Shinkyu Zasshi (Journal of Japanese Acupuncture and Moxibustion)" of the modern age

Nippon Shinkyu Zasshi Vo. 213 issued on September 10, 1921 (Taisho 10)

(Dainippon Shinkyushi Kai [Great Japan Acupuncturists and Moxibustionists Association])

[Legislatively, necessity of enacting the law of acupuncture and moxibustion physicians] Law maker of the House of Representatives, Lawyer, Bachelor of Laws-Ichiro Kiyose (Advisor of the association)

[Problems of the law of acupuncture and moxibustion physicians in terms of social policy] Law maker of the House of Representatives Kotaro Nakagawa (his background not known)

[Shinkyu Ishi-hou Ron (Discussing the Law of Acupuncure and Moxibustion Physicians)] Ryousai Yamazaki[Shigyousha toshite Shinkyu-I-Hou Hissu no Kaname (Necessity and Important points of the law of acupuncture and moxibustion physician as a person engaged in the business)]

[Problems of the law of acupuncture and moxibustion physicians viewed from the position of a physicist] Physician Kazumi Ishimitsu

Nippon Shinkyu Zasshi Vo. 247 issued on October 10, 1924 (Dainippon Shinkyushi Kai)

[Statement of the reasons for the petition concerning the enactment of the law of acupuncture and moxibustion physicians]

Nippon Shinkyu Zasshi Vo. 275 issued in March, 1927 (Dainippon Shinkyushi Kai)

[The petition concerning the law of acupuncture and moxibustion physicians passed both Houses] Ryousai Yamazaki

After the passage of the bill at the Lower House in 1923 (Taisho 11), no progress was made toward its enactment at the House of Lords and it was scrapped. Then, the "petition for the enactment of the law of acupuncture and moxibustion physicians" was re-submitted to the 46th Imperial Diet. Eventually it was not enacted.

As legal revisions and legislation were not realized, a series of processes are weathering. The author thinks it necessary for future development of Japanese acupuncture and moxibustion to verify the fact that is going to be forgotten by people.

5. Conclusion

In 1978, the two-year college of acupuncture and moxibustion was founded in Japan. And then the college became a university of four year system. Now there are nine universities of acupuncture and moxibustion in Japan, of which three universities have the master's program and one university has the doctoral program. Even so, no major changes have taken place in the social status of acupuncturists and moxibustionists during the period from the enactment of the post-war law No. 217 to the present. There may have been minor institutional changes in response to their request. Today 100 years have elapsed since the enactment of the nationwide ordinance of 1911 (Meiji 44), the author thinks that no dynamic changes have been seen in the relationship between the people and acupuncture and moxibustion.

In the United States, there are 60-70 schools of acupuncture and moxibustion (university or university graduate school), of which 60 schools are accredited as educational institutes for master's level programs by ACAOM (The Accreditation Commission for Acupuncture and Oriental Medicine)¹²⁾.

The United States brought acupuncture and moxibustion into the country 40 years ago and has rapidly arranged the education and system during these 30 years. This means that the United States has the environment in which an institutional position can be given and actually has been given to the method of treatment by adjustment/correction manual such as chiropractic and osteopathy and such method has been accepted culturally. It is obvious that the 1997 NIH statement created a momentum. Japan and the United States are guite different nations in terms of the social background, of course, and the healthcare system. However, what the author will be or is concerned about is dynamic movements between acupuncture and moxibustion and the people of the U.S.

Japan. which begun acupuncture and moxibustion practice much earlier than European countries and the United States, finds itself left behind in the world and is becoming shadowed under the influence of China. The underlying causes are lack of the base on which visions and strategies are planned and a manpower shortage. This may be contributed, in the author's opinion, by the ambiguous existence of acupuncture and moxibustion in the Japanese society.

The author thinks it necessary that the transitions Japanese acupuncture and moxibustion went through in about 150 years from the Meiji Restoration to the present be verified from the viewpoint of research. We urgently need to dig up facts that are still berried, observe unearthed facts, apprehend with philosophy and create the meaning.

