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## Special Feature Article

### Kampo Medicine in the Field of Psychiatry

Kazuo YAMADA

Division of Psychiatry, Tohoku Medical and Pharmaceutical University Hospital

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#### Abstract

Kampo medicine, a traditional medicine of Japan, was used in psychiatric practice in the latter half of the 18th century (the Edo era). Pharmacotherapy using Kampo formulas was carried out before the arrival of therapeutic drugs from the Western world. From that time to the present, the core of Kampo therapy has been “zuisho-therapy”, in which treatment proceeds according to the Kampo medical diagnosis (“sho”). In recent years, “evidence-based medicine (EBM)” has also been used in a similar way to modern medicines. In the present study, we discuss the future prospects and issues of kampo medicine in psychiatry based on the concepts of “vertical evidence” and “horizontal evidence”. Currently, most Kampo formulas prescribed in psychiatric clinics are those based on EBM (horizontal evidence) such as yokukansan for behavioral and psychological symptoms of dementia (BPSD). However, a minority of cases are prescribed a Kampo formula based on zuisho-therapy (vertical evidence). Thus, Kampo therapy that makes full use of horizontal evidence will probably continue to be performed in the future. Herein, we advocate for the use of vertical evidence of zuisho-therapy that has been cultivated over a long time. Previous studies suggest that yokukansan is effective for BPSD; however, for some cases who do not respond well to yokukansan, orangedokuto or saikokaryukotsuboreito may be effective. Further studies are needed to investigate combining horizontal evidence (modern medical evidence) and vertical evidence (zuisho-therapy).

**Keywords:** Kampo medicine, psychiatry, evidence, zuisho-therapy

## Introduction

The term “Kampo medicine” refers to traditional medicine in Japan. What many Japanese people (and perhaps even some of our readers) misunderstand is that Kampo is not traditional Chinese medicine (from the People's Republic of China). The traditional medicine practiced in China today is called “traditional Chinese medicine.” Although there are many similarities between Kampo medicine and traditional Chinese medicine, Kampo medicine has developed independently from traditional Chinese medicine since the Edo period in Japan (Qing Dynasty in China).<sup>5)</sup>

Both Kampo medicine and traditional Chinese medicine have their roots in the three major classics that were established during the Han Dynasty in China: Huangdineijing, Shennongbencaojing, and Shanghanlun. Huangdineijing is a classic that deals with acupuncture and moxibustion medicine, Shennongbencaojing is a classic that deals with pharmacology, and Shanghanlun is a classic that deals with pharmacotherapeutics. Shanghanlun, which is said to have been written by Zhang Zhongjing, was

later divided into Shanghanlun and Jinguiaolue, and is viewed as the most important classic that forms the basis of Kampo medicine.<sup>5)</sup>

It is considered that this ancient Chinese medical knowledge was imported into Japan from around the 5th to 6th century by immigrants and Japanese envoys to the Tang Dynasty, and that the medicine practiced in China at that time (with a possible slight time lag) was practiced as it was until the Muromachi era (Ming Dynasty in China). However, during the Edo era, the development of traditional Japanese medicine (Kampo) began as a unique form of traditional medicine, influenced by the interruption of exchanges between Japan and China (the so-called “national isolation” policy), the influence of the Confucian world, the absorption of European medical prescriptions and knowledge (Dutch medicine), and the decline of traditional Chinese medicine in the Qing Dynasty. In particular, the influence of Confucianism was significant (many of the medical doctors at the time were also Confucian scholars), and the teachings of Jinsai Ito, a Confucian scholar from the latter half of the 17th

century, who purported that “we should return to the original teachings of Confucius and Mencius” as a practical science, which resulted in the practice of medicine as a practical science, also promoted by Gen’i Nagoya, a medical doctor and student of Ito, who advocated “returning to the original work of Zhang Zhongjing (Shanghanlun and Jinguiyaolue).” Meanwhile, in the Qing Dynasty at that time, the influence of the study of ancient texts and other factors led to a gradual shift away from practical clinical medicine toward desk-based theory, and traditional medicine continued on a path of decline. In other words, it can be said that Kampo medicine separated from traditional Chinese medicine in the middle of the Edo period.

