

Research Article

A study on Herbal Formulations that are Effective at Treating Premenstrual Syndrome: A Retrospective Study over 12 Years

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Abstract

Physical discomfort occurring during about 10 days of the menstrual cycle right before the onset of menstruation is known as Premenstrual Syndrome (PMS). Mental symptoms are irritability and depression, physical symptoms are malaise/lethargy, a dull headache and dizziness. Studies have reported on a number of herbal formulations that are efficacious in treating different symptoms of PMS.

Subjects were 2,027 patients with PMS. The study period was from May 2012 to October 2024. Effectiveness of treatment was determined by asking patients about their level of satisfaction after taking the herbal formulation. Patients whose level of satisfaction with an herbal formulation prescribed for the same symptoms was 60% or higher were deemed to be responders, and the percentage of responders was defined as the effective rate of the formulation. The average level of satisfaction among responders was defined as the efficacy of the formulation.

Kampo formulations should be prescribed for PMS in the following order by symptom based on efficacy and effective rate.

Irritability: Tokaku-joki-to (for constipated patients only) > Kami-shoyo-san > Yoku-kan-san > Saiko-ka-ryukotsu-borei-to.

Depression: Hange-koboku-to > Kami-kihi-to > Nyoshin-san > Kami-shoyo-san.

Malaise/lethargy: Gorei-san > Hange-byakujutsu-temma-to > Kami-shoyo-san > Toki-shakuyaku-san (when focusing on effective

rate) Hange-byakujutsu-temma-to > Gorei-san > Kami-shoyo-san > Toki-shakuyaku-san (when focusing on efficacy).

Dull headache: Ryo-kei-jutsu-kan-to > Hange-byakujutsu-temma-to > Kami-shoyo-san > Gorei-san.

Dizziness: Hange-byakujutsu-temma-to > Gorei-san > Ryo-kei-jutsu-kan-to > Toki-shakuyaku-san (when focusing on effective rate) Hange-byakujutsu-temma-to > Ryo-kei-jutsu-kan-to > Gorei-san > Toki-shakuyaku-san (when focusing on efficacy).

The following formulations can be prescribed in cases of concomitant symptoms.

Malaise/lethargy, dizziness, and a dull headache or a combination of 2 of those 3 symptoms: Hange-byakujutsu-temma-to > Gorei-san.

Other symptoms (excluding irritability and dizziness or depression and dizziness): Kami-shoyo-san.

Keywords: Herbal medicine; Kampo extract; Kampo medicine; PMDD; PMS

Introduction

Physical discomfort occurring during about 10 days of the menstrual cycle right before the onset of menstruation is known as Premenstrual Syndrome (PMS), and its physical symptoms include malaise and lethargy, a dull headache and dizziness. Over the past few years, PMS with mental symptoms has been differentiated from PMS and is referred to as Premenstrual Dysphoric Disorder (PMDD) [1]. The most frequent symptom of PMS is irritability, followed by malaise and lethargy. The cause of PMS is still unknown, but abnormal sensitivity to luteal hormone has been suggested. Many women have the notion that PMS is “just the way it is” and many women are not seen at a hospital because they unaware that PMS can be alleviated with treatment. There are no established treatments for PMS and PMDD in modern medicine. Modern medicine offers symptomatic treatments such as analgesics for headaches, anti-vertigo medications for dizziness, and antidepressants for depressive symptoms. Recently, it has been reported that SSRI (Selective Serotonin Reuptake Inhibitors) is effective against PMDD [2,3]. Some studies have reported that PMS and PMDD can be relieved by taking oral contraceptives, but some studies have refuted this [4-7]. Over the past few years, numerous studies have reported that Oriental medicine, and especially herbal treatment and acupuncture, are effective against PMS [8-11]. Conventional herbal treatments, which involve decocting herbal medicines, have demonstrated a high level of efficacy. In Japan, instant preparations known as extracts, in which large amounts of constituent herbs are decocted in advance and then dried and powdered, are widely used based on the symptoms [12,13]. Herbal medicine using extracts of which 148 extracts are under medical insurance have become a treatment for PMS and PMDD with a high level of compliance by patients [14]. Studies have reported on a number of herbal formulations that are efficacious in treating different symptoms of PMS [15-24], but the optimal herbal formulation to prescribe for each symptom has not been established at the current point in time.

