THE JOURNAL OF ACUPUNCTURE AND INTEGRATIVE MEDICINE
KAMPO, ACUPUNCTURE AND INTEGRATIVE MEDICINE
Research on Theory, Practice and Integration

KAIM

The Journal of Kampo, Acupuncture and Integrative Medicine

INTERNATIONAL INSTITUTE OF HEALTH AND HUMAN SERVICES, BERKELEY

Volume 8, Number 1 · Spring 2013

Editorial
Clinical Practice Guidelines including Acupuncture
Hitoshi Yamashita

Japanese Acupuncture - Current Research
Japanese Traditional Medicine Text (7) – Orthopedic Disorders, D Acupuncture Research for Stiff Shoulders
Tomokazu Kikuchi

Kampo Medicine - Current Research
Clinical Experience for Functional Sterility, Complicated with Irregular Menstruation and Anovulatory Cycle, Administrated of *Saireito*
Takeshi Nakayama

Clinical Report 1 (Acupuncture)
Safety and Effects of Acupuncture Treatment Using Filiform Needles for Hemodialysis Patients
Hinata Sakuraba, Hiroshi Kondo, Shuichi Katai, Tomomasa Moriyama, Hiroaki Kinoshita, Takashi Ishizu and Aki Hirayama

Clinical Report 2 (Kampo Medicine)
Cornelia de Lange Syndrome with Recurrent Pneumonia
Hideaki Yamaguchi

Conference Report
The 3rd JSAM International Symposium on Evidence-based Acupuncture
- Evidence of the Effectiveness of Acupuncture for Headache -
Hitoshi Yamashita

ISSN:1559-033X

LIFENCE®

College Logos

We believe it is necessary to create a new way of thinking for the total understanding of "Life, Survival, and Health".

We decided to coin the world "Lifence" to express this.

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

Our college logos symbolizes the above.

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

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

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

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

GOTO

College of Medical Arts & Sciences

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

Research on Theory, Practice and Integration

EXECUTIVE EDITOR
Shuji Goto
Chairman, GOTO College of
Medical Arts & Sciences
Tokyo, Japan

ASSOCIATE EDITORS
Shuichi Katai
Ibaraki-ken, Japan
Hiromichi Yasui
Tokyo, Japan

EDITORIAL STAFF
Akihiro Souma
Hiromi Sasaki
Hiroshi Tsukayama
Hitoshi Yamashita
Junko Okubo
Kazunari Ozaki
Kengo Nakata
Masayuki Kashima
Naoya Ono
Noboru Mitsuhata
Sayaka Toda
Takao Namiki
Toshiaki Makino
Toshihiro Togo

PUBLISHER
Shuji Goto
International Institute of Health and
Human Services, Berkeley
2550 Shattuck Avenue, Berkeley
California 94704-2724, U.S.A.

The Journal of
Kampo, Acupuncture and Integrative Medicine

Volume 8, Number 1 ・ Spring 2013

TABLE OF CONTENTS

1 **Editorial**
Clinical Practice Guidelines including Acupuncture
Hitoshi Yamashita

2 **Japanese Acupuncture - Current Research**
Japanese Traditional Medicine Text (7) – Orthopedic Disorders, D Acupuncture Research for Stiff Shoulders
Tomokazu Kikuchi

6 **Kampo Medicine - Current Research**
Clinical Experience for Functional Sterility, Complicated with Irregular Menstruation and Anovulatory Cycle, Adinistrated of Saireito
Takeshi Nakayama

12 **Clinical Report 1 (Acupuncture)**
Safety and Effects of Acupuncture Treatment Using Filiform Needles for Hemodialysis Patients
Hinata Sakuraba, Hiroshi Kondo, Shuichi Katai, Tomomasa Moriyama, Hiroaki Kinoshita, Takashi Ishizu and Aki Hirayama

19 **Clinical Report 2 (Kampo Medicine)**
Cornelia de Lange Syndrome with Recurrent Pneumonia
Hideaki Yamaguchi

20 **Conference Report**
The 3rd JSAM International Symposium on Evidence-based Acupuncture
- Evidence of the Effectiveness of Acupuncture for Headache -
Hitoshi Yamashita

MISSION

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

小太郎漢方製薬株式会社

KOTARO PHARMACEUTICAL introduced in 1957 the world's first Kampo extract preparations on the market. Later, in 1967, six of our preparations could be covered in Japan for the first time by the health insurance and after 1976 more than 100 of our preparations were used in hospitals and clinics. Now it is half a century since we put our Kampo extract preparations on the market and believe, we made a major contribution to this industry.

In the future we intend to continue working in accordance with our company motto: "Still better Kampo for still more people" and provide pharmaceutical products of still higher quality.

Origin of the company's name

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

KOTARO PHARMACEUTICAL CO., LTD.
5-23 Nakatsu 2-Chome, Kita-ku, Osaka 531-0071, JAPAN
URL: http://www.kotaro.co.jp

Editorial

Clinical Practice Guidelines including Acupuncture

The NICE Guidelines (UK) for low back pains and headaches provide information about acupuncture, as is well known, but evidence-based clinical practice guidelines published in Japan have also begun to contain such information in recent years. As of 2013 at least, seven guidelines in Japan provide information about acupuncture. Among these, a grade of recommendation of A or B is given to acupuncture for low back pain, fibromyalgia, chronic headache (excluding tension-type headache, which is given a C grade of recommendation), and tennis elbow. A grade of recommendation of C is given to facial paresis and non-odontogenic toothache, and D is given to alopecia areata (acupuncture should not be performed). Such information about acupuncture is supposedly based on systematic reviews or meta-analyses of randomized controlled trials (RCTs), but in reality,there are some guidelines in which judgments have not been properly drawn out. For example, compared to the NICE guidelines, Japanese guidelines for tennis elbow overestimates acupuncture, as the grade of recommendation is based on the old Cochrane systematic review, while the guidelines for tension-type headache underestimates acupuncture. With respect to alopecia areata, its grade of recommendation goes against the guidelines' definition of recommendation grade to begin with, and is self-contradictory.

Thus, although clinical practice guidelines that deal with acupuncture treatment also exist in Japan, they are not yet sufficiently reliable. Why is this so? One reason is perhaps the absence of any committee that is well-versed in acupuncture treatment and aptly suited to preparing guidelines on the treatment of various diseases. Unlike drug therapy, clinical practice and RCT for acupuncture is complex and unique, so it is difficult for those who are not familiar with this difference to determine the grade of recommendation of acupuncture treatment. Sham acupuncture is frequently regarded as a control in relation to acupuncture treatment, but it actually differs from a placebo in an RCT of a drug, as it has certain specific effects. Another problem is that clinical practice guidelines in Japan mostly refer to RCTs of TCM acupuncture, due to the lack of sufficiently examined and publishedevidence of Japanese acupuncture treatment.

The fair evaluation of acupuncture treatment in clinical practice guidelines requires the participation of specialists who have knowledge of the characteristics of acupuncture practice and research. When compiling guidelines on diseases for which evidence of acupuncture treatment is gradually being accumulated, an open framework that invites the participation not only of physicians but also acupuncturists is thought to be instrumental to producing even fairer guidelines. Toward this end, it is important that acupuncture clinicians and researchers make greater efforts to more widely disseminate and raise awareness of the differences between acupuncture studies and pharmaceutical studies.

Hitoshi Yamashita, Lic. Ac., Ph.D.
Professor, Graduate School of Health Sciences
Morinomiya University of Medical Sciences, Osaka, Japan

Japanese Acupuncture - Current Research

Japanese Traditional Medicine Text (7) – Orthopedic Disorders, D Acupuncture Research for Stiff Shoulders

Tomokazu Kikuchi
Center of Oriental Medicine
Saitama Medical University Hospotal

The 2010 National Lifestyle Survey[1)] found that Stiff Shoulders were the number one complaint for women and the number 2 complaint for men, with more than 90% of the population having had experience with the condition. However, medically speaking, Stiff Shoulders are a subjective complaint with no clear definition. Further, in 2004, a study for orthopedic physicians called "Stiff Shoulder Research Project"[2)] found subjective physical symptoms including muscle tension and stiffness (Korikan) extending from the neck to the scapular area, characterized by a sense of pressure and dullness, but presented no clear definition of objective findings. Stiff shoulders are often said to be a uniquely Japanese symptom but epidemiological comparisons between the United States and Europe for [neck pain] and [stiff shoulders] found these symptoms distributed within and between different age groups and across gender lines. On the other hand, according to a National Survey (multiple answers possible) of people who sought treatment for stiff shoulders 24.6% went to hospitals, 20.1% went to clinics and 59.6% went to acupuncture, moxibustion and massage practitioners. Clearly a large proportion of the population are receiving treatment from Acupuncture, Moxibustion and Massage. Classical Oriental Medical theory describes damage by cold in the neck, shoulders, upper back leading to stiffness and pain.

Within the field of Pain Clinics, stiff shoulder is divided into three categories. The first has no clear pathology and is referred to "Essential Shoulder Stiffness". The second type may arise from spinal disorders or underlying shoulder disorders and is referred to as "Symptomatic Shoulder Stiffness". Finally, regardless of whether or not the patient presents with organic disease symptoms, if there are no objective shoulder stiffness findings, it is labeled "Psychogenic Shoulder Stiffness". In this paper, we will be discussing shoulder stiffness that is not the result of critical changes due to diseases or conditions that cannot be confirmed as neurological abnormalities.