Incidentally, the term “Kampo” was created in opposition to European medicine (then known as “Rampo”), which spread from Dejima in Nagasaki during the Edo period. The term “Kampo” is a domestic term, not of Chinese origin.

In relation to the traditional Japanese medicine of Kampo and psychiatry, as mentioned in the article by Hisanaga in this special feature, in the late 18th century of the Edo era, Kampo physicians such as Kinkei Nakagami were already using Kampo medicine for drug treatment from a psychiatric perspective, even at a time when there

were no therapeutic drugs in the Western world.

From that time until the present day, the core of Kampo medicine treatment has been “zuisho-therapy,” which is a form of treatment that proceeds in accordance with the Kampo medical diagnosis of “証 (sho).”

## I. What is “Zuisho-therapy”?

### 1. What is “sho”?

Kampo medicine (traditional medicine) and modern medicine are based on fundamentally different concepts, and as a natural consequence, their diagnostic and therapeutic methods are also different. The principle of Kampo medicine is to treat according to the “sho pattern)” (zuisho-therapy).<sup>5)</sup>

The term “sho” refers to a Kampo medical diagnosis or a target for use. Examples of Kampo medical diagnoses include “Kakkonto-sho,” “Maoto-sho,” “Keishito-sho,” and “Shosaikoto-sho.” For example, a condition that improves by taking Kakkonto is diagnosed as “Kakkonto-sho.” In modern Western medicine, the diagnostic name (e.g., “common cold syndrome”, “stomach ulcer”) does not indicate the treatment (treatment method), whereas in Kampo medicine, the treatment name is obtained by removing the character “sho” from the diagnostic name.

In other words, in Kampo medicine, “diagnosis” equals “treatment.”

To determine “sho,” the following four examinations (Bo, Bun, Mon, and Setsu) characteristic of Kampo medicine are performed. Treatment that ignores “sho” is likely to cause adverse effects (side effects), which is referred to “Gochi (erroneous treatment).”

## 2. Four Examinations = Examination to Determine the Patient's Condition

In Kampo medicine, a diagnostic method called “four examinations (Shishin)” is used to determine the patient's condition. “Four examinations” is a collective term for the following: “inspection (Boshin),” “auscultation and olfactory (Bunshin),” “inquiry (Monshin),” and “palpation (Sesshin).”

Boshin corresponds to the visual inspection of modern medicine, and the doctor observes the patient's physique, nutritional status, complexion, and skin color with their eyes.<sup>5)</sup> A characteristic examination method in Kampo medicine is “tongue diagnosis (Zesshin).” In Zesshin, the doctor observes the color of the tongue, presence or absence of tongue coating, distension of the tongue veins, and color of the gums.<sup>5)</sup>

Bunshin is a medical examination in which the doctor uses the auditory (or olfactory) sense to make observations.<sup>5)</sup> Specifically, these include the patient's voice (quality), type of cough, presence or absence of shaking sounds, and odor of stools or urine.<sup>5)</sup>

Monshin is similar to the medical interview in modern medicine, but the most important items in the medical interview in Kampo medicine are the presence or absence of chills, sweating, fever, thirst, dry mouth, and condition of the stools and urine.<sup>5)</sup>

Sesshin is the equivalent of palpation in modern medicine, where the doctor examines the patient by direct touch.<sup>5)</sup> Sesshin is broadly divided into “pulse diagnosis (Myakushin),” which mainly examines the pulse, and “abdominal diagnosis (Fukushin),” which mainly examines the abdomen.<sup>5)</sup>

For details of the actual method of Shishin, please refer to my book <sup>5)</sup> and other books on Kampo medicine.

In this article, the minimum precaution in prescribing Kampo medicine is only to determine “deficiency and excess” of the patient (i.e., whether the patient has an “excess pattern” or a “deficiency pattern”).<sup>5)</sup> The term “deficiency and excess” roughly refers to the strength of the patient's physical fitness. A person with good physical strength has an “excess pattern” and a person with relatively poor physical strength has a “deficiency pattern.” Patients who are in between the two types have a “medium pattern.” Patients with an “excess pattern” are usually well-built and muscular. They have a good appetite and are very active. Conversely, patients with a “deficiency

pattern” often have a skinny build and thin muscles, and even if they tend to be overweight, they are often referred to as “bloated.” They are less active and eat slowly.

