Review

Roles of Kampo Medicine in Modern Cancer Therapy: Towards Completion of Standard Treatment

Running title: Kampo in Cancer Therapy

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Abstract

Kampo Medicine is a traditional Japanese medicine that is well-integrated in modern medicine. Anti-cancer agents are highly developed, and evidence of standard treatment has accumulated. Kampo Medicine is needed to support patients with cancer who lose vital energy and feel cold. Cancer chemotherapy is associated with various adverse reactions, such as anorexia, general malaise/fatigue, and peripheral neuropathy, which are refractory to modern therapy. Recently, evidence of Kampo Medicines for these symptoms has been reported as randomized controlled trials (RCTs). The Japan Society for Oriental Medicine celebrated the first 20 years of the activities of evidence-based medicine (EBM) committee in June 2021. Among the activities of the EBM committee, Evidence Reports of Kampo Treatment contains RCTs and meta-analyses, including RCTs on cancer supportive care. There is accumulating evidence for the following Kampo formula for each symptom: Hangeshashinto for mucositis, rikkunshito for anorexia, goshajinkigan and ninjin’yoeito for peripheral neuropathy, hochuekkito for general malaise/fatigue, and shakuyakukanzoto for myalgia/arthralgia. However, there is insufficient evidence, and further clinical trials are needed. Supportive care with Kampo Medicine will lead to a more complete standard treatment for cancer.
Introduction

Kampo is a traditional Japanese medicine that originated from ancient Chinese medicine and developed greatly during the period between the 16th and 19th centuries. Since 1967, national health insurance has covered 148 Kampo products for ethical (medical) use. It would not be too late to learn Kampo medicine after obtaining a fellowship in any medical field. It is of great importance to judge the indications and limitations of Kampo medicine.

Drug therapies against cancer have greatly developed, such as cytotoxic agents, molecular targeting drugs, anti-angiogenic agents, and immune checkpoint inhibitors. These drugs have high levels of efficacy and safety, and it is necessary to complete standard treatment (standard of care) as much as possible, especially against highly aggressive cancers. On the other hand, tumor-bearing patients suffer from vital energy and coldness and need supportive care, including some warming measures, such as Kampo medicines. Therefore, we need to seek a balance between offense and defense (Fig. 1).

The concept of “Kampo for cancer supportive care” is supported by the industry, academia, and government in Japan. Industrial support includes the establishment of “The Future Vision for Kampo Medicines 2040 - Responsibility for People's Health and
Healthcare –” by the Japan Kampo Medicines Manufacturers Association in 2018².
Academic support includes the activities of the Kampo Study Group of the Japanese
Association for Supportive Care in Cancer (JASCC). A practical guide for the
application of Kampo medicine for cancer supportive care was published in 2020³.
Governmental support is shown in the description of Kampo as a supportive measure
for cancer patients in the Basic Plan to Promote Cancer Control Programs issued by the
Ministry of Health, Labour and Welfare of Japan in 2015⁴.
Cancer chemotherapy is associated with various adverse reactions. Although nausea,
vomiting, and neutropenia have been fairly overcome owing to the progress in anti-
emetic drugs and granulocyte colony-stimulating factors, there are symptoms that are
refractory to modern medicine, such as anorexia, general malaise/fatigue, and peripheral
neuropathy. Recently, RCTs have presented evidence regarding the effectiveness of
Kampo medicines against these symptoms.
The Japan Society for Oriental Medicine (JSOM) celebrated the first 20 years of the
evidence-based medicine (EBM) committee in June 2021⁵. Among the activities of the
EBM committee, Evidence Reports of Kampo Treatment (EKAT) includes RCTs and
meta-analyses. There are 90 RCTs and three meta-analyses regarding cancer supportive
care⁶.
In this review, I discuss the role of Kampo Medicine in cancer supportive care and
show recent evidence of various Kampo formulae.

1. Significance of Kampo in modern cancer medicine

In Japan, experts in many medical fields prescribe Kampo medicines, which is of
great significance in clinical practice because experts know the natural history of each
disease. Kampo medicines can be prescribed not only by Kampo experts, but also by
experts in various clinical fields. Broad application of Kampo medicines would clarify
the value of Kampo medicine and help patients and their families enjoy its merits. The
best selection of modern or Kampo medicines is recommended for each patient
according to the disease and its stage, recognizing the value of each medicine.

