

# AN OVERVIEW OF OUR SURGERY-ORIENTED KAMPO

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We began to use kampo drugs for postoperative patients in 1984. What we used frequently were Sho-saiko-to, Juzen-taiho-to, Hochu-ekki-to, and Dai-kenchu-to. We have used these Oriental medicines with Western surgical procedures in surgical patients, who are usually cancer-bearing patients. We have been trying to prove the effectiveness of kampo prescriptions with Western scientific methodology and succeeded partially at least. We presumptuously have tried to unite the two seemingly different medical theories, Oriental and Occidental. We think kampo helps to improve the nutritional status, immunological functions, bone status, and overall quality of life. The advance in the usage of kampo medicine for surgical patients is discussed with review of the literature.

## Introduction

Kampo medicine, as we understand it, is the Japanese modified version of traditional Chinese herbal medicine. The latter has its origin in Sheng Nong Period, ca. 2800 B.C. Sheng Nong, the Divine Plowman, had tasted many plants and identified those helpful for curing certain diseases. The herbal medicine developed and Zhang Chong Jin was a famous physician in the late Han Dynasty, ca. 2nd to 3rd Century A.D. Then the country suffered war and epidemics. Zhang wrote about herbal medicine and typhoid, calling the latter "harmful cold". Zhang's *Diagnosis and Treatment*, or *Shang han lun*, included 397 treatment methods, rules, and formulas. However, in Zhang's period, there was no surgery. Therapy with combination of kampo and surgery came into existence only recently. Our contribution in this field is discussed with review of the literature.

## Sho-saiko-to

According to the authors' memories, the first kampo medicine ever prescribed in our Department of Surgery II, Tokyo Women's Medical College (TWMC), was Sho-saiko-to (TJ-9, Xiao-

chai-hu-tang in Chinese), prepared by Tsumura Co., Tokyo, Japan, in the form of extract granules. One of the authors prescribed it to a patient with postoperative liver dysfunction in 1984. The Institute of Oriental Medicine of TWMC was not yet founded and many physicians regarded kampo as something analogous to superstition. Accordingly, the prescriber of TJ-9 was severely scolded by his senior surgeons. The drug was discontinued about four days later. In retrospect, this looks unusual, but probably it was not the natural reaction in the majority of surgeons then.

Multidisciplinary therapy for cancer was already being advocated in Japan in 1984, but was not the "rule" then. At least so it seemed to us. Many surgeons were proud that they could actually "cure" cancer by surgical resection only. Although paternalism, informed consent, and quality of life became major issues in the USA in the 1960s, the Japanese senior surgeons in 1984 seemed rather paternalistic to us.

Today, Sho-saiko-to (TJ-9) is widely accepted for postoperative liver dysfunction along with Dai-saiko-to (TJ-8, Da-chai-hu-tang in Chinese) and Saiko-keishi-to (TJ-10, Chai-hu-gui-zhi-tang in Chinese). Orientally, these medicines are

prescribed for liver dysfunction according to patient's constitution, or zheng (sho in Japanese). Occidentally, Abe et al. described pharmacological actions of saiko (Bupleurum root, chai hu in Chinese) drugs<sup>1)2)</sup>. Recently, researchers report effectiveness of saiko drugs for cancer<sup>3)4)</sup> and AIDS<sup>5)</sup>. Multi-center studies on TJ-9 are done all over Japan since years ago with good results.

### **Juzen-taiho-to and Hochu-ekki-to**

In 1984, the authors decided to continue to use kampo drugs in related hospitals outside, and got the impression that kampo drugs could be quite effective in some patients. At the same time, we focused our attention on interleukin 2 (IL-2) and nutritional status. Our data showed that IL-2 productivity was markedly compromised in patients with cancer recurrence<sup>6)</sup>.

In 1987, Professor Hamano became Director of the Department of Surgery II, TWMC. Under his direction, we continued our studies. Our early results were reported at Kampo Study Meeting of TWMC<sup>7)</sup>. As we were gastroenterological surgeons, we dealt mainly with gastric cancer patients.

