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# Patients Suffering from Intractable Diseases Treated Effectively with Medicines of Kampo and TCM

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Additional information is available at the end of the chapter

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#### **Abstract**

There are diseases that cannot be cured by conventional therapies.

In Japan, more than 90% of medical practitioners treat patients with alternative medicines such as Kampo medicine (herbal medicine based on Japanese Kampo theory) or traditional Chinese medicine (TCM) that do not respond to conventional treatments.

The author also treated these patients suffering from cardiovascular diseases, vasculitis diseases, nephrosis, hyperlipidemia, and female disorders including menstruation disorders, incurable pain diseases such as glossodynia and herpes zoster or herpes virus infectious diseases, and other diseases such as female-related ones and diseases that need five-face theory to cure and the administration of gui-zhi-fu-ling-wan (桂枝茯苓丸) before aspiration biopsy, in breast cancer patient, to raise the detection rate of cancer cells.

Interestingly, diseases specified as "intractable diseases" by the Japanese Ministry of Health, Labor, and Welfare sometimes respond to TCM treatment quite successfully, probably because TCM and Kampo medicine systems have their own theories and their own medicines quite different from that of conventional therapies.

Finally, I often experienced plural number of prescriptions for the problematic organs (based on five element theory) administered simultaneously often lead to dramatical improvement. This will mean problematic organs treated simultaneously will lead to quick recovery through synergistic actions among organs. The successfully treated clinical courses after the administration of TCM or Kampo medicines are described here.

**Keywords:** Alternative medicines, Kampo medicine, Traditional Chinese medicine (TCM), Intractable diseases, Synergistic action



## 1. Introduction

There exist diseases that cannot be cured by conventional therapies.

In Japan, more than 90% of medical practitioners treat patients with Kampo medicine (herbal medicine based on Japanese Kampo theory) or traditional Chinese medicine (TCM) that do not respond to conventional treatments.

Furthermore, about 80% of universities with medical departments have sections that deal specifically with Kampo medicine.

Many Japanese doctors use Kampo medicines, because of the existence of patients who are not successfully cured after trying all possible conventional therapies

I have been engaged in TCM treatment for more than 35 years, and I have used Kampo medicines or herbs selected based on TCM principles in patients who do not respond to conventional therapies including those who suffer terrible side effects with conventional medicines or cannot take them, for other reasons.

Interestingly, diseases specified as "incurable" by the Japanese Ministry of Health, Labor and Welfare, often respond to TCM treatment quite successfully.

TCM and Kampo medicine are treatment systems that have their own theories and their own medicines which consist of natural remedies.

These systems can be used as complementary or alternative therapy for conventional therapies.

In this chapter, I will introduce clinical courses after the administration of TCM or Kampo medicines, in cases of cardiovascular diseases, vasculitis diseases, nephrosis, hyperlipidemia and female disorders including menstruation disorders, incurable pain diseases such as glossodynia (burning mouth syndrome) and herpes zoster or herpes virus infectious diseases and other female-related diseases, and diseases that need five-face theory to cure.

Finally, by the administration of gui-zhi-fu-ling-wan (桂枝茯苓丸) before aspiration biopsy, in breast cancer patient, the detection rate of cancer cells was found to increase. Hereafter, the name of organ starting with capital letter means organ in TCM. The terminology of TCM is mainly based on WHO International Standard Terminologies on Traditional Medicine in the western Pacific region.

## 2. Cardiovascular disease

**Case 1**: 72-year-old Japanese female diagnosed with hypertrophic cardiomyopathy.

Main Complaint: Difficulty in breathing when walking

**Past History**: Tuberculous hilar lymphadenitis during childhood caused the patient one year off school. At age 39, her right ovary cystoma was resected.

Present Illness: Since the patient turned 40-years-old, she had suffered sudden difficulty in breathing and beating. Since she was 52-years-old, she easily got edema on the frontal part of her lower limbs and was diagnosed with hypertrophic cardiomyopathy. She had been taking drugs for hypertension. Menopause started at 45-years-old. She has been taking sleeping drug because of insomnia and excessive dreaming during sleep.

Her feet got chilly and cramped easily and often had to urinate in the night. She felt dizzy on standing up and easily got purple spots. The sole of her feet felt hot.

Present States: The patient was 161cm tall and weighed 51kg. Her pulse was 72 beats/min and was strong, slippery, string-like, both left and right chi-mai (尺脈) were somewhat weak, the tongue body was red, without fur, but with somewhat swollen sublingual collateral vessels, and her blood pressure (BP) was 150/76 mmHg.

Identification: Deficiency of Heart and Kidney Blood stagnation with water flood Heart deficiency with Lung collapse [1].

Treatment: Tonify Heart and Kidney and warm Lung. Activate blood to remove stasis. Promote diuresis, promote Yang circulation.

**Prescription**: Decoction of modified combinations of Zhi-gan-cao-tang (炙甘草湯), Guan-Xiner-hao-fang (冠心二号方) and Ba-wei-di-huang-wan (八味地黄丸): Zhi-gan-cao-tang (30g) added with chuan-xiong (川芎)2, jiang-xian (降香)2, dan-shen (丹参)3, hong-hua (紅花)1.5, dang-gui (当 帰)3, chai-hu (柴胡)2, pao-fu-zi (炮附子)1, fu-ling (茯苓)3, shan-zhu-yu (山茱萸)3, mu-dan-pi (牡丹 皮)3, huang-qi (黄耆)3, chen-pi (陳皮)2 (numerals mean g/day).

**Assessment**: I created a scale to difficulty in breathing. 0: not effective; 1: slightly effective, 2: effective, 3: quite effective, 4: very effective.

The patient began treatment at level 0.

Clinical course: The patient first visited me on January 29, X year. She started to take the full dose of the above medicines each day.

X year, February 24: She had improved to breathing score 0 to 1 when walking. From this day, her intake was decreased to 0.5 of the initial volume. On April 2, her score was 2. From this day on, she took 0.4 of the initial volume. By June 17, her breathing had improved to score 3. And her dosage changed to 0.3 of the initial volume.

This improved situation (Score 3) had continued for more than 4 years at the time of writing except when patient worked too hard, or does not get enough sleep.

Discussion: The patient's difficulty in breathing and palpitation when walking due to the Heart yang deficiency improved significantly by taking the prescription mentioned earlier.

Under the TCM theory, Zhi-gan-cao-tang (炙甘草湯) would not only tonify Heart yin and yang but also tonify the Lung qi and yin. Ba-wei-di-huang- wan (八味地黄丸) tonifies Kidney yin and yang and also supports the Lung through engendering route between Kidney and Lung. Additionally, Guan-xin-er-hao-fang (冠心二号方) removes blood stagnation and restores blood circulation. These formulas work synergistically to produce good overall condition. Guan-xiner-hao-fang is composed of chi-shao-yao (赤芍薬)5, chuan-xion (川芎)5, hong-hua (紅花)4, dan-shen (丹参)5, and Jiang-xian (降香) 4g/day. This formula was first reported at zhon-guo-yi-xue-ke-xue-yuan.

**Conclusion:** For 72-year-old Japanese female with hypertrophic cardio- myopathy, modified combinations of Zhi-gan-cao-tang (炙甘草湯), Guan-xin- er-hao fang (冠心二号方), and Ba-wei-di-huang-wan (八味地黄丸) have been very effective.

Case 2: A 53-year-old Japanese male. 167cm tall, weighing 54kg

Main Complaint: Dyspnea and palpitations

**Past History**: The patient suffered from a stomach ulcer at age 43. At this point he gave up cigarette and alcohol. He also suffered from irregular pulse and tachycardia.

**Present Illness**: The patient's first visit to our clinic was on June 4, 1986. Beginning in the middle of the preceding April, he often suffered dyspnea to the extent that he was unable to breathe for 8 seconds at a time; he also experienced tachycardia (160/min). Although he underwent a heart examination at the Red Cross Hospital including angiography, all results proved to be within normal limits. Because he suffered nettle rash as a side effect of certain injections, the medical doctor in charge denied him any prescription.

Due to the condition of his health, he was unable to play his favorite game, golf, and therefore wished to try herbal therapy.

The patient had little energy and his limbs felt cold. He liked to take hot things, and hated cold things.

**Present States**: The patient has a fair complexion. His pulse (72/min) is sunken and weak. BP was 120/76 mmHg.

**Identification**: Deficiency of Heart qi.

Treatment: Tonify Heart qi and yin.

**Prescription**: Zhi-gan-cao-tang (炙甘草湯): Zhi-gan-cao (炙甘草)3, dried sheng-jiang (乾生姜)1, Gui-zhi (桂枝)3, Ma-zi-ren (麻子仁)3, Da-zao (大棗)3, Ren-shen (人参)3, Di-huang (地黄)6, Mai-men-dong (麦門冬)6, E-jiao (阿膠) 2 numerals g/day.

Clinical Course: By June 17, 1986, the patient's dyspnea had improved and palpitations had decreased remarkably. By July 16, 1986, his dyspnea and palpitation disappeared. He continued taking this precription to prevent recurrence.

But gradually he decreased his intake to half of the initial volume in August, 2006. He wrote a letter of thanks to me saying that he was able to lead a happy life and play golf three times/ month without any trouble and that he would take this medicine throughout his life. His last request for this prescription was on September 8, 2006 (73-year-old).

Conclusion: For one 53-year-old Japanese male with incurable dyspnea and palpitation, Zhigan-cao-tang (炙甘草湯) worked remarkably.

## 3. Immune system, connective tissue and joint-related diseases including Churg-Strauss syndrome and Henoch-Shönlein-purpura

#### 3.1. Introduction

Kampo medicines improved blood test results and the quality of life (QOL) in two cases of vasculitis cases. One with Churg–Strauss-syndrome (CSS) and with Henoch–Shönlein-purpura (HSP), after inadequate treatment with conventional therapies

## 3.2. Summary

**Objective:** Two vasculitis syndrome patients, one with CSS (Case 1) and one with HSP (Case 2) exhibited persistent symptoms and abnormal blood tests after treatment with conventional therapies.

To improve their situation, based on the tenets of traditional Chinese medicine (TCM) theory, herbal medicines were applied.

**Methods:** Both cases were diagnosed with "blood stagnation" [1] and "dampness and heat" [2, 5, 6] and Case 1 had a "yang deficiency" [3]. Following TCM theory, we applied selected Kampo medicines.

Results: In Case 1, the patient presented with hypereosinophilia, venous thrombosis, pulmonary infarction, a decreased platelet count, ulnar nerve palsy and Raynaud's phenomenon, which led to a diminished QOL. After starting the Kampo medicines, the patient improved quickly and recovered within 11 months. In Case 2, persistent purpura, abdominal pain, and bloody feces quickly improved and disappeared after Kampo medicine treatment. Prednisolone was stopped at 21 days after starting the Kampo medicines and there has been no sign of relapse to date.

**Conclusion:** Kampo medicines helped clear the persistent abnormal symptoms and improve laboratory findings of two vasculitis syndromes, Churg–Strauss syndrome (CSS) and Henoch–Shonlein purpura (HSP), which had responded inadequately to the conventional therapies administered.

#### 3.3. Introduction

Churg–Strauss Syndrome (CSS) and Henoch–Sholein purpura (HSP) are classified as vasculitis syndromes, in which inflammation and blood vessel damage are common and may lead to various pathologies. CSS is rare, and necrotizing vasculitis involves small-and medium-sized arteries, capillaries, veins, and venules. The histopathological features of CSS are granulomatous reactions in the various tissues of any organ in the body, but lung involvement is predominant, with manifestations in the skin, cardiovascular system, kidney and peripheral nervous system, and also occasionally the gastro- intestinal tract. Although its pathogenesis is uncertain, it has a strong association with asthma, eosinophilia, granuloma and vasculitis.

HSP is usually seen in children, and is characterized by palpable purpura, arthralgia, gastro-intestinal signs and glomerulonephritis. It is a small-vessel vasculitis. The pathogenic mechanism is presumed to be immune-complex deposition. A skin biopsy specimen is useful to confirm leuko-cytoclastic vasculitis with IgA and C3 deposition by immune-fluorescence.

These diseases usually exhibit a good response to corticosteroid hormones. However, some patients do not completely recover and suffer from an incomplete remission state with degraded QOL.

The present CSS case improved to some degree with conventional therapies in a university hospital at the acute stage, but at the chronic stage he continued to exhibit hypereosinophilia, venous thrombosis, pulmonary infarction, decreased platelet count and Raynaud's phenomenon. The patient with HSP showed improvement primarily with steroidal hormones. However, his condition worsened soon after a tapering down of the prednisolone.

