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“Historical Significance of Standardization of Acupoint Locations”, the Second Japanese Acupoint Committee (8)
Makoto Mayanagi

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International Institute of Health and
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Makoto Mayanagi

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Editorial

Key Issues for Quality Control of Natural Medicinal Products

Traditional medicines have been utilized worldwide. Key issues on using the medicines in a modern medical care system are described below.

In general, a medicinal product consists of an active principle (active pharmaceutical ingredient: API) and additives, and quality evaluation is made for them. An API plays a central role in a medicinal product. It is evaluated from various points of view such as description, identification (e.g. UV, IR and qualitative tests), pH, melting point, purity (e.g. clarity and color of solution, heavy metals, fingerprinting for related substances), loss of drying, residue of ignition, and assay in a Western medicine. On the other hand, all of such test items cannot be adopted for traditional medicines because of special circumstances in natural products. Under these circumstances, there are two premises in using traditional medicines in a modern medical care system; i.e. (1) equivalency between modernized traditional medicines (e.g. extract products) and ancient ones (e.g. decoction), and (2) quality evaluated by modern science.

- (1) Modernized traditional medicines shall be assured equivalent to ancient ones. Historical facts of manufacturing processes from an era to another, adoption of manufacturing processes in classical texts, and confirmation of equivalency between modernized traditional medicines and ancient ones can link the past with the present and can assure efficacy and safety of modernized traditional medicines. In Japan, extract products, whose quality is equivalent to standard decoctions, have been marketed as Kampo extract products.
- (2) Contaminants such as heavy metals, residual pesticides, and/or microorganism, and intentional adulteration of active ingredients cause a number of human sufferings. Safety of traditional medicines depends on quality of the products. Quality evaluation methods used for Western medicines cannot directly be applied to modernized traditional medicines; thus, manufacturing controls as well as quality controls are absolutely required to obtain high-quality products.

In case of an extract product, what can be considered as an API? Is it a chemical compound, a natural raw material, or extract? Extract is the answer in the case. Chemical compounds are ingredients of natural raw materials; natural raw materials are components of traditional formulas; and extract is an API of an extract product. Quality of medicinal products depends on that of APIs and it is very important to control manufacturing and quality of APIs; however, situations in natural medicines are complicated as shown below.

Case A: Mixture of extracts individually obtained from raw botanical/animal/mineral materials

In this case, a finished product is considered a combination product, and “**each extract**” derived from a raw botanical/animal/mineral material is an API. Quality assurance of each extract is important. An overall pattern of each extract should be strictly controlled.

Case B: Extract obtained from mixture of raw botanical/animal/mineral materials

In this case, a finished product can also be considered a combination product; however, “**whole extract**” derived from raw botanical/animal/mineral materials is an API. An overall pattern of whole extract should be strictly controlled.

It is known that constituent profiles of extracts can be different between the above cases if natural materials contain alkaloids. This is important in considering APIs. For these years, international standardization of traditional medicines in East Asia including TCM, Kampo medicines and Korean medicines has been facilitated; however, we have more than one way of thinking on APIs. Difference in manufacturing processes requires different control items. We should bear in mind different targets in quality assurance of traditional medicines.

Hiro Sasaki, Ph.D.

Visiting Scholar, Lifence General Institute
Assistant Secretary-General, The Japan Liaison of Oriental Medicine

Japanese Acupuncture - Current Research

Japanese Traditional Medicine Text (6) – Orthopedic

Disorders C Sports

Toshikazu Miyamoto

Professor,

Graduate School of Comprehensive Human Sciences,

University of Tsukuba

1. Introduction

In our current society, the border between health and disease is often unclear. Health care and its focus now must aim to cure disease and include promotion of life style choices that improve quality of life and increase life expectancy, early detection of disease and early treatment. In the field of sports and athletic performance as well, beyond the treatment of sports injuries, treatment for prevention of injuries or for physical disabilities and conditioning, health maintenance and athletic performance have become important themes.

Oriental Medicine has characterized itself by aiming to “treat the unseen disease”, that is treating the tendency to develop disease (root causes) before the disease has a chance to disrupt essential physiological processes like immune function, respiratory capacity, circulation, digestive processes etc. In short, Acupuncture treatment starts with information about the athletes physical condition and practice environment/routines and aims to estimate and repair impediments due to past injuries, help prevent new injuries, fatigue and poor performance due to over use by teaching the athlete to maintain their optimally healthy condition. Akimoto et al¹⁾ reported the results of questionnaires regarding Acupuncture treatment answered by university athletes (577 subjects). The percentage of respondents who had experienced Acupuncture treatment was 51.3%. The researchers also reported that higher level athletes tended to have had more experience with acupuncture. Miyamoto et al²⁾, queried 195 athletes (141 men, 54 women) from Ibaraki prefecture, attending a national sports event; 31.3% of these athletes had experienced

acupuncture. Nichols et al³⁾ conducted a survey on opinions about Complementary and Alternative Medicine (CAM); subjects were 309 University of Hawaii athletes. Results showed that more than 46% of respondents had received some form of alternative or complimentary (CAM) treatment within the previous 12 months, a percentage greater than the general population. Contents of the CAM treatments included 38% massage, 29% chiropractic, 14% LomiLomi massage (unique to Hawaii) and 12% acupuncture. Compared to earlier research, Sports athletes who had tried acupuncture were more prevalent than in the average population and as the athlete’s level of performance increased, the rate of experience with acupuncture increased as well.

Historic references for sports athletes receiving acupuncture reach back to Homma’s research in 1949 and include 6 editions of “Ido no Nihon” Journal as well as numerous international and domestic reports⁴⁾. Concerning acupuncture sports medicine, Homma discussed 1) treatment prior to competition to improve endurance, maximum strength and power, dexterity and resistance to impact, 2) methods for measuring fatigue related to sports and treatment methods for rapid recovery, 3) Acupuncture and moxibustion for sports injuries and dysfunction, 4) sports medicine used with acupuncture and moxibustion treatment. Following Homma’s contributions to acupuncture sports medicine, research until the mid-1980’s focused mainly on case studies reported here and there.

In 1990, Miyamoto presented a series of 4 papers on acupuncture and Physical Therapy for sports injury⁵⁾. The topics include research on acupuncture treatment for sports and exercise, the current situation of acupuncture treatment for sports injuries and dysfunction and acupuncture treatment for muscle fatigue as it relates to sports and movement. Palham’s 2001 review article introduced the study of acupuncture treatment on muscle strength, cardio (aerobic) training, flexibility and sports performance, re-asserting the need for

systematic guidelines for acupuncture in the field of sports medicine⁶⁾.

Since 1980, the number of papers published within the area of sports and acupuncture treatment in major medical university journals (MEDICINA) (keywords: acupuncture, electro-acupuncture, embedded needles x sports injuries) has been steadily increasing: 98 reports between 1980-89, 328 reports between 1990-99, 969 reports between 2000-09 (See Figure 4). However, among the 1,395 papers reviewed, most were transcribed minutes from meetings and only 332 were original papers. Keywords from these research papers included 1) Acupuncture x Sports (175) 2) Acupuncture x muscle fatigue (47) 3) Acupuncture x muscle endurance (1) 4) Acupuncture x delayed onset muscle soreness (DOMS) (10) 5) Acupuncture x Sports injury/dysfunction (88) 6) Acupuncture x Conditioning (5).

Similarly, of the Sports related acupuncture articles published Internationally in Pub Med between 1980 and 2009, there was a similar and marked upward trend: (keywords included: acupuncture x sports injury, DOMS, muscle endurance, muscle fatigue, movement, motion, exercise) between 1980-89, 59 reports, between 1990-99, 140 reports, between 2000-09, 526 reports (See Figure 4). The frequency of relevant keywords was as follows: acupuncture x sports injury (17 reports), acupuncture x DOMS (4 reports), acupuncture x muscle endurance (12 reports), acupuncture x fatigue muscle (12 reports).

Clearly, despite the overall increase in the number of the internationally and domestically published papers, there is a distinctly small number of original reports from Japan in Japanese. Concerning the field of acupuncture research for sports medicine, of particular interest is the 2010 issued report on Clinical Sports Medicine, "Special Report: Evidence for the Effectiveness of Acupuncture Treatment for Sports Medicine"⁷⁾. Within the field of Sports injury and dysfunction, the researchers present a picture of current trends in

Sports Medicine Acupuncture and introduce randomized control trials using embedded needles to treat sports related injuries.

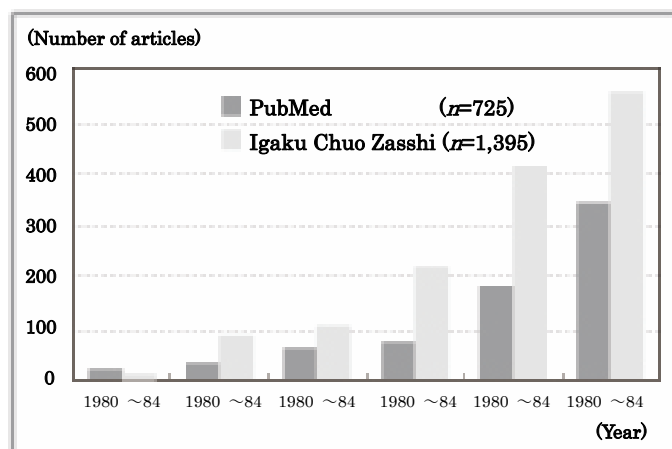


Figure 4: Number of Published Articles on Acupuncture for Sports Medicine

2. Clinical Studies Abroad

Kleihenzt al.⁸⁾, performed double blind RCTs on 52 sports athletes with shoulder tendinitis to investigate the efficacy of Acupuncture treatment. The subjects were divided into two groups: acupuncture that penetrates the skin layer or sham acupuncture that does not penetrate the skin layer completely. The results showed 1) for the acupuncture group pain, function, ROM, muscle strength (as measured by the Constant-Mureley-score all improved significantly more than the sham acupuncture group 2) three months following the treatment sessions a tracking questionnaire revealed that, although at the time the sessions were complete there had been no distinction between groups, the sham group reported distinctly different effects compared to the acupuncture group. Within the body of research using Acupuncture treatment for sports related injuries, this investigation represents the highest quality research.

