

## Efficacy of Waon Therapy for Fibromyalgia

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### Abstract

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**Objective** Fibromyalgia syndrome (FMS) is a chronic syndrome characterized by widespread pain with tenderness in specific areas. We examined the applicability of Waon therapy (soothing warmth therapy) as a new method of pain treatment in patients with FMS.

**Methods** Thirteen female FMS patients (mean age, 45.2±15.5 years old; range, 25-75) who fulfilled the criteria of the American College of Rheumatology participated in this study. Patients received Waon therapy once per day for 2 or 5 days/week. The patients were placed in the supine or sitting position in a far infrared-ray dry sauna maintained at an even temperature of 60°C for 15 minutes, and then transferred to a room maintained at 26-27°C where they were covered with a blanket from the neck down to keep them warm for 30 minutes. Reductions in subjective pain and symptoms were determined using the pain visual analog scale (VAS) and fibromyalgia impact questionnaire (FIQ).

**Results** All patients experienced a significant reduction in pain by about half after the first session of Waon therapy (11-70%), and the effect of Waon therapy became stable (20-78%) after 10 treatments. Pain VAS and FIQ symptom scores were significantly ( $p<0.01$ ) decreased after Waon therapy and remained low throughout the observation period.

**Conclusion** Waon therapy is effective for the treatment of fibromyalgia syndrome.

**Key words:** fibromyalgia, Waon therapy, thermal therapy

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### Introduction

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Fibromyalgia syndrome (FMS) is a chronic syndrome characterized by widespread pain with specific tender areas (1). Although the etiology of FMS is unknown, this syndrome is occasionally accompanied by rheumatoid arthritis and other autoimmune diseases (1). Several effective methods have been reported for the treatment of pain in patients with FMS. In addition to the use of anti-depressants and a new anti-convulsant (2), exercise and spa therapy have been suggested to improve the symptoms in FMS patients (3). However, the severity of symptoms in FMS patients varies widely, and exercise and spa therapy cannot be applied in many patients with disabilities in daily life due to their compromised physical condition. Therefore, improved methods for the treatment of such patients are necessary. A far infrared-ray dry sauna maintained at a constant temperature of 60°C has been shown to be a safe form of therapy in pa-

tients with a compromised physical condition, such as those with heart failure (4-6) as well as peripheral artery disease (7). Thermal therapy has been shown to improve hemodynamics in congestive heart failure by thermal vasodilation, as well as to relieve pain, improve walking ability and blood flow in patients with peripheral artery disease. Further, there was a decrease in subjective complaints among mildly depressed patients after thermal therapy (8). As thermal therapy has been demonstrated to be effective for relieving the symptoms in patients with chronic psychosomatic pain (9), we examined the efficacy of this type of treatment in patients with FMS.

Recently, we changed the terminology of “thermal therapy” to “Waon therapy (10)”, to make it easier to understand the true meaning as distinguished from other treatments, such as “local heat therapy for cancer”. “Waon” can be understood in Japanese as “soothing warmth”, meaning “warmth that comfortably refreshes the mind and body”. That is, “Waon” is the essence of “thermal therapy”, which

**Table 1. Patients' Characteristics**

No	Age	Sex	Complication	Duration of Fibromyalgia (months)	Number of tender points	Scores of pain VAS	Scores of FIQ
1	49	F	RA	4	18	8.0	
2	51	F	no	84	18	6.3	
3	60	F	Aortitis	3	16	9.0	
4	56	F	SLE	26	16	8.2	54
5	40	F	SLE	96	16	7.0	55
6	34	F	no	6	18	7.0	52
7	30	F	Behcet	7	18	8.0	46
8	50	F	no	12	11	4.0	33
9	75	F	SLE	11	18	7.5	59
10	27	F	no	29	18	5.0	20
11	25	F	no	60	18	4.8	51
12	30	F	SS	51	18	6.5	26
13	61	F	SSc	22	14	8.8	52