From the standpoint of TCM theory, we diagnosed the pathogenesis of these diseases as being related to "static blood" [1] and in vasculitis, as related to "dampness-heat" [2, 5, 6], primarily in the morbid vessels, and also, in Case 1, a yang deficiency (coldness of the fingers and limbs and/or sensitive to coldness) [3].

Case 1: A 13-year-old-boy with CSS

Main Complaints: Hypereosinophilia, left femoral venous thrombosis, pulmonary infarction, decreased platelet count, Raynaud's phenomenon, ulnar nerve palsy

**Past History**: For three years prior to his admission to the university hospital, the patient suffered from malaise, petechiae, purpura and allergic rhinitis. Hay fever also began from last year.

**Present Illness**: For 3 years prior to admission, main complaint started and also experienced pain with edema of the legs after extended walking, despite conventional therapies. He was diagnosed with CSS with hypereosinophilia, vasculitis with extravascular eosinophil accumulation, diffuse pulmonary infiltrate, and ulnar nerve palsy.

He also had left femoral deep venous thrombosis and pulmonary infarction. On the 5th day after hospitalization for suspected pneumonia with septic shock, he received pulse doses of methyl-prednisolone and gabexate mesilate. Following this treatment, his fever, chest pain, and diffuse pulmonary infiltrate disappeared and his eosinophile count normalized (Figure 1). For the persistent left femoral deep venous thrombosis and pulmonary infarction, he was given heparin and warfarin with prednisolone which are continued to be administered even after his discharge from the hospital (Figure 2). The pulmonary segmental shadow caused by the pulmonary infarction disappeared after 6 months. The left femoral deep venous thrombosis and ulnar nerve palsy disappeared after 9 months (Figures 1, 2, 3).

At 81 days after the patient's discharge from the hospital, the Kampo medicine "Chi-ling-tang (柴苓湯)" (TJ 114) [4] was started (2packs/day: for adult 3 packs is required; 3 pack includes 9 g of herbal mixtures consisting of 3g of excipient and 6g of dried herbal extracts. Dried herbal extracts/day is derived from chai-fu (.柴胡)7 g, zhu-ling (猪苓)3g, ze-xie (沢瀉)5 g, ren-shen (人

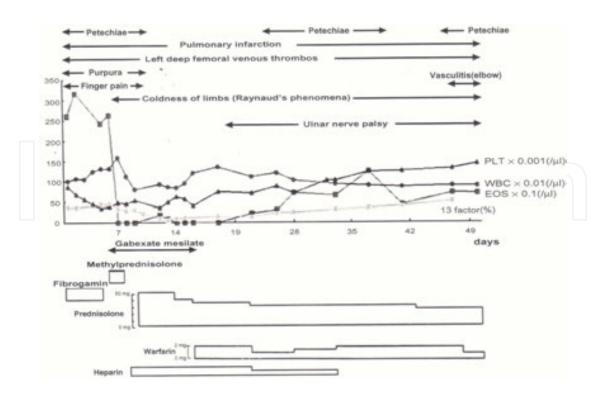


Figure 1. Clinical course during hospitalization of case 1.

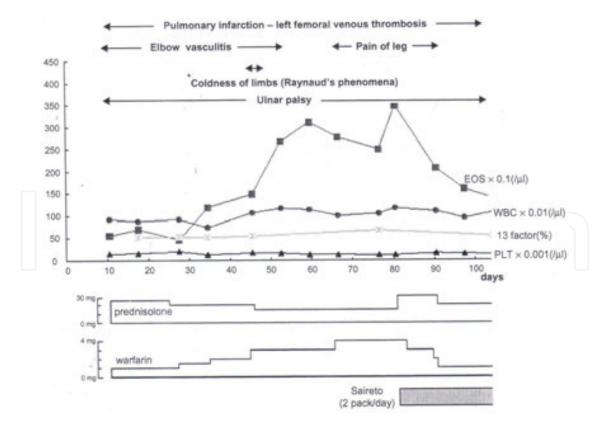


Figure 2. Clinical course after discharge from the hospital of Case 1.

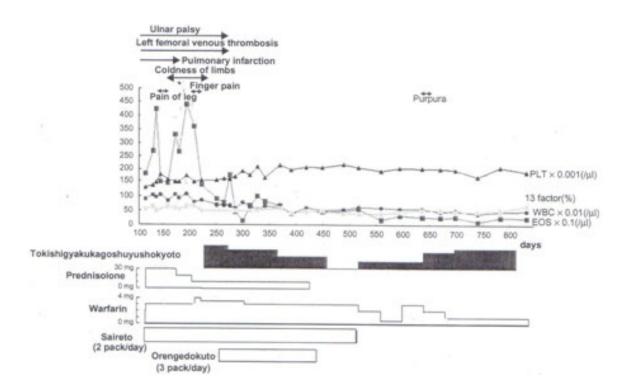


Figure 3. Clinical course after discharge of case 1

参)3g, ban-xia (半夏)5g, fu-ling (茯苓)3g, huang-qin (黄芩)3g, gan-cao (甘草)2g, to prevent the side effects of prednisolone. TJ indicates that this is a product of Tsumura Co (Akasaka, Minatoku, Tokyo, 107-8521 Japan).

The doctor in chief decided to apply Kampo medicine, because even at 7 months after discharge there were no signs of improvement and the patient's QOL was suffering. The patient visited the author's clinic on the 224<sup>th</sup> day after discharge from the hospital.

**Present States**: The patient's height was 166cm and weight was 65kg. He had a floating, fine, and weak chi mai (尺脈) (indicating Kidney yang deficiency). His tongue body was pale red and showed thin tongue fur. Sublingual collateral dark vessels were swollen.

**Identification**: Following TCM theory, the patient was diagnosed as having "static blood" [1] based on thrombosis and infarction of the blood vessels and dark vena sublingualis, as well as "dampness-heat" [2, 5] in the affected vessels, based on vasculitis, and as having "yang deficiency" [3] based on his cold limbs, sensitivity to coldness, and Raynaud's phenomenon.

**Treatment**: Activate blood to remove stasis. Add and promote yang circulation.

**Prescription**: Dan-gui-si-ni-jia-wu-zhu-yu-sheng-jiang-tang (当帰四逆加呉茱萸生姜) (Table 1) [7] for Yang deficiency to warm the channels, disperse cold, nourish the blood and unblock the blood vessels. For "blood stasis", mu-tan-pi (牡丹皮) [8], tau-gen (桃仁) (Table 1) [9], zhe-chong (虫) [10], and shui-zhi (水蛭) [11] were added and to remove dampness-heat, huang-lian-jie-dutang (黄連解毒湯) (TJ-15) (Table 2) [12–14] was prescribed.

Table 1 Composing herbs of :Dan-gui-si-ni-jia-wu-zhu-yu-sheng-jiang-tang-10.5772/60573 (当帰四逆加呉茱萸生姜湯)\*1 and main function of respective herbs in Human.(Decoction)

Name of the herb	Main function	
Radix Angelicae Sinensis(当帰:dang gui)3	Tonify and invigorates the blood	
Radix Paeoniae Lactiflorae	Strengthen the tonifying action of 当帰	
(芍薬:bai shao)3		
Ramulus Cinnamomi Cassiae(Keishi:gui zhi	)3 Warm the meridian and disperses cold	
Herba cum Radice Asari(細辛:xi xin)2	Disperses both internal and external cold	
Radix Glycyrrhizae Uralensis	Augument the Qi and strengthen the Spleen	
(甘草: gan cao)1		
Fructus Zizyphi Jujubae(大棗:da cao)5	Augument the Qi and strengthen the Spleen	
Caulis Mutong(木通:mu tong)3	Facilitate the flow in the channels and vessels	
Fructus Evodiae Rutaecarpae	Warm the middle, disperse cold, promotes the	
(呉茱萸:Wu zhu yu) 2 -	movement of Qi	
Zingiberis Officinalis Recens(dried)	Release the exterior and disperses cold	
(生姜: heng jiang)1		

<sup>\*1</sup> Tangkuei Decoction for Frigid Extremities plus Evodia and Fresh Ginger (Name in USA) Ref 13. numerals mean weight of dried herbs(g/day). For case 1, 2g of Mutanpi(牡丹皮) & Tao-ren(桃仁) and 0.5g of Zhe-chong(䗪虫) & shui-zhi(水蛭) were added to the above Prescriptions to decoct with water.

**Table 1.** Composing herbs of : Dan-gui-si-ni-jia-wu-zhu-yu-sheng-jiang-tang (当帰四逆加呉茱萸生姜湯)\*¹ and main function of respective herbs in Human.(Decoction)

Table 2 Composition of herbs in Orengedokuto(黄連解毒湯)

and main function of respective herbs

Name of the herb	
(Japanese:Chinese),N(g/day)	Main function
Rhizoma Coptidis	Clear heat and dry dampness
(黄連:huang lian),2	
Radix Scutellariae	Clear heat and dry dampness
(黄芩:huang qin),3	
Cortex Phellodendri	Clear heat and dry dampness
(黄柏:huang bai),1.5	
Fructus Gardeniae (Jasminoidis)	Clear heat and eliminates irritability
(梔子:zhi zi),2	

<sup>\*2</sup> Coptis Decoction to Relieve Toxicity(Name in USA) :Ref 18 Huang lian jie du tang(Name in china)

Table 2. Composition of herbs in Orengedokuto (黄連解毒湯) and main function of respective herbs

Clinical Course: After Kampo medicines were initiated, the patient's Raynaud's phenomenon, cold and painful limbs, and abnormal platelet count quickly normalized, and his hypereosinophilia gradually improved to a normal level, with transient deterioration, over a period of 10 months. The left femoral venous thrombosis and ulnar nerve palsy had disappeared by 9 months of treatment (Figure 2, 3).

**Discussion**: The Kampo medicines selected in this case were chosen for the particular activities of the herbs. They work synergistically to produce improvement.

Case 2 A 2-year-old boy

Main Complaint: Purpura, abdominal pain, bloody feces

**Past History**: In the middle of April 2000, the patient caught a common cold. On April 25, petechiae appeared on his right leg and then spread to his left leg and both forearms. Abdominal pain with watery diarrhea, bloody stool, and knee joint pain were also noted, with the latter appearing and recovering spontaneously.

**Present Illness**: As the purpura became aggravated, the patient was hospitalized and diagnosed with HSP. He was treated with prednisolone successfully for the abdominal pain and bloody stool, but the symptoms reappeared with the tapering of the drug (Figure 4). The family

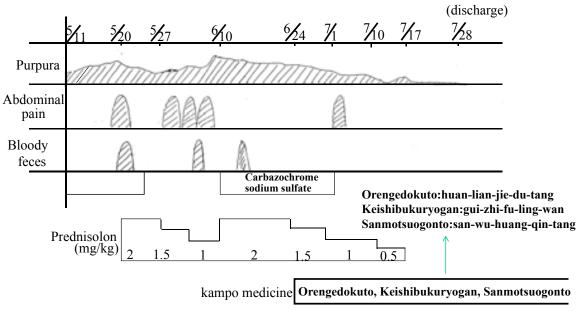


Fig 4. Clinical course of case 2 during hospitalization

Figure 4. Clinical course of case 2 during hospitalization

**Present States**: The boy was very nervous and crying, and the doctor in chief was unable to examine him.

**Identification**: Following TCM theory, he was diagnosed with "blood stagnation" for his purpura. Yin deficiency with yang hyperactivity [15] for his rapid pulse (90/min) and excita-

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Table 3	Composing herbs of Keshibukuryogan(桂枝茯苓丸)*3	and main functions of
	respective herbs in human	

Name of herbs	Main function
Ramulus Cinnamomi Cassiae	unblock the blood vessels and promote
(桂枝:gui zhi)	blood circulation
Sclerotium Poriae Cocos	transform phlegm and promote urination
(茯苓:fu ling)	nourishes the qi and calm the spirit
Radix Paeoniae(芍薬:shao yao)	relax spasm and alleviate abdominal pain
Cortex Moutan Radicis(牡丹皮:mu dan pi)	cool and invigorates the blood and dispel
	blood stasis
Semen Persicae(桃仁:tao ren)	invigorates the blood and dispel
	blood stasis

<sup>\*3</sup> Cinnamon Twig and Poria Pill(Name in USA). Gui zhi fu ling wan(Name in China).