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Kampo Medicine – Current Research

Effectiveness of Goreisan for Eliminating Brain Edema due to Intracranial Malignant Brain Tumors Akimune Hayashi, M.D. Department of Neurosurgery, Kanagawa Cancer Center Yokohama, Japan

ABSTRACT

Objectives: Hypertonic solutions and corticosteroids are widely used to eliminate brain edema complicated with malignant brain tumors. Their side effects, however, sometimes prevent them from long-term use. The author had tried to reduce brain edema with one of the traditional oriental medical prescription, Goreisan, which is well-known to promote diuresis and eliminate dampness, and to inhibit aquaporin 4 activity.

Methods: Since February 2003 to October 2010, Goreisan were prescribed to 60 patients (73 cases) with malignant brain tumors (male 33, female 27.24 through 82 years-old, mean 56.5). The efficacy were evaluated with subjective improvement level of symptom and neurological deficits: excellent (improvement rate 50%), good (improvement rate30~50% or medical decompression agents could be reduced by half and more),and no effect (improvement rate<30 %).

Results: Acceptable reliefs of their symptoms were obtained in 52 cases (71.2 %). There were no deteriorated cases. No significant complications were recognized.

Conclusion : Goreisan could be used as a substitute for hypertonic solutions and corticosteroids to eliminate mild to moderate brain edema.

Key words: goreisan, brain tumor, brain edema, aquaporin [Introduction]

Treatment of cerebral edema is a critical issue in the field of neurosurgery, and in effect, almost no advancement in its treatment has been made over the last several years.

Currently, medical reduce therapy to intracranial pressure in cerebral edema is limited to the use of two kinds of medicines, hyperosmotic diuretics and adrenocortical hormones. At least for these 30 years, new methods of medical treatment have not been introduced – this is the current situation surrounding cerebral edema. In practical clinical sites, except for D-sorbitol and D-mannitol injection solutions that are mainly used at the acute phase. concentrated glycerin/fructose injection solutions, Isosorbide liquid (oral), and adrenal corticosteroids (oral, drip infusion) are frequently used as diuretics. However. following hyperosmotic problems have been pointed out.

Specifically, it is the most problematic that concentrated glycerin/fructose injection solutions can only be used for drip infusions. Furthermore, under the present health-insurance system, the estimated usable period is defined, limiting to 2 weeks, or at most 3 weeks. For long-time use, special attention must be paid to water content and electrolyte abnormalities. Corticosteroids can be used either orally or intravenously and its effects are dramatic. On the other hand, its use is associated with increased susceptibility to infection. hemorrhage in the upper gastrointestinal and other various tract side-effects. So, there are many problems in the long-time use. And, ISOBIDE, an oral agent, is difficult to take because of its taste (thickly sweet/bitter) and it is in liquid form, which is a drawback in terms of convenience.

If pathological conditions of cerebral edema are observed from a Kampo point of view, it may be appropriate to recognize them as local water toxin. If so, appropriate diuretics should possibly improve it. In this report, the author takes up Goreisan (*Poria Powder with Five Herbs*), a representative Kampo diuretic prescription to examine its effects of improving cerebral edema and also reviewed the effects from the modern medical viewpoint to study to establish whether Goreisan can be used as an alternative drug to traditional intracranial decompression drugs.

[Case and method]

The subjects of the research were 60 patients, with a total of 73 symptoms, who experienced malignant brain tumor during the period of February 2003 to October 2010. Of them, 33 were male and 27 were female. Age 24-82 years old (average age 56.5). Brain tumors were divided into the following categories: primary brain tumor 18 patients (glioblastoma 8 patients, malignant glioma 5. primary malignant lymphoma of the brain 3, meningioma 1, and primary neuroectodermal tumor 1); metastatic brain tumor 39 (lung cancer 13, breast cancer 9, stomach cancer 3, kidney cancer 3, esophageal cancer 2, large intestine cancer 2, and 1 each of pancreatic cancer, bladder cancer, ovarian cancer, thyroid cancer, hepatic cancer, malignant melanoma, and nasopharyngeal cancer); delayed radiation necrosis of the brain 3.

Symptoms were those of increased intracranial pressure, such as headache nausea and vomit in 31 patients, and focal neurological symptoms in 54 patients (some patients had multiple symptoms).

