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Research Article

Effectiveness of Kampo Extract Formulations in Traditional Japanese Herbal Medicine

Tetsuya Isobe*

International Oriental Medical Center, Kamishidami, Moriyama, Nagoya, Aichi, Japan

Abstract

Traditional Japanese herbal medicine, known as Kampo medicine, has unique diagnostic methods. In Kampo medicine, herbal formulations have been prescribed since the Edo period based on the experience of eminent Japanese practitioners, including the great masters. An instant preparation called the Kampo extract formula is often used in Japan.

This study included 8,494 women who were seen as outpatients at our Women's Clinic for Traditional Herbal Medicine from May 2011 to April 2022. A total of 11,933 cases of herbal formulations were prescribed in this study population.

A suitable Kampo extract formula was selected based on the Kampo medicine diagnosis, and patients were treated with Kampo extracts from Tsumura. The initial prescription of Kampo extracts was a standard dose for 1 month, and its effectiveness was determined by asking patients about their level of satisfaction after taking the extract. Patients whose level of satisfaction was at least 60% were deemed 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.

The effectiveness of the Kampo formula was determined in 50 or more patients. The effective rate (%) and efficacy are written in parentheses immediately after the name of each formula used. As a representative formula, if a patient complained of "fatigue" and "being physically drained," then Hochu-ekki-to (effective rate 88.6%, efficacy 90.4) was prescribed first. If a patient had "fatigue," "anxiety or depression/insomnia" and "listlessness," then Kami-kihi-to (effective rate 85.6%, efficacy 86.7) was prescribed first. The effectiveness was obtained for 40 symptoms in all.

This study identified the most frequently used Kampo formulas based on symptoms. Medical personnel seeking to incorporate Kampo treatment should refer to the results of the current study when choosing a second prescription if the Kampo formula they prescribed was initially ineffective. Furthermore, determining Kampo extracts based on the results of the current study is useful and convenient for medical personnel who are too busy to learn Kampo medicine and for patients who are too busy to make a decoction daily.

Keywords: Herbal medicine; Kampo medicine; Oriental medicine; Traditional medicine

***Corresponding author:** Tetsuya Isobe, International Oriental Medical Center, Kamishidami, Moriyama, Nagoya, Aichi, Japan, E-mail: iso12-7@blue.ocn.ne.jp

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Introduction

Traditional Chinese medicine, which includes herbal medicine and acupuncture, originated in ancient China and has gradually spread to neighboring countries. Since trade and cultural exchange between Japan and China ceased around 1600, traditional medicine has developed uniquely over time in each country. As a result of these developments, traditional Japanese herbal medicine, known as Kampo medicine, has unique diagnostic methods [1]. In Kampo medicine, herbal formulations have been prescribed since the Edo period based on the experience of eminent Japanese practitioners, including the great masters. An instant preparation called the Kampo extract formula is often used in Japan. In contrast, in traditional Chinese herbal medicine, the patient's condition is diagnosed based on traditional Chinese logic known as dialectic, and Chinese herbs are prescribed based on the same logic. The integration of the merits of modern medicine has been attempted in recent years.

The traditional way of taking herbal formulations is, in principle, to decoct a day's supply of crude drugs of natural origin (denoted here simply as crude drugs) and to drink the supernatant of that decoction during the day. A decoction is made by putting a daily dose of the desired herbal formulation of crude drugs in 600-800 ml of water and heating it for 30-40 minutes until it is reduced to half its original volume. The quality of crude drugs varies depending on their origin, even if they are the same type. Decoction is time-consuming and crude drugs have a short shelf life, but decoction has an advantage since an optimal herbal formulation can be made for each patient by increasing or decreasing the amount of each crude drug in accordance with the patient's physique, constitution, and resistance. In contrast, an instant preparation called a Kampo extract formula (denoted here simply as a Kampo extract) is often used in Japan. The amount of a crude drug cannot be changed in accordance with the individual patient, but a Kampo extract is extremely convenient because it is portable and does not involve the time and effort of decoction. Kampo extracts were first developed by Dr. Shiro Hosono in Kyoto in 1950 or so. A Kampo extract is a powder made by decocting a large amount of a crude drug comprising each herbal formulation, concentrating and drying it, and mixing it with excipients [2]. Several companies currently manufacture them and a total of 148 herbal formulations that are covered by health insurance in Japan. Tsumura & Co. currently manufactures and sells the largest number of products, most of which are sold in 3 equal portions at a standard daily dose of 7.5 g for adults. Tsumura Kampo extracts are packaged in laminated aluminum foil and can be stored at room temperature for 3-5 years. Over the past few

years, the clinical effectiveness of various types of Kampo extracts has been reported [3-38], and several effective herbal formulations are listed by symptom in existing books of herbal formulations. However, the effectiveness of each herbal formulation for each symptom has not been determined. The current study compiled data on 12 years of experience with Kampo prescriptions at the same facility and it tallied the efficacy and effective rate of each effective Kampo formulation by symptom.