Table 3. Composing herbs of Keshibukuryogan (桂枝茯苓丸)\*3 and main functions of respective herbs in human

bility, and with "dampness-heat" [2, 5] based on the existence of vasculitis and his preference for cold rather than hot food. We prescribed Keishi-bukuryogan: Gui-zhi-fu-ling-wan (桂枝茯 苓丸) (Table 3) (TJ 25) for "blood stagnation" [1]. San-wu-huang-qin-tang (三物黄芩湯) (TJ 121: One day's dose include di-fang 6g, ku-shen 3g, and huang-qin 3g) [13, 16–18] for Yin deficiency with yang hyperactivity and Huan-lien-jie-du-tang (黄連解毒湯) (TJ 15) for "clearing dampnessheat" [2, 12-14].

As shown in Figure 4, in spite of the tapering down of the prednisolone, soon after the administration of the Kampo medicines, the purpura and abdominal pain drastically decreased and the bloody stool subsided. Despite the fact that the patient stopped the prednisolone 3 weeks after starting the Kampo medicines, his improved condition continued, leading to his discharge from the hospital [19].

Discussion: In Case 1, the platelet decrease might have been the result of a pulmonary infarction. The prednisolone pulse therapy may have aggravated the infarction despite the patient's good QOL. In CSS with eosinophilia and systemic vasculitis, "blood stagnation" is present due to the pulmonary infiltrate of eosinophils caused by the vasculitis. As mentioned earlier, mu-tan-pi (牡丹皮) [8], tau-ren (桃仁) [9], zhe-chong (虫) [10], and sui-zhi (水蛭) [11] resolved the blood stagnation and accelerated blood flow.

In the United States, Tokisigyakukagosyuyusyokyoto (Japanese pronun- ciation), Dan-gui-sini-jia-wu-zhu-yu-sheng-jiang-tang (当帰四逆加呉茱萸生姜) named as "The Decoction For Frigid Extremities plus Evodia and Fresh Ginger" [7], which means warm the channels, disperse cold and unblock blood vessels in TCM.

Inflammation implies "dampness-heat" in TCM, Huan-ren-jie-du-teng (黄連解毒湯) which traditionally relieves heat and dampness was applied. These formulas and remedies are considered to work synergistically to prompt recovery.

<sup>:</sup>Ref 22

In Case 2, as in Case 1, vasculitis has the characteristic of "heat and dampness", for which Huan-lien-jie-du-tang was applied. Deposits of immune complex in the blood vessels or purpura mean blood stagnation in TCM, for which Gui-zi-fu-ling-wang (桂枝茯苓丸) was applied. The fact that the patient preferred cold drink, and was feverish with a rapid pulse rate suggested Yin deficiency with internal heat [15], for which San-wu-huang- qin-tang was prescribed (TJ-121). These prescriptions are also believed to work synergistically to effect a quick recovery.

These cases of systemic vasculitis had "blood stagnation" and "dampness-heat" in TCM terminology. Properly selected remedies for "blood stagnation" and "heat and dampness" seemed to help to achieve patient improvement.

## 4. Kidney diseases

## 4.1. Alternative treatment for nephrotic syndrome with Kampo medicines including Ba-Wei-Di-Huang-Wan [20]

### 4.1.1. Abstract

The dose of steroid hormone was decreased or eliminated by the addition of Kampo medicines to cure patients suffering from nephrotic syndrome.

In two cases refractory to steroid hormone, the combination of ba-wei-di- huang-wan (八味地 黄丸), gui-zhi-fu-ling-wan (桂枝茯苓丸), and dang-gui- shao-yao-san (当帰芍薬散) or ba-wei-di-huang-wan, chai-ling-tang (柴苓湯), and the addition of various herbs (*Captis chinensis* Franch, *Gardenia jasminoides* Ellis, etc.) was very effective.

Based on these formulations, the new combination of Ba-wei-di-huang- wan (八味地黄丸), Xiaochai-hu-tang (小柴胡湯), Si-wu-tang (四物湯), and huang-lian-jie-du-tang (黄連解毒湯) (hereafter this combination of four prescriptions shortened to BXSH) proved to be effective in eight cases (one case refractory to steroids and therefore without steroid treatment, one case with steroid dependency and six cases with nephrotic syndrome). This combination was effective in five of six patients with proteinuria. In one recurrent case, the combination of Ba-wei-di-huang-wan and Bu-in-tang (補陰湯) led to recovery. These results show that these formulas may exert a synergistic effect responsible for improvement in urinary protein excretion.

### 4.2. Introduction

Patients with nephrotic syndrome commonly take steroid hormones. However, some patients experience many side effects. To decrease these steroidal side effects, Chai-ling-tang (柴苓湯) was often applied [4].

Because some side effect may persist, we tried to create new herbal combination.

Ba-Wei- Di- Huang-Wan is effective in treating oliguria, edema [21], and proteinuria [22]; xiao-chai-hu-tang (小柴胡湯), as a part of chai-ling-tang (柴苓湯), huan-lien-jie-du-tang (黄連解毒湯) as

antiphlogistic and si-wu-tang (四物湯) (di-huang, dang-gui, shao-yao, chuan-xiong) to tonify and accelerate the blood circulation are chosen to treat nephrotic syndrome. We describe our promising results below.

#### 4.3. Material and methods

We studied eight adults and three children who were diagnosed with nephrotic syndrome at other medical facilities that followed our instructions.

A treatment was deemed very effective (+2) when more than 2 years had passed without recurrence even after quitting steroid hormones after a combination therapy consisting of four prescriptions (BXSH) in steroid refractory and dependent cases. Another very effective (+2) case is without relapse for more than 2 years who took only Kampo medicines without steroid hormone. A treatment was deemed effective (+1), only during the intake of Kampo medicines, improvement was observed in the form of a reduction in daily proteinuria of more than 50% compared to patient's condition without Kampo medicines, or when the required steroid volume was reduced. And another effective (+1) case is as follows. The patient took a combination of steroids and Kampo medicine and proteinuria disappeared within 6 months, subjective symptoms improved and no recurrence was observed in more than 2 years after steroid hormones were stopped.

We obtained powdered prescriptions of ba-wei-di-huang-wan (八味地黄丸) (di-huang: 地黄 6, fuling: 茯苓 3, shan- zhu-yu: 山茱萸 3, mu-dan-pi: 牡丹皮 2.5, san-yao: 山薬 3, gui-pi: 桂皮 1; ze-xie: 澤瀉 3 and fu-zi: 附子 0.5; numbers indicate g/day), xiao-chai-hu-tang (小柴胡湯) (chai-fu.7g, ban-xia.5g, dried sheng-jiang.1g, huang-qin.3g, da- zao.3g, ren-shen.3g, gan-cao.2g; numbers indicate g/day), huang-lian-jie-du-tang (黄連解毒湯), and Si-wu-tang (四物湯). Hereafter, we refer to the mixture of the above mention- ed four prescriptions as BXHS. For adults, we prescribed full ~ half dose of ba-wei-di-huang-wan depending on weight. Infants were prescribed, 1/2 of the adult volume of ba-wei-di-huang-wan, and 1/3 of xiao-chai-hu- tang, huang-lian-jie-dutang, and si-wu-tang (BXHS).

(Composition of herbs respective prescriptions are listed in Reference 16.)

Sometimes to other cases ba-wei-di-huang-wan added with bu-zhong-yi- qi-tang (補中益気湯), bu-in-tang (補陰湯), dang-gui-shao-yao-san (当帰芍薬散), and gui-zhi-fu-ling-wan (桂枝茯苓丸) could be prescribed.

We obtained these prescriptions in powder form from Matsuura Yakugyo Co, Ltd (24–21, Enjo-Cho, Showa-Ku, Nagoya 466-0054, Japan) or Tsumura Co. LTD. These powdered prescriptions are made from filtrate of decoctions followed by spray drying.

The components of the decoction were derived from "Keiken Kampo Shoho Bunryo syu" [23]. We obtained appropriate herbs from Tochimoto Tenkaido Co, LTD (3–21 Suehiro\_cho, Kitaku, Osaka 530-0053, Japan).

When several different prescriptions were combined to make a single new prescription for decoction, and when the same herb was used in more than two prescriptions we used the largest volume of herb.

We prepared the decoction using with market boiling instrument. Kampo medicines are usually taken before meal. In cases of digestive system trouble, they are taken after a meal.

#### 4.4. Results

## 1. Effects to steroid-resistant nephrotic syndrome

## Case 1. M.O female. First onset at age 7

Three months' steroid treatment did not work for her. At the first visit to my clinic, her proteinuria score on the paper test was +4. She showed moon face, red striae and polytrichia.

At the insistence of the patient's mother, any conventional therapy including steroid hormone was stopped and 1/2 of the adult volume of ba-wei-di-huang-wan (八味地黄丸), gui-zhi-fu-ling-wan (桂枝茯苓丸) and dang-gui-shao-yao-san (当帰芍薬散) were prescribed which made her proteinuria disappear after 2 weeks.

She continued taking the same prescription for 4.7 months. At the time of the writing, more than 10 years have passed and she has had no recurrence.

Her treatment was estimated very effective (+2).

## Case 2.T.K female. First onset at the age 45 (Figure 5)

Nine years of conventional therapy at other hospital brought no improve-ment in this patient's condition. When she first visited my clinic, she was taking 10 mg of prednisolone and 50mg of cyclophosphamide every other day.

Her proteinuria level was 4.7g/day. For 25 weeks, she was treated with a decoction of a mixture of xiao-chai-hu-tang, huang-lian-jie-du-tang, and si-wu-tang (chai-fu.7g, ban-xia.5g, dried sheng-jiang.1g, huang-qin.3g, da- zao.3g, ren-shen.3g, gan-cao.2g, huang-lian.1.5g, huang-bo. 1.5g, zhi-zi 2g, dang-gui.4g, chuan-xiong.4g, di-huang.4g) with ba-wei-di-huang-wan (pill form: 1 day's full dose) which reduced her proteinuria to 1.1g/day. When she overworked herself, her proteinuria increased temporarily to 4.3g/day. We changed to a combination of bu-yin-tang (補陰湯) and ba-wei-di-huang-wan which decreased her proteinuria to ca 2g/day and more recently decreased further to approximately 1g/day (Figure 5).

In Figures 5 and 6, ba-wei-di-huang-wan (八味地黄丸) is expressed as Hj. shao-chai-fu-tang (小柴胡湯) is expressed Ss, si-wu-tang (四物湯) is expressed Sm, huang-lian-jie-du-tang as Og, and bu-yin-tang (補陰湯) as Hi based on Japanese pronunciation.

When she was 59 years old, the doctor in chief stopped all her conventional therapies. We assessed her treatment was effective (+1).

### Case 3. T.F. female. First onset at age 21

She relapsed five times whenever her intake of prednisolone reduced to below 20 mg/day. Betamethasone gabexate mesylate(B), and pulse therapy did not work at all. When a hematoma was produced by her kidney biopsy, her proteinuria level increased to 25g/day which then decreased with a dose of 60 mg of prednisolone/day. Cyclophosphamide was restarted at a

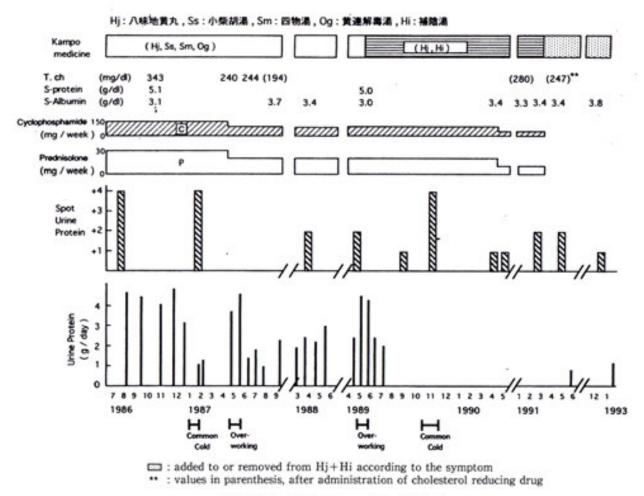


Fig 5. T.K. 61y. f. (corresponds to Table I)

Figure 5. T.K. 6ly. f. (corresponds to table 1).

dose of 50mg/day, and 2 months later when the patient's intake of prednisolone was reduced to 17.5g/day, no relapse occurred. And when her prednisolone was decreased to 15mg/day, she started taking BXHS mix prescriptions. After 13 months, she had no proteinuria and her intake of prednisolone was further reduced to 5mg/day. She had been taking 2.5mg of prednisolone to prevent relapse. But now more than 20 years had passed without any recurrence. We estimate her treatment effective (+1) (Figure 6).

