

## Research Article

# Comparison of the Effectiveness of Kampo Treatment for Dysmenorrhea Depending on the Presence or Absence of Endometriosis: A Retrospective Study Over 12 Years

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## Abstract

In modern medicine, endometriosis is known to be one of the causes of dysmenorrhea, and in Oriental medicine “stasis of the blood” or a “cold-syndrome” is considered to be a cause of menstrual cramps. Patients with endometriosis are considered to have “stasis of the blood. Some patients with “stasis of the blood” may have distended sublingual veins, and endometriosis can often be detected with ultrasound. Kampo treatment of menstrual cramps in patients with “stasis of the blood” includes an agent to “activate blood circulation”, and Kampo formulations with action “to regulate ‘qi’ and dissipate cold” are used to treat menstrual cramps in patients with a “cold-syndrome” by improving the flow of “qi” and blood and “warming” the uterus.

This study covered a period of 12 years from September 2012 to September 2024. Potential subjects were patients whose menstrual cramps failed to respond to analgesics and who were seen at this Center’s Department of Kampo medicine. Subjects were 318 patients who underwent a tongue examination and ultrasound and who then received Kampo treatment (205 with endometriosis, 111 without endometriosis).

The first formulation prescribed to patients with endometriosis according to ultrasound was Tokaku-joki-to if constipation was present and Keishi-bukuryo-gan if not. The second formulation pre-

scribed was Toki-shakuyaku-san. The third formulation prescribed was Toki-kenchu-to. In contrast, the first formulation prescribed to patients without endometriosis was Toki-kenchu-to. The second formulation prescribed was Toki-shakuyaku-san. The third formulation prescribed was Tokaku-joki-to if constipation was present or Keishi-bukuryo-gan if not.

In patients with endometriosis, effective rate was 96.7% for Tokaku-joki-to > 90.0% for Toki-shakuyaku-san > 65.2% for Keishi-bukuryo-gan > 54.5% for Toki-kenchu-to. In patients without endometriosis, effective rate was 87.5% for Tokaku-joki-to > 81.7% for Toki-kenchu-to > 79.7% for Toki-shakuyaku-san > 55.3% for Keishi-bukuryo-gan.

Effectiveness were higher in the patients with endometriosis than these in the patients without endometriosis in Tokaku-joki-to, Toki-shakuyaku-san, and Keishi-bukuryo-gan, which eliminate blood stasis. Effectiveness was higher in the patients without endometriosis than these in the patients with endometriosis in Toki-kenchu-to which improve the flow of “qi” and blood and “warming” the uterus. Tokaku-joki-to which has strongest action to eliminate blood stasis had highest effective rate in both the patients with and without endometriosis. These results imply the existence of “latent stasis of the blood.”

**Keywords:** Dysmenorrhea; Keishi-Bukuryo-Gan; Tokaku-Joki-To; Toki-Kenchu-To; Toki-Shakuyaku-San

## Introduction

Menstrual cramps or dysmenorrhea [1] is a condition that afflicts many women. Currently, many patients are using the Low-Dose (LD) pill [2] or the Ultra-Low-Dose (ULD) pill [3] with even lower hormone levels. Many patients with withdrawal bleeding (artificial menstruation) caused by the LD pill or ULD pill have very mild menstrual cramps and reduced menstrual flow. And for women over the age of 40, fourth-generation oral progestin with low androgenic activity [4] or progesterone-releasing intravaginal devices [5] and GnRH antagonists [6] and GnRH agonists [7,8] are used to stop menstruation itself and reduce menstrual cramps as much as possible. That said, there are still many patients who dislike the adverse reactions to hormones and who prefer to be treated with Kampo formulations. In modern medicine, endometriosis [9] is known to be one of the causes of menstrual cramps, and in Oriental medicine “stasis of the blood” [10] or a “cold-syndrome” is considered to be a cause of menstrual cramps. Patients with endometriosis or a uterine myoma are considered to have “stasis of the blood.” Some patients with “stasis of the blood” may have distended sublingual veins, and endometriosis can often be detected with ultrasound (and transvaginal ultrasound in particular). Ultrasound signs of endometriosis often include adenomyosis, in which endometriotic lesions form in the myometrium, causing the uterus to thicken and enlarge [11], and ovarian endometrioma (a “chocolate cyst”) [12], in which old blood and endometrial tissue that detached during each menstrual period accumulate in the ovaries and take the consistency of melted chocolate. Another site that is the most prone to endometriotic lesions is the Douglas cavity (the pouch between the uterus and rectum). These lesions are evident as tenderness in the

