

Clinical Applications of Kampo Medicine

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Introduction

Legitimate Japanese medicine until about 140 years ago was Kampo Medicine. Naturally, the Dutch medicine, representing the legitimate European medicine of the day, was at the time of its introduction to Japan a non-mainstream medicine. Yet, its contents gradually became known and thus started to spread, so that in 1804 a mastectomy was performed by Seishu Hanaoka under general anaesthesia in a patient with breast cancer. This showed the emergence of physicians highly skilled in both forms of medicine and represents a successful example of integrative medicine that occurred 200 years ago. Trends in the medical world attempting the integration of western and Kampo forms of medicine in Japan actually were not modern efforts, but have been an important topic for several hundred years.

Kampo medicine is widely used in daily medical practice. This form of medicine originally was a therapeutically oriented medicine with outstanding characteristics. The excitement during its revival movement in the 1930s frequently showed it to be superior to the western medical approach. However, later the developments in western medicine and related sciences, greatly expanded therapeutic possibilities. Correspondingly, the scope of application

of Kampo medicine has declined in proportion to the expansion of western medicine. However, currently it is still frequently applied for the treatment of many diseases for which western medicine is unable to provide satisfactory solutions.

In Japan, only a few physicians are specializing solely in Kampo medicine. Except for such extreme exceptions (that means almost always) physicians assume a western medical stance and add Kampo medical treatment as required. In other words, integrative medicine is practiced on a private level.

Described below is the generally practiced form of Kampo medicine in daily clinical routine. The descriptions are based on the experiences of the author and refer to the references 1 to 6 (either of which describes the general treatment of diseases). Citation of references from related research are indicated by numbers and are introduced in the order of their appearance.

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1. Geriatric Medicine

Among Japanese medical books, the "Kei Teki Shu" (1574) by Dosan Manase was the first to separate geriatric medicine from other clinical disciplines. Thus, Kampo medicine has a very long tradition of geriatric medicine, but with the addition of modern medical approaches in recent years, there are still more new developments. In particular the "Japanese Kampo Medical Care for the Elderly", edited by Katsutoshi Terasawa, is a very valuable book describing the Kampo medical treatment for senile diseases in great detail¹⁾.

Problems of particular importance in the elderly are aging induced changes in the central nervous system, the so-called cerebrovascular dementia and Alzheimer's disease, which are associated with dementia, depressive states, delirium and similar mental symptoms. Currently these symptoms are the subject of multi-center cumulative research. Particularly, research into the efficacy of *Uncaria Powder* for the treatment of cerebrovascular dementia and *Angelica and Peony Powder* for Alzheimer's disease appear promising^{2,3,4,5)}. Recent research into the clinical effects of *Liver-Inhibiting Powder* on 'Behavioral and Psychological Symptoms of Dementia (BPSD) has been performed, and the results were published in "J. Clin. Psychiatry" and similar organs⁶⁾.

In Kampo medicine, aging is closely related to the kidneys. Age related changes in bones and joints too

are often related to a weakening of the kidneys. For low back pain due to osteoarthritis, gonalgia and similar typical diseases of bones and joints in the elderly, the application of kidney tonifying preparations should be considered. The available data suggest that *Kidney Qi Pill* is effective for the treatment of postmenopausal osteoporosis.

There are several problems pertaining to diet also requiring careful attention, since aspiration for example may even be fatal. Certain reports and some research indicate that the use of *Pinellia and Magnolia Decoction* or *Lung-Clearing Decoction* for patients suffering from repeated aspiration pneumonia produces favorable results^{7,8)}.

Among the diseases of the urinary tract, Kampo medicines are frequently used for dysuria. *Kidney Qi Pill*⁹⁾ for the treatment of impending incontinence and *Middle-Reinforcing and Qi-Benefiting Decoction* or *Pueraria Decoction*^{10,11)} for abdominal pressure incontinence have been found to be effective in some studies. Kampo treatment also appears to be therapeutically useful during the early stages of hypertrophy of the prostate¹²⁾.

In the elderly, even simple infections like colds should not be taken lightly. The reason for this is that they may be complicated by bronchitis, causing loss of appetite and thus may easily lead to debility. The use of Kampo preparations during the early stages of infections in the elderly reportedly can lead to an early recovery at low costs. Akiba treated stationary patients suffering from upper respiratory inflammation or bronchitis and found a shorter duration of the morbidity and lower treatment costs than in patients treated only with western medications¹³⁾. Moreover, Kampo also appears to be useful for the treatment of refractory infections like those caused by MRSA (see section on infections)¹⁴⁾.

- 1) Terasawa K.: "Japanese Kampo Medical Care for the Elderly", Igaku-Shoin 2005
- 2) Shimada Y., Terasawa K., Yamamoto T. et al: A well-controlled study of *Uncaria Powder* and placebo in the treatment of vascular dementia, *J. Trad. Med.* 11: 246-255, 1994
- 3) Terasawa K., Shimada Y., Kita T. et al: *Uncaria Powder* in the treatment of vascular dementia a double-blind, placebo controlled study, *Phytomedicine* 4: 1522, 1997
- 4) Inanaga K., Dainson K., Ninomiya Y. et al.: Multi-center joint research into the therapeutic effects of *Angelica and Peony Powder* on cognitive disorders in the elderly, *Prog. Medicine* 16: 293-300, 1996
- 5) Yamamoto T.: Kampo and modern medical treatment of Alzheimer's disease, *Current Medicine* 5: 96-102, 1989
- 6) Arai H., Iwasaki K.: Effects of *Liver-Inhibiting Powder* on Associated Symptoms Cognitive Disorders, *Kampo Igaku* 29(4): 13-15, 2005
- 7) Mantani, N. et al: Effect of *Lung-Clearing Decoction*, a Kampo medicine, in relapsing aspiration pneumonia an open-label pilot study, *Phytomedicine*, 9: 195-201, 2002
- 8) Iwasaki, K. et al.: The traditional Chinese medicine banxia houpo tang improves swallowing reflex. *Phytomedicine*, 6: 103-106, 1999
- 9) Yamanaka H., Suzuki T., Tokunaga S. et al.: Kampo Therapy for Incontinence, *Kampo Igaku* 21(8): 2-10, 1997
- 10) Kase H., Akashi M., Satou T.: Effects of *Middle-Reinforcing and Qi-Benefiting Decoction* on Pressure Incontinence, *Kampo Igaku* 29(3): 19-21, 2005
- 11) Shin S., et al.: Usefulness of *Pueraria Decoction* for Pressure Incontinence, Summary collection of the 47th General Academic Conference of the Japan Society of Oriental Medicine, P126, 1996

- 12) Harada K.: Japanese & Chinese Pharmacotherapy for Urologic Disorders, *Japanese Journal of Clinical Urology* 45: 295-300, 1991
- 13) Akiba T.: Effects and possibility of reducing medical costs by local and systemic application of Kampo preparations, *Progress in Medicine*, 21(8): 1863-1865, 2001
- 14) Kitahara M., Ishikawa S., Hara K.: Protective effect of *Ten Strong Tonic Herbs Decoction* against infection after acute ischemic stroke in elderly patients. *Biotherapy* 17(3): 287-298, 2003

2. Skin, Hair and Nails

Skin diseases used to belong in the realm of surgery. That is due to the fact that there were so many infections of the skin that required surgery. Many preparations have been developed for the treatment of skin infections, but can also be applied to skin diseases other than infections and currently are in fact widely used. Seishu Hanaoka, who did the world's first surgery for breast cancer under general anaesthesia, invented the representative preparations for the treatment of skin disease *Antiphlogistic Decoction with Ten Herbs* and *Purple Cloud Ointment*. His experiences are still useful today.

For diseases in this field there are excellent modern medical treatments, leaving fewer pathologic conditions that would require the use of Kampo preparations. There was not a significant reference to the use of Kampo therapy, but nevertheless a combination with Kampo medicine frequently provides additional benefits¹⁾. Among these conditions, Kampo is used most frequently for the treatment of atopic dermatitis. Regarding this disease, the combination of appropriate skin care and Kampo medicine is effective. Experienced dermatologists achieve good results by combining various preparations²⁾. Here the effects of *Middle-Reinforcing and Qi-Benefiting Decoction* during infancy are particularly well known. The situation changes during childhood, adolescence and adulthood, where *Wind Dispersing Powder*, *For Eczema Decoction*, *Coptis Detoxifying Decoction*, *Bupleurum Liver-Clearing Decoction*, *White Tiger plus Ginseng Decoction*, *Yue Bi Decoction for Relieving Edema plus Atractylodes*, *Warming and Clearing Decoction*, *Head-Clearing Divaricate Saposhnikovia Decoction*, *Schizonepeta and Forsythia Decoction* and similar preparations are used. Still other effective preparations are available as decoctions. A significant number of physicians prescribe specially modified decoctions for refractory cases. Using a combination of topical steroids and Kampo preparations generally allows the physician to taper the dose of the topical drug application. The Kampo formulas are then used until patients are capable of managing self medication. These diseases are characterized clinically by their psychological aspects and some physicians also seek the cooperation of clinical psychologists for the therapy.

- 1) Morohashi M.: Current Situation and Use of Kampo Medicine in the Field of Dermatology, 27-46, *Kampo Report of Dermatology*, 1990
- 2) Ninomiya F.: Treatment of atopic dermatitis with extract preparations, *The Kampo* 13(1): 13-17, 1995

Steroid ointments or topical retinoids and similar western medical preparations are given priority for the treatment of psoriasis. Kuboki et al. reportedly found that a combination therapy with *Minor Bupleurum Decoction, Poria Powder with Five Herbs* had significantly improved effects on pruritus, erythema, scaling, infiltration, hyperplasia etc³⁾.

Topical steroid ointments alleviate the symptoms of seborrheic dermatitis, but the condition tends to be recurrent throughout life and therefore warrants a trial with Kampo therapy. *Antiphlogistic Decoction with Ten Herbs* or *Wind Dispersing Powder* are widely used for this purpose. Tsutsui et al. treated 30 patients with seborrheic dermatitis with *Wind Dispersing Powder* and reportedly found in their study a usefulness of 81.5%⁴⁾.

It has been recommended that *Yue Bi Decoction for Relieving Edema plus Atractylodes* or *Gentian Liver-Purging Decoction* are used in conjunction with western medical treatment during the acute phase of herpes zoster. For the treatment of postherpetic neuralgia as a late effect of this condition, *Ephedra, Aconite and Manchurian Wildginger Decoction, Cassia Twig Decoction plus Atractylodes and Aconite, Evodia, Fresh Ginger plus Chinese Angelica Cold Limbs Decoction* and similar preparations are used.

Formulas like *Schizonepeta and Forsythia Decoction, Cassia Twig and Tuckahoe Pill Plus Coix Seed, Antiphlogistic Decoction with Ten Herbs* etc. are generally used for the treatment of acne. A number of studies investigating this condition have also been performed. Okuma et al. performed a RCT using *Antiphlogistic Decoction with Ten Herbs* and *Coptis Detoxifying Decoction* in a combination with the usual topical applications and found for *Antiphlogistic Decoction with Ten Herbs* an efficacy of more than 75% and for *Coptis Detoxifying Decoction* of more than 40%⁵⁾. Hashimoto et al. used in a RCT *Schizonepeta and Forsythia Decoction* and tetracycline antibiotics and found for *Schizonepeta and Forsythia Decoction* an equivalent usefulness of 60.6%. A combination of both preparations reportedly resulted in a usefulness of 78.6%⁶⁾.

Research has also been done on palmoplantar pustulosis. Hashimoto et al. treated 97 patients with palmoplantar pustulosis with *Warming and Clearing Decoction* extract and reportedly found in the fourth week a usefulness of 59.8% and by the eighth week 69.8%⁷⁾. The research of Watanabe et al. using *Coptis Detoxifying Decoction* led to similar results⁸⁾. *Antiphlogistic Decoction with Ten Herbs* is also widely used.

Regarding rosacea, numerous studies have investigated *Antiphlogistic Decoction with Ten Herbs*. Nakanishi administered *Antiphlogistic Decoction with Ten Herbs* to 50 patients with rosacea and reportedly found in 46 of these patients a marked improvement in the diffuse erythemata⁹⁾.

- 3) Kuboki J., Harada S. Fujisawa R., et al.: Investigation of the Effects of TJ-114 (*Minor Bupleurum Decoction, Poria Powder with Five Herbs*) Combined with Topical Steroids for the Treatment of Psoriasis, *Journal of Clinical Therapeutics & Medicine* 17: 927-937, 1991
- 4) Tsutsui K., Hirone T., Tanaka T. et al.: Clinical Effects of *Wind Dispersing Powder* on Atopic Dermatitis, Seborrheic Dermatitis, Nummular Eczema and Chronic Eczema, *Kampo Igaku*, 118: 309-312, 1994
- 5) Okuma M.: Combination Therapy of Orally Applied Kampo Medicine and Topical Preparations, *Journal of Traditional Medicine* 10: 131-134, 1993
- 6) Hashimoto Y., Matsuo S., Iizuka H.: Experiences with *Schizonepeta and Forsythia Decoction* in the Treatment of Acne, Records of the 12th Meeting of the Research Group for Oriental Medicine in Dermatology, 46-53, 1994
- 7) Hashimoto Y., Matsumoto M.: Experiences with *Warming and Clearing Decoction* in the Treatment of Palmoplantar Pustulosis, "Kampo Therapy" Helpful for Daily Practice, 10: 51-155, 1991
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Urticaria is occasionally an indication for Kampo therapy. For acute urticaria, suitable western medical treatment has been established, so that circumstances specifically calling for the application of Kampo therapy are few. Chronic forms of urticaria also include refractory cases for which attempts at using Kampo therapy have been made. Yano used a Kampo medicine combination therapy on 19 patients with refractory chronic urticaria continuing the original treatment and found a usefulness in 10 of the patients, ineffectiveness in 7 and aggravation in 2 patients¹⁰⁾. The most frequently used preparation was *Bupleurum Liver-Clearing Decoction*, followed by *Wind Dispersing Powder* and *Minor Bupleurum Decoction, Poria Powder with Five Herbs* in that order. Horiguchi et al. treated 13 patients with chronic urticaria with *Capillary Wormwood Poria Powder with Five Herbs* and reported finding a slight usefulness in 85% of the cases¹¹⁾.

For warts, there used to be two traditional treatment forms in Japan. One was the direct application of moxibustion on the warts, something all acupuncturists would do. This is extremely effective. The other is the preparation of a Yokuinin decoction and drinking this infusion. This latter treatment has frequently led to very good results, so that dermatologists now are using the extract. Among the Kampo formulas, *Ephedra, Apricot, Coix and Licorice Decoction* is widely used.

When the cause of pruritus is determined, treatment should be directed at the etiology, otherwise this condition becomes an indication for Kampo therapy. For the treatment of senile dermal pruritus, *Kidney Qi Pill, Life-preserving Kidney-Qi Pill, Angerica Decoction, Antipruritus, Coptis Detoxifying Decoction* and similar preparations are used. RCTs have shown that the effects of *Kidney Qi Pill* or *Coptis Detoxifying Decoction* are comparable to antihistaminic drugs, achieving an improvement of approximately 70%^{12,13,14)}. The occurrence of dermal pruritus among patients with

chronic renal failure requiring dialysis is frequent and *Angerica Decoction*, *Antipruritus* has, in some cases, reportedly proven to be effective¹⁵. *Gentian Liver-Purging Decoction* or "*B*"*Character Decoction* are used for anal or genital pruritus.

- 10) Yanot T.: Kampo Therapy for Refractory Chronic Urticaria and Atopic Dermatitis, *Kampo Igaku* 19(7): 17-20, 1995
- 11) Horiguchi Y., Furukawa F. Mitani T. et al.: Clinical Experiences with *Antiphlogistic Decoction with Ten Herbs* and *Capillary Wormwood Poria Powder with Five Herbs* for the Treatment of Chronic and Acute Urticaria, *Proceedings of Dermatology*, 82: 365-368, 1987
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- 13) Fujita M., Ohno S., Miyaji Y. et al.: Therapeutic Effects of *Kidney Qi Pill* (Tsumura) on Refractory Senile Pruritus, *Proceedings of Dermatology*, 88: 175-179, 1993
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- 15) Sakaizawa I.: One Case in which *Angerica Decoction*, *Antipruritus* for the Treatment of Refractory Erythema and Pruritus in a Patient on Dialysis due to Chronic Renal Failure, *Kampo Igaku*, 29(3): 38, 2005

Decubitus ulcers are treated following a fixed protocol, but combination with Kampo preparations may result in an even better prognosis. Nagasaka used a decoction of Kigi Kenchu To Ka Bushi (that is *Astragalus Middle-Strengthening Decoction* with added Toki (Japanese angelica root) and Bushi (aconite root)) and observed many favorable outcomes¹⁶. *Middle-Reinforcing and Qi-Benefiting Decoction* and *Ten Strong Tonic Herbs Decoction* are also widely used.

Dermal affections caused by cold include frost bite for which *Evodia*, *Fresh Ginger plus Chinese Angelica Cold Limbs Decoction* is effective and frequently administered¹⁷. According to Mori, RCTs have also been performed. Burns among heat induced affections is principally treated by western medical therapy, but occasionally topical Kampo medications like *Purple Cloud Ointment* are also applied. There are case reports about the treatment of burn scars in patients for whom surgical treatment could not be performed¹⁸.

- 16) Nagasaka K. et al.: Therapeutic Experiences with *Astragalus Middle-Strengthening Decoction* for the Treatment of Decubitus Ulcers, *Kampo Medicine (Jap. Journal of Oriental Medicine)*, 49: 273-280, 1998
- 17) Mori S.: Clinical Experiences with *Evodia*, *Fresh Ginger plus Chinese Angelica Cold Limbs Decoction* for the Treatment of Frost Bite, *Kampo Shinryo* 3(1): 46-51, 1984
- 18) Shimizu J.: A Patient with Bum Ulcers Successfully Treated with Shiun K, *Kampo Igaku*, 20(4): 122-123 1996

3. Eye

Technical books about ophthalmology existed in the Tang period in China. In Japan, the first specialized physicians appeared in the 13th century. Yet, their experiences were not handed down to us, so that the treatment in this field was developed only in recent years. Among the diseases and conditions Kuroki wanted to treat with Kampo medicine were eye strain, dry eye, central retinitis, some forms of pigmentary degeneration of the retina, some forms of glaucoma, some forms of cataracts, prevention of the recurrence of uveitis, conjunctival injection (cause

unknown), pterygium, ticks, bulbar contusion, bulbar postsurgical care, neovascularization of the macula and similar conditions¹.

- 1) Kuroki S.: The Use of Kampo in These Cases - Eye Diseases: The Kampo for the Practical Physician No.3: 2-7, 1999

Regardless of whether conjunctivitis is of bacterial or viral origin, western medical treatment has priority. However, Yamamoto described patients he treated for keratomycosis or corneal herpes and obtained excellent results, stating that great expectations may be placed on Kampo therapy for infections of the eyes². Application of steroid or antiallergic eye lotions as well as orally applied medications for the treatment of allergic conjunctivitis are standard therapy, but Kampo medications used for allergic rhinitis appear to be effective for conjunctivitis as well. *Minor Blue Dragon Decoction*, *Yue Bi Decoction for Relieving Edema plus Atractylodes*, *Ephdra*, *Aconite and Manchurian Wildginger Decoction* and similar preparations are widely used. *Dwarf Lilyturf Decoction*, *Bupleurum Cassia Twig and Dried Ginger Decoction*, *Liver-Inhibiting Powder*, *Modified Merry Life Powder*, *Kidney Qi Pill*, *Ginseng Decoction* and similar preparations are used for the treatment of dry eye³. There is also cumulative research into the use of *Ginseng Nutrition Decoction*. Fukuda et al. divided a group of 60 patients with dry eye of unknown origin in a group of 30 patients treated with *Ginseng Nutrition Decoction* and a placebo for 30 patients. Both groups used the same eye lotions and were evaluated after 12 weeks. At this point, a slight improvement of the subjective symptoms was reportedly found in 63.3% of the patients in the treatment group as compared to 50% in the placebo group⁴.

- 2) Yamamoto S.: Kampo Therapy in Ophthalmology, *Journal of Kampo Medicine* 47(11): 10-18, 2000
- 3) Yamamoto S.: Kampo Treatment for Sjögren's Syndrome, *The Journal of Traditional Sino-Japanese Medicine* 14(3): 23-36, 1993
- 4) Fukuda Y., Narita Y., Miwa M. et al.: Effects of *Ginseng Nutrition Decoction* for Dry Eye - *New Ophthalmology* 12: 1427-1430, 1995

Some forms of glaucoma are indications for Kampo therapy. *Yue Bi Decoction for Relieving Edema plus Atractylodes*, *Minor Bupleurum Decoction*, *Poria Powder with Five Herbs*, *Uncaria Powder* and similar preparations are used to lower ocular pressure. Toshihiko Ueda treated glaucoma patients (22 patients with primary open angle glaucoma, 5 patients with closed angle glaucoma, 1 patient with secondary glaucoma, 1 patient with normal pressure glaucoma and 2 patients with ocular hypertension), in whom control with eye lotions alone had been found insufficient. Over a period of 24 weeks with *Minor Bupleurum Decoction*, *Poria Powder with Five Herbs*, he reportedly found a significant reduction in ocular pressure⁵. Kinugawa et al. analyzed 7 patients suffering from open angle glaucoma treated with *Yue Bi Decoction for Relieving Edema plus Atractylodes*, which resulted in a reduction in ocular pressure. He

reported that the ocular pressure reducing effects started to appear at the earliest a few hours following administration. These effects apparently continued, and even after a treatment period of 2 years, no side effects had been observed. Clinically, carbonic anhydrase inhibitors are the drugs of first choice used to achieve a reduction in ocular pressure, while *Yue Bi Decoction for Relieving Edema plus Atractylodes* may be administered as a maintenance drug⁶⁾. There are a large number of case reports pertaining to this disease.

5) Ueda T.: Effects of *Minor Bupleurum Decoction, Poria Powder with Five Herbs* on Glaucoma and Ocular Hypertension, *Kampo Medicine (Jap. Journal of Oriental Medicine)*, 46(6): 154, 1996

6) Kinugawa K., Sato K.: A Case Where *Yue Bi Decoction for Relieving Edema plus Atractylodes* was Effective in Reducing Ocular pressure in Glaucoma, *Kampo Igaku* 21(10): 19-21, 1997

Uveitis is treated with steroids, but heat clearing Kampo preparations like *Gentian Liver-Purging Decoction* or *Coptis Detoxifying Decoction* can also be used. Yamamoto used *Coptis Detoxifying Decoction* (heat clearing formula) and blood stasis expelling formulas (blood activating and stasis resolving formulas) in the treatment of 23 patients with uveitis in whom treatment in university hospitals or similar institutions had not led to any improvements. He sought Kampo therapy and observed a favorable course. This author states that the addition of aconite root was occasionally required for elderly patients. Kuroki et al. modified the Yang tonifying formula Jio Inshi for the treatment of patients with uveitis in whom treatment with heat clearing formulas like *Gentian Liver-Purging Decoction* alone did not lead to improvements. He observed an alleviation of the ocular symptoms in three patients⁷⁾.

7) Kuroki S., Son K.: There Cases in Which the Application of Yang Tonifying Preparations was Effective for Uveitis, *Kampo Medicine (Jap. Journal of Oriental Medicine)* 54: Separate Volume 248, 2003

Kampo preparations are also used for some forms of cataracts and in some cases have led to an improvement in visual acuity. Fujihira treated 284 patients (568 eyes) with senile cataracts with *Kidney Qi Pill* and reported an improvement in visual acuity in 54.6% of the patients⁸⁾. Kubota treated both eyes of 6 patients with senile cataracts over a period of 3 years with *Kidney Qi Pill* and reported that further progress of the cataract could be prevented⁹⁾. *Kidney Qi Pill*, *Ginseng Decoction* and *Ten Strong Tonic Herbs Decoction* are also used. However, even if an improvement in visual acuity is observed, there are no data that would suggest any changes in the ophthalmologically observed degeneration of the vitreous body with a few exceptions¹⁰⁾.

8) Fujihira K.: Treatment of Senile Cataracts with *Kidney Qi Pill*, *Kampo Medicine (Jap. Journal of Oriental Medicine)*, 24(4): 465-479, 1973

9) Kubota Y.: Treatment Results of Senile Cataracts with *Kidney Qi Pill* - Basics and Clinics, 23(6): 2359-2540, 1989

10) Yamamoto S.: Kampo Therapy of Senile Cataracts, *Current Kampo Therapy, Journal of Kampo Medicine & Herb*, 1985

For age-related macular degeneration there are excellent western medical treatments, but occasionally Kampo therapy is also very effective. Shizuka et al. reported cases in which treatment with *Kidney Qi Pill* improved visual acuity¹¹⁾. However, in most cases of this disease an efficacy cannot be anticipated unless decoctions are used. Kuroki et al. prepared formulas based on TCM theories and later published two case reports in which improvements in ocular findings were observed¹²⁾. Various studies have been performed dealing with macular edema (cause: branch retinal vein occlusion = BRVO, diabetic retinopathy = DR, central serous choroidopathy = CSC etc.). Generally, diuretic preparations like *Yue Bi Decoction for Relieving Edema plus Atractylodes* or *Minor Bupleurum Decoction, Poria Powder with Five Herbs* are used for these conditions. There is cumulative research into the use of *Minor Bupleurum Decoction, Poria Powder with Five Herbs*^{13,14)}.

11) Shizuka T., Arai M. Sato H.: One Case with Age-Related Macular Degeneration in *Kidney Qi Pill* induced Improvement in Visual Acuity, *Kampo Medicine (Jap. Journal of Oriental Medicine)* 56: Separate Volume 249, 2005

12) Kuroki S., Son K.: Two Cases of Age-Related Macular Degeneration (AMD), *Kampo Medicine (Jap. Journal of Oriental Medicine)* 56: Separate Volume 248, 2005

13) Iwashita K., Yamagishi K., Yuge K. et al.: Effects of *Minor Bupleurum Decoction, Poria Powder with Five Herbs* on the Macular Edema of Branch Retinal Vein Occlusion, *Clinical Ophthalmology*, 54: 1247-1251, 2000

14) Isobe Y., Inamura M., Okada K. et al.: Clinical Effects of *Minor Bupleurum Decoction, Poria Powder with Five Herbs* on Eye Diseases Associated with Macular Edema, *Pharmacology and Clinics*, 3: 165-179, 1993

Retinic pigment degeneration is a hereditary disease, but early initiation and continuous treatment with Kampo preparations reportedly allows its progression to slow down. Yamamoto observed a temporary normalization of the visual field and the appearance of peripheral visual field, but also stated that the nature of the disease requires an observation period of 20-30 years¹⁵⁾. Fujihira published one highly interesting case report where Kampo therapy induced a marked improvement in visual acuity.

15) Fujihira K.: A Case of Marked Improvement in Retinal Pigmentary Degeneration, *Journal of Traditional Sino-Japanese Medicine, Selected Case Reports* 188-189, Igaku Shuppan Center, 1984

4. Ear, Nose and Throat

Diseases in this field are indications for Kampo therapy, frequently for chronic inflammatory and allergic diseases, but it is also used for a number of other diseases that are often difficult to cure with western medicine.