## 2. Effects on steroid-dependent nephrotic syndrome

## Case 4. H.S. female. First onset at age 60.

This patient's initial proteinuria level was 10g/day with membranous nephropathy. When her intake of prednisolone decreased from 40mg/day to 5 mg/day, her nephropathy relapsed. At her first visit to my clinic, she was taking prednisolone at a dose of 15mg/day, and her proteinuria level was 2.2 g/day. After 26 weeks of intake of BXHS mix prescriptions, her proteinuria level had fallen to 0.7g/day which meant that the treatment was judged to be effective (+1). The patient was later able to reduce her intake of prednisolone to 2.5mg/day. At 3 years after discontinuing BXHS mix prescriptions, the patient recurred with a proteinuria level 3g/day despite intake of prednisolone. She was assessed to be effective (+1).

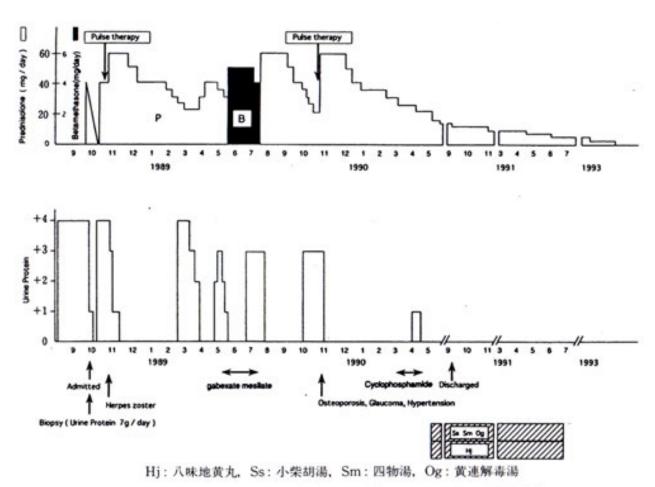


Figure 6. f. (corresponds to table 1) Fig 6. T.F. 21y. f. (corresponds to Table I)

**Case 5**. Y.M male. First onset at age 7.

This patient suffered from proteinuria (+4 with test paper) after being vaccinated for influenza. With the full-dose administration of betamethasone, his proteinuria disappeared. But a reduction in the intake (administration on a schedule of 3-days on, 4-days off), caused his proteinuria to reappear at a level of +1 with test paper. In order to break away from the betamethasone, he began taking BXHS mix prescriptions and 2 months later his proteinuria disappeared. Twenty months after starting BXHS together with betamethasone, he stopped taking betamethasone but continued BXHS for an additional 7 months. He has had no relapse for more than 20 years.

He will be evaluated very effective (+2).

**Other cases**: One male patient. First onset at age 36.

After spontaneous recovery from proteinuria, suffered a relapse (+4 with test paper) due to the aggravation of chronic prostatitis. His proteinuria level was 10 g/day and he was hospitalized. He was treated with steroid therapy which worked. To achieve steroid withdrawal, BXHS was prescribed with the goal of being protein-free. And he succeeded at 8 weeks. Three years after starting BXHS the patient's steroid was reduced to 7.5mg/day and further reduced

to 5mg and finally stopped after 22 months. Since the start of BXSH, there has been no relapse for 9.2 years. Recently, although the patient's chronic prostatitis was again aggravated, there was no relapse indicating complete recovery. He was deemed very effective (+2).

## 2. Quick start of BXHS together with steroid therapy

One of two cases, was effective. We present the effective case.

Case 6. H.H female. First onset at age 44.

Since 1 year ago, this patient was made aware of her proteinuria.

(+1~+2 with test paper) with membranous nephropathy. She was hospitalized with proteinuria (5 g/day). But it reduced to 2 g/day with 60mg/day of prednisolone. When steroidal intake decreased to 50mg, she started BXHS. After approximately 3 months' intake of BXHS, her urinary protein disappeared and she was discharged from the hospital. After taking steroid for 18 months, she stopped and remained protein-free for more than 4 years. She had been taking 1/4 of initial volume of BXHS without relapse more than 10 years. She was assessed very effective (+2).

## 2. To nephrotic syndrome cured by only Kampo medicines

Case 7. Y.O female. First onset at 50.

Proteinuria (2.7g/day) disappeared approximately 15months later after BXHS was started with a gradual decrease and then stopped after 4 years and 2 months. The patient took this medicine for more than 7 years to prevent relapse. She was deemed very effective (+2).

## 4.5. Appendix: Efficacy for proteinuria

We applied Kampo medicines to eight patients without postural proteinuria. BXHS worked in seven of eight patients (data not shown).

## 4.6. Discussion

Generally speaking, the pathology of nephropathy stems from an over permeability of the glomerular basement membrane to serum protein.

Furthermore, blood coagulation can be accelerated. Histologically, thrombosis with fibrin may be observed. The side effects of the administration of steroids for a long time include an increase in blood viscosity and platelet hyperfunction. It is quite natural for antiplatelet drugs to decrease the diapedesis of protein from the kidneys.

We applied ba-wei-di-huang-wan, xiao-chai-hu-tang, huang-lian-jie-du-tang, and Si-wu-tang. Results were described below.

As mentioned above, ba-wei-di-huang-wan warms the Kidney and improve the kidney function. Huang-lian-jie-du-tang worked to remove dampness and heat and also used si-wutang to accelerate blood circulation and improving anemic tendency. I also used xiao-chai-futang because it is the component of chai-ling tang which is used to eliminate steroid side effects

and for nephrotic syndrome in Japan. Additionally, it was used effectively by Otsuka and Yakazu for proteinuria and nephrotic syndrome [21, 22]. I selected these prescriptions for these reasons. I will propose instead of combination of huang-lian-jie-du-tang and si-wu-tang, wenqing-tang (温清飲) will be successfully replaced. Because, wen-qing-tang (温清飲) equals combination of huang-lian-jie-du-tang and si-wu-tang.

#### 4.7. Conclusion

The combination of ba-wei-di-huang-wan (八味地黄丸), shao-chai-hu-tang (小柴胡湯), huang-lian-jie-du-tang (黄連解毒湯) and Si-wu-tang (四物湯) works to decrease the intake of steroids or helps the patients to stop taking steroids in steroid-refractory and dependent cases and for general nephrotic syndrome.

## 5. Leukemia-related diseases

## 5.1. Abstract

A 41-year-old female was diagnosed with acute lymphocytic leukemia (ALL) at a university hospital. She could not tolerate chemotherapy and started alternative Chinese herbal medicine including zi-xue-tan (紫雪丹) (Table 6) at the time of her fourth recurrence. This provided transient improvement followed by aggravation after her intake was decreased. A blood test suggested complete recovery. Although cyclophosphamide had previously been ineffective, this time together with Chinese medicine, it led to a dramatic improvement.

#### 5.2. Introduction

Conventional therapies for leukemia have developed dramatically and now include such treatments as bone marrow transplantation (BMT). However, there remain the problems of side effects of chemotherapy, age limits for certain treatments, and a shortage of donors for BMT. Based on the clinical course of the case presented here, TCM should be considered as a potential alternative medicine treatment in some cases [24].

#### 5.3. Case report

A 41-year-old female developed bone pain in November, 1989. She had also been suffering from constipation and cold intolerance. She reported in her family history that her mother had been suffering from rheumatism and brain embolism. After a thorough examination, the patient was diagnosed with L2 (by the French–American–British, FAB, classification) acute lymphocytic lymphoma. Chemotherapy with vincristine, prednisolone, daunorubicin, mercaptopurine, methotrexate, L-asparaginase, vindesine, and adriamycin was instituted. Complete remission was achieved and the patient left the hospital in March, 1990.

However, she subsequently suffered relapse three times. After she left the hospital in complete remission in August, 1993, 54.2% peripheral blood blasts appeared simultaneously with hair

loss, nausea, diarrhea, candida stomatitis, mycotic pneumonia, and sepsis. As these side effects of chemotherapy were overwhelming, she refused all treatment at the hospital. Her family was told by the doctor that she had only 3 months to live. In April, 1994, she suffered from terrible weariness, insomnia, vertigo, and palpitations. She also suffered from inflammation of the mandibular joint (3–4 times/month) followed by difficulty in chewing food.

Lu Xi of the Lu family, noted for their treatment of acute febrile diseases (Wen bin), diagnosed her with acute febrile disease with stagnation of pathogenic heat, shortage of Qi (vital energy) and Yin including blood (xue) with blood stasis [24]. Her tongue body was pale and her lips were dark, indicating anemia and blood stagnation. Her pulse was thready and barely palpable. The patient elected to start TCM therapy on April 25, 1994.

At the beginning of the therapy, the patient showed the following values: white blood cells (WBC), 68000/µl; red blood cells (RBC), 231×10<sup>4</sup>/µl; hemo-globin (Hb), 8.2 g/dl; blasts (sum of blast cells and atypical cells), 61%; lactic dehydrogenase (LDH), 730 (Figure 7).

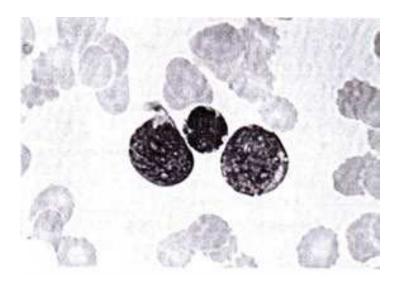


Figure 7. Findings of peripheral blood of patient 2 on May 17, 1994

Treatment was carried out to detoxify by supporting with Qi-tonic and Blood-tonic. The patient took prescriptions I-1, I-2, and I-3 as shown in Table 4 from April 25 to May 6, which increased her WBC to 69800/µl and decreased RBC to 204 x 10<sup>4</sup>/µl, Hb to 7.0 g/dl, and changed blasts from  $41480/\mu l$  to  $66799/\mu l$ .

We considered this aggravation to be due to the intake of I-1, I-2, and I-3, that is, Qi-tonic Huang-qi (黄耆. Astragali radix), Da-cao (大棗. Zizyphi fructus), and Blood-tonic Shu-di-huang (生地黄 Rehmanniae radix), Bai-shao-yao (白芍薬 Paeoniae radix), Long-yan-rou (竜眼肉 Longanae arillus), and Dang-gui (当帰. Angelicae radix), which may stimulate a presumably predominant multiplication of blasts with normal WBC. The coexistence of Qi-tonic and Blood-tonic in an environment with malignant cells may lead to a predominant uptake of both tonics preferentially by fast-growing malignant cells, followed by a recurrence of leukemia. Thus the patient

started to take Prescription II (Table 5) and modified Zi-xue-dan (紫雪丹) (Table 6), as listed in

He-ji-ivɪɪ-fano (和剳局方)

Table 4 2. Composition of the formulas applied (I-1,I-2,I-3)

