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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.

Editorial

House of Cards

1. Placebo

It was around 1970 that acupuncture and moxibustion treatment began to be recognized as a scientific research subject in Western societies. Since then 40 years has been spent to mainly pursue a single proposition. The special position is "acupuncture and moxibustion treatment is just placebo."The placebo effect is defined in a medical dictionary as the phenomenon in which "actions such as pain relief occur after a placebo, pharmacologically inert or ineffective, on the patient with the intended disease was administered aiming for its psychological effect." Although the existence of the placebo effect is hypothesized from the operational perspective and its mechanism and actual entity are unknown notions, the effect is widely recognized in the area of medicine. When acupuncture was going to cross the boarder and was to be incorporated into the medical domain, one of the challenges the acupuncture world was asked to address from a skeptical standing was to substantiate "acupuncture treatment is not placebo." Since a mythical literature explaining "The powerful placebo" by Beecher in 1955 contributed the placebo effect, which existence is believed based on a priori assumption, it has become the methodological foundation for scientific assessments in the medical domain together with various anecdotes. One of the authoritative medical journals, New England Journal of Medicine (NEJM) carried a journal with aggressive title "Is the placebo powerless?" by Hróbjartsson and Gøtzsche in 2001.

This literature describes the first attempt to objectively identify the quantity of placebo effect by consolidating data of randomized trials conducted earlier. The results of this study were incredible, showing that compared to non-treatment, there were none or very few evidences, if any, of the placebo effect that had been believed to be tens of percent in all treatments – this is still fresh in my mind.

The editor in chief commented about the results that "as everyone believed that the witches in the Wizard of Oz had supernatural power, they had power…similarly we had not seen things beyond the curtain, so we thought placebo was powerful." Mr. Bailar, the editor in chief of NEJM linked the people related to the medical field including himself to the inhabitants of the Oz. On the other hand, the keyword of in fact have not sufficiently substantiated is used as an obvious word, which functions as a high wall set up relentlessly before the persons who are trying to enter the medical territory.

Placebos have not been well accepted in the medical field, where they have been labeled and categorized as subjective and empirical things of no value. A factor contributed to the situation is that from a historical standpoint, physicians and surgeons have been dependent for a long period of time on what patients claimed. Other factor is that physicians and surgeons who were exposed to competition with practitioners of other fields have counteracted discourses of patients on the basis of objective and scientific theories to overwhelm and control patients and persons involved in other medicines. The emergency of Western medicine may have implications for the paranoid notion for placebos.

2. Is the "Sham Acupuncture" assumed placebo equivalent or not?

An intervention with sham acupuncture needles, which are made undistinguishable from real ones, is required for measuring the placebo effect and a wide variety of procedures have been attempted. The procedures can largely be grouped into invasive standard stimulation sham acupuncture, which applies needling into points considered inappropriate; invasive minimal sham acupuncture, which applies shallow needling into a fewer points to give as least stimulation as possible compared to real acupuncture; and noninvasive sham acupuncture, which seems like needles are inserted but they do not penetrate the skin. Although these are regarded as having validity because "those who have not experienced acupuncture cannot distinguish the differences between real acupuncture and sham acupuncture," evidence-based studies on the other important factor "ineffective" about placebos has not been made and the placebo effect is dependent on the unverified hypotheses - (a) "ineffective" when needles are inserted into non-acupuncture points, and (b) as well as the effect, the amount of stimulation increases or decreases according to the number of needles inserted and the needling depths. Proving the placebo effect is now required in general but the situation seems notions are running up before proving.

A result of this was yielded from a large scale project called German Studies carried out in Germany in the first decade of this century. This project is Phase III clinical trials in which 100 people were engaged for each trial to study whether to cover the effects of acupuncture treatment in the adjuvant setting for chronic pains including low back pain, knee pain, and headache by the public health insurance. Participants recruitment called for mobilizing clinical practitioners for 100 orders per trial with these hyper multi centre trials. The result of these trials showed that the real acupuncture group and the control group of sham acupuncture had equivalent potency. This matter requires analysis on whether the treatment effect in the real acupuncture group was inadequate, or whether the effects in both groups were equivalent. However, monitoring information in multi-centers and other quality control information are insufficiently available to plan a process analysis, and although therapeutic protocols are described, the information of the procedures actually performed cannot be collected from these trials. About skill of practitioners, factors related to the effect of treatment are not found. Whatever the case, such recognition is necessary that the beliefs of (a) "needling at non-acupuncture points has no effect", (b) the amount of stimulation increases or decreases depending on the number of inserted needles and the insertion depths" are hypotheses.

3. To miss trigger points on purpose

Nonetheless, if you are asked if the parties in the East Asia region concerned with acupuncture and moxibustion are involved in the runaway of researchers in the United States and European countries, you will not say "they are not responsible for it." This is because it is the parties in the East Asia region that have emphasized the differences between the acupuncture points and non-acupuncture points at every opportunity in order to advocate the meridian/acupuncture point system.

Japanese traditional acupuncturists define concept of acupoint (acupuncture point) as the point where the needle is inserted and manipulated in acupuncture therapy. Acupoint include following points,

- Meridian point: a point on the fourteen meridians and location had been predefined in classical text books.
- Extra point: a point that is not located on the fourteen meridians but the position and the property such as statement of virtues were predefined in the text books.
- Ashi point: an acupuncture point with no specific name nor definite location, the site of which is determined by tenderness or other pathological responses in palpation. It is hard to differentiate the ashi point on muscle meridian from the trigger point.

In other words, the locations of all acupoints used in treatment are not determined before starting the session. Some points are determined based on the condition of the patient of the day. In treating the musculoskletal system, the existence of ashi point often cannot be ignored. "Non-trigger points" in sham acupuncture or "acupuncture points not used for the related complaints" should be defined carefully.

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Japanese Acupuncture - Current Research

Acupuncture Treatment for Peripheral Facial Paralysis

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1. Introduction

The causes of facial nerve palsy may either be central or peripheral, but in this manuscript I will focus on the peripheral type of facial nerve palsy, for which comparatively numerous reports have been published in Japan and discuss the effects of the acupuncture and moxibustion treatment for this condition.

Bell's palsy and Ramsay Hunt syndrome are frequently observed among patients with peripheral facial nerve palsy, these two conditions being responsible for about 70% of all cases of facial nerve palsy in Japan[1,2]. Accordingly, research reports (or case reports) about the relevant acupuncture and moxibustion treatment in Japan also concentrate mostly on these two diseases[3-9]. The incidence of Bell's palsy ranges from 25 to 32 persons per 100,000 population, while that of Hunt syndrome has been reported[2] to be 2-3. Etiologic details for Bell's palsy remain obscure, but ischemia or virus infections have been pointed out as possible causes. In recent years reactivation of herpes simplex virus type 1 within the geniculate ganglion has been postulated as an important factor. On the other hand, Hunt syndrome is said to be caused by latent infection within the geniculate ganglion by varicella-zoster virus (VZV). The inflammation of the facial nerve results in any case in the development of edema and a resulting compression within the facial nerve canal then causes the development of ischemia, which in turn aggravates the edema and thus leads to a progressive affection of the facial nerve that then finally leads to the development of paralysis.

In the "Facial Nerve Palsy Treatment Guidelines[2] prepared by the Japan Society of Facial Nerve Research treatment with steroids or antiviral drugs or also facial nerve decompression is recommended depending on the severity of the paralysis during the acute phase of facial nerve palsy. In particular the recommendation for oral administration of steroids is ranked "A", meaning that it is strongly recommended and thus represents the most recommended form of treatment. Steroid monotherapy has been classified as recommendability A for the treatment during the acute phase, while the recommendability B was assigned only to massive dose steroid therapy for severe Bell's palsy. In this paper[2] I "could not verify the effectiveness of at the present moment" of the acupuncture and moxibustion treatment administered during the acute phase and therefore judged it to be of recommendability C2 (cannot be recommended due to a lack of scientific proof). Low frequency electrical stimulation could lead in case of ENoG (Electroneuronography) values of less than 40% to the development of synkinesis and as such has been classified as recommendability D (it is recommend not to administer this treatment). On the other hand, there are no treatment forms classified as recommendability A or B for the chronic phase and acupuncture and moxibustion treatment for chronic peripheral facial nerve palsy has not been mentioned. While there have been reports in Japan about the effectiveness of acupuncture and moxibustion treatment for Bell's palsy or Hunt syndrome its classification as C2 is truly regrettable, but this is probably the inevitable result of the importance in recent years attached to research results obtained through RCT (randomized control led trials), today considered to be the mainstream research tool.

2. Reports on acupuncture and moxibustion treatment for peripheral facial nerve palsy in Japan

While there have been no reports in Japan about the effectiveness of acupuncture and moxibustion treatment for Bell's palsy or Hunt syndrome[3,4,6-9] describing effects promoting the recovery from the palsy, there have also been no reports[5] about any adverse effects delaying the recovery.

Ando et al.[3] reported about their performance of more than 5 acupuncture and moxibustion treatment sessions in 28 patients (20 patients with Bell's palsy ; 8 patients with Ramsay Hunt syndrome), who had received within 6 months following the onset of peripheral facial nerve palsy steroids, brain metabolic stimulants, peripheral vasodilators, stellate blocks or vitamin complexes. As acupuncture treatment low frequency electrical acupuncture was applied to GB14, Taiyang, ST2, ST3, ST4, ST6, ST7, ST18, TE17 and LI4 on the hand of the affected side with maximal intensity that did not cause any pain (Fig. 1). Once or twice weekly was chosen as frequency for the acupuncture treatment and the severity of the palsy was assessed using the 40-point paralysis score described by Japan Society of Facial Nerve Research. The results showed, that when acupuncture treatment was started later than 30 days after the onset for patients in whom recovery after the onset had been slow, led to improvements in the palsy and the recovery trend reportedly continued over a duration of more than 6 months, while there were no side effects or complications associated with the acupuncture treatment.