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pouch of Douglas [13] evoked by the probe during an ultrasound or as tenderness in the posterior wall of the uterus during a rectal examination. Even if the uterus and ovaries are normal on ultrasound, tenderness often suggests the existence of endometriosis. The uterine muscles need to contract to achieve hemostasis during the shedding of the endometrium, but menstrual cramps can also occur when the uterine muscles contract too strongly during menstruation. More intense contractions as a result of a “cold” pelvic uterus are considered to be painful menstruation due to a “cold-syndrome” in Oriental medicine. A Kampo formulation referred to as an agent with the action “to activate blood circulation” has been used to “eliminate blood stasis” to treat painful menstruation caused by “stasis of the blood,” and a Kampo formulation that “warms” the pelvic cavity has been used to relieve painful menstruation caused by a “cold-syndrome.”

## Subjects and Methods

This study covered a period of 12 years from September 2012 to September 2024. Potential subjects were patients whose menstrual cramps failed to respond to analgesics and who were seen at this Center’s Department of Kampo Medicine or its Department of Acupuncture and Moxibustion. Subjects were 318 patients who underwent an ultrasound and who then received Kampo treatment (205 patients with endometriosis, average age: 30.4 years; 113 patients without endometriosis, average age: 36.9 years). Endometriosis was broken down into 37 patients with adenomyosis, 42 patients with an ovarian “chocolate” cyst, and 39 patients with tenderness in the Douglas cavity. Two patients with endometriosis also had a myoma in the myometrium. The Kampo formulations used in this study are all extracts. The formulations used as an agent to “eliminate blood stasis” [14] were Tokaku-joki-to [15], Keishi-bukuryo-gan [16,17], Toki-shakuyaku-san [18,19], and Tsudo-san. The formulations used to treat a “cold-syndrome” were Toki-kenchu-to [20] and Unkei-to [21]. In order of their potency at “eliminating blood stasis,” the formulations were Tokaku-joki-to > Keishi-bukuryo-gan > Toki-shakuyaku-san. However, the main crude drug in Tokaku-joki-to is from peach pits [22]. It has potent action to “activate blood circulation” and also has laxative action, so it is essentially useless for patients who are not constipated.

During actual treatment, the presence or absence of endometriosis was first determined with transvaginal ultrasound, followed by a tongue examination and asking patients if they were constipated or not. Patients with endometriosis and intractable constipation were prescribed Tokaku-joki-to (from Tsumura) in a standard dose of 7.5 g a day (3 packets/day) for 1 week. Patients started with 2 packets a day, and whether they developed diarrhea was determined. If constipation was not readily alleviated, the dose was increased by 1 packet/day. If diarrhea developed with 2 packets a day, the dose was decreased by 1 packet a day. If diarrhea still developed, the formulation was discontinued (11 patients). In some patients, the dose was adjusted in increments of half of a packet, resulting in normal bowel movements at a dose of 1.5 g or 2.5 g a day. If patients were able to take the formulation for 1 week without developing diarrhea, then they were continuously prescribed a dose for over 1 month until the end of menstruation based on their menstrual cycle. Patients were asked about their satisfaction with the formulation’s alleviation of menstrual cramps right after the end of next menstruation with taking a medication. Tokaku-joki-to also suppresses irritability before menstruation, so the patients were asked about reduced irritability before menstruation as well as reduced menstrual cramps. Patients who developed

diarrhea after taking just 1 packet of Tokaku-joki-to a day or those who had no response for alleviating menstrual cramp after taking Tokaku-joki-to for 1 month without developing diarrhea were switched to Keishi-bukuryo-gan. This formulation has no laxative action, so patients were prescribed 3 packets a day until the end of menstruation, and patients were asked about their satisfaction with it. If patients took Keishi-bukuryo-gan but it failed to sufficiently reduce menstrual cramps, they were prescribed 4 packets a day again. Tokaku-joki-to or Keishi-bukuryo-gan was selected as the first formulation prescribed for strongly eliminating blood stasis. If the first formulation prescribed was ineffective, that formulation was switched to Toki-kenchu-to. This formulation has no laxative action, so patients took the formulation for 1 month until the end of menstruation. If the formulation was similarly ineffective in treating menstrual cramps, then the formulation was switched to Toki-shakuyaku-san, which was the third formulation prescribed, and patients were asked about their satisfaction after the end of menstruation. In contrast, the first formulation prescribed to patients without endometriosis according to ultrasound was Toki-kenchu-to. The second formulation prescribed was Toki-shakuyaku-san. The third formulation prescribed was Tokaku-joki-to if patients had intractable constipation or Keishi-bukuryo-gan if patients did not have constipation. If the first to third formulations prescribed were all ineffective, Tsudo-san was prescribed at the standard dose if patients had constipation while Unkei-to was similarly prescribed in patients who did not have constipation regardless of the presence or absence of endometriosis.