Main functions	1-1 (Decoction)	1-2 Extracts of guipiteng ( <b>帰脾湯)</b>	1-3 Extracts of baweidihuangwa (八味地黄丸)
Clearing heat Removing pathogenic heat from blood Yin-tonic	*REHMANNIAE RADIX (shangdihuang 生地質 5.0) *SCROPHULARIAE RADIX		•REHMANNIAE RADIX (shengdihuang <b>生地黄</b> 3.0)
(清熱. 涼血. 補陰)	(xuanshen 玄参 5.0)		
learing heal 『Removing pathogenic heat from blood Resolving blood stagnation (清熱. 涼血. 活血)	<ul> <li>MOUTAN RADICIS CORTE (mudanpi 牡丹皮 5.0)</li> <li>PAEONIAE RUBRA RADIX (chishaoyac 赤芍薬 3.0)</li> </ul>		•MOUTAN RADICIS CORTEX (mudanpi 牡丹皮 2.5)
Activating blood circuration Resciving blood siagnation (活血)	NOTOGINSENG RADIX (tiangi 田七2.0) SALVIAE MIL TIORRHIZA RADIX (danshen 丹参 5.0)	<b>L</b> E	
Detoxitication Dissipating heat Repercussion (清熱. 保毒)	*VESPAE NICUS (ioufengfang <b>雲蜂房</b> 5.0)		
Promoting the flow of channeis and collaterals Clearing heat ( <b>通格.清熱</b> )	•LUMBRICUS (dilong 地電 3.0)		
Regulating Ci ( <b>理気</b> )	•CITRILEIOCARPAE EXOCARPIUM (qingpi 青皮 3.0)	•AUCKLANDIAE R (muxiang 木書 1	
·Ci-tonic (補気)	*ASTRAGALI RADIX (huangqi 黃耆 8.0) *ZIZYPHI FBUCTUS (dacao 大泉3.0) *GLYCYRRHIZAE RADIX (zhigancao 女甘草 2.0)	-ASTRAGALI RADI -ZIZYPHI FAUCTU (dacao 大東 2.0) -GINSENG RADIX (renshen 人参 3ATRACTYL ODIS (baizhu 白朮 3.0	S RHIZOMA (shanyao 山棗3.0) 0)
Yang-tonic (補陽)			•ACONTI TUBER (fuzi <b>附子</b> 0.5) •CINNAMOMI CORTEX (quipi <b>桂皮</b> 1.0)
Blood-tonic Yin-tonic (補血. 補陰)	PAEONIAE RADIX (baishaoyao 白芍薬 3.0	) (longyanrou <b>元</b> 月	Tuibin.
(Lin mr. Lin kar)	REHMANNIAE RADIX (shucihuang 熟地黄 5.0)	•ANGELICAE R. (danggui <b>当州</b>	
Promoting digestion (消滞)	•CRATAEGI FAUCTUS (shanzhazi 山楂子 3.0)		
*Stomachic (健胃)		•ZINGIBERIS SI PHIZOMA (shengliang &	
-Diuresis (利尿)		•PORIA (fuling <b>茯苓</b> 3	-PORIA (fuling 茯苓 3.0) -ALISMATIS RHIZOMA (zexie 沢瀉 3.0)
•Moderating ( <b>調和</b> )		•GLYCYRRHIZA (gancao 甘草	AE RADIX
Tranquilizing the mind ( <b>安神</b> )		•ZIZYPHI SPINO (suanzaoran •POLYGALAE R (yuanzhi 遠漏	<b>酸棗仁</b> 3.0) *2 RADIX
•Astringent (収斂)			•CORNI FRUCTUS (shanzhuyu 山茱萸 3.0

Pulverlzed extracts of 1-2 and 1-3 were obtained from Tsumura Co., Ltd., Tokyo, Japan.

The lower right number indicates intake (g/day) of respective herbs.

1: This has the function of Qi-tonic as well.

Table 4. Composition of the formulas applied ( I -1,  $\,$  I -2,  $\,$  I -3).

<sup>\*2:</sup> This has the function of blood-tonic as well.

## Table 53 Composition of prescription II and III

(4 Leukemia-related disease)

Main functions	П	Ш
Clearing heat Removing pathogenic heat from blood Yin-tonic (清熱. 涼血. 補陰)	•REHMANNIAE RADIX (shangdihuang 生地黄 5.0) •SCROPHULARIAE RADIX (xuanshen 玄参 5.0)	REHMANNIAE RADIX (shengdihuang 生地黄 5.0) SCROPHULARIAE RADIX (xuanshen 玄参 7.0)
<ul> <li>Clearing heat</li> <li>Removing pathogenic heat from blood</li> <li>Resolving blood stagnation (清熱. 涼血. 活血)</li> </ul>	•MOUTAN RADICIS CORTEX (mudanpi 牡丹皮 5.0)	•MOUTAN RADICIS CORTEX (mudanpi 牡丹皮 5.0) •PAEONIAE RUBRA RADIX (chishaoyac 赤芍薬 3.0)
<ul> <li>Activating blood circulation</li> <li>Resolving blood stagnation</li> <li>(活血. 桂疹)</li> </ul>	*EUPOLYPHAGA SINENSIS (chechong 庶虫 6.0)  *HIRUDO (shuizhi 水蛭 3.0)  *ZEDOARIAE RHIZOMA (ezhu 表术 3.0)  *SALVIAE MIL TIORRHIZAE RA (danshen 丹参 5.0)	■EUPOLYPHAGA SINENSIS (chechong 庶虫 6.0) ■TABANUS (mengchong 蛀虫 2.0) ■MYRRHA (moyao 没寨 3.0) (DIX
<ul><li>Detoxification</li><li>Dissipating heat (清熱. 解毒)</li></ul>		•VESPAE NICUS (ioufengfang 露蜂房 7.0)
•Regulating Ci (理気)	•AURANTII NOBILIS PERICAROIUM (chanpi 陳皮 3.0)	•CITRI LEIOCARPAE EXOCARPII (qingpi 青皮 3.0)
"Ci-tonic (補気)	-ASTRAGALI RADIX (huangqi 黄耆 5.0) -GINSENG RADIX (renshen 人参 3.0)	•GINSENG RADIX (renshen 人参 2,5)
•Blood-tonic (補血)	SPATHOLOBI CAULIS*(a) (jixueteng <b>瑞血藤</b> 5.0)  PAEONIAE RADIX (baishaoyao 白芍薬 3.0)  LONGANAE ARILLUS (longyanrou 龍眼肉 3.0)  REHMANNIAE RADIX (shucihuang 熟地黄 3.0)	•REHMANNIAE RADIX (shucihuang <b>熟地黄</b> 5.0)
•Yang-tonic (補遠)		-EPIMEDII HERBA (yinyanghuo 淫羊霍 3.0) -PSORALEAE SEMEN (ponuzhi 補骨脂 7.0)
•Purging •Dissipating heat (瀉 <b>下.解毒</b> )	•RHEUM PALMATUM RHIZOMA (dahuang <b>大黄</b> 1.0)	

(a): This has the function of activating blood circulation as well.

(4 Leukemia-related disease)

Table 5. Composition of prescription II and III

From May 16 to May 19, she was hospitalized for examination and her results were found to have improved remarkably. Her WBC count had fallen from 41900/µl to 28400/µl, with blasts decreasing from 96% to 69%. For anemia, the patient underwent blood transfusion (Figure 8). Her bone marrow, evaluated by tap, showed many malignant cells. Peripheral blood findings are shown in Figure 7.

Table 6 1. Composition of modified Zi-xue-dan written in He-ji-ju-fang

(4 Leukemia-related disease)

Main functions	components	(g)
Clearing heat Purging fire (清熱、瀉火)	· GYPSUM FIBROSUM (shigao 石膏) · CALCITUM	50
(AM, AA)	(hanshuishi 寒水石)	50
	(huashi 滑石)  · NATRIUM SULFURICUM	50
	(mangxiao 芒頓)	100
Dissipating excessive heat stagnation (火都発之)	· POTASSIUM NITRATE (xiaoshi 硝石)	100
Clearing heat Removing pathogenic heat from blood Yin-tonic (清熱、漆血、補陰)	· SCROPHULARIAE RADIX (xuanshen 玄参)	50
Dissipating heat and detoxifying Checking the liver and calming the wind (清熱、解毒、鎮肝、熄風)	· ANTELOPIS CORNU (lingyangjiao 羚羊角)	15
Dissipating heat and detoxifying Removing pathogenic heat from blood (清熱、解毒、液血)	- BOS CORNU (niujiao 牛角)	150
Tranquilization with heavy materials (重鎮、安神)	· MAGNETITE (cishi 磁石)	100
Warming Zhongjiao activating Qi (溫中行気)	· AQUILARIAE LIGNUM (chenxiang 沈香)	15
(AT1) A)	· EUGENIA CARYOPHYLLATA (dingxiang 丁香)	15
· Regulating Qi (理気)	· SAUSSUREAE RADIX (muxiang 木香)	15
Detoxyfying (解毒)	· CIMICIFUGAE RHIZOMA (shengma 升麻)	50
	· GLYCYRRHIZAE RADIX (gancao 甘草)	25

<sup>\*:</sup> The middle part of the body from the diaphragm to the umbillcus which contain viscera such as spleen and stomach. Every component was broken to be powderlike by using grinder. 1.5 g of this powder was taken at a time. Modified zixuedan: add nlujiao to and subtract xijiao, zhusha and shexiang from zixuedan (Hejijufang).

Table 6. Composition of modified Zi-xue-dan written in He-ji-ju-fang, (4 Leukemia-related disease)

Seven days after the patient's discharge from the hospital on May 26, her WBC and blast cells again increased to 52200/µl and 89%, respectively, implying worsening of the disease. This may have been caused by excessive Blood-tonic herbs. We accordingly increased her dose of modified Zi-xue-dan (Table 6) and started Ling-yang-jiao (羚羊角) on May 29. In Prescription III, Qi-tonic and Blood-tonic herbs were decreased. Kidney-tonic Yin-yang-huo (淫羊藿) and Bohuzhi (破胡紙) were added, and an-gong-niu-huang-wan (Table 7) was added to dissipate heat and detoxify. Nevertheless, the patient's high fever continued. Her WBC count increased

to  $99800/\mu l$  on June 6 and retinal bleeding occurred with bone pain unresponsive to indomethacin for which narcotics were required.

Calculus bovis	20%	0.60 g	
Radix curcumde	15%	0.45 g	
Margarita	10%	0.30 g	
Moschus	5%	0.15 g	
Asiatici	20%	0.6g	
Rhizoma coptidis	15%	0.45 g	
Honey	15%	0.45 g	
	100%	3.00 g	

Table 7. Contents of An-gong-nju-huang-wan (Beijing)

The increase in blastic cells suggests an autocrine phenomenon. Perhaps a different cell line that was suppressed by Zi-xue-dan and Prescription was activated and increased. Based on TCM theory, in prescription III, Yang-tonic yin-yang-huo (淫羊藿) and po-hu-zhi (破胡紙) were included to warm the kidneys and increase kidney function. As in bone marrow, the haemopoietic role will be carried out more with the Yang-tonic herbs.

The patient then took cyclophosphamide at doses of 50mg, 50mg, 100mg, 100mg, and 300mg for 7days in this order, even though it had not been effective 6 months earlier. Her WBC count on June 14 had decreased to 17700/µl. During the 7-day treatment with cyclophosphamide, the patient's severe bone pain continued, but disappeared almost completely on the 8th day. She was diagnosed with gout based on clinical symptoms, in spite of normal uric acid levels. Beginning on June 23, she took granulocyte-colony- stimulating factor (G-CSF) for 7 days. Every day, approximately 2 hours after G-CSF intake, she had a fever of 39°C, which was successfully reduced by indomethacin and which resolved when the G-CSF therapy was stopped.

After 750 mg of cyclophosphamide together with TCM for just 1 week, the patient's WBC decreased to near  $500/\mu l$ , with 4% blasts. This situation continued for approximately 1 month until An-gong-niu-huang-wan was stopped and other Chinese medicines were decreased to 1/4 dosage because her WBC did not increase above  $1000/\mu l$ . Complete relapse was achieved. The patient's renewed sensitivity to cyclophosphamide may be the result of an interval or partially by the change in her constitution created by taking Chinese medicine.

If we do not stop An-gong-niu-huang-wan and do not decrease Kampo medicine for the time being, the patient might survive longer. Sadly, there remain few treatment options for this patient.

In conclusion, a combination therapy with traditional Chinese herbs and chemotherapeutic agents may make it possible to reduce the total quantity of chemical drugs for some time. This may be particularly useful in cases of refractory leukemia.

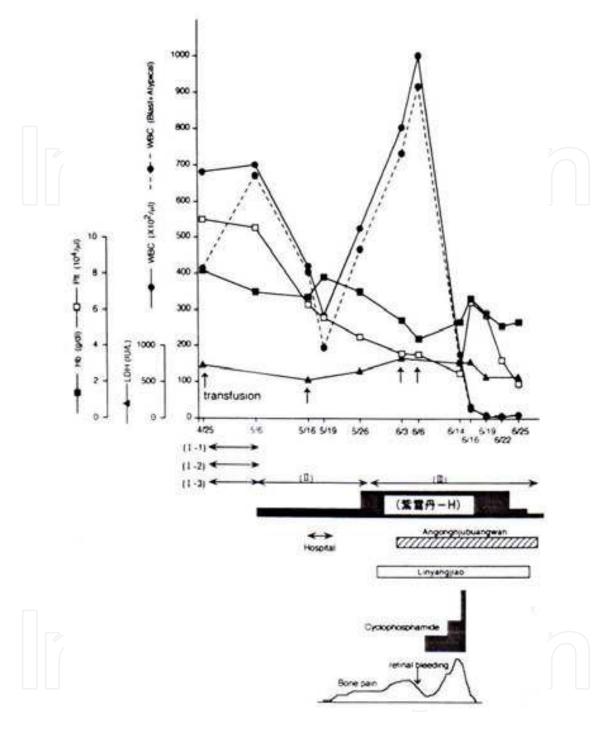


Figure 8. Clinical course of patient 2 since the start of treatment.

