

Effects of Waon Therapy on Chronic Fatigue Syndrome: A Pilot Study

Yuji Soejima, Takao Munemoto, Akinori Masuda,
Yuuki Uwatoko, Masaaki Miyata and Chuwa Tei

Abstract

Objective Chronic fatigue syndrome (CFS) is a disabling condition of unknown etiology, and no definitive therapy has been identified to date. We developed Waon therapy, a form of thermal therapy using a far-infrared dry sauna, and in this study herein examined its feasibility and safety in patients with CFS.

Methods Ten consecutive inpatients with CFS stayed in a 60°C sauna for 15 minutes and then rested on a bed under a blanket for an additional 30 minutes outside the sauna room. The treatments were performed once a day, five days a week for four weeks. Perceived fatigue, the primary outcome measure, was evaluated using a numerical rating scale before, during (two weeks after the commencement of therapy) and after therapy. The pain level, evaluated using a numerical rating scale, mood, assessed using the Profile of Mood States questionnaire, and performance status, assessed using a scale developed for CFS patients were also examined before and after therapy.

Results Perceived fatigue significantly decreased after therapy, although no significant reductions were observed during therapy. In addition, a negative mood, including anxiety, depression and fatigue, and the performance status significantly improved after therapy. However, the levels of pain and vigor did not change significantly. No patients reported any adverse effects during the therapy.

Conclusion These findings suggest that Waon therapy may be a useful and safe treatment for CFS.

Key words: chronic fatigue syndrome, fatigue, Waon therapy, thermal therapy, mood, pain

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Introduction

Chronic fatigue syndrome (CFS) is a disabling condition characterized by persistent or relapsing fatigue that is unrelied by rest and accompanied by a range of symptoms, including cognitive impairment, pain and sleep difficulties (1). Although the etiology of CFS remains unclear, various therapeutic approaches are available, including psychological, physical and pharmacological therapies. Of these, cognitive behavioral therapy (CBT) and graded exercise therapy (GET) appear to be the most promising treatments for CFS (2, 3). However, CBT and GET can be difficult to apply in CFS patients with severe impairment of daily activities, as these therapies usually include a graded activity program. Therefore, the development of improved and/or alter-

native methods of treatment for such patients is required.

We previously developed a form of thermal therapy known as “Waon therapy” (soothing warm therapy), which differs from traditional saunas (4, 5), and demonstrated that Waon therapy is beneficial for addressing a wide range of disorders, including chronic heart failure (4, 6), chronic pain (7), mild depression (8), peripheral artery disease (9) and fibromyalgia (10). Moreover, we previously reported two cases in which patients with CFS achieved substantial improvements in symptoms of fatigue, pain and sleep difficulties following Waon therapy (11). Waon therapy had no significant adverse effects in these patients and does not require any physical or mental effort (12). We therefore hypothesized that Waon therapy may be useful for treating CFS. The purpose of this study was therefore to examine the feasibility and safety of Waon therapy in patients with

CFS.

Materials and Methods

Patients

Potential participants included 11 consecutive patients referred to the inpatient ward of Kagoshima University Medical and Dental Hospital from our outpatient clinic or from primary care for the assessment and management of possible CFS. Ten of these 11 patients were confirmed to fulfill the US Centers for Disease Control and Prevention criteria for CFS (1) based on their history, laboratory data and results of physical and mental examinations. All 10 patients with CFS provided their informed consent to participate in this study. The study protocol was approved by the ethics committee of our hospital.

Waon therapy

Waon therapy, a form of thermal therapy, employs a far-infrared dry sauna at 60°C and is intended to soothe the patient's mind and body (12). It is performed without hydration (4). The patient is placed in a 60°C sauna (Onda, Kagoshima, Japan) for 15 minutes and then rests on a bed under a blanket for an additional 30 minutes to stay warm. All subjects were weighed before and after therapy, and oral hydration with water was used to compensate for any weight loss due to perspiration. The therapy was performed once a day, five days a week for four weeks, for a total of 20 sessions.

Eight of the 10 participants were under treatment with one or more drugs (including antidepressants, anxiolytics, hypnotics and analgesics) at the time of admission. Since these prescriptions had not been changed for at least three months prior to admission, we did not consider them to have any significant effect on the outcomes of Waon therapy. The administration of these agents thus remained unchanged during therapy.

Primary outcome measurement

The patients were asked to rate the perceived severity of their fatigue three times a day before meals (at 0600, 1200 and 1800) during their hospital stay using a numerical rating scale ranging from 0 (none) to 10 (most severe) (13). The mean scores for the three days before (Week 0), during (Week 2) and after therapy (Week 4) were then calculated.