Although survival rates of gastric cancer patients had bettered markedly, many were suffering then from postoperative unidentified clinical syndrome, consisting of variable symptoms. These symptoms might or might not be associated with cancer-bearing state, and might or might not be associated with recurrence. Hoping to improve the quality of life of those postoperative patients, we used kampo medicine<sup>8)9)</sup>. What we prescribed most often then was Juzen-taiho-to (TJ-48, Shi-quan-da-bu-tang in Chinese). This with Hochu-ekki-to (TJ-41, Bu-zhong-yi-qi-tang in Chinese) is regarded as bu ji (hozai in Japanese pronunciation), or supplementary prescription. Bu ji is said to be suited for patients who are xu zheng (kyosho in Japanese pronunciation), or in deficient condition. Bu ji is supposed to mainly supplement qi (ki in Japanese, vital energy). TJ-48 is special in that it also supplements xue (ketsu in Japanese,

blood). TJ-48 seemed an ideal drug for postoperative gastric cancer patients, who seemed to be in deficient condition to us.

As far as English or Japanese literature goes, no one before us has ever discussed bian zheng (bensho in Japanese), or determination of zheng, in patients with organ deficit. In all those thousands of years of Chinese medicine, or in hundreds of years of the Japanese modified version, which we call kampo medicine, this was so because surgery and herbal medicine probably did not coexist. We proposed that postoperative gastric cancer patients were xu zheng and used bu ji to get good results. Orientally, this per se means that our bian zheng was correct, since zheng, in short, is the pattern of patient's symptoms and signs indicating appropriate kampo prescription. When we spoke of this at a workshop at the 54th General Congress of the Japanese Society for Clinical Surgery, we met with certain approval<sup>10)</sup>. We said the same at the 45th General Congress of the Japan Society for Oriental Medicine and met with severe criticism<sup>11)</sup>. The moderator, Professor Nabeya of Kyorin university, concluded that more study was necessary. As our administration of bu ji seemed effective, we still think that postgastroectomy cancer patients are xu zheng, regardless of preoperative status, probably because of the organ deficit and lymphadenectomy.

Administering kampo drugs, we measured various immunological parameters such as IL-2 productivity, reactivity, receptor, CD4, CD8, natural killer (NK) activity, etc. We reported at the Eighth Hakata Symposium that with administration of TJ-48, IL-2 productivity seemed to recover earlier from postoperative depression than reported<sup>12)13)</sup>.

From blood count and biochemistry, we calculated Onodera's nutritional index (NI)<sup>14)</sup>. This is the sum of 10 times the serum albumin (g/dl) and 0.005 times the lymphocyte count (/mm<sup>3</sup>). This index is useful because it does not require special laboratory tests or difficult unusual bodily measurements. We reported that the change of NI was similar to that of NK activ-

ity. In stage III gastric cancer patients, there was clear malnutrition.

TJ-48 is usually selected over TJ-41 for patients with anemia as it supplements xue as well as qi. But special harsh taste and smell may discourage the patient from taking it regularly. Roughly speaking, indeed, we invariably selected TJ-41, which tastes better, over TJ-48 for such patients. They were usually postgastrectomy outpatients with anorexia, pain, insomnia, abdominal fullness, etc. We reported that Onodera's NI elevated significantly with alleviation of the symptoms.

The cells that make bones are of mesenchymal origin, as well as immunocytes. In fact, some regard bone mineral content as an index of immunological function in the aged<sup>15</sup>). As survival rates of gastric cancer patients bettered, many are suffering from bone disorder after gastrectomy<sup>16)17</sup>). This may be because of decreased intake of calcium or rapid passage of food in the small intestines<sup>18</sup>). We administered TJ-41 to postoperative gastric cancer patients with bone disorders. Although the results were not better than those for combined administration of vitamin D and calcium, TJ-41 improved bone disorders, as well as appetite and symptoms of the patients with no side effects.

Our reports on TJ-48 and TJ-41 may have contributed to make a trend in the Japanese surgical society. Nutrition, immunity, and bone mineral content seemed to improve, along with symptoms<sup>19</sup>). One of the authors gave a lecture over the radio. Other surgeons have reported effectiveness of TJ-48 for other gastrointestinal cancers<sup>20</sup>). Now, local study groups for TJ-48 or TJ-41 are active all over Japan.

When our results were published in the USA in 1994, we received letters and reprint requests from the USA, UK, Canada, and Cuba<sup>21</sup>). An abstract translated into Japanese was printed on a Japanese journal<sup>22</sup>).

### Dai-kenchu-to

Dai-kenchu-to (TJ-100, Da-jian-zhong-tang in Chinese) is an old prescription that originally

appeared in Jin kui yao lue, a part of Zhang's famous Diagnosis and Treatment, or Shang han lun. It is supposed to warm up the intestines affected with harmful cold. Professor Hamano, along with Professor Nabeya of Kyorin University, has been using TJ-100 for patients with postoperative adhesive ileus. Now multi-center study on TJ-100 is on way. Professor Kameoka has reported good results, using ultrasonography for diagnosis on postcolectomy patients<sup>23</sup>).