Ebiko et al.[4] reported the results of acupuncture treatments for a total of 29 patients with refractory Bell's palsy (n=14) and Hunt syndrome (n=15) presenting with a minimal ENoG value of 0% and in whom the test instrument scaled out during the nerve excitability test (NET). This treatise[4] describes that the initial treatment administered in the department of otolaryngology was basically a tapered administration of 30 mg of predonine, ATP preparations, vitamins, antiviral drugs etc. The average age of the patients was 44.3±12.8 years (mean±S.D.), duration of the morbidity 43.2±23.9 days, paralysis score 10.2±2.7 points, the acupuncture treatment (Fig. 1) consisted of retaining the needles (n=17) for 15 minutes on the affected site at GB3, GB14, GB2, ST2, ST6, ST4, above the angle of the mouth, below the angle of the mouth and LI4 as well as electroacupuncture applied to the point pairs GB3-GB14, GB2-ST2, ST6-ST4, above-below the angle of the mouth for 20 minutes with an intensity that did not cause the patients any discomfort (n=12). For the evaluation the 40-point paralysis score described by Yanagihara, presence of synkinesis or crocodile tears, facial spasm, or else the sequel score for the evaluation of facial stiffness (modified method of sequel assessment developed by Nishimoto and Murata et al.) were used.

Moreover, according to the Japan Society of Facial Nerve Research a score of less than 10 points of the 40-point full score represents incomplete paralysis, while a score of less than 8 points is a complete paralysis and a score of more than 20 points indicates a mild case, 10-18 points a moderately severe and a score of less than 8 points a severe case. Patients reaching a score of more than 36 points and do not have any more than moderately severe conjugated movements were judged as cured[2] and the paralysis score described in this paper[4] returned within 6 months to more 36 points, while no apparent after effects were observed in these cases of complete

recovery. The remaining cases were classified as incomplete recovery. In this paper[4] the paralysis score of the 29 patients at the start of the acupuncture treatment was 10.2±2.7 points and had improved 6 months later to 30.5±4.6 points. Among the 14 patients with Bell's palsy 4 patients reportedly recovered within these 6 months so far, that the paralysis score reached the normal range of more than 36 points and among the 15 patients with Hunt syndrome 1 patient recovered within these 6 months to achieve a more than 36 points score. The remaining 24 patients were classified as presenting incomplete recovery. There were no significant differences in the recovery process between the groups of patients with Bell's palsy and Hunt syndrome. As described above acupuncture treatment for peripheral facial nerve palsy has been reported to be effective.

Conversely, Kasuya et al.[5] reported the results of a retrospective study, where the authors determined the degree of nerve degeneration 2-3 weeks following the onset in a total of 111 patients with peripheral facial nerve palsy and used the 40-point paralysis score described by Japan Society of Facial Nerve Research to compare a group treated with acupuncture (n=61) and drugs as well as the differences in recovery between an acupuncture and pharmacologic combination therapy group as compared to a pharmacologic monotherapy group (n=50). Apart from the steroids used for the pharmacotherapy ATP preparations, administration of drugs for improving microcirculation, vitamin preparations etc. was also described. This paper[5] states, that "the recovery from paralysis was in the group of patients with an ENoG value of over 41% and treated with acupuncture only significantly inferior to that in the oral steroid treatment group", while comparison of groups with an ENoG value of over 21% no significant differences between the oral steroid treatment group and acupuncture combination therapy group were observed. Thus, in "between a group of patients with ENoG values of 1-20% treatment with massive steroid doses and a massive steroid dose and acupuncture combination therapy group no significant differences were observed." Thus, no recovery promoting effects could be observed in the medication monotherapy group and the medication and acupuncture combination therapy group, but reportedly no effects delaying recovery were observed either. Moreover, for the acupuncture treatment (Fig. 1) apart from the application of electroacupuncture to TE17 on the affected side for 15 minutes GB14, ST1, ST2, ST4, ST7, BL10, GB20, GB21, SI14 etc. application of hot packs to the face for 10 minutes served as an additional thermotherapy. Over a period of 1-2 months after the onset the patients were treated twice weekly and after that the acupuncture treatment was administered once per week.

Again, in the form of case reports the acupuncture treatment of a 70-year old patient[6] with Bell's palsy presenting with synkinesis 10 months after onset and the acupuncture treatment of a 29-year old patient with Bell's palsy 2 years after onset were reported[7]. In case of (6) electroacupuncture was applied to the affected side of the face, resulting in relief of the suffering from synkinesis and facial contracture as assessed with a VAS (visual analogue scale) and the 40-point paralysis score described by Japan Society of Facial Nerve Research as well as ENoG. Electroacupuncture (Fig. 1) was performed on the points GB14, ST2, SI18, ST4, using two different pulse generators to avoid synchronized muscle contractions from the GB14-ST2 and SI18-ST4 pairs. In the latter report[7] electroacupuncture was performed on the

affected side of the face at TE17, ST7, GB1, ST4, LI19 and GB14, using also the points Taiyang, ST2, ST3 etc. for the treatment (Fig.1). This resulted reportedly in improvements of the paralysis score and reduction of the temperature difference between the affected and healthy side of the face as measured with thermography.

Considering the contents of these reports we concluded that a combination therapy established in cooperation with an otorhinologist rather than an acupuncture monotherapy for peripheral facial nerve palsy is important. In particular during the acute phase of the peripheral facial nerve palsy steroid therapy and similar measures administered by the otorhinologist should be given priority and a combination with acupuncture later considered on the basis of the degree of recovery or severity of symptoms.

3. Application of the Koshi method of traditional acupuncture during the acupuncture treatment for peripheral facial nerve palsy

So far I have introduced reports about acupuncture treatment for peripheral facial nerve palsy in Japan, but since electroacupuncture treatment can cause synkinesia as described above, otolaryngologists currently seem to have reservations regarding stimulation on the affected side (worries about the development of conjugated movements[8,10].

Regarding case reports in this context the author has reported about the application of the Koshi method of traditional acupuncture to the face integrated in the acupuncture treatment for peripheral facial nerve palsy (Bell's palsy, Hunt syndrome). When symptoms are present on the left side, the Koshi method is applied to the right side, and for symptoms on the right side the acupuncture treatment is applied to the left side.

The first case was a 43-year old patient[8] diagnosed with Hunt syndrome, who was treated 18 days after onset with the Koshi method on the face using the retaining needle technique for the treatment. This patient received pharmacotherapy with steroids, antiviral drugs, cerebral circulation and metabolism ameliorators, vitamin preparations and eye drops to prevent dehydration of the eye, but according to the patient "the left side of the face almost does not move and the discomfort is not alleviated". Moreover, the attending physician asked the author "not to perform acupuncture treatment on the affected side". Thus, since the chief complaints were impaired movement of the muscles and discomfort on the left side of the face, simultaneously observing associated symptoms of inability to taste food, shoulder stiffness, dryness of the eye, insomnia, constipation etc. At the start of the acupuncture treatment (18 days after onset of the condition) the 40-point paralysis score as described by Yanagihara was 10 points. The VAS values representing the difficulties in moving the left side of the face and discomfort were 55 mm and 56 mm respectively. A total of 11 acupuncture treatment sessions was given at rate of 1-3 times per week. All needles only pierced the skin to a depth of about 5 mm and were then retained for 10 minutes (retaining acupuncture technique). For the acupuncture of the face the points GB14, Taiyang, SI18, ST4, TE17 and SI19 were needled (Fig. 2, upper row). Otherwise, based on (1) determination of the treatment according to pattern identification (bian zheng lun zhi) needles were inserted and retained at LR3, KI3, KI7 and SP6, (2) to improve blood circulation through the muscles of the shoulder girdle and relief muscle tension needles were retained in the point GB21 (Fig. 2, upper row). Acupoints not in the facial region were needled on both sides. This resulted in an improvement of

the paralysis score to 38 points by the tenth acupuncture treatment (39 days after onset), while both the difficulties in moving the muscles and the discomfort of the left side of the face had been alleviated and the associated symptoms shoulder stiffness, dryness of the eye, constipation and taste subjectively been improved.

