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ORIGINAL ARTICLE

Waon therapy improves the prognosis of patients with chronic heart failure

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Summary
Background: We developed a Waon therapy (soothing warm therapy) and have previously reported that repeated Waon therapy improves hemodynamics, peripheral vascular function, arrhythmias, and clinical symptoms in patients with chronic heart failure (CHF). The aim of this study was to investigate the effect of Waon therapy on the prognosis of CHF patients.
Patients and methods: We studied 129 patients with CHF in NYHA functional class III or IV who were admitted to our hospital between January 1999 and March 2001. In the Waon therapy group, 64 patients were treated with a far infrared-ray dry sauna at 60 °C for 15 min and then kept on bed rest with a blanket for 30 min. The patients were treated daily for 5 days during admission, and then at least twice a week after discharge. In the control group, 65 patients, matched for age, gender, and NYHA functional class, were treated with traditional CHF therapy. The follow-up time was scheduled for 5 years.
Results: Recent, complete follow-up data on each patient were obtained. The overall survival rate was 84.5% (Kaplan—Meier estimate). Twelve patients died in the control group and 8 patients died in the Waon therapy group at 60 months of follow-up.

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Cardiac events due to heart failure or cardiac death occurred in 68.7% of the control group but only 31.3% of the Waon therapy group ($P < 0.01$) at 60 months of follow-up. *Conclusion:* Waon therapy reduced cardiac events in patients with CHF. This therapy is a promising non-pharmacological treatment for CHF.

Introduction

Recently, many researchers have reported that vasodilators, such as angiotensin-converting enzyme inhibitors [1], angiotensin receptor blockers [2], and beta-blockers [3], improve prognosis in patients with chronic heart failure (CHF). Furthermore, new technologies to treat CHF, such as cardiac rehabilitation, cardiac resynchronization therapy, left ventricular assist devices, and left ventricular reconstruction surgery, have been developed over the past decade. Despite advances in therapy for heart failure, improving clinical outcomes of patients with acute heart failure remains a challenge for physicians. Re-hospitalization within 60—90 days occurs in approximately 30% of patients with acute heart failure [4].

We have developed a form of thermal therapy, namely Waon therapy, which differs from the traditional sauna and is useful in the treatment of CHF. Waon therapy is defined as ''therapy in which the entire body is warmed in an evenly heated chamber for 15 min at a temperature that soothes the mind and body, and after the deep-body temperature has increased by approximately 1.0—1.2 °C, the soothing warmth is sustained by maintaining the warmth at rest for an additional 30 min, with fluids supplied at the end to replace the loss from perspiration [5].'' We have already reported that Waon therapy, the repeated use of a dry sauna at 60 °C, improves hemodynamics [6], ameliorates symptoms [7], suppresses ventricular arrhythmias [8], and improves vascular function [9] in CHF patients. Recently, in a prospective multicenter case—control study, we found that 2 weeks of Waon therapy improved clinical symptoms and cardiac function in CHF patients [10].

Furthermore, we reported that repeated Waon therapy improves survival in TO-2 cardiomyopathic hamsters with heart failure [11]. However, the effect of Waon therapy on prognosis in CHF patients has not yet been elucidated. Thus, the purpose of this study was to investigate the effect of Waon therapy on the prognosis of CHF patients.

Methods

Patients and study design

The study subjects included 129 CHF patients who were admitted to Kagoshima University Hospital, Kagoshima City Hospital, or Kagoshima City Medical Association Hospital between January 1999 and March 2001. All patients received traditional medications for CHF, such as angiotensin-converting enzyme inhibitors or angiotensin receptor blockers, beta-blockers, diuretics, and digitalis. None of these patients was implanted with a defibrillator device. Sixty-four patients were treated daily with Waon therapy for 5 days after admission, and Waon therapy was continued at least twice a week in an out-patient clinic after hospital discharge. The remaining 65 control patients, who were matched with the Waon therapy group for age, gender, and etiology and severity of CHF, continued medical therapy for CHF.

Clinical characteristics at discharge from the first admission were considered as the patient's baseline characteristics. Data on body mass index, heart rate, systolic blood pressure, and diastolic blood pressure were also measured at discharge from the first hospitalization. The baseline data also included the more recent data on the cardiothoracic ratio (CTR) measured by chest radiography and left ventricular diastolic dimension and left ventricular ejection fraction measured by two-dimensional echocardiography during the first admission.