Minor Bupleurum Decoction, Poria Powder with Five Herbs is frequently used for the treatment of stasis of the auditory tube or exudative otitis media among the forms of otitis media and there are many cumulative studies^{1,2,3)}. *Minor Blue Dragon Decoction* and *Yue Bi Decoction for Relieving Edema plus Atractylodes* are reportedly effective for the treatment

of adult diseases⁴). When an edema of the external meatus of the auditory tube develops due to a common cold, *Pueraria Decoction* or *Minor Bupleurum Decoction plus Cyperus and Perilla Leaf Powder* can be employed. Specialized treatment for both the acute as well as chronic phase of purulent otitis media should be given priority, but if required, a Kampo combination therapy can also be used. In particular, in chronic cases that prove to be almost refractory to the ordinary therapies, the application of Kampo medicine should be attempted. Here *Pueraria Decoction*, *Minor Bupleurum Decoction*, *Major Bupleurum Decoction*, *Schizonepeta and Forsythia Decoction*, *Cassia Twig plus Astragalus Decoction* and similar preparations are used.

- 1) Nakajima T., Yanagida N., Niwa H., et al.: Therapeutic Effects of *Minor Bupleurum Decoction*, *Poria Powder with Five Herbs* for Exudative Otitis Media; *Clinical Otorhinolaryngology* 82(7): 1025-1030, 1989
- 2) Ito S., Hayashi N.: Clinical Experiences with *Minor Bupleurum Decoction*, *Poria Powder with Five Herbs* for The Treatment of Exudative Otitis Media; *Prog. Med.* 11: 3087-3091, 1991
- 3) Tanaka H.: Usefulness of *Minor Bupleurum Decoction*, *Poria Powder with Five Herbs* for Exudative Otitis Media; *Prog. Med.* 15: 1451-1452, 1995
- 4) Inoue H.: Immediate Effectiveness of a Combination Therapy with *Minor Blue Dragon Decoction* and *Yue Bi Decoction for Relieving Edema plus Atractylodes* in Adult Patients With Acute Exudative Otitis Media; *Clinical Otorhinology* 47(5): 361-366, 2001

Vertigo is a comparatively frequent indication for Kampo medicines among the diseases of the inner ear. This symptom may be the subject of a Kampo therapy whether the symptom is central or peripheral, and preparations are chosen depending on which of the symptoms are to be treated. For the treatment of Ménière's syndrome *Pinellia*, *Largehead Atractylodes* and *Tall Gastordia Decoction*, *Bupleurum plus Dragon's Bone and Oyster Shell Decoction*, *Tuckahoe*, *Cassia Twig*, *Largehead Atractylodes* and *Licorice Decoction* and similar preparations are used. Otherwise *Uncaria Powder* is used for vertigo due to insufficient cerebral circulation; *Tuckahoe*, *Cassia Twig*, *Largehead Atractylodes* and *Licorice Decoction* for the treatment of orthostatic syncope. For dizziness in the elderly during walking *North Water God Decoction* finds frequent application. There is cumulative research into the effects of *Pinellia*, *Largehead Atractylodes* and *Tall Gastordia Decoction*⁵). In cases of tinnitus, depending on its cause, there are many refractory forms rendering treatment difficult. For chronic forms of tinnitus there are cumulative studies regarding *Life-preserving Kidney-Qi Pill*, *Bupleurum and Cassia Twig Decoction*, *Uncaria Powder*, *Bupleurum plus Dragon's Bone and Oyster Shell Decoction* and similar preparations^{6,7,8,9,10}).

- 5) Kimura T., Yamanaka N., Kuki K.: Clinical Effects of *Pinellia*, *Largehead Atractylodes* and *Tall Gastordia Decoction* for the Treatment of Tinnitus; *Clinics of Ear and Nose* 45 (5) 443-449, 1999
- 6) Onishi S., Sawaki S., Tsuchiya K. et al.: Multi-center Joint Clinical Trial Regarding the Effects of Tsumura *Life-preserving Kidney-Qi Pill* on Tinnitus; *Developments in Otorhinolaryngology* 37(3): 371-379, 1994

- 7) Kida K., Ito Y., Akita S. et al.: Effects of *Bupleurum and Cassia Twig Decoction* on Chronic Tinnitus; *Clinics of Otorhinolaryngology*, Supplement 98: 31-34, 2001
- 8) Iwasaki N., Sakamoto M.: Clinical Evaluation of *Uncaria Powder* in the Treatment of Tinnitus; *Medical Journal of the National Noborito Hospital* 12: 20-23, 2001
- 9) Saito A.: Evaluation of the Effects of *Uncaria Powder* on Tinnitus Using Headache and Hypertension as Indices; *Clinics of Otorhinolaryngology*, Supplement 98: 20-30, 1998
- 10) Takei S., Masuno H., Ando M. et al.: 9th Kanto Conference on Kampo Research in Otorhinolaryngology; clinical reports; clinical effects of *Bupleurum plus Dragon's Bone and Oyster Shell Decoction* on hypertension associated with tinnitus; *Prog. Med.* 16(9): 2242-2245, 1996

Application of Kampo medicine appears to be of particular importance for viral rhinitis (common cold) among the diseases of the nasal cavity and accessory nasal sinuses. In Japan, preparations listed in the "Shang han lun" are most frequently used. For further detail please refer to the section on infections. The treatment of acute inflammation of the paranasal sinuses follows the guidelines for the treatment of common cold. Yet, Kampo medicine is used more often for the treatment of chronic inflammation of the paranasal sinuses. Here preparations like *Pueraria Decoction*, *Pueraria Decoction plus Szeshwan Lovage and Magnolia Flower*, *Magnolia Flower*, *Lung-Clearing Decoction* find application^{11,12}), but when the underlying pathology has been identified as phlegm-fluid retention, *Pinellia*, *Largehead Atractylodes* and *Tall Gastordia Decoction* or *Two Vintage Herbs Decoction* are also administered.

- 11) Shibuya K.: Experiences with *Magnolia and Lung-Clearing Decoction* for the Treatment of Refractory Chronic Inflammation of the Paranasal Sinus in Children; *Prog. Med.* 15: 1479-1481, 1995
- 12) Ito H.: Kampo Treatment of Chronic Inflammation of the Paranasal Sinus. Clinical effects of long-term administration of *Pueraria Decoction plus Szeshwan Lovage and Magnolia Flower* for the treatment of chronic inflammation of the paranasal sinuses in children; *Prog. Med.* 12: 2578-2585, 1992

Allergic rhinitis is widely treated with *Minor Blue Dragon Decoction* or *Ephdra*, *Aconite* and *Manchurian Wildginger Decoction* either alone or else in combination with antiallergic drugs. For year-round treatment of allergic rhinitis with *Minor Blue Dragon Decoction*, double-blinded randomized controlled studies (DB-RCT) showed significantly better effects than in the control groups. Examination of the general improvement shows a marked improvement in 12.0% of the cases, an intermediate degree of improvement in 32.6% and mild improvements in 39.1% and thus with overall favorable results. The usefulness has received an acceptable rating of 46.2%¹³). Regarding *Ephdra*, *Aconite* and *Manchurian Wildginger Decoction* there is some cumulative research¹⁴). Besides the above mentioned drugs *Pueraria Decoction*, *Pueraria Decoction plus Szeshwan Lovage and Magnolia Flower*, *Yue Bi Decoction for Relieving Edema plus Atractylodes*, *Tea-Blended Szechwan Lovage Powder*, *Bupleurum Cassia Twig and Dried Ginger Decoction*, *Tuckahoe*, *Licorice*, *Dried ginger*, *Magnoliavine*, *Manchurian wildginger herb*, *Pinellia rhizoma* and *Apicot kernel Decoction* and similar

preparations are also used.

Seasonal allergic rhinitis is also treated in approximately the same manner, but during asymptomatic periods it is recommended to administer a combination of *Middle-Reinforcing and Qi-Benefiting Decoction* and *Angelica and Peony Powder* as a preventive medication.

- 13) Baba J., Takasaka T., Inamura N. et al.: Effects of Year-around Treatment with *Minor Blue Dragon Decoction* on Allergic Rhinitis, single and double-blinded comparative studies, *Clinical Otorhinolaryngology* 88(3): 389-405, 1995
- 14) Ito H., Baba J., Tkagi I. et al.: Evaluation of the Pharmacologic Effects of *Ephdra, Aconite and Manchurian Wildginger Decoction* on Allergic Rhinitis Clinical effects on nasal obstruction, *Clinical Otorhinolaryngology* 52: 107-118, 1991

Pharyngitis and tonsillitis are usually considered to be caused by the intrusion of wind heat, so that during the early stages, Shinryo Kaihyo (xin liang jie biao = releasing the exterior with pungent-cool) treatment principle is applied. Since most of these diseases are bacterial infections, they are indications for antibacterial therapy, but Kampo medicine is also useful. For further detail please refer to the section on infections. Regarding pharyngitis there are case series studied using *Balloon Flower Root Decoction*¹⁵⁾.

- 15) Tsujihisa S., Maeda S.: Experiences with the Use of Tsumura *Balloon Flower Root Decoction* extract for the Treatment of Patients with Acute Upper Respiratory Infections Complaining About Pharyngitis, *Basics and Clinics*, 19(5): 481-485, 1985

Anomalies of the pharyngolarynx are considered to be a form of psychosomatic disease treated in western medicine with tranquilizers, but in refractory cases, *Combina Minor Bupleurum Decoction and Pinellia and Magnolia Decoction, Cyperus and Perilla Leaf Powder, Pinellia and Magnolia Decoction* and similar preparations may also be used^{16,17)}. For dryness of the mouth *Dwarf Lilyturf Decoction, Ginseng Nutrition Decoction, White Tiger and Ginseng Decoction* etc are used^{18,19)}. These preparations are also effective for ptyalolithiasis.

- 16) Tanino T., Takeda Y., Harada K. et al.: Experiences with Tsumura *Combina Minor Bupleurum Decoction and Pinellia and Magnolia Decoction* in Treating Abnormal Feelings of the Pharyngolarynx (from a multi-center joint study), *Prog. Med.* 11: 3111-3114, 1991
- 17) Motoo Y., Taga H.: Effects of *Cyperus and Perilla Leaf Powder* on Abnormal Sensations in the Pharyngolarynx Associated with Depressive Moods, *Kampo and Modern Therapy* 7(3): 249-251, 1998
- 18) Okawa S., Shindoi N., Akagawa Y.: Clinical Effects of *Ginseng Nutrition Decoction* in Patients with Dry Mouth, *Prog. Med.* 21: 1037-1039, 2001
- 19) Umino M., Nagao M., Muroga S.: Effects of *White Tiger plus Ginseng Decoction* in Elderly with Dry Mouth - Analysis of the correlation between improvement in subjective symptoms and the diagnostic pattern, *Kampo Medicine (Jap. Journal of Oriental Medicine)* 45: 107-113, 1994

5. Lung

Many diseases of the respiratory tract are in daily practice treated with Kampo medicine. The use of Kampo medicines for the treatment of the chronic phase of bronchial asthma has so far achieved quite remarkable results. Since the spread of steroid inhalants has fundamentally changed the basic western medical therapy of asthma, Kampo

preparations are now used less frequently than in the past. Still, since problems frequently develop in people continuously using bronchodilators or steroids, there is still a strong demand for Kampo preparations. Currently, the question of how Kampo therapy of patients otherwise treated with the most advanced modern western medical therapies should be employed is the subject of actively pursued research^{1,2)}.

Among the extract preparations, *Minor Blue Dragon Decoction, Ephedra, Apricot, Licorice and Gypsum Decoction, Five Tiger Decoction, Combina Minor Bupleurum Decoction and Pinellia and Magnolia Decoction, Mystery Decoction, Dwarf Lilyturf Decoction* etc., are used for spleen deficiencies; *Middle-Reinforcing and Qi-Benefiting Decoction, Four Gentlemen Decoction* etc., for the elderly with kidney deficiency *Kidney Qi Pill, Ophiopogon, Schizandra and Rehmannia Pill (Eight-immortal Pill for Longevity*, which can be substituted with a combination of the extract preparations *Dwarf Lilyturf Decoction + Six Ingredient Pill with Rehmannia*) are used. Refer to the section on pediatric disease regarding pediatric asthma.

Cumulative research includes RCTs using *Combina Minor Bupleurum Decoction and Pinellia and Magnolia Decoction* and multi-center case series studies^{3,4)}, both of which have achieved favorable results. Moreover, results of multi-center case series studies about *Minor Blue Dragon Decoction* showed a better than intermediate improvement in more than 52.2% of the cases⁵⁾. Also, treatment of adults suffering from bronchial asthma associated with dry cough using *Dwarf Lilyturf Decoction* revealed an antitussive effect in 69.4% of the cases⁶⁾.

- 1) Ito T.: The Role of Kampo Therapy in the Age of Steroid Inhalants, *Kampo Medicine (Jap. Journal of Oriental Medicine)* 55(4): 447-453, 2004
- 2) Terasawa K.: Allergy and Kampo Therapy, *Allergy* 47 (1), 1998
- 3) Nakajima S., Takagi H., Tsutani Y. et al.: Examination of the Usefulness of *Combina Minor Bupleurum Decoction and Pinellia and Magnolia Decoction* Extract Fine Granules for the Treatment of Bronchial Asthma, *Prog. Med.* 9: 3138-3151, 1989
- 4) Egashira Y. and Nagano H.: A multicenter clinical trial of *Combina Minor Bupleurum Decoction and Pinellia and Magnolia Decoction* in patients with steroid-dependent bronchial asthma. *Ann. NY Acad. Sci.* 685: 580-583, 1993
- 5) Egashira Y., Yoshida M., Nagano J.: Clinical Effects of *Minor Blue Dragon Decoction* on Bronchial Asthma - evaluation of a multi-facility open trial, *Kampo Medicine (Jap. Journal of Oriental Medicine)*. 45(4): 859-876, 1995
- 6) Tamaki T., Nizuma T.: Clinical Effects of *Dwarf Lilyturf Decoction* and Analysis of Excretory Components in the Urine - Antitussive effects of *Dwarf Lilyturf Decoction* on bronchial asthma and active principles. *Journal of the Tokyo College of Medicine and Dentistry* 57(1): 23-30, 1999

There are several approaches to the treatment of chronic obstructive pulmonary disease (COPD). Clinical trials using *Middle-Reinforcing and Qi-Benefiting Decoction* extract have been performed, but did not necessarily result in marked improvements⁷⁾. This disease is difficult to treat with extract preparations. Using decoctions, Haimoto on the other hand, reported outstanding results⁸⁾. A number of studies deal also with pulmonary emphysema⁹⁾.

- 7) Sugiyama Y., Kitamura S.: Effects of the Kampo Medication *Middle-Reinforcing and Qi-Benefiting Decoction* in the Treatment of COPD, *Japanese Thoracic Clinics* 56: 105-109, 1997
- 8) Haimoto H.: Treatment of Chronic Obstructive Pulmonary Disease - A compromise between Chinese and western medical therapies, *The Kampo* 15(2): 46-1, 1997
- 9) Shimoda T., Taniguchi T. Yasuoka A.: Clinical Effects of *Combind Minor Bupleurum Decoction and Pinellia and Magnolia Decoction* in the Treatment of Chronic Pulmonary Emphysema and its Influence on Bronchial Hypersensitivity, *J. Trad. Med.* 8: 426-427, 1991

Bronchitis is also a good indication for Kampo. Depending on the conditions of the cough and properties of the sputum, many different preparations are used. Cumulative research showed that for patients presenting either watery sputum, wheezing or cough, observation of the effects of *Minor Blue Dragon Decoction* during DB-RCT, revealed that the observed general improvement and improvement of individual symptoms were both significantly better than in the placebo groups¹⁰. Treatment of this disease requires identification of the etiologic agent, and based on these findings, administration of appropriate antibacterial drugs, but Kampo preparations are often used in combination with those antibacterial drugs. Some studies are emerging that focus on the observation of variations in pulmonary function during combination therapy with *Combind Minor Bupleurum Decoction and Pinellia and Magnolia Decoction* and macrolide antibiotics¹¹.

There are case series studies indicating that the use of *Pueraria Decoction Plus Szeshwan Lovage and Magnolia* is effective for the treatment of the sinobronchial syndrome^{12,13}. This disease is characterized mainly by the symptoms of bronchitis, but treatment of inflammation of the paranasal sinuses responsible for the condition, allows consequent pursuit of improvements.

- 10) Miyamoto S., Inoue H., Kitamura S.: *Minor Blue Dragon Decoction* for the Treatment of Bronchitis - Placebo controlled double-blinded comparative study, *Clinical Pharmacology* 17(8): 1189-1214, 2001
- 11) Tanno Y.: Kampo Therapy for Respiratory Diseases (round-table discussion) - Variations in pulmonary functions before and after a combination therapy with *Combind Minor Bupleurum Decoction and Pinellia and Magnolia Decoction* and macrolides, *Kampo Medicine (Jap. Journal of Oriental Medicine)* Vol. 21, Nol 10: 6-7, 1997
- 12) Egashira Y., Ushijima M.: Effects of a Combination Treatment of the Sinobronchial Syndrome (SBS), in Particular Erosive Panbronchiolitis with *Pueraria Decoction Plus Szeshwan Lovage and Magnolia*, *Kampo and Allergy* 4: 33-41, 1990
- 13) Kato S., Kishiro I., Onuma N. et al.: Long-term Combination Therapy Using Erythromycin and *Pueraria Decoction Plus Szeshwan Lovage and Magnolia* for the Treatment of Sinobronchial Syndrome, *Breathing* 17(8): 919-926, 1998

Bronchiectasis, during acute exacerbations, requires modern western medical treatment, mainly using antibiotics, but during the chronic phase it is a comparatively good indication for Kampo therapy. *Lung-Clearing Decoction, Yin Nourishing Real treasure Decoction, Tuckahoe, Licorice, Dried ginger, Magnoliavine, Manchurian wildginger herb, Pinellia rhizoma and Apricot kernel Decoction* have been used for the treatment.

Among the pulmonary infections, community-acquired

pneumonia is currently treated primarily with modern western medicine. However, Kampo therapy has been used so frequently, that it has actually controlled the survival prognosis. Accordingly, there have been many studies and combination therapies are still employed today. Thus, administration of antibacterial agents still represents the basics and Kampo medicine should not be the treatment of first choice.

Hospital acquired pneumonia develops based on a multitude of different factors and while it is generally not possible to provide a specific therapy, the condition is usually marked by a decrease in immune function associated with a high likelihood of infections. Under these circumstances either only Qi tonifying or else both Qi and Blood tonifying preparations like *Middle-Reinforcing and Qi-Benefiting Decoction* or *Ginseng Nutrition Decoction* are used. In cases of MRSA infections, or infections with non-specific acidophilic bacteria, effectiveness of antibacterial agents may hardly be expected and the same holds true for chronic infections of the lungs.

Ideopathic fibrotic interstitial pneumonia is a group of several disease entities. Except in a small number of exceptions, all of these forms are exceedingly difficult to treat. While that is so, there are a number of case reports dealing with Kampo medicine. Ito reported that mild cases of interstitial pneumonia can be treated with Kampo¹⁴. Preparations used so far in published cases include representative items like *Minor Bupleurum Decoction, Cassia Twig Decoction plus Atractylodes and Aconite, Bupleurum Cassia Twig and Dried Ginger Decoction, Kidney Qi Pill, Tuckahoe, Apricot Seed and Licorice Decoction* etc. Several valuable case reports have been published by Honma and also have been described in the introduction¹⁵.

14) Ito T.: Kampo Therapy for Respiratory Diseases, *Kampo Medicine (Jap. Journal of Oriental Medicine)* 54: 29-46, 2003

15) Honma Y.: Kampo Medical Treatment under Health Insurance, *Respiratory Division (26), Ideopathy Interstitial Pneumonia (IIP)* 29: 562-563, 1993

Note:

It is known that several Kampo preparations may induce drug interstitial pneumonia. Since 1992 several cases of drug interstitial pneumonia due to *Minor Bupleurum Dragon Decoction* have been reported. Statistically the condition occurs in about 4 out of 10,000 people. Considering that the incidence of interstitial pneumonia caused by the use of interferon in patients with chronic hepatitis is 25 times higher, this rate does not seem to be so high. Being completely different in nature from the interstitial pneumonia described in the main body of this text, this condition can be diagnosed early based on subjective symptoms and chest x-rays and discontinuing the offending drug at that time will lead to recovery. In severe cases treatment with steroids may be required, but the disease will basically run a benign course.

6. Heart

In traditional Kampo medicine there is no concept for blood pressure. Congestive heart failure is viewed as a form of edema, while coronary artery diseases are described as Kyohi (xiong bi = chest qi-blockage) and classified and treated under different entities. Only recently these symptoms have been summarized as circulatory diseases. Following the progress in modern medicine therapies, Kampo medicine is also developing.

The incidence of coronary artery diseases, that used to be rather low in Japan, is continuously increasing in association with the westernization of diet and life style.

Some forms of angina pectoris are an indication for Kampo medicine. The prognosis of patients with angina pectoris in Japan, compared to the prognosis of the same disease in America, is comparatively good and patients accordingly can be managed mostly on ordinary pharmacotherapy. Yet, often there are also indications for percutaneous transluminal coronary angioplasty (PTCA) or coronary artery bypass grafts (CABG). The frequency of both of these procedures is rising. The use of Kampo medicine is restricted to patients managed by pharmacotherapy. In particular, the use of Kampo preparations for effort angina requires a sufficiently thorough diagnosis. Conversely, Kampo medicine for atypical angina caused by vascular spasms is often rather effective and therefore warrants a try more than in patients with effort angina¹⁾. However, in these cases treatment with extracts proves to be difficult, so that decoctions are used. There are a number of case reports²⁾. Japanese people often present the indications for phlegm dispelling preparations like *Trichosanthes Fruit*, *Chinese Chive* and *Pinellia Decoction*, while blood activating and stasis resolving preparations are not required as much as in China. Otherwise, *Bupleurum plus Dragon's Bone and Oyster Shell Decoction*, *Coptis Detoxifying Decoction*, *Bupleurum Cassia Twig and Dried Ginger Decoction*, *Angelica Decoction* and similar preparations are also used. During the acute phase of a myocardial infarct, Kampo therapy is contraindicated. After initiating rehabilitation following the acute phase, however, Kampo therapy is employed in order to improve the general condition and prevent recurrences³⁾.

1) Haimoto H.: Traditional Chinese Medical Therapeutic Effects on Angina Pectoris and Coronary Angiographic Findings - from a standpoint of functional and structural diseases, *The Kampo* 15(1): 7-16, 1997

2) Kimura H., Furuta K., Mitsuma T.: *Major Sinking Into the Chest Decoction* for the Treatment of Microvascular Angina Pectoris - Clinical experiences, *Kampo Medicine (Jap. Journal of Oriental Medicine)* 54(5): 945-950, 2003

3) Sato Y.: Ischemic Heart Diseases and Rehabilitation: Kampo and Advanced Therapies 4(4): 361-365, 1995

Disorders of the pulse rate are classified as rhythm disorders, i.e., some forms of arrhythmia are indications for Kampo therapy. The medication varies

depending on the pathology. The classification into Kampo types and the names of western medical diagnoses do not necessarily match, but generally *Pinellia and Magnolia Decoction*, *Cassia Twig plus Dragon's Bone and Oyster Shell Decoction*, *Roasted Licorice Decoction*, *Bupleurum plus Dragon's Bone and Oyster Shell Decoction*, *Bupleurum Cassia Twig and Dried Ginger Decoction* and similar preparations are often used for paroxysmal supraventricular tachycardia and *Roasted Licorice Decoction* for the treatment of ventricular extrasystoles. There are cumulative studies regarding the use of *Bupleurum plus Dragon's Bone and Oyster Shell Decoction*⁴⁾.

4) Konnai K., Munakata M., Sato A.: Clinical Effects of *Bupleurum plus Dragon's Bone and Oyster Shell Decoction* on Tachycardia Developing during Administration of Ritodrine Hydrochloride, *Obstetrics and Gynecology* 65(12): 1767-1770, 1997

Among the forms of heart failure, the acute phase of congestive heart failure is principally an indication for treatment with modern medicine using diuretics and cardiotonic agents. Among the case reports where Kampo medicine had been used, there are occasional examples, where its use caused a remarkable improvement. Extracts are indicated for the chronic phases, causing improvement of mild congestive heart failure. Preparations used include *Fourstaman Stephania Decoction*, *Roasted Licorice Decoction*, *Kidney Qi Pill*, *North Water God Decoction*^{5,6,7)}.

Congestive heart failure

5) Yakubo S., Kinoshita Y. et al.: Clinical evaluation of *Fourstaman Stephania Decoction* (Mu-fang-Yi-Tang): A Japanese and Chinese traditional medicine for heart failure, *J. Trad. Med.* 19: 159-163, 2002

6) Ebe Y.: Treatment of Senile Heart Failure with Modifications of *North Water God Decoction* - 30th Japan Oriental Medicine Conference, Chu-Shikoku Branch General Assembly at the Tottori Conference 2001 (presentation)

7) Katayose H., Shirato K.: Experiences with *North Water God Decoction* for the Treatment of Patients with Severe Heart Failure Associated with Marked Atrial Blocks - 52nd General Assembly of the Japan Society for Oriental Medicine 2001 (presentation)

7. Systemic Hypertension

The first choice of treatment for hypertension is life style guidance and administration of antihypertensive drugs. In Japan there is no notion of trying to control high blood pressure by Kampo medicine alone. Although many case reports show that a successful reduction in blood pressure had been achieved with the administration of Kampo preparations alone, Kampo medicines are not considered to have a more reliable effect than diuretics, ACE inhibitors, ARB, calcium antagonists, β -blockers, α -blockers and similar preparations. Two cumulative studies deal with *Uncaria Powder*^{1,2)}. Both systolic and diastolic effects were observed. In actual clinical practice *Uncaria Powder* is widely used and attempts have been made to increase the antihypertensive effect by adding *Uncaria Powder* to this extract preparation³⁾.

This preparation acts by pacifying the liver and subduing yang in conditions marked by ascendant

hyperactivity of liver yang, which is a condition in modern hypertensives. Several reports describe the use of preparations for other pathologic conditions such as the use of *Pinellia*, *Largehead Atractylodes* and *Tall Gastordia Decoction* for congestions and excess of phlegm-dampness, and *Barbary Wolfberry*, *Chrysanthemum* and *Rehmannia Pill* or *Kidney Qi Pill* for liver and kidney deficiency^{4,5,6,7,8,9}.

Generally, Kampo medicines are not antihypertensives per se, but can be used for and appear to be useful for, associated symptoms. Frequently used extract preparations include among others, *Major Bupleurum Decoction*, *Coptis Detoxifying Decoction*, *Three Huang Heart-Clearing Decoction with Three yellow color Herbs*, *Bupleurum plus Dragon's Bone and Oyster Shell Decoction*, *Divaricate Saposhnikovia Miraculous Powder*, *Seven Herbs Decoction for Hypertension* and similar preparations.