The second case was 60-year old patient diagnosed with Bell's palsy who I started treating using the retaining needle acupuncture technique 50 days after the onset[9]. This patient too received pharmacotherapy including steroids, cerebral circulation and metabolism ameliorators, vitamin preparations and eye drops to prevent dehydration of the eye, had undergone facial nerve decompression and underwent stellate blocks once a week, but the "mobility of the right side of the face did not improve much". Accordingly, in addition to the chief complaint of impaired mobility of the right side of the face (at the beginning of the acupuncture treatment the relevant VAS value was 83 mm) there were also associated symptoms including shoulder stiffness (VAS of 57 mm), low back pain (VAS of 25 mm) and the paralysis score was 12 points. The acupuncture treatment was administered once or twice a week, where all needles were inserted only to a depth of about 5 mm and retained for 10 minutes (retaining acupuncture technique). All needles in the facial region were placed on the healthy side at GB14, Taiyang, SI18, ST4, TE17, SI19 and ST7 (Fig. 2, lower row). Otherwise, based on (1) determination of the treatment according to pattern identification needles were inserted and retained at LR3, KI3, KI7 and SP6, and (2) as for a selection of points on the affected channel needles were placed and retained in distinctly tender points at LI4, TE5, LI10, (3) to improve blood circulation through the muscles of the neck and shoulder and relief muscle tension needles were retained at GB21, SI11, SI13, SI14, SI15, BL23, BL25, BL52 and EX-B3 (Fig. 2, lower upper row). Acupoints not in the facial region were needled on both sides. This resulted in an improvement of the paralysis score to 38 points by the 27th acupuncture treatment (242 days after onset), the difficulties in moving the muscles of the face had been alleviated to a VAS score of 2 mm. The VAS score for the associated symptoms of shoulder stiffness and low back pain had improved to 22 mm and 14 mm respectively. Otherwise the patient commented on the effects of the received acupuncture treatment as "I started to sleep well", "the constipation is gone", "my stomach is feeling just fine", "my tinnitus has decreased", "I don't have any palpitations any more" etc.

Based on the above described results application of the Koshi method as an integral part of the acupuncture treatment for peripheral facial nerve palsy indicates the possibility that it promotes recovery, but it remains difficult to explain the exact mechanism at work during the promotion this recovery, including the improvement of associated symptoms. However, mainly animal experiments revealed that the acupuncture stimulation has effects that reportedly include reduction of muscle tension[11], improvement of muscular blood flow[12,13], improvement of neuronal blood flow[14,15], promotion of physical and mental relaxation[16], promotion of peristaltic bowel movements[17] and the like. Moreover, some reports also indicate, that the acupuncture stimulation does not only increase muscular blood flow at the stimulation site, but affects muscular blood flow on the contralateral side also[18]. This suggests the possibility that the acupuncture stimulation

applied to the healthy side in this case somehow affected the contralateral side via higher neuronal centers, or else the possibility, as described above, that the effects of the acupuncture stimulation improves symptoms in the facial region as well as associated symptoms like shoulder stiffness, low back pain, insomnia, constipation etc. On the other hand, however, the administration of steroids or other pharmacotherapy, the performance of facial nerve decompression, stellate ganglion blocks etc. may possibly have contributed to limiting the facial nerve conduction disturbances, or else the drugs may possibly have promoted repair of the facial nerve, indicating the possibility that combination therapy including acupuncture, pharmacotherapy and surgery promotes recovery.

Also, while improvement of the chief complaint(s) and associated symptoms is important regarding the acupuncture treatment for facial palsy, inhibition of the development of synkinesis is considered to be another important aspect of the treatment. Thus, treatment for facial palsy should be guided by careful observation and in case of performing acupuncture basically a combination therapy with the treatment administered by otorhinologists is essential.

Moreover, ENoG measurements made before and after the acupuncture treatment as well as RCTs conducted appear to be an important task for the future in order to objectively assess the effects of acupuncture treatment for peripheral facial nerve paralysis.

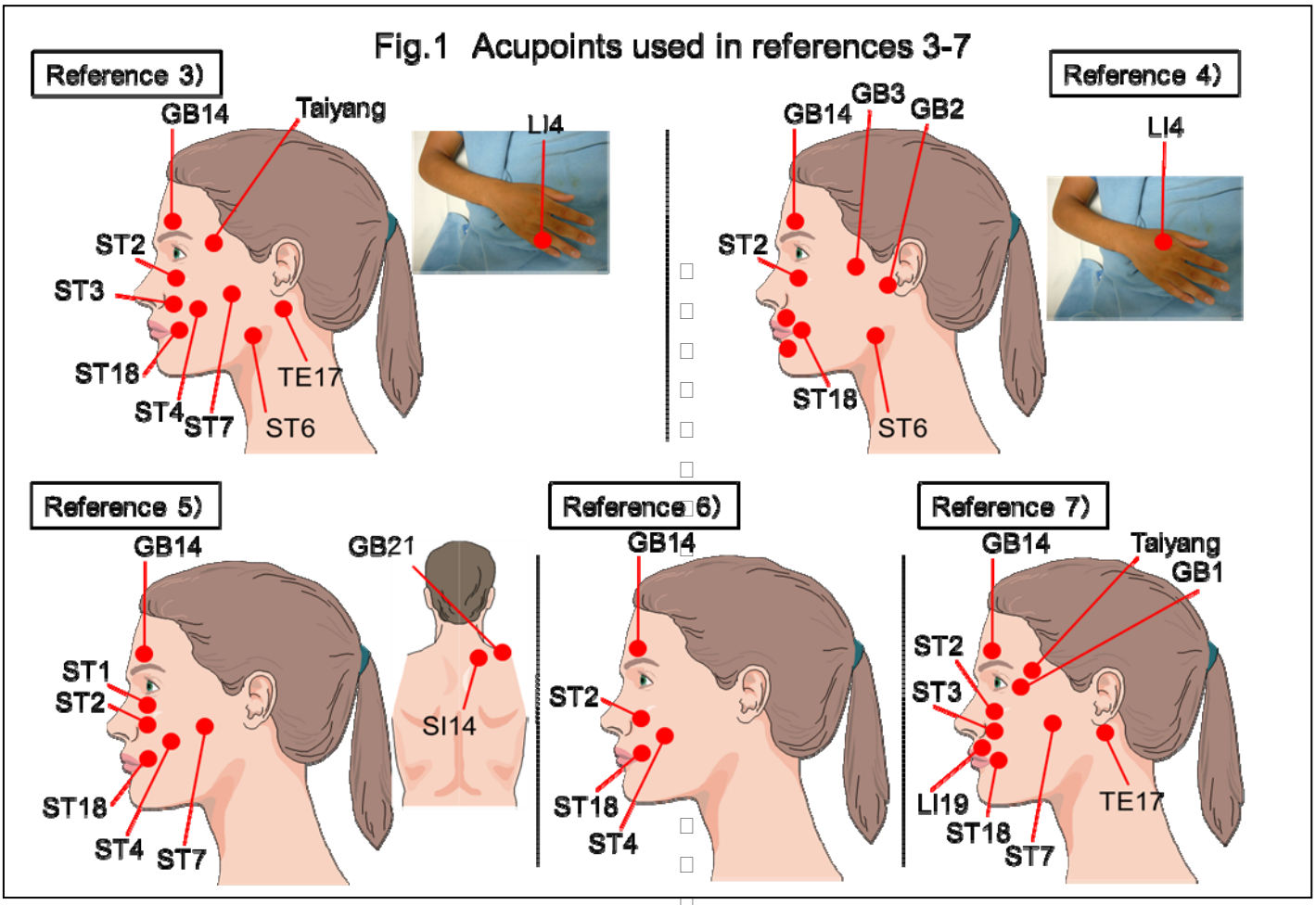

Chart with the acupoints used in references 3) through 7)
Acupuncture treatment was performed on the affected side of the face.