1. Pathophysiology of Stiff Shoulders

Until recently, the pathophysiology of stiff shoulders has been categorized as follows: instability of the cervical intervertebral discs, local tension in the sympathetic nervous system and additionally, circulatory disorders influencing the nerves and muscles. On the other hand, as for neck pain, causes have been hypothetically explained as due excessive muscle stimulation causing excessive tension in intervertebral joints, cervical discs or nerve roots as they relate to referred pain. Additionally, it is often thought that shoulder stiffness is a condition with mostly non-specific symptoms involving a vicious cycle of pain compounded by additional psychological and sociological factors[2)].

2. Acupuncture Treatment for Stiff Shoulders

With the exclusion of the psychological and sociological background attached to stiff shoulders, the functional abnormalities seen in the sympathetic nervous system, circulatory disorders influencing the muscles and nerves begin to form a clearer clinical picture. For the purposes of Acupuncture and Moxibustion treatment, keeping in mind the possibility of stimulating the subcutaneous tissues, we can anticipate effects in the skin, muscles, fascia, intervertebral joints and the peripheral nerves. It has been estimated that the effects of acupuncture are due to improved circulation in muscles and nerves [3)] and may be due to normalization of the autonomic nervous system mediated by higher levels of the central nervous system. The principle areas for stimulation are along the back of the skull, trapezius muscles of the neck and head and semi-spinalis muscle of the head (UB10, GB20), the

insertions of the Sternocleidomastoid and the Splenius muscles of the head (GB12), on the upper portion if the Trapezius (GB21), muscles that cross along the inter-scapular area (UB43), also, areas of the Splenius and the Scapulae Levator and the insertion of the Splenius at the superior border of the scapula (SI14). Common methods of stimulation include embedded needles, manual stimulation of filiform needles, and electro-acupuncture. It is necessary to pay careful attention to the patient's condition and level of pain so that the stimulation can be appropriately adjusted.

3. Acupuncture and Moxibustion Treatment for Stiff Shoulders–The Condition of Research Abroad

We performed a literature review of clinical trials on the effectiveness of Acupuncture and Moxibustion Therapy for Stiff Shoulders conducted by foreign researchers. 「PubMed」 was used as the dedicated Data Base for the literature review. Key Words included [neck pain], [neck disorders], [neck stiffness], [shoulder stiffness], [acupuncture], [moxibustion], [randomized controlled trial]. We are reporting on basic research and original content standards. Our exclusion criteria eliminated reviews and commentaries from this report. We found 23 reports that could be included. Evaluation methods included mostly VAS scores, NDS and SF-36 were also seen here and there. The most common type of control was a "no treatment" control group, placebo control (non-meridian acu-points or skin stimulation groups).TENS groups and massage groups were also used as comparative control groups. Compared to the "no treatment" control groups, acupuncture treatment could be accepted as a valid treatment method. However, when compared with placebos or other treatment-type controls, the point of view about acupuncture efficacy was not unified. This paper is targeted to non-specific shoulder problems (stiffness); as there are a variety of locations and causes of shoulder pain (work related, posture related, etc.). Although the area treated by acupuncture is 3-dimensional, few reports investigate which tissues will be stimulated beyond the superficial pre-determined acu-point. Additionally, the problem now is that, even if sham acupuncture is used as a placebo control, it has been shown to have a physiological stimulus. From now, we must investigate the causes of Shoulder Stiffness, how to conduct acupuncture to stimulate specific tissues and to grasp how this stimulation effects the disease process.

4. Characteristics of Shoulder Patients and Clinical Status

Compared to Westerners' "Stiff Neck Pain", Japan's stiff shoulders represent deeper psycho-social stress. Japan's Historical and Cultural background are thought to have been influential in the development of this uniquely Japanese shoulder stiffness. The consensus is that Japanese culture avoided, as much as possible, descriptions of psychological symptoms that appeared, instead, focus was placed on their physical representation. To better understand the clinical efficacy of Acupuncture treatment for Stiff Shoulders we conducted a Literature Search. Using a database of prominent Medical School Journals including the following keywords: Stiff Shoulders, Neck Pain, Acupuncture, Moxibustion, and Randomized Controlled Trials. The search provided 4 appropriate references. Nakajima[5] compared a local pain relief injection group with an acupuncture group. Reported results showed that for neck pain, acupuncture treatment was more effective in the short term and over the long run, so compared to other treatment methods, acupuncture was more effective. Nabeda et al. compared the superficial needle only and retaining needle after the needling sensations at the tender point, no difference was found within and between groups after 1, 2, 3 weeks. Furuya et al.,[7] investigated using 0.6mm embedded needles and placebo type embedded needles (using just the protective tape), comparing the baseline to post-stimulation readings and 3 days after the stimulation, they found that the subjects with true

embedded needles experienced significant improvement. Further, comparing positive and negative results of a load test on the cervical spine, while groups testing intervertebral joints and discs demonstrated no changes is test results, it was reported that in test groups for muscles and fascia, test changes were effectively confirmed. On the other hand, Ito et al.[8] used a Trigger Point (TP) Acupuncture group and a Standardized Acupuncture group, comparing these to sham acupuncture, after the treatment they reported that only the TP group's VAS scores dropped significantly. Because the research subjects were students and faculty members, "volunteer bias" should be considered to a certain degree. However, acupuncture treatment for stiff shoulders by treating muscles and fascia was found to be highly useful compared to treating with TP or the cervical spine.

Table 6: The change of acupuncture before and after with SF—36 and WAI by acupuncture treatment

	Before	After 1 month	P value
Mental Component Score	51.3±6.3	53.1±5.8	<.0001
Physical Component Score	44.0±10.0	47.2±8.5	<.0001
Physical functioning	53.6±6.4	54.0±6.4	.5998
Role physical	46.4±10.6	48.9±7.0	.0167
Bodily pain	42.4±9.0	48.9±9.0	< .0001
Vitality	48.5±9.0	50.5±8.0	.0714
General health perceptions	44.7±10.1	46.7±9.2	.1286
Social functioning	50.5±9.7	50.7±7.4	.9709
Role emotional	48.9±9.7	49.1±9.4	.8434
Mental health	47.2±9.1	48.9±8.0	.1134
Work ability index	36.1±6.5	37.4±5.7	.0058

Wilcoxon lunk sine test, n=61, mean±S.D.

5. Future Prospects

Rather than treat stiff shoulders as simply a symptom, we consider it necessary to assess the exact background factors to grasp underlying disease processes and clarify which tissues are being over-stimulated by life style factors and which areas need to be treated to return the body to normal function. We suggest performing comparative trials, if possible, by separating subjects into specific groups based on their personal reports, clinical findings and discrepancies between these. For example, dividing subjects into groups with personal pain reports (specific pain in a localized area) that coincide with clinical findings or a group with pain (non-specific pain) that conflicts with clinical finding. These subgroups with shoulder stiffness complaints could then be compared using tests that provide reproducible results (such as localized pressure pain at specific points of the joint, range of motion and muscle strength tests). Concerning evaluation methods, beyond the VAS pain indicator, QOL scales with multi-faceted questions and possible responses should be used. We have already been developing a non-specific task score/ protocol based on Furuya et al.'s work with embedded needles for VDT workers with non-specific shoulder pain. So for subjects with shoulder pain, we used VAS and QOL (SF-36) measures to clarify the usefulness of acupuncture for improving work effectiveness[9,10] and align the treatment with background factors that may be causing shoulder pain (Table 6). On the other hand, the most significant problem has become using "sham" acupuncture when establishing the comparison groups for acupuncture. So far only embedded needles have been considered appropriate because even the mere application of a guide tube to an acupuncture point has been shown to activate Polymodal receptors in the epidermis, so using normal filiform needles (豪鍼) for sham needling was considered unrealistic. At present, comparison with other treatments and acupuncture stimulation site

selection methodologies, acupuncture RCTs should be used to investigate the specific effects of back ground factors on shoulder pain. In the future, multifaceted evaluation results should be used to determine what back ground factors contribute to stiff shoulders, Acupuncture RCTs should be compared with other treatments and point selection methodology should be investigated to achieve specific effects.