- 1) Nagata K., Hara K., Kinoshita T. et al.: QOL in Hypertension and the Effects of *Uncaria Powder*, J. Trad. Med. 8: 252-253, 1991
- 2) Nagata K., Okamoto A., Kamano Y. et al.: Treatment of Hypertension with *Uncaria Powder* and QOL, J. Trad. Med. 6: 426-427, 1989
- 3) Bando S.: Practice of Kampo Therapy Based on Disease Names, Medical Yukon, 2004
- 4) Ogawa I.: Effectiveness of *Bupleurum plus Dragon's Bone and Oyster Shell Decoction* for the Treatment of Hypertension, Kampo Therapy 12, 1993
- 5) Sasaki A., Matsunaga A., Kusuda M. et al.: Effects of *Major Bupleurum Decoction* and *Uncaria Powder* on Essential Hypertension, Clinics and Research 70: 269-279, 1995
- 6) Ishikawa T., Umemura S.: Special: Strategies of Hypertension Therapies - Oriental medial therapies for hypertension, Therapy 82(4): 1367-1372, 2000
- 7) Arakawa K., Saruta T., Abe K. et al.: Double-Blinded Controlled Study of the Effects of *Coptis Detoxifying Decoction* on Accessory Symptoms of Hypertension, Clinics and Research 80(2): 354-372, 2003
- 8) Horino M.: Effects of *Three Huang Heart-Clearing Decoction with Three yellow color Herbs* on Hypertension, Kampo Medicine (Jap. Journal of Oriental Medicine) 53(1-2): 41-46, 2002
- 9) Katayose H.: Experiences with *Bupleurum plus Dragon's Bone and Oyster Shell Decoction* in the Cardiovascular in Ambulatory Practice, Kampo Medicine (Jap. Journal of Oriental Medicine) 52(1): 25-38, 2001

8. Blood Vessels and Lymphatics

Most of obstructive arterial diseases are caused by atherosclerotic changes, but there is almost no clinical research pertaining to the mechanism of action of Kampo medicine on this etiologic factor. Yet, a substantial amount of basic research has been performed. For example, treatment of rabbits with experimental models of atherosclerosis using *Bupleurum plus Dragon's Bone and Oyster Shell Decoction*, showed that the treatment was reportedly able to prevent disturbances of vascularization and some other effects¹.

- 1) Hasegawa M.: Antiatherosclerotic Modes of Action of Kampo Preparations and their Effects, Prog. Med., 15: 131-140, 1995

Regarding obstructive arterial diseases of the lower extremities, there is considerable experience pertaining to the treatment of intermittent claudication in patients with arteriosclerosis obliterans. Currently, mainly blood activating and stasis resolving preparations are administered, but kidney deficiency due to aging or

rheum turbidity, heat toxins also occur, so that it is often not possible to treat these conditions simply using the blood activation and stasis resolving principle. Widely used extract preparations include *Evodia*, *Fresh Ginger plus Chinese Angelica Cold Limbs Decoction*, *Cassia Twig and Tuckahoe Pill*, *Channels-Dredging and Blood-Activating Decoction*, *Szechwan Lovage and Angelica Decoction for Regulating Blood Flow*, *Kidney Qi Pill* etc.^{2,3,4,5}. The pathology of Buerger's disease may be different, but treatment principles are similar⁶. *Evodia*, *Fresh Ginger plus Chinese Angelica Cold Limbs Decoction* is often used for Raynaud's disease and there are relevant case series studies⁷.

- 2) Takahashi K., Sugano M., Totsuka O. et al.: Patients Treated with *Channels-Dredging and Blood-Activating Decoction Plus Coix Seed* for Arteriosclerosis Obliterans, Kanto Koshin Etsu Branch of the Japan Society of Oriental Medicine, 1999 Sectional Meeting in Gunma Prefecture (presentation)
- 3) Oikawa O., Fujiki N., Matsumoto A. et al.: Attempts at Treating Arteriosclerosis Obliterans (ASO) Induced Chronic Pain of the Lower Extremities with Combination Therapy - Autogenic Training and Kampo (*Peony and Licorice Decoction* and *Cassia Twig Decoction plus Atractylodes and Aconite*) - 35th General Conference of the Japan Society of Oriental Psychosomatic Medicine in 1999 (presentation)
- 4) Ide Y., Sekiyama H., Kitamura M. et al.: Three Patients with Arteriosclerosis Obliterans Successfully Treated with Kampo Medicine, Journal of the Japanese Pain Clinic Society 5(3): 327, 1998
- 5) Kaneki M.: Practical Application of Japanese Kampo Medicine for the Treatment of Arteriosclerosis Obliterans, Three cases, Kampo Medicine (Jap. Journal of Oriental Medicine) 47(6): 150, 1997
- 6) Kubo T.: Case Report of a Patient Following Quadruple Amputations due to Buerger's disease with Refractory Pain Treated with *Life-preserving Kidney-Qi Pill*, Hokkaido Study Group for Kampo Treatment of Elderly Patients, 7th Conference 1998 (presentation)
- 7) Kaneuchi H.: Comparison of Raynaud's Phenomenon in Patients with Connective Tissue Diseases and Thermographically Observed Skin Temperature - Pharmacologic Evaluation of *Evodia*, *Fresh Ginger plus Chinese Angelica Cold Limbs Decoction*, Summaries from the Public Toyooka Hospital 11: 69-76, 1999

Orthostatic hypotension is a good indication for Kampo therapy. Here *Tuckahoe*, *Cassia Twig*, *Largehead Atractylodes* and *Licorice Decoction*, *Poria Powder with Five Herbs* and similar preparations are used^{8,9}. Controlled clinical trials regarding the treatment of diabetics with orthostatic hypotension using *Poria Powder with Five Herbs* have been reported and demonstrated good results¹⁰. Moreover, *North Water God Decoction*, *Pinellia*, *Largehead Atractylodes* and *Tall Gastordia Decoction* and similar preparations have also been used for the treatment of hypotension.

- 8) Shiotani Y., Shintani T., Fujinaga H. et al.: Discussion of the Modes of Action of *Tuckahoe*, *Cassia Twig*, *Largehead Atractylodes* and *Licorice Decoction* and its Clinical Application, Kampo Medicine (Jap. Journal of Oriental Medicine) 50(1): 21-28, 1999
- 9) Shibahara N., Goto H., Kita T. et al.: Two Cases of Orthostatic Hypotension Where the Use of *Tuckahoe*, *Cassia Twig*, *Largehead Atractylodes* and *Licorice Decoction* was Effective - a discussion, Kampo Medicine (Jap. Journal of Oriental Medicine) 53(6): 244
- 10) Nakamura H., Nakamura T., Nakagawa T. et al.: Effects of *Poria Powder with Five Herbs* on Orthostatic Hypotension in Diabetics, Diabetes Frontier 11: 561-563, 2000

9. Blood

In TCM there are such concepts as blood deficiency and blood stasis. Although they do somewhat resemble hematologic diseases like anemia or congestion as they are understood in modern medicine, they are in practice different concepts. Accordingly, when treating diseases of the blood with Kampo medicine, an integration of these traditional and modern medical concepts has to be achieved.

For the treatment of diseases that can be treated with current medical methods, there is little use of Kampo medicine, but in cases where standard therapeutic methods cannot be established, they may have their practical application. Aplastic anemia or idiopathic thrombocytopenic purpura (ITP) are examples.

Anemia may have many causes and therapy depends on the relevant cause. Iron deficiency anemia is treated using preparations with added iron powder, but currently iron can also be administered orally or intravenously, so that former methods have now become redundant. Thus, with the progress of modern medicine, Kampo medicine in this field is used only under special circumstances.

For example, if substantial blood loss is anticipated during major surgeries, autologous blood is sometimes collected prior to surgery and thus artificially induces anemia. Under these circumstances attempts have been made to achieve an early recovery through treatment with Kampo medicine^{1,2)}.

Regarding leukemia and other myeloproliferative disorders, modern medical therapies are given priority. There is only a limited number of reports about treating these disorders with Kampo medicine. The same applies to lymphomas.

Idiopathic thrombocytopenic purpura (ITP) is not treated easily with Kampo medicine, but there are examples where *Back to the Spleen Decoction*, *Modified Back to the Spleen Decoction*, *Bupleurum and Cassia Twig Decoction* have led to favorable changes³⁾. This applies also to aplastic anemia or the osteomyelodysplastic syndrome for which there are some cumulative studies^{4,5)}.

- 1) Aoe H., Matsuo T., Ebisutani M. et al.: Effects of *Ten Strong Tonic Herbs Decoction* on Presurgical Autologous Blood Pooling in Cancer Patients, *Progress in Obstetrics and Gynecology* 17: 67-71, 2000
- 2) Aoe H., Sumida Y., Takada K. et al.: Effects of a Combination Therapy with Erythropoietin Preparations and *Ginseng Nutrition Decoction* on Presurgical Autologous Blood Pooling, *Progress in Obstetrics and Gynecology* 15: 67-71, 1998
- 3) Sakuragawa N., Yasunaga K., Nomura T. et al.: Multi-center Clinical Evaluation of TJ-137 (*Modified Back to the Spleen Decoction*) for the Treatment of Idiopathic Thrombocytopenic Purpura (ITP), *Clinics and Research* 70(11): 3711-3718, 1993
- 4) Miyazaki T., Uchino H., Kimura I. et al.: Clinical Usefulness of EK108, *Ginseng Nutrition Decoction*, for the Treatment of Aplastic Anemia, *Clinical Medicine and Pharmacology* 10(11): 2591-2603, 1994
- 5) Miyazaki T., Uchino H., Kimura I. et al.: Clinical Usefulness of *Ginseng Nutrition Decoction* for the Treatment of Osteomyelodysplastic Syndrome, *Clinical Medicine and Pharmacology* 10(11): 2575-2590, 1994

10. Alimentary Tract

Diseases in this field are extremely common in daily life and an enormous variety of Kampo medicines are provided for their treatment. An abundance of preparations are used that allow minute responses.

Among the forms of dyspepsia, functional indigestion is a good indication for Kampo therapy. For symptoms like pain or discomfort mainly in the upper abdominal region (upper abdominal distention, burning sensation, tympanism, yawning, nausea, retching, vomiting) the use of Kampo medicines should be considered, because they may be more useful than for other symptoms. Frequently used preparations include *Pinellia Heart-Purging Decoction*, *Coptis Decoction*, *Bupleurum and Cassia Twig Decoction*, *Stomach-Calming Powder*, *Middle-Soothing Powder*, *Tuckahoe Decoction*, *Ginseng Decoction* etc. Many reports deal with NUD and there are relevant cumulative studies¹⁾. Available data suggest that the preparation *Six Gentlemen Decoction* facilitates the excretory function of the stomach and a number of studies revealed the effectiveness of this preparation^{2,3,4,5)}. Not restricted to these preparations, there are also a number of other formulas for indefinite complaints of the upper abdomen. In particular, *Stomach-Calming Powder* suits the physical disposition of the Japanese, who are easily affected by dampness, and for people who are exposed to cold, *Middle-Soothing Powder* is a frequently used formula. For the above described reasons these two formulas are widely used as OTC preparations.

- 1) Muraki T., Sugiyama M.: Kampo Therapy of NUD (Non-Ulcer Dyspepsia) - Discourse on Kampo preparations - *New Drugs and Clinics* 46(4): 433-437, 1997
- 2) Harasawa S., Miyoshi A., Miwa T. et al.: Postmarketing Multi-Facility Joint Clinical Trial on the Effects of *Six Gentlemen Decoction* on Dysmotility Type Indefinite Complaints of the Upper Abdomen - intergroup comparison in double-blinded groups, *Progress in Medicine* 187(3): 207-229, 1998
- 3) Miyoshi A., Yachi A., Masamune O. et al.: Clinical Effects of *Six Gentlemen Decoction* on Indefinite Gastrointestinal Symptoms like Chronic Gastritis - Multi-Facility Comparative Trial Using Cisapride as Control, *Prog. Med.* 11: 1605-1631, 1991
- 4) Hamamoto T., Kadohara M., Yoshimura T. et al.: Multi-Facility Clinical Evaluation of *Six Gentlemen Decoction* for Indefinite Complaints of the Upper Abdomen, *Clinics and Research* 71(7): 1888-1894, 1994
- 5) Sato J., Shima H., Asaki S. et al.: Multi-Facility Clinical Evaluation of *Six Gentlemen Decoction* for Chronic Gastritis Associated with Indefinite Complaints of the Upper Abdomen, *Prog. Med.* 11: 1633-1645, 1991

While Kampo medicine provides a variety of formulas for the treatment of constipation, it attempts to regulate intestinal function without using laxatives to improve bowel movements. For conditions requiring the use of laxatives, *Formula include Rhubarb*, in particular *Rhubarb and Licorice Decoction*, is frequently used⁶⁾. This is a very simple preparation combining only the crude drugs Daio (rhubarb root) and Kanzo (licorice root) that is mild and regularly used by many people in whom constipation is not associated with abdominal pain. For scybalum *Hemp Seed Pill* with its "moistening the intestines to loosen

the bowel" action is used, a condition particularly frequent in the elderly with an accordingly high demand⁷⁾. Conversely, *Minor Middle-Strengthening Decoction* or *Major Middle-Strengthening Decoction* are preparations lacking any laxatives and therefore serve to regulate intestinal function.

- 6) Miyoshi A., Masamune O., Fukutomi H. et al.: Clinical Effects of *Rhubarb and Licorice Decoction* According to New Evaluation Criteria, *Alimentary System* 22: 314-328, 1996
- 7) Sato H.: Elderly and Kampo (constipation, diarrhea, loss of appetite, gastric distention), *Kampo and advanced therapies for disorders of the alimentary tract* 2(1): 15-18, 1993

Among the forms of diarrhea, acute diarrhea is principally an indication for western medical treatment. *Poria Powder with Five Herbs* is very effective for the treatment of rota virus induced acute gastroenteritis, so that this is an often selected preparation⁸⁾. This applies also to Norwalk virus induced conditions. Most of the chronic forms of diarrhea are non-inflammatory and among these a substantial portion is considered to be due to irritable bowel syndrome (IBS). The treatment of IBS conforms to that of diarrhea. Crohn's disease and ulcerative colitis will be discussed later.

- 8) Hashimoto H.: Comparative Study of Applications of *Poria Powder with Five Herbs* and *Minor Bupleurum Decoction*, *Poria Powder with Five Herbs* Applied as Enemas as Treatment for Pediatric Viral Gastroenteritis Associated with Vomiting, *Kampo Igaku* 25: 73-75, 2001

Among the diseases of the stomach and duodenum, *H. pylori* induced gastritis can now be relieved due to the advances in antibacterial therapies, so that the role of Kampo medicine has declined in this field. Yet, Kampo preparations are still used as a first choice treatment for this disease. The prescriptions match those described above for indigestion. For *Pinellia Heart-Purging Decoction* there are some cumulative studies⁹⁾. *Six Gentlemen Decoction* is used for endoscopically confirmed erosive gastritis and has reportedly been associated with a 92.9% ratio of better than mild improvement¹⁰⁾.

- 9) Miyoshi A., Murohisa B., Kitagawa M. et al.: Examination of the Usefulness of Kanebo's *Pinellia Heart-Purging Decoction* for the Treatment of Gastritis (Acute Gastritis, Acute Exacerbations of Chronic Gastritis), *Prog. Med.* 13: 1627-1632, 1993
- 10) Makino S., Yasutake K., Irie K. et al.: Effects of *Six Gentlemen Decoction* on Verrucose Gastritis, *Kampo Igaku* Vol. 20, No. 6: 17-21, 1996

Currently H₂-blocker and proton pump inhibitors are available for the treatment of gastroduodenal ulcers, so that Kampo medicine is used only in a supplementary function. Regarding the use of *Three Huang Heart-Clearing Decoction with Three yellow color Herbs* and *Coptis Detoxifying Decoction* there are cumulative studies¹¹⁾. Moreover, Kampo medicine is also administered in patients in whom peptic ulcers have healed, in order to prevent their recurrence and reportedly have been proven to be useful¹²⁾. Also, a number of case reports showed that Kampo therapy was effective, when modern medications could not be used for one reason or other¹³⁾.

- 11) Namiki M., Yachi A., Yoshida Y. et al.: Investigation into the Usefulness of *Three Huang Heart-Clearing Decoction with Three yellow color Herbs* and *Coptis Detoxifying Decoction* for the Treatment of Gastritis or Peptic Ulcer, *Clinics and Research* 71: 1585-1597, 1994
- 12) Watanabe H.: Examination of Maintenance Therapy for Peptic Ulcer Using a Combination with Kampo Medicine, *Kampo Igaku*, Vol. 19, No.1: 6-7, 1994
- 13) Haimoto H.: Isolated Kampo Therapy for the Acute Phase of Gastroduodenal Ulcer 3(1): 4-6, 2001

Irritable bowel syndrome in Japan is exceedingly frequent, found in about 35% of outpatients visiting departments of gastrointestinal diseases. This disease, being a sort of psychosomatic disease, may not be easily resolved by using Kampo medicine, but is generally considered to be a good indication for frequently used preparations like *Pinellia Heart-Purging Decoction* or *Cassia Twig Decoction plus Peony*. Classified by types *Ginseng Decoction*, *North Water God Decoction*, *Ginseng, Poria and Atractylodes Macrocephala Powder*, *Open the Spleen Decoction* and similar preparations are used for the treatment of the diarrhetic type, while for the constipation type *Modified Merry Life Powder*, *Rhubarb and Licorice Decoction*, *Hemp Seed Pill*, *Cassia Twig Decoction plus Peony* and *Rhubarb* are used. For a form characterized by alternating constipation and diarrhea *Cassia Twig Decoction plus Peony*, *Cold Limbs Powder*, *Important Formula for Painful Diarrhea* and the like are used, but for the gas type associated with abdominal pain *Areca Seed Decoction with Nine Herbs* or *Cyperus and Perilla Leaf Powder* is used. There is an extremely large number of case reports, and for *Cassia Twig Decoction plus Peony*, *Stomach-Calming Powder* and *Cyperus and Perilla Leaf Powder* also cumulative studies^{14,15,16,17)}.

- 14) Sasaki D., Uehara A., Hiwatashi N. et al.: Clinical Effects of *Cassia Twig Decoction plus Peony* on Iritable Bowel Syndrome, *Clinics and Research* 75: 1136-1152, 1998
- 15) Mizuno S., Nagata K., Yoshida K. et al.: Therapeutic Effects of *Cassia Twig Decoction plus Peony* on Iritable Bowel Syndrome, *Diagnosis and Therapy* 73: 1143-1152, 1985
- 16) Tokutomi K.: Results of Using *Stomach-Calming Powder* for Iritable Bowel Syndrome, *Kampo and Clinics* 43: 1187-1194, 1996
- 17) Shiramine K., Hisamura M., Akita K. et al.: Effects of *Cyperus and Perilla Leaf Powder* on Gas Type Irritable Bowel Syndrome, *Kampo Igaku* Vol. 23, No. 2, 1999

Crohn's disease is an intractable condition for which there is a small number of valuable case reports¹⁸⁾. Treatment is not aimed directly at this disease, but rather at the symptoms of ileus that may be caused by it and the available cumulative research revealed its usefulness¹⁹⁾.

- 18) Kogure T., Shimada Y., Tosa H. et al.: A Patient with Recurrent Crohn's Disease in whom Treatment with Japanese Kampo Medicine Proved to be Highly Effective, *Kampo Medicine (Jap. Journal of Oriental Medicine)*
- 19) Takazoe M., Yamauchi H.: Attempt at Medical Treatment of Symptoms of Ileus in Crohn's Disease: Usefulness of *Major Middle-Strengthening Decoction*, *Research Team for the Investigation of Refractory Inflammatory Intestinal Disorders*, 1997 Research Report: 137-141, 1998

Ulcerative colitis responds well to treatment with Kampo medicine and numerous studies have been

performed^{20,21}). In mild cases Kampo may be used independently, but in intermediately to severe cases Kampo is administered in the form of a combination therapy with salazopirine or steroids. Used extracts include *Cassia Twig Decoction plus Peony*, *Cassia Twig Decoction plus Piony and Rhubarb*, *Minor Bupleurum Decoction*, *Poria Powder with Five Herbs*, *Bupleurum and Cassia Twig Decoction*, *Scutellaria Decoction*, *Szechwan Lovage Rhizoma*, *Angelica Root*, *Ass-hide Glue and Argy Womwod Leaf Decoction* and similar preparations; but for serious therapy, decoctions are required. There is cumulative research regarding *Minor Bupleurum Decoction*, *Poria Powder with Five Herbs*^{22,23}).

20) Matsuike T., Suzuki Y., Nozawa H. et al.: Significance of Kampo Therapy for the Treatment of Ulcerative Colitis, *Prog. Med.* 19(4): 879-885, 1999

21) Takahashi T.: Kampo Therapy for Inflammatory Bowel Diseases (Ulcerative Colitis, Crohn's Disease), *Kampo and Advanced Therapies* 5(3): 225-229, 1996

22) Suzuki Y., Matsuike T., Nozawa H. et al.: Indications for and Limitations of *Minor Bupleurum Decoction*, *Poria Powder with Five Herbs* in the Treatment of Ulcerative Colitis, *Current Medicine* 11: 132-136, 1996

23) Okubo A., Masuda H., Hayashi N. et al.: Experiences with the Use of Kampo Therapy (*Minor Bupleurum Decoction*, *Poria Powder with Five Herbs*) for Ulcerative Colitis, *Medical Journal of Nippon University* 55: 286-289, 1996

Kampo medicines are also useful in the field of abdominal surgery. There is cumulative research regarding the use of *Major Middle-Strengthening Decoction* for the treatment of Ileus caused by abdominal surgery^{24,25,26,27}). Moreover, in a department of abdominal surgery, *Major Middle-Strengthening Decoction* was administered to facilitate the recovery of intestinal peristaltic, which resulted in a shortening of the hospital stay by several days. Consequently, this is useful in improving cost efficiency.

24) Kubo N., Uchida Y., Akiyoshi T. et al.: Effects of *Major Middle-Strengthening Decoction* on Ileus - Multi-facility study, *Prog. Med.* 15 (9): 1962-1967, 1995

25) Yokota H., Kobayashi H., Kasamaki S. et al.: Research into the Prevention of Postsurgical Adhesive Ileus, *Japan Medical News* 3986: 16-18, 2000

26) Sugiyama M.: Investigation of the Usefulness of *Major Middle-Strengthening Decoction* for Postsurgical Adhesive Ileus, *Prog. Med.* 12: 1668-1372, 1992

27) Furukawa Y., Kawasaki N., Hanyu N.: Effects of *Major Middle-Strengthening Decoction* on Ileus Following Surgery of Alimentary Tract - Basics and Clinics - *Kampo and Advanced Therapies* 12(3): 235-241, 2003

Among the diseases of the anus, hemorrhoids and hemorrhoidal bleeding are indications for Kampo therapy. For hemorrhoids, the preparation "*B*" *Character Decoction*, developed in the 19th century by a Japanese physician, is widely used and there are relevant cumulative studies²⁸). Clinically, depending on the pathologic condition, this is frequently combined with 'activating blood and resolving stasis', 'clearing heat and removing toxins', 'Qi tonifying' and 'upraising' preparations. In puerperal women, attention has to be paid to hemorrhoids that do not improve within one month following delivery. Some cumulative studies show the results of the application of this preparation in such patients²⁹). Conversely, for

pain associated with spasms of the internal sphincter muscle of the anus, *Peony and Licorice Decoction* is administered and, according to a number of studies, produced favorable results³⁰). Moreover, for the treatment of incarceration of hemorrhoids *Ephedra*, *Apricot*, *Licorice and Gypsum Decoction* is used and occasionally has produced dramatic results, but this usage is peculiar to Japan.

28) Yoshio T., Ynagida K., Sumiyama Y. et al.: Clinical Effects of "*B*" *Character Decoction* on Internal Hemorrhoids, *New Drugs and Clinics* 40: 2087-2096

29) Honda T. et al.: Women and Hemorrhoidal Diseases, No. 4 - Effects of Kampo ("*B*" *Character Decoction*) - *Maternal Hygiene* Vol. 31, No. 1, 1990

30) Endo T.: Clinical Results of the Application of *Peony and Licorice Decoction* for Pain Associated with Spasms of the Internal Sphincter Muscle of Anus Due to Anal Laceration, *New Drugs and Clinics* 49: 712-719, 2000

11. Liver, Biliary Tract and Pancreas

Among the lesions of the liver, those associated with icterus used to be major indications for this therapy for diseases like acute hepatitis A and the below described lesions of the gallbladder. Beside these conditions, the final stage of hepatocytic damage liver cirrhosis and a number of complicating conditions were the subject of initial therapeutic attempts. Since therapeutic interventions during the early stages of chronic hepatitis recently became possible, and in conjunction with the progressive clarification of the "state of disease" even for other forms of liver diseases, Kampo therapies using Kampo preparations have been developed. Kampo medicine is frequently used for chronic viral hepatitis, regardless of whether this is hepatitis B or C. Some DB-RCT studies examined the use of *Minor Bupleurum Decoction* for the treatment of hepatitis B and reportedly achieved significantly better results than in the control groups¹). Yet, many physicians do not consider *Minor Bupleurum Decoction* to be the ideal preparation and administer it rather as a decoction that can be freely modified^{2,3,4,5,6}). The other comparatively frequently used extracts include *Modified Merry Life Powder*, *Minor Bupleurum Decoction plus Cassia Twig and Tuckahoe Pill*, *Bupleurum and Cassia Twig Decoction*, *Bupleurum Cassia Twig and Dried Ginger Decoction* and similar preparations. A number of physicians have pointed out that histologically the morphology of hepatitis C differs from that of hepatitis B, and viewed from the standpoint of Kampo medicine, deficiency patterns are more frequent; so that prescriptions vary from those applied for hepatitis B. *Middle-Reinforcing and Qi-Benefiting Decoction*, *Summer Heat-Clearing and Qi-Benefiting Decoction*, *Six Gentlemen Decoction* and similar spleen and stomach tonifying preparations are used^{7,8,9}). Recently, combination therapies using PEG-interferon and ribavirin have become the standard therapy, but available data indicate that a further combination with Kampo medicines achieves better results. There are cumulative studies dealing with interferon combination therapies. Moreover, regarding transition from hepatitis C to liver cirrhosis following an interferon therapy, a number of excellent

studies show significantly better effects than for ordinary liver protective drugs¹⁰⁾.

- 1) Mizuta M., Murata K., Morimoto T. et al.: Evaluation of *Minor Bupleurum Decoction* for the Treatment of Chronic Hepatitis - Investigation Using Single and Double Blinded Studies - Liver, Gallbladder, Pancreas 12(1): 155-168, 1986
- 2) Fujiwara K., Mochida S.: Kampo Therapy for Diseases of the Liver, Gallbladder and Pancreas - Kampo therapy for viral hepatitis - Kampo and Advanced Therapy 5(3): 240-246, 1996
- 3) Itoh T.: Effect of Kampo Treatment on chronic viral hepatitis on the basis of traditional diagnosis, Journal of Traditional Medicines 16(1): 7-14, 1999
- 4) Nakada K., Furue M., Takakuwa H. et al.: Kampo Therapy for Chronic Liver Disorders, Japanese Oriental Medical Journal 33(3): 25, 1983
- 5) Baba H.: Effects of *Modified Merry Life Powder* in the Treatment of Chronic Hepatitis, Kampo Medicine (Jap. Journal of Oriental Medicine) 33(4): 29-34, 1983
- 6) Haimoto H.: New Traditional Chinese Medical Therapies for Chronic Active Hepatitis - Pilot study dealing with detoxification/resolving phlegm/activating blood - Clin. J. Trad. Chin. Med. 16(2): 146-150, 1995
- 7) Ito T., Nagasaka K., Kita T. et al.: Clinical Effects of *Middle-Reinforcing and Qi-Benefiting Decoction* in the Treatment of Patients with Chronic Hepatitis C - Correlation between the presence of Qi deficiency pathology and effectiveness - Kampo Medicine (Jap. Journal of Oriental Medicine) 50(2): 215-223, 1999
- 8) Shimizu H.: Hepatitis C - Concepts and Therapies - Clin. J. Trad. Chin. Med. 15(4): 370-374, 1994
- 9) Kumada H.: Effects of *Minor Bupleurum Decoction* for the Treatment of Hepatitis C Non-responsive to Interferon, Clinics of Adult Diseases 24(8): 1103-1109, 1994
- 10) Nakajima O., Sone Y., Onishi H. et al.: Inhibitive Effects of *Minor Bupleurum Decoction* on the Progression from Hepatitis C to Liver Cirrhosis, Clinics and Research 76(5): 1008-1015, 1999

Regarding autoimmune hepatitis, reports indicated that in individual cases certain ingenious modifications of the prescriptions led to a relief of the symptoms, while the standard therapy with steroids was used more in the sense of a complementary therapy and thus allowed a gradual dose reduction or even interruption of the steroid therapy. Certain cumulative studies document the latter case using *Minor Bupleurum Decoction*, *Poria Powder with Five Herbs*¹¹⁾.