Below are the research results from Brattberget al.⁹⁾, they compared the effects of steroid injections with acupuncture treatment for tennis elbow. Their finding are as follows 1) Compared to the control

group, the acupuncture group reported significantly more relief from pain. 2) Seventy percent of the acupuncture group had received steroid injections in the past, but had experienced little relief as a result. 3) Several subjects in the steroid injection group experienced a worsening of symptoms, but no such negative result or side effects of the treatment were experienced by the acupuncture group. According to the NIH and WHO, this research represents grounds for establishing acupuncture as the treatment for choice for Tennis Elbow. Further, Trinh et al. conducted a systematic review of Acupuncture for Tennis Elbow and Epicondylitis. However, many of the subjects for the study developed tennis elbow from activities other than tennis. Concerning domestic Japanese research, clinical studies of Tennis Elbow are not uncommon but comparative studies examining the relative effectiveness of acupuncture have not yet been researched.

Zhang et al.¹⁰⁾ investigated previous cases of ankle joint sprains treated with acupuncture, and found tension in the Peroneus and Tibialis Anterior muscles, local swelling, pain and feelings of anxiety were all lessened. Hahm¹¹⁾ reported that in rats with ankle sprains, electro-acupuncture of 2 Hz frequency was effective for relieving pain and reducing edema and 100Hz electro-acupuncture was effective for pain reduction alone. Park et al.¹²⁾ found that electro-acupuncture stimulation of 2 Hz frequency inhibited inflammation in injured ankle joints. Koo et al.¹³⁾ reported that a combination of 100Hz and 2Hz electro-acupuncture stimulation effectively increased the load bearing capacity in subjects with sprained ankles.

Virchota et al.¹⁴⁾ divided 48 athletes with plantar fasciitis into three groups: acupuncture, sham acupuncture and general injury recovery treatments including stretching, icing, aspirin-like pain relievers and practice restrictions and then assessed degree of pain, pressure pain and training satisfaction. Research results showed that, compared to sham acupuncture and general injury

recovery protocols, acupuncture provided significantly greater pain relief but also that, compared to the other test groups, pressure pain was not significantly improved in the acupuncture group.

3. Current Progress and Developments in Japanese Clinical Research

Effectiveness of Acupuncture for Sports Injuries and Development

Takazawa et al.¹⁵⁾ of the Japan Gymnastics Society presented Sports Medicine Research data on the percentages of athletes with specific injuries who had used acupuncture treatment for their conditions: of the 226 athletes with low back pain, 13.3%, of the 97 athletes with Spondylolysis 6.2%, and of the 140 athletes with disc herniation 15.0% were reported to have tried acupuncture. Further, it was reported that at the Tsukuba University Sports Medicine Hospital, low back pain was the most commonly treated complaint, 40% of all patients receiving acupuncture.

Miyamoto et al.¹⁵⁾ investigated 163 university level athletes who sought acupuncture for their specific injuries. Their results showed that, compared to the first treatment, following the last treatment athletes reported significant improvements in their ability to practice for low back pain, disc herniation and Spondylolysis, but pain relief was felt most by those athletes complaining of low back pain and disc herniation. Izumi et al.¹⁶⁾ also compared the results of 28 athletes following the first and terminal treatment, reporting that training condition, JOA score (Japan Orthopedic Society of low back pain Treatment Performance Criteria) significantly increased but the levels of pain and especially pain while moving the torso and trunk did not improve significantly.

Ito et al.¹⁷⁾ investigated 8 athletes with chronic low back pain who had been treated with acupuncture but had not achieved significant improvement. Treatments were continued for 2 weeks, 9 points on the lower limb were needled until

the third session, thereafter, sessions included retention needling at known trigger points for 10 minutes. Following the trigger point treatment, a VAS score was obtained and reported to verify improvements in experienced pain. The authors reported positive changes in VAS scores but no changes in JOA scores.

Miyamoto et al.¹⁸⁾ interviewed and investigated 43 subjects with pulled hamstrings. These subjects received electro-acupuncture treatments for 1-2 weeks with an average number of 7.6 treatments and, compared to the first treatment, following the final treatment, the subjects reported significant improvements in levels of pain and training condition.

Yoshida et al.¹⁹⁾ investigated the efficacy of electro-acupuncture stimulation on rats with pulled muscles (injured for the study). Compared with only the eccentric contraction group, researchers reported improvement of muscle tension and pain thresholds. Further, Yoshida et al.²⁰⁾ treated model mice with muscle injuries to investigate the effect of electro-acupuncture on degree and rate of recovery and found that, compared to the control group, the electro acupuncture accelerated recovery rates. Overall, there are few high level evidence based clinical research projects in Japan. However, a majority of these reports indicated that, regardless of where the injured area is located, acupuncture treatments help reduce pain and improve athletic training condition during treatment. Unfortunately, there are almost no double blind comparative tests in the literature. However, within Japan, along with an increase in clinical research, the response mechanism of acupuncture using animals for experiments is advancing.

b Randomized control trials on Athletes and Sports Medicine

The difficulty regarding acupuncture research is that, unlike pharmaceutical research, “blinding” both the subjects and the practitioner from the

research protocol is extremely complicated. However, because embedded needles are 1) depending on the stimulation, usually painless so subjects unfamiliar with acupuncture are more easily “blinded” 2) can be inserted with or without a needle tip so practitioners can be instructed to insert the needles without examining the needle tip and to then fix them in the desired location with tape, thereby “blinding” both the subject and the practitioner. For these reasons, embedded needles are very useful for double blind clinical acupuncture studies in general and, as will be discussed below, for sports athletes in particular. Miyamoto et al.²¹⁾ investigated the effectiveness of embedded needles for muscle pain and tension in marathon runners using a randomized double blind protocol utilizing placebo needles as the control. Subjects were 15 university students participating in a full marathon for the first time. Data and materials were collected and analyzed by individuals not involved in the needling or the marathon. Subjects were divided into two groups, the first group included 8 athletes needled with regular embedded needles, and the second group included 7 athletes needled with well-disguised “placebo” embedded needles.

The embedded needles or the placebo devices were placed bi-laterally on 8 acu-points on the lower legs before the start of the scheduled race and removed 5 days later. Data was recorded prior to the race and 5 days following the race. Measurements included VAS for muscle pain, creatine kinase (CK), lactate dehydrogenase isozyme (LDH), trunk flexion and muscle tension. The results of the research findings are as follows: 1) Muscle pain was significantly reduced following the marathon for those athletes with embedded needles ($p > 0.01$) 2) CK, LDH isozyme, LDH 4, LDH5 were all significantly elevated following the race ($p > 0.01$) so it was concluded that embedded needles were ineffective in moderating these cellular products. 3) There was no change in trunk flexion between the two subject groups. 4) Increased muscle tension was

observed in both the VastusLateralis and VastusMedialis muscles ($p>0.05$) indicating that the embedded needles were ineffective in reducing muscle tension. 5) Runners with embedded needles tended to have shorter race times. 6) Athletes were unable to determine if they had been needled with true needles or the control needles. Based on these results, it was concluded that embedded needles slightly reduced muscle pain following a marathon.

Kaneko et al.²²⁾ investigated whether Triathletes experienced less post-race pain following treatment with embedded needles compared to placebo type embedded needles. One hundred forty-nine male and female triathletes were recruited and divided into two groups; the embedded needle group had 79 subjects and the placebo needle group had 70. The placebo needle was the same item used by Miyamoto et al. discussed above. Both groups were needled using the same points, bi-laterally: UB23, UB24, UB25 and UB32. Needles were placed just before the start and removed as the athletes finished. Data was collected using a VAS score for 6 muscles in the lower limb before and after the race, as well as the day following the race. Results were reported as follows: 1) For both groups, muscle pain increased significantly following the race ($p>0.01$). 2) Excluding the Gluteal muscles, muscle pain for the embedded needle group decreased significantly the day following the race compared to immediately following the race ($p>0.01$, $p>0.05$). Athletes reported feeling their condition had returned to pre-race levels. 3) For the placebo group, on the day following the race, athletes reported less hamstring pain compared to immediately following the race ($p>0.05$). 4) Athletes in both groups were unable to determine if they had been needled with true needles or the control needles. From these results, the researchers suggested that embedded needles inhibited the delayed onset muscle soreness characteristic in athletes following strenuous exercise in athletes.

From Miyamoto and Kaneko's research, we have two comparative research studies demonstrating that embedded needles and carefully crafted tip-less placebo needles can be used to effectively blind the subjects and the practitioners to the research protocol, as evidenced by the inability of the subjects and practitioners to accurately determine which needles had been used. Further, embedded needles clearly reduced the muscle pain that commonly follows longer strenuous sporting events such as marathons and triathlons.