VAS, visual analog scale; FIQ, fibromyalgia impact questionnaire; RA, rheumatoid arthritis; Aortitis, Aortitis syndrome; SLE, systemic lupus erythematosus; Behcet, Behcet disease; SS, Sjögren syndrome; SSc, systemic sclerosis.

we have been improving and refining over the past 18 years. The temperature of 60°C is lower than conventional saunas and obviating the discomfort from heat stimulation of sympathetic nerve systems (4). Additionally, our previous reports showed the efficacy of Waon therapy in reducing various subjective symptoms of patients with depression or chronic fatigue syndrome, alongside benefits observed for heart failure and peripheral artery disease patients (8, 9). Recently, our paper entitled "Waon therapy" was published (11) and subsequently, the new terminology has become widely known and used worldwide.

## Patients and Methods

### Patients

Thirteen patients (all female; mean age, 45.2±15.5 years old; range, 25-75) who fulfilled the criteria of the American College of Rheumatology gave their written informed consent to participation in this study. Five patients had primary FMS (Nos. 2, 6, 8, 10, 11). Three patients also had systemic lupus erythematosus (Nos. 4, 5, 9), one had rheumatoid arthritis (No. 1), one had Behçet's disease (No. 7), one had aortitis syndrome (No. 3), one had Sjögren syndrome (No. 12), and one had systemic sclerosis (No. 13). The durations of FMS were 4 to 84 months. Two patients (Nos. 2 and 6) did not take any medicine, 4 patients took anti-inflammatory drugs (Nos. 1, 4, 7, 8 and 13), 8 patients took low dose of prednisolone (<10 mg) (Nos. 1, 3, 4, 5, 7, 9, 12, and 13), and 6 patients took anti-depressants (Nos. 8-13). There was no evidence of active inflammation, other than fibromyalgia symptoms in FMS patients known to have autoimmune disease. Five patients (Nos. 1, 7, 10, 11, and 12) had quit their jobs, and another three (Nos. 3, 5, and 6) had taken a leave of absence from work because of FMS; the remaining five patients were homemakers. The patients' activities in daily

life were also limited by FMS, but none of those in the present study were bedridden due to their symptoms. Table 1 summarizes the patients' characteristics.

### Waon therapy

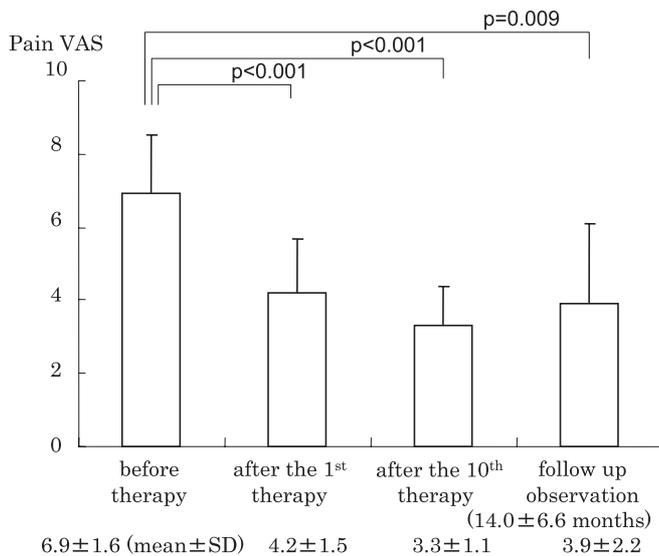
"Waon therapy" is defined as "therapy in which the entire body is warmed in an evenly heated dry chamber for 15 minutes at 60°C that soothes the mind and body. The deep-body temperature increases approximately 1.0-1.2°C. The soothing warmth effects are sustained by maintaining the warmth at rest for an additional 30 minutes, with fluids corresponding to perspiration being supplied at the end".

Seven patients (No. 1 to 5, 12, and 13) received Waon therapy once per day, 5 days/week in hospital, and the remaining six (No. 6 to 11) patients received Waon therapy twice a week at our outpatient clinic. The drugs administered were the same from 4 weeks before commencement of treatment and through all 10 sessions of Waon therapy. All patients were guided to take a bath in warm water (40-41°C, 10 minutes) at home every day except on the day of Waon therapy.