Secondary outcome measurements

Secondary outcome variables, including pain, mood and performance status, were measured before (Week 0) and after (Week 4) therapy.

The patients were also asked to rate the perceived severity of their pain in the same manner as described above (14). The mean scores were then calculated for the three days before and after therapy.

The Profile of Mood States (POMS) questionnaire (15)

was used to evaluate the subjects' mood before and after therapy. The POMS consists of 65 items that assess six dimensions of the mood construct: anger, anxiety, confusion, depression, fatigue and vigor. Of the six subscales, we assessed anxiety, depression, fatigue and vigor. Higher scores for anxiety, depression and fatigue indicated a greater disturbance of mood, whereas higher scores for vigor reflected a better mood.

The severity of fatigue and daily activity levels were evaluated before and after Waon therapy by an independent clinical physician using a scale for the performance status developed for patients with CFS (16, 17). This descriptive scale ranges from 0 (best performance status) to 9 (worst performance status) and assesses whether CFS patients are: 0) able to carry on a normal lifestyle without fatigue and act without limitations; 1) able to carry on a normal social life and work, but often aware of fatigue; 2) able to carry on a normal social life and work, but require frequent rest due to general fatigue; 3) unable to carry on a normal social life or work several days a month due to general fatigue and require rest at home; 4) unable to carry on a normal social life or work several days a week due to general fatigue and require rest at home; 5) able to perform light tasks, but find it difficult to carry on a normal social life and work and require rest at home several days a week; 6) able to perform light tasks on good days, but require rest at home for at least half a week; 7) unable to carry on a normal social life or light tasks, but able to care for themselves without assistance; 8) able to care for themselves to some extent, but require frequent assistance and spend at least half of the day in bed; and 9) unable to care for themselves, requiring constant assistance and spending all day in bed.

Statistical analysis

The statistical analyses were performed using the IBM SPSS Statistics version 22 software program (IBM Corp., Armonk, USA). The Friedman test followed by the Bonferroni correction for multiple comparisons was performed to compare the scores for perceived fatigue before (Week 0), during (Week 2) and after (Week 4) therapy. The Wilcoxon signed-rank test was used to assess the differences in the secondary outcome variables before (Week 0) and after (Week 4) therapy. All p values are two-tailed, with a p value of <0.05 considered to be indicative of a statistically significant difference. The data are presented as the median and interquartile range.

Results

Table 1 shows the clinical features of the 10 patients (eight women, two men) who participated in this study. The participants ranged in age from 15 to 60 years. All patients had reported prolonged fatigue lasting ≥ 9 months with impairments in memory and/or concentration in addition to post-exertion malaise. All but one patient (Patient 5) complained of muscle and/or multi-joint pain and all but one pa-

Table 1. Baseline Characteristics of Ten Patients with Chronic Fatigue Syndrome Treated with Waon Therapy

Patient	Age (years)	Sex	Duration of illness (months)	Symptoms according to CDC criteria for chronic fatigue syndrome									
				Unexplained fatigue	Impairment in memory or concentration	Sore throat	Tender lymph nodes	Muscle pain	Multi-joint pain	Headaches	Unrefreshing sleep	Post-exertion malaise	
1	60	M	14	+	+	+	-	+	-	+	+	+	
2	34	F	42	+	+	+	-	+	+	-	+	+	
3	43	F	59	+	+	+	-	+	+	+	+	+	
4	17	F	14	+	+	+	-	+	-	+	+	+	
5	15	F	9	+	+	-	-	-	-	+	+	+	
6	34	M	27	+	+	+	+	+	+	-	+	+	
7	15	F	10	+	+	-	-	-	+	+	+	+	
8	23	F	75	+	+	-	-	+	+	+	+	+	
9	16	F	11	+	+	+	-	+	+	+	-	+	
10	19	F	29	+	+	-	-	+	-	+	+	+	

CDC: US Centers for Disease Control and Prevention

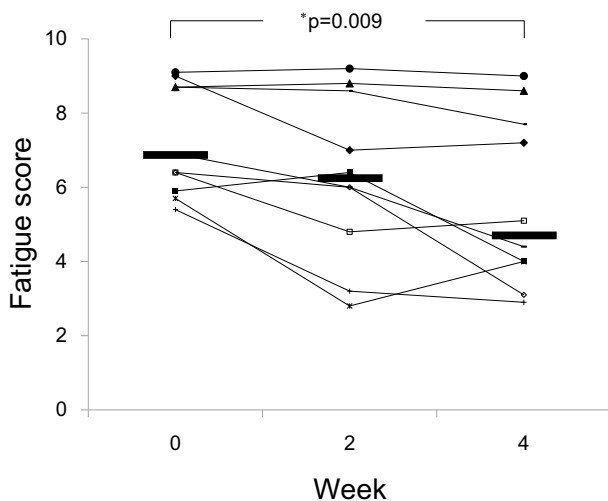


Figure. Changes in the fatigue scores for the 10 patients with chronic fatigue syndrome treated with Waon therapy over four weeks. The bold bars represent the median values for the scores obtained at Week 0, Week 2 and Week 4. Higher scores indicate greater severity. * Bonferroni correction for multiple comparisons following the Friedman test.