- 11) Masuda A., Kajii N., Omura R. et al.: Therapeutic Effects of *Minor Bupleurum Decoction*, *Poria Powder with Five Herbs* on Autoimmune Hepatitis Regarding Steroid Dose Reduction and Relief of Side Effects - Diagnosis and Therapy 81(4): 911-915, 1993

Fatty liver (both alcoholic and non-alcoholic fatty liver diseases) is caused mainly by alcohol consumption, obesity, diabetes mellitus, hypertriglyceridemia etc. To improve these factors, in particular the fatty liver due to overfeeding, *Major Bupleurum Decoction* was administered and found in cumulative studies to be useful¹²⁾.

- 12) Ishioka T., Miura H., Shinoi T. et al.: Clinical Research into the Effects of *Major Bupleurum Decoction* on Fatty Liver due to Overfeeding, Basics and Clinics: 4425-4431, 1992

Regarding liver cirrhosis, the state of disease in Kampo terms differs for the compensated and decompensated phases, so that the type of preparation varies.

During the compensated phase, the therapy follows the therapy for chronic hepatitis, but fibrosis is here viewed as a manifestation of blood stasis, so that often activating blood and resolving stasis medicinals

are added. The decompensated phase calls mainly for skillful management of water metabolism, requiring foremost combinations of diuretics¹³⁾. In extremely rare cases, administration of large doses of *Poria Powder with Five Herbs* reportedly resulted in the overnight disappearance of large amounts of ascites¹⁴⁾. Moreover, the use of *Poria Powder with Five Herbs* in patients with decompensated liver cirrhosis associated with ascites non-responsive to diuretics, had reportedly been effective in 40% of the patients¹⁵⁾. The above described studies used extracts, but generally decoctions are prescribed for decompensated liver cirrhosis. *Middle-Reinforcing and Qi-Benefiting Decoction*, *Qi-Reinforcing and Middle-Being Healthy Decoction*, *Separate and Reduce Decoction*, *Areca Seed Decoction with Nine Herbs*, *Bolster the Spleen Decoction*, *North Water God Decoction*, *Augmented Five-Ingredient Powder with Poria* and similar formulas are basic preparations. Conversely, cumulative studies showed that treatment with *Ginseng Nutrition Decoction* improved the thrombocytopenia associated with liver cirrhosis.¹⁶⁾

- 13) Okubo H., Amaki S., Fujita S. et al.: Kampo Therapy for Liver Cirrhosis, Kampo and Advanced Therapies 5(3): 247-252, 1996
- 14) Imadaya A. et al.: Elimination of Refractory Ascites Through Sweating - A case treated with large amounts of *Poria Powder with Five Herbs* extracts - Kampo Medicine (Jap. Journal of Oriental Medicine) 32(4): 37-42, 1981
- 15) Takamori S., Furuki T., Miyazaki T. et al.: Investigation of the Usefulness of *Poria Powder with Five Herbs* for the Treatment of Compensated Liver Cirrhosis, Kampo Igaku 13(10): 300-305, 1989
- 16) Iwata K., Kamimura S., Shijo S. et al.: Administration of *Ginseng Nutrition Decoction* for the Treatment of Liver Cirrhosis - In particular regarding the effects on thrombocytopenia, Clinics and Research 72(3): 746-750, 1995

Some research has been done on the inhibition of the progression from liver cirrhosis to liver cancer through administration of Kampo medicines. These studies clearly showed that through the administration of *Minor Bupleurum Decoction* or *Ten Strong Tonic Herbs Decoction* the incidence of liver cancer decreased significantly^{17,18)}. Recent published studies indicated this as a possible mechanism for the functioning of *Minor Bupleurum Decoction* as a radical scavenger.

- 17) Oka H., Yamamoto S., Kuroki T. et al.: Prospective Study of Chemoprevention of Hepatocellular Carcinoma with *Minor Bupleurum Decoction* (Tj-9), Cancer 76(6): 743-749, 1995
- 18) Higuchi K., Watanabe A.: Investigation of the Inhibition of the Progression from Liver Cirrhosis to Liver Cancer Through Administration of *Ten Strong Tonic Herbs Decoction* Methods in Kampo Pharmacology 5: 29-33, 2000

Gallstones, excluding asymptomatic cases, are currently removed by endoscopic cholecystectomy. While today the surgical removal constitutes the general form of treatment, this condition used to be a good indication for Kampo medicine. Even today Kampo medicines are used in some selected cases. *Major Bupleurum Decoction* is a representative preparation and there are 2 cumulative studies dealing with it^{19,20)}. The removal of stones with Chinese medicine is not performed in Japan. Regarding

cholecystitis or choledocholithiasis there are some case reports, but generally these conditions are not considered to be indications for Kampo therapy.

- 19) Shoda J., Matsuzaki, Y., Tanaka N. et al: The inhibitory effects of dai-chai-hu-tang (dai-saiko-tou) extract on supersaturated bile formation in cholesterol gallstone disease. *Am. J. Gastroenterol* 91(4): 828-30, 1996
 20) Fujita K.: Effects of *Major Bupleurum Decoction* for Cholelithiasis Attacks, *Kampo Medicine (Jap. Journal of Oriental Medicine)* 45(2): 411-421, 1994

Among diseases of the pancreas, mild forms of acute pancreatitis are an indication for Kampo medicine, but usually are treated with western medicine, so that there are only few case reports and no cumulative studies. During the intermittent phases of compensated chronic pancreatitis, this condition is frequently treated with Kampo medicine. Yet, there are only a few published studies. Tanaka et al. reported on Kampo therapy used with 62 patients presenting hyperamylasemia, who were suspected to suffer from chronic pancreatitis. Combined efficiency was 38.8%, and among the preparations, *Bupleurum and Cassia Twig Decoction* was used in 15 patients, *Liver-Soothing Decoction* in 16, *Pinellia Heart-Purging Decoction* in 9, *Life-Prolonging Pinellia Decoction* in 6, *Middle-Soothing Powder plus Tuckahoe* in 4, *Nourish the Stomach Decoction with Aucklandia and Amomum* in 5 and *Galanga and Bitter orange Decoction* in 3 patients²¹⁾. The efficacy in this trial was not particularly high, but the trial included mostly patients that had already consulted multiple western medical facilities and for whom Kampo therapy eventually became the final resort. When taking this situation into consideration, the standard results would probably be evaluated higher.

- 21) Nakada K., Hosono Y., Hosono H. et al.: Kampo Therapy of Chronic Pancreatitis, *Kampo Medicine (Jap. Journal of Oriental Medicine)* 36(4): 25-44, 1986

12. Gynecology

Since women have menstruations and give birth, the necessity to comprehend pathologic conditions that differ from those in men has been recognized since ancient times. Traditionally, the *Jin gui yao lue*, compiled by the end of the second century established a specialty of treating women. Later in the "Qian jin fang" (compiled by the middle of the seventh century), the section on gynecology was put at the top of this script. In Japan, this field was separated from other fields since the 15th century and in the first half of the 18th century Genetsu Kagawa (1700-1777) discovered approximately at the same time as the British William Smellie, that the fetus assumes an inverted position within the uterus and developed a large number of innovative techniques and preparations. Current gynecologists and obstetricians still inherit this tradition, skillfully using a small number of Kampo medicines for the relevant therapies. Many of the diseases in this field are indications for Kampo

therapy based on experience.

Regarding abnormal bleeding prior to menopause, Kampo medicines are frequently used for both hypermenorrhea and dysfunctional uterine bleeding. Generally hormone therapy is performed, but specialists also use Kampo therapy either as an adjunctive or independent therapy. There are cumulative studies regarding *Szechwan Lovage Rhizoma, Angelica Root, Ass-hide Glue and Argy Womwwod Leaf Decoction*^{1,2,3)}. Naturally, in the presence of organic disease, modern medical treatment is given priority.

- 1) Iwabuchi S.: Hemostatic Effects of *Szechwan Lovage Rhizoma, Angelica Root, Ass-hide Glue and Argy Womwwod Leaf Decoction* on Dysfunctional Uterine Bleeding, *Kampo Medicine (Jap. Journal of Oriental Medicine)* 50: 883-890, 2000
 2) Hatano K., Terawaki S., Tomonari S.: Hemostatic Effects of *Szechwan Lovage Rhizoma, Angelica Root, Ass-hide Glue and Argy Womwwod Leaf Decoction*, *Medical Journal of the Oita Prefectural Hospital* 14: 95-103, 1985
 3) Inaba Y., Hori S., Hosoi N. et al.: Treatment of Dysfunctional Uterine Bleeding with *Szechwan Lovage Rhizoma, Angelica Root, Ass-hide Glue and Argy Womwwod Leaf Decoction* Extract, *Obstetrics and Gynecology* 8: 825-836, 1983

Premenstrual tension syndrome (PMS) is a good indication for Kampo therapy. Presenting as a typical pattern of Qi stagnation and blood stasis, treatment with Kampo medicine has already developed into a standard⁴⁾. The representative preparation *Modified Merry Life Powder* is frequently used, while *Angelica and Peony Powder, Cassia Twig and Tuckahoe Pill, Warm the Menses Decoction and Goddess Powder* are also widely used.

- 4) Ushiroyama T.: Kampo Therapy for Dysmenorrhagia and Premenstrual Syndrome, *Kampo Therapeutic Manual for Physicians Specializing in Gynecology (Nagai Publications)*: 56-59, 2003

Dysmenorrhagia is almost always associated with Oketsu (blood stasis) so that blood activating and stasis resolving medicinals are used in relevant prescriptions. *Cassia Twig and Tuckahoe Pill* is a frequently used preparation and besides this, *Peach Kernel Purgative Decoction, Negotiation Decoction, Modified Merry Life Powder* and similar preparations are also widely used. When channel warming and cold dispelling (Onkei Sankan) is required, *Evodia, Fresh Ginger plus Chinese Angelica Cold Limbs Decoction* or *Middle-Soothing Powder* may be considered. *Middle-Soothing Powder* is reportedly very effective for menorrhagia associated with marked stomach cold affecting the entire body. In cases of blood deficiency, *Angelica and Peony Powder*, or for spleen deficiency *Minor Middle-Strengthening Decoction* or else *Angelica Middle-Strengthening Decoction* are commonly used. As a special use, the short-term administration of *Cassia Twig and Tuckahoe Pill* during menstruation has been recommended and produced favorable results⁵⁾. Moreover, research conducted in recent years clearly showed that *Peony and Licorice Decoction* inhibits the prostaglandin

production, so that attempts have been made to administer this preparation in synchronization with the menstrual cycle⁶⁾. Secondary dysmenorrhea, due to endometriosis or submucosal myomata, is also a good indication for Kampo therapy, but often the western medical treatment receives priority.

5) Ota H., Tanaka T., Kushima T.: Short-term Administration of *Cassia Twig and Tuckahoe Pill* During Menstruation for the Treatment of Dysmenorrhea, *Progress of Kampo Research in Gynecology and Obstetrics* 17: 48-50, 2000

6) Imai A, Ito M., Tamaya T.: Mechanisms of the Inhibition of Prostaglandin Production by *Peony and Licorice Decoction*, *Kampo Igaku* 20: 218-221, 1996

Regarding irregular menstruation *Cassia Twig and Tuckahoe Pill*, *Peach Kernel Purgative Decoction* and similar blood activating and stasis resolving preparations are widely used. In addition, *Modified Merry Life Powder* and like Qi stagnation blood stasis formulas, blood tonifying preparations like *Four Herbs Decoction*, *Evodia*, *Fresh Ginger plus Chinese Angelica Cold Limbs Decoction*, *Aconite and Ginseng Decoction* and the like Yang tonifying and cold dispelling prescriptions, Qi mobilizing drugs like *Pinellia and Magnolia Decoction*, *Cyperus and Perilla Leaf Powder* or else heat clearing preparations like *Coptis Detoxifying Decoction* or *Three Huang Heart-Clearing Decoction with Three yellow color Herbs* also find, their application depending on the presenting pattern. In this area Kampo medicines are prescribed as a standard therapy^{7,8)}.

7) Kawakami S., Umeki M., Ikuta Y. et al.: Kampo Therapy in our Clinic and its Effects on Irregular Menstruations, *Progress of Kampo Therapy in Gynecology and Obstetrics* 21: 52-56, 2004

8) Ushiroyama T.: Kampo Knowledge for Gynecologists and Obstetricians, 6. Kampo Therapy and relief from irregular menstruation (General Remarks)

Smooth muscle myoma uteri is the most frequently observed benign tumor of the female genitalia and there are many reports about its treatment with Kampo medicine^{9,10,11)}. The question whether the myoma can be reduced in size using Kampo medicine is very important and there have been several related studies. Inoue et al. used *Cassia Twig and Tuckahoe Pill* and measured the size of the myoma with ultrasound. A number of studies reported the relevant ratios of size reduction^{12,13)}.

9) Sakagami S.: Myoma Uteri, *Gynecology and Obstetrics* 42: 79-91, 1990

10) Aiba S.: Is Kampo Effective? *Gynecology and Obstetrics* 45: 1192-1193, 1991

11) Dozono H.: Kampo Therapy of Myoma Uteri, *Gynecology and Obstetrics* 71: 669-672, 1995

12) Inoue S., Nakada M., Kataoka Y. et al.: Investigation of the Myoma Uteri Size Reducing Effect of *Cassia Twig and Tuckahoe Pill* Measured with Ultrasound, *Progress of Kampo Research in Gynecology and Obstetrics* 14: 59-62, 1997

13) Inoue S., Nakada M., Kataoka Y. et al.: Investigation of the Myoma Uteri Size Reducing Effect of *Cassia Twig and Tuckahoe Pill* Measured with Ultrasound (second report), *Progress of Kampo Research in Gynecology and Obstetrics* 15: 57-62, 1997

Endometriosis is frequently identified as the cause for abnormal bleeding or secondary dysmenorrhea and Kampo therapy is often attempted. The administration of *Cassia Twig and Tuckahoe Pill* for the purpose of avoiding surgery has been reported¹⁴⁾.

14) Tanaka T.: Effectiveness of *Cassia Twig and Tuckahoe Pill* Extract Tablets Administered with the Purpose of Avoiding Surgery in Endometriosis like Diseases, *WE No. 4*: 7-8, 2003

Several clinical reports deal with ovarian insufficiency. Studies in which *Angelica and Peony Powder* was administered to all patients with ovarian insufficiency showed a tendency towards increasing concentrations of estrogen and progesterone during the luteal phase¹⁵⁾. Patients with various ovarian disorders were treated either with clomiphene alone (52 patients) or a combination therapy of clomiphene and *Angelica and Peony Powder* (41 patients) and led to the publication of highly interesting results¹⁶⁾. Moreover, when 34 patients with polycystic ovarian syndrome (PCOS) presenting hypertestosteronemia were treated with *Angelica and Peony Powder*, a reduction in testosterone levels was reported for 30 (91%) of these patients¹⁷⁾.

15) Koyama T, Ohara M, Ichimura M. et al.: Effect of Japanese Kampo medicine on hypothalamic-pituitary-ovarium function in women with ovarian insufficiency, *Am J Chin Med*, 16: 47-55, 1988

16) Yasui T., Kahara M., Aono T. et al.: Investigation of the Efficacy of a Combination Therapy of Clomiphene and *Angelica and Peony Powder* in Patients Without Ovarian Disorders, *Journal of the Japan Society of Infertility* 40: 83-91, 1995

17) Takahashi K., Kitao M.: Polycystic Ovarian Syndrome (PCOS) and Kampo, *Gynecology and Obstetrics* 42: 201-208, 1990

Patients non-responsive to western medical therapies for infertility are treated with Kampo medicines, which often successfully lead to pregnancies. Generally, *Angelica and Peony Powder*, *Cassia Twig and Tuckahoe Pill*, *Peach Kernel Purgative Decoction*, *Warm the Menses Decoction*, *Modified Merry Life Powder*, *Minor Middle-Strengthening Decoction*, *Ten Strong Tonic Herbs Decoction* and similar preparations are used. Infertility in patients with hypertestosteronemia or hyperprolactinemia is treated with *Peony and Licorice Decoction*, which reportedly leads to a significant reduction in the concentration of both hormones^{18,19)}. Moreover, in patients with antibodies against sperm, treatment with *Minor Bupleurum Decoction*, *Poria Powder with Five Herbs* has been reported²⁰⁾. Please refer to the section on urogenital diseases regarding male infertility.

18) Yanaginuma T., Okamura T., Takeuchi T. et al.: Blood Androgen Concentration Lowering Effects of *Peony and Licorice Decoction* in Women with Hypertestosteronemia, Ovulation inducing effects and safety - multi-facility joint study, *Journal of the Japan Society of Infertility* 33: 606-616, 1988

19) Ito N., Omi Y., Inazawa N. et al.: Experiences with *Peony and Licorice Decoction* in Women with Latent Hyperprolactinemia, *Practice of Gynecology and Obstetrics* 49: 1161-1164, 2000

20) Kano T., Furudo M., Okuyama K. et al.: Causes of Infertility in our Clinic and Analysis of Treatment Results Obtained Mainly with *Minor Bupleurum Decoction*, *Poria Powder with Five Herbs*, *Japan Infertility Journal* 38: 671-679, 1993

Generally, menopausal syndrome is treated with hormone therapy, but many physicians also consider Kampo medicine to be a treatment of first choice. According to an investigation by Margaret Lock, there

are major differences between symptoms reported by Americans and Europeans on the one hand and Japanese women on the other. Japanese women allegedly suffer from a greater variety and more severe symptoms²¹. This is an appropriate view and in Japan there is abundant experience with the application of Kampo medicines that are used for very minutely tuned treatments²². For hot flashes, *Modified Merry Life Powder*, *Coptis Detoxifying Decoction*, *Bupleurum plus Dragon's Bone and Oyster Shell Decoction*, *Bupleurum Cassia Twig and Dried Ginger Decoction*, *Warm the Menses Decoction* and similar preparations, as well as for numerous indefinite complaints other than the above listed formulas. Drugs like *Pinellia and Magnolia Decoction*, *Cyperus and Perilla Leaf Powder*, *Tangerine Peel*, *Pinellia Rhizoma plus Liver-Inhibiting Powder*, *Cold Limbs Powder*, *Goddess Powder*, *Modified Back to the Spleen Decoction*, *Uncaria Powder* etc. are also selected depending on the presenting pattern. There are also a number of clinical studies^{23,24,25,26,27,28,29,30}. The osteoporosis associated with menopause is basically considered to be a kidney deficiency and thus treated using *Kidney Qi Pill*, *Six Ingredient Pill with Rhemannia* and similar preparations³¹. One report states that *Kidney Qi Pill* is effective for the treatment of senile vaginitis³².

- 21) Lock M.: Mythologies of Menopause in Japan and North America 1993
- 22) Ushiroyama T.: Kampo Therapy for Climacteric Disorders, Kampo Therapeutic Manual for Physicians Specializing in Gynecology (Nagai Publications): 50-55, 2003
- 23) Maruo T., Katayama K., Mochizuki M. et al.: Kampo Therapy for Climacteric Disorders - in particular examination of the usefulness of *Cassia Twig and Tuckahoe Pill*, Gynecology and Obstetrics 45: 167-176, 1993
- 24) Morioka N., Wakatsuki A., Sagara Y. et al.: Effects of *Modified Merry Life Powder* on Climacteric Disorders, Progress of Kampo Research in Gynecology and Obstetrics 12: 79-85, 1993
- 25) Koyama T., Aso T.: Kampo Therapy for Women in Effulgent Fire Age, Evaluation using simplified climacteric indices, Progress of Kampo Research in Gynecology and Obstetrics 9: 30-34, 1992
- 26) Tamaya T., Ito M., Ito T.: Unidentified Clinical Syndrome, in Particular Investigation of the Usefulness of Kampo Preparations for Climacteric Disorders (*Bupleurum Cassia Twig and Dried Ginger Decoction*, *Modified Merry Life Powder*, *Bupleurum plus Dragon's Bone and Oyster Shell Decoction*), Kampo Medicine (Jap. Journal of Oriental Medicine) 44: 71-81, 1994
- 27) Nishimura K., Umekawa T., Kanazawa K. et al.: Experiences with *Uncaria Powder* for the Treatment of Climacteric Disorders, Progress of Kampo Research in Gynecology and Obstetrics 17: 125-127, 2000
- 28) Chimura T., Nakahara K., Miyata R. et al.: Clinical Effects of *Modified Merry Life Powder* on Indefinite Complaints During Climacteric Disorders, Medical Care and New Drugs 27(11): 18-24, 1990
- 29) Chimura T., Koseki K., Sanjo N. et al.: Clinical Effects of *Modified Merry Life Powder* on Indefinite Complaints During Climacteric Disorders (II), Medical Care and New Drugs 29(3): 145-151, 1992
- 30) Sagara Y., Morioka N., Wakatsuki A.: Experiences with *Modified Merry Life Powder* for the Treatment of Climacteric Disorders - In particular regarding evaluation methods of combinations of subjective and objective symptoms - Gynecology and Obstetrics 60(2): 290-296, 1993
- 31) Ushiroyama T.: Kampo Therapy of Elderly Women - Urinary incontinence, arteriosclerosis, osteoporosis - Kampo Therapeutic Manual for Physicians Specializing in Gynecology (Nagai Publications): 89-94, 2003
- 32) Inoue S., Ueno T., Kusanishi H. et al.: Therapeutic Effects of *Six Gentlemen Decoction* on Senile Vaginitis, Progress of Kampo Research in Gynecology and Obstetrics 17: 140-145, 2000

13. Obstetrics

Medical questions related to pregnancy and childbirth have since ancient times been discussed separate from other issues. In medical schools established in the 8th century, women specialists were trained in this field. Since the 15th century, obstetrics was separated from the other medical specialities and relevant specialists engaged in comparatively high levels of medical practice. Marked progress was achieved after the emergence of the aforementioned Kanetsu Kagawa in the 18th century.

Pregnancy is associated with various disorders that are treated with Kampo medicines¹. For example, for the treatment of the common cold during pregnancy, *Cyperus and Perilla Leaf Powder* or *Cassia Twig Decoction* are used instead of modern prescriptions. *Minor Pinellia Decoction plus Tuckahoe* or *Pinellia and Magnolia Decoction* have been used for morning sickness. Cough during pregnancy has been treated with *Dwarf Lilyturf Decoction*. *Angelica and Peony Powder* is administered by Japanese physicians to ensure an uneventful pregnancy and Nakata et al. reported "its administration during pregnancy resulted in a 100% safe delivery ratio"². They also reported that for "patients visiting our clinic because of their inability to conceive or the occurrence of spontaneous abortions early after conception, e.g., patients with so-called "habitual abortion", *Angelica and Peony Powder* is extremely effective, so that 4 out of 5 patients were safely able to conceive and deliver a child". Also, due to its inhibition of uterine contractions, this preparation is expected to be effective for the treatment of threatened abortion³.

Therapeutic attempts have been made with Kampo medicine for Preeclampsia. The results of observations of the effect of *Angelica and Peony Powder* in 5,000 pregnant women reported by Noguchi et al. showed that in the treatment group the incidence of preeclampsia decreased significantly⁴. Kampo medicines, including mainly diuretic preparations, will be helpful for the prevention of this condition.

Szechwan Lovage and Angelica Decoction for Regulating Blood Flow is used to regulate the physical condition following delivery. This preparation, with its blood activating and stasis resolving properties, was developed by a famous physician in China of the Ming period to treat various postpartum symptoms. Later this concept was inherited in Japan and thus led to its present use. There are a number of case reports⁵.

- 1) Ushiroyama T.: Pregnancy and Kampo, Kampo Therapeutic Manual for Physicians Specializing in Gynecology (Nagai Publications) P50-55, 2003
- 2) Nakata K., Yamaoka K., Konishi E. et al.: Clinics of *Angelica and Peony Powder*, Kampo Medicine (Jap. Journal of Oriental Medicine) 28(3): 101-107, 1978

- 3) Chimura T. et al.: Effects of Treatment with *Angelica and Peony Powder* for Threatened Abortion, *Gynecology and Obstetrics* 41(8): 722-731, 1989
- 4) Noguchi K.: Investigation of Patients with Preeclampsia Over the Past 10 Years in our Clinic, in particular regarding the administration of Kampo medicine and maternal classes, *Jap J Prim Care* 8: 131-133, 1985
- 5) Kiuchi C.: Case Report: *Szechwan Lovage and Angelica Decoction for Regulating Blood Flow*: The Kampo for the Practical Physician, No. 6: 11-13, 2000

14. Arthritis and Musculoskeletal Disorders

Many of these disorders are associated with pain. Among patients consulting medical facilities specializing in Kampo therapy, the most frequent complaint is pain associated with the locomotor system. The cervical syndrome, peri-arthritis humeroscapularis (frozen shoulder), low back pain, sciatica, gonarthrosis and similar disorders are all good indications for acupuncture therapy and equally good indications for Kampo therapy.

Osteoarthropathy (osteoarthritis) is in daily life a commonly observed disorder. Among the patients seeking Kampo therapy, gonarthrosis is the most frequent disorder and represents, unless the deformity has reached a rather extreme degree, a good indication for Kampo therapy^{1,2)}. The nature of this disorder in the initial phase is mainly a dysregulation of water metabolism, so that treatment results with preparations suitable for the presenting pattern, even if it is associated with the development of hydrarthrosis, are comparatively good. *Cassia Twig plus Yu Bi Decoction* and *Stephania and Astragalus Decoction* are widely used preparations and often rather effective. A number of cumulative studies dealing with *Stephania and Astragalus Decoction* show that the addition of Hobushi (prepared aconite tuber) powder apparently improved the efficacy³⁾. Cumulative studies about *Yue Bi Decoction for Relieving Edema plus Atractylodes* showed significant improvements in clinical findings and results of synovial fluid examinations of patients presenting with local heat sensation, swelling and tenderness of the joints⁴⁾. When these diseases run a somewhat protracted course, blood stasis develops and thus makes blood activating and stasis resolving preparations like *Cassia Twig and Tuckahoe Pill*, *Szechwan Lovage and Angelica Decoction for Regulating Blood Flow* necessary⁵⁾. In case of severe pain, aconite tuber is added.

When the disease has been present for a certain period and is associated with severe deformations, acupuncture treatment or blood letting is used concomitantly. Naturally, inclusion of these treatment forms is recommended right from the beginning.