In the event that the type cannot be determined, it is advisable to assume that the patient has a “deficiency pattern,” as Kampo drugs for “excess pattern” patients are more likely to cause adverse effects (side effects) when used for “deficiency pattern” patients. As long as it is possible to determine whether the patient has an “excess pattern” or a “deficiency pattern,” the treatment will not be significantly misguided. However, if the determination is erroneous, serious side effects may ensue, necessitating caution.

### 3. Determining the “Pattern (Sho)”

In addition to the findings obtained from Shishin mentioned above, we also utilize ancient Chinese literature from the Han period onwards, which has accumulated over the long history of China, as well as ancient Japanese literature mainly from the Edo era onwards. Furthermore, we draw upon the “traditional key of treatment (Kuketsu, which means secrets and mysteries that are not written down but are directly passed on orally)” left behind by the great doctors of the past to infer “Sho.”

The aforementioned knowledge, comprising ancient literature and oral instructions, is employed to ascertain which Kampo drugs, or Sho, are to be employed.

### 4. “Horizontal Evidence” and “Vertical Evidence”

There are concepts called “horizontal evidence” and “vertical evidence.” They collectively make up the so-called “traditional key of treatment (Kuketsu)” (therefore, there are no references cited) by Dr. Eiji Matsuoka (Professor Emeritus at Tokyo Gakugei University), who has long been studying Chinese literature related to Kampo medicine.

According to Dr. Matsuoka, there are two types of evidence required for Kampo treatment. One is “evidence-based medicine (EBM),” which is based on the constructed evidence that is currently emphasized in modern medicine, and involves selecting drugs in the same way as modern medicine. Decisions are often based on the results of randomized controlled trials (RCTs) or meta-analyses of specific Kampo drugs for specific diseases (modern medical diagnoses). Examples include yokukansan for behavioral and psychological symptoms of dementia (BPSD) and daikenchuto for the prevention of ileus. As this evidence is required for all drugs on the market in

principle, it is referred to as “horizontal evidence” for convenience.

On the other hand, the content written in many ancient manuscripts (ancient medical books) and the concept of “Sho” (diagnosis) have survived and been passed down through the centuries. This alone is probably of equal value to “horizontal evidence.” It could also be said that *zuisho*-therapy is another form of “vertical evidence.”

In other words, determining “Sho” is tantamount to making full use of the vertical evidence of ancient literature and *Kuketsu*.

##### 5. Current State of Kampo Medicine in Japan: Is *Zuisho*-therapy Being Practiced?

A 2011 survey conducted by the Japan Kampo Medicines Manufacturers Association targeting general clinicians revealed that 89% of doctors prescribe Kampo drugs. However, many of these prescriptions are not *zuisho*-therapy, but rather “non-traditional Kampo (Byomei Kampo),” as described below.

So, how many doctors are able to practice *zuisho*-therapy, or Kampo medicine based on “vertical evidence”? We do not know the exact number, but it is possible to make an estimate. The Japan Society for Oriental Medicine defines a Kampo specialist as “a doctor who has obtained a qualification as a specialist in Western medicine, and who

has also fully mastered Kampo medicine, is able to perform Kampo-specific examinations, and provide Kampo treatment suited to the symptoms and physical makeup of each individual patient” (from the Japanese version of the society's website),<sup>1)</sup> so it is considered that Kampo specialists practice *zuisho*-therapy. As of November 2021, there were 1,999 Kampo doctors certified by the Japan Society for Oriental Medicine,<sup>1)</sup> which is a decrease from the 2,148 doctors as of March 2017. It is estimated that less than 10% of these are psychiatrists. Therefore, it seems that psychiatrists who practice *zuisho*-therapy are now close to becoming an endangered species.

From another perspective, it is possible that many doctors who prescribe Kampo drugs in Japan use them without reference to the theory of Kampo medicine (= *zuisho* therapy). Prescribing according to modern Western medical diagnosis regardless of the diagnosis is commonly referred to as “non-traditional Kampo (Byomei Kampo).” In Japan today, it is very likely that Byomei Kampo treatment is applied in many cases.