All 129 patients were followed-up for 5 years, and cardiac events, such as cardiac death and re-hospitalization due to heart failure, were compared between the control and Waon therapy groups.

The study protocol was approved by the Ethics Committee of the Faculty of Medicine, Kagoshima University. Informed consent was obtained from all of the patients.

Waon therapy

Waon therapy uses a far infrared-ray dry sauna, which is evenly maintained at 60 °C and differs

Table 1 Baseline clinical characteristics.

	Waon therapy group		Control group
	P-value		
	($n = 64$)	($n = 65$)	
Age (years)	61.9 ± 12.1	64.6 ± 9.2	ns
Gender (M/F)	40/24	42/23	ns
DCM/ICM/Other disease	39/16/9	45/13/7	ns
NYHA functional class (average)	2.6 ± 0.6	2.6 ± 0.5	ns
Body mass index (kg/m^2)	22.6 ± 3.0	21.9 ± 3.5	ns
Heart rate (beats/min)	74 ± 13	71 ± 9	ns
Systolic BP (mmHg)	112 ± 15	111 ± 17	ns
Diastolic BP (mmHg)	77 ± 69	70 ± 10	ns
CTR (%)	56.2 ± 5.7	54.8 ± 5.9	ns
LVDd (mm)	58.9 ± 11.7	59.0 ± 7.8	ns
LVEF (%)	38.5 ± 15.2	35.8 ± 10.9	ns
AF (%)	32.8	36.9	ns
Medications			
ACE-I or ARB (%)	68.8	64.6	ns
Beta-blocker (%)	60.9	56.9	ns
Digitalis (%)	39.1	49.2	ns
Diuretics (%)	73.4	83.1	ns
Statin (%)	18.8	13.8	ns

DCM, dilated cardiomyopathy; ICM, ischemic cardiomyopathy; NYHA, New York Heart Association; BP, blood pressure; CTR, cardiothoracic ratio; LVDd, left ventricular diastolic dimension; LVEF, left ventricular ejection fraction; AF, atrial fibrillation; ACE-I, angiotensin-converting enzyme inhibitor; ARB, angiotensin receptor blocker; ns, not significant.

from traditional sauna. Waon therapy has no hydration pressure and was performed as previously reported [6]. Briefly, the patients were placed in a supine or sitting position in a sauna system evenly maintained at 60 °C for 15 min, and then, they underwent bed rest with a blanket to keep them warm for an additional 30 min. All patients were weighed before and after the therapy, and oral hydration with water was used to compensate for weight lost due to perspiration.

Statistical analyses

Data were analyzed using Stat View 4.0. All data are expressed as the mean ± SD. Differences in baseline characteristics were evaluated by the chi-square test or unpaired *t*-test. The cardiac event point was the time-to-the-first-event of combined cardiac death or re-hospitalization due to heart failure. Cardiac event curves were analyzed with Kaplan—Meier method, and the log-rank test was

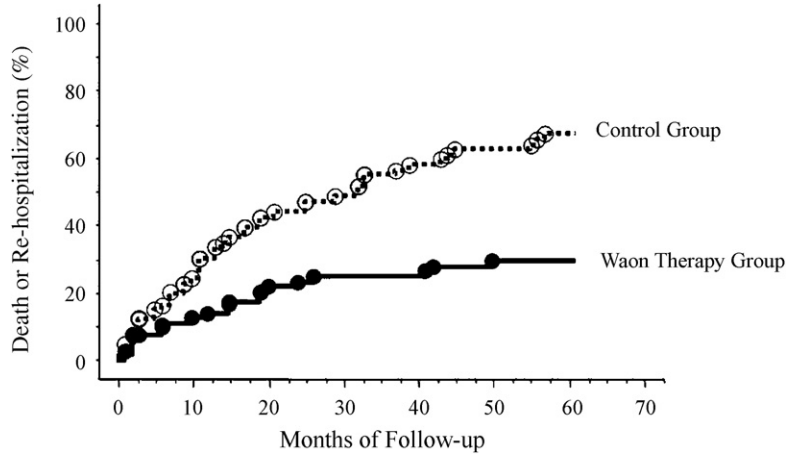

Figure 1 Re-hospitalization due to heart failure or cardiac death rate was 68.7% in the control group compared to 31.3% in the Waon therapy group ($P < 0.01$) at 60 months of follow-up.

used to assess the differences between two groups. A value of $P < 0.05$ was considered statistically significant.