- 1) Nagao K.: *Comprehensive Oriental Medical Therapy of Gonarthrosis, Kampo and Most Advanced Therapies* 5(4): 343-348, 2000
- 2) Nishizawa Y., Nishizawa K., Amenomori Y. et al.: Analgesic Effects of Anti-inflammatory drugs and Kampo Preparations for Bilateral Gonarthrosis - Comparison of the capability for continuous locomotor function and improvement of the quality of life, *Pain and Kampo Medicine* 8: 17-32, 1998

- 3) Otani T., Matsumoto H., Kawakubo M. et al.: Clinical Effects of *Stephania and Astragalus Decoction* on Gonarthrosis, *Journal of the Tokyo Knee Society, The Tokyo Journal of Knee Joint* 18: 31-33, 1998
- 4) Sugiyama S.: Effects of *Yue Bi Decoction for Relieving Edema plus Atractylodes* for Gonarthrosis, *Kampo Medicine (Jap. Journal of Oriental Medicine)* 48(3): 319-325, 1997
- 5) Matsumoto K.: Explanation of Kampo Preparations, *Szechwan Lovage and Angelica Decoction for Regulating Blood Flow* - First modification - On Blood Stasis, *Oriental Medicine* 8(6)

The use of *Stephania and Astragalus Decoction* in patients in whom hydrarthrosis developed following surgical removal of the lateral meniscus under orthoscopic observation reportedly led to favorable results⁶⁾.

- 6) Otsuka K.: Effects of *Stephania and Astragalus Decoction* in Patients After Knee Surgery, *Kampo Igaku* 25(1): 15-17, 2005

Among the crystal arthropathy forms, gout is the disease that is most frequently observed. Kampo therapy is somewhat effective for acute attacks. The pathology is viewed as damp heat and the preparations *Yue Bi Decoction for Relieving Edema plus Atractylodes* and *Gentian Liver-Purging Decoction* are widely used for this condition. In case of severe pain the treatment is combined with western medical measures, but the independent use of Kampo is quite effective and it remains useful even after the most severe pain has subsided. Continuous use of the preparation therefore, provides comparatively quick relief of both swelling and pain. Currently, no preparations have been reported, that would be able to definitively decrease the hyperuricacidemia. Yet, there are some theoretical hypotheses and a few case reports.

Neck pain is a frequently observed condition among the pain syndromes. In Japan, this is often called the cervical syndrome. Chronic neck pain in most cases is caused by osteoarthropathy and is generally subject to conservative therapy. Yet, this is a good indication for acupuncture therapy. With this treatment modality, pain is frequently relieved after short treatment periods.

Kampo therapy appears to be extremely useful. The muscles of the neck and shoulder are associated with the greater and brighter yang areas, so that *Pueraria Decoction* by itself may be used to improve pathologic conditions in these regions. Modifications obtained by addition of Sojutsu or Bushi are also frequently used. Nishina administered *Pueraria Decoction* to a total of 78 patients, including 41 patients with cervical spondylosis, 31 patients with cervical syndrome, 3 trauma patients and 3 patients with other conditions and reported, that under suitable conditions the treatment was effective in two thirds of the patients⁷⁾. Beside from *Pueraria Decoction*, *Cassia Twig Decoction plus Atractylodes and Aconite*, *Channels-Dredging and Blood-Activating Decoction*, *Swordlike Atractylodes and Largehead*

Atractylodes Decoction, *Coix Seed Decoction* and similar preparations are also used.

7) Nishina F: *Pueraria Decoction* and the Pulse in Orthopedic Diseases, *Kampo Therapy* Vol. 4, No. 3: 48-50, 1985

Reference

Although almost unnoticed in America and Europe, "stiff shoulders" is an extremely important symptom in Japan. An often asked question is, whether the concept of "shoulder stiffness" is prevalent in Japan. Numerous works deal with this symptom and researchers like Kuriyama have discussed this from a historical point of view, which is of great interest from the perspective of current Kampo medicine⁸⁾. In modern Japan this symptom frequently observed in daily practice is not a disease, but still disturbs daily life. Many researchers also view this condition as the preliminary stage for the development of other diseases. For example, the associated symptom of hypertension, one of the symptoms preceding stroke (when the muscles of the neck stiffen, this may interfere with the blood flow from the neck and thus lead to congestion of cerebral venous system and thus eventually to vessel rupture). Treatment of shoulder stiffness associated with cervical syndrome may help to improve the aforementioned conditions, so that this is a very important symptom. Naturally, acupuncture treatment and blood letting can provide instant relief, but Kampo medicine can be very effective too. The most commonly used preparation is *Pueraria Decoction*. A number of studies have thermographically investigated the effect of this formula on shoulder stiffness⁹⁾.

8) Kuriyama S.: Reflections on Shoulder Stiffness, edited by Yamada, Kuriyama: Disease and Medicine in History, 37-62, Shibunkaku Publications 1997

9) Yakubo S., Komaki K., Yagi H. et al.: Improvement of *Shoulder Stiffness* Using *Pueraria Decoction* and Thermographic Investigations, *Kampo Medicine (Jap. Journal of Oriental Medicine)*. 47(5): 795-802, 1997

Whiplash injuries are a relatively common trauma of the neck. If the initial treatment is not successful, it may result in a protracted course of the condition which consists of a mixture of psychosomatic symptoms that may prove to be difficult to heal. There are a number of good Kampo preparations for this condition. During the acute phase, the conditions are considered to be characterized by blood stasis. In order to expel the formed blood stasis from the body, preparations also including cathartics like *For Contusion Decoction* or *Dreging and Dissipating Powder*, are used. The chronic phase is considered to be characterized by Qi stagnation and blood stasis and thus *Modified Merry Life Powder* is used. When dampness accumulates within the muscles of the neck, preparations like *Pueraria Decoction*, *Cassia Twig Decoction plus Atractylodes and Aconite* or *Swordlike Atractylodes and Largehead Atractylodes Decoction* are used.

Scapulohumeral periarthritis (frozen shoulder) is a fairly common condition among Japanese and most are probably due to disorders of the rotator cuff. It occurs comparatively frequently in both men and women over the age of 40. Based on the age of onset, the condition is popularly called "50-year-old Shoulder" (pain in the shoulders around the age of 50). This too is a good indication for acupuncture treatment and can

effectively be supplemented by Kampo medicine¹⁰⁾. For neck pain preparations like *Pueraria Decoction plus Atractylodes and Aconite*, *Cassia Twig Decoction plus Atractylodes and Aconite*, *Swordlike Atractylodes and Largehead Atractylodes Decoction* or *Coix Seed Decoction* are used. For cases of long standing, the presence of blood stasis is considered, so that the aforementioned drugs are used in combination with blood activating and stasis resolving preparations like *Cassia Twig and Tuckahoe Pill*.

10) Ogawa H.: Scapulohumeral Periarthritis and Cervical Spondylosis, *Kampo and Most Advanced Therapies*, 9(3): 229-234, 2000

For low back pain, acupuncture is the treatment of first choice and supplemented by Kampo medicine; but the latter is also very effective by itself. Yet, both effectiveness and the choice of preparations vary depending on the etiology^{11,12)}. Even in cases of herniation of a lumbar intervertebral disk associated with radicular pain, treatment with Kampo medicine may help to alleviate the symptoms. Among extract preparations, *Cassia Twig and Tuckahoe Pill*, *Evodia, Fresh Ginger plus Chinese Angelica Cold Limbs Decoction*, *Kidney Qi Pill*, *Channels-Dredging and Blood-Activating Decoction*, *Powder for Five Kinds of Stagnations* etc. and among the decoctions *Yin-Tonifying Decoction*, *Angelica Pubescens and Sanjisheng Decoction* and similar preparations are used. In cases of severe pain, the addition of aconite tuber may be required.

11) Fukuda Y.: Kampo Therapy for Low Back Pain and Lumbar Spondylosis, *Kampo and Most Advanced Therapies* 5(4): 359-362, 1996

12) Shirafuji T.: Kampo Therapy for Neuralgia (including herpes zoster), *Modern Oriental Medicine* 14(2): 35-39, 1993

For the treatment of low back pain due to lumbar spinal canal stenosis, *Kidney Qi Pill* has been used and cumulative studies showed an efficacy of 68%, while similar cumulative studies with *Life-preserving Kidney-Qi Pill* showed an efficacy of 55%, thus a high efficacy for either of these formulas^{13,14)}.

13) Hayashi Y., Saito E., Takahashi O.: Usefulness of *Kidney Qi Pill* for the Treatment of Lumbar Spinal Canal Stenosis *Geriatr. Med.* 32(5): 585-591, 1994

14) Yamagami H., Hashizume K., Sakamoto T. et al.: Effects of *Life-preserving Kidney-Qi Pill* in the Treatment of Lumbar Radicular Pain - with particular focus on variations in subjective and objective symptoms, *Pain and Kampo* 7: 25-28, 1997

The concept of autoimmune disease did not exist in TCM. Yet, for articular rheumatism, a representative disease of this group, many therapies have been devised. The other forms of connective tissue diseases were almost not recognized and probably only individual symptoms were dealt with. Currently, better therapies for these diseases are available than before.

Rheumatoid arthritis (RA) is a disease for which Kampo offers hope. This disease includes various types, stages and grades. Based on these, the prognosis changes, Kampo therapy is particularly effective

during the initial stages of RA. Early diagnostic criteria for ARA showed that the probability for people who were suspected of having RA, the number of patients in a Kampo treatment group (in whom the diagnosis of RA was definitely established) after several years, reportedly appeared to be lower than in a group of patients not treated with Kampo¹⁵. Besides this report, there is an abundance of other reports that also provide similar suggestions^{16,17,18}.

Traditionally, the symptoms of RA are considered to be due to the intrusion of the three evils wind, cold and dampness in the body. Clinically, these symptoms also include a feeling of heat in the joints, so that the symptoms are also often viewed as heat symptoms. Choice of the prescription has to be modified depending on the degree of pain, heat sensation and the general condition. For the therapy, basic preparations like *Cassia Twig Decoction plus Atractylodes and Aconite*, *Cassia Twig Peony*, and *Anemarrhena Decoction*, *Two-parts Cinnamon Twig Decoction* and *One-part Maidservant from Yue Decoction*, *Stephania and Astragalus Decoction*, *Disband Painful Obstruction Decoction* are used and then modified depending on the relevant considerations of cold and heat factors. Usually this disease can not be properly treated with extracts, so that many physicians use the corresponding decoctions. In particular, the skillful application of *Wild Aconite Tuber* constitutes a key point of the therapy and specialized physicians conduct the therapy by exactly controlling the amount of alkaloids like aconitine and mesaconitine. Some RA case reports have described dramatic improvements by using formulas containing comparatively large amounts of *Wild Aconite Tuber*¹⁹. There are some cumulative studies dealing with *Minor Bupleurum Decoction*, *Poria Powder with Five Herbs* or *Stephania and Astragalus Decoction*^{20,21,22}.

- 15) Ebe K.: New Cases of Chronic Rheumatoid Arthritis, Investigation of 10 cases, *Phi tau o* 1(4): 4-12, 2001
- 16) Haimoto H.: Recent Situation Regarding Chronic Rheumatoid Arthritis, *Clin. J. Trad. Chin. Med.* 18(4): 370-381, 1997
- 17) Fukuda Y.: 54th Academic Conference of the Japan Society of Oriental Medicine, Academic Symposium: Kampo Therapy for Rheumatoid Arthritis, 1. Probing the possibilities of Kampo preparations, *Kampo Medicine (Jap. Journal of Oriental Medicine)* 54(6): 1064-1067, 2003
- 18) Nagasaka K., Hikiami H., Tatsumi T. et al.: Examination of 43 Patients with Chronic Rheumatoid Arthritis, *Kampo Medicine (Jap. Journal of Oriental Medicine)* 51(2): 241-246, 2000
- 19) Furuta K., Mitsuma T., Shintani T. et al.: Three Cases of Dramatic Improvements Associated with Poisoning Symptoms Using Uzu Containing Preparations, *Kampo Medicine (Jap. Journal of Oriental Medicine)* 50(2): 247-255, 1999
- 20) Matsuura M.: Effects of *Minor Bupleurum Decoction*, *Poria Powder with Five Herbs* in the Treatment of Chronic Rheumatoid Arthritis (RA), Recordings of the 10th Clinical Wakan Yaku Research Group Modern Physician, 14: 403-408, 1994
- 21) Borijini, M. J. et al: TJ-114(*Minor Bupleurum Decoction*, *Poria Powder with Five Herbs*), an herbal medicine in rheumatoid arthritis. A preliminary "go-no go" clinical trial. *J. Clin.Rheumatol* 2: 309-316, 1996
- 22) Tanaka M., Ono S., Suzuki T. et al.: Usefulness of *Stephania and Astragalus Decoction* for the Treatment of Chronic Rheumatoid Arthritis, *Journal of the Japan Society of Oriental Medicine* 40: 73-77, 1989

Regarding other connective tissue diseases like SLE, PSS or SSc, Kampo therapy is added to the respective western medical therapies, but so far there are only a few reports^{23,24,25}.

- 23) Ono S.: Kampo Therapy for Systemic Lupus Erythematoses, *Kampo and Most Advanced Therapies* 2(4): 333-339, 1993
- 24) Imadaya A.: Withdrawal from Steroid Therapy Facilitated by Kampo Therapy, a case of Long-term Remission in a Patient with Systemic Lupus Erythematoses, *The Journal of Traditional Sino-Japanese Medicine* 104, 1989
- 25) Matsuda K.: Therapeutic Guidelines for Kampo Health Care Services, Progressive Systemic Scleroderma (PSS), revised edition (Organization: Japan Society of Oriental Medicine): 199-202, 1993

Behcet's disease, with its aphthous ulcers of the oral mucosa, genital ulcers and skin symptoms, can be sufficiently treated with Kampo medicine and is thus a comparatively good indication for this treatment modality. Generally, *Warming and Clearing Decoction*, *Ten Strong Tonic Herbs Decoction*, *Modified Merry Life Powder* and similar preparations are used. For the oral lesions, *Coptis Detoxifying Decoction* or *Licorice Decoction* are taken into the mouth, in such a way that the drugs come in contact with the affected sites before swallowing. For *Warming and Clearing Decoction* there are placebo controlled clinical trials and case series studies^{26,27}.

- 26) Kaneko F.: *Warming and Clearing Decoction* for the Treatment of Behcet's Disease, *Prog. Med.* 6: 384-386, 1986
- 27) Hashimoto T., Takeuchi A., Mori S. et al.: Clinical Effects of *Warming and Clearing Decoction* for the Treatment of Behcet's Disease, *Therapy and New Drugs* 20(10): 2283-2285, 1983

Kampo therapy has also been tried for the treatment of Sjögren's syndrome, for dryness of the oral cavity and the eyes. Basically, dryness is considered to be due to a lack of fluids and therefore Yin tonifying formulas are administered. *Dwarf Lilyturf Decoction*, *Ginseng Nutrition Decoction*, *Bupleurum Cassia Twig and Dried Ginger Decoction* and similar preparations are comparatively well used. There are comparative trials and case series studies using *Dwarf Lilyturf Decoction*, as well as multi-center case series studies using *Ginseng Nutrition Decoction*^{28,29,30}.

- 28) Ono S., Suzuki T., Doi Y.: Effects of *Dwarf Lilyturf Decoction* on Disorders of Saliva Secretion in Sjögren Syndrome, *Rheumatism* 30: 10-16, 1990
- 29) Tonotsuka N., Abe M., Tahara K. et al.: Effects of *Dwarf Lilyturf Decoction* on Dryness of the Eyes in Sjögren's Syndrome, *Journal of the Society for Wakan Yaku* 6: 436-437, 1989
- 30) Yokohari R., Kishimoto S., Tanimoto K. et al.: Clinical Effects of *Ginseng Nutrition Decoction* (EK-108) on Dryness of the Eyes and the Oral Cavity in Sjögren's Syndrome, *Clinical Medicine and Pharmacology* 9: 1959-1968, 1993

15. Kidney

Kidney diseases are often associated with edema. Yet, examination of literature older than 100 years, makes the distinction of whether the edema mentioned in the relevant works is due to cardiac or renal diseases difficult. Naturally, at that time, the histologic identification of the lesions had not yet been possible so that application of records of those days to

current clinical practice, with a few exceptions, is difficult. On the other hand, there is a growing trend in recent years to apply the data of hematologic examinations and histopathologic findings to Kampo clinical practice.

Chronic renal diseases remain difficult to treat with western medicine and in the end have to rely on dialysis. Kidney transplantations are performed in Japan, but the number of cases is small. A variety of different approaches to these diseases using Kampo therapy have been attempted, and among these, some epoch-making forms have received considerable public attention. Yet, for these attempts, no extracts were used. Rather large amounts of crude drugs were selectively administered in special treatment forms.

First, it has been proven that creatinine levels decrease in response to treatment with large amounts of astragalus(milk-vetch) root. Haimoto discovered during the treatment of several patients with chronic renal insufficiency that among numerous crude drugs, astragalus root is independently capable of decreasing the creatinine level¹⁾. Moreover, treatment results indicated that efficacy improves even further by adding red peony root. Conversely, Ebe devised, based on his own original theory and again centering on astragalus root formulations, a mixture made up of different crude drugs (red peony root, rhubarb rhizoma, trichosanthes seeds, pinellia tuber) with similar effects and has already used this formula for several dozens of patients^{2,3)}. Among these there is a substantial number of patients in whom the start of the dialysis treatment could be significantly delayed or else the frequency of the required dialysis sessions decreased.

The findings obtained from these studies indicated that rhubarb apparently decreased BUN and creatinine^{4,5,6,7)}. According to relevant clinical and experimental research, these effects have been verified. Traditionally, *Poria Powder with Five Herbs, Separate and Reduce Decoction, Bolster the Spleen Decoction, Middle-Reinforcing and Dampness-Removing Decoction*, and similar preparations have been used as diuretics. With a few exceptions, sufficient efficacy was observed only in rare cases. In recent years, based on Chinese experiences, the combination of Houttuynia herb, astragalus radix and imperatae rhizoma has proven to be effective. Recent follow-up studies from Japan yielded similar results. This drug mixture too is used as a decoction and appears to be effective⁸⁾.

Kampo medicine can be used for various conditions in dialysis patients. For example, *Warming and Clearing Decoction* is administered for dermal pruritus developing in patients undergoing dialysis and its efficacy has been shown in case studies⁹⁾. *Peony and Licorice Decoction* is administered for muscle cramps and case studies¹⁰⁾ have shown an efficacy of 88.5%. Case studies regarding the use of *Minor Bupleurum Decoction plus Poria Powder with Five Herbs* for

osteoarthritis related to dialysis^{11,12)} have shown an efficacy of 61%. In any case, the usefulness of Kampo medicines was very good.

- 1) Haimoto H.: Efficacy of Astragalus Root in Decreasing Serum Creatinine Levels in Chronic Renal Failure, *Φ υ τ ο* 7(1): 4-9, 2005
- 2) Hashimoto M., Ebe Y.: Kampo Therapy for Chronic Renal Failure (1) *Clinical Journal of Traditional Chinese Medicine* 25(4): 482-487, 2004
- 3) Hashimoto M., Ebe Y.: Kampo Therapy for Chronic Renal Failure (1) *Clinical Journal of Traditional Chinese Medicine* 26(1): 88-94, 2005
- 4) Oura H., Yokozawa T.: Pharmacologic Action and Effects of Rhubarb The *Journal of Traditional Sino-Japanese Medicine* 12(2): 87-92, 1991
- 5) Tarasawa K., Shibahara N.: the Role of Kampo Therapy in the Treatment of Renal Diseases - Opinions by Kampo Experts, *Kampo & the Newest Therapy* 8(2): 101-105, 1999
- 6) Oura H., Yokozawa T.: Efficacy of Japanese and Chinese Medicine (Wakan Yaku) in the Treatment of Experimental Renal Failure - Kidney and Dialysis (Extra Edition) 26: 38-42, 1989
- 7) Mitsuma T. et al.: Research into Rhubarb and Rhubarb Containing Kampo Preparations for the Treatment of Chronic Renal Failure (Second Report), *The Japanese Journal of Nephrology* 29: 195-207, 1987
- 8) Haimoto H. et al.: Traditional Chinese Treatment of Chronic Nephritis and Nephrotic Syndrome, *The Kampo* 14(3): 62-68, 1996
- 9) Arisaka M., Kusano E., Asano Y. et al.: Clinical Experiences with the Use of Onsei In for the Treatment of Pruritus in Dialysis Patients, *Kidney and Dialysis* 35: 565-569, 1993
- 10) Kumakura M., Hyodo T., Tomimitsu E. et al.: Fast-acting Properties of *Peony and Licorice Decoction* for Muscle Cramps in Dialysis Patients, *Dialysis Care* 6: 75-79, 2000
- 11) Oka Y., Miyazaki M., Takatsu S. et al.: Importance of Early Discovery of Osteoarthritis in Dialysis Patients - Study of the Usefulness of *Minor Bupleurum Decoction, Poria Powder with Five Herbs*, *Journal of the Japan Dialysis Society* 33: 1371-1376, 2000
- 12) Takasu S., Hatamura T., Sasahara K.: Clinical Effects of *Minor Bupleurum Decoction, Poria Powder with Five Herbs* on Osteoarthritis in Dialysis Patients, *Kampo Shinryo* 15: 18-21, 1996

The concept of glomerular nephritis was established in recent years. Moreover, this disease was only treated when it was associated with such macroscopically visible anomalies of the body like edema. Today, in addition to the aforementioned sign, abnormal biochemical data, proteinuria or hematuria (including microscopic hematuria) have become treatment indications and the range of treatment indications for Kampo medicine has also been broadened.

Acute postinfectious glomerular nephritis used to be a frequently observed disease, but today its incidence has decreased due to the wide spread use of antibiotics, so that the chances to treat the condition with Kampo have diminished. Some forms of IgA nephropathies respond well to Kampo therapy and there are RCTs verifying this finding¹³⁾. Nephrotic syndrome is a disease for which Kampo medicine has been used widely and even today continues to be under used, although under fairly restricted conditions. Histopathologic examination shows that disorders of the minimal change group and membranous nephropathy respond well to Kampo medicine. There are relevant data regarding the use of *Minor Bupleurum Decoction, Poria Powder with Five Herbs*^{14,15,16,17)}. Moreover, a combination of the above mentioned Houttuynia cordata, astragalus radix and imperata rhizoma is effective for the treatment of edema and proteinuria, characteristics of this disease.

- 13) Yoshikawa N., Ito T., Sakai T. et al.: Prospective Controlled Study Using *Minor Bupleurum Decoction, Poria Powder with Five Herbs* for the Treatment of Pediatric IgA Nephropathy with Focal, Minimal Mesangial Proliferation, *The Japanese Journal of Nephrology* 39: 503-556, 1997
- 14) Tojo S., Yoshitoshi Y., Nagasawa T. et al.: Ethical Kampo Preparations for Chronic Glomerular Nephritis and Nephritic Syndrome: Clinical Effects of *Minor Bupleurum Decoction, Poria Powder with Five Herbs* (First Report), *Multi-facility Open Trial, Kidney and Dialysis* 31(3): 613-625, 1994
- 15) Ito K., Okada T., Kitagawa T. et al.: Ethical Kampo Preparations for Pediatric Chronic Glomerular Nephritis and Nephritic Syndrome: Clinical Effects of *Minor Bupleurum Decoction, Poria Powder with Five Herbs*, *Multi-facility Open Trial, Kidney and Dialysis* 36: 1237-1246, 1994
- 16) Yoshikawa T., Ito T., Takekoshi Y. et al.: Pediatric Steroid Reactive Nephritic Syndrome, Initial Steroid Treatment Period and Recurrence in Patients Treated with a *Minor Bupleurum Decoction, Poria Powder with Five Herbs* Combination Therapy - Prospective Controlled Study, *The Japanese Journal of Nephrology* 40: 587-590, 1998
- 17) Yasaki T., Hirose S.: Clinical Effects of *Minor Bupleurum Decoction, Poria Powder with Five Herbs* on Pediatric Nephritic Syndrome, *Journal of Traditional Medicine* 4: 203-206, 1987

16. Urology

Regarding urologic diseases, ancient textbooks refer to the "Five Lin" (five stranguries): stone, Qi, unctuous, consumptive and bloody Lin. These are general terms for conditions currently designated as cystitis, urinary stones, hematuria, syphilis and dysuria etc. Today, specific therapies have been proposed for these individual conditions and not the traditional concept of "Lin"¹⁾.

- 1) Ishibashi A.: Kampo Therapy of Urologic Diseases (Continued), for Practical Physicians, *The Kampo No.3*: 2-7, 1999

Among the urogenital infections Kampo medicine is effective for acute cystitis, but the condition is usually treated with antibiotics. In ordinary clinical practice it is, however, not possible to provide a preventive therapy with antibiotics, so that Kampo therapy is given to those patients for whom the condition has progressed to the chronic stage. *Umbellate Fungus Decoction, Combine Umbellate Fungus Decoction and Four Herbs Decoction, Gentian Liver-Purging Decoction, Powder for Five Kinds of Stranguria, Heart-Clearing Lotus Seed Decoction, Kidney Qi Pill* are frequently used preparations. There are case series studies dealing with the use of *Combine Umbellate Fungus Decoction and Four Herbs Decoction* for the treatment of ureter syndrome²⁾.

- 2) Sugaya K., Nishizawa O., Noto H. et al.: Effects of *Umbellate Fungus Decoction* and *Combine Umbellate Fungus Decoction and Four Herbs Decoction* for the Treatment of Ureter Syndrome, *Urology Bulletin* 38: 731-735, 1992

Among the forms of bacterial prostatitis, acute infections are an indication for antibiotics. Chronic bacterial prostatitis, nonbacterial prostatitis or the chronic prostatitis syndrome cause similar symptoms for which western medical treatment is not sufficiently effective. For these conditions Kampo therapy is often very effective. *Gentian Liver-Purging Decoction* is frequently used³⁾. Combination with *Kidney Qi Pill* may in some cases give better results. Beside these formulas, there are studies dealing with *Life-preserving*

Kidney-Qi Pill and *Cassia Twig and Tuckahoe Pill*. Cumulative studies have been performed for *Cassia Twig and Tuckahoe Pill* among the above mentioned preparations and showed effectiveness in 12% and slight effectiveness in 66.4% of the treated patients⁴⁾.

- 3) Takashi M., Haimoto H.: Experiences with Kampo Therapy for Patients with Chronic Prostatitis presenting with a Greasy Tongue Coating, *Φ υ τ ο* 1(2): 16-18, 2001
- 4) Harada K.: Usefulness of Blood Stasis Expelling Drugs for the Treatment of Chronic Prostatitis - Using Mainly *Cassia Twig and Tuckahoe Pill*, *WE No.7*: 9-10, 2004

In most cases of urinary tract stones causing colicky pain, Kampo medicine alone cannot provide relief, but there have been many attempts at using it. *Peony and Licorice Decoction, Umbellate Fungus Decoction* and *Peony and Licorice Decoction, Major Middle-Strengthening Decoction* and similar preparations have been prescribed. A new indication in this field is the excretion of the stone fragments following ESWL (extracorporeal shock wave lithotripsy). For this purpose, the combination of large amounts of fluid replacement with the administration of *Umbellate Fungus Decoction* has been proposed and tested in comparative clinical trials⁵⁾.

- 5) Takada M., Yano H., Kambara N. et al.: Effects of *Umbellate Fungus Decoction* on Post-ESWL stone excretion, *Acta Urologica Japonica* 43:311-314 1997

Erectile dysfunction in men is not due to a single cause and the indications for Kampo therapy are limited, but it is used for psychogenic or age dependent cases. *Kidney Qi Pill, Middle-Reinforcing and Qi-Benefiting Decoction, Bupleurum plus Dragon's Bone and Oyster Shell Decoction, Cassia Twig plus Dragon's Bone and Oyster Shell Decoction* have been selected and used⁶⁾. *Middle-Reinforcing and Qi-Benefiting Decoction* is frequently used for the treatment of oligospermia or insufficient motility of sperm found in cases of male infertility. Several hours after the administration of *Middle-Reinforcing and Qi-Benefiting Decoction* the number of sperm and sperm motility have been confirmed to markedly increase^{7,8)}. Preparations like *Kidney Qi Pill* or *Life-preserving Kidney-Qi Pill* have similar modes of action and the latter preparation has been shown in case series studies to increase the number of sperm in case of oligospermia and very efficiently improve motility in asthenospermia⁹⁾.