References

1) Ministry of Health, Labor and Welfare: Overview of the national livelihood Census, 2006, 2007.
2) Kenji Takagishi et al.: Research Project on the Shoulder (2004-6). Japan Society of Orthopedic Surgery 82(10): 901-911, 2008
3) Tomokazu Kikuchi et al.: Effect of electro-acupuncture stimulation on circulation to the trapezius muscle— 99mTcO4 —A study using the clearance method. Kampo Medicine 61(6): 834-839, 2010
4) Satoshi Yamaguchi: Effects of Acupuncture Treatments: Trends in Research Findings. The Journal of the Japanese Society of Balneology, Climatology and Physical Medicine58 (4): 232-240, 1995
5) Miwa Nakashima et al.: Study on acupuncture for neck pain by a randomized, controlled trial with local injection. Journal of Japan Society of Acupuncture and Moxibustion 57(4): 491-500, 2007
6) Tomoyuki Nabeta et al. Randomized controlled pilot study of acupuncture on neck stiffness. Journal of the Japan Society of Acupuncture and Moxibustion; 47(3): 173–81, 1997
7) Eiji Furuya, et al.: The Effects of Thumbtack Needling on Upper Back Muscle Stiffness, Journal of Japan Society of Acupuncture and Moxibustion, 52 (5): 553-561, 2002.
8) Kazunori Ito et al.: Trigger point acupuncture trials on University students with shoulder stiffness—A Questionnaire Survey from the results of Acupuncture Clinical trials. Journal of Japan Society of Acupuncture and Moxibustion 56(2): 150-157, 2006
9) Rika Suzuki et al.: Effects of Acupuncture for VDT workers (1) Influence on Neck, Shoulder Stiffness and Eye Strain. Journal of Japan Society of Acupuncture and Moxibustion 60(5): 829-836, 2010
10) Tomokazu Kikuchi et al.: Effects of Acupuncture for VDT workers (2) Influences on QOL and Work Productivity and Comfort. Journal of Japan Society of Acupuncture and Moxibustion 61 (1): 51-58, 2011

Kampo Medicine - Current Research

Clinical Experience for Functional Sterility, Complicated with Irregular Menstruation and Anovulatory Cycle, Administrated of Saireito

Takeshi Nakayama
Department of Obstetrics and Gynecology, Shizuoka Kosei Hospital

[Abstract]

Kampo therapy for sterility is often used as single or adjunctive agent medicated with a western medicine, for primarily treating the functional abnormalities such as anovulation. Typically, the chief patterns of administration are *tokishakuyakusan*, *unkeito*, and other agents that improve blood deficiency. Many researches have been reported concerning their efficacy in treatment of sterility. In recent years, however, many patterns other than the type of blood deficiency may be present due to food satiation and the stress-related disease. Thus, newer approaches of Kampo therapy adapted for the modern age would be necessary for the treatment of sterility.

Therefore, we tried administrating *saireito*, a formulation to treat Qi stagnation and fluid retention, for patients with sterility complicated with irregular menstruation or anovulatory cycle. Its excellent efficacy was demonstrated by assessment of changes in sex hormonal levels, the recovery rate of menstrual cycle, and the rates of ovulation and pregnancy before and after the oral administration. Since *saireito* has ever exerted the alleviating effect on stress in some cases in addition to the improving effect on ovarian function, it is estimated to be an effective administration for patients with sterility accompanied with the menstrual irregularity or the anovulatory cycle.

Key words: Primary Sterility, Saireito, Irregular Menstruation, Anovulatory Cycle

[Introduction]

Saireito is a combination formula made up of *shosaikoto* and *goreisan* for the treatment of stagnation of liver Qi and fluid disturbance. It is supposed to have endogenous steroid hormone-like actions and inhibits platelet aggregation and its effects for the treatment of gestational edema and habitual abortion have been confirmed in the field of obstetrics and gynecology. Recently it has reportedly shown to be effective for polycystic ovary syndrome and is therefore expected to be an effective therapeutic drug for the treatment of abnormal endocrine metabolism.

In infertility patients, the presence of "Qi" disorder like Qi depression or Qi stagnation has been pointed out. Moreover, the metabolic syndrome has developed into a social problem, so there are not many cases which blood deficiency is the predominantly major. Therfore, we tried *saireito* in patients with functional sterility complicated by irregularities of menstruation or ovulation disorders. We examined variations in female hormone concentrations, menstrual cycle, variations in ovulation ratio and the occurrence of pregnancies associated with the internal use of *saireito* to determine whether *saireito* is an effective drug for the treatment of infertility.

[Methods]

During the period from January 2008 until December 2011, we prescribed *saireito* extract granules (Kracie) 8.1 g/bid before the meals after obtaining a sufficient informed consent for 24 (average age 34.7±4.5 years) out of 89 patients who visited our clinic with the desire to have children and presented with irregular menstruation like oligomenorrhea or amenorrhea and were diagnosed to suffer from ovulation disorders or functional sterility. Patients with organic factors like myoma uteri or the like female factors or else male factors were excluded. Each individual patient underwent oriental medical examinations to establish the disease pattern that were subsequently analyzed, but prescribed *saireito* regardless of the pattern. For this reason the formula may possibly have have been administered for off-label use. The ethics committee of our clinic discussed the issue and approved, that in

cases of apparent deviation from the pattern patients in question were excluded from the study. Blood examinations were performed before the administration, 4 and then 8 weeks later between the 5th to 7th day after onset of the menstruation and the variations in the measured LH, FSH, LH/FSH, testosterone values examined. Also, any variations in the menstrual cycle and the occurrence of ovulations before and after the administration of *saireito* were confirmed with reference to the basal body temperature. Establishment of pregnancies was later confirmed by the delivery.

The occurrence of adverse events related to the internal use was also investigated. We attempted at the same time also to make a comparative study pertaining to Qi, Blood and Water including all infertility patients, those treated with *saireito* as well as the patients in whom pregnancies occurred after treatment with *saireito*.

[Results]

The 24 infertility patients presenting with irregular menstruation were treated with *saireito*. In 15 of these patients a recovery of the menstrual cycle could be observed (menstrual cycle improvement ratio 63%). Also, based on the basal body temperature ovulations were observed in 14 of the patients with anovulatory cycles and among these ovulation was definitely established in 9 patients (ovulation ratio 64%).

Table 1: List of patients who became pregnant

	Age	BMI	Gravidity	Parity	Abortion	Menstrual cycle (before)	Menstrual cycle (after)	Ovulation (before)	Ovulation (after)	Duration until pregnancy (Cycle)	PCOS
1	33	26.6	1	1	0	Oligomenorrhea	Normal	No	Yes	4	No
2	28	17.5	1	0	0	Oligomenorrhea	Normal	No	Yes	3	Yes
3	34	19.9	0	0	0	Oligomenorrhea	Normal	Yes	Yes	2	No
4	34	20.1	0	0	0	Oligomenorrhea	Normal	No	Yes	4	No
5	42	28.4	2	1	1	Oligomenorrhea	Normal	No	Yes	3	No
6	33	22.6	0	0	0	Oligomenorrhea	Normal	Yes	Yes	6	No
7	40	21.1	5	1	3	Oligomenorrhea	Normal	Yes	Yes	7	No
8	31	21.8	1	1	3	Oligomenorrhea	Normal	No	Yes	2	No
9	24	20.7	1	1	1	Oligomenorrhea	Normal	Yes	Yes	6	No
10	32	18	0	0	0	Oligomenorrhea	Normal	No	Yes	5	Yes
11	34	23.6	0	0	0	Oligomenorrhea	Normal	Yes	Yes	4	No
12	34	19.3	0	0	0	Oligomenorrhea	Oligomenorrhea	Yes	Yes	6	Yes
13	37	17.4	0	0	0	Oligomenorrhea	Oligomenorrhea	No	Yes	12	No
14	40	24.9	0	0	0	Oligomenorrhea	Oligomenorrhea	No	Yes	4	No
15	37	21	2	1	1	Oligomenorrhea	Normal	Yes	Yes	3	No
16	39	39	2	2	0	Oligomenorrhea	Normal	Yes	Yes	7	No

Among the 24 infertility patients pregnancies occurred following treatment with *saireito* in 16 women (pregnancy rate 67%, see Table 1).
Treatment duration with *saireito* until establishment of pregnancies was on the average 4.9±2.5 weeks. Moreover, while 6 out of the 24 patients were diagnosed with Polycystic Ovary Syndrome (PCOS), pregnancies occurred in 3 of those patients (pregnancy ratio 50%). A breakdown of the outcome in the 16 women who got pregnant showed ongoing pregnancies in 14 (87%) women and spontaneous abortion in 2 (13%). The delivery in those women, who actually gave birth was uneventful for both mother and child, considered to be also due to the fact, that the children had simultaneously been medicated and obvious anomalies were not observed.

Regarding fluctuations in the gonadotrophic hormone levels the LH values before, 4 and 8 weeks respectively after the administration were 7.1±4.8, 5.5±2.8 and 4.7±1.1 mIU/ml. While the LH concentration tended to be both before and after the administration low, significant differences were not observed. The LH/FSH ratio was 0.88±0.62, 0.62±0.27 and 0.55±0.13 respectively and decreased significantly before and afer the administration.($P<0.05$). No significant differences were observed in FSH and testosterone levels (Figure 1).