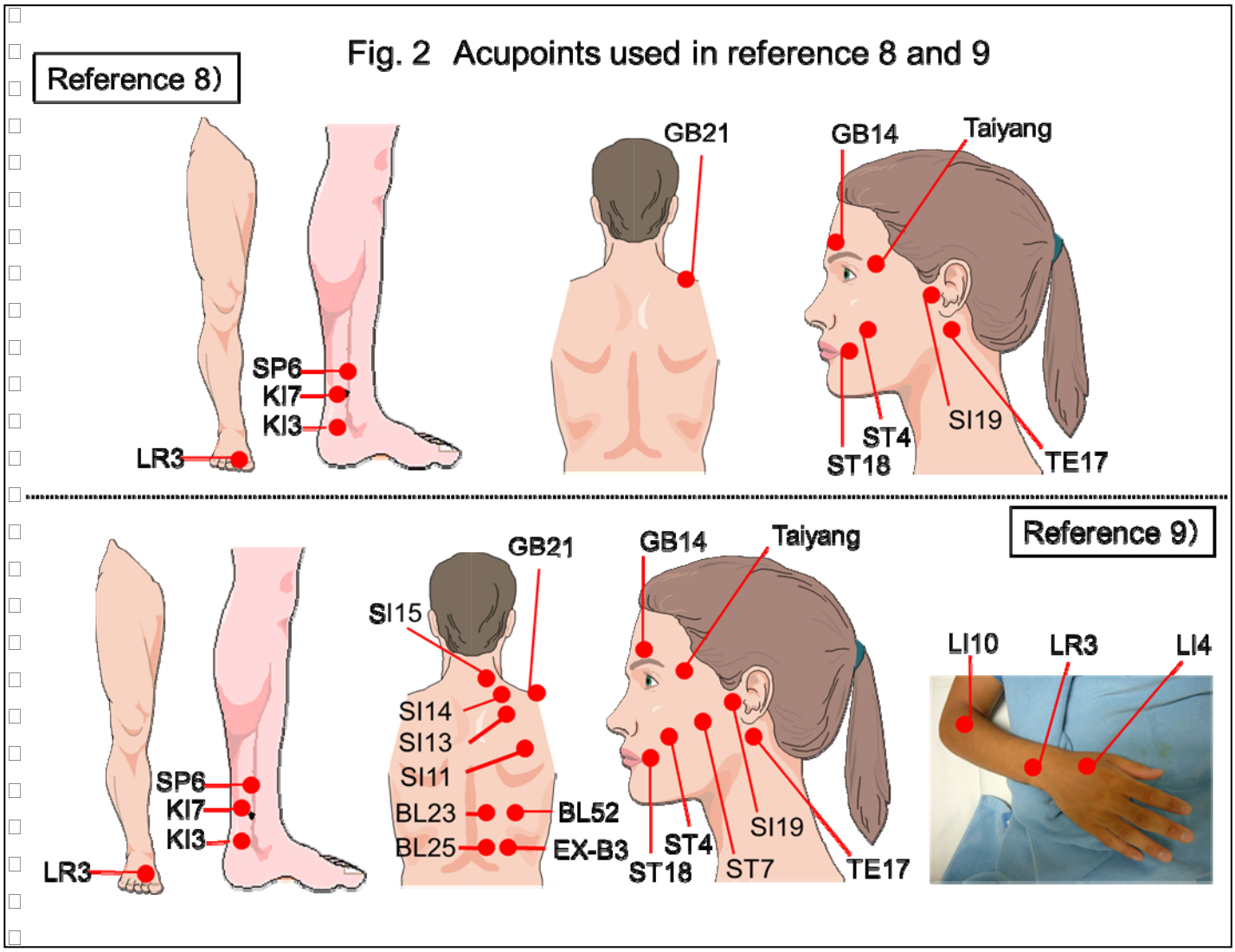

Chart with the acupoints used in references 8 through 9

Application of the Koshi method during acupuncture treatment performed on the healthy side of the face.

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Kampo Medicine - Current Research

Collagen Disease

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Collagen diseases and the relative diseases are immune system disorders and the causes remain to be identified. Because of unexplained causes, the treatment with Western medicine is aimed at control of further progression of the diseases to later stages or relief of worsening conditions and symptoms. Drugs used for the purposes, such as steroids and immunosuppressant drugs, will cause various adverse effects, and medical resources are consumed at the same time. In the situation, the treatment with Kampo medicines, which are relatively cheap with few adverse effects, is meaningful. In effect, there are many reports suggesting Kampo medicines play positive roles in controlling symptoms of collagen diseases as well as a worsening of the diseases, enabling to reduce the volume of immunosuppressant agents and alleviate their side effects.

Many of collagen diseases and the relative disorders often cause pain, swelling, and stiffness of joints and the musculoskeletal system and for the reason, collagen diseases are often generalized as a group of "rheumatic disorders" - a traditional concept of Western medicine after Greek medicine. Kampo medicine has a similar concept called "bi pattern or arthritis." This concept was established and discussed 2,000 years ago in the most old classical book "Yellow Emperor's Canon of Medicine / Plain Conversation". Even in the present days, collagen diseases and the relative diseases of joints and musculoskeletal swelling, pain and stiffness are approached, in principle, with discussions based on the ancient arthritis concept. However, musculoskeletal symptoms cover only part of a wide array of collagen diseases. For other symptoms, Kampo medicine handles individual symptoms as separate clinical conditions and has not regarded them as a single disease concept for long. Therefore, the modern Kampo medicine does not have a unified view of etiology and pathogenic mechanisms that can pinpoint accuracy of the pathological conditions that can explain the natural history including varieties of symptoms, development of diseases, and prognosis. In our time, most individual symptoms of a disease are separately approached. Studies to search for etiology and pathogenic mechanisms of each collagen disease are desired in order to enhance the treatment performance of short-term symptoms and to achieve full-scale improvement of the prognosis.

Introduced hereunder are recent notable clinical trials in Japan on typical collagen diseases and similar diseases such as rheumatoid arthritis, SLE, and Sjogren's syndrome.

Rheumatoid arthritis

Rheumatoid arthritis is known as one of the most common types of collagen diseases. Western medicine of today has made a major breakthrough in the treatment method of rheumatoid arthritis. The main stream treatment is to slow down disease progression with the administration of a group of medications (different types of drugs) known as DMARDs which mainly use immunodepressant agents such as Methotrexate (MTX). Especially in recent years, a new treatment for rheumatoid arthritis has begun to be performed aiming at a complete remission by powerfully controlling disease activities with monoclonal antibody agents, referred to as biologically derived agents, against anti TNF-α antibodies and other immune/inflammation inducing substances. As image inspection technologies advance in recent

years, it has become known that joint destruction starts one to two years after symptoms first appeared, much earlier stages than thought. For this reason, it has begun to be recommended that DMARDs and biological agents be used in as early stages as possible with the objective of preventing joint damage. In compliance with this, the diagnostic criteria have been revised in order to diagnose rheumatoid arthritis in its early stages[1]. Furthermore, efforts are being made to identify, among unclassifiable joint inflammation disorders, a group having the high possibilities of progressing to rheumatoid arthritis[2]. However, given side effects of DMARDs, high costs of biological drugs, and problems of immnosuppression, wariness persists about the thought of lowering the treatment threshold of rheumatoid arthritis in the early stages that has the possibility of spontaneous remission. In view of reductions in the usages of DMARDs and biological drugs, alleviation of their adverse effects, and means of treatment for some refractoy rheumatoid arthritis, relatively low-cost Kampo treatment with less adverse effects may mean a great deal as used to be.

In the Kampo treatment of rheumatoid arthritis in Japan, "*keishikajutsubuto*" and "*eppikajutsuto*" are often used in Japan in light of the historical use of the formulae described in "Shan Han Lun" and "Jin Gui Yao Lue"[3),4),5)]. There are many reports published on the use of "*keishakuchimoto*" for relatively advanced rheumatoid arthritis and "*daibofuto*" for advanced joint deformation. On the other hand, a group of practitioners referred to as Gosei School, who emphasize on the prescriptions of the Ming Era, recently published a report that *jiinkokato* was effective for rheumatoid arthritis in its early stages[6]. There is a notable report on *boiogito*. In this research, relatively a large number of patients with rheumatoid arthritis were tested and an appropriate assessment method was used; Tanaka administered for six weeks *boiogito* to RA32 patients, who met the diagnostic criteria of definite RA under American College of Rheumatoid standard criteria; neither changes to the drugs they had used nor new drug additions were made; and changes in Lansbury indexes of individual patients were monitored. The results revealed effective in 14 patients (44%), slightly effective in 5 (16%), remained unchanged in 5 (16%), and worsened in 4 (13%). The duration of morning stiffness, the number of painful joints, and the number of swollen joints significantly improved. Their grip strength and CRP showed a tendency for improvement. From these results, the group determined *boiogito* was effective for RA[7].

Nagasaka, et al administered Kampo treatment to RA54 patients and assessed its effectiveness. Their average disease duration was 13 years and mean values of Steinbrocker's functional/stage classification were class2.3 and stage2.5. The 35 patients had been using Western-style medicines since before the initial visit. The overall effect was "markedly effective" in 41% of the patients, "effective" 10%, "slightly effective" 18%, and "ineffective or exacerbated" 31%. Twenty-six patients were able to discontinue the Western medicines/reduce the body weight. Among the prescriptions that yielded the result of "slightly effective" or more assessed by the modified Lansbury Index, *boiogito* had the highest respose rate. Next followed by modified *keishikaryojutsubuto bushito*, then modified *keishinieppiichito*. *Boiogito* increased the response rate with more-than-usual amounts of *Astragali* Radix and *Sinomeni* Caulis et Rhizoma. And, Nagasaka, et al. further claimed that if no effect was obtained from the single use of *keishikaryojutsubuto*, the administration combined with *boiogito* increased the response rate[8]. As just described, *boiogito* is often applied

to rheumatoid arthritis in Japan - a characteristic methodology of Japanese Kampo medicine. However, this is not the case in other countries. It should be noted that unlike in other countries, that *Sinomenim acutum* Rehder et Wilson instead of *Stephania tetrandra* S.Moore (Fen fang ji) is the main ingredient of boiogito in Japan.

SLE

SLE in many collagen diseases shows the richest varieties of symptoms and prognoses. It is also known as a disease that can cause dramatic symptoms and outcomes both in short and long terms. It is difficult to say that similarly to Western medicine, Kampo medicine has acquired complete comprehension of the real clinical conditions. Therefore, in most cases, SLE treatment is given only to respond to individual patients and symptoms from beginning to end, so trial reports in a comprehensive way are scarce. Even the same types of SLEs have different patterns of symptom developments in individual patients and the disease conditions ranges from extreme severity to the severity for which only follow-up is necessary but treatment is not required and the severity to the extent that transient worsening is repeated but the condition spontaneously becomes stable. Here lies the problem of difficulty to judge the effective degrees of treatment interventions. In such situation, multiple cases were reported in which clinical conditions improved by the use of Extract of *ninjinto*[9]. The report on the use of *ninjinto*, having the efficacy of dissipating cold and warming yang, for SLEs with fever symptoms is out of common and noteworthy.

Sjogren's syndrome

In recent years, notable reports on randomized clinical trials of Sjogren's syndrome have been published.