Goreisan used in the research was TSUMURA Goreisan Extract Granules (2.5g/pack). manufacturer Tsumura Co., Ltd. The patients who had been clinically judged as having increased intracranial pressure from the beginning, to such levels that required the administration of hyperosmotic diuretics and adrenocortical hormones were excluded from the subjects of administration. And administration was made to cerebral edema of the Western medical disease name, regardless of Kampo medical sho.

After patients were explained that there was "edema" in the indications of Goreisan covered by the health insurance system, 3 packs/day were given to them according to the defined usage instructions. In the case there were insufficient improvements in symptoms, Goreisan was quickly changed to steroids or other cerebral decompression therapy.

Effects assessment was made based on subjective improvements in the symptoms of increased intracranial pressure or neurological symptoms with the overall ratings: Markedly improved (50% or more improvement); effective (30% or more improvement - less than 50%, or the concomitant cerebral decompression drug was reduced to half or discontinued.); ineffective (less than 30% improvement).

[Results]

Improvements were observed in 52 symptoms (71.2%): Markedly improved in 19 (26.0%), effective in 33 (45.2%), ineffective in 21 (28.8%). In the patients that had no improvements, some had also no effects of steroids. With the focus on headache (31patients), improvements were observed in 26 (83.9%): markedly improved in 11 (35.5%), effective 15 (48.4%), and ineffective in 5 (16.1%), became worse -nil. In the patients with favorable responses, the effect appeared quickly, at the latest within several days. In addition, there were no side-effects of Goreisan.

[Representative case]

A case of effectiveness (Fig. 1). 52 year-old female with metastatic cerebellar tumors caused by lung cancer. As obstructive hydrocephaly was imminent, there were headaches, nausea and vomiting, and ataxic gait. From the imaging findings, most physicians conceivably might opt for the decomposition therapy of cerebral pressure. In this case, however, Goreisan (TJ17) 7.5g and Saireito (*Minor Bupleurum Decoction*) (TJ114) 7.5g were used in combination and symptoms of above were relieved. The parallel use of these prescriptions was intended for double dose administration of Goreisan.

A case of ineffectiveness (Fig. 2). Left side: 66-year old female with metastatic brain tumors caused by lung cancer. Left-sided hemiparesis was present. No improvements in neurological symptoms were made with Goreisan because the motor area was directly damaged.

Right side: 82 year-old male. Due to metastatic brain tumors by large intestine cancer, agnosia was present. Goreisan was not effective. Oral steroids were also not effective. The factors contributing to ineffectiveness of Goreisan were as follows:

1) The tumor size was large,

2) Tumors grew quickly,

3) The formation of associated brain tumors was fast,

4) This is the case in which the volume of associated cerebral edema was assumed to be small. This was especially evident in tumors developed in the area with a small capacity having scarce space for buffering intracranial pressure, such as the posterior cranial fossa. In the case in which a tumor directly caused neurological deficits, as a matter of course, no improvements in nerulogical symptoms were observed and no steroids were effective.

[Consideration]

In the description of Goreisan in Shang Han Lun, there is the following sentence: Goreisan is mainly used for the symptoms of wind stroke associated with attack of fever, which do not resolve for 67 days and the condition being still severe with exterior and interior symptoms, becoming thirsty and craving for water, and upon drinking water, vomiting like a continuous fountain. This sentence is often referred to when explaining gastrointestinal symptoms. When wind stroke, heat sensation, vomit are viewed from the stand point of cranial surgery, it can be realized that they are similar to headache, disturbed consciousness, and vomit attributable to the symptoms of increased intracranial pressure. In the days the Shang Han Lun was written, it is quite unlikely that there was a pathological concept of "symptoms of increased intracranial pressure." There was, however, a good likelihood that Goreisan was used based on the diagnosis of signs and symptoms. And, there is a published article that our Japanese leaders have already used Goreisan at the dawn of brain tumor treatment¹⁾.

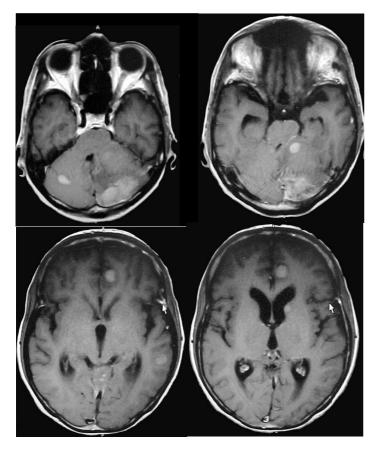


Figure 1

A case of effectiveness. 52 year-old female with metastatic cerebellar tumors caused by lung cancer.