Therefore, I would like to propose the target “Kampo Medicine recognized and
needed by modern medicine”. Dr. Kyushin Yumoto (1876-1941) is a pioneer of
contemporary Kampo Medicine in Japan, and he tried to combine East and West
Medicines. Dr. Shigeaki Hinohara (1911-2017) describes in his book “Therefore,
medicine is interesting” that Japanese doctors should utilize Kampo Medicine more
when there is a limitation of Western Medicine⁷.
Supportive care is defined by the National Cancer Institute of the United States of
America as follows: “Care given to improve the quality of life of patients who have a serious or life-threatening disease. The goal of supportive care is to prevent or treat as early as possible the symptoms of a disease, side effects caused by treatment of a disease, and psychological, social, and spiritual problems related to a disease or its treatment. Also called comfort care, palliative care, and symptom management”.8

A patient who suffers from side effects of cancer chemotherapy has a mixed pathophysiological status. There are limitations in individual care for each symptom, which leads to polypharmacy. On the other hand, Kampo diagnosis is a comprehensive, holistic approach that directly suggests a proper Kampo formula (Fig. 2). Therefore, Kampo can solve the problem of polypharmacy. The problems and possible resolutions of Kampo are summarized in Table 1.

In addition, the reasons why the timing of Kampo drugs is usually described as “before or between meals” are as follows. Firstly, if Kampo drugs are taken after meals, the absorption of Kampo components could be delayed, because the absorptions of foods and Kampo drugs would compete with each other. Secondly, Kampo drugs are glycosides, which are hydrolyzed by intestinal flora. Postprandial Kampo medication would influence this hydrolysis. Finally, Kampo products are approved for the coverage by the national health insurance only as the “before or between meals” ways of medication.

2. Various Kampo formulae for the symptoms in cancer patients
2-1. Chemotherapy-induced mucositis

Indications for health insurance of hangeshashinto include oral mucositis and diarrhea.

An RCT on chemotherapy-induced diarrhea was reported by Mori et al.9 This study compared the efficacy and safety of hangeshashinto with a group not administered with the drug, showing that the incidence of severe (grade 3 and 4) diarrhea was significantly lower in the hageshashinto group than in the control group.

An RCT on chemotherapy-induced oral mucositis was reported by Matsuda et al.10. This study was a multicenter, placebo-controlled, double-blinded RCT. Patients with grade 1 oral mucositis were treated with either hangeshashinto or placebo. Although the incidence of grade 2 or higher was not significantly different between the two groups, the mean duration of grade 2 oral mucositis was significantly shorter in the hangeshashinto group than in the placebo group.

Case presentation 1: A 70 year-old woman visited our outpatient clinic. She underwent surgery for pancreatic head cancer successfully three years ago. However,
she suffered from oral mucositis, postprandial diarrhea, anorexia, and anxiety. Her physical findings were as follows: Height: 162 cm, weight: 48 kg, oral cavity: reddish but not aphthous, and chest: no heart murmur. There was abdominal tenderness at the epigastrium and slightly increased intestinal peristaltic sounds. There was no leg edema. Her Kampo medical findings were as follows: Tong: thick white coating; Pulse: sunken; and Abdominal: intermediate abdominal strength, epigastric tenderness, and resistance. Hangeshashinto was prescribed at a dose of 7.5 g/day. The above four symptoms were ameliorated in two weeks. She could then enjoy trips with her husband.

2-2-1. Chemotherapy-induced peripheral neuropathy

Chemotherapy-induced peripheral neuropathy (CIPN) can be roughly classified into axonopathy and neuronopathy. Taxanes, such as paclitaxel and docetaxel, cause axonopathy, which can be ameliorated by cessation or reduction of each drug. On the other hand, platinums, such as oxaliplatin, cause neuropathy, which often becomes severe and continues for several years after therapy. Goshajinkigan has been used in the treatment of diabetic peripheral neuropathy. There are RCTs on the efficacy of goshajinkigan for taxane-induced peripheral neuropathy\textsuperscript{11,12}. Kaku et al.\textsuperscript{11} reported the efficacy of goshajinkigan for paclitaxel-induced peripheral grade 1 neuropathy in patients with gynecologic cancers. The change in the number of incidences of abnormal current perception threshold ratio at 6 weeks of administration was significantly smaller in the goshajinkigan plus vitamin B12 group than in the vitamin B12 alone group. Abe et al.\textsuperscript{12} reported the preventive efficacy of goshajinkigan for docetaxel-induced peripheral neuropathy in patients with breast cancer. The incidence and grade of CIPN were significantly lower in the goshajinkigan group than in the control group (non-administrative group).