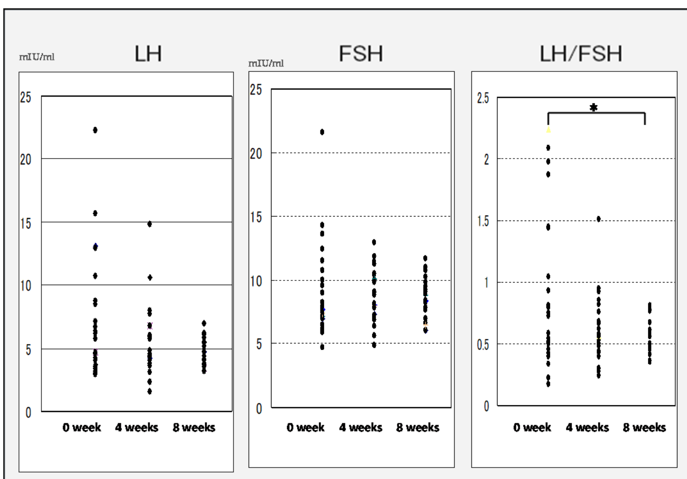


Figure 1: Fluctuations in hypophyseal hormones associated with the administration of *saireito*

Adverse events associated with the internal use included the occurrence of mild diarrhea, vomiting and similar symptoms of gastroenteritis in one patient (4.2%), but these were alleviated by discontinuing the medication. Otherwise, including clinical laboratory tests, no problematic side effects were observed.
Examination of Qi, Blood and Water during the visits of the 89 infertility patients showed Qi deficiency in 31 cases (35%), Qi stagnation in 39 (44%), Blood deficiency in 50 (56%), Blood stagnation in 31 (35%) and Water stagnation in 26 (29%) patients. Regarding the 24 patients treated with *saireito* 9 (38%) presented with Qi deficiency, 10 (42%) with Qi stagnation, 13 (54%) Blood deficiency, 10 (42%) Blood stagnation and 8 (50%) with Water stagnation. Among the 16 women in whom a pregnancy occurred 6 (38%) presented with Qi deficiency, 6 (38%) with Qi stagnation, 8 (50%) Blood deficiency, 7 (44%) Blood stagnation and 7 (44%) with Water stagnation (Table 2).

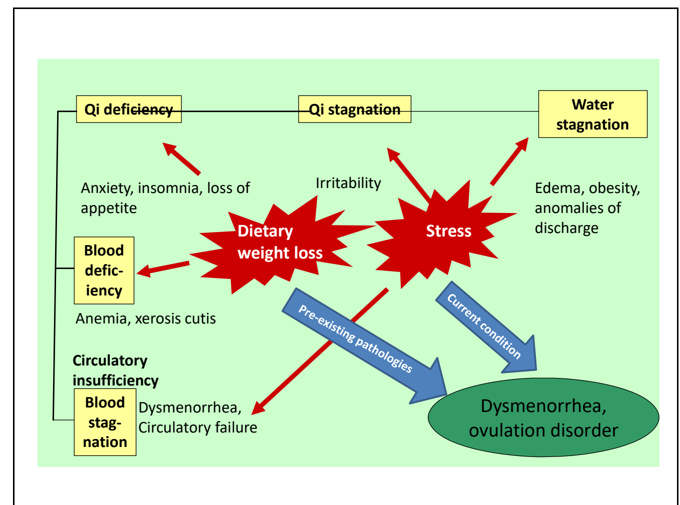
Table 2: Patterns in infertility patients and patients treated with *saireito*

	Qi deficiency	Qi stagnation	Blood deficiency	Blood stagnation	Water stagnation
All infertility patients (89 patients)	31/89 (35%)	39/89 (44%)	50/89 (56%)	31/89 (35%)	26/89 (29%)
Patients treated with *saireito* (24 patients)	9/24 (38%)	10/24 (42%)	13/24 (54%)	10/24 (42%)	8/16 (50%)
Patients treated with *saireito* in whom a pregnancy occurred	6/16 (38%)	8/16 (50%)	8/16 (50%)	7/16 (44%)	7/16 (44%)

[Discussion]
The factors responsible for female infertility can broadly be classified into functional and organic disorders. Disorders of tubal patency, intrauterine disorders, peritubal adhesion, myoma uteri, endometriosis etc. can be mentioned as organic

anomalies, but the progress in assisted reproductive technology (ART) and fiberscopic surgery have led to remarkable improvements in therapeutic results[1). While progress in recombinant preparations and gonadotropin therapies allowed to achieve higher ovulation ratios in cases of functional anomalies, the pregnancy ratio has not markedly changed and conditions like ovarian hyperstimulation syndrome (OHSS) and multiple pregnancies cannot be avoided. The results of infertility treatment have improved remarkably, but there are still some infertility patients whose cause is unknown, and even if the infertility treatment with ART is performed, there are many patients who have difficulty getting pregnant because of infertility[2)]. Among oriental medical concepts regarding infertility the "kidneys" are thought to control reproduction, so that the condition is considered to be based on menstrual anomalies due to "kidney deficiency"[2)]. However, the condition is often influenced by multiple factors like anemia and chilling correlated to "Blood deficiency", "Blood stagnation" caused by circulatory insufficiency, stress-induced mental conditions like "liver depression and Qi stagnation", "disorders of the body's fluid metabolism" due to disorders of pelvic blood flow etc., which often are present in various combinations (Figure 2). Some reports state, that abdominal or tongue examinations showed in actual clinical practice a close correlation of liver depression and Qi stagnation, "Blood stagnation" and "disorders of the body's fluid metabolism" with infertility, so that *Bupleurum* preparations or drugs for overcoming Blood stagnation are effective[2)]. Regarding the "pattern" of infertility a study conducted in 1989 showed that approximately 65% of the cases presented with a deficiency pattern, while excess patterns were reportedly found in less than 10%. Regarding anomalies of Qi, Blood and Water "Qi deficiency" was reported found in 32%, "Qi stagnation" in 37%, "Blood deficiency" in 61% and "Blood stagnation" in 22% respectively[3)]. For this reason formulas for the treatment of "Blood deficiency": *Tokishakuyakusan* and *unkeito* were frequently chosen and there are multiple reports on their effects in the treatment of infertility[4,5)].

Figure 2: Pathology in modern infertility patients (personal proposal)



Saireito is a combination formula composed of *shosaikoto* and *goreisan* that includes 12 crude drugs and is designed to alleviate stagnation of liver Qi and disorders of the body's fluid disturbance. The original text in the "Shi yi de xiao fang 世医得効方)(Effective Formulas from Generations of Physicians " by Wci Yi - Lin (危亦林 1277-1347) says "very effective for curing wind damage, summerheat damage and malaria" and the formula was mainly used for conditions associated with inflammation. Asada Sohaku's text "Futsugo Yakushitsu Hokan" contains the passage: "This formula is used for people with a *shosaikoto* pattern to alleviate feelings of distress accompanied by excessive thirst combined with diarrhea. It is particularly effective for summerheat epidemics.", describing the symptoms of the *shosaikoto* pattern. Main indications are nephrotic syndrome, chronic nephritis and similar renal diseases, chronic hepatitis etc. where a mild degree of edema is observed, heat stroke and the like acute forms of enteritis, exudative otitis media, habitual headache as well as a combination with steroid hormones (to reduce dose or alleviate side effects). Regarding the mechanism of action it has been reported to stimulate the hypothalamus – hypophysis – adrenal system, while *Glycyrrhizae* Radix inhibits the cholesterol metabolism in the liver and reportedly increases steroid production[6)]. In the field of obstetrics and gynecology *saireito* is used for the gestational

edema associated with habitual abortion, and used especially often during pregnancy. *Saireito* administered as a treatment of habitual abortion has been reported to be safe for the fetus even during fetal organ period[7]. It is therefore presumed to be one of safe therapeutic drugs for patients desiring to have children. Recently multiple reports describing cases in which pregnancies have been established through treatment with *saireito* have been published[8,9]. We therefore conducted this study based on the assumption, that *saireito* is an effective formula for the treatment of infertility.

When 24 patients complaining of infertility associated with menstrual irregularities were treated with *saireito*, pregnancies were established in 16 of these patients (67%) within a period of 4.9±2.5 weeks. In 9 (64%) out of 14 patients in whom anovulatory cycles were observed, ovulations were confirmed based on the basal body temperature. In former reports about Kampo treatment for infertility *tokishakuyakusan* led to an ovulation ratio of 44% and a pregnancy ratio of 22%, while Unkeito similarly led to an ovulation ratio of 50-60% and a pregnancy ratio of 18%[10]. Thus, compared to the aforementioned Blood deficiency improving formulas, *saireito* achieved even higher ovulation and pregnancy ratios. Comparing the levels of the gonadotrophic hormones before and after administration showed a decreasing tendency for LH values and moreover a decrease in the LH/FSH ratio ($P<0.05$). *Saireito* probably stabilizes the gonadotrophic hormone balance, thereby possibly enabling an effective action at hypophseal hormone levels. Regarding PCOS the number of cases was few with only 6 patients, but in 3 (50%) of those a pregnancy was established. Thus, establishment of pregnancies was observed in a comparatively high number of cases treated with *saireito*.