Subjects and Methods

A suitable Kampo extract formula was selected based on the Kampo medicine diagnosis, and patients were treated with Kampo extracts from Tsumura. The Kampo formula used have been indicated with their number from Tsumura (e.g., Kakkon-to TJ1). This study compiled data from 11 years of experience with Kampo formula prescribed by the current author at the same facility, and it tallied the efficacy and effective rate of each effective herbal formulation according to symptoms. Subjects were 8,494 women who were seen as outpatients by this facility's women's clinic for traditional herbal medicine from May 2011 to April 2022 and who took herbal formulations prescribed in 11,933 cases. The initial prescription of an herbal formulation was, in principle, a standard dose (3 packets of a Tsumura extract per day for adults) for 1 month, and its effectiveness was determined by asking patients about their level of satisfaction after taking the herbal formulation [39,40]. If a patient desired increased effectiveness after taking the initial dose, the dose was increased to 4 packets per day as needed, and the patients were asked about its effectiveness again after taking that dose for 1 month. When increased effectiveness was requested, up to 6 packets per day were similarly prescribed again. If a patient reported that the initial dose was ineffective and the patient was switched to a different Kampo formula or if the same patient presented with different symptoms at different times, then each instance was treated as a separate case. 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% (44). The average level of satisfaction among responders was defined as the efficacy of the formulation. When multiple types of Kampo formula were prescribed at the same time, different formula were instructed to take them at least 30 minutes apart in order to avoid mixing of the constituent crude drugs in the stomach. The rationale for this is that each Kampo formula consists of a specific combination of crude drugs that produces a particular effect. The reason why a particular composition of crude drugs is effective in treating a particular condition has yet to be scientifically elucidated, but that approach has been arrived at based on longstanding human wisdom and experience. The composition of crude drugs is thought to change when the crude drugs that comprise multiple Kampo formula are mixed, resulting in different efficacy from that of each initial formulation. This is presumed to reduce efficacy from its original level before mixing. The standard dosage of a Kampo extract in traditional Japanese herbal medicine is 3 packets (7.5 g in most instances) per day, which is the minimum dosage required for it to be effective. Forgetting to take the extract is more likely to reduce the efficacy of treatment than mixing it with food, so patients were allowed to take the extract after meals in this study. When the daily dosage was increased to 4 packets, 2 packets were prescribed in the morning and 2 in the evening. Patients were allowed to take up to 2 packets at a time regardless of whether they took a combination of an odd or even number of packets, unless they were taking a special Kampo formulation. Most herbal formulations tend to be tasteless, so patients were allowed to take them with their preferred flavored beverage but not with water. In the 12 years covered by this study, the author has never experienced any decrease in effectiveness due to changes in beverages or taking formulations after meals.

Patient data were strictly managed at the facility with patients indicated by their initials 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 Kampo formula taken by 50 or more patients are shown in table 1. For each of the formulas shown in Table 1, patients were divided into responders and non-responders, and the average number of packets given to each group and the results of a t-test between the two groups are shown in Table 2. For each formula, a t-test was performed to compare the age of patients in the two groups. There were no significant differences in age for any of the formulations, so the average age of the patients in the two groups is shown in table 2. Kampo formula used is described in Japanese style.

Symptom or condition	Kampo formulation	Effective rate (%)	Efficacy
(1) Physical fatigue	Hochu-ekki-to(TJ41)	88.6 (373/421)	90.4
(2) Mental fatigue	Kami-kihi-to(TJ137)	85.6 (285/333)	86.7
(3) Premenstrual irritability	Tokaku-joki-to(TJ61)	84.5 (49/58)	80.3
	Kami-shoyo-san(TJ24)	84.3 (316/375)	77.6
	Yoku-kan-san(TJ54)	76.8 (76/99)	75.7
(4) Premenstrual deppresion	Hange-koboku-to(TJ16)	77.4 (41/53)	81.7
(5) Premenstrual lethargy	Gorei-san(TJ17)	86.2 (150/174)	85.6
(6) Migrain	Goshuyu-to(TJ31)	78.9 (123/156)	82.3
	Senkyu-cha-cho-san(TJ124)	74.1 (43/58)	81.5
(7) Dull headache	Hange-byakujutsu-tem-ma-to(TJ37)	86.9 (313/360)	86.4
deteriolate in rain, premense	Gorei-san(TJ17)	83.1 (54/65)	85.6
(8) Dizziness	Hange-byakujutsu-tem-ma-to(TJ37)	84.2 (213/253)	87.7
Feeling of floating	Gorei-san(TJ17)	75.8 (69/91)	85.2