4. Summary

Within the field of acupuncture research for sports medicine and injuries, there has been a recent trend toward increased domestic and international research, however there are still few high level evidence based reports available. The difficulties associated with acupuncture treatment during clinical trials include 1) the ethical difficulty of requesting that serious athletes performing daily training programs participate in comparative trials where the placebo control may offer no particular benefit to them, 2) the reality that an integral part of acupuncture treatment involves stimulation with needles, it is often difficult to mask these sensations during clinical trials.

For these reasons, a good deal of creativity is necessary to develop effective research models that maintain the integrity of acupuncture methods and techniques but also meet the necessary criteria for double-blind comparative studies. Despite these challenges, Japan is endeavoring to expand its role in basic research projects that include acupuncture treatment for sports related conditions such as promoting early recovery of post-exercise muscle weakness and repair, preventing muscle atrophy during injury recovery and speeding muscle repair and development. Compared to foreign countries' clinical research, Japan has been conducting advanced research on fundamental areas of sports medicine. However, none of these have been

published in English Journals, so from now there must be more active transmission of Japanese reports abroad. There is a summary of these results in Table 5.

Table 5: Summary of Acupuncture Treatment for Sports Performance and Injuries

1	Year by year we have seen an increase in Acupuncture research for Sports Medicine, but advanced reports are still relatively uncommon.
2	Concerning the topic of Sports Injury, compared to the few available foreign research studies, Japanese research maintains higher quality methodology.
3	Domestic (Japanese) research projects often examine the treatment of low back pain in athletes. Acupuncture has often been shown to reduce pain and improve ADL and athletic performance.
4	The response mechanism behind acupuncture treatment for sports injuries such as ankle sprains and pulled muscles have been reported in papers both abroad and in Japan using both clinical trials and animal research.
5	Japanese randomized double-blind clinical trials have been used to demonstrate the significant effectiveness of embedded needles in reducing post-exertion muscle pain for endurance sports such as marathons and triathlons.

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Kampo Medicine - Current Research

Kampo (Japanese Traditional) Medicine and Gastrointestinal Symptoms in Pediatric Surgery

Keiko Ogawa-Ochiai

Associate Professor

Clinic of Japanese-Oriental (Kampo) Medicine,
Department of Otorhinolaryngology & Head and Neck Surgery
Kanazawa University Hospital

Summary

With the dramatic improvements in the prognosis of pediatric surgical diseases indefinite symptoms related to the digestive organs associated with prolonged survival are now also frequently observed. For these patients Kampo medicines then become a powerful choice. Frequently used prescriptions in the field of pediatric surgery for diseases of the digestive system *rikkunshito*, *daikenchuto*, *shokenchuto*, *inchinkoto*, *daiokanzoto*, *hangekobokuto*, *yokukansan*, *juzentaihoto* and *hainosankyuto* are outlined here. In order to meet the enthusiasm of pediatric surgeons, Kampo experts must cooperate in efforts to search for new indications.

[Introduction]

The progress in medicine has dramatically improved the prognosis of pediatric surgical diseases. Associated with this progress an increase in indefinite symptoms related to the digestive organs due to the prolonged survival has been observed. Yet, further improvements in postoperative long-term quality of life (QOL) and ADL (Activities of Daily Living) still need to be achieved. Under these circumstances the value of Kampo medicines has received attention for their action in adjusting the general condition of the patients. Moreover, during daily clinical pediatric surgical practice, even if surgery is not required, many patients are counseled regarding symptoms of the digestive organs and Kampo medicines are at that time a powerful choice. In this manuscript we will discuss first mainly pediatric surgical diseases of the digestive organs and later would like to outline the frequently used prescriptions in the field of pediatric digestive system diseases *rikkunshito* (Liu Jun Zi Tang),

daikenchuto (Da Jian Zhong Tang), *shokenchuto* (Xiao Jian Zhong Tang), *inchinkoto* (Yin Chen Hao Tang), *daiokanzoto* (Da Huang Gan Cao Tang), *hangekobokuto* (Ban Xia Hou Po Tang), *yokukansan* (Yi Gan San), *juzentaihoto* (Shi Quan Da Bu Tang) and *hainosankyuto* (Pai Nong San Ji Tang) with reference to clinical trials.

[Overview of pediatric surgical diseases]

1) Gastroesophageal Reflux Disease (GERD)

Based on the anatomical characteristics a mild reflux from the stomach into the esophagus happens in all infants. It occurs in 50% of newborn under three months of age and 67% of the 4-month old, but resolves often spontaneously when the infants start to assume a sitting position. The gastroesophageal reflux in 10% of infants under 1 year of age is said to be associated with complications. The symptoms associated with gastroesophageal reflux are called Gastroesophageal Reflux Disease (GERD). A portion of these symptoms are due to hypoactivity of the sphincter of the lower esophagus. Persistent reflux causes inflammation of the lower esophagus. Due to the still immature faculty of speech of the infants, they cannot complain of heartburn and the condition may manifest as bad mood, frequent crying, decreased appetite, abdominal pain, throat pain, asthma, chronic cough, middle ear infection etc. This shows, that once these infant specific characteristics are understood, in cases of indefinite complaints of the upper abdomen or a variety of other symptoms, the possibility of GERD should also be suspected. Also, since experience has shown, that the use of Kampo medicines in infants is comparatively safe, their application is worth a try.

Actually, in addition to the clinically easy development of gastroesophageal reflux in infants, aerophagia, constipation, frequent crying, excessive feeding of milk and other factors may contribute to the condition. *Rikkunshito* is used as the drug of choice for infants with GERD, but when aerophagia is the main aggravating factor, *hangekobokuto* and similar prescriptions can be effective. Even if the drug of choice

is not effective, Kampo medicines may be advantageous if there is a next therapeutic choice.

2) Anal atresia (anorectal anomaly)

Anal atresia is properly called anorectal anomaly. This anomaly is caused by incomplete development of the urorectal septum separating the urogenital sinus and the anorectal region, persisting cloacal duct or deficient opening of the anal membrane. There is no sex difference in incidence rate. The condition is classified into a high level type above rectum and coecum, an intermediate level and a low level type. Frequently fistulas develop between the lower end of the rectum and urethra on one side and the perineum on the other side. Approximately 70% of anorectal anomalies are complicated by some other form of anomaly. Complication of anorectal anomaly with spinal anomalies, cardiac anomalies, esophageal atresia, renal malformation and the like are called VATER (or VACTER, VACTERL) association.

Presentations made on academic conferences regarding Kampo treatment following surgery for anorectal anomalies are mainly reports dealing with the use of Daikenchuto.

Management of bowel movements following surgery for anorectal anomalies, in particular maintenance of normal bowel movements and toilet training, is extremely important. Measures like enemas etc. are a great burden on the guardians and meet at higher age of the children with greater resistance. It is not an overstatement, that toilet training towards independent evacuation until a time when communal life like school starts, will affect the future of that particular child. Examination of the development of the rectal muscle group allows to assess, whether the constipation is mainly of organic origin, or whether training will likely lead to improvement. In cases of a high probability of improvement through training, Kampo medicines play an important role as supportive treatment promoting in particular independent evacuation.

3) Hypertrophic pyloric stenosis

Hypertrophic pyloric stenosis is a disease characterized by continuous vomiting in newborn and hypertrophy of the pyloric ring. Fiberscopic surgery has developed as curative surgery for hypertrophic pyloric stenosis and the number of cases is increasing, but there is still no agreement as to whether fiberscopic surgery is actually the optimal therapy for this condition. The continuous vomiting is considered to be due to the hypertrophic pyloric ring, but spasms of the pyloric muscles themselves are also a conceivable cause for the vomiting treated with atropine sulfate. If the treatment of this disease with atropine sulfate is done appropriately, most of the cases are cured¹⁾. Prior to oral administration 6 times/day, 0.01 mg/kg is administered intravenously and when the vomiting has stopped, the regimen is switched to 0.02 mg/kg per os 6 times/day. A gradual increase in the uptake of milk paralleled by a gradual reduction of the atropine sulfate dose led in 45 out of 52 patients (87%) to a cure without complications. The average duration of the hospitalization was 13 days. In those patients in whom the administration of atropine sulfate was not effective, *rikkunshito* was reportedly effective²⁾. There is a possibility that a combination therapy may lead to an earlier improvement.

4) Hirschsprung's disease

Hirschsprung's disease is a congenital functional obstructive disease of the intestines where the gangliocytes of the intestinal canal are lacking from the anal side extending towards the mouth, impairing the peristaltic movements of the intestinal canal. The range of the aganglionosis varies widely, but the prognosis worsens in proportion with the size of the aganglionic region. The condition is classified as follows.

(1) short segment aganglionosis: the aganglionic region is restricted to the sigmoid colon, 70-80%

(2) long segment aganglionosis: the aganglionic region extends past the descending colon towards the mouth, 20%

(3) total colon aganglionosis: the aganglionic region affects the entire colon, 1-2%

(4) extensive aganglionosis: the aganglionic region extends into the small intestines, 2%

(5) ultra-short segment aganglionosis: an aganglionic region is observed within the lower third of the anorectal canal, 4-5%.