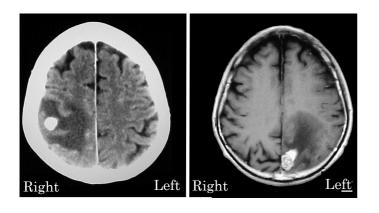


Figure 2

A case of ineffectiveness. Left side: 66 year-old female with metastatic brain tumors casued by lung cancer. Right side: 82 year-old male. Due to metastatic brain tumors by large intestine cancer, agnosia was present. Oral steroids were not effective.

The treatment of symptoms of increased intracranial pressure complicated by cerebral edema is essential for treating not only brain tumor, head trauma. and cerebrovascular disorder. Urea, 50% hypertonic glucose, and various diuretics used at the early stage as pressure lowering drugs have faded out because they have an advantage of exhibiting a strong action of lowering intracranial pressure and a disadvantage of re-elevation of intracranial pressure as a rebound phenomenon. Hyperosmotic diuretics and adrenocortical hormones are two best drugs among those currently used to lower intracranial pressure. As mentioned in the foregoing, however, there are many constraints on use and side-effects, so they might not be ideal drugs.

In the meantime, Oriental medicine defines cerebral edema as a localized water toxin, so that the "water draining" method may possibly be applied. Goreisan, one of representative diuretics²⁾³⁾ for draining water is highly safe for use and quite different from diuretics of Western medicine in the properties that it hardly causes the local incidence of electrolyte abnormalities although it exerts the action of locally adjusting the water balance, and furthermore it has the least risk of evoking the state of dehydration⁴⁾.

The effects of Goreisan on cerebral edema complicated by intracranial malignant brain tumor were studied this time and as a result, the overall improvement rate was 71.2%. About the improvements limited to headaches, the result was 83.9%. The overall improvement rate of 71.2% is not a bad value as direct neurological damages cannot improve even if cerebral edema has resolved. Although a selection bias occurred in choosing subjects for testing treatment in this research, Goreisan should be sufficiently worthy of being chosen as one of cerebral depressants, if taking into account all of intracranial malignant tumors of each subject, the condition of complicated cerebral edema and the symptoms of elevated intracranial pressure, and the neurological symptoms.

Pharmacological functions of water draining of Goreisan are still under the process of elucidation, but in recent years, its reaction against aquaporins (AQO) known as water channels is attracting attention⁵⁾⁶⁾.

It was reported in 1990 that AQPs, which are membrane proteins, are selective allowing only water molecules to passively move without accompanying the movement of electrolytic ions⁷). There are thirteen types of known or identified AQPs. The expression of AQP1^{3,4,5,8,9,11,12} in the brain has been verified. Major AQP subtypes are two types of AQP1 and AQP4⁸⁾. AQP1 water channels are localized mainly in the choroid plexus epithelia. However AQP4 water channels mostly located in the central nervous system are abundant in the subarachnoid cavity, ventricles of the brain, and neuroglia cells close to cerebral blood vessels. They are deemed to be deeply involved in water metabolism of the brain. For the reason, the study of AQP4 has now most advanced⁹⁾.

Factors attributable to cerebral edema are classified into five types, vasogenic, cytotoxic, osmotic, hydrostatic, and interstitial. Major factors are vasogenic and cytotoxic. The most common type of cerebral edema caused by brain tumor is vasogenic edema occurring when the blood-brain barrier is broken or lost.

According to the results of an animal experiment using AQP4 deficient mice¹⁰, AQP4

works to protect cells against a cytotoxic type of cerebral edema, whereas it aggravates cerebral edema against a vasogenic type of cerebral edema. In other words, AQP4 promotes the inflow of water into cells in cytotoxic cerebral edema, whilst it promotes the excretion of water in vasogenic cerebral edema. In actuality, it is known that the expression of AQP4 is augmented in the perivascular glial end feet, which are the important element to form the blood-brain barrier, in pathological conditions of malignant tumor, trauma, cerebrovascular damages, and water toxin that cause the formation of a vasogenic cerebral edema. So, it is assumed that AQP4 re-absorbs extracellular fluids. functioning toward relieving cerebral edema. In fact, in malignant glioma, the expression of AQP4 significantly increases in the tumor itself than in the area of tumor infiltration, i.e. the area of tumor periphery, and a correlation seems to exist between the extent of tumor formation and the extent of edema formation¹¹⁾. In this way, it seems that although AQP4 has bilateral characters of edema formation and edema relief, there are still many unknown points about AQP4. At the moment, however, it is expected that inhibiting the functions of AQP4 could lead to diminishing cerebral edema¹²⁾.