	Ryo-kei-jutsu-kan-to(TJ39)	74.2 (132/178)	87.7
(9) Vertigo	Saikoka-ryukot-su-borei-to(TJ12)	63.1 (41/65)	84.6
(10) Hot flash	Toki-shakuyaku-san(TJ23)	75.2 (221/294)	81.1
Climacteric disorder	Keis-hi-bukuryo-gan(TJ25)	72.9 (180/247)	81.8
	Kami-shoyo-san(TJ24)	71.1(91/128)	79.6
(11) Generalized coldness	Shimbu-to(TJ30)	75.6 (65/86)	80.7
(12) Coldness of lower body	Hachimi-jio-gan(TJ7)	67.5 (79/117)	79.7
	Ryo-kyo-jutsu-kan-to(TJ118)	42.9 (33/77)	79.2
(13) Coldness of extremities	Toki-shigyaku-ka-goshuyu-shokyo-to(TJ38)	69.2 (155/224)	77
(14) Proven consti-pation	Bofu-tsusho-san(TJ62)	95.4 (83/87)	79.1
	Tokaku-joki-to(TJ61)	90.5 (153/169)	79
	Choi-joki-to(TJ74)	79.7 (102/128)	75
(15) False proof constipation	Juncho-to(TJ51)	70.2 (59/84)	77.6
(16) Difficulty falling asleep	Sansonin-to(TJ103)	84.5 (131/155)	85.8
(17) Shallow sleep	Kami-kihi-to(TJ137)	80.2 (162/202)	86.3
(18) Abdominal bloating	Dai-kenchu-to(TJ100)	84.6 (77/91)	86.2
(19) Stodginess	Rikkunshi-to(TJ43)	81.7 (98/120)	84.5
(20) Stomachache	Anchu-san(TJ5)	78.0 (39/50)	90.9
(21) Diarrhea	Ninjin-to(TJ32)	81.5 (66/81)	84.3
(22) Menorrhagia	Kyuki-kyogai-to(TJ77)	90.0 (45/50)	77.4
(23) Leg cramps	Shakuyaku-kanzo-to(TJ68)	97.8 (90/92)	96.2
(24) Dripping nose	Sho-seiryu-to(TJ19)	86.0 (178/207)	78.1
(25) Generalized edema	Gorei-san(TJ17)	73.6 (78/106)	86.2
	Sairei-to(TJ114)	65.1 (54/83)	81.6
(26) Edema of lower body	Boi-ogi-to(TJ20)	76.9 (80/104)	84.9
(27) Stiff shoulder	Kakkon-to(TJ1)	74.6 (141/189)	74.9
(28) Sore throat	Kikyo-to(TJ138)	92.8 (90/97)	98.6
(29) Frequent urination	Hachimi-jio-gan(TJ7)	72.9 (62/85)	79.7
(30) Menstrual crump	Tokaku-joki-to(TJ61)	84.9 (45/53)	76.4
	Toki-shakuyaku-san(TJ23)	84.9 (73/86)	75.4
	Toki-kencyu-to(TJ123)	73.8 (127/172)	74.7
	Keis-hi-bukuryo-gan(TJ25)	60.2(68/113)	74.6
(31) Dry cough	Bakumondo-to(TJ29)	91.4 (53/58)	87.5
(32) Kneel pain	Gosha-jinki-gan(TJ107)	79.2 (42/53)	86.5
(33) Low back pain	Gosha-jinki-gan(TJ107)	78.4 (40/51)	79.9
	Hachimi-jio-gan(TJ7)	72.4 (71/98)	86.1
(34) Acne	Sei-jo-bofu-to(TJ58)	66.7 (66/99)	77.8
(35) Eczema & Hives	Oren-gedoku-to(TJ15)	72.5 (66/91)	77.1
(36) Atopic dertitis	Unsei-in(TJ57)	66.0 (33/50)	76.5
	Keigai-rengyo-to(TJ50)	57.7 (30/52)	75.3
(37) Irritability	Kami-shoyo-san(TJ24)	82.7 (110/133)	79.9
	Yoku-kan-san(TJ54)	72.5 (95/131)	75
(38) Anxiety & Depression	Hange-koboku-to(TJ16)	89.9 (205/228)	84.3
	Kami-kihi-to(TJ137)	84.6 (302/357)	86.1
(39) Nervousness	Hange-koboku-to(TJ16)	85.2 (69/81)	83
Overstrained	Sha-kanzo-to(TJ64)	84.0 (79/94)	86.2
Panic attack	Saikoka-ryukot-su-borei-to(TJ12)	77.1 (54/70)	83.1
(40) Emotional instability	Nyoshin-san(TJ67)	87.5 (49/56)	81

Table 1: Efficacy and effective rate of Kampo formulas taken by 50 or more patients.