Generally, clomifene citrate or gonadotropin preparations are used for in the field of infertility therapy as the therapeutic drug for the treatment of ovulatory disorders. Yet, since they might cause the development of OHSS besides their other effects, multiple pregnancies could develop in case of superovulation. For these reasons the benefits of Kampo therapy with its fewer side effects is currently reconsidered. Some reports point out, that in modern society the pathology of infertility patients suggests a strong psychosomatic correlation, which bestows great importance on healing "Qi" anomalies with the Kampo therapy[11]. In particular "liver depression and Qi stagnation" and "disorders of the body's fluid metabolism" are frequently observed pattern in infertility patients, so that *saireito*, designed to heal stress or obesity seems to the indicated for the "pattern" of modern infertility patients. In practice Murata's report in 1989 found that 32% of the patterns were "Qi deficiency", 37% "Qi stagnation", 61% "Blood deficiency" and 22% "Blood stagnation"[3], while the current study revealed 35% of the patterns to be "Qi deficiency", 44% "Qi stagnation", 56% "Blood deficiency" and 35% "Blood stagnation", indicating that the portion of "Qi stagnation" and "Blood stagnation" has increased as compared with former reports, which in turn is possibly correlated to the larger number of established pregnancies through treatment with *saireito*. Moreover, the effectiveness of *saireito* for the treatment of PCOS has recently also been confirmed[12,13]. PCOS is an endocrine disorder associated with irregularities of menstruation or polycystic ovaries, hyperandrogenemia or increased secretion of LH. The pathology suggests, based on the presence of obesity or insulin resistance, a correlation with the metabolic syndrome[14]. This may lead to ovulatory disorders and thus frequently be correlated to the pathology of infertility, so that *saireito* presumably is beneficial for infertility patients suffering from complication with PCOS.

It is well known that *tokishakuyakusan* or *unkeito* are used as Kampo therapy for infertility and their use is by now general practice. In recent years the nature of the infertility "pattern" is possibly changing, so that for infertility patients in whom these formulas do not lead to the establishment of pregnancies, a therapy based on Kampo diagnosis is adopted when it seems to be necessary to choose a more suitable formula. Verification of the effectiveness of *saireito* still needs further study, but for modern infertility patients and complicating menstruation irregularities or ovulatory disorders *saireito* can be considered to be one effective formula.

[Conclusions]

The internal use of *Saireito* for the treatment of infertility complicated by menstruation irregularities or ovulatory disorders has led in many patients to a normalization of the menstrual cycle or the establishment of pregnancies. Apart from improving ovarial function, *saireito* also alleviates the stress associated with infertility treatment and is therefore considered a possibly effective formula for the treatment of infertility.

[References]

1. Satoshi Hayakawa: Usefulness of Kampo therapy for the treatment of infertility. Journal of Clinical and Experimental Medicine; 2003; 204: 1011-1014
2. Naohisa Ushiroyama: The role of Kampo therapy in the treatment of infertility. Obstetrical and Gynecological Therapy; 2001; 83: 45-50
3. Takaaki Murata: Introduction into Kampo therapy in obstetrics and gynecology; Kampo and infertility. Obstetrical and Gynecological Therapy; 1989; 58: 693-702
4. Toshihiro Aono: Effectiveness of *tokishakuyakusan* for the treatment of infertility. Progress in the research into Kampo therapy in the field of obstetrics and gynecology; 1995; 12: 52-57
5. Masao Igarashi: Effects of *unkeito* and *tokishakuyakusan* for the treatment of infertility; in particular ovulatory disorders and luteal insufficiency. Kampo Igaku 1985;9:85-88
6. Izumi Iwai: Influence of *saireito* on the hypothalamus – hypophysis – adrenal system in rats. Hormones and Clinic; 1992; 40: 745-748
7. Masanori Iwaki: Safety of *saireito* in the treatment of infertility. Prog Med 1999; 19: 1969-1971
8. Tsuyoshi Nakayama: Therapeutic possibilities of *saireito* in the treatment of infertility. Prog Med 2010; 30: 14-15
9. Four cases in which a combination therapy with *saireito* led to pregnancies: Toshitake Moriyama. Medicine and Pharmacology; 2011; 66: 123-128
10. Toshiyuki Yasui: Practical lectures to learn Kampo therapy from experts; menstrual irregularities, female infertility. Clinical Obstetrics and Gynecology; 2008; 62: 1061-1066
11. Takashi Kano: Infertility as a psychosomatic disorder in medical care. Psychosomatic medicine; 2009; 49: 1171-1176
12. Atsushi Sakai: Investigations of the usefulness of Saireito for the treatment of polycystic ovary syndrome. Clinical Obstetrics and Gynecology; 2000; 54: 1330-1333
13. Machi Okamoto: Effects of *saireito* on the ovarian function of patients with polycystic ovary syndrome. Reprod Med Biol 2010; 9: 191-195
14. Rotterdam ESHRE/ASRM-Sponsored PCOS Consensus Workshop Group: Revised 2003 consensus on diagnostic criteria and long-term health risks related to polycystic ovary syndrome. Fertil Steril 2004; 81: 19-25.

Clinical Report 1 (Acupuncture)

Safety and Effects of Acupuncture Treatment Using Filiform Needles for Hemodialysis Patients

Hinata Sakuraba[1)], Hiroshi Kondo[1)], Shuichi Katai[2)], Tomomasa Moriyama[2)], Hiroaki Kinoshita[1,2)], Takashi Ishizu[3)] and Aki Hirayama[1)]

1) Center for Integrative Medicine, Tsukuba University of Techonology, Tshukuba, Japan,
2) Faculty of Health Sciences, Tsukuba University of Technology, Tsukuba, Japan,
3) Department of Nephrology, Tsukuba Central Hospital, Ushiku, Japan

1. Introduction

The number of dialysis patients in Japan in 2010 was 300,000 and continues to grow[1)]. Many patients on hemodialysis often suffer from various conditions like amyloidosis induced arthralgia or pruritus of unidentified etiology, hemodialysis induced fatigue etc.[2)]. It has been pointed out, that since the patients are complaining of the above mentioned physical symptoms, their Quality of Life (below abbreviated QOL) is worse than that of healthy persons[3,4)]. Many of the listed symptoms can be treated with medications physicians prescribe, but often the achieved improvements are not satisfactory, so that many of the staff members in charge of the hemodialysis treatment agonizes over how to treat these conditions[5)]. Complementary and Alternative Medicine (below CAM) has received much attention for possible solutions it may provide and thus a "Study meeting for Research into Maintenance of Hemodialysis Patients with Complementary and Alternative Medicine" approved by the Japanese Society for Dialysis Therapy (JSDT) has been held[6)]. During this study meeting various results of CAM treatments have been reported, where many reports dealt with acupuncture treatment as a representative form of CAM. Acupuncture treatment has in Japan a long history as a therapy form and is both extremely popular and well known[7)]. It is also one of the few therapies of which a national qualification is approved. Our investigation reported many hemodialysis staff and hemodialysis patients interested acupuncture therapy[2,5,8)].

Several reports both abroad and in Japan deal with the effect of acupuncture treatment for hemodialysis patients. Abroad effects related to the improvement of pruritus, erectile dysfunction, gastroparesis have been reported[9,10,11)]. On the other hand, in Japan Okuno et al. used 0.6 mm press needles (Pyonex, SEIRIN Co., Ltd., Shimizu, Japan[12)]) for the treatment and reportedly achieved alleviation of pain and improvements of the QOL[13)].

Okuno et al. also used similar press needles for a crossover comparative study and reported effectiveness for intractable pruritus in hemodialysis patients[14)]. Moreover, regarding case reports dealing with the use of filiform needles for the treatment of complications in hemodialysis patients Kasuya et al. reported effectiveness for lumbar spinal canal stenosis and Sakaguchi et al. for the treatment of intermittent claudication respectively[15,16)]. However, in a systematic review of acupuncture treatment of hemodialysis patients published in 2010 only 6 relevant reports were analyzed and moreover no positive results could be deduced from studies with larger number of case reports[17)]. In other words, while reports pertaining to acupuncture treatment of hemodialysis patients can be found worldwide, there are only few studies guaranteeing a certain quality level. Also, the number of publications itself still remains rather low.

We observed during the performance of our study using filiform needles for the treatment many cases, where those had been effective. In this study we examined for the first time in Japan the safety and effectiveness of the use of filiform needles in acupuncture treatment of hemodialysis patients at the bedside.

2. Methods

1) Subjects

Subjects of the present study were hemodialysis outpatients at the T.C. Hospital Dialysis Center in Ushiku city of Ibaraki prefecture. A questionnaire was performed prior to the study and 3 of the patients requesting acupuncture treatment included as subjects (Table 1). On that occasion the hemodialysis

specialist at the same center confirmed, that there were no physical problems that would affect the performance of the acupuncture treatment. From all subjects a written and signed informed consent form was obtained for this study.

Table 1 Subjects

	Dialysis history	Age	Sex	Symptoms
Subject 1	5 years	74	male	low back pain, numbness of left leg
Subject 2	4 years	50	male	numbness of right hand, low back pain, pain
Subject 3	32 years	59	female	low back pain, pain of both shoulder joints, shoulder stiffness

(Symptoms classified according to hemodialysis history, age and sex)

Current symptoms of the subjects are as follows. Subject No. 1 was a 74-year old man with a dialysis history of 5 years. Symptoms treated with acupuncture are low back pain and numbness of left leg. The symptoms developed 5 years ago and worsened recently. At an orthopedic clinic he was diagnosed with lumbar spinal canal stenosis and treated in osteopathy clinics with electricity, but the condition did not improve. The second subject was a 50-year old man with a hemodialysis history of 4 years and treated for numbness of right hand, low back pain and pain of the right leg. The symptoms developed after a traffic accident in September 2008. They were treated with oral medication and compresses, which was not very effective. The third subject was a 59-year old woman with a hemodialysis history of 32 years and treated for low back pain, pain of both shoulder joints and shoulder stiffness. The symptoms developed several years ago and x-ray examination performed at an orthopedic clinic showed degeneration of lumbar vertebrae and osteophytes at the shoulder joint. She is currently treated with oral medication and compresses.