Some surgeons may be the most materialistic among physicians. They usually do not believe in harmful cold or qi or xue or shui. However, since ileus has been a nerve-racking problem for surgeons, they are now happy to use TJ-100. Acceptance of TJ-100 among surgeons probably marked the acceptance of kampo in the Japanese medical society.

In 1990, the Japan Society for Oriental Medicine accredited three doctors from the Department of Surgery II to be "specialists" in Oriental medicine. Not many doctors got this title and we were proud that our works were widely accepted. Next year, the Society became a subsociety of the Japan Medical Congress. With all these developments, the use of TJ-100 for patients after abdominal surgery has become almost a routine in our Department now. TJ-100 seems especially effective for postoperative adhesive ileus. There seems to exist a prophylactic anti-ileus effect. It is interesting that TJ-100 is effective for both diarrhoea and constipation.

### Discussion

As we have obtained good results using kampo drugs, we will compare the concepts of medicine in Oriental and Occidental context (Table 1). Certainly we would like to know the reason why kampo remedies were effective, if there was a reason at all. Kampo prescriptions have multiple components and are well balanced. This is in strong contrast to Occidental drugs that are usually single molecular and meant for just one pharmacological action. But this means that such drugs, almost by defini-

**Table 1** Comparison of medicine in the East and the West

|                    | Oriental medicine   | Occidental medicine (New agents)          |
|--------------------|---|---|
| Material           | Natural compounds   | Synthetic chemical compounds              |
| Composition        | Multiple components   | Single molecular component                |
| Pharmacology       | Multiple actions (Unknown action ?)                                       | Single pharmacological action             |
| Clinical effect    | Mild  | Strong                                    |
| Side effects       | Rare  | Frequent                                  |
| Target diseases    | Functional ?  | Organic ?                                 |
| Application theory | Ying Yang<br>Xu Shi<br>Qi Xue Shui<br>Zheng, constitution?<br>Integrative | Pathophysiology<br><br><br><br>Analytical |
| Character          | "Individual" medicine   | "Mass" medicine                           |

Ying Yang : relativity of disease condition or category, "negative" or "positive" .

Xu Shi : deficient or robust.

Qi Xue Shui : vital energy, blood, and water (bodily fluids).

One of the beneficial characteristics of Oriental medicine is that side effects are rare. However, the application theory is difficult to understand. In short, Oriental medicine is "individual" while the Occidental medicine that we usually use is "mass" medicine. (See text.)

tion, have many "side effects". Conversely, in Occidental context, many of kampo prescriptions may not satisfy the criteria for a "drug".

It is certain that Occidental drugs are more potent than kampo drugs. However, unfortunately their side effects seem more frequent and severe. Occidental drugs have been developed by biosynthesis and modifications of side chains, although they have their origin in natural compounds. This trend of natural to chemical/synthetic seems somewhat reversed recently after all those side effects have been reported. Now people seem to be looking for things gentle for the environment and the nature. In Oriental context, man is a part of the nature. So now, the trend of the age is from chemical to natural.

We think the sense of balance is very important in kampo practice. Kampo drugs seem to act mildly when and where needed. Originally, there was the concept that drug and food had the same origin (ishoku-dogen in Japanese), and this concept can be considered as the ultimate drug delivery system. In a way, kampo medicine is a prodrug. People could maintain their health with oral administration of herbs and seeds (prodrugs) available on each season. The

evolution of scientific technology has made it possible to have almost any food despite the season or the weather or the soil.

In Occidental context, it once seemed that man had almost overcome the nature. But it turned out that environmental pollution, for example, became a serious problem. What we call technology, medicine inclusive, has made longevity possible, but at the same time, we are faced with "advanced" and unnatural conditions. People now suffer from obesity, diseases related to stress, lack of exercise, hypervitaminosis, and newer disease entities. Who can say that these conditions are not related to newer technologies? Clearly, we cannot go back to primitive life, but understandable is the trend of chemical to natural. This seems related to consumer movements to avoid chemical preservatives and food additives, for instance. Many patients dislike taking too much medicine. Now we can treat or prevent diseases by taking kampo drugs, if we regard them as drugs at all.

On the other hand, one may recall that detection of plant compounds having immunostimulative or antiviral activities is now under way<sup>24)25)</sup>. Such approach may be according to the concept that drug and food have the same

origin. One of the authors' thesis showing the immunostimulative effects of guanidinocaproic acid methanesulfonate in cancer patients' blood had the same approach<sup>26)</sup>. The compound is similar in chemical structure to arginine, which has been reported to have immunostimulative effects<sup>27)28)</sup>.