We also experienced another case not reported here of leukemia/lympho- blastic lymphoma (LBL) in which the patient was unable to receive chemotherapy due to terrible side effects. Traditional Chinese medical doctor, Lu Gan Fu, applied Zi-xue-dan (紫雪丹) for pathogenic heat and detoxification, which was able to reduce the patient's WBC count including leukemic cells [24]. He could survive 4 years and 10 months, though before starting TCM therapy his physician in charge told his family the patient could live 2 months.

## 6. Hyperlipidemia-related disease

## 6.1. Ayurvedic herb, Tinospora cordifolia

Tinospora cordifolia (Tin) is widely used in Southeast Asia as folk medicine for various diseases including diabetes mellitus (DM) [25]. In Japan, mechanism in decreasing blood cholesterol was reported in catabolism to bile acid [26].

We studied the effect of Tin in lowering blood total cholesterol (TC), triglycerides (TGs), very low-density lipoprotein (VLDL) and high-density lipoprotein (HDL) in 4 patients with hyperlipidemia. We prescribed powdered Tin at a dose of 0.75g/day for these four patients for 6 months. We examined blood TC, TGs, VLDL, and HDL before starting, once a month during administration, and at 17 days after stopping this herb.

#### 6.1.1. Abstract

Tinospora cordifolia (Tin) was administered to four patients with hyperlipidemia for approximately 6 months and TC, TGs, VLDL, and HDL were measured once a month.

In three cases, on sampling in December, TGs tended to decrease (Figures 9, 10, and 11, Ayurvedic herb.Tinospora cordiforia) and subsequently kept similar level and increased after discontinuation of Tin. TCs seem to keep similar level during testing period. VLDL tend to decrease during Tin administration in Figures 9, 10, and 11. Tin seems to have some influence on the human lipid metabolism, especially in TG and VLDL. Our subject who had a family history of DM (Figure 12) showed different patterns in TG, VLDL from cases shown in Figures 9, 10, and 11. She may have a different lipid metabolism due to a shortage of insulin action or insulin resistance with her family history of DM, which requires further clarification through continued research in this field.

#### 6.1.2. Materials and methods

The four patients had all been taking their own herbal medicines for their constitutions. We tested the effect of powdered Tin without changing their regularly taken medicines including herbal medicine. For breakfast of test day, they each had a small portion of rice and some pickled vegetables, and tested at my clinic about noon, I drew blood from a vein on the left hand. Their breakfast was small and quite similar every time that blood was drawn.

Case 1: A 78-year-old Japanese female; height: 156cm; weight: 45kg.

She had been suffering from constipation, anal prolapse, and hyperlipidemia, and has adrenal tumor. She had been taking modified bu-zhong-yi-qi-tang (補中益気湯) for 3 years.

Case 2: A 75-year-old Japanese female; height: 154cm; weight: 55kg. She had slight hyperlipidemia and cholelithiasis.

Case 3: A 74-year-old Japanese female; height: 154cm; weight: 45.6kg. She catches cold easily. She has not been strong since childhood and is sensitive to cold. From time to time when she had her blood tested, the doctor informed her that she had hypercholesterolemia. She had been

taking modified chai-ling-tang (柴苓湯) with ba-wei-di-huang-wang (half dose/day) for more than 7 months.

Case 4: A 56-year-old Japanese female; height: 155 cm; weight: 56 kg.

Her parents had a family history of DM. She had been taking ba-wei-di- huang-wang (八味地 黄丸) and gui-zhi-fuling-wan (桂枝茯苓丸: full dose of 1 day) for more than 1 year.

We prescribed powdered Tin (regular volume, 0.75 g/day) for these four patients for 6 months. I examined blood level of TC, TGs, VLDL, and HDL before starting, once a month during administration, and at 17 days after stopping this herb. LDL was calculated as total-Cho extracted HDL plus 1/5 TGs.

#### 6.1.3. Results and discussion

In Case 1, LDL showed a small increase at the initiation of Tin, but then decreased consistently even after Tin was discontinued and remained low for approximately 1 month. At 2 months after the discontinuation of Tin, however, it started to increase. TG had decreased from 152 to 83 mg/dl at 2 months after initiating Tin, and remained nearly constant until 1 month after stopping Tin. HDL increased from the beginning until 1 month after stopping Tin. In short, in Case 1, LDL and TG kept decreasing and HDL kept increasing. A high level of TC might reflect HDL concentration, which does not necessarily mean bad hyperlipidemia. For her Tin seemed to play a good role to decrease the level of TG, LDL and increase of HDL (Figure 9).

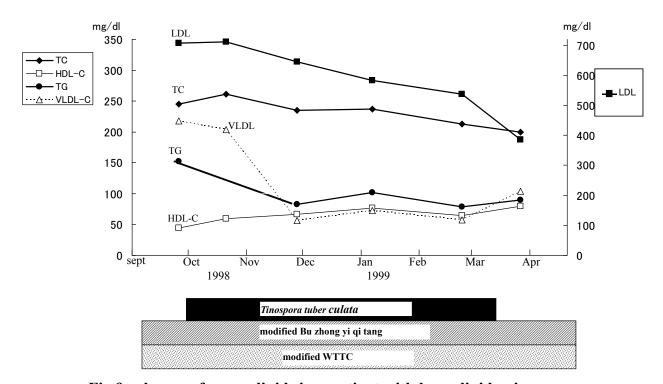


Fig 9. change of serum lipids in a patient with hyperlipidemia

Figure 9. change of serum lipids in a patient with hyperlipidemia

In Case 2, from October 7 till November 28, TC, LDL, and TGs all decreased. However, early in the new year, the patient ate her favorite herring roe every day. At January 7, TC and LDL had increased while TGs kept decreasing. The patient's LDL level at 20 days after stopping herring roe had decreased slightly. The intake of herring roe did no influence to the ability of Tin to decrease TG levels. But after stopping Tin, TG, VLDL, and TC similarly increased which implies that Tin can decrease TG levels. In this case Tin did not influence HDL level (Figure 10).

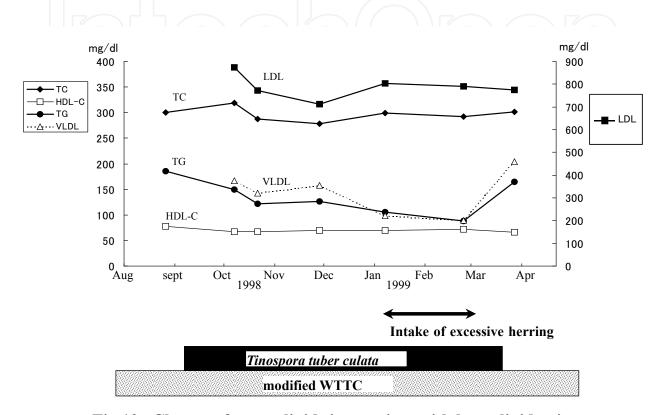


Fig 10. Change of serum lipids in a patient with hyperlipidemia

Figure 10. Change of serum lipids in a patient with hyperlipidemia

In Case 3, TC, LDL, and HDL all tend to increase until second sampling, and then increased again after Tin was discontinued.

Until the time of the third sampling, the patient had been taking antibiotics for inflammation associated with otitis externa, which would have influenced her lipid metabolism. After stopping Tin, all levels increased. This may mean that Tin can decrease the blood levels of TC, LDL, VLDL, and TG. But I cannot explain why LDL increased at the beginning of Jan- uary. The patient's TG level tends to remain same normal level (Figure 11).

In Case 4, unfortunately, three spots could not be measured for her private reason, but it is clear that, from January until the time when Tin was continued, all factors increased except HDL and that after Tin was discontinued, they all decreased. This implies that Tin was not effective in decreasing blood levels of TC, LDL, VLDL, or TGs in this case. We therefore recommend that this patient should take conventional medicine for hyperlipidemia (Figure 12). Her family history of DM may play a role in this phenomenon and must be further clarified.

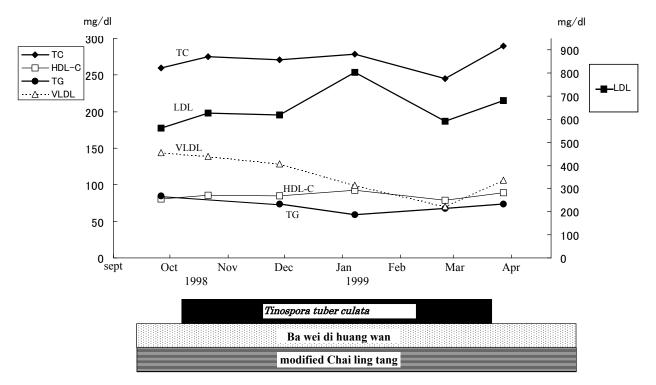


Fig 11. Change of serum lipids in a patient with hyperlipidemia Figure 11. Change of serum lipids in a patient with hyperlipidemia

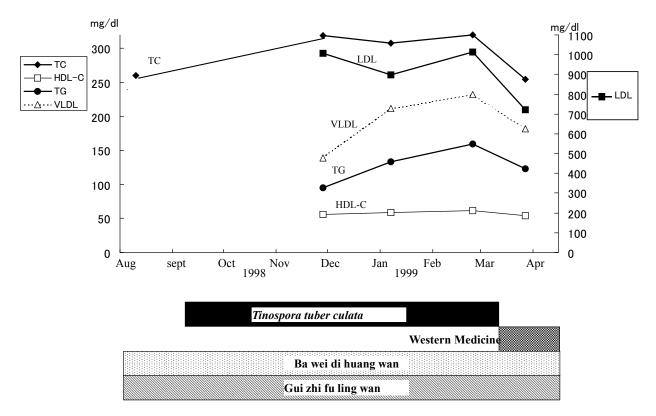


Fig 12. Change of serum lipids in a patient with hyperlipidemia Figure 12. Change of serum lipids in a patient with hyperlipidemia

Finally, except Case 4 with family history of DM, Tin tends to decrease the level of TG and VLDL and tend to increase HDL in Case 1 and 3.

Finally, Tin may play a role to decrease human hyperlipidemia in TG and VLDL level, which must be clarified about the mechanism in future.

## 6.2. Kampo or TCM (Dandao-paishi-tang)

#### 6.2.1. Abstract

Some patients with hyperlipidemia do not wish to pursue conventional therapies because of their side effects. Two such patients requested that I prescribe herbal medicine to decrease the blood levels of TG and TC. The Chinese herb combination known as modified Dandao-paishitang (DDPT; 胆道排石湯) (Table 8) which is generally used to promote the excretion of gallstones, was administered to two patients with high blood TG levels.

Table 8 Modified Dandaopaishi tang(DDPT:胆道排石湯) (daily dose)

	<u> </u>	
Desmodiumstyracifolium.	Jin-qian-cao (金銭草)	6g
ScutellariaeRadix.	huang-qin(黄金)	$5\mathrm{g}$
Poncirustrifoliate	zhi-gu(枳殼)	$5\mathrm{g}$
Rosa banksiae	mu-xiang(木香)	$5\mathrm{g}$
Melia azedarach var.subtrpinnata	chuān-liàn-zǐ(川楝子)	5g
Curcuma aromatic	yu-jin(郁金)	$5\mathrm{g}$
Rheirhizome	da-huang(大黄)	1g
Artemisiaecapillarisspica	yin-chen-hao(茵陳蒿)	2g
Natrii Sulfas	mang-xiao(芒消)	1g

Table 8. Modified Dandaopaishi tang (DDPT:胆道排石湯) (daily dose)

In the first case, a 66-year-old male, TG levels decreased from 634 mg/dl to 273 mg/dl during 4 years' intake (Figure 13). The second case, a 66-year-old Japanese female since 61 year suffering from DM and hyperlipidemia, took DDPT for 4 months. Her TG levels decreased from 815 mg/dl to 442 mg/dl, but then increased again when she decreased the volume of DDPT intake (Fig 14) [27].

Case 1: A 66-year-old Japanese male, 171cm tall and weighing 81kg, first visited our clinic in February 1984, because of hyperlipidemia and cholelithiasis. His blood pressure was 156/100. He had had cholelithiasis previously in 1976 which was left untreated because it improved. Since 1982, when he suffered from acute hepatitis A, he had been diagnosed with hyperlipidemia at every medical checkup. As he suffered occasional bouts of cholelithiasis that had a thick gall bladder wall, I diagnosed him with liver-gallbladder dampness-heat syndrome (Figure 13).