A far infrared-ray dry sauna system (Onda, Kagoshima, Japan) maintained at a constant temperature of 60°C was used for Waon therapy. The patients were placed in the supine or sitting position in a sauna at 60°C for 15 minutes, and then transferred to a room maintained at a temperature of 26-27°C where they were covered with blankets from the neck down to keep them warm for 30 minutes. The patients were weighed before and after Waon therapy; oral hydration with water compensated for lost weight. The purpose of weight compensation was to prevent dehydration, as patients may lose between 200 mL and 500 mL during Waon therapy (4).

### Estimation of therapeutic effect

All patients rated their severity of pain using the visual

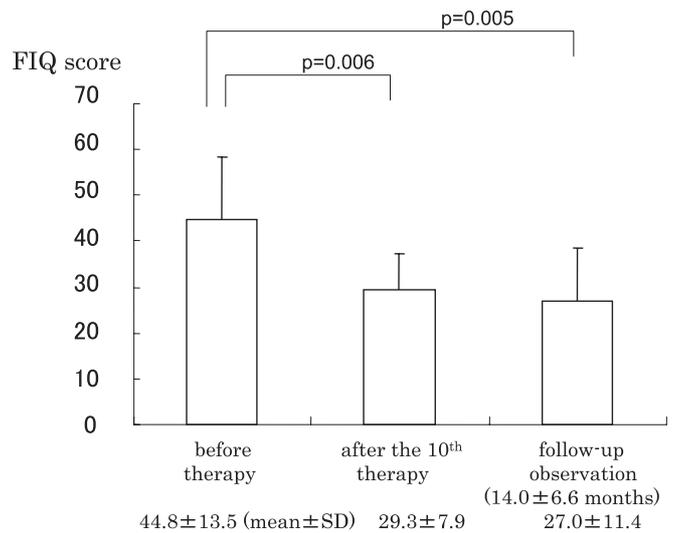


**Figure 1.** The bar graph shows the mean±SD scores of pain on the visual analog scale (VAS) before and after the 1st and 10th sessions of Waon therapy, and at the follow-up observation. The VAS scores were improved after the 1st session of Waon therapy and the effects were maintained throughout the observation period.

analog scale (VAS) before and after the first and 10th sessions of Waon therapy. Two patients (Nos. 1 and 2) were no longer under observation after the 10th therapy session, while the remaining eleven patients received follow-up and rated their pain symptoms using the VAS. The median follow-up period was 14 months (range: 6-30 months). Ten patients (Nos. 4-13) completed the Fibromyalgia Impact Questionnaire (FIQ) (12) before and after the 10th session of Waon therapy, and bimonthly thereafter throughout the follow-up period. The FIQ consists of seven questions regarding symptom scores of pain, pain at work, fatigue, mood in the morning, stiffness, anxiety, and depression. Comparisons of scores of pain symptoms by VAS or symptoms in the FIQ were examined for statistical significance by paired t-tests with a value of  $p < 0.05$  taken to indicate significance.

## Results

All patients received 10 sessions of Waon therapy without significant side effects. All patients reported a decrease in pain by about half (11 to 70%) after the first session of Waon therapy, and the effect was reduced before the next session of Waon therapy in half of the patients. The effect of Waon therapy became stable after 10 treatments, with subjects reporting pain reduction of 20-78%. In most cases, the effects were maintained throughout the observation period. Mean scores of VAS for pain before, after the first and the tenth sessions of Waon therapy, and in the follow-up observation period were  $6.9 \pm 1.6$ ,  $4.2 \pm 1.5$ ,  $3.3 \pm 1.1$ , and  $3.9 \pm 2.2$ , respectively, and the values after Waon therapy were significantly lower than those before Waon therapy ( $p <$



**Figure 2.** The bar graph shows the mean±SD of fibromyalgia impact questionnaire (FIQ) scores before and after the 10th session of Waon therapy and the follow-up observation. The FIQ scores were improved after Waon therapy and the effects were maintained throughout the observation period.