##### 6. Byomei Kampo

The practice of prescribing Kampo drugs based on the names of modern Western medical diagnoses, rather than

Kampo-style Sho diagnoses, is known as “Byomei Kampo.” As mentioned above, the Kampo drug is originally prescribed according to Kampo-style Sho diagnoses, but this is the practice of prescribing Kampo drugs based on modern Western medical diagnoses.

Examples of Byomei Kampo include kakkonto for the common cold, shoseiryuto for hay fever (allergic rhinitis), shakuyakukanzoto for painful muscle spasms, daikenchuto for the prevention of ileus (intestinal obstruction), and yokukansan for BPSD. In many cases, the minimal precautions in prescribing Kampo drugs, such as considering the patient's “deficiency and excess” condition, are not even taken into account, so it is estimated that the response rate is lower and incidence of side effects is higher than with *zuisho*-therapy.

However, this does not mean that Byomei Kampo is universally bad. Although Byomei Kampo is a method of using Kampo drugs that is disliked by Kampo doctors, in recent years, as mentioned in the Mizukami’s paper in this special feature, there have been reports of clinical findings with a high level of evidence. Therefore, even if it is Byomei Kampo, I would like to believe that it is at least applied in accordance with EBM, as described below.

## II. Treatment in Accordance with Evidence-based Medicine (EBM)

Some Kampo drugs have been confirmed to be effective through RCTs in the same way as drugs used in modern medicine. The diagnostic names of the target diseases in these RCTs are not Kampo medicine-style Sho, but rather modern medical diagnostic names.

According to a survey by the EBM Committee of the Japan Society for Oriental Medicine,<sup>2)</sup> 614 RCTs on Kampo drugs had been reported as of 2019. In addition, 14 meta-analyses had also been reported.

In the fields of psychiatry and neurology, as mentioned in the Mizukami’s paper in this special feature, there are many reports on the efficacy of Yokukansan for BPSD, but there are also other RCTs known to target core symptoms of dementia (*chotosan*, *hachimigan*), delirium (*yokukansan*), schizophrenia (*yokukansan*), anxiety (*saibokuto*), post-traumatic stress disorder (*saikokeishikankyoto*), sleep disorders (*sansoninto*, *orengedokuto*, *yokukansankachimpihange*, *anchusan*), and extrapyramidal symptoms caused by antipsychotic drugs (*Shakuyakukanzoto*).<sup>2)</sup>

Although the use of these Kampo drugs in treatment can be broadly considered Byomei Kampo, in terms of the fact that

the same research has been done as in modern medicine, it can be said to be “treatment in accordance with Evidence-based Medicine (EBM).”

In addition, Kampo drugs have been included in treatment guidelines for various diseases in recent years. According to a survey conducted by the EBM Committee of the Japan Society for Oriental Medicine,<sup>3)</sup> 135 treatment guidelines include descriptions of Kampo drugs, but only 40 of these include cited papers, evidence grading, and recommendation grading. There were also 51 cases involving cited papers but no evidence or recommendation grading, and the remainder had neither cited papers nor evidence or recommendation grading.

### III. Integrating Horizontal and Vertical Evidence

Unlike modern pharmaceuticals, which have a short history (no drug has been used as a psychotropic for more than 200 years), Kampo drugs have prevailed in history from ancient China to the Edo period in Japan. It is considered possible to utilize not only horizontal evidence, as typified by EBM-compliant treatment, but also vertical evidence, known as *zuisho*-therapy. Therefore, what is needed for Kampo medicine in the future is the integration of horizontal and vertical evidence.

As an example, the integration of horizontal and vertical evidence can be considered using the treatment of BPSD (Figure 1).

The efficacy of yokukansan for BPSD has been demonstrated by the results of multiple RCTs and meta-analyses. Therefore, from an EBM perspective, it is considered appropriate to prescribe yokukansan, for which horizontal evidence has been established. As physicians who have prescribed yokukansan for BPSD have observed, it is effective for a certain number of patients. Nevertheless, it should be noted that yokukansan may not be effective in all cases. It can also cause side effects such as hypokalemia (due to the inclusion of the herbal medicine licorice in yokukansan) and loss of appetite.