We started modified da-chai-hu-tang (大柴胡湯) consisting of chai-fu (柴胡) 6, ban-xia (半夏)4, gan-sheng-jian (乾生姜)1.5, huang-qin (黄芩)3, da-zao (大棗) 3, zhi-shi (枳実)2, da-huang (大黄)1, huang-lian (黄連)1, gua-lou-ren (栝楼仁)3, and mu-dan-pi (牡丹皮)2g/day in February 1984, and continued treatment until October of 1987 but without success. In October 1987, we changed to modified dan-dao-paishi-tang (DDPT). With this change, the patient's TG levels decreased from approximately 600 mg/dl to 400 mg/dl before cholecystectomy, and further decreased to 203 mg/dl after surgery in April 1991, at which point he stopped taking herbal medicines.

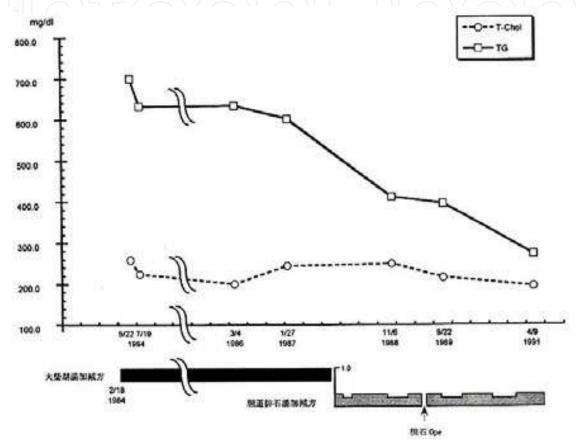


Figure 13. The change of levels of TC, TG in case 1

Case 2: A 60-year-old Japanese female, 152 cm tall and weighing 54 kg, who refused conventional therapy had been taking ba-wei-di-huang-wan (八味地黄丸: full dose/day) with powdered type of extract of zhi-gan-cao-tan (炙甘草湯) and xiao-chai-hu-tang (小柴胡湯) together with gui-zhi-fu-ling-wan (桂枝茯苓丸) because unless she take these prescriptions her fasting glucose level increase above 150 mg/dl. When her TG level surpassed 800 mg/dl in December, 1987, we prescribed modified dan-dao-paishi-tang (DDPT) without changing the medicines described earlier, and her TG level had decreased to 450 mg/dl by April 1988. As she suffered from appetite loss, stomach fullness and loose stool, her intake was reduced to 1/6, which led to 735 mg/dl in May 1989. She repeated the pattern of a high dosage of DDPT followed by a low blood TG level, then digestive system symptoms, then a lower DDPT intake followed by high blood TG. Finally, she persisted in taking only a small amount of DDPT, which led to an increase in TG. TC showed a similar tendency to TG, but was not so conspicuous as TG in this

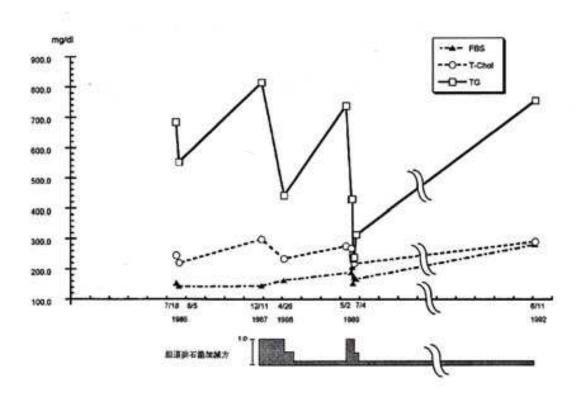


Figure 14. The change of levels of TC, TG in case 2

patient. These results may be related to the patient's DM condition and/or to the fact that she did not excise regularly and was on no specific diet (Figure 13).

#### 6.2.2. Discussion

In Case 1 and 2 and two other cases (data not shown), DDPT was able to decrease TG levels. In Case 2, DDPT seem to work dose-dependently. Unless the digestive system is weak, DDPT can be used without complications. Of course, exercise is required with herbal medicine. It has been suggested that DDPT may promote the secretion of bile acid, which promotes lipid absorption. If this were the case, blood TG levels should be elevated; but in fact the opposite occurs. Further study is required to clarify the actions of DDPT.

## 7. Pain-related diseases

## 7.1. Sprains, bruises, and arthritis

## 7.1.1. Abstract

It takes a long time to recover from sprains, bruises, and arthritis, which often involve both pain and a decline in QOL. We applied two Kampo medicines, zhi-da-pu-yi-fang (治打撲一方: remedy for contusion) (Tsumura & Co. 7.5 g/day) to resolve inflammation and restore injured

parts ("dampness- heat" in TCM), and Ba-wei-di-huang-wan (八味地黄丸) to restore presumed minute bone injury and to regulate metabolism (kidney tonic in TCM). We treated sprains, bruises, and arthritis in 10 patients (40–85 years of age; 1 male, 9 female) using the visual analog scale (VAS) to assess pain in the affected body parts before and after the administration of Kampo medicines. In almost all cases, recovery began promptly and pain disappeared within approximately 2 weeks. Large doses for a short time seemed to achieve quicker recovery [28].

## 7.1.2. Bruises

**Case 1:** A 67-year-old Japanese female was involved in a traffic accident and suffered bruising of the left hip without bone fracture. The two prescriptions were started immediately. At seven days, her VAS scare had immediately from 10. Charmes completely pain-free 28 days after the accident (Fig.

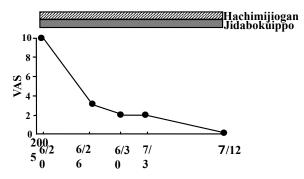


Figure 15. Change in pain (britises theres in natio decision of the state of a 67-year -old Japanese female)

Japanese female

#### 7.1.3. Sprain

Case 2: A 72-year-old Japanese female with osteoporosis and rheumatoid arthritis sprained her right ankle and was treated with the conventional therapies for 1 month without any improvement to her VAS score of 9. After initiating Kampo medicine, her pain disappeared completely after

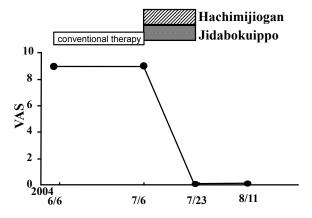


Figure 16. Change of pain(right ankle sprain) after administration of Kampo Figure 16. Change of pain (right ankle sprain) after administration of Kampo medicine (72 years female)

#### 7.1.4. Arthritis

A 72-year-old Japanese female had been treated with conventional therapies for more than 6 years without stable recovery. After taking Kampo medicines for 14 days, she reported no pain (Figure 17).

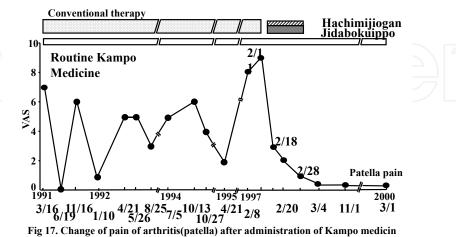


Figure 17. Change of pain of arthritis (patella) after administration of Kampo medicin (72- year-old female)

## 7.1.5. Discussion

Among components of 治打撲一方, gui-zhi (桂枝: *Chinamomi Cassesiae*) and ding-zi (丁子: *Caryophylli Flos*) promote blood circulation, and chuan-xiong (川芎: *Ligustici Chuanxiong* Rhizoma) accelerates blood circulation and blood stasis. In a Japanese clinical study, chuangu (川骨: *Nupharis* Rhizoma) was found to stop bleeding and accelerate the reabsorption of bleeding in the body. Da-huang (大黄: *Rhei* Rhizoma) removes substances produced by a resolving hematoma and other affected parts, which accelerates hematoma resolution. Po-su (樸樕: *Quercus* Cortex) is thought to have detoxifying, antiphlogistic, and astringent properties. Gan-cao (甘草: *Glycyrrhizae Uralensis* Radix) regulates and harmonizes other herbs. With Bawei-di-huang-wan (八味地黄丸), it serves as a kidney tonic and accelerates the bone metabolism, which supports the recovery of injured parts with two prescriptions (Tsumura & Co 7.5 g/day).

## 7.2. Acute herpes zoster [29]

#### 7.2.1. Abstract

The intake of hot water extracts including Ganoderma lucidum or WTMCGEPP (Wisteria floribunda 0.38, Trapa natans 0.38, Miristica agrans 0.38, Coix lachryma-jobi 0.75, cultivated Ganoderma lucidum 0.75, Elfuinga applanata 0.38, tissue cultured Panax ginseng 0.3, and Punica granatum 0.38; numbers designate dry weight g/dose) decreased the pain of acute shingles in five Japanese patients, two with herpes zoster with trigeminal ophthalmia (74 years), one with lower body zoster (70 years), one with herpes zoster oticus (17 years), and one with leg herpes (28 years) without conventional therapies including antiviral drugs. In all patients, pain began to decrease within a few days of the initiation of intake and completely

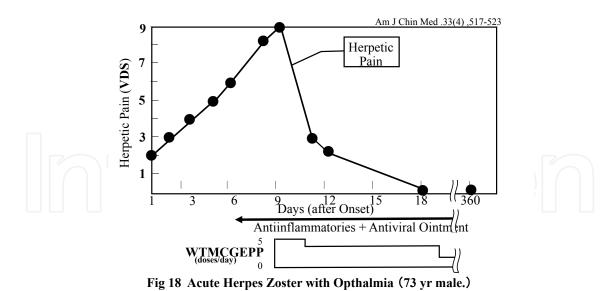


Figure 18. Acute Herpes Zoster with Opthalmia (73 yr male.)

disappeared within 10 days. There were no instances of postherpetic neuralgia (PHN) within a follow-up period of more than 1 year.

Additionally WTMCGEPP increased NK cell activity during intake of for 3 months in 4 females (mean: 51 years) and in 9 weak infants who are outpatients of university hospital (data not shown).

Case 1: This patient was 158 cm tall and weighed 65 kg. Several days prior to his consultation, he had been on a bus tour and suffered lack of sleep and fatigue. On day 1, he felt pain on the left sinciput of his face. Vesicles appeared and the left half of his face was swollen with pain at a verbal descriptor scale (VDS) level of 1. His pain increased day by day and reached VDS 5 on the 6th day. He was diagnosed with shingles at a local hospital. Neither antiviral ointment nor anti-inflammatory medicine worked, and his pain increased to VDS 6. By day 8, the pain was intense and the patient's left eye was swollen shut with mucus and deteriorating skin lesions. When he visited us with VDS 9, we prescribed 5 doses per day of WTMCGEPP. After 2 days of administration, his pain started to decrease and his swollen face and eye improved enough that he was able to see clearly (Figure 18). Even though his doses were reduced, his pain continued to decrease, soon reaching VDS 2. By day 12, the patient's rhinorrhea had decreased significantly. On day 18, he achieved complete recovery with a VDS score of 0. At the time of writing, he has been pain-free for more than 10 years. Herbs composing WTMCGEPP was obtained from Tochimoto Tenkaido Co, Ltd.

Case 2: The patient was a 17-year-old Japanese female (165 cm, 54 kg) with acute herpes zoster otitis. She had become very tired due to lack of sleep while studying very hard for exams for 5 days before the onset of this pain. As she felt severe right ear pain, she visited an otolaryng-ologist, who diagnosed her with acute herpes zoster otitis and recommend starting conventional therapy immediately. However, she refused this treatment because her grandmother insisted on taking herbal medicines and requested WTMCGEPP therapy, which she started (6 doses per day) on the 3rd day from the onset of pain (Figure 19). The pain gradually decreased

and, even though she then decreased her intake, her QOL remained satisfactory and her pain continued to decrease. On the 15th day, she was completely free of pain.

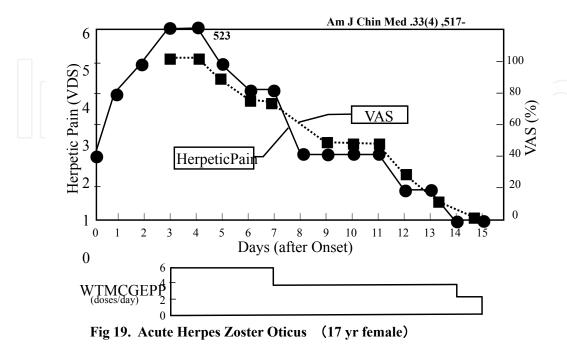


Figure 19. Acute Herpes Zoster Oticus (17 yr female)

**Discussion**: Only a combination of herbs is able to replace antiviral drugs for shingles. WTMCGEPP therapy can be begun at any time after the onset of shingles, while antiviral drugs must be started before 3 days after onset. This difference may be due to differences in the pain-killing mechanism. Further research is necessary to clarify this issue.