Treatment consists of resection of the aganglionic region of the intestines. When the region affected by the aganglionosis is limited, the condition often runs a favorable course. However, in conditions like (3) and (4) marked by extensive areas of aganglionosis postsurgical diarrhea or colitis may easily develop and progress into septicemia and shock. Further, due to a reduction in the absorption intravenous nutrition is required over a prolonged period. The general condition and parameters including the nutritional state, electrolytes, urinary volume etc. must therefore be carefully observed.

In particular in cases of extensive resections destruction of the intestinal bacterial flora through the use of antibiotics is undesirable. However, because infants are easily susceptible to infections, the use of antibiotics is often necessary. For common cold or upper respiratory infections the early use of Kampo medicine can avoid the administration of antibiotics and is thus extremely important. The authors often use *shoseiryuto* or *kakkonto* for sick children. *Maoto* was mostly unsuitable following surgery of the gastrointestinal tract, because the condition is predominantly one of "spleen deficiency". Usually administration of *kenchuto* resembling formulas tends to result in a lower susceptibility to common colds. Although it is difficult to provide evidence to substantiate this claim, Kampo medicine played definitely an important role in the improvement of the individual conditions.

5) Hirschsprung's disease related diseases

Chronic and continuous intestinal obstruction caused by deficient or absent of normal peristaltic movements of the intestinal tract are refractory diseases. These include Megacystis-Microcolon-Intestinal Hypoperistalsis Syndrome

(MMIHS), Chronic Idiopathic Intestinal Pseudo-Obstruction (CIIP) and hypoganglionosis.

In these diseases the regions affected by the lesions are often very large and the distribution of gangliocytes throughout the intestinal tract is not uniform. Prolonged central venous hyperalimentation is required and bowel movement management extremely difficult, rendering the long-term prognosis poor. Causes of death include infection of the central venous catheter and a transition towards bacterial translocation from enteritis can lead to sepsis. Recently, transplantation of the small intestine has also been attempted, but the choice of donors difficult because of the strong rejection. Occasionally relevant case reports describe that *daikenchuto* was markedly effective for MMIHS or CIIP³⁻⁵). This is highly significant. When the author administered Shokenchuto to patients with CIIP in his care, septicemia and enteritis due to repeated central venous hyperalimentation infections already led to the loss of absorption from the intestinal tract and therefore, so that the formula did not show any effects at all. Through the early introduction of Kampo medicine, provided bowel movement management is possible, the vicious cycle of enteral infections or intestinal dysfunction can be broken and there is a sufficient probability of improvement in the long-term prognosis. Further investigations in this field are desirable.

6) Perianal abscess

Perianal abscesses are relatively common in outpatients during infancy and the incidence is higher in boys. This suggests an immunological immaturity restricted to the anorectal region that is characteristic of infancy⁶). Most cases heal spontaneously, but there may be repeated recurrences and treatment periods often extend over long periods. Ambulatory treatment for pain and care of the wound etc. pose a great burden on the sick child and its family. In the past incision of the abscess and administration of antibiotics constituted the mainstream therapy, but the number of reports on the value of using Juzentaihoto have increased⁷⁻¹⁰). It is not an exaggeration to state, that it has already been

established as a therapeutic drug for the treatment of perianal abscess. Juzentaihoto is compounded of ginseng, cassia bark, *Cnidium rhizome*, *Rehmanniae Radix*, hoelen, *Atractylodes rhizome*, *Astragali Radix*, angelica root, peony and *Glycyrrhiza glabra*. Examination of the composition reveals, that this formula is a combination of *shimotsuto* and *shikunshito* with the addition of cassia bark and *Astragali Radix*. In addition of supplementing Qi and Blood it conceivably also has exterior supplementing effects. In particular *Astragali Radix* is said to have diuretic and swelling dispersing, internal expulsion and detoxifying actions, which would explain the effectiveness of Juzentaihoto for perianal abscesses.

Recently published reports describe *hainosankyuto* as being effective during the acute phase of perianal abscesses. Also, while no clinical studies have been published yet, there have been related reports on academic conferences. *Hainosankyuto* is comprised of *Zizyphi fructus*, orange pease, peony, platycodon, *Glycyrrhiza glabra* and ginger. Asada Sohaku too mentioned that the effect of this formula is "due to the combination of orange pease and platycodon". By combining *hainosan* and *hainoto* the pus discharging action is amplified.

Regarding the combination of orange pease and peony the "Synopsis of the Golden Chamber" (Jin Kui Yao Lue) also stipulates in the section for *Kijitushakuyakuto*: "for abdominal pain after delivery, when a person cannot lie down because of vexation and fullness, *kijitushakuyakuto* will control this ... and at the same time controls abscesses". This shows, that it acts to dispel some kind of swellings by relieving muscle tension. During the acute phase of perianal abscesses tumors are formed from pus, so that discharge of this pus leads to healing. That is why administration of *Hainosankyuto* during the acute phase has adequate effects. Further investigations in this field are desirable.

[Explanation of the individual formulas]

1) *Rikkunshito*

For loss of appetite, early feeling of fullness during meals, gastric discomfort, stomach-upset and similar digestive symptoms found not only in adults, but also in infants. When in case of infants the food intake continues to be low because of these symptoms, they may impair growth, making it necessary to achieve improvements earlier than in adults.

The concept expressed by the general term Functional Dyspepsia (FD), which is characterized by continuing epigastric digestive symptoms in adults, even if organic diseases have been ruled out, has been proposed and here too *rikkunshito* has received attention as one therapeutic choice. *Rikkunshito* increases the discharging capacity of the stomach and improves the adaptive relaxation of the stomach. This conceivably results in improvement of the so-called early satiety during meals. The L-arginine content of this formula, providing the substrate for the nitric oxide (NO) involved in causing an appropriate adaptive relaxation of the stomach, is probably related to this action¹¹⁾.

In the period following pediatric digestive organ surgery electrogastrography reportedly verified the effectiveness of *rikkunshito* for epigastric indefinite symptoms in the absence of organic diseases. Following administration of *Rikkunshito* (0.2 g/kg/day (tid)) for an average of 10 months improvement of the irregularities in gastric myoelectric activity were observed¹²⁾. For the pathologic condition a combination therapy with the H2 blocker famotidine (0.8 mg/kg/day (bid)) and *Rikkunshito* (0.2 g/kg/day (tid)) was used and after disappearance of the clinical symptoms improvements of the irregularities in gastric myoelectric activity were observed. This suggests, that a combination therapy using famotidine and *Rikkunshito* possibly contributes to improvements in gastric myoelectric activities and the coordination of the latter¹³⁾. Also, according to recent reports based on improvements in symptoms and esophageal pH monitoring, a decrease in the duration of esophageal acid exposure and acid clearance time have been observed in pediatric patients with GERD. This

suggests, that treatment of GERD with Rikkunshito alone too seems to be possibly under certain circumstances¹⁴⁾. Moreover, some reports describe that this formula improved the delay in gastric emptying time in GERD after cardioplasty in children with severe psychosomatic disorders¹⁵⁾.

In the field of pediatric surgery there is frequent counseling for pediatric patients presenting with upper gastrointestinal symptoms, but in whom surgery of the digestive organs is not indicated. In these cases too *rikkunshito* represents an important therapeutic choice. Then again, *rikkunshito* probably promotes appetite by increasing the secretion of active ghrelin¹⁶⁾. Thus, it is also effective for loss appetite, even if there are no obvious upper gastrointestinal symptoms.

From the long-term perspective, after administering *rikkunshito* some effects like improved appetite, alleviation of stomach upset and epigastric bloating, improvement of growth impairment and fatigue are often observed. Prognosis can be assumed to be favorable, when *rikkunshito* is continued for several months, in case effects have been observed at this point of time. It is further important to instruct the patients to use single doses, if symptoms should recur.

2) *Daikenchuto*

Daikenchuto, first mentioned in the "Synopsis of the Golden Chamber" (Jin Kui Yao Lue), is a formula compounded of 2 parts of *Zanthoxylum piperitum*, 5 parts of *Zingiber siccatum* and 3 parts of ginseng with added malt extract. The source text states: "severe cold pain in chest and heart, vomiting and inability to eat or drink, chilling within the abdomen, rising of Qi from the abdomen to the hypochondrium, it emerges from the skin and flows up- and downwards to the head and feet; thus *daikenchuto* cures people suffering from pain that cannot be approached or touched." Thus this formula is considered to be beneficial for conditions abdominal pain and vomiting due to chilling and where abnormal peristaltic movements of the intestines are observed in the abdominal region.

Pharmacologically this formula is said to have peristalsis adjusting actions and increases blood flow in the intestinal tract. It has been clarified, that this action is mediated by the calcitonin gene related peptide (CGRP). *Daikenchuto* promotes the release of CGRP by peripheral nerves, induces RAMP1, initiates generation of large amounts of CGRP1 receptors and thereby increases the blood flow in the intestinal tract¹⁷⁾. In the field of adult surgery it is frequently used for postsurgical intestinal movement disorders (ileus), where it shortens the time until the first postoperative flatus and thus reportedly contributes to a shortening of the hospital stay¹⁸⁾. The improvement of postsurgical ileus induced by this formula is presumably due to an improvement in peristaltic movements of the intestinal tract, which in turn is brought about but the increased blood flow in the intestines. This formula has been reported to be useful in pediatrics for the treatment of postsurgical adhesive intestinal obstruction or early postsurgical recovery from dysperistalsis^{19,20)}. This applies in particular for the use as a conservative treatment for postsurgical ileus infusion of the formula through an ileus tube^{19,20)}. Additionally, it has also been reported to improve constipation or evacuation disorders following surgery for anorectal anomalies in infants²⁰⁻²⁴⁾ as well as chronic constipation^{20,24)}.