2) Treatment

The treatment was performed at the bedside, while the patients underwent their hemodialysis. Needles were Seirin (Shimizu, Japan) disposable filiform needles with a diameter of 0.16 mm (No. 1) and 0.18 mm (No. 2) of a length of 40 mm and 50 mm respectively (Figure 1). The treatments were performed by an acupuncturist with more than 10 years of clinical experience. Points were selected depending on symptoms and conditions, patients were in supine position (Figure 2-1), or if needling of the back was necessary turned on their side while watching out for the shunt (Figure 2-2). The needles were inserted using a guide tube to a depth varying from several millimeter to several centimeter and retained for a period between 10 and 15 minutes.

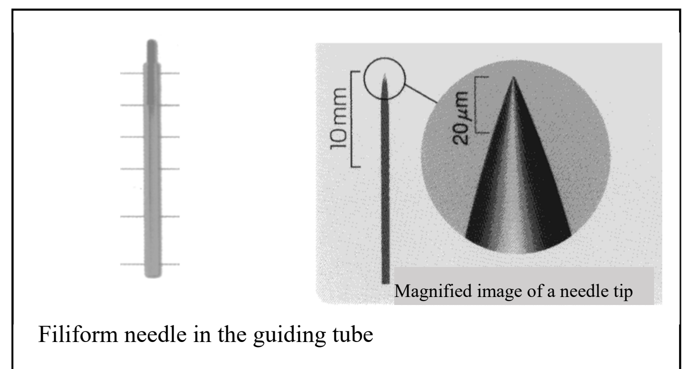


Figure 1 Disposable filiform needle

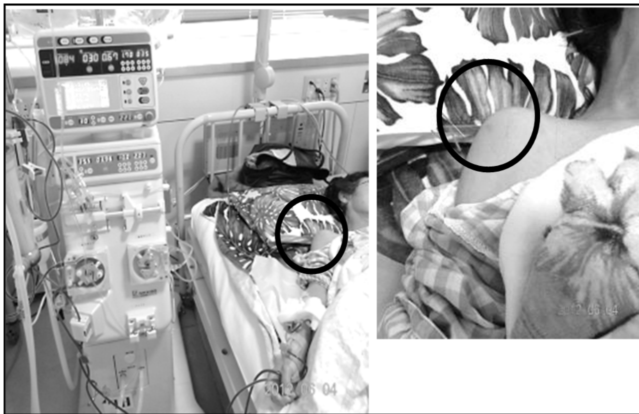


Figure 2-1 Treatment situation (supine position)

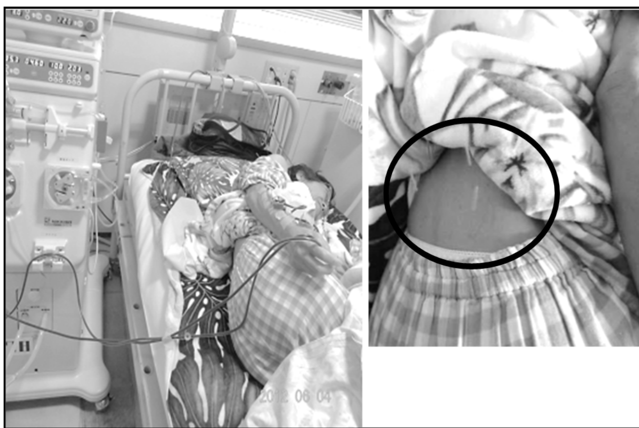


Figure 2-2 Treatment situation (lateral position)

3) Protocol and evaluation

One evaluation was performed prior to the start of the study and after that the duration defined as a 5-week treatment period and a following 5-week post treatment observation period. Treatments were administered once a week for a total of 5 weeks. During the post treatment observation period a total of 5 assessments were made at a rate of once a week (Table 2).

Table 2 Protocol

	Before	Intervention	Observation
Situation		treatment	resting
Period		5weeks	5weeks
Outcome	One time	Every week	

For the evaluation we used two different methods depending on the subject of the assessment. First we asked about the general condition and assessed the answers with the 6-step Face Scale (Figure 1). The other evaluation method was a Visual analog scale (below called VAS) where the patients assessed the severity of the treated symptoms between a level of 0 meaning "no problem at all" and 100 meaning "worst so far".

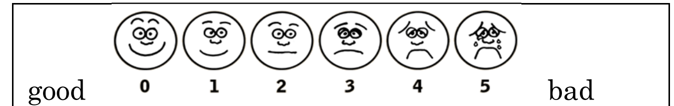


Figure 3 Face Scale

4) Incident, accident measures

There are no reports about using filiform needles for acupuncture treatment of patients undergoing hemodialysis in Japan. For us this was a new challenge too, so that we used past experiences as a reference in an effort to avoid or suppress the occurrence of incidents or accidents as shown in Table 3. Further, we asked the subjects to report any possible disadvantages caused by the acupuncture treatment directly to the physicians, nurses or dialysis staff in efforts to obtain still more detailed information.

Moreover, for the conduction of this study it was examined and approved by the ethics committee of the Center for East-West Integrative Medicine of affiliated with the Department of Health Sciences of the Tsukuba University of Technology.

Table 3 Incident, accident measures

* A sufficiently informed consent was obtained in advance.
* Use of disposable needles based on considerations pertaining to an easy susceptibility to infection.
* The physical condition was assessed and needling stimulation intensity gradually increased, to avoid acupuncture induced sudden drops in blood pressure.

* Physical and dialysis conditions were confirmed on the day in question prior to the treatment and in case of bad conditions the feasibility of the treatment itself was assessed and stimulus dose adjusted.
* No needling near visible blood vessels or shunts.
* Confirmation that the previous treatment site did not show signs of internal hemorrhage or other anomalies.
* Preparation of an incident report format used for detailed documentation and data accumulation regarding incidents.

3. Results

First we would like to address the occurrence of incidents and accidents. There were 3 cases (20%) out of the total of 15 treatments all three subjects received. Regarding their nature these incidents included internal bleeding, triggering of the alarm of the dialysis equipment during change of position and inadvertent touching the needles (retained needles) during the acupuncture treatment by the staff while attending to the patient. A physician took care of the situation in any case and critical events did not occur. The internal bleeding occurred at a needling site at the shoulder joint, but the patient him/herself did not complain about any pain or discomfort. The alarm was triggered by a change in position, turned off by a nurse and after that did not occur again. The contact with a needle while attending to a patient during an acupuncture treatment by a staff member was due to incomplete explanation for the staff members. After that we put up written announcements making it obvious, that the particular patient is receiving acupuncture and thereby solved this problem.

Next, Figure 4 shows how the subjects were classified depending on their general condition. The figure shows the average values of results obtained during the 5-week treatment and post treatment observation periods. Examination of the Face Scale showed, that it improved for subject 1 from the pretreatment value of 3.0 to 2.3 during the treatment period and 2.2 in the post treatment observation period. For subject 2 the value improved from the pretreatment value of 4.0 to 2.3 during the treatment period, but aggravated to 2.7 during the post treatment observation period. For subject 3 the value almost did not vary from the pretreatment value of 2.0 to 2.3 during the treatment period and similarly 2.3 during the post treatment observation period (Figure 4).

Figure 4 Results of the Face Scale

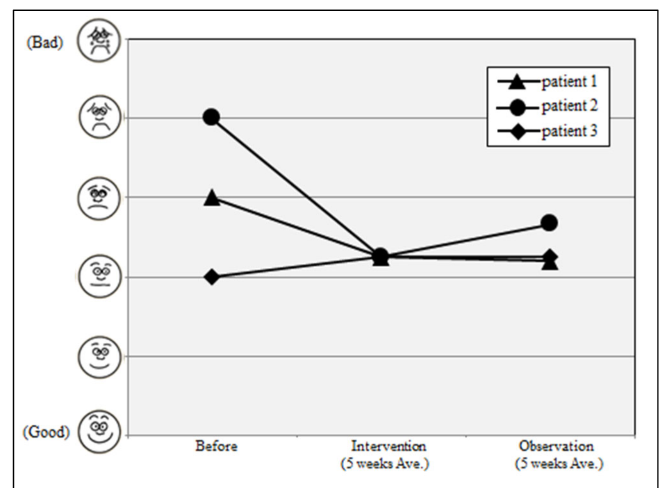


Figure 5 shows the evaluation results for each symptom obtained with a VAS. As with the Face Scale these too are the average values obtained during the 5-week treatment and post treatment observation periods. For subject No. 1 the two symptoms low back pain and numbness of the left leg, for subject No. 2 the three symptoms numbness of the right hand, low back pain and numbness of the right leg and for subject No. 3 the four symptoms low back pain, pain of both shoulder joints and shoulder stiffness were evaluated and the average values for each of the subject shown (Figure 5, left side). Looking at subject No. 1 shows a pretreatment value of 67.5, that decreased only little during the treatment period to 63.3. During the post treatment period, however, it rose to 69.5, which is higher than the pretreatment value. For subject No. 2 the pretreatment value was as high as 73.3, but markedly improved during the treatment period to 54.6 and almost maintained that level, namely 55.6,

during the post treatment period. Subject No. 3 showed during the pretreatment period a value of 60.0 that improved as in subject No. 2 during the treatment period to 50.3. During the post treatment period it showed a slight tendency towards returning to the pretreatment level to 54.7.