	Kampo formulation	Mean age	Dosed number of packs		P(t-test)
			Responder	Nonre-sponder	
(1)	Hochu-ekki-to(TJ41)	45.9	3.3	3.1	0.009
(2)	Kami-kihi-to(TJ137)	46.8	3.7	3.3	0.000048
(3)	Tokaku-joki-to(TJ61)	37.5	2.4	2.1	0.57
	Kami-shoyo-san(TJ24)	37.7	3.6	3.3	0.0011
	Yoku-kan-san(TJ54)	37.9	3.4	3.3	0.6
(4)	Hange-koboku-to(TJ16)	35.6	3.5	3.3	0.2
(5)	Gorei-san(TJ17)	39.3	3.4	3.3	0.49
(6)	Goshuyu-to(TJ31)	43.3	3.5	3.2	0.0015
	Senkyu-cha-cho-san(TJ124)	44.2	3.7	3.1	0.00009
(7)	Hange-byakujut-su-temma-to(TJ37)	41.8	3.7	3.3	0.00009
	Gorei-san(TJ17)	42.4	3.3	3.4	0.69
(8)	Hange-byakujut-su-temma-to(TJ37)	43.7	3.7	3.3	0.0025
	Gorei-san(TJ17)	41.3	3.4	3.1	0.039
	Ryo-kei-jutsu-kan-to(TJ39)	44.5	3.4	3.3	0.2
(9)	Saikoka-ryukot-su-borei-to(TJ12)	45.8	3.4	3.2	0.3
(10)	Toki-shakuyaku-san(TJ23)	50.1	3.5	3.2	0.00003
	Keis-hi-bukuryo-gan(TJ25)	51.5	3.6	3.1	0.0000003
	Kami-shoyo-san(TJ24)	50.5	3.5	3.3	0.32

(11)	Shimbu-to(TJ30)	44.1	3.6	3.1	0.0004
(12)	Hachimi-jio-gan(TJ7)	47.9	3.4	3.1	0.007
	Ryo-kyo-jutsu-kan-to(TJ118)	43.4	3.6	3.2	0.0016
(13)	Toki-shigyaku-ka-goshuyu-shokyo-to(TJ38)	41.6	3.5	3.2	0.0013
(14)	Bofu-tsusho-san(TJ62)	46.1	3.3	3.1	0.6
	Tokaku-joki-to(TJ61)	39.7	2.2	1.9	0.37
	Choi-joki-to(TJ74)	41.8	2.5	2.5	0.8
(15)	Juncho-to(TJ51)	46.3	3.1	2.6	0.0003
(16)	Sansonin-to(TJ103)	48.7	4.1	3.7	0.017
(17)	Kami-kihi-to(TJ137)	47.9	3.7	3.5	0.08
(18)	Dai-kenchu-to(TJ100)	42.1	5.1	5.1	0.97
(19)	Rikkunshi-to(TJ43)	42.9	3.3	3.2	0.8
(20)	Anchu-san(TJ5)	41.5	3.1	3	0.3
(21)	Ninjin-to(TJ32)	39.6	3.2	3.1	0.6
(22)	Kyuki-kyogai-to(TJ77)	43.5	3.3	3	0.0035
(23)	Shakuyaku-kanzo-to(TJ68)	59.9	1.7	1.3	0.4
(24)	Sho-seiryu-to(TJ19)	41.5	4.3	4	0.28
(25)	Gorei-san(TJ17)	42.2	3.3	3.3	0.7
	Sairei-to(TJ114)	44.8	3.2	3	0.07
(26)	Boi-ogi-to(TJ20)	44.2	3.6	3.3	0.1
(27)	Kakkon-to(TJ1)	44.9	4.8	3.9	0.00043
(28)	Kikyo-to(TJ138)	52.2	3	3	0.009
(29)	Hachimi-jio-gan(TJ7)	55.5	3.5	3.1	0.0098
(30)	Tokaku-joki-to(TJ61)	36.1	2.2	0.9	7.7E-07
	Toki-shakuyaku-san(TJ23)	32.8	3.7	3.1	0.0012
	Toki-kencyu-to(TJ123)	31.3	3.6	3.2	0.0011
	Keis-hi-bukuryo-gan(TJ25)	34.7	3.7	3.1	0.0000005
(31)	Bakumondo-to(TJ29)	46.9	3.2	3.1	0.5
(32)	Gosha-jin-ki-gan(TJ107)	65.2	3.8	3.4	0.15
(33)	Gosha-jin-ki-gan(TJ107)	57	3.4	3.2	0.2
	Hachimi-jio-gan(TJ7)	50.5	3.3	3.2	0.1
(34)	Sei-jo-bofu-to(TJ58)	31.1	3.5	3.2	0.016
(35)	Oren-gedoku-to(TJ15)	43.4	3.3	3.2	0.9
(36)	Unsei-in(TJ57)	37.2	3.6	3.4	0.3
	Keigai-rengyo-to(TJ50)	34.9	3.4	3.1	0.1
(37)	Kami-shoyo-san(TJ24)	42.9	3.6	3.1	0.00057
	Yoku-kan-san(TJ54)	42.2	3.4	3.1	0.013
(38)	Hange-koboku-to(TJ16)	44.4	3.8	3.2	0.000002
	Kami-kihi-to(TJ137)	46.7	3.6	3.2	0.000013
(39)	Hange-koboku-to(TJ16)	44.4	3.7	3	0.00032
	Sha-kanzo-to(TJ64)	48.2	3.3	3.1	0.1
	Saikoka-ryukot-su-borei-to(TJ12)	44.6	3.8	3.1	0.00046
(40)	Nyoshin-san(TJ67)	37.8	3.7	3.1	0.012