For Megacystis-Microcolon-Intestinal Hypoperistalsis Syndrome (MMIHS), a functional anomaly of the intestinal tract or Chronic Idiopathic Intestinal Pseudo-Obstruction (CIIP) the available western medical therapies are currently limited.

Postsurgical constipation is frequent in infants, where chilling of the intestinal tract is one of the causes for dysperistalsis, so that *daikenchuto* is the drug of first choice. This does not contradict the Kampo medical concepts pertaining to *daikenchuto*. Moreover, the formula is indicated in healthy infants too, when chilling adversely affects intestinal movements. However, in case it should be ineffective, other Kampo formulas need to be considered.

The dose of 6 packages of *daikenchuto* extract per day for adults is rather large, but this dose serves only as a

rough estimate and can be increased or decreased as appropriate. Since *daikenchuto* is a warming formula, it should be dissolved in hot water and then allowed to cool before ingesting, but if ingestion is difficult, commercially available jelly, wafers or a little honey can also be added.

Administered for the treatment of ileus 1 package of *daikenchuto* is dissolved in 50 ml of hot water, allowed to cool and then infused through an ileus tube. After application of an appropriate amount and clamping the ileus tube for 30 to 60 minutes the contents is released. Similarly dissolved material can also be applied in form of enemas. The above described treatment is administered as required once to three times a day.

Zanthoxylum piperitum, *Zingiber siccatum* do provide a sort of warming stimulus. Since *Zanthoxylum piperitum* "disperses cold dampness, but people with lung and stomach heat avert it" *daikenchuto* may not be suited in cases of heat in the intestinal tract. In terms of Kampo medical concepts infants are considered to have a purely yang body, they tend to be hotter than adults and therefore *daikenchuto* is rarely indicated in healthy infants. Accordingly, it happens that while *daikenchuto* had been effective during postsurgical recovery, the infants suddenly cannot tolerate it any longer. In this case it can be necessary to temporarily discontinue the administration or switch to a different formula. It must not be forgotten, that the condition of the body constantly changes.

3) *Daiokanzoto*

In the "Synopsis of the Golden Chamber" it says: "for people who immediately vomit on eating, *daiokanzoto* controls the condition". It is used for a condition, where people vomit immediately after meals due to poor flow in the intestines. Also, the entry pertaining to *Daiokanzoto* in Asada Sohaku's text "Butsugo Yakushitsu Hokan" reads: "when there is no desire for the so-called 'southern fume' of this formula, you must first open the 'northern lights', meaning that the stomach content closed up in the stomach must be guided as stool to prevent it from upsurging and to stop

the vomiting." Thus, like opening a small window on the north to let in a southern breeze in order to guide the obstruction in the stomach towards the excrements will prevent the vomiting caused by upsurging. Regarding this usage the formula has a wide range of application as a Kampo medicine.

Pharmacologically the sennoside content of the rhubarb is broken down by intestinal bacteria and after reduction metabolized into potent laxative rheinanthrones stimulating the colonic submucosal neural plexi in the intestinal wall to promote the movements of the smooth muscles. Subsequently the colonic mucosal epithelial cells inhibit the phosphodiesterase activity and thereby inhibit the absorption of water, salts, glucose, xylose etc.²⁵⁻²⁶). The transport capacity of the small intestine is not affected, so that the amount of feces and its water content increase dose independently and thereby promote bowel movements. Compared to an application of rhubarb alone increased tenesmus at the onset of the laxative action can be significantly inhibited when using *daiokanzoto*^{26,27}). Moreover, renal function is also improved and without affecting urinary pH a marked increase in urinary output and electrolyte (Na, Cl) excretion has been observed. The tannin content of rhubarb increases renal blood flow and the glomerular filtration rate, leading to an improvement in renal function²⁶⁻²⁸).

There are only few reports on the use of *daiokanzoto* for infants, but it has been reported useful for severe constipation in school children²⁹) and reportedly be effective in 56% of patients with constipation following treatment for Hirschsprung's disease³⁰). As stated above, in cases of constipation in infants after surgery or diseases *daikenchuto* is the drug of first choice. This happens often when in healthy infants changes in dietary habits led to a febrile syndrome of the viscera, i.e., separation of clear and turbid elements in the colon is not processing smoothly. In this case this rhubarb containing formula should be taken into consideration. Concretely, it is considered useful when patients complain of accumulation of scatoma in the colon,

constipation due to hardened feces, abdominal pain due to the accumulation of feces or vomiting or else decreased appetite. Moreover, even if *daikenchuto* is useful, occasionally combination with *daiokanzoto* allows the treatment form so eloquently described as "when there is no desire for the so-called southern fume of this formula, you must first open the northern lights".

4) *Inchinkoto*

Inchinkoto has first been mentioned in the "Treatise on cold-induced diseases" (Shang Han Lun) and "Synopsis of the Golden Chamber" and is compounded of three crude drugs, namely of 3 parts of *Artemisiae capillaris flos*, 1 part of rhubarb and 4 parts of gardenia. Pharmacologically, the gardenia constituents iridoid glucoside geniposides and the intestinal metabolite Genipin have a non-bile acid dependent cholagogic action, activate a bilirubin transporter (multidrug resistance-associated protein: Mrp2), while the *Artemisiae capillaris flos* constituent dimethylesculetin reportedly has a relaxing action for the sphincter of Oddi^{31,32}. Also, in rat models of hepatic fibrosis the concentration of liver hydroxyproline, serum hyaluronic acid increase, the expression and activation in hepatic extracellular matrix (type III procollagen mRNA) increases while the proliferation of activated Kupffer cells is inhibited, thereby allegedly inhibiting the development of hepatic fibrosis³³.

Cases of clinically effective treatment of patients with delayed postsurgical biliary atresia, recurrent icterus, liver function failure with *Inchinkoto* have been reported³⁴⁻³⁷. Following administration of Tsumura's *Inchinkoto* extract for a period of 2 to 4 years after surgery for the treatment of pediatric postsurgical biliary atresia, improvements in serum GOT, GPT, γ -GTP and hyaluronic acid levels were observed. While similar improvements of serum GOT and GPT over time were observed in non-treated patients too, the serum γ -GTP and hyaluronic acid levels did not improve over time. This confirmed liver protective and anti-liver fibrotic effects of *Inchinkoto*³⁵.

Also, adult cases of delayed onset hyperbilirubinemia following liver transplantation with small-for-size grafts also suggest the possibility, that *Inchinkoto* will lead to improvements. In the field of pediatric surgery too the number of liver transplants for the treatment of biliary atresia is increasing and applicability of this formula in infants seems conceivable.

Conclusions

Kampo therapy too is about to develop into an established therapeutic choice in the field of pediatric surgery. This can also be interpreted as a manifestation of the enthusiasm with which pediatric surgeons use those choices, as long as they lead to improvements in their patients. Kampo expert physicians should cooperate in order to investigate new indications and thus respond to the aforementioned enthusiasm. Since individual differences are particularly marked in infants, the therapy for each individual patient must be considered separately. If that is done, still greater developments are expected to be accomplished for Kampo therapy in the field of pediatric surgery.

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Clinical Report 1 (Acupuncture)

A Case Where Blood Letting was Effective for Health Problems Following Multiple Traffic Accidents

Takara Yamami

Ehime Prefectural Central Hospital,
Institute of Oriental Medicine

Introduction

At the Ehime Prefectural Central Hospital, Institute of Oriental Medicine we diagnose conditions based on sequential and point location reaction analyzes. Following the diagnosis we then apply traditional Oriental medical techniques with reference to the traditions handed down by our predecessors (mostly Ken Sawada, Isaburo Fukaya, Kunisei Kudo, Domei Yakazu) (Figure 1). The sequential analysis allows comprehensive assessment of the patients mainly based on his/her life history and facilitates understanding any health disorder related factors up to the time of the patient's first visit. The analysis of reaction at the point locations confirms findings obtained through inspection and palpation and compares these to the signs. Regarding the point location findings and acupuncture and moxibustion treatment we refer mainly to the classics centering around the "Compilation of the Twelve Principles of the Nine Ancient Needles", emphasizing pressure hypersensitive indentation, pressure hypersensitive bulging, congestion, fine floating vessels, edema and similar findings and then administered techniques like moxibustion, acupuncture and vessel puncturing.

For images of the acupoint findings described mainly in the "Compilation of the Twelve Principles of the Nine Ancient Needles", where it says "凡用鍼者、虛則實之、滿則泄之、宛陳則除之、邪勝則虛之。" deficiency states are identified by the character "員=yuan", which here indicates images of depression and softening. Conditions described as repleteness or fullness are associated with congestion. The term 宛陳 = wan chen refers to fine floating vessels. A state of prevailing evil is described as "方 = fang" and associated with images of bulging, swelling and

induration. Adding edema to those images the findings of pressure hypersensitive indentation, pressure hypersensitive bulging, congestion, fine floating vessels, edema are confirmed.