- 6) Ikeuchi T.: EBM in Kampo Therapy - Current Situation - 3. Overview over the current situation of EBM in various fields, 7) EBM and Renal and Urologic Diseases, *Prog. Med.* 22(9): 53-56, 2002
- 7) Li Ping, Takase K., Mukobayashi M. et al.: Clinical Effects of *Middle-Reinforcing and Qi-Benefiting Decoction* in the Treatment of Male Infertility, *Progress in Obstetrics and Gynecology* 48(4): 406-410, 1996
- 8) Akiyama M., Oeda T., Akiyama H. et al.: Clinical Experiences with *Middle-Reinforcing and Qi-Benefiting Decoction* in the Treatment of Male Infertility, *Chapter of Urology in Western Japan* 59(5): 442-446, 1997
- 9) Ohashi M., Ishikawa H., Yauchihara H. et al.: Efficacy of *Life-preserving Kidney-Qi Pill* in the Treatment of Male Infertility - Seminal Fluid Findings Obtained with an Automatic Seminal Fluid Analyzer, *Journal of the Japanese Society of Fertility and Sterility* 39(2): 79-83, 1994

The initial stages of prostate hypertrophy are an indication for Kampo therapy. *Kidney Qi Pill* is a frequently used preparation and there are case series studies dealing with its application^{10,11}. When treatment with *Kidney Qi Pill* alone is insufficiently effective, the hypertrophy of the prostate gland can be viewed as a manifestation of blood stasis. Some studies demonstrated that treatment with blood activating and stasis resolving preparations like *Cassia Twig and Tuckahoe Pill* or *Rhubarb and Moutan Bark Decoction* (in case of a decoction Choryu To) appears to be beneficial¹².

10) Harada K.: Treatment of Urological Diseases with Japanese and Chinese Medicine; 4. Diseases of the Prostate and Micturation Disorders, Clinical Urology 45: 295-300, 1991

11) Yoshida K., Nakagawa Y., Tani Y. et al.: Clinical Effects of *Kidney Qi Pill* for Prostate Hypertrophy, The Clinical Report 9: 2861-2870, 1991

12) Yamamoto I.: Outline of Kampo Therapy for Diseases of the Lower Urinary Tract: Miscellaneous Records of Oriental Medicine 3, ("Essays of eastern medicine" Vol.3): 637-648, 1983

Urinary incontinence is frequently observed in elderly patients, particularly in women. It is likely that patients do not report this symptom because of embarrassment. For the treatment of pressure incontinence, the preparation *Middle-Reinforcing and Qi-Benefiting Decoction* with its "upraising" properties is widely used¹³. Kase et al. administered *Middle-Reinforcing and Qi-Benefiting Decoction* to seven patients who did not wish to undergo surgical treatment of pressure incontinence, and evaluated the results with the questionnaire proposed by the International Consultation on Incontinence (ICI). They found that the average incontinence score reportedly dropped from 10.4±3.7 points to 6.3±5.0 points¹⁴. Moreover, in recent years it has been noticed that *Pueraria Decoction* also has incontinence inhibiting actions. The discovery of this effect was made by Prof. Shin, who found that treatment of female outpatients in an obstetrics and gynecology clinic suffering from common cold with *Pueraria Decoction* resulted in an alleviation of the incontinence occurring simultaneously with the cure of the cold. Prof. Shin conjectured that this effect is probably due to a contraction of the internal cystic sphincter induced by the ephedrine contained in *Pueraria Decoction*, while the component paeoniflorin of peony root seems to induce relaxation of the smooth muscles of the bladder¹⁵. Impending incontinence is considered to be one pathologic form of kidney deficiency, so that here kidney tonifying preparations like *Kidney Qi Pill* and *Life-preserving Kidney-Qi Pill* are widely used¹⁶.

13) Murakami Y.: Effects of *Middle-Reinforcing and Qi-Benefiting Decoction* on Mobile Kidneys and Pressure Incontinence, Acta Urologica Japonica 34: 1841-1843, 1988

14) Kase H., Akashi M., Sato T.: Effects of *Middle-Reinforcing and Qi-Benefiting Decoction* on Pressure Incontinence, Kampo Igaku 29(3): 19-21, 2005

15) Shin S. et al.: Usefulness of *Pueraria Decoction* on Pressure Incontinence; 47th Conference of The Japan Society for Oriental Medicine, Summary Collection P126, 1996

16) Yamanaka H., Suzuki T., Tokunaga S. et al.: Kampo Therapy for Micturation Disorders, Kampo Igaku 21(8): 2-10, 1977

17. Nervous System

Many diseases in this field are indications for acupuncture therapy, but a combination therapy with Kampo medicine is more effective. Traditionally there has been a lot of experience with stroke and headache. For various forms of degenerative cerebral diseases, Kampo therapy has been effective to a certain extent and today numerous therapeutic trials are performed.

Regarding headache, both tension headache and migraine are both good indications for Kampo therapy. Widely used preparations include *Evodia Decoction*, *Poria Powder with Five Herbs*, *Pueraria Decoction*, *Pinellia*, *Largehead Atractylodes* and *Tall Gastordia Decoction*, *Tea-Blended Szechwan Lovage Powder*, *Cassia Twig plus Ginseng Decoction*, *Coptis Detoxifying Decoction* and similar formulas. Each of these preparations are used for corresponding disease states, but the TCM classification may not necessarily always be the same, so that prescriptions may differ. Among these, *Poria Powder with Five Herbs* is a characteristic Japanese formula not found in Chinese textbooks. Haimoto found through skillful application of clinical epidemiologic methods an efficacy of over 90% when the preparation was used for the treatment of headache associated with a drop in atmospheric pressure. The odds ratio of the correlation between headache and the drop in atmospheric pressure was reportedly 16.2¹⁾. In Japan, *Evodia Decoction* has traditionally been used for the treatment of this condition and there are a substantial number of related studies. A case series study showed better than simple improvements in 77 out of 147 patients²⁾. The data of another case series study examining 30 patients with tension headache showed that the treatment was effective in 23 patients (that is an efficacy of 76.3%)³⁾. Yet, in actual clinical practice the efficacy does not seem to be that high. Moreover, treatment with this preparation reportedly results in improvements of vascular headache, but statistical differences were not observed. However, sometimes there are cases with dramatic improvement. Case series studies examining the use of *Pueraria Decoction* for the treatment of tension headache showed at the fourth treatment week an efficacy of 66.3%⁴⁾. Some case series studies deal with the treatment of tension headache using *Uncaria Powder*, or else chronic headache in patients with cerebrovascular disorders and reported effectiveness for both conditions^{5,6)}. Treatment of trigeminal neuralgia follows the therapeutic guidelines for headache.

1) Haimoto H.: Discussion of Clinical Epidemiologic Research into Chronic Headache and the Correlation with Shifting Atmospheric Depressions, $\Phi \nu \tau \circ$ 1(3): 8-15, 1999

2) Maeda K., Miyagi A., Sugawara T. et al.: Effects of *Evodia Decoction* on Chronic Headache, Kampo Igaku 22: 55-57, 1998

3) Akamine M., Hyoudo Y., Ashihara M. et al.: Usefulness of *Evodia Decoction* for Tension Headache, Japan Oriental Psychosomatic Medical Research 15: 36-38, 2000

- 4) Yamamoto M.: Clinical Effects of *Pueraria Decoction* on Chronic Tension Headache Caused by Stiffness of Shoulders and Neck, *The Japanese Journal of Clinical and Experimental Medicine* 72: 1299-1303, 1995
- 5) Kimura K., Sasao S.: Clinical Effects of Tsumura's *Uncaria Powder* for Chronic Headache in Patients with Cerebrovascular Disorders, *Geriat. Med.* 27: 445-449, 1989
- 6) Takada O.: Usefulness of *Uncaria Powder* for Chronic Tension Headache, *Kampo Igaku* 22: 121-124, 1998

Throughout a lengthy history, a number of different therapies have been administered for epilepsy. During the 18th century in Japan, apart from the ordinary treatment, "vomitting" (intentional induction of emesis) was performed occasionally as part of the therapy, but did not produce sufficient results. Currently, various adapted forms of Kampo therapy are used in conjunction with modern western medical treatment, but independently cannot be expected to be effective. For the treatment of refractory pediatric epilepsy there are reports about using *Minor Bupleurum Decoction plus Cassia Twig Decoction plus Peony*, *Minor Bupleurum Decoction plus Minor Middle-Strengthening Decoction*, *Bupleurum and Cassia Twig Decoction* and similar preparations, where the data indicate an efficacy of 30-70%. For details please refer to the section on pediatrics.

Cerebrovascular disorders have for a long time been recognized as an extremely frequent condition and constituted the number one cause of death in the Japan 50 years ago. Today, in conjunction with the progress in modern medicine, fatal cases have become much rarer, but the incidence of small infarcts and bleedings are still frequent. Additionally, these conditions as a sequela of surgical intervention have emerged as a new pathology. During the acute phase of these diseases, western medical treatment is given priority. Kampo therapy is performed during the acute phase only under special conditions or else during the chronic phase (late effect period). In recent studies, Kimoto administered *Poria Powder with Five Herbs* in order to alleviate cerebral edema immediately following a stroke (including lacunar stroke) and reported achieving a better prognosis than with the ordinary therapy alone⁷⁾. For the treatment of sequelae of this disease (hemiplegia, articulation disorders and the like) acupuncture is very well suited and Kampo therapy is used more supportively. *Coptis Detoxifying Decoction*, *Major Bupleurum Decoction*, *Bupleurum plus Dragon's Bone and Oyster Shell Decoction*, *Uncaria Powder*, *Liver-Inhibiting Powder*, *Angelica and Peony Powder*, *Cassia Twig and Tuckahoe Pill*, *Cassia Twig Decoction plus Atractylodes and Aconite*, *Kidney Qi Pill* and similar preparations are used. In this field many case series studies and randomized controlled trials have been performed^{8,9,10,11,12,13,14,15,16)}.

Regarding treatment with decoctions, further modifications of the therapy have been applied.

- 7) Kimoto H.: Application of Kampo medicine to acute cerebral infarction: Summary of 14 cases and comparison of their clinical prognosis with the result of Japan Standard Stroke Registry Study (JSSRS) *J. Trad. Med.* 20(2): 68-73, 2003
- 8) Ushikubo Y., Sakurai T., Yokouchi T. et al.: Effects of *Coptis Detoxifying Decoction* on Cerebrovascular Disorders and Quantitative Evaluation of Blood Flow, *Journal of New Remedies & Clinics* 47: 176-183, 1998
- 9) Ito E., Takahashi A., Kuzuya F.: Clinical Effects of *Coptis Detoxifying Decoction* on Stroke, *Geriat. Med.* 29: 303-313, 1991
- 10) Otomo E., Togi H., Kogure K. et al.: Usefulness of *Coptis Detoxifying Decoction* for the Treatment of Cerebrovascular Disorders - Controlled study with Ca Hopantenate as the Control Using the Envelope Method, *Geriat. Med* 29: 121-151, 1991
- 11) Araki G.: Effects of *Coptis Detoxifying Decoction* on the Sequelae of Cerebrovascular Disorders - Particularly discussing improvements in cerebral circulation (vertigo, dizziness), *Geriat. Med* 29: 1587-1599, 1991
- 12) Ito E., Uchida M., Sakakibara T. et al.: Effects of *North Water God Decoction* on the Sequelae of Cerebrovascular Disorders, *The Japanese Journal of Clinical and Experimental Medicine* 71: 562-568, 1994
- 13) Matsushita S., Ueda S., Ouchi Y. et al.: Usefulness of *Uncaria Powder* for the Treatment of Accessory Symptoms of Cerebrovascular Disorders, Chronic Cerebral Circulatory Insufficiency and Hypertension, *Geriat. Med* 33: 1333-1341, 1995
- 14) Ito K., Yamamoto H., Nishihara T. et al.: Investigation of the Usefulness of *Kidney Qi Pill* for the Treatment of Various Symptoms in Patients with Hypertension or Cerebrovascular Disorders (excluding the acute phase) - Multi-facility crossover double-blinded trial, *Diagnosis and Treatment* 76(4): 1096-1114, 1988
- 15) Fukushima T., Tomonaga M., Tanaka A. et al.: Clinical Effects of *Angelica and Peony Powder* on the Sequelae of Cerebrovascular Disorders, *The Japanese Journal of Clinical and Experimental Medicine* 71: 1065-1070, 1994
- 16) Goto H., Shimada Y., Mitsuma T. et al.: Effect of *Cassia Twig and Tuckahoe Pill* on asymptomatic cerebral infarction for short term, *J. Trad. Med* 19: 46-50, 2002

Regarding cerebrovascular dementia, research about *Uncaria Powder* and similar preparations is progressing. Please refer for further details to the section on mental diseases.

Several preparations have been tried in form of combination therapies with western medical treatment during the initial phase of Parkinsonism. So far, *Liver-Inhibiting Powder* and *Tangerine Peel, Pinellia Rhizoma plus Liver-Inhibiting Powder* are representative formulas¹⁷⁾. In recent years case series studies with *Coptis Detoxifying Decoction*, *Tea-Blended Szechwan Lovage Powder*, *Six Gentlemen Decoction* and similar formulas have also been performed^{18,19,20)}.

- 17) Ogawa S.: Purpose and Application of *Liver-Inhibiting Powder* and *Tangerine Peel, Pinellia Rhizoma plus Liver-Inhibiting Powder*, *Kampo Medicine (Jap. Journal of Oriental Medicine)* 49(3): 330-334, 1998
- 18) Ito M.: Clinical Experiences with *Coptis Detoxifying Decoction* for the Treatment of Parkinson's Disease, *The Clinical Report* 26: 1519-1524, 1992
- 19) Shizuma N., Muramatsu S., Ikeguchi K. et al.: Effects of *Tea-Blended Szechwan Lovage Powder* on the Dyskinesia of Parkinson's Disease, *Kampo Medicine (Jap. Journal of Oriental Medicine)* 51: 1087-1091, 2001
- 20) Hiyama Y., Tosa H., Terasawa K. et al.: The effects of *Six Gentlemen Decoction* on Parkinsonian patients with unstable effect of levodopa/carbidopa, *J. Med. Pharm. Soc. WAKAN-YAKU* 8: 83-88, 1991

Since approximately 60% of the patients with Bell's palsy recover spontaneously without any treatment, many patients do not necessarily require therapy. This condition is a good indication for acupuncture therapy and improvement immediately

after the treatment is not uncommon. Therefore the use of Kampo medicine is not required. Several RCTs have been reported that compare this medication with a steroid group^{21,22}. According to these studies, there were not any major differences between the two groups.

21) Horiguchi I., Otake T.: Comparison of the Therapeutic Effects of Steroids and *Minor Bupleurum Decoction*, *Poria Powder with Five Herbs* on Peripheral Facial Palsy (Bell's Palsy), *Kampo & the Newest Therapy* 7(4): 363-368, 1999

22) Obata H., Otake T., Ishikura H.: Usefulness of *Minor Bupleurum Decoction*, *Poria Powder with Five Herbs* for the Treatment of Facial Palsy - A comparison with steroids, *Pain Clinic*, *Pain Clinic* 16(1): 49-52, 1995

Occasionally the use of Kampo medicine in the treatment of myasthenia gravis makes a dose reduction in anticholinesterase agents possible. Several case reports indicated the use *Middle-Reinforcing and Qi-Benefiting Decoction* or *Pueraria Decoction* and there is research on the use of *Six Gentlemen Decoction*²³.

23) Oikawa O.: Application of *Six Gentlemen Decoction* in the Field of Neurology, *Prog. Med.* 23(8): 2163-2169, 2003

18. Psychiatric Disorders

A multitude of mental diseases have been recorded from ancient to modern times. In TCM, various preparations have been devised depending on the state of the relevant disorders. Since there had been no classification of diseases like those used today (for example the DSM classification), it remains difficult to determine what modern disease the disorders described in those days correspond to. The disorders in this field were viewed as anomalies of the Zhang-Fu, the viscera and organs, revealing most often problems of heart, liver, spleen and gallbladder. In the course of the pattern, identification anomalies of these viscera and bowels were found causing the problem. In Japan, the "Shang han lun" or "Jin gui yao lue" offers a diversity of preparations for the treatment of these conditions. Active research into relevant formulas has been conducted since the Tang dynasty and led to suitable applications.

Among common psychiatric disorders, Kampo therapy is used as an integral part of behavior therapy, social therapy, psychotherapy and medical treatment of stress & adjustment disorders (situational disorders). Regarding anxiety disorders, the components of the anxiety may be either psychogenic or somatic. Kampo medicines include preparations capable of reducing the anxiety in itself and are used as a matter of course. It is frequently observed that through improvement of the physical symptoms, the related anxiety is alleviated. For this reason, it is necessary to base the prescription not on disease names, but follow the Kampo medical pattern identification. The most frequently observed general anxiety disorders are often treated with preparations like *Pinellia and Magnolia Decoction*, *Tangerine Peel, Pinellia Rhizoma*

plus Liver-Inhibiting Powder, Bupleurum and Cassia Twig Decoction, Bupleurum plus Dragon's Bone and Oyster Shell Decoction, Middle-Reinforcing and Qi-Benefiting Decoction, Back to the Spleen Decoction, Modified Merry Life Powder, Cyperus and Perilla Leaf Powder, Warm the Gallbladder Decoction, Goddess Powder, and Coptis Detoxifying Decoction. These formulas are also employed for panic disorders and obsessive-compulsive disorders (OCD) and suitable drugs are administered based on the SHO (symptoms and signs). There are a number of case series studies regarding this topic^{1,2,3,4,5}.

1) Kudo Y., Mori A., Asai M. et al.: Clinical Effects of *Modified Merry Life Powder* for Various Forms of Necrosis, *Journal of Clinical Therapeutics & Medicine* 8(12): 2989-3007 1992

2) Okamoto K., Hasama T., Okamoto R. et al.: Effects of *Pinellia and Magnolia Decoction* on Neurosis, *The Journal of Traditional Sino-Japanese Medicine* 15(4): 571-576, 1994

3) Ohara K., Fukazawa H., Suzuki Y. et al.: Clinical Effects of *Bupleurum plus Dragon's Bone and Oyster Shell Decoction* and *Pinellia and Magnolia Decoction* on Neurosis, *Journal of New Remedies & Clinics* 34(1): 131-141, 1985

4) Shinozaki T.: Effects of *Tangerine Peel, Pinellia Rhizoma plus Liver-Inhibiting Powder* in 30 Neurosis Patients with Irritation as Their Chief Complaint, *Kampo Shinryo* 18(2): 42-44, 1999

5) Shinozaki T.: Effects of *Bupleurum plus Dragon's Bone and Oyster Shell Decoction* in 15 Neurosis Patients with Irritation as Their Chief Complaint, *Kampo Igaku* 24(3): 122-124, 2000

Somatoform disorders (abnormal illness behavior) are a group of disorders that are very difficult to conceptualize. Yet, Kampo therapy occasionally appears to be useful. These conditions are not approached directly from their mental aspects, but by relieving physical problems with Kampo therapy the relevant mental conflicts are sometimes relieved. Many Kampo preparations act by improving physical dysfunction and are administered in order to improve the physical disposition of the patients. For chronic pain disorders, Kampo therapy does not appear to be very effective. However, it can in rare cases, be effective when the pathology is properly identified according to Kampo medical concepts.

To date no systematic studies on the application of Kampo therapy for schizophrenic disorders have been performed. Yet, there are a number of accessory approaches. One of these was the administration of *Coptis Detoxifying Decoction* to 10 patients in whom symptoms had been stabilized through treatment with antipsychotic drugs, where subsequently during the observation period an improvement in the total score of the brief psychiatric rating scale (BPRS) was noted. This took the form of significant improvement in depressive moods, delusions of guilt, delusions of persecution and agitation⁶. Another approach was the treatment of 12 patients complaining of mild to moderate restlessness with *Kidney Qi Pill* extract. The observation of the four parameters: loss of motivation, anxiety, restlessness and depressive moods, showed significant improvement⁷.

- 6) Yamada K., Kamba S., Onishi M. et al.: Clinical Effects of *Coptis Detoxifying Decoction* During Convalescence From the Active Phase of Schizophrenia, *Kampo Medicine (Jap. Journal of Oriental Medicine)* 47(4): 603-607, 1997
- 7) Ozaki S., Morita H., Shimomura Y.: Clinical Effects of *Kidney Qi Pill* and Needling of the Back on Schizophrenia (inhibition of auditory hallucinations through kidney tonification), *Oriental Medicine* 21(3): 69-75, 1993

Among mood disorders (depression & mania), history shows a comparatively large number of attempts at using Kampo therapy for depression which led to the selection of several effective preparations. Clinically, these are effective when used in the form of combination therapies with western medications. *Middle-Reinforcing and Qi-Benefiting Decoction, Modified Back to the Spleen Decoction, Pinellia and Magnolia Decoction, Cyperus and Perilla Leaf Powder, Six Gentlemen Decoction, Minor Middle-Strengthening Decoction, Ginseng Nutrition Decoction, Bupleurum plus Dragon's Bone and Oyster Shell Decoction* and similar preparations are used. There are also case series studies for these formulas^{8,9,10,11}.

- 8) Ohara K., Nishimoto M., Miyasato K. et al.: Effects of *Middle-Reinforcing and Qi-Benefiting Decoction* on the Loss of Appetite Associated with Depression, *Prog. Med.* 14(6): 1705-1712, 1994
- 9) Kudo Y., Mori A., Asai M. et al.: Clinical Evaluation of Kami Kihii in the Treatment of Various Neurotic Disorders, *Journal of Clinical Therapeutics & Medicine* 8(12): 2989-3007, 1992
- 10) Ohara K., Fukazawa H., Suzuki Y. et al.: Clinical Effects of *Bupleurum plus Dragon's Bone and Oyster Shell Decoction* and *Pinellia and Magnolia Decoction* in the Treatment of Neurosis, *Journal of New Remedies & Clinics* 34(1): 131-141, 1985
- 11) Tsutsui S., Igarashi M., Takekoshi I. et al.: Experiences with *Pinellia and Magnolia Decoction* in the Treatment of Depression and Depressive Moods, *Journal of New Remedies & Clinics* 42(9): 1913-1920 1993

Insomnia is treated among the sleep disorders with psychotherapy, life style guidance and pharmacotherapy in that order; but in reality, hypnotics are applied rather lightheartedly. Kampo medicines do not act like western soporific medications, but are more adjusted in a way to suit the various disease states. From a Kampo medical point of view, sleep disorders are considered to be caused by anomalies of organs like the heart, liver, or gallbladder and prescriptions are administered according to the relevant pathologies. *Wild Jujube Seed Decoction, Coptis Detoxifying Decoction, Modified Merry Life Powder, Pinellia and Magnolia Decoction, Back to the Spleen Decoction, Warm the Gallbladder Decoction, Liver-Inhibiting Powder* and similar preparations are selected. By treating patients who developed a triazolam dependency, with *Wild Jujube Seed Decoction*, Ozaki et al. succeeded in gradually decreasing the frequency of the triazolam use. Reportedly, many patients were finally able to sleep relying only on *Wild Jujube Seed Decoction*¹². Moreover, when Ozaki et al. used a combination therapy of zopiclone and *Wild Jujube Seed Decoction*, the sleep duration increased in spite of a facilitated

elimination of zopiclone from the blood and the QOL on the following day reportedly improved¹³.

- 12) Ozaki T.: Description of Patients who were Able to Completely Withdraw from Hypnotics by Using Tsumura's *Wild Jujube Seed Decoction*, *Japan Society of Ryodoraku Medicine* 42(7): 4-15, 1997
- 13) Ozaki T., Ohara S., Saito K.: Combined Effect of Zopiclone and *Wild Jujube Seed Decoction* in the Treatment of Insomnia, *Kampo Igaku* 22(5): 22-23, 1998

Dementia is a disease difficult to treat. It is frequent among the elderly and currently there are no therapeutic measures available for the treatment of the three forms of cortical dementia. Research into the use of Kampo medicine for this condition has just begun, but some interesting results have already been published. First, DB-RCTs using *Uncaria Powder* have received much attention. Terasawa et al. administered in several facilities either *Uncaria Powder* or a placebo to 139 patients with cerebrovascular dementia and reported for the former a significantly better improvement than that obtained with the latter¹⁴. The studies conducted by Shimada et al. could also be interpreted in a similar way (placebo and RCTs)¹⁵. Based on these studies the improvement in spontaneous conversations, poor facial expressions, decreased calculation abilities, night delirium, sleep disorders, hallucinations and delirium was in the *Uncaria Powder* group significantly better than in the placebo group. There are also multi-facility case series studies using *Coptis Detoxifying Decoction* that show significant improvements^{16,17}. *Uncaria Powder* is not effective for cerebrovascular dementia, but is for Alzheimer's disease¹⁸. Regarding this disease, there are a number of excellent studies using *Angelica and Peony Powder*¹⁹. Hagino et al. focused on the neuroendocrine action of this drug and found in experiments using rats that it causes an increase in the number of nicotinic acetylcholine receptors and the concentration of catecholamines in the cerebral cortex and hippocampus, thereby determining that this has an inhibitive effect on the dementia²⁰. Results of research in this area look very promising.

- 14) Terasawa K., Shimada Y., Kita T. et al.: *Uncaria Powder* in the treatment of vascular dementia a double-blind, placebo controlled study, *Phytomedicine* 4: 1522, 1997
- 15) Shimada Y., Terasawa K., Yamamoto T. et al.: A well-controlled study of *Uncaria Powder* and placebo in the treatment of vascular dementia, *J. Trad. Med.* 11: 246-255, 1994
- 16) Araki G.: Investigation of the Effects of *Coptis Detoxifying Decoction* on Dementia, *Journal of Senile Dementia* 4: 110-117, 1990
- 17) Araki G.: Effects of *Coptis Detoxifying Decoction* on Senile Dementia, *Therapeutic Research* 15: 986-994, 1994
- 18) Yamamoto T.: Kampo Therapy of Alzheimer's Disease, *Current Medicine* 5: 96-102, 1989
- 19) Inanaga K., Dainoson K., Ninomiya Y. et al.: Therapeutic of *Angelica and Peony Powder* on Senile Cognitive Disorders, Multi-facility Joint Research, *Prog. Med.* 16: 293-300, 1996
- 20) Hagino N., Koyama T.: Stimulation of nicotine acetylcholine receptor synthesis in the brain by *Angelica and Peony Powder*(TJ-23).Recent Advances in the Pharmacology of Kampo (Japanese herbal) Medicines 144-149, Excerpta Medica, Tokyo, 1988

19. Endocrinology

The growing knowledge about various hormones in the body and the organs that secrete them has in recent years clarified many questions. Regarding diseases in this area, hyperthyroidism is marked by visible characteristics and specific clinical symptoms. This condition has been recognized since ancient times, but most other diseases in this field were not clearly defined. This is only natural because there had been no concept of endocrine function. Even though the nature of these diseases has gradually been clarified in recent years, there are almost no studies showing the efficacy of Kampo therapy. The only condition for which there are many reports is hyperthyroidism. Regarding this disease, a modern biomedical therapy has been established and Kampo therapy is used only ancillary. *Roasted Licorice Decoction, Bupleurum Cassia Twig and Dried Ginger Decoction, Bupleurum plus Dragon's Bone and Oyster Shell Decoction* and similar preparations are frequently used. Several reports also deal with combinations of thyroid drugs and Kampo medicines¹⁾. Tachino described three cases in which good control was achieved using thyroid drugs and *Roasted Licorice Decoction*. Moreover, he reported a comparative study treating 35 patients divided in two groups Group A treated with thyroid drugs and *Roasted Licorice Decoction* and group B treated with thyroid drugs and propranolol hydrochloride. The improvements in tachycardia and subjective symptoms were reportedly much better in group A²⁾.