Table 2: Mean age and Average dosed number of packs in each responder or non-responder.

The results as shown in Table1 were obtained based on the following diagnosis. The effective rate (%) and efficacy are written in parentheses immediately after the name of each formula used. Both (1) and (2) are prescriptions for fatigue, but (1) is for physical fatigue and (2) is for mental fatigue. Mental fatigue causes listlessness and disturbance of sound sleep along with malaise, and anxiety over stress due to mental fatigue causes a depressed mood. When mental fatigue becomes chronic, amnesia also develops. Therefore, if a patient complained of "fatigue" and "physically drained," then Hochu-ekki-to (effective rate 88.6%, efficacy 90.4) was prescribed first. If a patient had "fatigue", "anxiety or depression/insomnia" and "felt listless," then Kami-kihi-to (85.6%, 86.7) was prescribed first. In reality, physical fatigue and mental fatigue are presumably both present in many instances, but the prescription is determined by which form of fatigue is more evident. (3), (4), and (5) are prescriptions for premenstrual syndrome and are categorized by principal symptoms they treat. (3) is a prescription for irritability of premenstrual syndrome, and Tokaku-joki-to (84.5%, 80.3) is the first prescription for patients with constipation. The first prescription for patients without constipation is Kami-shoyo-san (84.3%, 77.6) and the second prescription is Yoku-kan-san (76.8%, 75.7). Hange-koboku-to (77.4%, 81.7) was used as the first prescription for Premenstrual depression (4). Gorei-san (86.2%, 85.6) was used as the first prescription for Premenstrual lethargy (5). (6) and (7) are prescriptions for headaches, which are divided into headaches that occur on or before rainy days or 10 days prior to menstruation (dull headaches) and headaches that are unrelated to rainy days or that occur prior to menstruation (migraines). Goshuyu-to (78.9%, 82.3) was used as the first prescription for migraines (6) and Senkyu-chacho-san (74.1%, 81.5) was used as the second prescription. Hange-byakujutsu-temma-to (86.9%, 86.4) was used as the first prescription for dull headaches (7), and Gorei-san (83.1%, 85.6) was used as the second prescription. (8) and (9) are prescriptions for dizziness. Hange-byakujutsu-temma-to (84.2%, 87.7) was used as the first prescription for lightheadedness, which was described as "feeling of floating" or for a more severe feeling of dizziness, Ryo-kei jutsu-kan-to (74.2%, 87.7) was used as the second prescription, and Gorei-san (75.8%, 85.2) was used as the third prescription. Saikoka-ryukot-su-borei-to (63.1%, 84.6) was the first prescription for vertigo. (10) is a prescription for hot flashes, which are the principal symptom of what is known as climacteric syndrome. If the patient had yet to reach menopause, Toki-shakuyaku-san (75.2%, 81.1) was the first prescription, Keishi-bukuryo-gan (72.9%, 81.8) was the first prescription for coldness in the lower extremities, and Kami-shoyo-san (71.1%, 79.6) was the first prescription for constant irritability. (11), (12), and (13) are herbal formulations to treat coldness. Shimbu-to (75.6%, 80.7) was the first prescription for generalized coldness, Hachimi-jio-gan