Results

Baseline patient characteristics

Baseline clinical characteristics in the control and Waon therapy groups are shown in Table 1. There were no significant differences in age, gender, or etiology and severity of CHF between the two groups. In addition, there were no significant differences in the use of CHF medications, such as angiotensin-converting enzyme inhibitors, angiotensin receptor blockers, beta-blockers, digitalis, diuretics, or statins between the two groups.

Cardiac events

All 129 patients were followed-up for 5 years; there was no death due to non-cardiac events during this study, and the overall survival rate was 84.5%. Twelve patients died in the control group and 8 patients died in the Waon therapy group over 60 months of follow-up. Re-hospitalization due to worsening CHF occurred in 44 patients in the control group and 20 patients in the Waon therapy group.

The cardiac event rate, such as cardiac death or re-hospitalization due to heart failure was 68.7% in the control group and 31.3% in the Waon therapy group ($P < 0.01$) at 60 months of follow-up.

Kaplan—Meier analysis demonstrated that Waon therapy significantly reduced the cardiac event rate compared with the control group, and the reduction of cardiac events by Waon therapy was 38% at 60 months of follow-up (Fig. 1).

Discussion

This retrospective follow-up study demonstrated that Waon therapy decreased cardiac death and re-hospitalization in patients with CHF over a 60-month follow-up period. Although we have already reported in an animal study that repeated Waon therapy improved survival in TO-2 cardiac hamsters with CHF [11], this is the first report to show the beneficial effect of Waon therapy on the long-term prognosis of CHF patients.

We have already reported that Waon therapy induced thermal vasodilation of the systemic and pulmonary arteries and veins, reduced cardiac preload and after-load, and improved hemodynamics and clinical symptoms in CHF patients [6]. In addition, we have reported that 4 weeks of Waon therapy significantly improved clinical symptoms, increased ejection fraction, and decreased cardiac size on echocardiography and chest radiography in CHF patients [7]. Recently, we confirmed the beneficial effects and safety of Waon therapy applied for 2 weeks in CHF patients in a prospective multicenter case—control study [10].

We previously demonstrated that Waon therapy improved not only cardiac function, but also endothelial function in patients with CHF. We have reported that 2 weeks of Waon therapy significantly reduced brain natriuretic peptide blood levels and improved flow-mediated vasodilation in CHF patients [9]. Furthermore, we have reported that Waon therapy for 2 weeks decreased ventricular premature contractions and increased heart rate variability in CHF patients [8], suggesting that Waon therapy decreased sympathetic nervous activity and improved ventricular arrhythmias.

In addition, Waon therapy improved vascular function in patients with coronary risk factors [12,13] or peripheral arterial disease [14,15] and improved exercise capacity in patients with chronic obstructive pulmonary disease [16].

Waon therapy improves cardiac and vascular function and reduces ventricular arrhythmias in CHF patients. We think that these beneficial effects of Waon therapy led to the reduction of cardiac events in CHF patients in the present study.

Furthermore, we reported that Waon therapy increased mRNA and protein expression of endothelial nitric oxide synthase (eNOS) and production of nitric oxide (NO) in Syrian golden hamsters [17] and TO-2 cardiomyopathic hamsters [18]. This up-regulation of eNOS and NO may play an important role in the beneficial effects of Waon therapy in CHF patients.

Study limitation

This study was a retrospective study to investigate the effect of Waon therapy on the prognosis in patients with CHF. A further prospective randomized multicenter study is needed to clarify the beneficial effect of Waon therapy on the prognosis of CHF patients.

In addition, patients in the Waon therapy group went to the hospital at least twice per week. In contrast, patients in the control group went to the hospital once per month. Therefore, this difference in frequency of hospital visits may affect the result of this study.

Conclusion

In this retrospective follow-up study, we demonstrated that Waon therapy reduced cardiac events due to heart failure over a 60-month follow-up period. Therefore, this therapy is a promising non-pharmacological treatment for CHF.

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