Nishizawa, et al. tested *bakumondoto* in a clinical trial of 229 patients suffering from primary Sjogren's syndrome with six-month administration. They were divided into two groups. A group of 115 patients were given *bakumondoto*. B group of 114 patients were given a placebo. The results revealed that the amounts of both saliva and tears significantly increased more in A group than baseline values. This increase was negatively correlated with the increasing rate of the saliva secretion group and the progression degree of salivary gland destruction on Lubins & Holt sialographic intensity classification. Saliva secretion amounts continuously increased in A group after the administration and became stable after six weeks and onward. The amounts of salivary gland secretion decreased in B group. Subjective symptoms improved in A group, whereas those became worse in B group. Inflammatory reactions such as CRP and ESR findings significantly improved in A group with a fewer adverse effects in terms of the number of episodes and patients. In A group, pain improved and keeping the health and QOL significantly improved compared to pre-administration. The overall rates significantly differed in all items between the two groups with 80.9% of "improvement" or above in A group and 0.9% in B group and those who desired re-administration were 92.0% in A group and 6.1% in B group[10].

Ohno administered 64 patients with a definite diagnosis of Sjogren's syndrome *bakumondoto* as a medicine with the action of water retention and additionally given drugs to tonify the kidney ("*rokumigan" and "hachimijiogan*") to the patients who were diagnosed by Kampo medicine as having kidney-deficiency. The results were compared with the control group of Kampo treatment (*hochuekkito*). In the group that received the Kampo medicine having the action of

water retention, 2 of 32 patients dropped out. In the control group, 4 of 32 dropped out. Monitoring was made with 30 vs. 28. The results showed that "*bakumondoto*," "*bakumondoto* + *rokumigan*," and "*bakumondoto* + *hachimijiogan*" showed significant differences after four weeks of administration in the amounts of saliva secretion compared to "*hochuekkito*". Moreover, the groups of additional administration of "*rokumigan*" and "*hochuekkito*" had a significant increase in the amounts of saliva secretion compared to the group of *bakumondoto* only[11].

The above results are noteworthy in the sense that Kampo medicines having the action of water retention were used for the main symptom of dryness of Sjogren's syndrome and effectiveness of the Kampo medicines was verified.

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Clinical Report 1 (Europe)

Shonishin in Europe (1)

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Therapeuticum rhein-main, Germany

Shonishin is presented in four parts

1. Significance and development
2. Theoretical basis of Shonishin
3. Shonishin-study
4. Future prospects

1. Significance and development

Spreading of Shonishin

In the past few years a steadily increasing interest in Shōnishin has become noticeable also outside Japan, especially in the German-speaking area (Germany, Austria, Switzerland) and in the English-speaking area (USA, Great Britain).

So what makes Shōnishin so popular with therapists, parents and children? -Well, there are many reasons:

- Therapists reason their increasing interest in it considering the fact that Shōnishin meets the holistic aspiration and the treatment successes speak for themselves.
- They are appreciative that a theoretical basis has been established which Shōnishin is based on (The theory will be focused on at a later point).
- Furthermore it is the simple and effective way of treatment with Shōnishin which makes the treatment method very popular with therapists.
- Children love this treatment as it has a pleasant feel to them.
- The acceptance of Shōnishin as a treatment method is very high with parents as they appreciate the gentle, non-invasive proceeding very much.

Another reason for the spreading of Shōnishin is that this treatment method can be used field-specifically. Depending on the therapist's professional background, as a doctor, alternative practitioner, Shiatsu-practitioner, physiotherapist or midwife, the patient collective, and thereby the indications, are different. By way of example, approximately 70-80% of all midwifes in Germany do have an acupuncture education - and thereby the qualification to absolve a further training in Shōnishin. For them, Shōnishin offers great opportunities to support newborn babies suffering from sucking weakness, abdominal pain, developmental retardation or even screaming babies. In the event of a needle phobia, Shōnishin is an alternative for pregnant women while preparing for birth or as a supporting treatment for women who have recently given birth and suffer from involutional problems or plugged milk ducts. Unlike as for the midwives, the area of application of Shōnishin for orthopedics is completely different. Their focus is mainly on children with problems related to posture and the musculoskeletal system. On the other hand pediatricians preferably apply Shōnishin with infants suffering from problems of the digestive system, the respiratory system or developmental disorders, whereas allergies and neurodermatitis are in the foreground with older children. General practitioners are rather dealing with children or adolescents whose range of topics includes concentration problems in school, ADHS or enuresis.

Shiatsu-practitioners often apply Shōnishin in combination with baby-shiatsu or children-shiatsu, in order to support them in their development. Physiotherapists can show better successes in the treatment of hemi paretic children, as the usually increased tonicity can be decreased by additional treatment with Shōnishin and thereby the children become more treatable.

Education and Quality Standard

There are no regulated educational criteria so far. The offer ranges from one-day courses to training courses of several days' duration. In the interest of the small and big children, high quality standards in Shōnishin education should be defined.

For that reason the Shōnishin education offered by the author (Fig. 1) is based on current research of the traditional Japanese medicine as well as of the Western health sciences. A fundamental training in a meridian therapy (e.g. acupuncture) is the educational requirement. Explaining the knowledge about children's development from the Western and from the Eastern perspective is an important part of the education. Communicating the course contents will need a training at least of six days' duration and additional further trainings in regular intervals.

The author is aspiring to a university certification for the Shōnishin education.

Fig. 1: Practicing with dolls

2. Theoretical Basics of Shonishin Energetic Development Model

In order to be able to establish a "new" treatment method in Europe, it needs an explanatory model. During more than 20 years of practical work of the author and his wife, the following development model has evolved and proved its worth as a basis for the therapeutical approach for treatment with Shōnishin.

This development model unites the knowledge of modern neurosciences, developmental psychology and developmental physiology with knowledge and experience of the traditional Chinese and Japanese medicine. It states that according to the motoric and sensory development stages, each energetic stage of development does build on a previously gained stage of development.

Especially meridians play a super ordinate role in this respect. They represent a communication network which connects the child with its outside world. Via this connection the meridians enable the integration of reflexes and stimuli. Thereby, they are also responsible for the child's development of posture, movement, patterns of behavior and personality. This knowledge about the interpendences between motoric, sensory and energetics opens new points of view on children's development, which results in specific therapeutic approaches. It becomes particularly exciting when the interconnectedness between meridians and Western developmental physiology- and psychology becomes visible. Especially then, when it becomes noticeable which meridian respectively which meridians control which stage of development and what happens, if a disorder occurs in that level of interconnectedness. This knowledge forms the foundation for treatment of children of all ages with Shōnishin.

Development of the Meridians

As well as the locomotor system and the sensory system, the energetic system hasn't differentiated itself completely at the time of the birth. According to the motoric and sensorial development, a maturation of the meridians takes place gradually. Therefore stimuli are needed, on which the not yet specified meridians react in different ways- or even don't react. Only with the achievement of school readiness the meridian system can be regarded as fully developed.

Three Circulations

On closer inspection this may be summed up as follows:

For a start, during the first year of a child's life, in each case four of later twelve main meridians are cooperating in community, so that there are three groups, each consisting of four not yet differentiated meridians. The three circulations known from TCM do develop out of the existing, undifferentiated "meridian pool".

Each of the three circulations has its own specific development- and life theme:

Front Circulation (Fig. 1) - This one provides the impetus for finding the own center, regarding motor functions as well as the emotional realm. Feeling the own limits and those of others are aspects of this circulation, too.

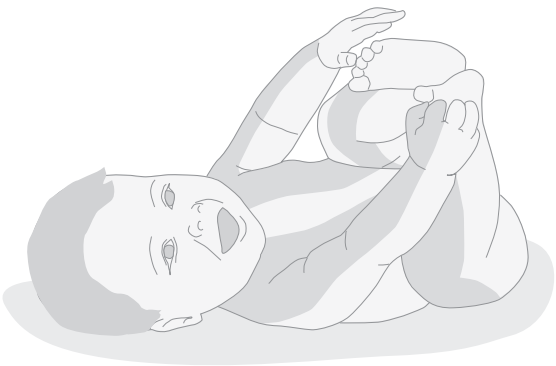

Fig. 1: Front circulation

Sidewise Circulation (Fig.2) - Most everyday movements are based on rotation of the body. In the baby age, turning over from the back to the belly and the other way around later on are the first rotation exercises and are originated from the sidewise circulation. This includes the bodily, mental and social flexibility.

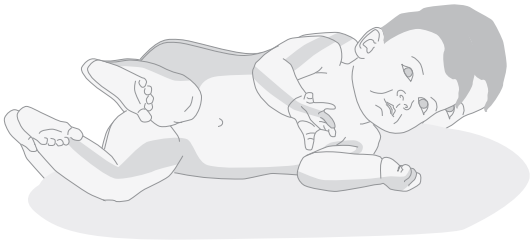

Fig.2: Sidewise Circulation

Rear Circulation (Fig.3) - The baby's development step from resting on a forearm while lying on its belly to the quadrupedal posture, or even taking an upright position in order to leave the bed in the morning as an adult, are qualities of the rear circulation. The impulse for the inner and the outer erection is originated from this circulation.

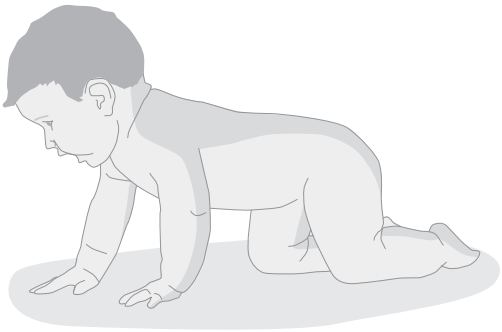

Fig.3: Rear Circulation

Six Axes (Keiraku)

With ongoing development a readjustment takes place as well as on the motoric and on the energetic level - The quadruped turns into a biped. For that reason a "top" and a "bottom" come into existence. At the same time a readjustment of the meridians, communicating with each other, takes place within the corresponding circulations - it comes to a top-bottom-connection of the corresponding Yin- respectively Yang- meridians, the so called **six axes**. These have fully developed when the child's verticalisation (full ability to bring the pelvis into an upright position) is completed at the age of about two years.