If you only have knowledge of horizontal evidence in such a situation, treatment with Kampo drugs will reach an impasse. You may have to choose an antipsychotic or other psychotropic drug as your next move. Of course, there is the possibility that an antipsychotic drug will be effective, but there is also the risk of increasing mortality.

However, when combined with knowledge of vertical evidence, a different prescribing approach can be taken.

First, if yokukansan does not show any effects or if side effects persist, we

consider that it was not the “Yokukansan-sho.” Then, we perform Shishin to determine which Sho is most likely, and change to a Kampo drug that is likely to be effective. Initially, the conditions for Yokukansan-sho fall between “medium pattern” and “deficiency pattern” when classified as “deficiency and excess,” and are accompanied by symptoms such as insomnia (difficulty falling asleep and disturbed sleep), agitation, irritability, eyelid cramps, and trembling of the limbs, and on abdominal examination, it is characterized by tension in the rectus abdominis muscle and mild epigastric distension (tenderness and resistance in the epigastric region, see Figure 2). Therefore, BPSD failing to fit the above criteria may not constitute Yokukansan-sho.

For example, if a patient does not calm down even after being administered yokukansan, the constitution is between “excess pattern” and “medium pattern,” there is a tendency towards hypertension, and the patient presents with “epigastric stuffiness and resistance (Shinkahiko)” on abdominal examination, but does not present with “fullness and discomfort in the chest and hypochondrium (Kyokyokuman),” there is a possibility of “Orengedokuto-sho.” In addition, if the patient also has constipation, it may be “San'oshashinto-sho.” In such cases, orengedokuto or

san'oshashinto (used only for “excess pattern” patients) would be selected. Similarly, in the case of a patient with a confirmed diagnosis who has obvious “fullness and discomfort in the chest and hypochondrium (Kyokyokuman)” on abdominal examination and can feel the abdominal aorta pulsating (“ki”) on the right side of the navel, (although in some cases this may not be felt), there is a possibility of “Saikokaryukotsuboreito-sho, so it would be best to change to saikokaryukotsuboreito.

Even in the case of BPSD, if the main symptoms are apathy and anorexia, it is good to use “Jingi-zai” such as ninjin'yoeito (used only for “deficiency pattern” patients).

Furthermore, if yokukansan is found to be effective to some extent but gastrointestinal disorders are also observed, and if a significant “ki” is felt during abdominal diagnosis in patients with deficiency syndrome, it is likely that “Yokukansankachimpihange-sho” is the cause, and thus it would be advisable to prescribe yokukansankachimpihange.

As described above, by making full use of the tools left behind by the ancient physicians known as vertical evidence (zuisho-therapy), it is possible to provide more detailed, tailor-made Kampo treatment. Although much time has passed since the concept of tailor-

made treatment was first proposed, it can be said that *zuisho*-therapy is the tool for tailor-made treatment left behind by the great physicians of the past. The author believes that the harmonization of treatment in accordance with EBM (horizontal evidence), i.e., modern medical evidence, and *zuisho*-therapy (vertical evidence) will lead to the practice of tailor-made treatment. Knowledge of horizontal evidence can be easily obtained these days using the Internet and other electronic media. However, knowledge of vertical evidence cannot be acquired overnight. Training doctors to be able to use vertical evidence will be a challenge for the future.

#### IV. Three Initiatives of the Japan Society for Oriental Medicine

As examples of the integration of horizontal and vertical evidence, I would like to outline three initiatives by the Japan Society for Oriental Medicine: the specialist physician system, *Kampo* treatment evidence report, and large-scale study on *Kampo* treatment and prevention for COVID-19 infection.