- 1) Yukimura Y.: Combination Therapies with Kampo Preparations for Hyperthyroidism - Kampo Medicine (Jap. Journal of Oriental Medicine) 35(2): 47-54, 1984
- 2) Tatsuno I.: Three Cases of Hyperthyroidism, Modern Kampo Therapy: 280-283 Toyo Gakujuitsu Shuppansha, 1985

20. Diabetes Mellitus

Diabetes mellitus has been known since ancient times in both western Europe and China as a disease where sweet urine is passed. Yet, during antiquity or the middle ages, it was not known that this disease was due to an insufficient secretion of insulin and the resulting hyperglycemia. Likewise it was not known that leaving the condition unattended and uncontrolled will eventually result in the manifestation of microvascular lesions. In TCM, symptoms like intensely dry mouth, voracious appetite and the passing of large amounts of urine were classified as being related to the upper, middle or lower portion of the body and thus appropriate therapies were devised. Although this is a useful classification indicating suitable therapies and preparations, the basis of diabetes therapy remains diet and exercise. Diet, caloric intake in particular, in relation to carbohydrates, poses problems for which Yoichiro Ebe

has proposed an epoch-making diet (since this is not directly related to Kampo medicine its description will be omitted here). Naturally, Kampo medicine is helpful for the therapy on any level of the disease. *White Tiger Phis Ginseng Decoction, Major Bupleurum Decoction, Kidney Qi Pill, Heart-Clearing Lotus Seed Decoction, Poria Powder with Five Herbs* and similar preparations are prescribed depending on the symptoms. Wagazuma et al. performed a randomized controlled study treating 18 patients with type II diabetes with *Heart-Clearing Lotus Seed Decoction* and compared these with the patients in a control group. The researchers observed a significant difference between the two groups, where combined 'improvement' and 'slight improvement' was reportedly 58.38%¹⁾. Moreover, Wagazuma et al. also described obtaining favorable results with long-term treatment of diabetics with *Poria Powder with Five Herbs*²⁾.

The focus of interest in Kampo therapy regarding diabetes is its effects on the manifestation of peripheral neuropathies associated with this disease. Some case series studies have described the effects of *Kidney Qi Pill* and *Life-preserving Kidney-Qi Pill*^{3,4,5,6)}. Also, some reports state that *Life-preserving Kidney-Qi Pill* appears to be effective for the treatment of diabetic corneal disorders⁷⁾.

- 1) Azuma M., Motomiya M., Toyoda T.: Results of Clinical Trials Using *Heart-Clearing Lotus Seed Decoction* for the Treatment of Diabetes, Kampo Medicine (Jap. Journal of Oriental Medicine) 45: 339-344, 1994
- 2) Azuma M., Sato G., Fukuzawa M.: Long-term Course of Diabetes Therapy Using *Poria Powder with Five Herbs*, Journal of Traditional Medicine 19(S): 56, 2002
- 3) Mikura R., Suzuki S., Iino S.: Therapeutic Effects of *Kidney Qi Pill* and *Six Ingredient Pill with Rhemannia* on Diabetic Neuropathies, Bell Medico, 7(6): 21-22, 1992
- 4) Sakamoto N., Sato Y., Goto Y. et al.: Oriental Medical Treatment of Diabetic Neuropathies - Comparative Trial with *Life-preserving Kidney-Qi Pill* and Cobalamine, The Journal of the Japan Diabetes Society 30(8): 729-737, 1987
- 5) Tawata M., Kurihara A., Nitta K. et al.: The effects of Goshajinnkigan, a herbal medicine, on subjective symptoms and vibratory threshold in patients with diabetic neuropathy. Diabet.Res.Clin.Pract 26: 121-128, 1994
- 6) Taniuchi K., Kashimura H., Fujiwara K. et al.: Clinical Effects of a 1-Year Administration of *Life-preserving Kidney-Qi Pill* for Diabetic Neuropathies, Journal of New Remedies & Clinics 36(4): 636-646, 1987
- 7) Nagaki Y., Hayasaka S., Hayasaka Y. et al.: Effects of *Life-preserving Kidney-Qi Pill* on corneal sensitivity supedial punctate keratopathy and tear secretion in patients with insulin-dependent diabetes mellitus AM, J. Chin. Med. 31: 103-109, 2003

21. Lipid Abnormalities

Almost none of the metabolic diseases had been recognized in the past as a disease. The concept of lipid anomalies was first established when the technologies to measure lipid concentrations in blood became available and the relevant knowledge regarding metabolism had developed. Accordingly, new Kampo concepts were needed and corresponding therapies sought.

Regarding hyperlipemia, there are no preparations that definitely lower total cholesterol and neutralize fat concentrations, but *Major Bupleurum Decoction* or *Bupleurum plus Dragon's Bone and Oyster Shell Decoction* reportedly did lower these values to a certain extent^{1,2,3,4,5}. Research into effects of Kampo preparations influencing the lipid metabolism on arteriosclerosis has begun. Itakura concentrated his experiments on the LDL cholesterol in rabbits and assumed that *Major Bupleurum Decoction* inhibits oxidation of LDL cholesterol, phagocytosis by macrophages and prevented the adhesion of lipid to the vessel wall⁶. Hasegawa treated patients for 4 years with *Bupleurum plus Dragon's Bone and Oyster Shell Decoction* and then examined vascular function by measuring the aortic pulse wave velocity and the carotid arterial system using ultrasonic transduction. Reportedly, antiarteriosclerotic activity was observed in either case⁷. For these studies, extract preparations were used. By proper adjustments of decoctions even slightly better results are expected and currently are the subject of investigation.

- 1) Murakami T., Oku J., Kimura Y. et al.: Treatment for Hyperlipidemia by Kampo-drugs, *J. Trad. Sino-Japanese Med.* 11(1): 35-40, 1990
- 2) Sasaki A., Matsunaga A., Handa K. et al: Effects of *Major Bupleurum Decoction* on Hyperlipemia - Comparison with Clinofibrate, *The Japanese Journal of Clinical and Experimental Medicine* 68: 3861-3871, 1991
- 3) Yamano S., Sawai F., Hashimoto T. et al.: Effects of *Major Bupleurum Decoction* on Serum Lipids and Brain Circulation - Comparison with elastase, *Kampo & the Newest Therapy* 4: 309-313, 1995
- 4) Miki S., Yashijima A., Wada M. et al.: Effects of *Major Bupleurum Decoction* on Serum Lipids and Examinations of the Coagulation System in Diabetics, *Journal of Traditional Medicine* 7(2): 120-124, 1990
- 5) Onuma, T. et al: Effects of *Bupleurum plus Dragon's Bone and Oyster Shell Decoction* (Kampo medicine) on abnormal plasma lipoprotein and glucose metabolism in diabetic Patients, A comparison to Dai-saiko-to, *J. Trad. Med.* 12: 124-128, 1995
- 6) Itakura H.: Kampo Medicine and Arteriosclerosis (interview), *Kampo Igaku* 20(4): 11-13, 1996
- 7) Hasegawa M.: Anti-arteriosclerotic Actions of *Bupleurum plus Dragon's Bone and Oyster Shell Decoction* (interview), *Kampo Igaku* 21(5): 11-13, 1997

22. Nutrition

Establishment of sound knowledge pertaining to nutrition is a rather recent event. Comprehension of the necessary amounts of nutrition and an evaluation of the nutritional status in Kampo medicine has been vague in the past making the overall image obscure until the establishment of modern nutrition science.

Among the nutrition disorders, the one being viewed as particularly problematic for modern man is obesity. The basic situation in obesity is a problem with caloric intake (in particular carbohydrates) and caloric consumption. Thus, the condition does not call for an active use of Kampo medicine. However, the use of Kampo medicine can occasionally lead to weight reduction of a few kilograms. One aspect of this weight loss is a Kampo medicine stimulated

excretion of surplus body water, for which, for example, *Stephania and Astragalus Decoction* can be used¹. When this preparation is administered during the treatment of gonarthrosis, it induces an alleviation of articular symptoms and at the same time may often result in a weight reduction of about 2-3 kg. Yoshida et al. administered *Stephania and Astragalus Decoction* to 19 patients with diabetes of the visceral obesity type for whom exercise is difficult because of the underlying disease and reportedly observed a significant decrease in visceral fat as well as a decrease in cholesterol levels². Another suitable preparation is *Divaricate Saposhnikovia Miraculous Powder*. This preparation has traditionally been classified as an exterior-interior releasing formula, but because it contains Rhubarb and Mirabilite, it improves bowel movements and thus facilitates the excretion of surplus materials through the feces. Several studies have dealt with this topic³. Akiyama et al. administered *Divaricate Saposhnikovia Miraculous Powder* to obese patients with mutations of the β_3 -adrenergic receptor gene, finding a marked reduction in the waist/hip ratio and reportedly also observed an improvement in insulin resistance⁴.

- 1) Sento S., Tanaka N.: Effects of *Stephania and Astragalus Decoction* on Physical Symptoms due to Anomalies in Water Metabolism and Obesity, *Therapeutic Research* 20(6): 2021-2028, 1996
- 2) Yoshida M., Takamatsu J., Yoshida S. et al.: Effects of *Stephania and Astragalus Decoction* in Diabetics with Visceral Type Obesity, *Kampo Medicine (Jap. Journal of Oriental Medicine)* 49(2): 249-256, 1998
- 3) Sekine N.: Investigation of the Clinical Usefulness of *Divaricate Saposhnikovia Miraculous Powder* for Hypertension and Obesity, *Prog. Med.* 24(11): 2803-2806, 2004
- 4) Akiyama T., Yoshikawa H., Tanaka H. et al.: β_3 adrenergic receptor Effects of *Divaricate Saposhnikovia Miraculous Powder* in Obese Patients with Gene Mutations, *Digestion and Absorption* 21(2): 159-162, 1998

Several reports indicated that treatment with Kampo medicine is beneficial for the eating disorder anorexia nervosa⁵. The use of *Minor Bupleurum Decoction*, *Liver-Inhibiting and Spleen-Assisting Decoction* has been recommended, but the ratio of successful treatments is not very high. Regarding bulimia nervosa, there are no reports. Disorders of vitamin metabolism are not considered to be an indication for Kampo medicines.

- 5) Otsuka K.: Five Case Reports About Anorexic Disorders (Psychogenic Lack of Appetite), *Jap. J. Orient. Med.* 7: 21-22, 1956

23. Infectious Diseases

The development of TCM is closely related to infectious diseases. One important Chinese classic text, the "Shang han lun", is widely known for its descriptions of the treatment of so-called cold induced disease. Even for infectious diseases that appeared later, it provided the basis for the development of therapies based on entirely new concepts for the age. The episodes surrounding Li Dong-Yuen's creation of

the formula *Middle-Reinforcing and Qi-Benefiting Decoction* in the 12th century are famous. Following epidemics of new diseases from the 16th to the 17th century, the concept of "heat induced disease" was established, later providing major contributions to the treatment of infectious diseases, so that it came to be listed as an important item in most textbooks.

Historically, since the "Shang han lun" was taken very seriously in Japan, the prescriptions listed in this classic text have been applied widely for this kind of disease. For infectious diseases of the warm type, prescriptions developed later have been used for the relevant conditions.

Today, progress in public health and hygiene as well as improvements in comprehensive patient management due to the appearance of antibiotics or antibacterial agents, various vaccines, fluid replacements etc. led to a significant reduction in potentially fatal infections. For this reason the application of Kampo medicine to the treatment of infectious diseases in modern Japan is now quite limited. Yet, there are still many diseases treated either solely with Kampo preparations or else in combination with modern medical therapies.

For the common cold and the common cold syndrome, Kampo medicine is used as the treatment of first choice and there are numerous dissertations documenting its use. The symptoms of the common cold are similar to those appearing during upper respiratory infections or diseases of the upper alimentary tract and often develop later into specific diseases. In Japan there is the proverb "The cold is the origin of all diseases". Not only during the initial stages of the common cold, but also with a whole group of similar conditions attempts have been made to cure the emerging symptoms with Kampo medicine. Regarding Kampo medicine, great importance was assigned to the "Shang han lun" since the middle of the 18th century and medical care performed based on its medical concepts. It offers preparations suitable for the treatment from the onset of acute febrile diseases and through their various stages. The methodology outlined in this book enables practical application of Kampo to the treatment of common cold and the treatment carried out along its guidelines. Japanese physicians actually practicing Kampo medicine consider the "Shang han lun" as the therapeutic foundation regarding infectious diseases and the treatment of the common cold meticulously implements the contents of this book. Many physicians specialized in Kampo medicine consider the treatment of the common cold to be the basics of Kampo therapy and a large number of dissertations deal with this topic^{1,2)}.

The most frequently used formula is *Pueraria Decoction*. Because this formula suits the Japanese physique very well, it is generally used during the early phase of the common cold and apart from that may also be useful as a preventive medication during epidemics^{3,4,5)}. Basic studies show that it inhibits the release of PGE2 etc. and have clarified a number of other actions as well^{6,7)}. Generally, many prescriptions can be used for the wind and cold induced common cold. During the early phase, other formulas beside *Pueraria Decoction*, like *Ephedra Decoction*, *Cassia Twig Decoction*, *Cassia Twig and Ephedra half and half Mixture Decoction*, *Bupleurum and Cassia Twig Decoction*, *Ephedra*, *Aconite* and *Manchurian Wildginger Decoction*, *Cyperus* and *Perilla Leaf Powder*, *Ginseng* and *Perilla Decoction* are used. Following the passage of a few days, *Minor Bupleurum Decoction* and its modifications or *Bamboo Shavings Gallbladder-Warming Decoction* are used. In case of a protracted course, *Middle-Reinforcing and Qi-Benefiting Decoction* and other tonifying formulas come into use. Kampo preparations permit general treatment even when patients are allergic to western medicines⁸⁾.

In Japan there are a few prescriptions for wind-heat conditions. This is due to the fact that the concept of heat induced disease was not adequately introduced in Japan from China. Until the middle of the 19th century there were relatively few epidemics of heat induced disease. While the representative extracts *Honey Suckle* and *Forsythia Powder* or *Mulberry* and *Chrysanthemum Flower Decoction* are not available, this concept has now found wide acceptance and both preparations are used as decoctions. OTC prescriptions are employed, or else these preparations are substituted with *Head-Clearing Divaricate Saposhnikovia Decoction* or *Schizonepeta and Forsythia Decoction*.

Cumulative research indicates that in RCT using both *Ephedra*, *Aconite* and *Manchurian Wildginger Decoction* and generic cold medicines *Ephedra*, *Aconite* and *Manchurian Wildginger Decoction* apparently led to a significantly better improvement in the symptom complex during the early phase of the disease⁹⁾. Again, DB-RCT studies showed that after more than 5 days following onset, patients with common cold (corresponding to the lesser yang disease state) treated with *Minor Bupleurum Decoction* fared significantly better than the placebo group¹⁰⁾. The efficacies of *Dwarf Lilyturf Decoction* and dextromethorphan hydrobromide were examined in a comparative study¹¹⁾ for the treatment of cough as the sole remaining symptom, after the other cold symptoms had subsided.

- 1) Ito T.: Treatment of the common cold syndrome in Kampo medicine, *Clinical All-round* 49(10): 2697-2698, 2000
- 2) Homma Y.: Usefulness of Kampo medicine for the treatment of patients with febrile syndromes, *Kampo Medicine (Jap. Journal of Oriental Medicine)*. 46(2): 285-291, 1995
- 3) Yanagi K. et al: Usefulness of a single dose of *Pueraria Decoction* during the early phase of common cold, in: Summaries of the lectures held at the 52nd General Conference of The Japan Society for Oriental Medicine, P243, 2001
- 4) Kaji M., Kashiwagi S., Hayashi J. et al: Clinical effects of *Pueraria Decoction* for the common cold, *Jpn. J. Clin. Exp. Med.* 70: 3266-3272, 1993
- 5) Nishimoto T., Higasa K., Matsumoto K.: Clinical effects of *Pueraria Decoction* drinks for the common cold (*Medical Care and New Drugs*) 28: 1433-1440, 1991
- 6) Nakahata N., Ishimoto H., Ohizumi Y. et al: Effects of *Pueraria Decoction*, *Minor Bupleurum Decoction* and *Ephedra Decoction* on prostaglandin production and hydrolysis of inositol phospholipids in cultured rabbit astrocytes, *Kampo Igaku* 17: 200-217, 1993
- 7) Kurokawa M., Imakita M., Kumeda C. A. et al.: *Pueraria Decoction* suppressed interleukin-1 α production responsive to interferon and alleviated influenza infection in mice, *J. Trad. Med.* 13(3): 201-209, 1996
- 8) Yamaguchi H.: Common cold in patients with drug induced hepatitis: Lecture seminar on Kampo medicine for medical students, 1997
- 9) Homma Y., Takaoka K., Yozawa H.: Comparative study using the envelop method to determine the usefulness of *Ephedra*, *Aconite* and *Manchurian Wildginger Decoction* for the common cold syndrome, *Kampo Medicine (Jap. Journal of Oriental Medicine)* 47(2): 245-252, 1996
- 10) Kaji M., Kashiwagi S., Yamakido M.: Double-blinded comparative study using *Minor Bupleurum Decoction* and a placebo for the treatment of the common cold, *Jap. J. Clin. Exp. Med.*, 78(12): 2252-2268, 2001
- 11) Fujimori K., Suzuki E., Shimojo F.: Comparison of the efficacy of *Dwarf Lilyturf Decoction*; *Ophiopogon* production to and dextromethorphan hydrobromide for residual cough following improvement of the common cold syndrome (pilot study), *Kampo Medicine (Jap. Journal of Oriental Medicine)*, 51(4): 725-732, 2001

In daily clinical practice, antiviral agents like Tamiflu, Relenza or Symmetrel, are used for the treatment of influenza. Kampo preparations when employed skillfully, are also quite effective^{12,13,14}. Many of the formulas given in the "Shang han lun" are used for the treatment of this kind of disease in Japan. This particular classic lists an abundance of prescriptions designed for the treatment of pathologic conditions caused by the invasion of wind cold evil. Among extracts, *Ephedra Decoction* is frequently used, but a combination of *Cassia Twig Decoction* and *Ephedra*, *Apricot*, *Licorice* and *Gypsum Decoction* to prepare *Major Blue Dragon Decoction*, also finds application¹⁵. During influenza epidemics *Pueraria Decoction* has been used for prevention and reportedly was found to be effective¹⁶.

- 12) Iwasaki K.: Special: New strategies for the treatment of cold and influenza; Cold and cold remedies as viewed in Kampo medicine, *Current Therapy* 20(10): 1049-1053, 2002
- 13) Koizumi K.: Special: Management of the common cold syndrome and influenza for the primary care physician: An approach to the common cold with Kampo medicine, *Journal of Therapy* 85(12): 3205-3210, 2003
- 14) Kimoto H., Kuroki H.: Significance of Kampo medicine during influenza epidemics, *Journal of Traditional Medicine* 20(S): 146, 2003
- 15) Mitani K.: Case studies of patients with high fever treated the extract preparation *Major Blue Dragon Decoction*, *phil KAMPO* 4: 15-16
- 16) Yakazu D.: Prevention of influenza, *Sokai* December issue 1975: 93-94

Most of the other infectious diseases require western medical treatment. Yet, some infectious

diseases, difficult to treat with western medicine, are still treated with Kampo preparations. For example, *Middle-Reinforcing and Qi-Benefiting Decoction*, *Ten Strong Tonic Herbs Decoction* or *Ginseng Nutrition Decoction* are used for the treatment of chronic MRSA infections^{17,18}.

- 17) Kitahara M., Ishikawa S., Hara K.: Protective effect of *Ten Strong Tonic Herbs Decoction* against infection after acute ischemic stroke in elderly patients, *Biotherapy* 17(3): 287-298, 2003

- 18) Kitahara M.: The Effect of Supplementing Formulas for the Treatment of MRSA infections in Neurosurgery, *Evolving Kampo* 2005, 1(1): 14-15

Regarding HIV infections, research has just started, but future results are anticipated with great expectations. Please refer to the section on pediatric diseases regarding measles, epidemic parotiditis, roseola infantum, rota virus infections, Kawasaki syndrome and similar pediatric diseases.

24. Cancer

In this field there are no Kampo prescriptions that are definitely effective. However, Kampo medicine is used as adjunctive therapy following surgery for various malignant tumors, or else in combination with chemotherapy or radiation therapy and here plays a significant role¹. Frequently used preparations include *Middle-Reinforcing and Qi-Benefiting Decoction*, *Ten Strong Tonic Herbs Decoction*, *Ginseng Nutrition Decoction* etc. and there is an extensive body of research pertaining to these drugs^{2,3,4,5,6}. The purpose of the Kampo therapy is to provide relief for the suffering of the patients, prevent or alleviate the side effects of western medical therapies, improve immune function, prolong survival and improve the QOL. Each of the above mentioned preparations improve immune function and influences NK cell activity. In this field there is an abundance of basic research and the drugs are topics in the relevant academic societies^{7,8,9}. Many basic studies have been performed on those topics and their results support the clinics. Saiboku has investigated the inhibitive actions of the aforementioned three preparations on the development of metastases and it is now becoming clear that there are differences in their respective mode of action. He states that the manifestation of the effects of Kampo preparations may possibly be related to physical disposition or else organ selectivity¹⁰.

In actual therapy, a number of cases that can be treated with extracts are rather limited, so that the use of decoctions is required. Here the experiences gathered in China prove to be useful and a significant number of physicians put them to practical use. Those physicians determine the Kampo medical pattern (SHO) according to the location of the malignant tumor and its type and then prepare and administer suitable formulas (which contain crude drugs with antitumor activity)¹¹. Shimizu selects the crude drugs

corresponding to the malignant tumors of the individual's bowels and viscera and has proposed preparations to be administered following surgery, radio- or chemotherapy respectively¹²⁾.

- 1) Okamoto T., Sairenji M.: Significance of Kampo in the Treatment of Cancer, Kampo and Most Advanced Therapies 4(2): 123-128, 1995
- 2) Kuroda T., Imai J., Tamakuma S.: Prevention of Anticancer Drug Side Effects by *Ten Strong Tonic Herbs Decoction* and Clinical Immunologic Investigations Biotherapy 3(4): 789-795, 1989
- 3) Fujiwara M., Kohmoto Y.: Usefulness of *Ten Strong Tonic Herbs Decoction* in the Treatment of Myelostasis due to Chemotherapy for Gynecologic Cancers, Journal of the Gynecology and Obstetrics in Chugoku and Shikoku Region 47(2): 153-157, 1999
- 4) Abe K.: Effects on Side Effects due to Chemotherapy Following Cancer Surgery, Prog. Med. 9: 2916-2922, 1989
- 5) Hasegawa K., Fukunishi H., Kiyoshige T. et al.: Journal of Traditional Medicine 11, 181-187 1994: Clinical Effects of a Combination Therapy with Kampo preparations (*Ginseng Nutrition Decoction*, *Ten Strong Tonic Herbs Decoction*) to Alleviate the Side Effects of Carcinostatic Agents
- 6) Sugimachi K.: Research into the Usefulness of *Ginseng Nutrition Decoction* as an Adjuvant Chemotherapy After Surgery for Gastric Cancer, Clinics and Research 72(2): 182-186, 1998
- 7) Kawakita T., Nomoto K.: Immunopharmacologic Actions of *Ginseng Nutrition Decoction* and its Clinical Application, Prog. Med. 19: 2113-2121, 1999
- 8) Kawakita T., Nomoto K.: Immunopharmacologic Actions of *Middle-Reinforcing and Qi-Benefiting Decoction* and its Clinical Application, Prog. Med. 18: 801-807, 1998
- 9) Nakawa H., Sai B., Tsuno N. et al.: Effects of *Ten Strong Tonic Herbs Decoction* and *Middle-Reinforcing and Qi-Benefiting Decoction* on Cells with Induced Cancer Genes, Kampo and Most Advanced Therapies 4(2): 129-132, 1995
- 10) Saiki I.: Cancer Metastases and Kampo Preparations, Science 75(7): 842-845, 2005
- 11) Kotaka S.: Regarding Therapies for Malignant Tumors - Discussion, TCM Clinics 17(2): 2-5, 1996
- 12) Shimizu H.: New Medical Revolution, Shuei Publications: 139-145, 2004

25. Pediatrics

The field of pediatrics, even when viewed historically, has been from a comparatively early period divided into subspecialties leading to the emergence of specialists, so that there is an abundant body of experience with various diseases. In particular, the ancient experiences with infectious diseases are currently very helpful. Yet, the progress of modern medicine in recent years resulted in a comparative narrowing of the range of indications for Kampo therapy. Simultaneously, new indications have arisen or have been developed, opening a new field.

Regarding acute infections, applications have been attempted, in particular for the early phase of the so-called viral common disease. For the treatment of epidemic parotitis (mumps) the use of *Minor Bupleurum Decoction*¹⁾, for measles *Cimicifuga and Pueraria Decoction*¹⁾ and *White Tiger plus Ginseng Decoction*²⁾, for roseola infantum *White Tiger plus Ginseng Decoction*³⁾ has been reported.

Due to the low age of onset, the treatment of influenza with antiviral preparations is limited and therefore often calls for the administration of Kampo medicine. *Ephedra Decoction*, *Pueraria Decoction* and

similar preparations are widely used. Abe conducted a comparative trial observing 783 patients divided into a group treated with Kampo medicine and a control group treated with western medications. According to this study, progression to severe stages occurred in the Kampo treatment group only infrequently⁴⁾.

- 1) Abe K.: Clinical Effects of *Minor Bupleurum Decoction* for the Treatment of Mumps and *Cimicifuga and Pueraria Decoction* for the Treatment of Measles, Journal of the Japan Pediatric Oriental Medicine Society 13(1): 14-20, 1997
- 2) Mizutani K.: Experiences with the Use of *White Tiger plus Ginseng Decoction* (TJ-34) for the Treatment of Pediatric Febrile Diseases - In particular regarding measles, Pediatric Clinic 43(6): 1361-1364, 1990
- 3) Abe K., Tanaka K.: Effects of *White Tiger plus Ginseng Decoction* on Roseola Infantum, Kampo Medicine (Jap. Journal of Oriental Medicine) 47(6): 118, 1997
- 4) Abe K.: Comparison of Therapeutic Results of Treating Type A Hongkong Influenza with Kampo Medicine, Western Medicine or Amantadine Hydrochloride, 63rd Yamakage Pediatric Conference, 1999

The common cold is a good indication for Kampo medicine. During the early stages, *Pueraria Decoction*, *Ephedra Decoction*, *Bupleurum* and *Cassia Twig Decoction*, *Ephedra*, *Aconite* and *Manchurian Wildginger Decoction* and similar preparations are used. There are a number of case series studies, but their description will be omitted here. Clinically problematic is interference with ordinary daily life in children due to recurrent upper respiratory tract infections. These children are highly susceptible to the common cold, and once they are affected, the disease tends to run a protracted course. They may only be able to consume small amounts of food, suffer from recurrent diarrhea and become exhausted with light physical exercise. This type of child in Japan is said to have a "weak constitution". Long-term application of *Minor Bupleurum Decoction* or *Bupleurum and Cassia Twig Decoction* to these children has often been observed to reduce their susceptibility to infections and builds physical strength⁵⁾. Akiba et al. administered *Bupleurum and Cassia Twig Decoction* for a long period to 14 children suffering from recurrent infections (catching cold easily) and reported an efficacy of 78%⁶⁾. There are also other case series studies dealing with the use of *Bupleurum and Cassia Twig Decoction* in similar cases, where Koga et al. found an efficacy of 88% (total number of patients 16)⁷⁾, Mine found 90% (total number of patients 10)⁸⁾. Some case series studies also investigated *Minor Bupleurum Decoction*⁹⁾. Iwama et al. treated 12 children with recurrent tonsillitis with *Bupleurum Liver-Clearing Decoction* and reported an efficacy of 80%¹⁰⁾.