(67.5%, 79.7) was the first prescription for coldness in the lower body, Ryo-kyo-jutsu-kan-to (42.9%, 79.2) was used as the second prescription, and Toki-shigyaku-ka-goshuyu-shokyo-to (69.2%, 77.0) was the first prescription for coldness in the extremities. (14) and (15) are prescriptions for constipation. If the patient had not defecated for several days, the severity of proven constipation was considered. Tokaku-joki-to (90.5%, 79.0) was prescribed when the patient had not defecated for about one week, and Choi-joki-to (79.7%, 75.0) was prescribed for constipation lasting about 3 days. If the patient had false proof constipation and the patient also wished to lose weight, Bofu-tsusho-san (95.4%, 79.1) was prescribed. Juncho-to (70.2%, 77.6) was the first prescription for "constipation due to a hypo-functioning condition." (16) and (17) are prescriptions for insomnia. Sansonin-to (84.5%, 85.8) was prescribed for "difficult falling asleep," and Kami-kihi-to (80.2%, 86.3) was prescribed for nocturnal sleep arousal, dreaming and other symptoms of shallow sleep. Dai-kenchu-to (84.6%, 86.2) was used as the first prescription for abdominal bloating (18). Rikkunshi-to (81.7%, 84.5) was used as the first prescription for stodginess (19). Anchu-san (78.0%, 90.9) was used as the first prescription for stomachache (20). Ninjin-to (81.5%, 84.3) was used as the first prescription for diarrhea (21). Kyuki-kyogai-to (90.0%, 77.4) was used as the first prescription for menorrhagia (22). Shakuyaku-kanzo-to (97.8%, 96.2) was used as the first prescription for leg cramps (23). Sho-seiryu-to (86.0%, 78.1) was used as the first prescription for dripping nose (24). (25) and (26) are prescriptions for edema. Gorei-san (73.6%, 86.2) was prescribed for acute generalized edema, and Sairei-to (65.1%, 81.6) was prescribed for chronic edema. Boi-ogi-to (76.9%, 84.9) was prescribed for edema of lower body. Kakkon-to (74.6%, 74.9) was used as the first prescription for stiff shoulder (27). Kikyo-to (92.8%, 98.6) was used as the first prescription for sore throat (28). Hachimi-jio-gan (72.9%, 79.7) was used as the first prescription for frequent urination (29). (30) is a prescription for menstrual cramps. If a patient was constipated and ultrasound revealed endometriosis, Tokaku-joki-to (84.9%, 76.4) was used as the first prescription. If the patient with endometriosis was not constipated, Keishi-bukuryo-gun (60.2%, 74.6) was used as the first prescription. Toki-kencyu-to (73.8%, 74.7) was used as the first prescription for patients without endometriosis, and Toki-shakuyaku-san (84.9%, 75.4) was used as the second prescription. Bakumondo-to (91.4%, 87.5) was used as the first prescription for dry cough (31). Gosha-jinki-gan (79.2%, 86.5) was used as the first prescription for kneel pain (32). (33) is a prescription for lower back pain. Hachimi-jio-gan (72.4%, 86.1) was used as the first prescription for lower back pain, and Gosha-jinki-san (78.4%, 79.9) was used as the second prescription. Sei-jo-bofu-to (66.7%, 77.8) was used as the first prescription for acne (34). Oren-gedoku-to (72.5%, 77.1) was used as the first prescription for eczema & hives (35). (36) is a prescription for atopic dermatitis. Unsei-in (66.0%, 76.5) was used as the first prescription for atopic dermatitis, and Keigai-rengyo-to (57.7%, 75.3) was used as the second prescription. (37) is Kampo formula for irritability, and Yoku-kan-san (72.5%, 75.0) was prescribed for patients who were usually irritable regardless of menstruation, and Kami-shoyo-san (82.7%, 79.9) was prescribed for patients who were irritable prior to menstruation. (38) is a prescription for patients complaining of anxiety and presenting with a depressed mood. However, the first prescription for patients who felt a plum stone-like obstruction of the throat was Hange-koboku-to (89.9%, 84.3). The first prescription for patients with listlessness and insomnia was Kami-kihi-to (84.6%, 86.1). (39) is a prescription for nervousness, overstrained, or panic attacks. Hange-koboku-to (85.2%, 83.0) was the first prescription for mainly anxiety, and Sha-kanzo-to (84.0%, 86.2) was the first prescription for palpitations. Saikoka-ryukotsu-borei-to (77.1%, 83.1) was the first prescription for excessive sensibility and overstrain. (40) is a prescription for emotionally unstable patients with varying irritability and depression and emotional incontinence. Nyoshinsan (87.5%, 81.0) was the first prescription. It is an herbal formulation that can also be used to treat postpartum neurosis.