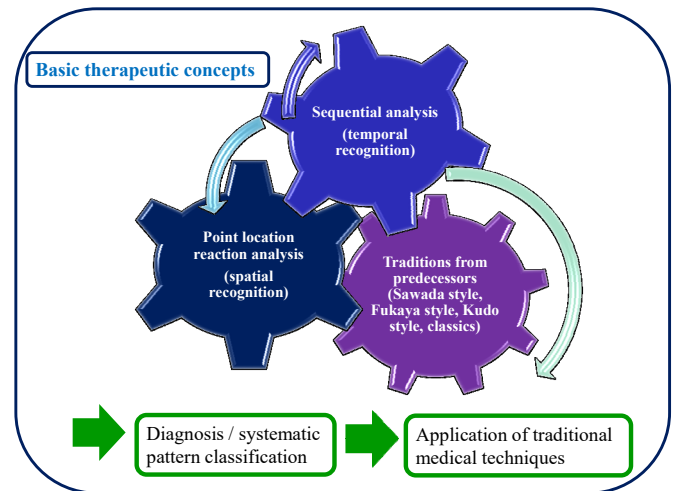


Figure 1

Regarding acupuncture and moxibustion treatment moxibustion serves as an excess technique. Further, regarding the needling technique the text says: "徐而疾則實": meaning the needles are slowly inserted and quickly withdrawn, while "呼盡內鍼・候吸引鍼・推闔其門" means that the needles are inserted at maximum expiration and withdrawn after waiting for the inspiration, after which the insertion site of the needles is massaged with the fingers to close the needling hole; listed as a technique also considered to be an excess technique (named: excess round needling). Next I would like to consider vessel puncturing at the well points and skin vessel puncturing as a form of purgative method and fine floating vessel puncturing as an elimination method. As a deficiency method "疾而徐則虛" the needle is quickly inserted and slowly withdrawn in case of deficiency, "吸則內鍼・吸則轉鍼・候呼引鍼・呼盡乃去": describing that the needles are inserted during inspiration, twirled also during inspiration and withdrawn after waiting for the expiration so that the needle is completely withdrawn when the expiration has been completed. This too is a deficiency technique (named deficiency needling).

Moreover, in our institute we add as an excess method warming needles and as a deficiency method skin vessel puncturing.

The patient visited out clinic with chief complaints of health impairments (neck and shoulder stiffness, dull headaches, low back pain, numbness of the left leg and left arm etc.) following traffic accidents. I report this case here, because the treatment presumably contributed to an improvement of the QOL.

Patient: 52 years, male, local public service employee (road and infrastructure maintenance).

[Sequential analysis]

Chief complaints were neck and shoulder stiffness, dull headaches, low back pain, numbness of the left leg and left arm etc. that occurred following traffic accidents. At the age of 51 he was hit by a car in a head-on collision while riding a motorcycle, the impact rendering him unconscious. The results of CT and x-ray imaging did not show skull injuries, fractures or ruptures of internal organs and he was diagnosed with "rupture of the left biceps brachii muscle" and whole body contusions. Starting about one month after the accident neck and shoulder stiffness, dull headaches, low back pain, numbness of the left leg developed. After a period of half a year suddenly numbness of the left arm developed. Currently, when he passes the accident site on his way to work with his car, the dull headache increases in intensity and continues until noon. For that reason he reported driving to be trying.

Also, looking back at the patient's past life showed, that he had met with accidents at the age of 6, 18, 19, 37 and 48 years, leading to health impairments. He married at 25, between 26 and 31 his children were born; at 39 he had a new house built and ran into trouble with the neighborhood. Here too health problems developed simultaneously with the mentioned events. The third son is still a student,

but the other children are independent and he now lives only with his wife.

The diagnosis derived from the sequential analysis showed a correlation between the onset of health problems and multiple accidents, marriage, wife's pregnancy and birth, newly-built house and trouble with the neighborhood, inferring a decreased resistance to blood stagnation and mental stress induced health impairments.

Regarding the sequential analysis both modern Western as well as Oriental medical assessments are important and here in particular comprehension of the correlation between life events and health impairments. It is in this context important to understand what the patient thought at the time the events occurred and how he behaved, how he interacted with family members and society and imagine what happened to the family based on those results. Also, it must not be forgotten to take the mental state of the patient into account.

[Point location reaction analysis]

Checking the reactions mainly at the site of the back transport point, abdominal alarm points, sea points, source points. It is important to reduce prejudices and confirm the reactions at the point locations open-mindedly.

Pressure hypersensitive indentation (α) was found at GV12, GV11, BL11, SI11 (left), BL45, BL20, BL23, BL52, BL25, CV4. Pressure hypersensitive bulging (β) was found at BL10, GV13 (left), from TE15 – BL43, BL17 – BL18, ST19 – LR14, ST36, LI11. Edema (γ) was found at GV20. Fine floating vessels (δ) were observed from GV12 – GV11, BL11 (left), TE15 (right), TE14, SI10 (right), GV6, GV3, from the greater trochanter down to the vicinity of GB31, behind GB34 (left), anterior chest. Point location reactions like congestion (ω) was confirmed at GV20, in posterior region of the neck and similar locations. Based on the diagnosis derived from point reaction location analysis, the extensive development of fine floating vessels and the mental status the reactions

found at GV20, upper governing vessel, BL17-18, ST19 – LR14 suggested that the development of blood stagnation and a decreased resistance to mental stress had probably induced the health impairments (Figure 2).

【Findings】

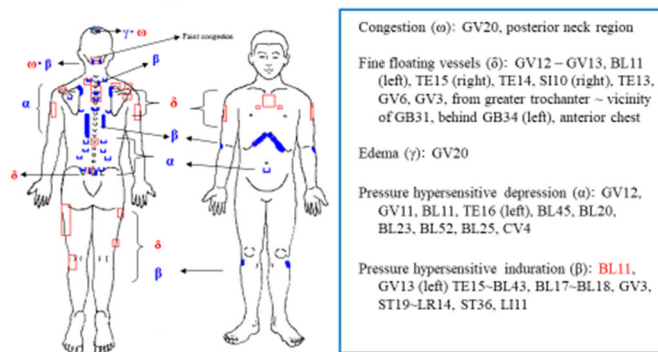


Figure 2

[Acupuncture and moxibustion treatment]

The diagnosis based on sequential and point location reaction analyzes coincide so that we treated points at which blood stagnation and mentally induced reactions were found. We punctured the fine floating vessels at BL11 (left), GV12, GV6, GV3, GB31 (left), behind GB34 (left). Puncturing of indurations was performed at BL17. Tonifying puncturing was performed at GV12. We instructed the patient to treat himself with moxibustion at home at BL11, BL13, BL11, SI16 (left), BL20, BL52, BL25, LI11, ST36. The acupuncture and moxibustion treatment based mainly on the above described pattern was performed at a rate of once every 2 to 4 weeks. The Kampo formula Saibokuto 7.5 g was also prescribed (Figure 3).

[Course]

During the 4th treatment we added puncturing of indurations at BL43, during the 7th treatment also puncturing of indurations at TE15, BL17, which led to improvements of the neck and shoulder stiffness, numbness of the left arm and dull headache. Vessel puncturing of fine floating vessels at GV3 and

puncturing of deficiency bulging performed both during the 7th treatment improved the low back pain and numbness of the leg.

Approximately 2.5 months following the first visit (completion of one treatment set) all chief complaints were rated as "B". After 8 months (completion of two treatment sets) the chief complaints were rated as either "A" or "B". Moreover, symptoms other than the chief complaints had also improved (Figure 4).

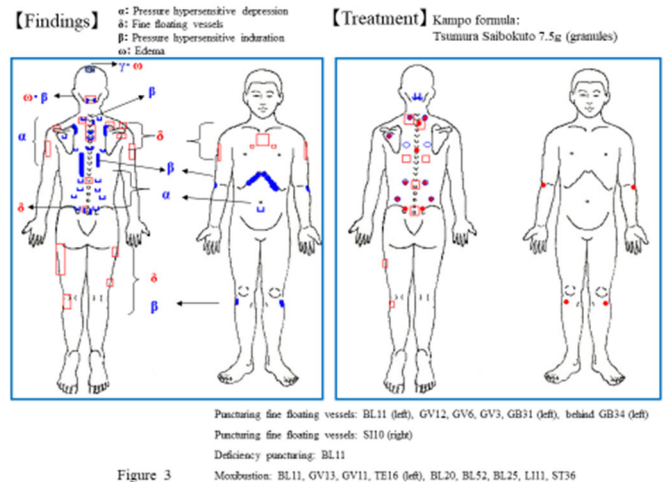


Figure 3

【Course】

*A: Has improved
*C: Has not changed
B: Has improved but hurts sometimes
D: Gradually worsens

Treatment sets	I-⊕ (appr. 2.5 months later)	I-⊕ (appr. 8 months later)
General condition	B	—
Health concerns	B	—
Inconvenience during daily living	A	—
A: neck and shoulder stiffness	B	A
B: dull headache	B	B
C: low back pain	B	B
D: numbness of left leg	B	A
E: numbness of the 1 st to 3 rd digits of the left hand	B	A
Left shoulder pain	B	A
Soft stools	A	A
Fatigability	B	B
Dyspnea	B	A
Eye strain	B	A
Irritability	B	A
Nausea, vomiting	B	A

Figure 4

[Discussion]

The sequential and point location reaction analyzes showed blood stagnation (fine floating vessels) and traumatic injuries from multiple accidents, the pooling of stagnant blood subsequently resulting in liver injury which then in turn led to the development of the chief complaints associated with

psychological symptoms. The sequential and point location reaction analyzes facilitated a comprehensive understanding of the patient and the administration of the acupuncture and moxibustion treatment, but except for the chief complaints it was not considered to relate to improvements in the other symptoms. The acupuncture and moxibustion treatment corresponding to the findings at the point locations had presumably been very effective for relieving the symptoms.