0.001, after the first and the tenth sessions, respectively, and  $p = 0.009$  on the follow-up observation) (Fig. 1). Symptom scores of FIQ before Waon therapy were  $44.8 \pm 13.5$  and ranged from 20 to 59. The scores decreased significantly after the 10th session of Waon therapy ( $29.3 \pm 7.9$ , range 19-40,  $p = 0.006$ ), and the improvement in the score was maintained throughout the observation period ( $27.0 \pm 11.4$ , range 12-42,  $p = 0.005$ ) (Fig. 2). Tender points were also decreased by Waon therapy from  $15.8 \pm 4.3$  (before therapy) to  $8.2 \pm 6.6$  (last follow up), and the difference was statically significant ( $p = 0.006$ ). Disease had progressed at the last observation point in three cases; this was due to mental and physical stress of work in two cases (Nos. 5 and 11) and due to complicated disease fluctuation in the remaining case (No. 13). Seven patients did not continue Waon therapy at the outpatient clinic due to difficulty with frequent visits in three cases (Nos. 1-3) and due to improvement of physical condition in four cases (Nos. 5, 6, 11, and 13). The remaining six patients are currently continuing Waon therapy twice a week. Two patients (Nos. 1 and 2) are no longer under clinical observation because of psychological problems and clinical remission, respectively. The remaining 11 patients visit our outpatient clinic regularly and show improvement or stabilization of disease. Five of 8 patients (Nos. 3, 5, 6, 7, and 11) who had quit or taken a leave of absence from work have since returned to work with improved physical condition following Waon therapy.

## Discussion

We observed marked pain reduction with Waon therapy in patients with FMS, which seemed to be related directly to this form of treatment because the patients reported improvement in their symptoms immediately after the first ses-

sion. The effect of Waon therapy was maintained in most cases. Further, the patients' social activities were also increased as a result of this form of therapy. In the present study, we treated 8 FMS patients with autoimmune diseases (AID) and 5 FMS patients without AID. Although the symptoms of secondary FMS patients were easily affected by activity of complicated AID, all 8 patients lacked active disease other than fibromyalgia symptoms. We propose that Waon therapy improved fibromyalgia symptoms equally in FMS patients with or without AID. The absence of a comparative estimation in a larger sample of FMS patients with or without AID limits the generalizability of these inferences.

Quantitative assessment of FMS symptoms was done using FIQ system. The FIQ was designed in the USA to estimate overall disease activity by a scoring system based on daily life activity, the affected days, and symptoms (12). Because of differences between Japanese and American or European lifestyle, the Japanese FIQ was proposed recently (13). In the present study, differences in life condition among patients in hospital or out-patient clinic confined us to using only one part of the scoring system for symptoms. In the future, the Japanese FIQ will be used as the scoring system of total clinical activity in FMS patients.

Although thermal therapy, such as spa treatment, has also been reported to be effective, Waon therapy is more convenient; patients who wish to continue treatment can easily receive Waon therapy twice a week, because the therapy takes only about one hour and does not require expensive equipment. In addition, the safety of Waon therapy will allow most patients with compromised physical condition to undergo treatment without adverse effects. In the case of deep warm water bath, hydrostatic pressure increase venous return flow which may cause adverse effects in such patients.

Previously, we reported the efficacy of Waon therapy in patients with chronic psychosomatic pain (9). Although the precise mechanism of pain reduction by Waon therapy is unclear, mild warming of the whole body has been shown to exhibit sedative effects via the sensory nerve endings (14). Waon therapy also promotes capillary dilatation and relieves muscular spasms related to tonic muscle contraction and pain (15). A recent study indicated the involvement of oxidative stress in the pathogenesis of FMS (16). In addition, Waon therapy has also been reported to reduce the levels of oxidative stress (17). Although the present study included only 13 patients, the effects observed here were dramatic. Further clinical studies in larger FMS patient populations are required to confirm the effects of this method of treatment.

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