Responders were given more doses of formulations than non-responders as shown in Table 1. If a patient showed no signs of improvement after taking 3 doses per day for 1month, further improvement should not be expected even if the doses are increased. If, in contrast, a patient showed signs of improvement but effectiveness was only partial, further improvement could be expected if the doses are increased up to 6 doses per day. For formulations with significant differences in the doses given, an average of 4 doses per day (2 doses for Tokaku-joki-to, 3 doses for Choi-joki-to, and 6 doses for Daikenchuto) is considered necessary. Shakuyaku-kanzo-to is intended for temporary use in case of muscle cramps and requires 2 packets per dose. Kakkon-to for neck/shoulder stiffness and Shousei-ryu-to for pollinosis (nasal discharge) require 2 packets per dose in most patients.

Many of the patients with menstruation-related symptoms such as PMS, menstrual cramps, or acne or atopic dermatitis were in their 30s, those with climacteric disturbances such as hot flashes, muscle cramps, frequent urination, and lower back pain were in their 50s, those with knee pain were in their 60s, and those with other symptoms were in their 40s.

Discussion

Matching between formulas and symptoms was attempted based on the results of Kampo treatment data obtained over the past 12 years. Hange-byakujutsu-temma-to was the first prescription for dizziness in (8), Ryo-kei jutsu-kan-to was the second prescription, and Gorei-san was the third prescription. However, the efficacy of Gorei-San (75.8%) was higher than that of Ryo-kei jutsu-kan-to (74.2%), so Gorei-San should be the second prescription and Ryo-kei jutsu-kan-to should be the third prescription. Ryo-kyo-jutsu-kan-to was used as the second prescription for coldness in the lower body in (12), but its effective rate was low (42.9%). Therefore, Keishi-bukuryo-gan, which had a higher effective rate (82.6%, 19/23) despite being given to fewer patients, should be the second prescription. In the future, Keishi-bukuryo-gan should be used as the second prescription for coldness in the lower extremities, and if the compiled data indicate that its effective rate exceeds 67.5%, then Keishi-bukuryo-gan should overtake Hachimi-jio-gan as the first prescription. The first prescription for menstrual cramps without endometriosis (30) was Toki-kencyu-to with an effective rate of 73.8%, and the second prescription was Toki-shakuyaku-san with an effective rate of 84.9%. However, a comparison of their effective rate indicates that the first prescription and the second prescription should be swapped. The first prescription for lower back pain (33) was Hachimi-jio-gan with an effective rate of 72.4% and the second prescription was Gosha-jinkii-gan with an effective rate of 78.4%, but this effective rate indicates that the precedence of these two formulations should also be switched. As a result, Hachimi-jio-gan could be the first prescription for both lower back pain and knee pain.

The following observations can be made when looking at formulations given to fewer than 50 patients. The effective rate of

Kami-shoyo-san in treating irritability of premenstrual syndrome was 84.3% (316/375), its effective rate in treating depression was 68.8% (11/16), and its effective rate in treating malaise/lethargy was 94.4% (17/18), so this single formulation may be able to alleviate all 3 symptoms at the same time. Similarly, the effective rate of Toki-shakuyaku-san in treating generalized coldness was 87.5% (7/8), its effective rate in treating coldness in the lower extremities was 68.8% (11/16), and its effective rate in treating coldness in the extremities was 72.0% (18/25), so this formulation may be a panacea for the alleviation of coldness. The effective rate with which Hange-byakujutsu-temma-to treated dull headaches aggravated by rainy days and prior to menstruation was 86.9% (313/360), and the effective rate with which it treated lightheadedness-dizziness was 84.2% (213/253), so this formulation may alleviate both dull headaches and lightheadedness. The effective rate with which Gorei-San treated heaviness in the stomach was 100% (9/9), its effective rate in treating nausea was 93.3% (14/15), and its effective rate in treating diarrhea was 87.5% (14/16), so Gorei-San may be useful for a wide range of gastrointestinal disorders. The hope is to examine these findings in a larger number of patients in the future.