[Conclusions]

The goal of medical care people are seeking is to switch from therapy towards an improvement in QOL. The treatment of diseases leads to improvements in functional disorders and disabilities and we believe people are looking for all-inclusive improvements of interferences with daily living. For that reason the problems should not be approached using the skills of individuals, but rather be subject of a team approach (Figure 5).

【Conclusions】

It requires team work to switch the purpose of medical care from therapy to improvement of the QOL.

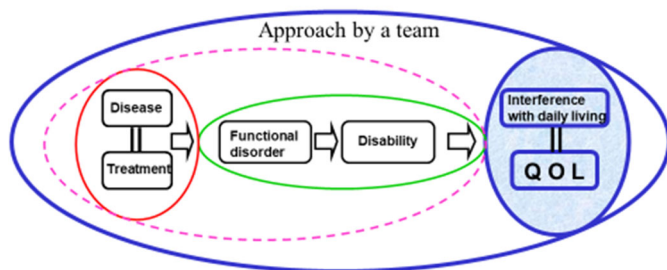


Figure 5

Clinical Report 2 (Kampo Medicine)

Maobushisaishinto for Non-dipper Hypertension

Narihiro Fujii

Tokando Medical Clinic

Case	69-year-old male
Chief complaint	Non-dipper hypertension
Past medical history	not particular
Family history	Hypertension (-); Father: prostate cancer; Mother: gastric cancer
Social history	Smoking: 10 cigarettes/day until 2008, thereafter quit. Drinking: Occasionally

History of present illness:

The patient visited our clinic on 5/25/XXXX after experiencing occasional staggering. He had a blood pressure of 185/110mmHg in his right arm and 175/100mmHg in his left. He underwent a complete medical checkup every year, but was never questioned about blood pressure. He weighs 69kg, marking an increase of 2kg from the previous year. He underwent an endocrine examination but no particular problem was detected. He was prescribed an oral medication of valsartan(80)1T, and was told to record his blood pressure at home. As a result, his nighttime blood pressure was found to be high, indicating non-dipper hypertension. In winter, his weight increased to 72kg, his blood pressure increased at home, and his systolic blood pressure measured 150-160mmHg. His antihypertensive drug was thus switched to valsartan + trichlorotiazide MD1Tab on 12/24. With a blood pressure of 115 – 135/90-70mmHg, he continued to display non-dipper hypertension. He continued the oral administration, and returned to the clinic on 7/6/XXXX+1.

Appetite:	Ordinary
Bowel movement:	Once a day; no change
Bladder movement:	6 – 8 times, once during the night
Sleep:	Good

Other symptoms: Sensitivity to cold (-),
Sensation of warmth (-)

Present illness:

Height: 169cm; Weight: 72kg; BMI: 25.2

Anemia (-); Edema (-)

Blood pressure: 130/70mmHg; Pulse: 55/min,
regular

Stethoscopy and tapping found no particular
abnormality

Good complexion, light pink tongue with a light,
dry coating

Pulse: On the right, inch-bar-cubit is stable and
slightly string-like; on the left, inch-bar is stable
and slightly string-like, and cubit is slightly
sunken.

Abdominal examination: Ventral horn – moderate;
Abdominal pressure 3/5; Epigastric fullness (-);
Chest side painfulness (left and right 1+);
Splashing sound in epigastric region (-);
Palpitation (-); Weakness (+)

Blood biochemical examination: No particular
problem

Progress: The nocturnal rise in blood pressure was
seen as poor prognosis, so Maobushisaishinto 5g
was administered on 7/6 to improve nighttime
blood pressure.

No subjective complaint from the patient
himself. A re-examination on 8/6 showed no
change in the rise and drop in blood pressure,
but blood pressure pattern changed from a non-
dipper to a dipper pattern (Fig. 1).

Flow of the defense qi

Physiological condition: The defense qi is produced
from the hydration shell in the lienogastric artery,
and flows through the entire body. It flows around
the Yang parts of the body during the daytime and
around the Yin parts during the nighttime (Fig. 2),
and flows through the entire body 50 times in a day.
That is, it flows through the Yang parts 25 times
during the daytime and through the Yin parts 25
times during the nighttime. It then flows through
the five organs.

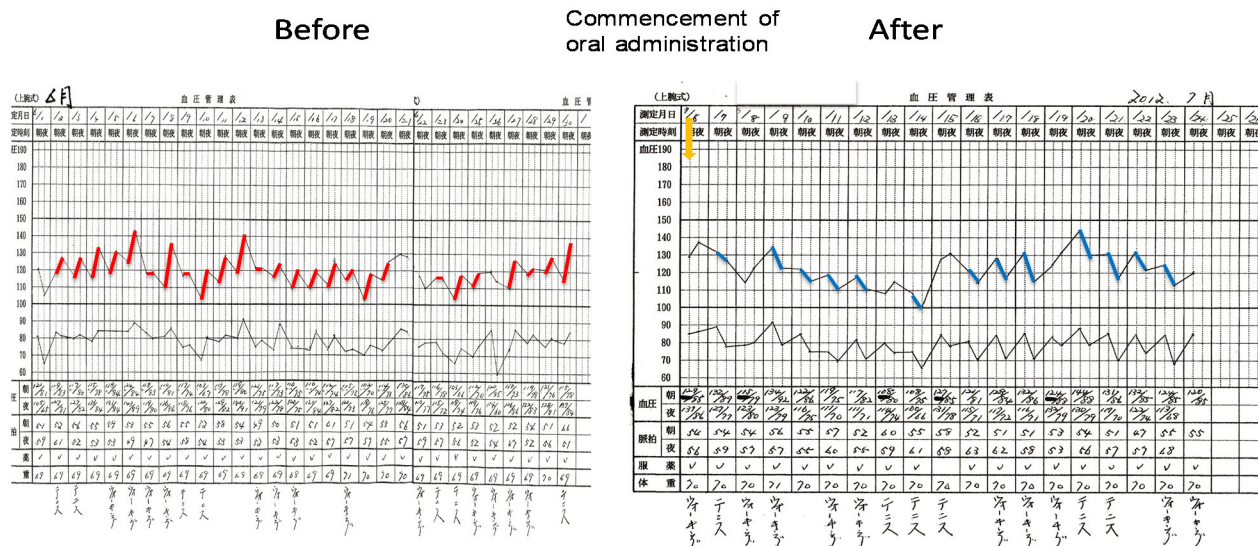


Fig. 1: Non-dipper hypertension changed to dipper hypertension by administering Maobushisaishinto

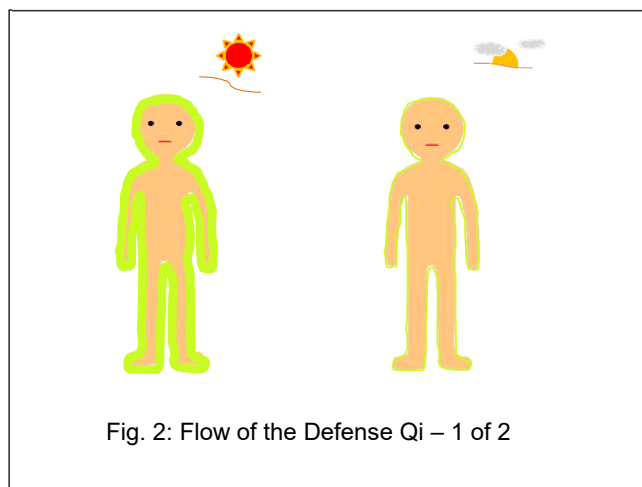


Fig. 2: Flow of the Defense Qi – 1 of 2

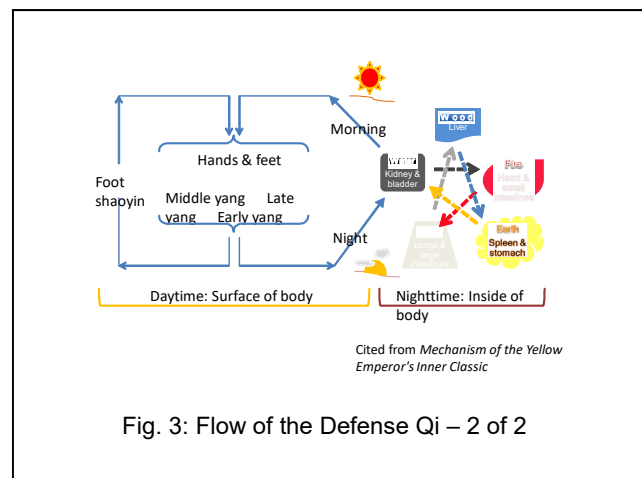


Fig. 3: Flow of the Defense Qi – 2 of 2

At dawn, the defense qi finishes circulating through the Yin parts and is discharged through the eyes as Yang qi. This makes people open their eyes and wake up.

This Yang qi flows along the bladder meridian to the little toes.

The Yang qi that separates from the outside of the eyes flows along the small intestine meridian to the little fingers. From the outside of the eyes, it might also flow along the gall bladder meridian to the fourth toe, then up along the triple energizer meridian to the tips of the fingers.