**Addendum:** WTMCGEPP was presented at the International Congress on Complementary & Alternative Medicines (ICCAM) in 2005, when many acupuncturists wanted to buy. But unfortunately it proved that selling them from Japan to another country was forbidden.

WTMCGEPP may be taken in many different types of cases to reduce pain and improve QOL. Evidences from my own experience include the following cases:

- In advanced lung cancer who had brain metasis, WTMCGEPP worked to improve various aspects of the patient's degraded QOL, such as general fatigue, cough frequency, and bone pain in the metastatic lesions. The patient's family was told she had 2 months to live, but by taking this remedy, her symptoms almost disappeared and she survived with improved QOL for 2 years.
- 2. A patient who suffered cough and bone pain due to the metastasis of breast cancer to the lungs took this prescription. Her cough and bone pain gradually decreased and finally disappeared. Tumor marker decreased as well while she was taking this remedy. However, when she stopped taking it, thinking she had achieved complete recovery without consulting with me, she suffered recurrence.

- **3.** WTMCGEPP worked in a weak infant suffering from infections related to Epstein-Barr virus (EBV), cytomegalovirus (CMV), and/or herpes simplex virus that required repeat admissions to the hospital [30, 31].
  - i. A 5-year-old boy with EBV and CMV infection suffering from frequent bronchial asthma and chronic bronchitis with fever was not cured by conventional therapy, but was cured by WTMCGEPP.
  - ii. A 6-year-old Japanese girl with herpes labialis suffered pain during eating which disappeared after 3 days of WTMCGEPP treatment.
  - iii. A 60-year-old man with herpes genitalis felt an unpleasant sensation with genital pain when he was tired. After intake of WTMCGEPP for several days, the pain disappeared. WTMCGEPP is a good choice for this patient because he seemed to develop tolerance for antiviral drugs.
  - **iv.** WTMCGEPP works herpes labialis and herpes genitalis very well. But patients with leukemia or lymphoma do not want to take it. Because of a feeling of wrongness. Of course, I never prescribe WTMCGEPP to them. I wish to study to find the reason.
- 4. In Japan, for patients suffering from hepatitis C, many Kampo medicines are applied. I often added WTMCGEPP not to progress to liver cancer, which seems relatively effective [32].

### 7.3. Menorrhagia-related pain

In Japan, gui-zhi-fuling-wan (桂枝茯苓丸) to remove blood stasis and accelerate blood circulation is most commonly used for menorrhagia-related pain. If this does not work, the dose is increased or a prescription to warm the Kidney yang, like Ba-wei-di-huang-wan, may be added. In more severe case of blood stasis, she-chong-yin (折衝飲) (tao-ren: 桃仁, 5; hong-hua: 紅花, 2; niu-xi: 牛膝, 3; mu-dan-pi: 牡丹皮, 3; chi-shao: 赤芍, 3; dang-gui: 当帰, 5; chuan-xiong: 川芎, 3; Yan-huo-suo: 延胡索, 3; gui-zhi: 桂枝, 3g/day) will work dramatically. Of course, dan-gui-shao-yao-san (当帰芍薬散) may be used in patients with a weak constitution. Patients with Qi stagnation and a disorder of the menstrual cycle may benefit from xion-gui-tiao-xue-yin (芎帰 調血飲).

#### 7.4. Glossodynia-related pain

Glossodynia is often difficult to cure with conventional therapies, but some Kampo medicines have been reported to be effective. I present one case here [33].

Case 1: A 74-year-old Japanese female (height, 150 cm; weight, 35 kg) suffered from sore tongue and appetite loss with atrophic gastritis since 1 year ago. She had had alopecia 5 years previously. On September 20 (X year), both sides of her tongue were reddish and rough. By October, her tongue was sore all over without fur (mirror tongue).

All treatment at a national hospital failed to improve her condition. One dentist recommended that she receive Kampo treatment. At her first visit to my clinic, she was diagnosed with Yin deficiency of the Heart and Spleen, Kidney Yang deficiency, Liver Qi depression tending to transform into fire based on oral dryness and heat, constipation, aversion to the cold, dry skin, depression and insomnia, a reddish tongue body without fur, dark sublingual vessels and string-like, slippery and sunken pulse.

Prescriptions: One-third of 1 day's intake of powder type of extracts of liu-jin-zi-tang (六君子湯) (can- shu: 蒼朮 4; da-cao: 大棗 3; ren-shen: 人参 4; chen-pi: 陳皮 2; ban-xia: 半夏 4; gan- cao: 甘草 1; fu-ling: 茯苓 4; sheng-jiang;生姜 0.5: numbers indicate g/day), and long-dan-xie- gan-tang (竜胆潟肝湯) (dang-gui: 当帰 1.5, syao-yao: 芍薬 1.5, chuan-xiong: 川芎 1.5, di- huang: 地黄 1.5, huang-lian 黄連 1.5, huang-qin: 黄岑 1.5, huang-bo: 黄柏 1.5, shan-zhi-zi: 山梔子 1.5, lian-qiao: 連翹 1.5, bao- he: 薄荷 1.5, mu-tong: 木通 1.5, ban-fang-feng: 浜防風 1.5, che-qian- zi: 車前子 1.5, gan-cao: 甘草 1.5, and 2 g/day of long-dan: 竜胆; and ze-xie: 澤瀉) and 2/3 of 1 day's intake of ba-wei-di- huang- wan (八味地黄丸) (di-huang: 地黄 6, fu-ling: 茯苓 3, shan- zhu-yu: 山茱萸 3, mu-dan-pi: 牡丹皮 2.5, san-yao: 山薬 3, gui-pi: 桂皮 1; ze-xie: 澤瀉 3 and fu-zi: 附子 0.5; numbers indicate g/day) were administered until Xyear November 26th, when her tongue body was reddish and without fur, indicating a severe Yin deficiency. I added One day's intake of zi-yin-jiang- huotan (滋陰降火湯)/day (can-shu: 蒼朮 3, dang-gui: 当帰 2.5, di-huang: 地黄 2.5, mai-men-dong: 麦門冬 2.5; syao- yao: 芍薬 2.5, huang-bo: 黄柏 1.5, chen-pi: 陳皮 2.5, gan-cao: 甘草 1.5, tian-men-dong: 天門冬 2.5, and zhi-mu: 知母 1.5).

Three days later, she telephoned to tell me that her tongue pain had decreased dramatically, and on December 10 her tongue and stomach were pain-free, suggesting that her tongue pain stems from Yin deficiency (Fig.20).

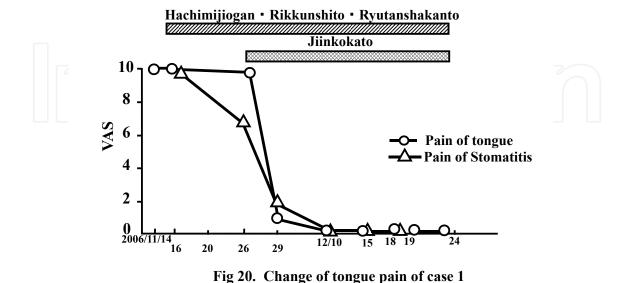


Figure 20. Change of tongue pain of case 1

Discussion: For intractable diseases, I experienced plural number of necessary prescriptions suitable for the organ with diseases (five element theory) are required to improve. As mentioned above, liu-jin-zi-tang (六君子湯) is for Spleen and long-dan-xie-gan-tang (竜胆潟肝湯) is for Liver and ba-wei-di-huang-wan (八味地黄丸) was for Kidney and for total deficiency of yin, zi-yin-jiang- huo-tan (滋陰降火湯) was prescribed to get quick recovery. This means we finally treat five organs (five element theory) at a time which means the treatment with synergy with pleural prescriptions will be most important for intractable diseases (Fig.20).

### 8. Other diseases

## 8.1. Obstetrics- and gynecology-related diseases

- 1. The Japanese Kampo diagnosis method known as "Zheng" (証) helps to identify the problem in infertile women and, with the proper Kampo medicine treatment chosen based on "Zheng" (証) they may succeed in having a baby [34].
- 2. Amenorrhea sometimes is difficult to cure. A 23-year-old female (154cm; 50kg) had been taking female hormones for amenorrhea for 4 years. Soon after stopping the hormones, amenorrhea recurred. Intake of Ba-wei-di- huang-wan (八味地黄丸) with wen-jing-tang (温 経湯) for 4 months did not work. Based on my diagnosis of Yang deficiency of the kidney and spleen, and dysfunction of the thoroughfare and conception vessels (衝任失調), I prescribed dang-gui-si-ni-jia-wu-zhu-yu-sheng-jiang-tang (当帰四逆加呉茱萸生姜湯) with pig placenta (胎盤) and xiong-gui-tiao-xue-yin (芎帰調血飲). Within 2 months, menstruation started again. Probably, the first two prescriptions cannot improve dysfunction of the thoroughfare and conception vessels and Kidney yang deficiency. But dang-gui-si-ni-jia-wu-zhu-yu-sheng- jiang-tang with Pig placenta tonify and warm Liver meridian, Kidney, and Spleen. Xiong-gui-tiao-xue-yin additionally supported to regulate qi and accelerate blood stasis which succeeded in curing her amenorrhea.
- 3. Premenstrual syndrome (PMS): Some females suffer from various type of PMS [35].
- Case 1. One 46-year-old female who suffer from irritability was successfully treated with xiong-gui-tiao-xue-yin (芎帰調血飲 6 g/day) added with jia-wei-gui-pi-tang (加味帰脾湯 7.5 g/day) (full dose is 7.5 g/day) symptoms disappeared after 8 weeks.
- Case 2. One 47-year-old female suffer depression spiritless and headache. She was treated with xiong-gui-tiao-xue-yin and gui-zhi-fu-ling-wan. Four weeks later all symptoms disappeared.
- Case 3. One 34-year-old female suffer headache and hypogastrium pain and sensitiveness to cold who was successfully treated with dang-gui-si- ni-jia-wu-zhu-yu-sheng-jiang-tang and xiong-gui-tiao-xue-yin after 4 months' intake [35].

## 8.2. Epilepsy

To three adult patients with epilepsy refractory to standard antiepileptic medications, buyang-huan-wu-tang (補陽還五湯) were administered. All three patients showed substantial

improvement in the frequency and severity of seizures. This treatment will rely on the resolution of blood stagnation in cerebrovascular systems [36].

## 8.3. "Five Elements Theory" must be applied to get the treatment

When we treat patients with various symptoms, we usually treat for severest symptoms like cough, with mai-men-dong-tang. This is for Lung. But sometimes prescriptions for lung did not cure cough at all. Example is shown below.

When patients suffering from chronic cough and various Kampo medicines for the cough do not work. To this case I apply "Five Elements Theory".

- One 72-year-old female suffer chronic coughing. Her coughing started when she started to feel cold and get sensitiveness to cold probably because of her aging. I thought her aged Kidney deprive vital energy of lung which will cause her chronic cough. Actually, administration of ba-wei-di-huang- wan (八味地黄丸) stopped coughing after intake of 1 month.
- Another case of diarrhea (38-year-old) which continued more than 3 weeks which did not response to various Kampo medicines for digestive system. I thought this diarrhea would be the result of Liver overwhelm the Spleen. I prescribed jia-wei-xiao-yao-san (加味逍遥 散) to suppress Liver. A week later her diarrhea almost disappeared [37].

## 8.4. Application of Gui-zhi-fu-ling-wan (桂枝茯苓丸) for the diagnosis of breast cancer in diagnostic hormonal therapy

In spite of improvement in imaging technique for breast cancer, many latent microcarcinomas go undetected. Diagnostic hormonal therapy with antiestrogens may induce terrible side effects in some patients. Thus, excisional biopsy is required for an accurate diagnosis of malignancy.

Gui-zhi-fu-ling-wan (桂枝茯苓丸) has been effective in treating mastopathy and has almost no side effects. Thus, we tested its use as an alternative to antiestrogens. Gui-zhi-fu-ling-wan was administered to 116 patients out of 218 with mastopathy. Four were suspected to have breast cancer and were later definitively diagnosed with breast cancer, two by fine-needle aspiration cytology and two by excisional biopsy. Gui-zhi-fu-ling-wan proved to be useful in the diagnostic hormonal evaluation of mastopathy and in the diagnosis of breast cancer [38].

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