Five Phases

With an increasingly differentiated and controlled emotional expression and a refinement of the motoric capabilities, another "pairing" of meridians has been enabled which takes place when reaching school readiness. Now the child is able to receive stimuli to a greater extent, to get in touch with and to react on its environment, and to communicate with it using an individual pattern of action and reaction. During the three circulations an inside-outside-connection of the meridians develops in addition to the already existing top-bottom-connection- the **five phases.**

Now the meridian system can be regarded as being fully developed. So in the time from birth until reaching school readiness, motoric skills, sensory, emotion, socialization and enrgetics have developed step by step, whereby each step of development is built on the previous one.

The Shōnishin therapist should know and take in consideration these facets and correlations of development. For that reason specific diagnostic methods are required in order to find out in each case at which stage of energetical development a disorder or disease occurred for the first time. Therapeutic treatment will be applied adjusted to this step of development.

Clinical Report 2 (Japan)

A Patient Who Feels Nauseous on Exposure to the Sun

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[Case] Male of 52 year-old, working in the painting industry.

[Chief complaint] "Become nauseous when exposed to the sun."

[Current medial history]

Since 26 years old, he had suffered a low-grade fever and nausea. Detailed examinations had not detected abnormalities and tranquilizing agents had been administered for 10 years without improvement.

When he was around 46 years old, he began to develop additional symptoms of becoming nauseous, light headed and collapsing upon exposure to the sun. On hot days, hot flashes, fatigue in the lower limbs, sleeplessness, nocturnal sweating, and buzzing in the ears appeared. These symptoms were exacerbated during summer and relieved during winter. He poured water over his head to continue to work. However, because of the chief complaint, he often got off work.

Before visiting our hospital, he had received a complete examination without any findings of abnormalities.

August 3, he made the initial visit to us.

Findings at initial visit

[Inspection] His physique was intermediary with pale complexion. He seemed to have too much trouble for sitting on a chair and almost fall down.

He became out of breath and words could not be spoken continuously, giving the impression of a negligent air.

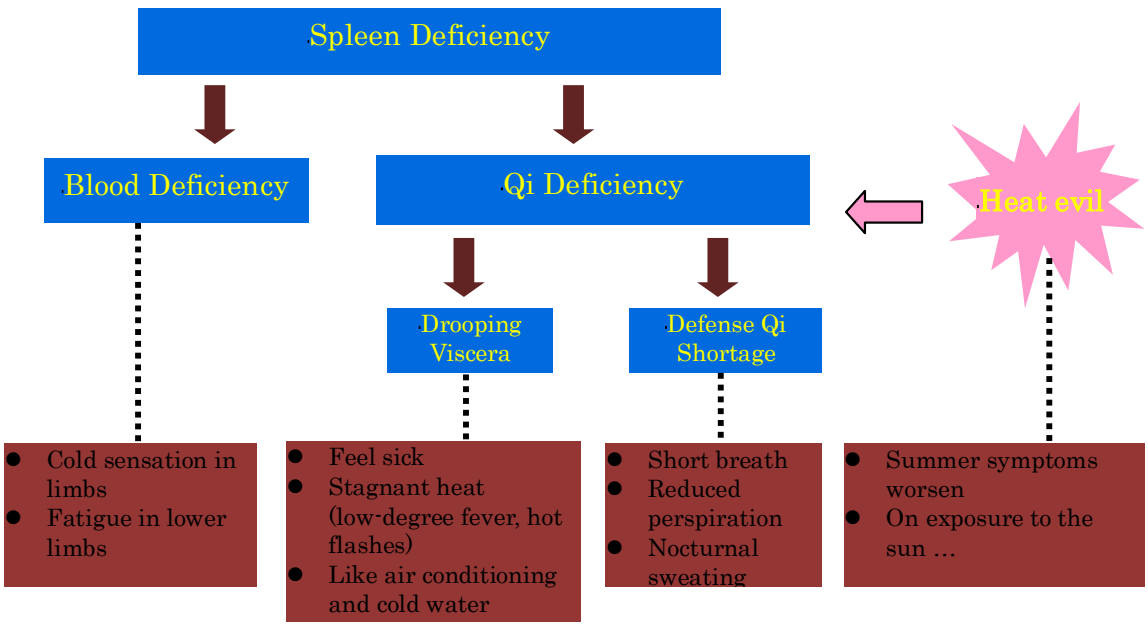
His tongue was enlarged and purple colored with pale yellow furs.

[Inquiry] He had a dry mouth. His appetite decreased during summer. Defecation was two times a day and normal. He seldom had perspiration and when sweating occurred, he felt good. Although he had no difficulty falling asleep, he woke during the night. He easily got frustrated. Four limbs were cold. He liked refrigerated air conditioning and water of a cold spring.

[Palpation] The pulse was deep, thin, and slippery.

Abdominal examinations detected 3/5 of the abdominal strength and a light bloated feeling in the chest and hypochondrium region and tenderness in the para-umbilical regions.

Analysis of clinical conditions



It can be thought from the low-grade fever and nausea for 20 years that the patient had an underlying spleen qi deficiency which induced qi deficiency and blood deficiency. Especially intense symptoms of progressed spleen qi deficiency with the drooping of viscera were observed. Because of qi deficiency, a shortage of defense qi occurred and thereby the role of sweating that normalizes the body temperature did not work properly, resulting in an internal accumulation of heat. Thus he liked the air conditioning and water from the cold spring.

It can also be thought from the long-time low fever and hot flashes and the general symptoms including fatigue that there were underlying deficiency fire and deficiency heat caused by a shortage of source qi. It is possible that summer-heat as a pathogenic factor made deficiency fire and deficiency heat further burn up in conjunction with the internal cause, upsetting the patient's health at a burst on exposure to the sun. In such process, the symptom of spleen-qi deficiency with the drooping viscera may have intensely appeared.

Prescription

LI Dong Yuan says in his book "Pi-wei-lun (Spleen-Stomach Theory)" that "fire and source qi cannot stand side by side," "If either one of them is dominant, the other loses," and "if drugs with sweet taste and body warming characteristics, such as Astragali Radix, Ginseng Radix, and Glycyrrhizae Radix are used, deficiency heat recedes voluntarily." He proposed the treatment method of using drugs with a warming action to remove fevers and invented prescriptions including *hochuekkito*.

The author selected *hochuekkito* that nourishes the stomach-spleen and activates qi to nourish chest qi.

Course

One week later, the patient felt an improvement in his physical condition. Sleep continued longer. Fatigue in the lower limbs was relieved. *hochuekkito* only was continuously administered.

Three weeks later, his physical condition was good. Fatigue in the lower limbs disappeared. The feeling of heat trapped in the body disappeared and he was able to do his job.

(Pulse) Deep and thin

(Tongue) Enlarged, dark red, covered with thin white furs.

The patient had slight constipation.

The patient received the instruction to continue to take the oral administration with adjustment in small quantities.

Clinical Report 3 (Japan)

One Case that had Effect of Modified Hochuekkito on Qi Deficiency Headache

Hiromichi Yasui
Japan Institute of TCM Research

Case: Female of 75 years old

Initial visit: May 15, 2006

Chief complaint: Headache

Present medical history: Headache developed after the patient gave a birth in her 30s. Ever after headache had continued for long and she had regularly been using analgesic agents. She overused Norshin four years ago and optical illusions appeared. So she was psychiatrically hospitalized in a nearby general hospital. After this, she received outpatient treatment at the hospital. The diagnosis was "depressive psychosis" and "headache." She was depressed with severe everyday headache. The pain was a dull ache type in the entire head and not a pulsating type. The onset of headache was not associated with weather changes. According to her husband, she had mild dementia and was receiving treatment.

Drugs now being taken: Depas (1.5 g), Risperdal (1), Miradol (150), Marzutene-S (1.5), Tredomin (25) 2 times/2 tablets, Gramalil (25) 1 tablet, Toledomin (25) 2 tablets, Silece (1), Artane (2), Kyorin AP2 1.0 divided into 2 doses

Past medical history: No special mention.

Present symptoms: Appetite; good. Sleep; insomnia. Urination; 5 times/day. Night urination; once. Defecation; once in 2 days. Normal stools. Dryness of the mouth. Feeling of sluggish.

Present condition: cm kg. Body temperature 35.6 degrees C. Blood pressure 112/76mmHg

She had a slightly dark expression on her face and looked helpless. She did not talk first and when answering to questions, she always asked for her husband's agreement. It seemed her headache was agonizing and she looked deeply pained.

Pulse condition: Deep and slippery, 60/min.

Tongue condition: Slightly dark colored with furs (-), swollen sublingual veins (-), moist.

Abdominal condition:

Course: At the initial visit, Extract of *hochuekkito* 6.0 g + Extract of *chotosan* 7.5g were given for 7 day doses. From the day after the start of administration, headache became eased, but the condition was changeable and unstable, becoming good and then bad during a day. However, her overall condition seemed good. On May 29 (2nd visit), she received the above prescription for 28 day doses. Subsequently she visited to the hospital on June 26 when headache was eased but a lassitude sensation still remained. In compliance with her complaint, the extract form was changed to decoction - *hochuekkito* + *chotosan.* A month later, headache further improved. However, the sensations of lassitude and fatigability remained unchanged. At the visit of August 21, headache (pain in the temples) was present. The pain was the type of being constricted. She complained of feeling lassitude. And a further modification to the prescription was made. With the switch to this new formulation, she mostly did not feel headache. In her subsequent visits to the examination room, she conversed with the author in a smiling tone of voice and the agonizing symptoms exhibited at the initial visit disappeared.