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Citation: Isobe T (2025) A study on Herbal Formulations that are Effective at Treating Premenstrual Syndrome: A Retrospective Study over 12 Years. J Altern Complement Integr Med 11: 540.

Received: December 24, 2024; **Accepted:** January 03, 2025; **Published:** January 10, 2025

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Subjects and Methods

Subjects were 2,027 patients with PMS or PMDD who were seen by this Center's Department of Oriental Medicine and who received herbal treatment with an extract. The study period was from May 2012 to October 2024.

During the initial visit, patients were prescribed (as shown in Table 1) a standard dose of an extract (from Tsumura, 3 packets a day) that was considered appropriate for their symptoms. The dose duration (in days) was until the patient had her second period. Patients were asked to return upon their second menstrual period, and alleviation of symptoms in the 10 days before the second period was evaluated based on the level of patient satisfaction. If symptoms were not alleviated, the type of herbal formulation was switched, and medication was prescribed in the same manner as for the first period. If symptoms were relieved but only slightly, the dosage was increased to 2 doses of 4 packets per day, and the patient was prescribed a dose to last until her second menstrual period. If, after receiving 2 doses of 4 packets per day, the patient's symptoms were relieved compared to 3 doses of 3 packets per day but the relief was slight, the dosage was increased to 3 doses of 6 packets per day and medication was similarly prescribed. Tokaku-joki-to has laxative action, so the dose was started at 2 packets per day and increased to 3 packets per day if diarrhea did not occur. If diarrhea occurred after 2 packets per day, the dose was reduced to 1 to 1.5 packets per day and efficacy was evaluated. If the patient needed to take more than one herbal formulation, she was asked to take them at least 30 minutes apart. Patients were informed that they did not need to restrict themselves to water or tea when taking an herbal formulation. The order of Kampo formulations each symptom shown in table 1 were determined by author based on the experience of Kampo predecessor.

	1st prescription	2nd prescription	3rd prescription	4th prescription
Irritability	Tokaku-joki-to	Kami-shoyosan	Yoku-kan-san	Saiko-ka-ryukotsu-bore-to
Depression	Hange-ko-boku-to	Kami-kihi-to	Nyoshin-san	Kami-shoyosan
Malaise/lethargy	Gorei-san	Hange-byakujutsu-temma-to	Toki-shakuyaku-san	Kami-shoyosan
Dull headache	Hange-byakujutsu-temma-to	Gorei-san	Ryo-kei-jutsu-kan-to	Kami-shoyosan
Dizziness	Hange-byakujutsu-temma-to	Ryo-kei-jutsu-kan-to	Gorei-san	Toki-shakuyaku-san

Table 1: The order of precedence in which formulations were prescribed by symptom during the period of this study.

In this study, effectiveness of treatment was determined by asking patients about their level of satisfaction after taking the herbal formulation [9,25,26]. Patients whose level of satisfaction with an herbal formulation prescribed for the same symptoms was 60% or higher were deemed to be responders, and the percentage of responders was defined as the effective rate of the formulation. The rationale for this definition is that patients were randomly selected to ask about their level of satisfaction once they finished taking the formulation, and at the same time, they rated their distressing symptoms on a 6-point scale (① disappeared, ② mostly disappeared, ③ considerably alleviated, ④ alleviated, ⑤ slightly alleviated, and ⑥ signs of

alleviation seemed to appear). The relationship between rated alleviation of symptoms and the level of satisfaction was examined, and results revealed a close correlation between alleviation of symptoms rated as ①-② and a level of satisfaction of 90-100%, alleviation of symptoms rated as ②-③ and a level of satisfaction of 80-90%, alleviation of symptoms rated as ③-④ and a level of satisfaction of 70-80%, alleviation of symptoms rated as ④-⑤ and a level of satisfaction of 60-70%, alleviation of symptoms rated as ⑤-⑥ and a level of satisfaction of 50-60%. The average level of satisfaction among responders was defined as the efficacy of the formulation.