In regard to AQP1, its expression increases in the cytoplasm in malignant glioma. The levels of the expression are related to the degree of the malignancy and the expansion of the edema area the tumor periphery. There is on а documentation¹³⁾ reporting that although in metastatic cerebral tumor, AQP1 does not express in the tumor, its expression increases in the tumor area on the tumor periphery. On the basis of this report, AQP1 inhibitors may have the possibility of becoming a new method of treatment for cerebral edema complicated by malignant cerebral tumor.

It has been reported that, of the crude drugs (Arisma composing Goreisan Rhizoma, Polyporous Schlerotium, Atratylodes Lancea Rhizoma, Tuckahoe, and Cassia Bark). Polyporous Schlerotium, Atratylodes Lancea Rhizoma, and Tuckahoe have the effect of inhibiting AQP4 and control concentration-dependent water permeability of cell membraines¹⁴⁾¹⁵⁾. In all the subject patients of this time, conditions did not become aggravated in association with the use of Goreisan. At least, it does not seem likely from this result that the inhibitory action of Goreisan on AQP4 works for promoting brain edema. Therefore, Goreisan can be considered to have the possibility of being used safely as an AQP4 inhibitor and is expected to function to reduce cytotoxic edema in tumors as well as vasogenic edema in the area of tumor periphery.

For the future, measures to enhance its clinical effectiveness must be taken. Japanese extracts contain lower volumes of crude drugs compared to the decoctions of Traditional Chinese Medicine, so it is hard to avoid thinking that the medicinal efficacy of Japanese extracts will be relatively weak. Therefore, it should be considered in the extract-based daily treatment to increase the dosage or combine Choreito (Umbellate Fungus Decoction) or Bukuryoin (Tuckahoe Decoction) in order to increase the volume of Polyporous Schlerotium, Atratylodes Lancea Rhizoma, and Tuckahoe. The use of Saireito (Minor Bupleurum Decoction) that could induce endogenous hormones is worthy of being considered as a combination drug with Goreisan and steroids.

[Conclusion]

Goreisan can be applied as a therapeutic drug and as an alternative medicine to oral drugs of Western medicine, such as steroids and Isobide for cerebral edema complicated by malignant cerebral tumor.

Since Goreisan is easy to use for a long period and evokes mostly no abnormalities of water and electrolyte balance, it should be considered as one of depressants for elevated intracranial pressure.

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Clinical Report 1 (Japan)

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Introduction

Jizusoippo is a formula created in Japan. It is comprised of 9 crude drugs and indicated mainly for swellings of the epidermis (to dispel dampness) and improvement of blood flow (activate blood) and acts to improve the skin condition (clearing heat and removing toxins). As stated in the introduction by Yasui it is often used as a formula specifically for skin diseases like atopic dermatitis or seborrheic dermatitis. On this occasion we would like to present a case of recurrent folliculitis refractory to western medical treatment, where diet, lifestyle guidance and treatment with Jizosoippo led to improvements.

The patient was a 19-year old male.

Chief complaint: recurrent folliculitis

The anamnesis of the present illness showed, that dying his hair in October during his third year in senior high school led to the development of a large swelling on his head. The lesion reached the size of a golf ball and its contents was aspirated by a local physician. This was not a malignancy, but he was nevertheless referred to a university department of dermatology. He was diagnosed with multiple folliculitis.

According to his mother, the above mentioned swelling developed by the time, the admission to a university had been settled. Later, the patient tended to stay up late, indulged in an unbalanced diet and neglected his health. Even after consulting a university department of dermatology exacerbations recurred and because the condition did not show any signs of improvement, he was referred in August of the following year to the Department of Japanese and Chinese Medicine of the Chiba University Hospital. At the time he came for consultation there were protuberant folliculitis lesions on the head with oozing exudate. They were particular marked at the frontal hair line, the back of the head and on the vortex (photo, at the time of visiting our clinic).