tient (Patient 9) suffered from unrefreshing sleep, while only one patient (Patient 6) reported tender lymph nodes.

A low-grade fever was observed in seven of the 10 patients prior to Waon therapy; the fever improved in two of the seven patients after therapy.

Primary outcome measurement

The scores for perceived fatigue decreased in eight of the 10 patients with CFS treated with Waon therapy over four weeks (Figure). The score for perceived fatigue was 6.7 (5.9-8.8) at Week 0, 6.2 (4.4-8.7) at Week 2 and 4.8 (3.8-7.9) at Week 4. The Friedman test indicated a significant difference between the fatigue scores obtained at these three time points ($p=0.002$), and a further analysis using a multiple comparison procedure showed the scores for perceived fatigue at Week 4 to be significantly lower ($p=0.009$) than those obtained at Week 0, while a downward trend was observed in the scores for perceived fatigue from Week 0 to

Week 2 ($p=0.059$).

Secondary outcome measurements

The scores for pain, mood (anxiety, depression, fatigue and vigor) and the performance status before (Week 0) and after (Week 4) Waon therapy are summarized in Table 2. The Wilcoxon signed-rank test demonstrated that the level of awareness of pain did not change significantly after therapy, whereas the POMS scores for anxiety, depression and fatigue significantly decreased ($p=0.008$, $p=0.018$ and $p=0.005$, respectively) after therapy. In contrast, the scores for vigor were not significantly altered, while the scores for the performance status significantly decreased ($p=0.005$) after therapy.

No patients reported any adverse effects.

Discussion

In this pilot study, we evaluated the effects of four weeks of Waon therapy in 10 patients with CFS and found that the level of fatigue gradually decreased during the therapy, resulting in significant improvements after therapy. Moreover, both a negative mood, such as that involving depression and anxiety, and the level of daily activity improved after the therapy, without any adverse effects.

We believe that Waon therapy can be safely performed in CFS patients without causing acute inflammation, infection or a high fever (4-12). Far-infrared rays are absorbed by the skin, with almost no absorption by air. The heat produced in the skin induces thermal vasodilation, thus increasing the blood flow in the skin. The blood warmed in the skin subsequently circulates throughout the body, warming other body parts (18, 19). Waon therapy utilizes far-infrared rays in a room evenly heated to 60°C. This temperature is lower than that of conventional North European-style saunas, which usually employ a temperature of 80°C or higher. The heat causes little dermal irritation, which warms the patient's body comfortably, thus allowing them to relax (12).

The exact cause of fatigue in cases of CFS remains unclear, although several reports have described a relationship with a reduced cardiac output (20, 21). A correlation has

Table 2. Comparison of Values for Secondary Outcome Variables before and after Waon Therapy over Four Weeks

Variables	Waon therapy		p value*
	Before Median (Interquartile range)	After Median (Interquartile range)	
Self-rating scale [†]			
Pain	5.2 (2.9–7.6)	4.2 (1.3–5.8)	0.059
POMS [‡]			
Anxiety	47.5 (44.0–57.0)	39.5 (36.8–51.5)	0.008
Depression	55.0 (46.3–61.0)	46.0 (42.5–50.5)	0.018
Fatigue	61.5 (51.5–69.0)	54.0 (39.0–59.3)	0.005
Vigor	36.5 (32.0–42.3)	41.5 (33.0–47.8)	0.172
Performance status [§]	6.5 (5.8–7.0)	3.5 (2.8–5.3)	0.005

* Wilcoxon signed rank test.

[†] Numerical rating scale (0–10) with higher scores indicating greater severity.[‡] Higher scores for anxiety, depression, and fatigue indicate greater disturbance of mood; higher scores for vigor indicate a more vigorous mood.[§] Likert-type scale (0–9) with higher scores indicative of a worse performance status.