Patient data were strictly managed at the facility with patients indicated by only their medical chart number so that individuals could not be identified. Verbal informed consent was obtained from the patients prior to conducting this study. This study began once it was approved by the ethical review board of this facility. There are no conflicts of interests in this study.

Results

The effectiveness of each Kampo formulation in treating PMS or PMDD is shown in table 2.

		Tokaku-joki-to	Kami-shoyosan	Saiko-ka-ryukotsu-bore-to	Yoku-kan-san
Irritability	Effective rate	85.7% (54/63)	84.6% (367/434)	83.3% (15/18)	77.1% (91/118)
	Efficacy	79.7	77.9	79.7	75.8
Depression		Hange-ko-boku-to	Kami-kihi-to	Nyoshin-san	Kami-shoyosan
	Effective rate	82.6% (57/69)	80.0% (12/15)	80.0% (12/15)	73.3% (11/15)
	Efficacy	83.2	84.2	79.6	78.6
Malaise/lethargy		Kami-shoyosan	Toki-shakuyaku-san	Gorei-san	Hange-byakujutsu-temma-to
	Effective rate	94.7% (18/19)	90.0% (27/30)	87.4% (201/230)	85.4% (41/48)
	Efficacy	89.4	85.6	86.5	87.8
Dull headache		Ryo-kei-jutsu-kan-to	Hange-byakujutsu-temma-to	Kami-shoyosan	Gorei-san
	Effective rate	93.3% (14/15)	88.9% (312/351)	88.9% (8/9)	81.3% (61/75)
	Efficacy	91.8	88	89.4	86.4
Dizziness		Hange-byakujutsu-temma-to	Toki-shakuyaku-san	Gorei-san	Ryo-kei-jutsu-kan-to
	Effective rate	85.9% (170/198)	81.3% (13/16)	79.7% (51/64)	72.9% (70/96)
	Efficacy	87.7	89.2	85.4	87.8

Table 2: Efficacy and effective rate of formulations by symptom based on the results of this study.

In patients complaining of irritability (677 patients), herbal formulations are listed below in descending order of efficacy and effective rate. Given the small number of patients taking Saiko-ka-ryukotsu-borei-to, the formulation was relegated to fourth place based on efficacy and effective rate.

Efficacy: Tokaku-joki-to> Kami-shoyo-san> Yoku-kan-san> Saiko-ka-ryukotsu-borei-to

Effective rate: Tokaku-joki-to> Kami-shoyo-san> Yoku-kan-san> Saiko-ka-ryukotsu-borei-to

Tokaku-joki-to was used for constipated patients only.

In patients complaining of depression (127 patients), herbal formulations are listed below in descending order of efficacy and effective rate. Given the similarly small numbers of patients taking the 3 formulations other than Hange-koboku-to, the formulations were ranked second place or lower based on efficacy and effective rate

Efficacy: Hange-koboku-to > Kami-kihi-to > Nyoshin-san > Kami-shoyo-san

Effective rate: Hange-koboku-to > Kami-kihi-to =Nyoshin-san > Kami-shoyo-san

In patients complaining of malaise and lethargy (346 patients), herbal formulations are listed below in descending order of efficacy and effective rate. Given the small number of patients taking Kami-shoyo-san and Toki-shakuyaku-san, the formulations were relegated to third place or lower based on efficacy and effective rate.

Efficacy: Hange-byakujutsu-temma-to > Gorei-san > Kami-shoyo-san > Toki-shakuyaku-san

Effective rate: Gorei-san > Hange-byakujutsu-temma-to > Kami-shoyo-san > Toki-shakuyaku-san

In patients complaining of a dull headache (492 patients), herbal formulations are listed below in descending order of efficacy and effective rate. Given the small number of patients taking Ryo-kei-jutsu-kan-to and Kami-shoyo-san, the formulations were relegated to third place or lower based on efficacy and effective rate.

Efficacy: Hange-byakujutsu-temma-to > Gorei-san > Ryo-kei-jutsu-kan-to > Kami-shoyo-san

Effective rate: Hange-byakujutsu-temma-to > Gorei-san > Ryo-kei-jutsu-kan-to > Kami-shoyo-san

In patients complaining of lightheadedness or dizziness (385 patients), herbal formulations are listed below in descending order of efficacy and effective rate. Given the small number of patients taking Toki-shakuyaku-san, the formulation was relegated to fourth place based on efficacy and effective rate.