Prescription from the dermatology department: Achromycin, Caslon, Antebate lotion

Items of the anamnesis

- dry mouth, marked spontaneous sweating
- meat centered diet
- constipation (once every few days, feeling of residual stools)
- dizziness: history of vagal reflexes, occurrence of syncopes
- micturition: Micturition desire triggered by tension. High urinary frequency

Kampo medical examination

The pulse was in between the deep and superficial layer, of intermediate size and strength.

The tongue had a slightly dark red shade, was a little enlarged, showed no teeth marks and was markedly moist with a white coat; sublingual veins were slightly engorged.

Abdomen: intermediate abdominal strength, mild tension of the rectus abdominis muscle, presence of tenderness to the left and right of the umbilicus.

Based on the above findings of eczema above the neck, a condition between deficiency and excess, mild degree of blood and water retention and constipation, we used only Jizosoippo. During the next visit 2 weeks later the flares had decreased to about half their original scope and the itching showed a decreasing tendency too.

After treatment over a period of 3 months, the forehead lesions had disappeared and a decrease in papules on the back of the head and its vortex was observed (photo 2).

According to the patients wish the treatment was continued over half a year and then terminated because of improvement.

Profile – Jizusoippo (Hodokubenkai)

The formula Jizusoippo was created by Futei Fukui in 1725-1792 and its contents later slightly modified by Asada Sohaku to become the formula used today. Its naming suggests, that it is a "formula to treat eczema of the skull", but today it is used for skin diseases everywhere on the body. It carries the nickname *Major Szeshwan Lovage and Rhubarb Decoction*.

The formula has the following composition.

- 3 g of Cnidii rhizoma
- 3 g of Atractylodes lancea rhizome
- 3 g of Forsythia

2 g of Ledebouriellae radix

- 1 g of Glycyrrhiza
- 1 g of Nepeta japonica
- 1 g of Safflower
- 0.5 g of Rhubarb
- 2 g of Lonicera japonica

[Efficacy] Expels wind and activates blood, clears heat and remove toxins, expels dampness [Main indication] Wind -dampness, heat toxin

[Explanation of the formula]

Nepeta japonica and Ledebouriellae radix disperse wind evil; Atractylodes lancea rhizome and Ledebouriellae radix remove dampness; Cnidii rhizoma activates blood and at the same time supports the free coursing function of the liver and in conjunction with Atractylodes lancea rhizome dispels the wind evil from the blood. Forsythia, Lonicera japonica and Glycyrrhiza clear heat and remove toxins, and together with Rhubarb cool and remove heat toxin from the blood. Safflower in conjunction with Cnidii rhizoma and Rhubarb alleviates blood stagnation and prevents evil from remaining in blood. The combination of the ascending properties of Cnidii rhizoma and descending properties of Rhubarb ensure a balance of the ascending and descending properties.

Clinical Application

This formula is used specifically for skin diseases. Originally it was used for infants with eruptions on the skull, secretions, itching and eschar. While it is currently used not only for eruptions on the skull, but anywhere on the body, also in adults, its application is not surprisingly particularly high for eruptions on the skull or the face. It is particularly frequently used for cases with atopic dermatitis, so that research has been carried out regarding this indication. The Rhubarb in this formula may not be necessary for people with daily regular bowel movements, but the addition of a small amount of Rhubarb probably gives better results.

1. Atopic dermatitis

Otsuka Keisetsu (1900-1982) was the first person to use this formula for the treatment of atopic dermatitis. The historical record mentions that in 1970 this disease was rare and there were only few refractory cases. Like for example as follows.

The patient was a 5-year old boy. Shortly after birth eczema developed and he received various treatments, but because the condition failed to improve he was brought to consultation. Most of the lesions were located on the arms and neck, as well as on the medial side of the knees. He caught easily cold, which then led to a congested nose and his voice tended to get hoarse. Occasionally there were nose bleedings. Appetite varied extremely and was not constant. He drank plenty of water. One bowel movement per day. After 2 weeks of treatment with Jizusoippo the skin became smooth and almost all of the eruptions had receded. After continuing the medication for another 4 weeks the eruptions had disappeared without a trace¹⁾.