The Yang qi that is discharged from the preauricular area flows along the stomach meridian down to the toes. The Yang qi that is discharged from the parotid flows along the large intestine meridian to the fingers.

Of the above, the Yang qi that reaches the feet flows from the soles to the kidney meridian channel at the medial malleolus. From here, it flows along the kidney meridian to the kidneys, and from the kidneys to the heart, lungs, liver, spleen, and kidney, where it completes its round of the Yin part and once again flows out through the eyes and around the Yang parts.

Conclusion

High blood pressure during the nighttime improved with *maobushisaishinto*. The exterior defense qi pattern cannot be evaluated subjectively, but there are clearly symptoms that can be improved with *maobushisaishinto*. If *maobushisaishinto* could improve the exterior defense qi pattern, it could also be used for other diseases.

Medical History in Japan

Historical Significance of the Standardization of Acupoint Locations”, the Second Japanese Acupoint Committee (8) “Detailed Guide to the Location of Acupoints” from the classics to the WHO standardization”, pp411-422, Tokyo, Ishiyaku Publishing, June 2009 (partially revised)

Makoto Mayanagi

Graduate School of Humanities

Ibaraki University

(continued from KAIM Journal vol.6 no.1, no.2, no.3, no.4, vol.7 no.1, vol.7 no.2 and vol.7 no.3)

7. Yuan, Ming, Qing periods and the influence on and changes within the Chinese character culture area

The Jin edition of [Newly published with supplementary notes] *Tóng Rén Shù Xué Zhēn Jiǔ Tú Jīng* has been reprinted during the Yuan period at least once. Further, it is also known that the Ming government allowed to make rubbed copies of the "Newly Cast Bronze Figure Illustration of Acupuncture and Moxibustion" stone relief, but during the Ming and Qing periods numerous books entitled "Bronze Figure" were published and became popular. Thus the bronze figure or the Ming Tong came to be representative names for books illustrating meridians and acupoints, but on the other side led to the development of differences between the various books. The Korean government reprinted, based on the Jin edition of [Newly published with supplementary notes] *Tóng Rén Shù Xué Zhēn Jiǔ Tú Jīng*, the Chonghua Yuzhi'an Qinyoushutang edition four times which presumably continued to exert a considerably influence. On the other hand, in Japan the Ming edition has been reprinted during the early Edo period only once and thus had not as much influence as the "Elaboration of the Fourteen Meridians" (*Shi Ji Jing Fa Hui*), that has been reprinted as many as 17 times [18]. Currently, examination of about 500 Vietnamese ancient medical texts by the author did not allow to demonstrate any direct influence of the *Tóng Rén Shù Xué Zhēn Jiǔ Tú Jīng*.

8. Modern spread throughout the world and fourth standardization by the WHO

The third standardization by the Song government had varying degrees of influence on the Yuan, Ming and Qing periods as well as in the individual countries within the culture sphere using Chinese characters. However, depending on the degree of emphasis on the classics as well as employed techniques and tools, these differences and the accumulation of clinical experiences led in postmodern times to extensive fluctuations between the individual texts in the various countries, in particular regarding acupoint locations.

Today, with the support of the WHO, acupuncture and moxibustion has developed to the point, where it plays an important role in the global medical care. The WHO began around 1980 within the framework of a traditional medical program its attempts at standardization of acupoints. In 1991 the Western Pacific Office published the "WHO International Standard Terminologies on Traditional Medicine in the Western Pacific Region". The Part 1 of this work is based on the Tensei or Tiansheng bronze figure of the Song period, while The Chinese Academy of Sciences uses a picture of a replica of the Ming period bronze figure manufactured by Professor Ma jixing, and in Part 2 a picture of the bronze figure in the possession of the Tokyo National Museum is used. However, at that point the determination of standardized expression of meridians and acupoints reached a limit. And in 2006, after repeated discussions researchers from Japan, China and Korea completed an international standardization of acupoint locations.

Conclusion

Meridians and acupoints as the framework for acupuncture and moxibustion medicine have been standardized on a conceptual first level. The second level was standardization on the theoretical level, the third one a standardization on a national level. In order to establish logically unified concepts for the

discovered phenomena, and furthermore a theoretical unification to generalize changes obtained through experiences and the relevant deducted concepts can be said to have been performed within an expanding scope of this history. However, this very process, even if it had subjectively been unified logically, still remained hidden behind a pseudo-scientific veil but was not yet science. Ultimately, it was inevitable that differences will emerge later on.

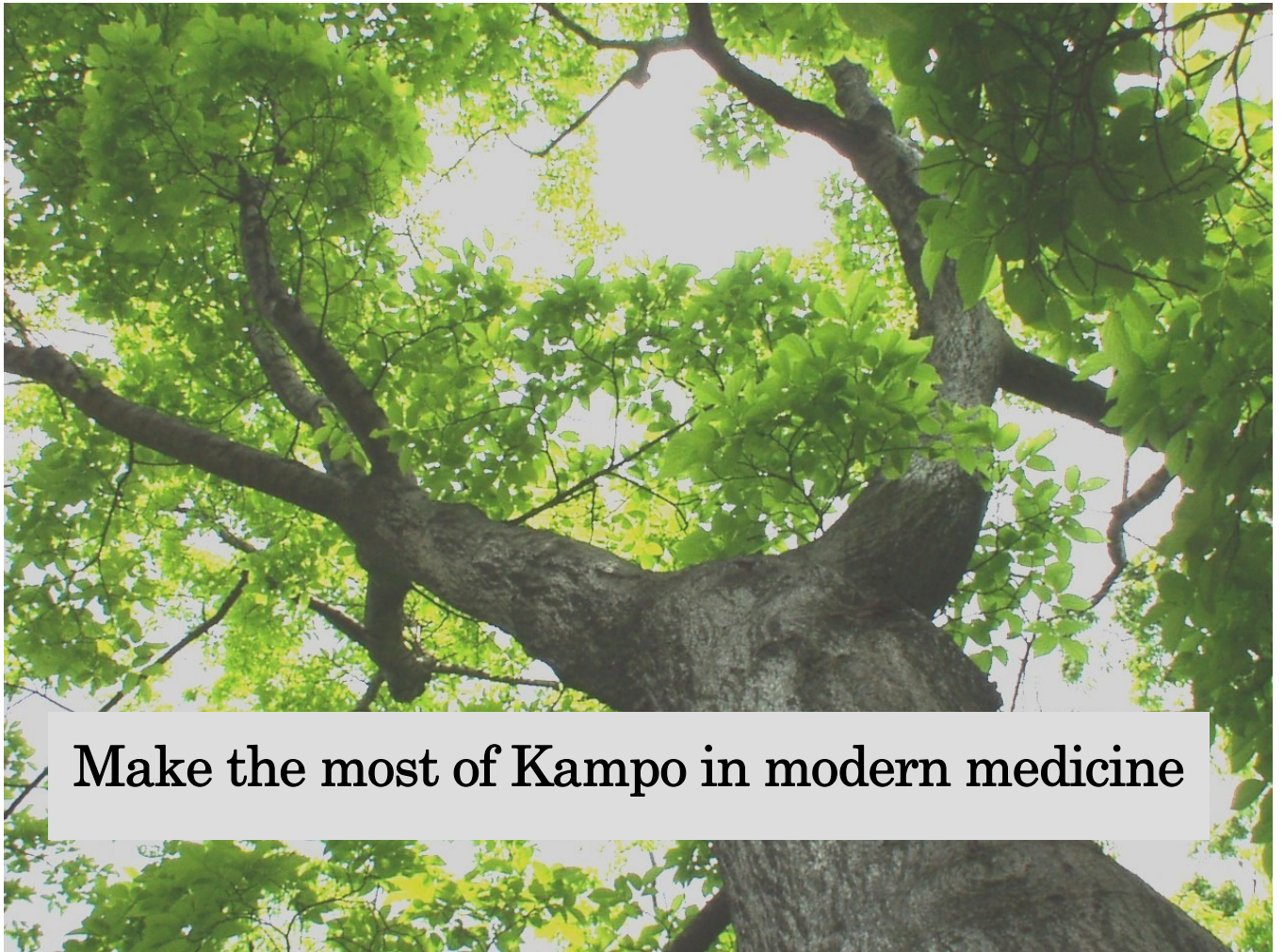
Yet, through the standardization of the locations on this occasion objectivity has been added and led to the fourth standardization on a global level. It is precisely the reflection on these first to fourth standardizations that shows a typical example of the history related to the transmission of traditional skills to the present that then further develop, deepen and spread as a firmly established scientific technique.

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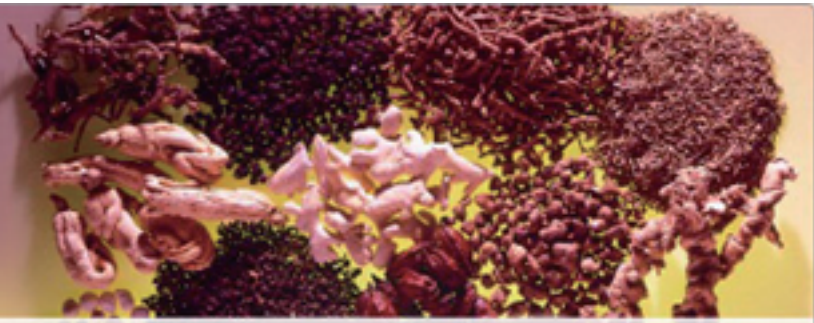
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