As mentioned above, the Japan Society for Oriental Medicine's system for certifying *Kampo* specialists aims to train doctors who can perform *zuisho*-therapy (i.e., doctors who can use vertical evidence). Those who have a

Japanese medical license, are certified or specialized in a medical society that belongs to the basic domain set by the Japan Medical Specialty Board, have been a member of the Japan Society for Oriental Medicine for at least 3 years and have acquired the required number of credits (7 credits), and have received clinical training in Oriental medicine at a training facility designated by the Japan Society for Oriental Medicine for at least 3 years are eligible to take the exam.<sup>1)</sup> To become a *Kampo* Specialist, one must submit a list of 50 cases and a clinical report on 10 of these cases, pass the certification exam (written and oral), and renew the certification every five years.<sup>1)</sup>

The *Kampo* Treatment Evidence Report is a database that compiles data from high-level evidence reports such as RCTs and meta-analyses related to *Kampo* treatment.<sup>2)</sup> This is truly a database that has accumulated horizontal evidence. It was compiled mainly by the EBM committee of the Japan Society for Oriental Medicine, and can be used for free even if the user is not a member of the Japan Society for Oriental Medicine. The latest version is the 2019 edition, but data are updated regularly. In addition, the EBM committee of the Japan Society for Oriental Medicine has also investigated clinical guidelines that mention *Kampo*

drugs, and has published the results of its findings.<sup>3)</sup>

Four large-scale studies on Kampo treatment and prevention of COVID-19 infection are currently underway simultaneously: “A structured summary of a study protocol for a multi-center, randomized controlled trial (RCT) of COVID-19 prevention with Kampo medicines” (Clinical Research Registration: jRCTs031200150); “A multi-center, randomized controlled trial by the Integrative Management in Japan for Epidemic Disease (IMJEDI study-RCT) on the use of Kampo medicine, kakkonto with shosaikotokakikyosekko, in mild-to-moderate COVID-19 patients for symptomatic relief and prevention of severe stage: A structured summary of a study protocol for a randomized controlled trial” (Clinical Research Registration: jRCTs021200020); “A multicenter, observational study of Western and Kampo medicine treatment for mild and moderate COVID-19 patients (including suspected patients) to alleviate symptoms and reduce severity of disease” (Clinical Research Registration: UMIN000041301); and “Survey on the efficacy and safety of Kampo treatment in patients with COVID-19-related sequelae” (Clinical Research Registration: UMIN000044318).<sup>4)</sup> The first two

studies are RCTs targeting specific Kampo drugs, and they pursue horizontal evidence. The latter two are studies that verify the effects of Kampo drugs through zuisho-therapy, and they apply vertical evidence to the treatment of COVID-19 infection. All of these studies are being conducted by the Japan Society for Oriental Medicine, with the collaboration of numerous member doctors, hospital staff, and patients. We eagerly await the results.

### Conclusion

This article outlines the history of Kampo medicine, zuisho-therapy (vertical evidence), treatment based on EBM (horizontal evidence), practical integration of horizontal and vertical evidence in the treatment of BPSD, and the three initiatives of the Japan Society for Oriental Medicine, using the keywords “vertical evidence” and “horizontal evidence.”

The integration of horizontal evidence (modern medical evidence) and vertical evidence (zuisho-therapy) will undoubtedly present a challenge in the future.