Later, physicians inspired by this case used the formula for the treatment of atopic dermatitis and thus accumulated relevant clinical experience. A number of case reports or case series studies has been submitted. Seki et al. reported a case of a 55-year old woman with adult atopic dermatitis. By the age of 40 erythematous patches associated with pruritus and desquamation developed in this woman on the face and were treated by a local physician with topical steroids, but because neither this resulted in complete recovery nor did similar treatments in several other clinics led to any remission and a topical steroid induced rosacea-like dermatitis developed as a complication, Kampo treatment was initiated. After the patient had been treated with Shosaikoto (Xiao Chai Hu Tang) for 6 months, the condition had healed almost completely²⁾.

Yamamoto et al. evaluated the results after treating 36 patients with adult atopic dermatitis with Jizusoippo (7.5-15.0 g) over a period of 4 or 8 weeks and reported marked improvements in 9 patients (25%), improvements in 8 patients (22.2%), mild improvements in 10 patients (27.8%) and no changes in 9 patients (25%)³.

Cases where atopic dermatitis is associated with bronchial asthma often receive a combination therapy with Makyokansekito or Shoseiryuto. Otsuka mentioned that addition of Ephedra and gyps to Jizusoippo improves not only the eczema but also the asthma4).

Some cases of atopic dermatitis also respond to Eppikajutsuto. That is because the combination of Ephedra and gyps can dispel damp heat. Even in cases without asthma the combination of Jizusoippo and Makyokansekito can achieve similar results.

Ito reported the markedly effective treatment of a 1-year old girl with atopic dermatitis using a combination of Makyokansekito and Jizusoippo⁵⁾.

2. Seborrheic eczema

Jizusoippo has originally been developed for the treatment of pediatric seborrheic eczema. Today this disease can quickly be alleviated through topical application of steroid ointments, but in former times there was no really good treatment.

When Otsuka used Jizusoippo for a 4-year old girl in whom shortly after birth erythematous lesions developed on the head and face, who complained of pruritus, formation of thick scabs from which serum oozed out if they were removed only to form new scabs, the pruritus was alleviated after about 10 days and after about 40 days the condition had completely been cured. Administration of the same formula over a period of 2 months following a recurrence again led to a complete recovery⁶. This was in 1953.

The number of physicians using this formula for seborrheic eczema in infants increased after the publication of this report. I will cite a case report from Yakazu.

The patient was a 4-month old girl. One and a half month after birth apparently itchy erythematous lesions developed on the head, that were associated with copious secretions and the skin started to peel off. The regions affected gradually increased in size and by the time of the first consultation had spread to the back, the entire abdomen and buttocks. At a department of dermatology the condition was diagnosed as pediatric seborrheic eczema and treated, but did not improve. Following administration of Jizusoippo half of the erythematous lesions disappeared after about one month, 2 months later approximately 80% had healed and after 3 months the condition had healed almost completely. Since the administration of the drug appetite increased, the infant gained weight and got well⁷⁾.

This formula is currently also used for adult seborrheic eczema. It is indicated for erythematous lesions developing on the head and face.

Yamamoto et al. administered this formula to 10 patients (adults) with seborrheic eczema and reported a marked improvement in 3, improvements in 2 and no changes in 3 patients³⁾.

3. Furunculosis

This formula is often effective for the treatment of erythematous lesions of the head, regardless of the diseases causing them.

A dermatologist referred a middle-aged man with furuncles continuously developing on the head non-responsive to treatment with antibiotics to Terutane Yamada, who advised the patient to take this formula. After about 1 months of administration the patient had almost completely recovered⁹⁾.

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Clinical Report 2 (Japan)

Modified Merry Life Powder was Effective for a Patient having Vomit Mihoh Koga, M.D., Kampo Specialist Research Assistant of Division of Clinical Pharmacology and Therapeutics and Division of General Medicine Jikei University School of Medicine

[Case] Female of 16 years old

[Chief complaint] Epigastric abdominal pain and nausea

[Past medical history/family history] No particular mention

[Current medical history]

Two days ago, she had a discomfort itching sensation in the epigastric region and then nausea appeared. Vomiting started at the night. On the following day, vomiting did not stop and she made a visit to the psychosomatic medicine of a nearby hospital, where she received psychotropic agents and anti-anxiety drugs. At nightfall, vomiting stopped. However, epigastric abdominal pain and vomit were not relieved and she visited our department.