Diagnosis: Qi Deficiency Headache

Treatment method: Nourishing qi to activate the flow of qi

Course: Resulstingly, following were decocted on August 21 (*modified hochuekkito*)

Astragali Radix 8, *Ginseng* Radix 4, *Atractylodis* Rhizoma 4, *Angelicae Acutilobae* Radix 3, Citri *Unshiu* Pericarpium 2, *Ziziphi* Fructus 2,

Bupleuri Radix 2, *Cimicifugae* Rhizoma 1, *Zingiberis* Rhizoma 1, *Glycyrrhizae* Radix 2 *Angelicae Dahuricae* Radix 4, *Cnidium* Rhizome 4, *Chrysanthemi* Flos 2 – for 28-day doses

At the visit of September 28, she claimed that although slightly eased, headache appeared periodically. So, the same prescription was administered for further 35 days. On November 7, headache was relieved – far better than previous condition. Since then, mostly no headache has appeared.

Consideration:

The development of this headache was linked with depression. Headaches associated with depression are classified by The International Classification of Headache Disorders 2nd Edition (ICHD-II) into the subcategory of "headaches attributed to psychiatric disorders" under the category of secondary headaches. Although depression headaches are very common in our daily life, there is no necessity in Kampo medicine to specifically categorize this type of headache and the Kampo treatment methods can be patterned to some extent.

In Western medicine, psychiatric disorders presenting with depression are detailed into varieties of groups, such as depression, of course, psychoneurosis, schizophrenia, and organic mental disorders including dementia. Psychiatric disorders are usually treated with psychoactive drugs including anti-depressant drugs. Meanwhile, there are quite a number of clinical conditions that have benefits of Kampo drugs. In the treatment of psychiatric disorders with Kampo, clinical conditions are divided into a few types and the most frequently used prescription is *hochuekkito* that has the action of supplementing qi and enhancing the flow of qi. Some patients with depression-associated headaches have had relief with this prescription. Moreover, there are published data evidencing the usefulness of *senkyuchachosan*. And there is a case report in which *chotosan* was effective.

Hochuekkito is frequently used for the treatment of depression. This prescription can also be applied to depression-associated headaches. *senkyuchachosan* is a potential candidate for depression-associated headaches. Thus, for the treatment of depression, following prescriptions should be taken into account: *hochuekkito*, or *senkyuchachosan,* or *hochuekkito* + *senkyuchachosan*, or *hochuekkito* + *chotosan*. If blood deficiency is observed, either *kihito* or *ninjinyoeito* is a good candidate. However, the first choice drug will be *hochuekkito* + *senkyuchachosan*.

In the case of this report, *hochuekkito* plus *Angelica Dahurica* Radix*, Cnidium* Rhizoma*, and Chrysanthemum Flower* were decocted and administered. The final prescription was mostly settled into this formulation. If the form of extract is to be used, the Extract of *hochuekkito* + Extract of *senkyuchachosan* will produce similar effects.

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Extract of *senkyuchachosan* was administered to 55 patients with the diagnosis of mood disorders (depressive disorders). The prescription was effective in 35 and headache disappeared in 20 within two weeks and the medication was discontinued. And, *senkyuchachosan* was administered to 24 patients with the diagnosis of schizophrenia; 19 patients were considered to have had effects with the disappearance of headache and the medication was completed. Most of the patients with schizophrenia mentioned that "the use of *senkyuchachosan* cleared the head," or "the foggy head became clear with the prescription."

Front Line of Kampo Medicine

Review 1 of Academic Meeting Concerning Pharamaceutical Sciences (2)

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Graduate School of Pharmaceutical Sciences
Nagoya City University

This series introduce latest studies on Kampo medicines presented at the Society's meetings. The second installment of the series will provide the studies presented at The 27th Annual Meeting of Medicinal and Pharmaceutical Society of WAKAN-YAKU.

Quality preservation of crude drugs, Research for identification

Wu et al. of University of Toyama made analysis of diversity of ingredients contained in the products on the peony market and reported that most of the red peonies produced in China were originated from *Paeonia lactiflora* but some were originated from *P. veitchii*. And they further clarified that the red peony originated from *P. veitchii* contains slightly more amounts of paeoniflorin and pentagalloyl glucose than *P.lactiflora*, but ingredients of both spices are not different.

Studies on problems arising from preparing Kampo medicines

Himeno et al. of University of Toyama showed that when a Kampo formula was decocted and the decoction was heated again after being stored for ten hours at room temperature, no changes occurred in the amounts of the ingredients. And they reported there would be no problem if the amount/formula for a daily use was decocted at a time and then divided portions were taken.

Basic pharmacological research for Kampo medicines

Visasul et al. of Niigata University of Pharmacy and Applied Life Sciences reported the effectiveness of *shomyakusan (Generate the Pulse Powder)* for memory disturbance induced in mice when scopolamine was intraperitoneally administered.

Endo, et al. of Kitasato University reported that *saireito (Minor Bupleurum Decoction plus Poria Powder with five Herbs)* and *orengedokuto (Coptis Detoxificating Decoction)* had the effects on ulcerative colitis in mice induced by the oral administration of dextran sulphate.

Oka et al. of University of Toyama reported that they had administered *hachimijiogan* to the models of chronic renal impairment in 5/6 nephrectomized rats and observed renal protective effects by the activation of hypoxia inducing factor 1α. Kanako, et al. of University of Toyama examined renal protective effects of *keishibukuryogan (Cassia Twig and Tuckahoe Pill)* using the same models as above and reported that this Kampo formula had inhibitory effects on the kidney becoming fibrotic - stronger effects that cannot be seen from losartan. And Shibahara, et al. of the same University reported that they had performed gene expression analysis using the remaining portion of the kidney and found there were changes in the expression of the genes involved in kidney becoming fibrotic, such as matrix metallopeptidase or kallikrein. Moreover, Nakatsuka et al of the same University reported that they had administered the single medicinal herb *Rhubarb* to the same models, observing its inhibitory effects on kidney fibrosis, and it had the mechanisms different from those of *keishibukuryogan*.

Jyou et al. of University of Toyam reported that *goreisan (Poria Powder with Five Herbs)* had been administered to models of high blood

pressure induced by giving saline water to hemi-nephrectomized rats, resulting in significant increases in the expressions of Na^+/K^+-ATPase, beta-1 protein, aquaporin 1 and 2, through which *goreisan* improved kidney impairment.

Sakurai, eta al. of University of Toyama compared inhibitory effects for 50 types of protein kinase of 10 kinds of crude drug extracts composing *juzentaihoto (Ten Strong Tonic Herbs Decoction)* and suggested the comparison could be used as an omics research tool.

Kojima et al. of Musashino University reported that they had administered geniposide, which is a composing element of *gardenia fruit*, to spontaneously obese mice (TSOD mice) and observed the inhibitory effects on body weight gain, visceral fat accumulation and subcutaneous fat accumulation.

Yamabe et al. of University of Toyama observed the effects of lowering the levels of blood sugar and blood LDL in spontaneously diabetic mouse models (db/db mice) by administering *Kangen-karyu* (granules), and reported *Kangen-karyu* has the effects of improving diabetes. And, Park et al of the same University reported that they observed the effects of lowering levels of blood sugar, the effects of controlling triglyceride levels, and renal-protective effects by the administration of loganin contained in Asiatic Cornelian Cherry Fruit to the same models.

Kamei et al. of University of Toyama reported that significant declines was observed in increased levels of blood sugar and increased epididymal adipose tissue mass in rat models of obese fed a high-fat diet by the administration of *hachimijiogan*.

Kaminari et al. of Kracie reported that *bofutsushosan (Divaricate Saposhnikovia Miraculous Powder)* had been continuously administered orally to mice fed a high-fat diet, showing the inhibitory effects of weight gain and weight increase of white adipose tissues, suggesting that *bofutsushosan* has anti-obesity effects.

Cho et al. of University of Toyama reported that *chotosan* improved memory disturbance in aging promoted SAM mice and as the mechanisms, the improvement was due to its action of promoting NMDA-type glutamate receptor signals.

Aoki et al of Kitasato University reported that an increase in anti-virus antibody values was observed in influenza virus-infected mice by the administration of *maoto (Ephedra Decoction)*.

Nagai, et al of the same University reported *shoseiryuto (Minor Blue Dragon Decoction)* inhibited antibody value from increasing and showed anti-inflammatory effects and the recovery of the decreased expression of aquaporin 5 in mouse models of airway inflammation induced by ovalbumin inhalation.

Nohara, et al of Meijo University produced frequently sneezing mouse models by nasally administering compound 4/80 to mice and reported the significant inhibitory effects of *shoseiryuto (Minor Blue Dragon Decoction)* and *maobushisaishinto (Ephedra, Aconite and Manchurian Wildginger Decoction)* on frequent sneezing.

Sekiya et al of Kitasato University orally administered *hochuekkito* to mice that was given methotrexate intraperitoneally and compared changes in temperature-controlled expressions of the immunorelated molecule mRNA and they clarified the effects of *hochuekkito* on

immune-enhancement of the intestinal tract.