A t-test was used to compare patient satisfaction in the group with endometriosis and the group without endometriosis by formulation using a t-test with a level of significance of 2.5%.

In this study, effectiveness of treatment was determined by asking patients about their level of satisfaction after taking the herbal formulation [21,22]. 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 and efficacy (=average satisfaction of responders) of Tokaku-joki-to, Toki-shakuyaku-san, Keishi-bukuryo-gan, and Toki-kenchu-to by whether patients had endometriosis or not are shown in table 1.

According to table 1, effective rate in patients with endometriosis was 96.7% for Tokaku-joki-to > 90.0% for Toki-shakuyaku-san > 65.2% for Keishi-bukuryo-gan > 54.5% for Toki-kenchu-to. Effective rate in patients without endometriosis was 87.5% for Tokaku-joki-to > 81.7% for Toki-kenchu-to> 79.7% for Toki-shakuyaku-san > 55.3% for Keishi-bukuryo-gan. In patients with endometriosis, efficacy was almost 76 for all 4 formulations, and differences depending on the formulation were not noted. In patients without endometriosis, efficacy was close to 75 for all 4 formulations, and differences depending on the formulation were not noted.

Nine patients failed to respond to the first to third formulations prescribed (6 with endometriosis, 3 without endometriosis). Tsudo-san was prescribed in the standard dose if patients had constipation, and Unkei-to was similarly prescribed if patients did not have constipation, regardless of the presence or absence of endometriosis. Of 6 patients with endometriosis, 2 of 3 responded to Tsudo-san and 2 of 3 responded to Unkei-to. Of 3 patients without endometriosis, 1 of 2 responded to Tsudo-san and 1 of 1 responded to Unkei-to.

The number of patients with endometriosis and their age and the number of patients without endometriosis and their age were noted in table 2. According to table 2, average age of the patients with endometriosis was higher by 6.5 age than one of the patients of no endometriosis finding.

		Tokaku-joki-to	Toki-shakuyaku-san	Keishi-bukuryo-gan	Toki-kenchu-to
endometriosis(+)	Effective rate	96.7%(29/30)	90.0%(18/20)	65.2%(43/66)	54.5%(24/44)
	Efficacy	76.2	76.7	76.3	75
	Mean No. of Package	1.8	4.1	3.8	3.6
no endometriosis	Effective rate	87.5%(21/24)	79.7%(59/74)	55.3%(26/47)	81.7%(103/126)
	Efficacy	75.2	74.8	74.2	75.2
	Mean No. of Package	1.9	3.7	3.5	3.7

**Table 1:** The effective rate and efficacy of 4 formulations classified by whether patients had endometriosis or not and the average number of packets of each extract required for treatment.

Discussion

The effective rate of Tokaku-joki-to was 96.7% in patients with endometriosis vs. 87.5% in those without endometriosis, the effective rate of Keishi-bukuryo-gan was 65.2% in patients with endometriosis vs. 55.3% in those without endometriosis, the effective rate of Toki-shakuyaku-san was 90.0% in patients with endometriosis vs. 79.7% in those without endometriosis, and the effective rate of Toki-kenchu-to was 54.5% in patients with endometriosis vs.81.7% in those without endometriosis. Tokaku-joki-to, Keishi-bukuryo-gan, and Toki-shakuyaku-san had greater effective rate in patients with

	Numbers of patients	Average age	10s	20s	30s	40s	50s	60s
Patients with endometriosis	113	36.9±7.9	1	21	38	50	3	0
Patients with no endometriosis finding	205	30.4±10.6	45	50	63	39	8	0

**Table 2:** The number of patients with endometriosis and their average age and the number of patients without endometriosis and their average age.