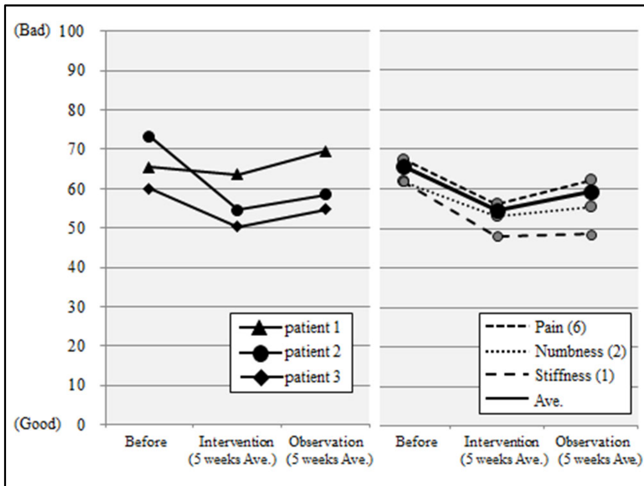


Figure 5 Results of the VAS

The following shows a classification of symptoms used for the examination of the results. The the classification of therapeutic targets in all three subjects showed pain (6 cases), numbness (2 cases), stiffness (1 case). Examining first the complaints of pain showed a pretreatment VAS value of 67.5 that improved during the treatment period to 56.3. However, during the post treatment observation period it tended to return to a level of 62.2. Regarding the numbness the pretreatment value was 62.0 and improved similar to that of pain to 53.1. This value too returned slightly during the post treatment observation period to 55.6, but not as much as in the case of pain. Finally, the pretreatment value of 62.0 for a feeling of stiffness improved during the treatment period to 48.0 and was basically maintained at 48.5 during the post treatment observation period.

4. Discussion

We performed a multifaceted study about acupuncture treatment for hemodialysis patients dealing with the concepts of the dialysis staff pertaining to the safety and effectiveness of acupuncture treatment, the needs of the patients and further the effectiveness of acupuncture treatment.

In this study we attempted to use filiform needles for the treatment of patients undergoing hemodialysis, for which previously no reports have been published in Japan. We kept the number of subjects low and conducted it as a pilot study. We made the best use of our previous therapeutic experiences and concentrated foremost on the safety. The results showed for this study an incidence of incidents/accidents of 20% requiring the intervention of a physician, but serious sequelae for the patients did not occur. Investigation of each incident showed that internal bleeding even occurred with 0.6 mm press needles, suggesting that this is unavoidable in hemodialysis patients presenting with a heightened bleeding tendency[15]. It is therefore essential to make sure patients understand this risk when obtaining an informed consent. Problems arising from staff coming contact with the patients were solved by putting up announcement boards. It is important to thoroughly announce the acupuncture treatment to the staff, implement all conceivable safety precautions and in case of incidents relevant measures should be examined one by one and implemented. Finally, fluctuations in blood pressure induced by changes in position are not limited to this particular study, but may occur whenever the patient changes his/her position. However, since there is a possibility of major accidents, the practitioner too should be careful to observe the shunt and any changes in position, possibly assisting the patient when necessary.

Regarding the treatment effects 2 of the subjects reported, their physical condition improved as compared to the pretreatment condition. Interestingly all subjects maintained a stable condition during the treatment and the post treatment observation period. This may be interpreted as lasting effects of the acupuncture treatment, but the physical condition is strongly

influenced by the dialysis method and the living environment, so that further studies are necessary. The symptoms of all patients improved during the treatment period, but tended to approach the pretreatment level again during the post treatment observation period. Classified by symptoms all complaints of pain, numbness and stiffness improved during the treatment period and tended to return slightly, but did not return to the pretreatment level. Based on the above described results treatment with filiform needles can to a certain degree be evaluated as being effective.

In this study we found that acupuncture treatment with filiform needles at the bedside during hemodialysis does not cause any serious adverse events and is to a certain degree effective for alleviating pain, numbness and stiffness. Yet, regarding pain and stiffness 0.6 mm press needles reportedly have also caused improvements[13]. Compared to press needles filiform needles are considered to pose a higher risk, so that the balance between the risk of serious adverse events and beneficial effects is important. We therefore think, that it is necessary to collect more cases, compare and investigate them, accumulate incident/accident information and publish the relevant information pertaining to effects and safety.

References

1. Committee of Renal Data Registry, Japanese Society for Dialysis Therapy, Tokyo, Japan: Overview of Regular Dialysis Treatment in Japan (As of 31 December 2010), Therapeutic Apheresis and Dialysis, 16(6), 483–521, 2012.
2. Sakuraba H., Takeuchi H., Takeuchi M., Syoji M., Moriyama T.: Questionnaire survey of complaints and acupuncture treatment in maintenance hemodialysis patients, Therapeutic Apheresis and Dialysis (Japanese), 40(6), 513-516, 2007.
3. Takai I., Shinzato T., Maeda K., Fukuhara S.: Measuring Health-Related QOL; A new endpoint for clinical Dialysis patient QOL: An attempt to use SF-36.: The Japanese Journal of Clinical Dialysis, 13(8), 1107-1113, 1997.
4. Mittal SK, Ahern L, Flaster E, Maesaka JK, Fishbane S.: Self-assessed physical and mental function of hemodialysis patients. Nephrol Dial Transplant, 16(7), 1387-94, 2001.
5. Sakuraba H., Mukai Y., Sawazaki K., Masuda F.: Questionnaire survey concerning acupuncture treatment to dialysis facilities in Mie Prefecture. Journal of the Japan Society of Acupuncture, 60(2), 209-215, 2010.
6. Agishi T.: 3th HD-CAM report. Clinical Engineering, 15, 1216-1229, 2004.
7. Togo T., Urata S., Sawazaki K., Sakuraba H., Ishida T., Yokoyama K.: Demand for CAM Practice at Hospitals in Japan: A Population Survey in Mie Prefecture, Evid Based Complement Alternat Med, 2011;2011:591868. Epub 2011 Jun 18.
8. Sakuraba H., Sawazaki K., Honda T., Moriyama T.: Possibility for Acupuncture Treatment in Maintenance Dialysis Medical Treatment – From a Questionnaire Survey completed by Dialysis Medical Treatment Staff-. Journal of the Japan Society of Acupuncture, 56(1), 76-83, 2006.
9. Che-Yi, C., C. Y. Wen, et al. Acupuncture in haemodialysis patients at the Quchi (LI11) acupoint for refractory uraemic pruritus. Nephrol Dial Transplant. 20(9): 1912-15, 2005.
10. Kim, K. H., T. H. Kim, et al. Acupuncture for erectile dysfunction in a non-diabetic haemodialysis patient: a case report. Acupunct Med. 29(1): 58-60, 2011.
11. Kim, K. H., T. H. Kim, et al. Acupuncture for symptomatic relief of gastroparesis in a diabetic haemodialysis patient. Acupunct Med. 28(2): 101-103, 2010.
12. SEIRIN Co.ltd.: Product Information. SEIRIN Co.ltd. Homepage, http://www.seirin.tv/.

13. Okuno T., Yasuno T., Sakai T., Akamatsu M., Agishi T.: Clinical study including 32 patients about the effects of press needles used for acupuncture treatment of patients on maintenance hemodialysis; Modern Acupuncture and Moxibustion; 3(1): 19-27, 2003.
14. Sakuraba H., Sawazaki K., Takeuchi H., Takeuchi M., Masuda F., Moriyama T.: The study about introduction and effect of the acupuncture which aimed at the QOL maintenance and improvement in a hemodialysis patient -A practice of the acupuncture for an itching - The Japan Kidney Foundation, 30(2), 167-174, 2007.
15. Kasuya D., Yamamoto K., Etou F.: Two cases of acupuncture treatment for lumbar spinal canal stenosis due to hemodialysis-related spondyloarthropathy. Kampo Med, 54(4), 773-779, 2003.
16. Sakaguchi S., Yamazaki T., Ikefuji H., Kawakami C., Nakayoshi T., Endo H., Umeda T., Wakayama I., Ujita T.: The clinical effects of acupuncture treatment on intermittent claudication in a diabetic hemodialysis patient. Therapeutic Apheresis and Dialysis(Japanese), 39(7), 1257-63, 2006.
17. Kim, K. H., M. S. Lee, et al. Acupuncture for treating uremic pruritus in patients with end-stage renal disease: a systematic review. J Pain Symptom Manage. 40(1), 117-125, 2010.

Clinical Report 2 (Kampo Medicine)

Cornelia de Lange Syndrome with Recurrent Pneumonia

Hideaki Yamaguchi
Tosei General Hospital

Case: 6-year-old girl with Cornelia de Lange Syndrome and recurrent pneumonia

The patient was clinically diagnosed with Cornelia de Lange Syndnrome, and received six operations since her neonatal period. They included diaphragmatic hernia repair surgery, colectomy, colostomy, esophagocardioplasty, and pyloroplasty. She began to develop recurrent respiratory tract infections at the age of 1. At the age of 4, the frequency of her being hospitalized increased, and it eventually got to the point where she was admitted to the hospital eight times in a year, for a total of 100 days.