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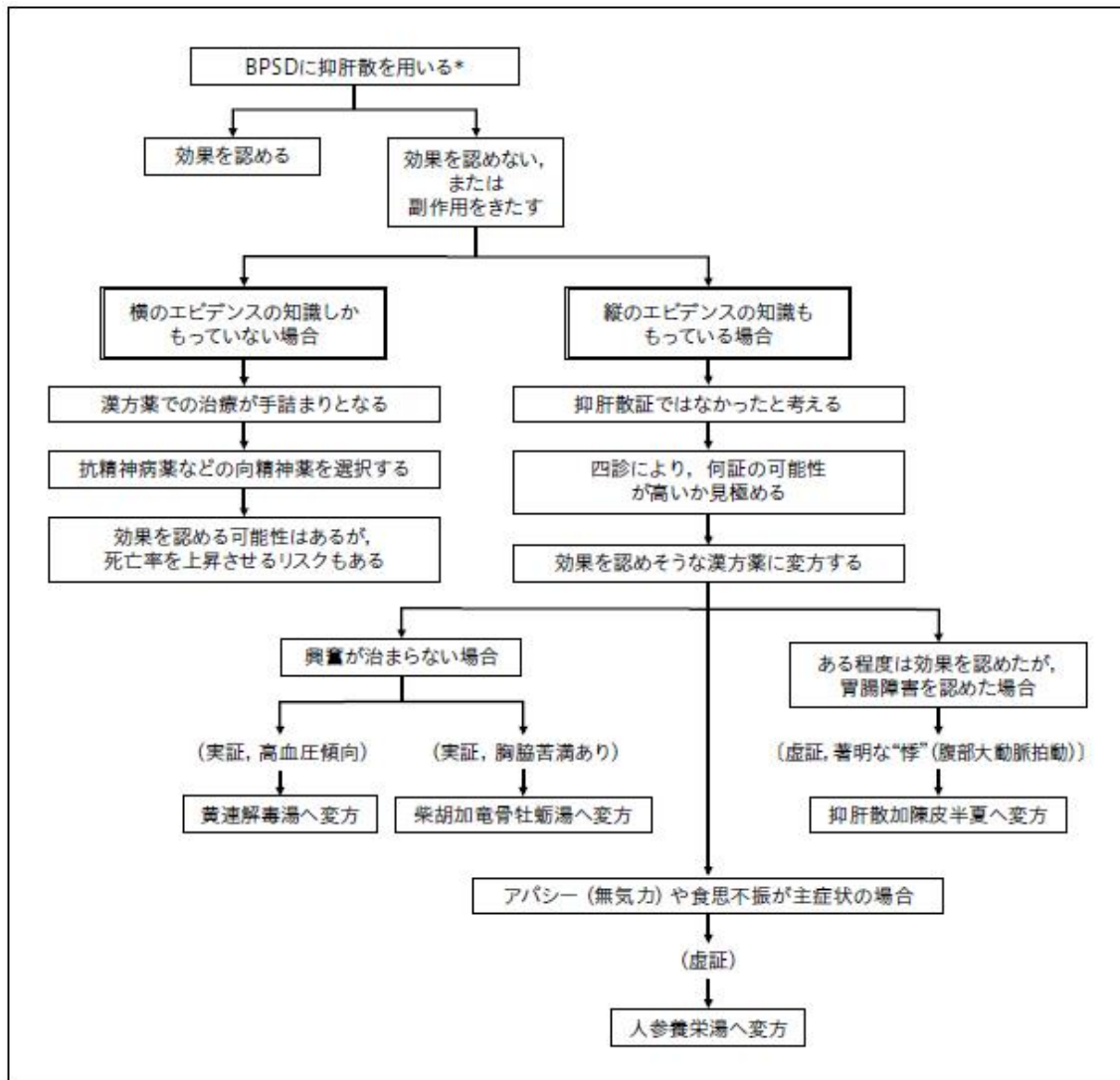


図1 横のエビデンスと縦のエビデンスの融合例 (BPSD の治療)

\* BPSD に対する抑肝散の効果は、複数の RCT やメタアナリシスの結果によって証明されているため。

Figure 1: Example of Horizontal and Vertical Evidence Integration (Treatment for BPSD)

\* The efficacy of Yokukansan for BPSD has been proven by the results of multiple RCTs and meta-analyses.

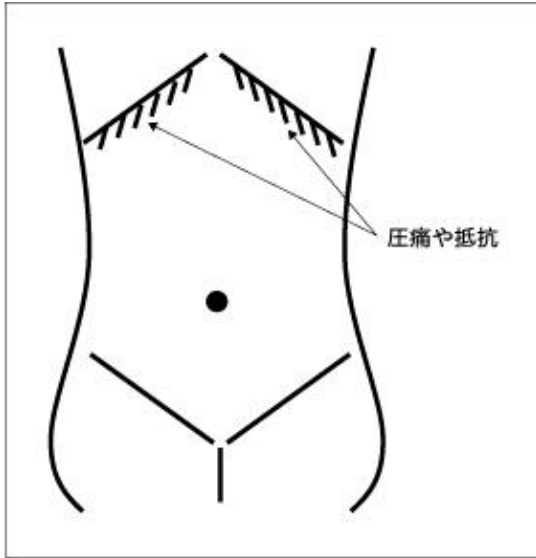


図2 胸脇苦満

「柴胡」を含む漢方薬の使用目標となる。

Figure 2: Fullness and Discomfort in Chest and Hypochondrium (Kyokyokuman)

The goal of using Kampo medicine including “Saiko.”