Similar symptoms had appeared sometimes since she was 12 years old. The symptoms tended to develop when she was tired or the abdominal area became cold. Once developed, the symptoms persisted for two days to one week. Examinations at other hospital revealed no abnormalities.

[Present condition]

Inspection: Moderate body frame. Tongue: with white furs.

Inquiry: She claimed that usually she had appetite and the gastrointestinal condition was good.

Defecation was regular /once a day.

Urine amount was a lot.

Limbs became cold and easily frostbitten.

Easily caught a cold. Although a high

fever did not develop, the condition was painful.

Menstruation tended to be delayed with menstrual cramps.

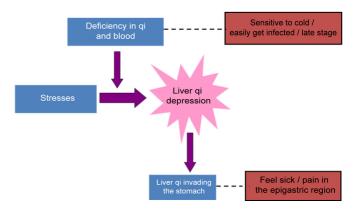
Palms were sweaty.

Good sleep.

Did not get irritated.

Palpation; Pulse – floating, string-like, and fast.

Abdomen – the entire abdominal region was hard, abdominal rectus muscles on both sides were tense with stuffiness and rigidity below the heart, and tenderness in the right para-umbilical region.



Prescription:TSUMURA24KamishouyousanExtract Granule5.0g/2 x

Kamishouyousan (Pharmacopoeia of Ancient China)

Bupleurum Root 9.0 (3.0), Atractylodes Ovatae Rhizoma 9.0 (3.0), Wild Mint 1.0 (1.0), Roasted licorice root 4.5 (1.5), Japanese Angelica Root 9.0 (3.0), Tuckahoe 9.0 (3.0), Cape Jasmine 3.0 (2.0), White peony 9.0 (3.0), Ginger 3.0 (1.0), Tree Peony Bark 3.0 (2.0)

Efficacy: Activation of the flow of liver-qi and elimination of its depression, harmonization of the blood, and purge of fire.

Major indication: Liver-qi depression with blood deficiency and transformation into fire.

Course:

Two weeks later, she could take the medicine.

The day after the start of the internal use of the medicine, abdominal symptoms disappeared. The patient became able to sleep well. She was aware that the prescription was appropriate for her.

String-like pulse. There were fullness in the chest and hypochondrium on both sides, tension in the abdominal rectus muscles on both sides, tenderness in both para-umbilical regions, and lower abdominal numbness. The same prescription was maintained.

Two months later, stomachache developed before the menstruation cycle began. Although nausea occurred resulting in vomiting, the condition recovered quickly. The tongue was dark red. There were fullness in the chest and hypochondrium on both sides, tenderness in both para-umbilical regions, and lower abdominal numbness. The same prescription was maintained. Four months later, she was well. Menstrual cramps were becoming eased. Hands were still cold. Fullness in the chest and hypochondrium resolved.

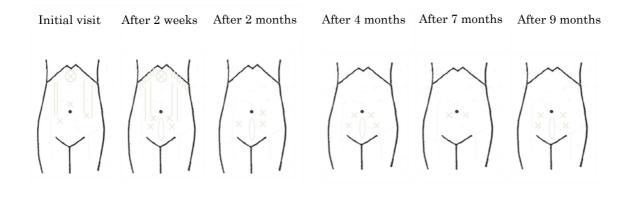
She was instructed to adjust the dose amount to 2.5-5.0g/day based on the extent of coldness.

Seven months later, she was in good shape with the use of 25g of the medicine before sleep. If she forgot to take it, a sense of discomfort appeared.

The diagnosis of the abdomen revealed only mild tenderness in the para-umbilical regions.

Nine months later, she was feeling well and stopped the use of the medicine. Then she vomited at a night, so she took the medicine. In the following morning, nausea and vomiting resolved. Recovery became fast.

One year and ten months now, with no symptoms, she is in good condition.



Prescription (4)

Futei Fukui's Jizusoippo Hiromichi Yasui Japan Institute of TCM Research

Profile