Certainly, arginine is contained in food. So arginine-rich diet may stimulate immunity. Purification of arginine from food may make an Occidental drug to stimulate immunity. Intramuscular or intravenous (parenteral) administration of such may be more effective than oral. Monitoring of the serum concentrations of arginine may help to decide optimal dosage. A side chain may be modified in arginine to make a more potent drug, may be guanidinocaproic acid. Is it really so? What about intestinal bacterial flora?

One should note that Oriental way and therefore kampo way are not in purification and isolation of a single molecular compound from crude ingredients. For example, Tashiro clearly showed the argumentation of the paragraph above is incorrect, using chromatography of kampo drugs, urine, and serum<sup>29)</sup>. Oral administration of a kampo prescription may change the products of the intestinal flora. These products are the real pharmacologically active compounds. Therefore, serum levels of the components of the original drug can be meaningless. Conventional double blind test is useless to evaluate kampo medicine. Tashiro's establishment is in clear contrast to conventional pharmacology. The authors think kampo medicine may be also related to gut-associated lymphatic tissues (GALT). This may partially explain the better outcome of breast cancer patients than gastrointestinal cancer patients. We are not forgetting the great achievements of chemoendocrine radiotherapy, but at least, the former can freely eat.

Oral administration seems a key point in kampo practice. Kampo medicine can be described as "individual" medicine, in contrast to Western medicine, which we regard as "mass"

medicine. Purified Western drugs are usually effective in the majority of patients. Kampo remedies must be administered according to zheng. Otherwise they may be ineffective or even cause adverse effects. Therefore kampo medicine is "individual", and zheng is important. Zheng seems to have yet unknown relationship with differences in the intestinal bacterial flora, as well as patient's build and heredity<sup>30)</sup>.

Zheng is difficult to understand although we have been trying cast a light of almost alien but widely accepted Western medical theory. Although *bian zheng* varies among kampo physicians, and between Chinese and Japanese physicians, there seems to exist a vague agreement<sup>31)</sup>. For example, for liver dysfunction, the saiko drugs mentioned before are used. TJ-8 is used for patients who are not *xu zheng*. TJ-9 and TJ-10 are for patients in deficient condition, the latter for more deficient patients. TJ-41 seems effective for still more deficient patients. An interesting fact is that the amount of saiko decreases in the order of TJ-8, TJ-9, TJ-10, TJ-41. For really deficient patients with liver dysfunction, saiko can no longer be used. For these patients, TJ-48 with its tonic effect seems useful. The latter two are considered supplementary prescriptions. We think most kampo physicians would agree on the above, but the issue of zheng is yet to be elucidated. More understanding on bacterial flora or genetics seems necessary.

That kampo remedies have multiple components also apply to supplementary prescriptions. Some of the components have antagonistic pharmacological actions to each other. For example, some act to stimulate immune response<sup>32)</sup>, while others seem to suppress it. So kampo drugs seem to act on a subtle balance, which is what we have previously meant by the ultimate drug delivery system. Kampo drugs seem to act to maintain homeostasis, neuroendocrine immune system inclusive. Nutritional status, which we have shown to improve, can be regarded as an index of homeostasis.

Since our administration of supplementary prescriptions did not enhance immunity effectively in patients without malnutrition, we proposed that in cancer-bearing state, different processes of cytotoxicity or blast formation were damaged, leading to apparently discrepant results. Kampo prescriptions may act on multiple sites to repair immunity. As discussed before, kampo prescriptions act not only to enhance immunity, but rather to maintain homeostasis of the organism. We think this may also apply to so-called biological response modifiers, or BRMs, which are now used in cancer therapy<sup>33</sup>. Kampo prescriptions may be regarded as BRM. Furthermore, one should note that kampo prescriptions such as TJ-48 contain ingredients that may have antagonistic actions to each other. As discussed before, it may not be regarded as “drug” for immunotherapy at all in the West, but such seems the way in the East.

Our results showed that NK activity and Onodera's NI, and IL-2 reactivity and its receptor had statistically significant relationship. But for each patient, the results showed much variance and discrepancy. So we thought that supplementary prescriptions had direct and indirect actions on immunity. Indirect actions obviously seemed related to nutritional status. We were happy with our results, but one of the criticisms that we received was that TJ-48 or TJ-41 had only ambiguous direct action on immunity. Those critics would continue that what we were saying was that kampo increased appetite. If prostrated patients ate, it was only natural that immunity or bone disorder or whatever would get better. No pharmacological action was present, they said. Even if this were true, to increase the appetite of a cancer patient would be a great beneficial effect in our opinion. If a patient felt better and became active, it would be a great improvement. There are reports suggesting that exercise stimulates immunity<sup>34</sup>.