Case presentation 2: A 50-year-old man with multiple skin tumors was diagnosed with cancer of unknown primary cause (poorly differentiated adenocarcinoma). The patient was treated with carboplatin and paclitaxel. He complained of numbness of the extremities after the second cycle of chemotherapy. General findings: Height, 168 cm; weight, 67 kg; general malaise; mild appetite decrease; and nocturnal pollakisuria. Kampo medical findings: tongue: no coating, slightly reddish; pulse: weak; abdominals: weak strength and weakness of the lower abdominal region. Based on these findings, goshajinkigan was prescribed at a dose of 7.5 g/day. The CIPN did not progress after the administration of goshajinkigan, and remained at grade 1. The above chemotherapy regimen was administered without any decrease in dose, and six scheduled cycles were completed. Therefore, the relative dose intensity was 100%, resulting in a complete
response with diminishing of all skin tumors.

2-2-2. Oxaliplatin-induced peripheral neuropathy.

The efficacy of goshajinkigan has been examined in retrospective\textsuperscript{13}, prospective single arm\textsuperscript{14}, phase 2\textsuperscript{15}, and phase 3\textsuperscript{16} studies, and two meta-analyses\textsuperscript{17,18} concluded that there is no confirmed efficacy of goshajinkigan for oxaliplatin-induced peripheral neuropathy. Recently, the efficacy of ninjin’yoeito for oxaliplatin-induced peripheral neuropathy was reported by Motoo et al.\textsuperscript{19} in the “HOPE-2” study. They showed that the grade of oxaliplatin-induced chronic peripheral neuropathy was significantly lower in the ninjin’yoeito group than in the control group (ninjin’yoeito non-administration). On the other hand, the relative dose intensity of oxaliplatin was significantly greater in the ninjin’yoeito group than in the control group. Therefore, ninjin’yoeito can reduce peripheral neuropathy and increase the efficacy of oxaliplatin. Overall survival and recurrence-free survival tended to be prolonged compared with those in the control group, although the differences were not significant.

2-3. Chemotherapy-induced myalgia/arthralgia

Yoshida et al.\textsuperscript{20} reported their RCT on the efficacy and safety of shakuyakukanzoto for patients with non-small cell lung cancer. Fifty patients were randomly assigned to either the shakuyakukanzoto group or the control group (shakuyakukanzoto non-administration). The incidence and grade of chemotherapy-induced myalgia/arthralgia were significantly lower in the shakuyakukanzoto group than in the control group.

Case presentation 3: A 60 year-old woman visited our outpatient clinic with myalgia/arthralgia after chemotherapy (carboplatin plus paclitaxel) for advanced uterine cervical cancer. She had mild renal dysfunction, and her gynecological doctor prohibited the use of non-steroidal anti-inflammatory drugs. Kampo diagnosis revealed that her tongue was normal, her pulse was string-like, and her abdominal muscle tension was increased. Shakuyakukanzoto was administered at a dose of 7.5 g/day. She visited our clinic after a week, saying that she was so happy because she had only mild myalgia/arthralgia after chemotherapy. She continued chemotherapy with one-week shakuyakukanzoto administration.

2-4. General malaise/fatigue

Jeong et al.\textsuperscript{21} reported that hochuekkito significantly ameliorated cancer-related fatigue in an RCT. Although American ginseng showed significant efficacy for cancer-related fatigue in a double-blind RCT\textsuperscript{22}, there has been no other RCT on the Kampo
Case presentation 4: A 45-year-old woman visited our outpatient clinic because of fatigue and insomnia. She had undergone surgery for breast cancer half a year ago and received hormonal therapy with a 5-year plan. She returned to work one month after the operation, and felt considerable fatigue, compared to her feeling before the surgery. Nevertheless, she could not sleep well, and her fatigue gradually deteriorated. Physical findings: height, 150 cm; weight, 42 kg. She had mild anemia and was exhausted. She complained of general malaise, anorexia, exertional palpitations, and depression.

Kampo diagnosis: The patient’s tongue was covered with white fur. Pulse: small, deficient, string-like. Abdomen: weak strength, mild right hypochondric discomfort. Hochuekkito at a dose of 7.5 g/day was administered for postoperative fatigue, and sansoninto at a dose of 5.0 g/day was prescribed for insomnia. Her symptoms started to improve after two weeks, and apparently ameliorated in one month.

Case presentation 5: A 38-year-old woman was referred to our outpatient clinic because of nivolumab-induced general malaise. The patient had an esophageal melanoma with liver metastases. Immune-related adverse events were ruled out after biochemical tests, including thyroid function. Physical findings: height, 162 cm; weight, 38 kg; and an enlarged liver palpated through the skin. Kampo diagnosis: The patient’s tongue had no fur, and her pulse was deficient and sunken. Her skin was markedly dry. Her abdominal strength was weak, and brisk pulsation in the supra-umbilical region was observed. Juzentaihoto was prescribed at a dose of 7.5 g/day, and her general malaise was markedly decreased compared to the previous cycle of nivolumab. She was able to continue treatment thereafter.