The patient showed no susceptibility to infection, and general examinations and immunological tests showed no abnormality. The recurrent pneumonia was thought to occur mainly from diaphragmatic paralysis on the left side. Kampo therapy was considered, as no effective control could be found in Western medicine.

Present status: Weight 11kg. No speech.
Treatment: Assuming a dual deficiency in the lung and spleen, qi and yin deficiency, and congestion of lung heat, the following prescription (decoction) was administered (daily dose; brewed and taken in 2 to 3 separate doses per day).

Astragali Radix 8g
Ephedrae Herba 1g
Ophiopogonis Radix 5g
Armeniacae Semen 3g
Bupleuri Radix 3g
Platycodi Radix 2g
Ziziphi Fructus 3g
Glycyrrhizae Radix 1g
Gypsum Fibrosum 4g (short-term usage)

Initially, the patient refused to take the prescription. However, her mother thought of ways of taking it, such as by baking a cake mixed with the decoction or adding it to the sauce when making simmered vegetables. As a result, the patient was able to take about two-thirds of the daily dose every day.
She was admitted to the hospital once after two-and-a-half months, but has not required hospitalization thereafter, and her symptoms markedly improved. The prescription was administered for a year and five months while making adjustments, and the symptoms have stabilized even after terminating the prescription.
Observation: Kampo therapy based on the reinforcing and reducing method is effective against recurrent infections. However, decoction is no less effective in flexibly addressing severe cases such as this particular case.

Reference: Cornelia de Lange Syndrome is a congenital disease that is characterized by delayed physical and intellectual development. Patients with Cornelia de Lange Syndrome have a distinct appearance, including a small head, thick eyebrows that meet in the middle, a small pointed nose, a small chin, excessive body hair, and small hands and feet. Cornelia de Lange Syndrome also accompanies various malformations of the organs and epilepsy. Certain genetic mutations are seen in roughly half of all patients.

Conference Report

The 3rd JSAM International Symposium on Evidence-based Acupuncture – Evidence of the Effectiveness of Acupuncture for Headache -

Hitoshi Yamashita
Graduate School of Health Sciences,
Morinomiya University of Medical Sciences,
Osaka, Japan

On June 7 and 8, 2012, the 3rd JSAM International Symposium on Evidence-based Acupuncture was held at Yokkaichi Municipal Culture Hall in Mie Prefecture, under the sponsorship of The Japan Society of Acupuncture and Moxibustion (President: Shuji Goto). JSAM has previously held its first international symposium in 2006 themed on osteoarthritis of the knee, and the second symposium in 2009 themed on low back pain, to promote understanding of the concept of evidence-based medicine (EBM) among its members, and to reinvigorate studies that present clinical evidence of acupuncture and moxibustion in Japan based on an awareness of the status of overseas studies. This third symposium was themed on headaches, and also included a program for discussing sham acupuncture, which is causing a controversy about the appropriateness of its control groups.

Pre-symposium lectures first introduced the features of Japanese acupuncture to participants from Japan and overseas. Based on surveys, six speakers gave lectures on the present state of acupuncture practice in Japan, the characteristics of acupuncture patients, the history and present state of pediatric acupuncture and meridian therapy, and an overview of Japanese acupuncture in Europe.

Session 1 began after the opening ceremony. Dr. Sakai Fumihiko (Saitama Neuropsychiatric Institute) and Prof. Hisaka Igarashi (Kanagawa Dental College of Medicine Yokohama Clinic), leading authorities on headache research in Japan gave a presentation on the latest classification of headaches and the characteristics of headache patients. Next, Prof. Byung-Cheul Shin (School of Korean Medicine, Pusan National University) lectured on acupuncture and moxibustion therapy for headaches in South Korea, followed by Ms. Mari Suzuki (Saitama Medical University), who gave a report on acupuncture and moxibustion case series studies in university hospitals in Japan.

Session 2 was themed on acupuncture for headaches. Prof. Benno Brinkhaus (Institute for Social Medicine, Epidemiology and Health Economics, Charité University Medical Center) introduced the results of large-scale RCTs on acupuncture for headache that was conducted in Germany, and gave his interpretation of the overall evidence. Dr. Myeong Soo Lee (Korea Institute of Oriental Medicine) gave an outline of systematic reviews of RCT papers on acupuncture for headache, and noted the problems in the quality of RCTs on acupuncture. Mr. Tomokazu Kikuchi (Saitama Medical University) mainly reported on the results of a basic research on acupuncture for primary headache conducted by the research team to which he belongs.

In Session 3 held on the following day, Prof. Shoko Masuyama (Morinomiya University of Medical Sciences) gave an overview of clinical trials of acupuncture in Japan, and underlined some issues on quality of the studies. Prof. Brinkhaus discussed research methodology in clinical trial on acupuncture, and emphasized that the selection of trial design and control group depends on the primary research question. Mr. Yasuhisa Kaneko (Tokyo College of Medico-Pharmaco Technology) introduced the thumbtack needle effect in the sports field, followed by Prof. Kenji Kawakita (Meiji University of Integrative Medicine), who explained the mechanisms of physiological activities produced

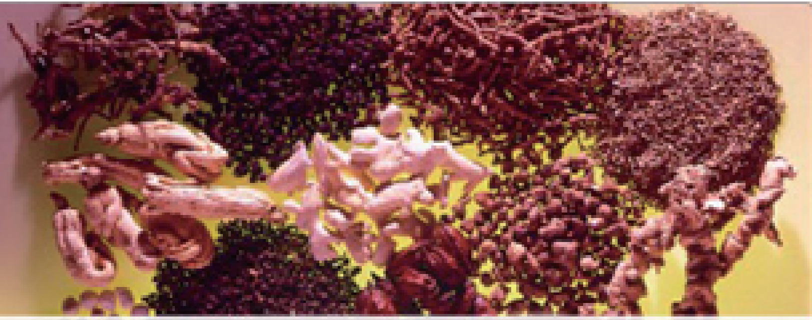
by various sham interventions used in recent clinical trials of acupuncture, and logically emphasized that even shallow stimulations on the skin can have a clinical effect. Lastly, Dr. Stephen Birch (Foundation for the Study of Traditional East Asian Medicine, Amsterdam) pointed to the fact that sham acupuncture in RCTs are frequently misinterpreted by reviewers and readers, although it is not a placebo treatment, and expressed his concern that wrong study designs are being selected for the relevant research question.

In Japan, acupuncture and moxibustion have been utilized to treat diseases and maintain health since olden days as a matter of course, precisely because they existed as traditional medicine. For this reason, the idea of examining the evidence that acupuncture and moxibustion are effective had never emerged until recently. As a result, clinical studies that are conducted in Japan from the standpoint of EBM have lagged behind foreign countries. This symposium is thought to have provided a renewed awareness of this issue and other such issues among acupuncture and moxibustion researchers and school teachers in Japan. It was particularly a large achievement that acupuncture and moxibustion researchers and clinicians acquired a common understanding of the need to disseminate information about the characteristics of Japanese acupuncture and moxibustion and papers that introduce Japanese acupuncture and moxibustion to the outside world, as well as the need to more accurately evaluate the clinical effects and physiological activity of sham needling that is used in the Western countries as a placebo control group and the comprehensive clinical effects of acupuncture that includes not only specific effects but also skin stimulation effects.

The symposium underlined the importance of organizing more international symposiums, workshops and other similar opportunities in Japan in order to foment greater understanding of Japanese acupuncture and moxibustion.

Dedication to Crude Drugs

SINCE1928



Tochimoto wishes • • • to be a partner of a wide range of industries from the pharmaceutical to the food and the beauty by providing natural and herbal medicines of good quality.

The crude drugs like many other creatures on earth are raised by bountiful NATURE.

Humankind earns as well grace from Mother Nature and is blessed as a member of natural world.

PROFILE *of* TOCHIMOTO

Since Tochimoto was appointed as a Japan-China friendship trading firm in 1963, we have expanded our business overseas, mainly with China.

We import a variety of quality-controlled natural resources from all over the world for maintaining wellness.

TOCHIMOTO TENKAIDO CO., LTD.

3-21 Suehiro-cho, Kita-ku, Osaka 530-0053, JAPAN

www.tochimoto.co.jp

Kracie

KEEPING PACE WITH THE TIMES,
MILD MEDICAL TREATMENT FOR HUMAN

twice or three times a day, possible to select

We wish you a healthy living

For more information, please contact
Kracie Pharmaceutical,Ltd.
20-20, Kaigan 3-chome, Minato-ku, Tokyo 108-8080

http://www.kampoyubi.jp
Printed in Oct.2007

My choice is SEIRIN

What's yours?

For painless acpuncture treatments
I always trust Seirin.
New patients are surprised by its comfort,and my
regular clients ask for it by name.

Exceptional Products.

Join the thousands of distinguished professionals
who have counted on SEIRIN for over 30 years to provide
the highest quality needles for you,
and a painless experience for your clients.

SEIRIN®
www.seirin.jp

Like us on Facebook