endometriosis, and only Toki-kenchu-to had greater effective rate in patients without endometriosis. When a t-test was performed on the group with endometriosis and the group without endometriosis, Tokaku-joki-to, Keishi-bukuryo-gan, and Toki-shakuyakusan had greater effective rate, especially only Tokaku-joki-to had significantly greater effective rate (P=0.082) among the 3 formulations which eliminate blood stasis. This may be because endometriosis is a condition involving “stasis of the blood” in Oriental medicine, and therefore the first 3 formulations may have had greater effective rate as agents to “eliminate blood stasis.” The ranked effectiveness of the first 3 formulations coincides with their ranked potency at “eliminating blood stasis.” In contrast, Toki-kenchu-to had significantly greater effective rate (P=0.0011) in the group without endometriosis. Toki-kenchu-to has action to “warm” and circulate “qi” and blood, so it was effective against menstrual cramps caused by a “cold-syndrome.” A look at the efficacy by formulation revealed a trend similar to that for the effective rate of the 4 formulations, in the order of whether patients had endometriosis or not.

The number of packets of each Kampo formulation extract that was required to achieve satisfactory effectiveness was, when rounded off, 4 packets a day for the 3 formulations other than Tokaku-joki-to and 2 packets a day for Tokaku-joki-to. Tokaku-joki-to has potent laxative action, so few packets can be taken without leading to diarrhea. Nonetheless, it was best at alleviating dysmenorrhea compared to the other formulations. Moreover, Tokaku-joki-to also has action to reduce irritability before menstruation. For patients with intractable constipation who do not develop diarrhea with Tokaku-joki-to, this formulation simultaneously alleviates constipation, menstrual cramps due to endometriosis, and irritability before menstruation while also reducing the burden of taking the formulation.

Distended sublingual veins are a sign suggesting “stasis of the blood” in Oriental medicine. The incidence of distended sublingual veins was 7.96% (9/113) in patients with endometriosis and 4.47% (8/205) in patients without endometriosis. The most effective formulation was Tokaku-joki-to, which has a potent action “to activate blood circulation,” regardless of whether patients had endometriosis or not. This suggests that patients with no signs of endometriosis according to ultrasound and patients with no signs of “stasis of the blood” according to a tongue examination are more likely to have “latent stasis of the blood.”

According to classification by years of table 2, most common years in patients with endometriosis were 30s and 40s, most common years in patients without endometriosis were 10s, 20s, 30s. These results imply that the most popular cause of dysmenorrhea can be endometriosis (blood stasis) in middle-aged generation, can be cold-syndrome in younger generation.

## Conclusion

In patients with endometriosis, the effective rate of Kampo treatment of dysmenorrhea was 96.7% for Tokaku-joki-to > 90.0% for Toki-shakuyaku-san > 65.2% for Keishi-bukuryo-gan > 54.5% for Toki-kenchu-to. Efficacy (=average satisfaction of responders) was almost 76 for all 4 formulations. Thus, the order of precedence for Kampo formulations should be Tokaku-joki-to or Toki-shakuyaku-san (Tokaku-joki-to if constipated, Toki-shakuyaku-san if not) as the first formulation prescribed, Keishi-bukuryo-gan as the second formulation prescribed, and Toki-kenchu-to as the third formulation prescribed.

In patients without endometriosis, the effective rate of Kampo treatment of dysmenorrhea was 87.5% for Tokaku-joki-to > 81.7% for Toki-kenchu-to > 79.7% for Toki-shakuyaku-san > 55.3% for Keishi-bukuryo-gan. Efficacy (=average satisfaction of responders) was almost 75 for all 4 formulations. Thus, the order of precedence for Kampo formulations should be Tokaku-joki-to or Toki-kenchu-to (Tokaku-joki-to if constipated, Toki-kenchu-to if not) as the first formulation prescribed, Toki-shakuyaku-san as the second formulation prescribed, and Keishi-bukuryo-gan as the third formulation prescribed.

Both effective rate and efficacy were higher in the patients with endometriosis than these in the patients without endometriosis in Tokaku-joki-to, Toki-shakuyaku-san, and Keishi-bukuryo-gan. which eliminate blood stasis. Both effective rate and efficacy were higher in the patients without endometriosis than these in the patients with endometriosis in Toki-kenchu-to which improve the flow of “qi” and blood and “warming” the uterus.

Tokaku-joki-to which has strongest action to eliminate blood stasis had highest effective rate in both the patients with and without endometriosis. This result implies the existence of “latent stasis of the blood.”

The results of current study differed from the order in which the formulations were prescribed over 12 years.

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