Although multidisciplinary therapy is the rule in treating cancer, no therapy is free from side

effects. Ministry of Public Welfare has reported even fatal cases. With improvement of survival rates, more and more patients are having impaired quality of life from side effects of cytotoxic anticancer chemotherapy or radiotherapy<sup>35</sup>. Kampo prescriptions seem to reduce the side effects of toxic agents used in anticancer chemoradiotherapy, with only minimal side effects of their own<sup>36</sup><sup>37</sup>. The rarity of side effects of kampo is good, especially for cancer patients.

Multiple actions of kampo prescriptions may be extremely beneficial in some instances. As the life expectancy of the Japanese is the highest in the world, aged patients are increasing. There are more cancer patients in the elderly population. These patients frequently have multiple complications and may be taking many drugs. For example, one of the authors recently reported an effective use of Hachimijio-gan (TJ-7, Ba-wei-di-huang-wan in Chinese) in an octogenarian<sup>38</sup>. He had hypertension, bronchietasis, angina pectoris, benign prostate hypertrophy, etc. He was taking 13 drugs regularly, one on need, and was using two patch drugs. With administration of TJ-7, he was good on four other drugs regularly and one on need only. Thus kampo prescriptions can contribute to saving of medical expenditure. Since Ministry of Public Welfare seems to be trying to limit the health budget, kampo remedies, if used properly, can be quite contributable.

Surgery and kampo practice should have a complementary relationship. Cancer patients usually come to surgical department when the lesions are local. As surgeons, we believe that for local diseases, surgery has an overwhelming advantage over other therapeutic modalities. Yet internal and external environments or diathesis that contributed to carcinogenesis may persist after surgery. It is common knowledge that the disease can no longer be regarded as local in the event of recurrence or metastasis. It should be considered general. Postoperative cancer patients are frequently associated with unidentified clinical syndrome, which is

**Table 2** Problems of cancer-bearing patients and surgery-oriented kampo

| Local                    | Systemic   |
|--------------------------|--|
| Tumor (Analytical)       | Internal and external environments, metastasis (Constitution? disposition? integrative)<br>Neuroendocrine immune functions |
| Mass effect, etc.        | Disturbance of homeostasis, nutritional status   |
| Local symptoms and signs | Unidentified clinical syndrome   |
| ↓                        | ↓  |
| Surgical treatment       | Kampo treatment  |

Note that surgery and kampo practice have a complementary relationship, although there is much to be elucidated. The important point here is to improve the quality of life of these patients. (See text.)

usually difficult to treat with conventional Occidental drugs. The cause of the syndrome may be side effects of interdisciplinary adjuvant chemoradiotherapy or unknown progression of cancer, or something else. From these considerations, it seems rational to administer supplementary kampo drugs to postoperative cancer patients in deficient condition. Such use of kampo medicine in surgery, which is what we mean by surgery-oriented kampo, would help to improve the general status and quality of life of surgical patients (Table 2).

Recently, more surgeons in Japan are using kampo prescriptions<sup>39</sup>. However, on the other hand, traditional Chinese and kampo physicians seem to put too much emphasis on traditional logic and classical literature of thousands of years ago. We are trained in Western medicine, and felt much honored to speak at the First Congress of the Surgical Kampo Society<sup>40</sup>.

### Conclusion

We think that a new hybrid field of surgery-oriented kampo may be promising. It can contribute much, while saving medical expenditure, to improve the quality of life of long survivors after cancer operation.

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### 我々の外科漢方についての概論

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堀江 良彰・加藤 一彦・浜野 恭一

近年術後の障害に対して、また癌の集学的治療の一環として、漢方方剤が用いられるようになってきた。当外科においては、小柴胡湯、十全大補湯、補中益気湯、大建中湯などが頻用されている。

我々は東洋医学に西洋医学の光を当て、西洋的な外科手術と東洋医学を相補的に併用することにより、主として担癌患者である外科患者の quality of life を改善することができるのではと考えた。我々は癌術後患者は虚証であると弁証し、主として補剤を用いたが、栄養状態、免疫能、骨塩量、および自覚症状の改善を見たので報告してきた。最近の外科漢方の展開に些かなりとも貢献できたと自負しているので、上記の方剤について、また外科漢方の考え方について概観する。