Efficacy: Ryo-kei-jutsu-kan-to > Hange-byakujutsu-temma-to > Gorei-san > Toki-shakuyaku-san

Effective rate: Hange-byakujutsu-temma-to>Gorei-san >Ryo-kei-jutsu-kan-to>Toki-shakuyaku-san

A Kampo formulation to treat irritability, Tokaku-joki-to has laxative action, so it was only used to treat constipated patients.

Discussion

The order in which formulations were prescribed to patients complaining of irritability was Tokaku-joki-to (for constipated patients only), Kami-shoyo-san, Yoku-kan-san, and Saiko-ka-ryukotsu-borei-to as shown in table 1. Formulations should be prescribed in the following order based on both efficacy and effective rate as shown in table 2.

Tokaku-joki-to > Kami-shoyo-san > Yoku-kan-san > Saiko-ka-ryukotsu-borei-to

The order in which formulations were prescribed to patients complaining of depression was Hange-koboku-to, Kami-kihi-to, Nyoshin-san, and Kami-shoyo-san as shown in table 1. Formulations should be prescribed in the following order based on both efficacy and effective rate as shown in table 2.

Hange-koboku-to> Kami-kihi-to Nyoshin-san = Kami-shoyo-san

The order in which formulations were prescribed to patients complaining of malaise/lethargy was Gorei-san, Hange-byakujutsu-temma-to, Toki-shakuyaku-san, and Kami-shoyo-san as shown in table 1. Formulations should be prescribed in the following order as shown in table 2.

Formulations should be prescribed in the following order when focusing on effective rate.

Gorei-san > Hange-byakujutsu-temma-to > Kami-shoyo-san > Toki-shakuyaku-san.

Formulations should be prescribed in the following order when focusing on efficacy.

Hange-byakujutsu-temma-to > Gorei-san > Kami-shoyo-san > Toki-shakuyaku-san.

The order in which formulations were prescribed to patients complaining of a dull headache was Hange-byakujutsu-temma-to, Gorei-san, Ryo-kei-jutsu-kan-to, and Kami-shoyo-san as shown in table 1. Formulations should be prescribed in the following order based on both efficacy and effective rate as shown in table 2.

Hange-byakujutsu-temma-to > Gorei-san > Ryo-kei-jutsu-kan-to > Kami-shoyo-san.

The order in which formulations were prescribed to patients complaining of dizziness was Hange-byakujutsu-temma-to, Ryo-kei-jutsu-kan-to, Gorei-san, and Toki-shakuyaku-san, as shown in table 1. Formulations should be prescribed in the following order as shown in table 2.

Formulations should be prescribed in the following order when focusing on effective rate.

Hange-byakujutsu-temma-to > Gorei-san > Ryo-kei-jutsu-kan-to > Toki-shakuyaku-san.

Formulations should be prescribed in the following order when focusing on efficacy.

Hange-byakujutsu-temma-to > Ryo-kei-jutsu-kan-to > Gorei-san > Toki-shakuyaku-san.

As revealed by this study, the ideal order in which to prescribe formulations is the same as the order in which the author has been prescribing these formulations during the period studied. However, exceptions were the order in which formulations were prescribed for malaise and lethargy when focusing on efficacy and the order in which formulations were prescribed for lightheadedness or dizziness when focusing on effective rate. In these 2 exceptions, Gorei-san and Hange-byakujutsu-temma-to swapped places.

Many patients often suffer multiple symptoms at the same time. Formulations that were efficacious against concomitant symptoms are based on table 2.

In case of irritability, depression, malaise/lethargy, and a dull headache where 2 or 3 of the 4 symptoms were concomitant, Kami-shoyo-san was the only formulation that was efficacious against those symptoms, in these cases, Kami-shoyo-san should be the first formulation prescribed.

In cases of irritability, depression, and malaise/lethargy where 2 of the 3 symptoms were concomitant, Kami-shoyo-san was efficacious against those symptoms. In these cases, Kami-shoyo-san should be the first formulation prescribed.