- 5) Hirose S.: Children With Weak Constitution, 3(3): 253-257, 1994
- 6) Akiba T., Araki Y., Nakajima A. et al.: Improvements Caused by Long-term Application of *Bupleurum and Cassia Twig Decoction* in Children Susceptible to Common Cold, Kampo Medicine (Jap. Journal of Oriental Medicine) 41: 149-155, 1991
- 7) Kouga M.: Easy Susceptibility to Infection (recurrent airway infections) and Saiko Preparations, Journal of the Research of Japan Kampo Medicine for Pediatrics 13(1): 71-75, 1997

- 8) Mine M.: Practical Experiences with *Bupleurum and Cassia Twig Decoction* in the Treatment of Nursery School Children Suffering from Frequent Recurrent Infections, General Meeting at the Third Conference of The Society of Ambulatory and General Pediatrics of Japan, 1993
- 9) Iwama M., Iriyama E.: Effects of *Minor Bupleurum Decoction* on Recurrent Febrile Airway Infections, *Kampo Igaku* 25: 115-117, 2001
- 10) Iwama M.: *Bupleurum Liver-Clearing Decoction* for the Treatment of Recurrent Tonsillitis, *Journal of the Japan Society of Pediatrics*, 1995

Regarding infections of the gastrointestinal tract, vomiting associated with the early phase of acute viral gastroenteritis and treatment with *Poria Powder with Five Herbs* has received much attention. In particular, for the treatment of vomiting associated with rota virus induced gastroenteritis, this medication applied as suppository or enema has frequently been reported as being extremely effective^{11,12,13,14}. This formula has traditionally been applied orally like other Kampo formulas, but in cases of vomiting, the administration may prove difficult. If a rapid onset of the effect is required, pediatricians sometimes prepare and administer suppositories or enemas themselves. Regarding this use, section 74 of the "Shang han lun" lists the "water reversal pattern" and describes the practical application of *Poria Powder with Five Herbs* for its treatment. Moreover, in developing countries, where modern medical equipment like intravenous drip infusions are not available, this preparation could play an important role in lowering mortality.

- 11) Hashimoto H.: The Effects of *Poria Powder with Five Herbs* on Vomiting Associated with Common Cold Induced Gastroenteritis - Ideas of facilitating oral application, *Kampo Igaku* 25: 178-180, 2001
- 12) Fukutomi O., Matsuo N., Teramoto T. et al.: Examination of *Poria Powder with Five Herbs* Enemas for the Treatment of Vomiting Associated with Acute Pediatric Gastroenteritis, *Japanese Journal of Pediatric* 53: 967-970, 2000
- 13) Hashimoto H.: Comparative Study of *Poria Powder with Five Herbs* and *Minor Bupleurum Decoction*, *Poria Powder with Five Herbs* Enemas for the Treatment of Vomiting Associated with Pediatric Viral Gastroenteritis, *Kampo Igaku* 25: 73-75, 2001
- 14) Yoshida M.: Effects of *Poria Powder with Five Herbs* Suppositories for the Treatment of Vomiting in Infants and Children, *Oriental Medicine* 28(3): 36-38, 2000

Acute bronchitis, asthmatic bronchitis etc. are among those respiratory diseases for which Kampo medicines are frequently used. *Ephedra*, *Apricot*, *Licorice* and *Gypsum Decoction*, *Minor Blue Dragon Decoction*, *Minor Bupleurum Decoction*, *Combine Minor Bupleurum Decoction and Pinellia* and *Magnolia Decoction*, *Dwarf Lilyturf Decoction* and similar preparations are frequently used, but since these are very ordinary diseases, no case series studies are available. Mycoplasma pneumoniae does not particularly require treatment with Kampo medicine, but during the acute phase, a combination of the antibacterial medication with *Minor Bupleurum Decoction* and *Lophatherus and Gypsum Decoction* was able to shorten the required treatment period with the antibacterial agents and also decreased the

duration of the morbidity in the treatment group¹⁵. Moreover, some studies showed that in a group treated with *Ephedra*, *Apricot*, *Licorice* and *Gypsum Decoction* during the chronic phase, it shortened the duration of coughing and led to an earlier normalization of the CRP values¹⁶.

- 15) Miyazaki Z., Mori K.: Acute Mycoplasma Pneumonitis, *Minor Bupleurum Decoction and Lophatherus and Gypsum Decoction*, 2001

- 16) Miyazaki Z., Mori K.: Convalescence Period of Mycoplasma Pneumonitis, *Ephedra*, *Apricot*, *Licorice* and *Gypsum Decoction*, 1994

Among the diseases of the cardiovascular system, Kampo therapy is often applied to orthostatic hypotension. Mori et al. treated 74 patients meeting the diagnostic criteria for orthostatic dysregulation with *Bupleurum and Cassia Twig Decoction* and observed improvement for all symptoms. The severity of all symptoms after 4 weeks of treatment was significantly lower than that before treatment. Regarding the chief complaint, a more than mild improvement was reported for 64.7% of the cases¹⁷. There are also reports about the use of *Pinellia*, *Largehead Atractylodes* and *Tall Gastordia Decoction*, *Middle-Reinforcing and Qi-Benefiting Decoction*, *Minor Middle-Strengthening Decoction* and similar preparations^{18,19}, either of which showed favorable results. Arrhythmia too is an indication. Otsuka et al. treated 31 children with extrasystoles with *Roasted Licorice Decoction* extract and found an improvement in supraventricular extrasystoles of approximately 70%, for ventricular extrasystoles a rate of 62%, and reported the resolution of the comparatively dangerous ventricular tachycardia in 4 out of 5 patients²⁰.

- 17) Mori M., Yamada K., Saka M. et al.: Clinical Application of *Bupleurum and Cassia Twig Decoction* for Orthostatic Dysregulation, *Japanese Journal of Pediatrics* 45: 1964-1974, 1992

- 18) Tsuru N.: Clinical Experiences with *Pinellia*, *Largehead Atractylodes* and *Tall Gastordia Decoction* and *Minor Middle-Strengthening Decoction* in the Treatment of Orthostatic Dysregulation, *Japanese Journal of Pediatric* 48: 585-591, 1995

- 19) Tomita H., Chiba S., Kadowaki J. et al.: Clinical Effects of *Middle-Reinforcing and Qi-Benefiting Decoction* for Orthostatic Dysregulation in Children, *The Journal of Pediatric Practice* 60: 162-167, 1997

- 20) Otsuka Y.: Extrasystoles (Arrhythmias), *The Journal of Pediatric Practice* 67: 1481-1481, 1988

Kampo medicine is also used for the treatment of constipation in children. Muramatsu et al. treated 72 constipated children without any organic disease with *Major Middle-Strengthening Decoction* extract and reported improvement in 69.4% of the cases after one week and 79.2% after two weeks²¹. Aoki et al. treated refractory constipation in severely handicapped children with *Hemp Seed Pill* and *Rhubarb and Licorice Decoction* and observed a significantly increased frequency of spontaneous bowel movements and also a significantly decreased frequency of enema administrations and thus stated that both preparations are useful²².

The range of application of Kampo therapy in pediatrics has recently widened. *Major Middle-Strengthening Decoction* is used to treat early transport disorders or the development of adhesive ileus following gastrointestinal surgery and in many reports, has been described as very useful^{23,24}. When western medical treatment of pediatric hemorrhoids or perianal abscesses proves difficult, the application of *Middle-Reinforcing and Qi-Benefiting Decoction* reportedly led to good results. Muramatsu et al. treated 65 patients (all children were male and age ranged from 22 days to 5 years) with perianal abscesses or hemorrhoids with *Ten Strong Tonic Herbs Decoction*, observing the course in comparison to a 28-patient control group in which only incisions and pus drainage were performed. In the treatment group (3 patients dropped out, because they were unable to use the medication) 13 required an incision and 1 patient required surgery, but the remaining 48 patients (77.4%) reportedly healed. There is a report describing that short-term therapeutic results were best in the *Ten Strong Tonic Herbs Decoction* treatment group²⁵.

21) Muramatsu T., Kawamura K., Kuriyama Y. et al.: Usefulness of Treatment with *Middle-Reinforcing and Qi-Benefiting Decoction* for Chronic Pediatric Constipation - Evaluation with a constipation score, Japanese Journal of Pediatric Surgery 32: 285-290, 2000

22) Aoki H., Nishikura T., Ono S. et al.: Kampo Therapy for Constipation in Severely Handicapped Children - Comparison of *Hemp Seed Pill* and *Rhubarb and Licorice Decoction*, Kampo Igaku 21(28): 21-24, 1997

23) Fukushige T., Takamatsu H., Noguchi H. et al.: Clinical Experiences with *Major Middle-Strengthening Decoction* for Insufficient Postsurgical Peristalsis, Ileus, Prog. Med. 17(9): 2554-2558, 1997

24) Kawase K., Satomi A., Yoshida H. et al.: Clinical Experiences in Our Department with *Major Middle-Strengthening Decoction*, Prog. Med. 17(9): 2550-2553, 1997

25) Muramatsu T., Fuseya S.: Clinical Experiences with *Ten Strong Tonic Herbs Decoction* for the Treatment of Perianal Abscesses in Infants, Japanese Journal of Pediatric Surgery 32: 1322-1325, 2000

In most cases, idiopathic thrombocytopenic purpura (ITP) develops as an acute form and is resolved spontaneously after a few months, but for patients with chronic forms not responsive to treatment, Kampo therapy is also performed. Takeda et al. administered *Modified Back to the Spleen Decoction* to 7 children with ITP resistance to western medical treatment and achieved an efficacy of 33%²⁶. Occasionally there are also individual case reports about this disease.

26) Takeda T., Nagatate N., Hatae Y. et al.: Clinical Experiences with *Tsumura Modified Back to the Spleen Decoction* for the Treatment of Chronic Thrombocytopenic Purpura, Iryo 46(12): 1016-1019, 1992

Kampo therapy is used for patients with Henoch-Schönlein purpura resistant to western medical treatment. Single case reports have been published²⁷.

27) Tsuji Y., Abe Y., Hisano M. et al.: Cases of Allergic Purpura Effectively Treated with Kampo, Kampo Igaku 27: 169-172, 2003

The application of Kampo therapy during the early stages of Kawasaki disease is reportedly associated with a favorable prognosis. Hirota et al. divided 19 patients in the acute phase of Kawasaki disease into two groups and treated both groups with the required western medical therapy. Group 1 (including 11 patients) received *Coptis Detoxifying Decoction* and was then compared with a placebo group (8 patients). The results revealed that a combination therapy of vitamin E and *Coptis Detoxifying Decoction* for Kawasaki disease improves the anti-inflammatory effects and lipid metabolism, also improving the prognosis for the vascular changes and has therefore been described as an excellent therapy²⁸.

28) Hirota A., Senaga R., Kawashima S.: Examination of the Effects of *Coptis Detoxifying Decoction* on Kawasaki Disease Using a Double-Blind Study, Japanese Journal of Pediatrics 38: 2329-2335, 1985

The therapy for pediatric bronchial asthma in recent years has made enormous progress, so that the opportunities for using Kampo medicine are now less frequent than before. Yet, a wealth of experiences with the application of Kampo therapy for this disease has accumulated and is now used widely. Numerous preparations are used, but the most widely used preparation is *Combina Minor Bupleurum Decoction and Pinellia and Magnolia Decoction* and several case series studies have investigated its application. Ito et al. conducted a randomized controlled trial (RCT) examining 43 pediatric patients with bronchial asthma divided into a *Combina Minor Bupleurum Decoction and Pinellia and Magnolia Decoction* treatment group including 23 patients and a tranilast treatment group of 21 patients. Twelve weeks after the treatment, general improvement and better than mild improvement was observed in 95% of the patients in the *Combina Minor Bupleurum Decoction and Pinellia and Magnolia Decoction* group, whereas the same ratio was reportedly 73.7% in the tranilast group²⁹. Watanabe et al. treated 22 patients with atopic asthma over a period of three months with *Combina Minor Bupleurum Decoction and Pinellia and Magnolia Decoction* extract and found improvements in 16 of the patients (72.8%) and better than mild improvements in 22 patients (100%)³⁰. *Minor Blue Dragon Decoction* is also frequently used. Inoue et al. treated 9 patients about to develop an attack that started with runny nose, sneezing and then developed into cough and phlegm with *Minor Blue Dragon Decoction* extracts. This reduced the number of attacks significantly. In six of these patients, improvements were observed³¹. When the treatment with extract preparations remains ineffective, the application of decoctions is worth a try and has been reported to produce good results³².

- 29) Ito S., Mikawa H.: Effects of *Combind Minor Bupleurum Decoction and Pinellia and Magnolia Decoction* in the Treatment of Pediatric Bronchial Asthma - Multi-facility joint research And Comparative Trial with Tranilast, The Clinical Report 26: 3993-3998, 1992
- 30) Watanabe H.: Long-term Administration of *Combind Minor Bupleurum Decoction and Pinellia and Magnolia Decoction* for Exercise Induced Asthma and Airway Hypersensitivity in Bronchial Asthma, Kampo Medicine (Jap. Journal of Oriental Medicine) 41: 233-239, 1991
- 31) Inoue K.: Clinical Effects and Limitations of Kampo Therapy for Bronchial Asthma, Pediatrics of Japan 31: 531-540, 1990
- 32) Yamaguchi H.: Experience with the Use of Decoctions for the Treatment of Pediatric Bronchial Asthma Where Western Medical Treatment Has Become Difficult, $\Phi \upsilon \tau \circ 1(4)$: 14-17, 2001

Regarding atopic dermatitis, *Bupleurum Liver-Clearing Decoction*, *Wind Dispersing Powder*, *Coptis Detoxifying Decoction*, *Middle-Reinforcing and Qi-Benefiting Decoction*, *Warming and Clearing Decoction*, *For Eczema Decoction*, *White Tiger plus Ginseng Decoction*, and similar preparations are prescribed and there are many related studies. Temporarily, high hopes have been placed on Kampo therapy for this disease in Japan due to an aversion to steroids. Yet, except for a very small number of cases, it has been shown that with proper skin care the treatment of this condition is not that difficult. Today Kampo medicines are not used as frequently as in the past and independent treatment with Kampo medicine is not performed. Still, Kampo therapy does have a certain beneficial effect on this disease. Among the case series studies, particular attention has been paid to the effects of *Middle-Reinforcing and Qi-Benefiting Decoction* for the treatment of infants (which differs from that in adults). Tsuji et al. administered *Middle-Reinforcing and Qi-Benefiting Decoction* to 187 patients aged between 3 and 6 years with atopic dermatitis. Observing these patients for a period of 24 weeks, workers found improvements for all the items: pruritus, erubescence, papules, vesicles, erosion, hyperplasia, lichenification and scratch marks. In the 24th week, the number of patients that could be evaluated was 71. Marked improvement was found in 23.9%, intermediate improvement in 62.0% and better than mild improvement in 85.9%. Further, the use of topical steroids could significantly be decreased³³⁾. When Ito et al. treated 25 children with atopic dermatitis in whom topic medications had not been sufficiently effective over a period of 12 weeks, they observed significant differences in the improvement following the second week and thus reportedly achieved a better than mild improvement in general condition in about 80% of the patients³⁴⁾.

- 33) Tsuji Y., Tsujimoto Y., Iikura Y. et al.: Investigation of the Clinical Usefulness of *Middle-Reinforcing and Qi-Benefiting Decoction* for the Treatment of Pediatric Atopic Dermatitis, The Japanese Journal of Clinical and Experimental Medicine 70: 290-299, 1993
- 34) Ito S.: Clinical Experiences with the Use of *Bupleurum Liver-Clearing Decoction* Granules for the Treatment of Atopic Dermatitis, The Journal of Traditional Sino-Japanese Medicine, Vol. 10 No.1, Supple. Kampo Therapy for Intractable Diseases or Conditions, second volume: 202-203, 1989

Regarding renal and urinary diseases, several studies have dealt with the use of Kampo medications for chronic glomerular nephritis, nephrotic syndrome and IgA nephropathy. *Minor Bupleurum Decoction*, *Poria Powder with Five Herbs* extract was administered over a period of 1 year to 101 patients with chronic glomerular nephritis (including 32 patients with IgA nephropathy) and 129 patients with nephrotic syndrome in a multi-facility case series study. Improvements were achieved in 63.8% of the patients with chronic glomerular nephritis and 61.5% of the patients with nephrotic syndrome. Regarding the tissue forms, this patient population included 46 patients with proliferative changes of whom 62.5% showed better than mild improvements with 36.4% of the 11 patients with focal sclerosis showing mild improvement. In 28 patients with IgA nephropathy, better than mild improvements were observed in 67.9% of the cases, and in 94 patients with nephrotic syndrome presenting minimal changes, better than minor improvements were reportedly observed in 61.7% of the cases³⁵⁾. Yazaki et al. treated 80 pediatric patients with nephrotic syndrome over an average period of one year with *Minor Bupleurum Decoction*, *Poria Powder with Five Herbs* and thus could reportedly observed some degree of prevention of recurrences and a dose reduction in steroids³⁶⁾. Ito et al. used *Minor Bupleurum Decoction*, *Poria Powder with Five Herbs* extract for 221 patients with nephrotic syndrome in combination with steroid medications and observed a reduction in the frequency of recurrences³⁷⁾. Yoshikawa et al. used *Minor Bupleurum Decoction*, *Poria Powder with Five Herbs* for 101 patients with IgA nephropathy showing mesangial proliferation in a RCT and found after 2 years normalization of the urinary findings in 46% of these patients, which was a significantly higher ratio than in the control group³⁸⁾. Based on these facts, Ito et al. concluded that *Minor Bupleurum Decoction*, *Poria Powder with Five Herbs* alone in the treatment of IgA nephropathies during childhood, characterized histologically by minimal changes or else focal mesangial proliferation, is capable of significantly inhibiting proteinuria and hematuria³⁹⁾. Although few in number, some reports also describe purpuric nephritis⁴⁰⁾.

Since aggravation of IgA nephropathy may be triggered by infections, it has become clear that tonsillectomy in conjunction with steroids leads to an improvement in the hematuria. In other words, if no infections occur, there will also be no aggravation in the renal lesions. As stated above, since treatment with Kampo medicine decreases the susceptibility to infection, formulas like *Bupleurum and Cassia Twig Decoction* or *Minor Bupleurum Decoction* (these formulas are included in the preparation *Minor Bupleurum Decoction*, *Poria Powder with Five Herbs*) etc. are used in order to decrease the chances for infection in attempts at improving the prognosis of this disease.

- 35) Yoshikawa N., Ito T., Takekoshi Y. et al.: Combination Therapy with *Minor Bupleurum Decoction*, *Poria Powder with Five Herbs* for Patients with Steroid-reactive Pediatric Nephrotic Syndrome During the Early Treatment Phase with Steroids and Recurrences - Prospective controlled study - Journal of The Japanese Society of Nephrology 40: 587-590, 1998
- 36) Yasaki T., Hirose S.: Clinical Effects of *Minor Bupleurum Decoction*, *Poria Powder with Five Herbs* for Pediatric Nephrotic Syndrome, Journal of Traditional Medicine 4: 203-206, 1987
- 37) Ito K., Okada T., Kitagawa T. et al.: Ethical Kampo Medicines for Pediatric Chronic Glomerular Nephritis and Pediatric Nephrotic Syndrome: Clinical Effects of *Minor Bupleurum Decoction*, *Poria Powder with Five Herbs* - Multi-facility open trial - Kidney and Dialysis 36: 1237-1246, 1994
- 38) Yoshikawa N., Ito T., Sakai T. et al.: Prospective Controlled Trial Using *Minor Bupleurum Decoction*, *Poria Powder with Five Herbs* for the Treatment of Pediatric IgA Nephropathy Showing Focal and Minimal Mesangial Proliferative Lesions, The Japanese Journal of Nephrology 39: 503-556, 1997
- 39) Ito K., Miyagawa S.: Chronic Nephritis, IgA Nephropathy, Purpuric Nephritis, The Journal of Pediatric Practice 67: 1462-1466, 2004
- 40) Tsuru N., Tokieda K., Niimi K.: Clinical Effects of Tsumura *Minor Bupleurum Decoction*, *Poria Powder with Five Herbs* in the Treatment of Pediatric IgA Nephropathy and Purpuric Nephritis, The Japanese Journal of Clinical and Experimental Medicine 67(9): 236-242, 1990

Among the neurological diseases Kampo medicine is frequently applied for epilepsy. Several reports describe the use of *Bupleurum and Cassia Twig Decoction*, *Minor Bupleurum Decoction and Cassia Twig Decoction plus Peony*, *Bupleurum plus Dragon's Bone and Oyster Shell Decoction*, *Minor Middle-Strengthening Decoction* and similar preparations for the treatment of refractory epilepsy difficult to control by western medical treatment. Okabe administered Kampo medicine to 26 patients with refractory epilepsy and reportedly observed marked effectiveness in one patient (disappearance of attacks) and an effectiveness in 12 patients⁴¹⁾. Sugimoto et al. administered in addition to the ongoing treatment, anticonvulsants Tsumura *Minor Bupleurum Decoction* extract granules and Tsumura *Minor Middle-Strengthening Decoction* extract granules to 30 patients (24 patients with mental retardation, 8 patients with cerebral paralysis) with refractory epilepsy, particularly patients presenting complex partial seizures. They observed 2.5 years after initiation of the combination therapy, a marked effectiveness in 5 patients, effectiveness in 6, temporary effectiveness in 5, no effects in 10 and aggravation in one patient, resulting in an overall efficacy of 40%⁴²⁾. Seki too administered *Minor Bupleurum Decoction and Cassia Twig Decoction plus Peony* to 24 patients with refractory epilepsy and reportedly observed marked effectiveness in 4 patients and effectiveness in 3, resulting in an overall efficacy of 29%⁴³⁾.

41) Okabe T.: Kampo Therapy of Neurologic Diseases in Children, The Journal of Traditional Sino-Japanese Medicine 12: 29-37, 1991

42) Sugimoto T., Yasuhara A., Nishida N. et al.: Kampo Combination Therapy for Refractory Epilepsy - Treatment with *Minor Bupleurum Decoction* and *Minor Middle-Strengthening Decoction*, Japanese Journal of Pediatrics 45(12): 2875-2880, 1992

- 43) Seki T.: Effects of Kampo Medicine (Combined Application of *Minor Bupleurum Decoction*, *Cassia Twig Decoction plus Peony*) on Refractory Epilepsy, Oriental Medicine 19: 16-22, 1995

In the field of Kampo therapy many attempts at improving the various problems or disturbances occurring during the developmental phase of children have been made. Kin et al. used Licorice, *Wheat and Chinese Date Decoction* for 8 pediatric patients with breath holding spells and intractable epilepsy to the antiepileptic agents, and reported clear findings of clinical efficacy with four complete responses and four effective responses⁴⁴⁾. Itakura et al. used *Licorice, Wheat and Chinese Date Decoction* for 24 patients with night terrors and reported finding an efficacy of 87%⁴⁵⁾. The formula *Liver-Inhibiting Powder* is also used for this disease. Several attempts have also been made for patients with autism or ADHD, in whom pharmacotherapy is difficult. Ida administered *Major Bupleurum Decoction*, *Cold Limbs Powder*, *Liver-Inhibiting Powder* and similar preparations to 30 autistic patients (including adults), in whom treatment had been initiated under the age of 13 years and described an overall improvement ratio including 100% improvement in sleep disorders, 88.9% improvement in hyperactivity, 71.4% improvement of temper tantrums, 78.3% improvement of panic attacks, 87.5% improvement for self-mutilation, 90.0% improvement of sudden outbursts of violence, 77.8% improvement of compulsive retention, 68.8% improvement in compulsive behavior, 80.0% improvement of ritual behavior, 83.3% improvement of unreasonability and 80.8% improvement in communication skills⁴⁶⁾. Okashima et al. used various different Kampo medicines in the treatment of severely handicapped children presenting night terrors, displaying violent behavior and similar symptoms and described favorable results obtained through this treatment. The formulas used included *Licorice, Wheat and Chinese Date Decoction* extract, *Liver-Inhibiting Powder* extract, *Modified Merry Life Powder* extract and similar preparations⁴⁷⁾. Takeuchi et al. treated various problems in children with developmental disorders (Asperger disorder, higher function autism, ADHD, extensive developmental disorders, mental retardation with autistic tendencies) with Kampo medicine and described 9 cases in which an improvement had been achieved⁴⁸⁾.

Liver-Inhibiting Powder is a formula frequently used for diseases in this field. This formula was listed by the famous physician Xue Kai in his own textbook of pediatrics in the 16th century. It is particularly noteworthy that he added a statement that "both mother and child should take the drugs". As an excellent pediatrician he was well aware of the mother's influence on the child's diseases and thus

explained the importance of treating the mother as well when children are sick. A number of reports have described the practical application of this concept^{49,50,51,52,53}.

Egawa treated 97 patients with the Kampo medical pattern (SHO) of the *Liver-Inhibiting Powder* with *Tangerine Peel, Pinellia Rhizoma and Liver-Inhibiting Powder* and reported an efficacy of 55%. Although he is a pediatrician, he included mothers, aged 30-50, in his study. They were also treated with this formula. The author explains that treating the mother facilitates follow-up observations of the children⁵⁴. Nishimura et al. explained that the simultaneous treatment of mother and child based on historical views and the current variety of clinical applications can be substantiated citing multiple cases⁵⁵.

In the treatment of adult psychosomatic orders, Kampo medicine may not have any effect on the mental aspects. However, in children it is extremely effective for hyperactivity, tension, sleep disorders, tantrum and similar neuropsychologic symptoms. The situation here is markedly different from that in adults.

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53) Kobayashi T., Nagasawa K.: One Case of Myospasia Impulsiva Where Simultaneous Treatment of Mother and Child with *Liver-Inhibiting Powder* was Markedly Effective, *Kampo Igaku* 27: 75, 2003

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Yamaguchi, employed at a large hospital in Aichi prefecture, treats almost all conditions ranging from those encountered in a pediatric emergency room to many chronic diseases. While training many interns, and being the head of the pediatric department, he has at the same time a profound knowledge of Kampo medicine. He treated 89 patients with Kampo medicine (decoctions) for whom standard western medical treatment proved difficult and published the results. The overall improvement ratio of 64% was very positive. This work certainly verifies that Kampo medicine will play in the future a very important role in this field⁵⁶.

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Conclusions

Current Kampo therapy for a number of representative diseases has been described. Kampo medicine is a system with an extremely broad range of applications of which only a portion has been described here. Due to the lack of space, descriptions of the theoretical aspects of Kampo medicine have been kept to a minimum. A comprehensive list of these descriptions is found in cited references.