POMS: profile of mood states

also been suggested between feelings of fatigue and cardiac indices in healthy individuals (22). The thermal vasodilation resulting from Waon therapy reduces cardiac pre- and after-load, which has been reported to significantly improve the ejection fraction in patients with chronic heart failure (4). The cardiac function was not evaluated in the present study; however, feelings of fatigue may potentially be reduced in CFS patients as a result of hemodynamic improvements induced by Waon therapy.

Oxidative stress is also believed to be involved in the pathophysiology of CFS (23), and various reports have noted that both increased oxidative stress and the depletion of antioxidants are related to the degree of symptoms such as feelings of fatigue (24–26). In addition, we previously demonstrated that Waon therapy significantly decreases the levels of F₂-isoprostanes in patients with at least one coronary risk factor (27) and the levels of hydrogen peroxide in patients with heart failure (28). Furthermore, Robinson et al. (29) reported higher levels of F₂-isoprostanes at rest in CFS patients than in healthy individuals, noting that the difference was immediate and remained 24 hours after exercise. Waon therapy involves a total of 45 minutes of bed rest once a day; however, the regular exercise performed in CBT and/or GET programs is not required for Waon therapy. For this reason, Waon therapy not only reduces oxidative stress, but also indirectly avoids increases in oxidative stress brought on by exercise, meaning that it likely reduces fatigue in addition to other symptoms.

In addition to fatigue, pain is considered to be a major cause of disability in patients with CFS. The detailed mechanisms by which thermal therapy achieves reductions in pain are unclear; however, gently warming the entire body is thought to have a sedative effect due to the consequent effects on nerve endings (30). Oxidative stress also appears to be related to the pain experienced by CFS patients (25, 31), and recent studies have demonstrated that transient receptor potential (TRP) channels are expressed as nociceptors in sensory nerve terminals and play an impor-

tant role in pain sensation (32). Within the TRP channel family, TRP vanilloid 1 (TRPV1) is usually activated at >43 °C. However, the threshold for activation of TRPV1 may be lowered below a normal body temperature by oxidative stress and the actions of inflammatory modulators (33, 34). Waon therapy warms the body evenly at 60°C (12) and reduces oxidative stress (27, 28). We therefore anticipated that Waon therapy would reduce the pain associated with CFS. However, although a trend toward reduced pain was noted within four weeks after the initiation of Waon therapy (p=0.059), this reduction did not reach statistical significance. Likely reasons for this finding include the relatively low statistical power of the study resulting from the small sample size, the inability to adequately evaluate the degree of pain using a self-rating scale alone and an insufficient duration of therapy required to achieve a reduction in pain. Further studies are thus required to investigate whether Waon therapy can be used to reduce pain in patients with CFS.

Psychiatric disorders, such as depression and anxiety, are frequently comorbid in patients with CFS (35, 36). However, the associations between CFS and psychiatric disorders remain unclear. There are several possible explanations for the coexistence of depression and CFS: a) depression causes CFS; b) depression is a secondary feature of CFS; c) depression and CFS have common risk factors resulting in a high level of comorbidity of the conditions; and d) the association is due to overlap in the criteria used to define the disorders (37). In the present study, a depressive mood and anxiety decreased after therapy in the CFS patients, as was their fatigue. Therefore, our findings appear to support hypothesis (c) above (37). This notion is also supported by the observations of Caseras et al. (38), who found that fatigue-provoking stimuli induce not only fatigue, but also anxiety, in CFS patients, who subsequently feel more fatigue and anxiety than healthy controls. Therefore, the reduction in fatigue brought about by Waon therapy in the present study may have reduced the levels of depression and anxiety. Moreover, the relaxing effect of warming the body at a rela-

tively low temperature (8, 12) likely also contributed to reducing negative feelings. However, the patients with CFS underwent Waon therapy in a hospital setting, which may have been a confounding factor in the treatment outcomes of depression and anxiety.

A number of limitations must be considered when interpreting the present findings. For example, the sample size was small, and the study protocol employed a before-and-after therapy model rather than a comparative controlled design. In addition, the therapy was administered in hospitalized patients, and the study lasted for only four weeks. Finally, as the assessments of fatigue and pain were based on individual feelings and behavioral observations, the study lacks sufficient validity and reliability. Therefore, the effectiveness of Waon therapy must be examined using controlled studies with larger numbers of subjects performed over longer periods in an outpatient setting.

In conclusion, our results suggest that Waon therapy employing a far-infrared dry sauna may be useful for treating CFS. Waon therapy appears to be safe and imposes little mental or physical burden on the patient. Nevertheless, further clinical studies in larger CFS patient populations are needed to verify these findings.

The authors state that they have no Conflict of Interest (COI).

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