In cases of malaise/lethargy, a dull headache, and dizziness, Gorei-San and Hange-byakujutsu-temma-to were efficacious against all 3 symptoms. Therefore, Hange-byakujutsu-temma-to should be the first formulation prescribed considering efficacy and effective rate (average effective rate: 86.7%, average efficacy: 87.8) and Gorei-san should be the second formulation prescribed (average effective rate: 82.8%, average efficacy: 86.1).

In cases of malaise/lethargy and dizziness, Gorei-san, Hange-byakujutsu-temma-to, and Toki-shakuyaku-san were efficacious in treating both symptoms, but Toki-shakuyaku-san was excluded due to the small number of patients. Considering efficacy and effective rate, Hange-byakujutsu-temma-to should be the first formulation prescribed (average effective rate: 85.7%, average efficacy: 87.8) and Gorei-san should be the second formulation prescribed (average effective rate: 83.6%, average efficacy: 85.9).

In cases of only a dull headache and dizziness, Hange-byakujutsu-temma-to, Gorei-San, and Ryo-kei-jutsu-kan-to were efficacious against both symptoms, but few patients took Ryo-kei-jutsu-kan-to for a dull headache. Therefore, considering efficacy and effective rate, Hange-byakujutsu-temma-to should be the first formulation prescribed (average effective rate: 87.4%, average efficacy: 87.9), and Gorei-san should be the second formulation prescribed (average effective rate: 80.5%, average efficacy: 85.9).

In cases of malaise/lethargy and a dull headache, Gorei-san, Hange-byakujutsu-temma-to, and Kami-shoyo-san were efficacious against both symptoms, but few patients took Kami-shoyo-san. Therefore, considering efficacy and effectiveness, Hange-byakujutsu-temma-to should be the first formulation prescribed (average effective rate: 87.2%, average efficacy: 87.9) and Gorei-San should be the second formulation prescribed (average effective rate: 84.4%, average efficacy: 86.5).

In cases of irritability and a dull headache or depression and a dull headache, only Kami-shoyo-san was efficacious against both symptoms, so Kami-shoyo-san should be the first formulation prescribed in these cases.

In cases of irritability and dizziness or depression and dizziness, no formulations were efficacious against both symptoms, so multiple formulations may be necessary.

In cases of all 5 symptoms, no formulations were efficacious against all of the symptoms, so multiple formulations are necessary.

In terms of the regularity with which a formulation is prescribed to treat a combination of symptoms, Hange-byakujutsu-temma-to > Gorei-san in cases of malaise/lethargy, dizziness, and a dull headache or when 2 of the 3 symptoms are concomitant. In cases of combinations of other symptoms, Kami-shoyo-san was prescribed except in cases of irritability and dizziness or depression and dizziness.

Conclusion

Kampo formulations should be prescribed for PMS and PMDD in the following order by symptom based on efficacy and effective rate as revealed in this study.

Irritability: Tokaku-joki-to (for constipated patients only) > Kami-shoyo-san > Yoku-kan-san > Saiko-ka-ryukotsu-borei-to.

Depression: Hange-koboku-to > Kami-kihi-to > Nyoshin-san > Kami-shoyo-san.

Malaise/lethargy: Gorei-san > Hange-byakujutsu-temma-to > Kami-shoyo-san > Toki-shakuyaku-san (when focusing on effective rate) > Hange-byakujutsu-temma-to > Gorei-san > Kami-shoyo-san > Toki-shakuyaku-san (when focusing on efficacy).

Dull headache: Ryo-kei-jutsu-kan-to > Hange-byakujutsu-temma-to > Kami-shoyo-san > Gorei-san.

Dizziness: Hange-byakujutsu-temma-to > Gorei-san > Ryo-kei-jutsu-kan-to > Toki-shakuyaku-san (when focusing on effective rate) > Hange-byakujutsu-temma-to > Ryo-kei-jutsu-kan-to > Gorei-san > Toki-shakuyaku-san (when focusing on efficacy).

The following formulations can be prescribed in cases of concomitant symptoms.

Malaise/lethargy, dizziness, and a dull headache or a combination of 2 of those 3 symptoms: Hange-byakujutsu-temma-to > Gorei-san.

Other symptoms (excluding irritability and dizziness or depression and dizziness): Kami-shoyo-san.

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