2-5. Anorexia

Basic experiments have been conducted on the efficacy of rikkunshito in treating cisplatin-induced anorexia. Rikkunshito increases the excretion of ghrelin from gastric parietal cells and the expression of the ghrelin receptor in the hypothalamus. There is also a crossover RCT on the efficacy of rikkunshito for cisplatin-induced anorexia in patients with gastric cancer and lung cancer.

Case presentation 6: A 63 year-old woman visited our outpatient clinic because of chemotherapy-induced anorexia. She received carboplatin plus paclitaxel for recurrent ovarian cancer. She had peripheral neuropathy and general malaise, in addition to anorexia. Kampo diagnosis: She was depressed and worried about her disease. Her tongue had intermediate white fur, her pulse was deficient, and her abdominal strength was weak, with tenderness, resistance, and splashing sounds in the epigastric region.
Based on these findings, rikkunshito at a dose of 7.5 g/day and kososan at a dose of 7.5 g/day were prescribed. Her appetite oral intake gradually increased, and she was able to continue chemotherapy.

Case presentation 7: A 76 year-old man was referred from a urology clinic due to anorexia and fatigue. He received hormonal therapy for advanced prostate cancer with multiple bone metastases. He was fragile, fatigued, and had no appetite for taste disorders. Kampo diagnosis: His tongue had thin white fur. The patient’s pulse was floating and deficient. His abdomen showed weak strength, epigastric tenderness and resistance, and mild right hypochondric discomfort. Hochuekkito at a dose of 7.5 g/day was administered, and one month later, he said “That Kampo medicine was great. It made me energetic, and my appetite gradually recovered. I became able to do some farming chores.” He received both hormonal therapy from urology and Kampo treatment at our clinic.

Case presentation 8: A 70 year-old woman received the carboplatin plus paclitaxel regimen for carcinomatous peritonitis of unknown primary cancer at a cycle of three weeks. She experienced anorexia from day 1 to day 7 after each chemotherapy, and her performance status was 3. Kampo diagnosis: She looked exhausted. She felt coldness in her lower extremities. She could not sleep well and often woke up at night. She had anemia with a hemoglobin concentration of 8-9 g/dL. Her tongue had no fur, her pulse was sunken and small, and her abdominal strength was weak with epigastric pulsation. Based on these findings, ninjin’yoeito at a dose of 9.0 g/day was prescribed, and her appetite recovered within three weeks. Subsequently, she continued chemotherapy, which finally led to a complete response, and her ascites disappeared. Her chemotherapy regimen was changed to paclitaxel plus bevacizumab, and ninjin’ yoeito was continued. She survived for approximately five years since the onset of the disease in good condition. She even desired to do volunteer work, which surprised her family and medical staff.

3. Clinical viewpoints for Kampo formula determination

  We should not stick to one symptom; instead, it is of great importance to observe the patient as a whole, as if we were looking at a distant mountain. It is a clinical tip to seek any subjective symptoms or objective findings other than the chief complaint by history taking and physical examination from the viewpoint of Kampo Medicine. Through these procedures, we can obtain hints regarding the prescription of a proper Kampo formula. This tip is also important to determine the second or third choice of the Kampo formula when we cannot obtain a sufficient clinical response with the first choice.
Kampo plays an important role in controlling the side effects of cancer chemotherapy. However, further contributions would be possible for Kampo; for example, to improve nutritional status and support for getting jobs and reasons for living (Fig. 3).

Conclusions
Today, experts in various medical fields can prescribe Kampo formulae. Clinical evidence, especially RCTs in the English language, have been published by authors from Japan. Listening to the narrative of a patient and taking detailed physical examinations will lead to the determination of proper Kampo formulae.

Conflict of interest statement
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offense

Attack with anti-cancer agents having high-grade of evidence

cancer

defense

Patient receiving chemotherapy

Decrease in energy and willpower

Kampo for support
Comprehensive and holistic approach

Multi-component system

Mixed pathophysiology

Kampo formula (Treatment)

Kampo comprehension (Diagnosis)
management of side effects

nutritional improvement

support for getting jobs and reasons for living
Table 1. Problems in supportive care in cancer and their solutions with Kampo

| Problem                                           | Solution with Kampo                                      |
|---------------------------------------------------|----------------------------------------------------------|
| Tendency to polypharmacy                         | One formula for multiple symptoms                        |
| Most supportive drugs are expensive              | Kampo products are cheap                                 |
| Some supportive drugs have side effects           | Kampo’s side effects are rare                             |
| No remedy for refractory symptoms                 | Kampo has potentials to ameliorate refractory symptoms   |
| Small number of experts in supportive care       | Education of Kampo is in progress                        |