The following strengths and weaknesses of traditional Japanese herbal medicine were identified as a result of comprehensively examining the efficacy and effective rate of each Kampo formula. The efficacy with which Kikyo-to treated a sore throat (28) was 92.8% and its effective rate was 98.6%, and the efficacy with which Shakuyaku-kanzo-to treated leg muscle cramps (23) was 97.8% and its effective rate was 96.2%. This indicates that a sore throat and muscle cramps are easily cured to Kampo treatment. Kikyo-to and Shakuyaku-kanzo-to are effective in 5-10 minutes since Kikyo-to consists of 2 crude drugs, Kikyo and Kanzo, and Shakuyaku-kanzo consists of 2 crude drugs, Shakuyaku and Kanzo. The efficacy with which Hochu-ekki-to treated physical fatigue (1) was 88.6% (373/421) and its effective rate was 90.4%, and the efficacy with which Kami-kihi-to treated mental fatigue (2) was 85.6% (285/333) and its effective rate was 86.7%, so fatigue is a symptom that can be easily alleviated by Kampo treatment, and physical fatigue is more easily alleviated than mental fatigue. The efficacy with which Sansonin-to treated difficulty falling asleep (16) was 84.5% (131/155) and its effective rate was 85.8%, and the efficacy with which Kami-kihi-to treated disturbance of sound sleep (17) was 80.2% (162/202) and its effective rate was 86.3%. The efficacy and effective rate of both formulations exceeded 80%, indicating that insomnia is a symptom that can be easily alleviated by Kampo treatment. The efficacy with which Goshuyu-to and Senkyu-chacho-San treated migraines (6) exceeded 80% and the efficacy and effective rate with which Hange-byakujutsu-temma-to and Gorei-san treated dull headaches (7) on rainy days or prior to menstruation both exceeded 80%, indicating that headaches are amenable to Kampo treatment. The efficacy with which Hange-byakujutsu-temma-to, Ryo-kei jutsu-kan-to, and Gorei-san treated dizziness (8) exceeded 80% and the efficacy with which Saikoka-ryukotsu-borei-to treated vertigo (9) exceeded 80%, indicating that dizziness is also amenable to Kampo treatment. The efficacy with which Gorei-san and Sairei-to treated generalized edema (25) exceeded 80%, and the efficacy with which Boiogito treated edema in the lower body (26) also exceeded 80%, indicated that edema is also easily alleviated by Kampo treatment. The effective rate with which Hachimi-jio-gan and Ryo-kyo-jutsu-kan-to treated coldness in the lower body (12) and Toki-shigyaku-ka-goshuyu-shokyo-to treated coldness in the extremities (13) was lower than 70%, and their efficacy was around 70%. The effective rate with which Seijo-bofu-to treated acne was lower than 70%, and its efficacy was around 70%. The effective rate with which Unsei-in and Keigai-rengyo-to treated atopic dermatitis was lower than 70%, and their efficacy was around 70%. The effective rate with which Kakkon-to treated neck/shoulder stiffness (27) was 74.5% and its efficacy was 74.8%. These results indicate that coldness, skin conditions, and neck/shoulder stiffness are not amenable to Kampo treatment.

A look at a list of effective Kampo formulas by symptom in specialized books on herbal formulations did not reveal which formulations are most frequently used, but the current retrospective study over 12 years has revealed the frequency of use of these formulations. Of course, the most effective Kampo formula for each patient does not necessarily coincide with the frequency of use, but it can be used as a reference for selecting prescriptions in the future. To fully master the Kampo diagnosis of traditional Japanese herbal medicine, volumes written by the great masters need to be read, and to fully master the dialectics of traditional Chinese medicine, this difficult theory needs to be understood. Books on both traditional Japanese herbal medicine and traditional Chinese medicine are written in Chinese characters; consequently, mastering these practices is even more difficult for medical personnel in countries that do not use Chinese characters. Therefore, medical personnel seeking to incorporate Kampo treatment can refer to the results of the current study when choosing a second prescription if the Kampo formula they initially prescribed was ineffective. Furthermore, determining Kampo extracts based on the results of the current study is useful and convenient for medical personnel who are too busy to learn Kampo medicine and for patients who are too busy to make a decoction daily. In the future, the aim is to increase the number of patients to improve the effectiveness of Kampo treatment based on Kampo diagnosis and to obtain modern scientific evidence [41]. In Japan, specialized education on Kampo treatment is provided to medical students at specific medical colleges [42], with the intent of spreading Kampo medicine worldwide for integration with modern medicine [41, 43,44].

Conclusion

This study identified the most frequently used Kampo formulas based on symptoms. Medical personnel seeking to incorporate Kampo treatment can refer to the results of the current study when choosing a second prescription if the Kampo formula they initially prescribed was ineffective. Furthermore, determining Kampo extracts based on the results of the current study is useful and convenient for medical personnel who are too busy to learn Kampo medicine and for patients who are too busy to make a decoction daily.

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