Yamamoto et al of University of Toyama reported that they had examined the influence of *kakkonto (Pueraria Decoction)* in mouse model of food allergy induced by the oral administration of ovalbumin to mice and observed a significant increase in regulatory T cells, suggesting *kakkonto* has the improving effects on food allergy.

Kimura et al of Ehime University reported that the oral administration of flavonoid contained in Scutellaria Root improved impairment of the dermal layer induced by ultraviolet radiation to hairless mice.

Kimura et al. of University of Toyama reported that in the models of pressure ulcers produced by applying pressure to rats, *kigikenchuto* (*Kigi Middle-Strengthening Decoction*) showed the effect of improving pressure ulcers by suppressing the expression of MCP-1.

Munekata et al. of Keio University reported that the administration of *juzentaihoto (Ten Strong Tonic Herbs Decoction)* to mice increased the expression of interferon-stimulated gene 15 in the lamina propria mucosae of the large intestine, enhancing the production of interferon.

Onuma et al. of Tokyo University of Pharmacy and Life Sciences reported that in cultured hepatocytes of healthy rats treated with the extract of Rhizoma and Radix Forbes *Notopterygium*, enzymes involved in drug metabolism were induced and detoxication of foreign substances was promoted.

Yamada et al. of St. Marianna University School of Medicine reported that in the *yokukansan (Liver-Inhibiting Powder)* administered rabbits, blood flow increased in the orbital short posterior ciliary arteries with lowered ocular pressure.

Handa et al. of Fukuoka University reported that the administration of *yokukansan* to rat models of Alzheimer's induced by treated cerebral ischemia-reperfusion abnormalities + intracerebroventricular administration of amyloid-beta showed the complete recovery effects on memory impairment.

Ito et al. of Kitasato University reported that the antidepressant effects of *kososan (Cyperus and Perilla Leaf Powder)* were observed in the models of depression induced by the application of chronic mild stress to mice.

Hori et al. of Showa University observed that *kamishoyosan (Modified Merry Life Powder)* showed the improving effects on the spontaneous tunnel in menopausal models in ovariectomized mice, suggesting it is effective for unidentified complaints associated with menopause.

Kanayama et al. of The University of Tokushima observed the suppressing effects of *Kujin* Extract (*Sophora Angustifolia* Root Extract) on cytokine expression induced by stimulating rat basophil leukemia cells (RBL-2H3 cells) with IgE, and isolated maackian to identify it as an active ingredient.

Liu of Hokuriku University reported that *yokukansan (Liver-Inhibiting Powder)* showed the protective effects on apoptosis by treating rat PC12 cells derived from pheochromocytoma with Abeta 40.

Clinical research for Kampo drugs

Sato et al. of Oita University reported that the levels of neuropeptides were measured to

compare those before and after the single administration of *goshajinkigan* Extract (*Life-Preserving Kidney-Qi Pill* Extract) in healthy males, showing significant increases that were caused by the administration in the levels of vasoactive intestinal polypeptides and calcitonin gene-related peptides with slightly increased blood flow rates, blood pressures, and pulse rates.

Ozeki et al. of Osaka University reported that there was a significant correlation between stagnant water scores and parameters showing cardiac muscle function.

Watanabe et al. of Suwa Chuo Byoin reported on their experience in which they had made the single administration of *Astragalus* Root or *Hedysarum Polybotrys* Root to patients with chronic kidney disease with the result of a decline in serum creatinine levels in either of them.

Others

Kashu et al. of Hyogo College of Medicine conducted a drug lymphocyte stimulation test (DLST) by treating peripheral lymphocytes prepared from the blood withdrawn from healthy people with crude drug extracts, and clarified that the reactions were found significantly positive to "*Prepared Aconiti Daughter Tuber*" and "*Gardenia Fruit*." They reported that in drug allergy diagnosis, false-positive reactions to these two drugs are prone to be detected.

Kampo Formula Developed in Japan (3)

Saikoseikanto

Hiromichi Yasui
Japan Institute of TCM Research

Profile

The currently used *saikoseikanto* is a modified formula of the original *saikoseikanto* (*Bupleuri* Radix, *Scutellariae* Radix, *Ginseng* Radix, *Cnidium* Rhizoma, *Gardeniae* Fructus, *Forsythiae* Fructus, *Platycodi* Radix, *Glycyrrhizae* Radix) described in the "Wàikē shūyào Pivot of External Medicine". The formula modified by Dohaku Mori (1867-1931) is characterized by exercising his ingenuity in adding "*shimotsuto*" and "*orengedokuto*" to the original prescription.

The current constituents are as follows:

Bupleuri Radix 2 g
Scutellariae Radix 1.5 g
Phellodendri Cortex 1.5g
Coptidis Rhizoma 1.5g
Trichosanthis Radix 1.5 g
Glycyrrhizae Radix 1.5 g
Platycodi Radix 1.5 g
Arctii Fructus 1.5 g
Gardeniae Fructus 1.5 g
Rehmanniae Radix 1.5 g
Paeoniae Radix 1.5 g
Cnidii Rhizoma 1.5 g
Angelicae Acutilobae Radix 1.5 g
Menthae Herba 1.5 g
Forsythiae Fructus 1.5 g

[Efficacy] Heat-clearing and relieving toxins/soothing liver and blood activation
[Indications] Heat toxin/liver depression/blood stasis
[Drug actions] *Coptidis* Rhizoma, *Scutellariae* Radix, *Phellodendri* Cortex, and *Gardeniae* Fructus work to clear heat and expell toxins in *orengedokuto*, while *Angelicae Acutilobae* Radix, *Paeoniae* Radix, *Cnidii* Rhizoma, and *Rehmanniae* Radix work to nourish and cool the blood and activate blood in *shimotsuto*. *Bupleuri* Radix, *Arctii* Fructus, *Forsythia* Capsule, *Platycodi* Radix, *Trichosanthis* Radix, *Menthae* Herba, and *Glycyrrhizae* Radix work to dispel wind and heat, expell toxins and dispel pus. Especially *Arctii* Fructus and *Platycodi* Radix repress throat inflammation.

Clinical application

Mori devised this prescription for improving the scrofulous constitution of children. Scrofulous is a syndrome caused by allergic reactions relating to a tuberculosis infection. Scrofulous was often seen in childhood in those days. The symptoms include swollen lymph glands of the neck and other places, which were accompanied by eczema, keratoconjunctivitis, blepharitis, rhinitis or cheilitis, presenting a peculiar sickly visage. With the decreasing of tuberculosis, such patients decreased and are not seen today. Today, with the benefits of the past experience, the prescription is used for respiratory tract infections, atopic dermatitis, other skin disorders, and neurotic diseases that are recurring in children. Of course, this formula has indications for adults.

1. Recurrent upper respiratory inflammation in children (especially tonsillitis)

This formula is often used for tonsillitis and sinusitis that recur in childhood. A long term administration (more than six months) is needed for these diseases.

Iwama, et al. have released a document on their study in which *saikoseikanto* was administered to

12 child patients (age 2-8, 5 males, 7 females) having tonsillitis recurrently, a half of the patients had tonsils assessed as grade II of Mackenzie's classification with white furs on the cryptae. These patients received the formula (0.1g/kg/day) for about one year when the disease stage marginally passed the acute stage. Although eight patients developed a fever after one month of oral administration, a fever onset did not appear after two months. Ten patients used to suffer from a fever every day during 2-5 months prior to the start of the administration. The onset of fever, however, decreased to only three times a year. Two patients were not responsive to the treatment, one of which had a tonsillectomy[1]. There is other report published on this formula by Fujii[2].

This formula containing 15 kinds of crude drugs is complex in its constitution and has been created with the concept different from that of "Shāng hán lùn." This suggests that children's susceptibility to infections has a variety of aspects, which elucidation remains to be seen.

2. Atopic dermatitis

Atopic dermatitis is a refractory skin disorder and it is increasing in recent years. *Saikoseikanto* is often used for this disorder occurring in childhood.

Horiguchi, et al. report that when this prescription was used together with topical steroids to 34 patients in total in the groups of atopic dermatitis with mild to serious severity, the combination use was effective in 84% of all patients and it was also effective in each group, whereas when petroleum jelly was combined instead of steroids, this combination use was effective in 64% (this case, many of the patients in the group of mild severity showed marked effectiveness and many patients of the groups of moderate and serious severity had no effect or became worsened) [3].

Mikawa, et al. report that they prescribed *saikoseikanto* for children with atopic dermatitis (15 male and 10 female) who had not obtained sufficient effects even though the causes of the disease were eliminated or by the use of topical ointments to assess the effects of itching. From one week administration, they obtained the impression of "slightly improved" to "very improved" in 80% of the children[4].

Ito administered *saikoseikanto* for 12 weeks to 25 children aged 2-15 with atopic dermatitis who had not had adequate effects by the application of topical creams. The results showed that after 2 weeks and onwards, improvements were observed with significance differences and more-than-improved were shown in 80% of all patients[5].

3. Neurosis

Saikoseikanto contains *Bupleuri* Radix, which is a typical drug for soothing the liver, Wild Mint, which has both actions of soothing the liver and dispersing pathogenic factors, *shimotsuto*, which nourishes the liver, and many heat clearing drugs, which cure the pathological conditions of depressed liver qi transforming into fire. Therefore, this formula is used for neurosis and it is often used especially for neurosis in young children.

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