

PRELIMINARY CLINICAL EXPERIENCE WITH WAON THERAPY IN KOREA: SAFETY AND EFFECT

IL-SUK SOHN, MD¹, JIN-MAN CHO, MD¹, WOO-SHIK KIM, MD¹, CHONG-JIN KIM, MD¹, KWON-SAM KIM, MD¹, JONG-HOA BAE, MD¹ AND CHUWA TEI, MD²

¹DEPARTMENT OF CARDIOLOGY, KYUNG HEE UNIVERSITY SCHOOL OF MEDICINE, SEOUL, KOREA

²DEPARTMENT OF CARDIOVASCULAR, RESPIRATORY AND METABOLIC MEDICINE, KAGOSHIMA UNIVERSITY, KAGOSHIMA, JAPAN

BACKGROUND: Waon therapy has beneficial effects on chronic heart failure (CHF), peripheral arterial disease, and other various diseases. This was to assess the safety and effect of Waon therapy by echocardiography for the first time in Korea.

METHODS: Ten patients with CHF were enrolled. The patients with a light gown were placed in a sitting-position in an evenly maintained 60°C dry sauna system for 15 minutes, and then after leaving the sauna, they underwent bed rest with a blanket to keep them warm for an additional 30 minutes. Waon therapy was performed once a day, 5 days a week.

RESULTS: Four of the 5 patients who had been treated for more than 2 weeks as protocol noted improvement of heart failure (HF) symptoms and decrease in left ventricular (LV) volume. There were trends in improvement of LV ejection fraction and parameters of diastolic function after the therapy although statistical significance was lack. No one complained of worsening of HF symptoms. In each session, body weight (61.8±10.2 kg vs. 61.6±10.3 kg, $p=0.008$) and blood pressure (systolic, 119±28 vs. 111±27 mmHg, $p=0.005$; diastolic, 69±12 mmHg vs. 63±10 mmHg, $p=0.005$) were significantly decreased, oral temperature (35.9±0.4°C vs. 37.0±0.9°C, $p=0.017$) was increased by 1.0°C at the end of sauna bathing, but the heart rate (71±10/min vs. 72±8/min, $p=0.8$) was not changed.

CONCLUSION: We have experienced Waon therapy which was safe and well tolerated and some beneficial effects for patients with CHF. Large scale randomized study is needed to apply Waon therapy as a promising therapy in Korean HF patients.

KEY WORDS: Waon therapy · Heart failure · Echocardiography.

INTRODUCTION

Waon therapy using an evenly maintained dry sauna system at 60 degree centigrade, that differs from the traditional sauna has been studied exclusively by Tei¹⁾ in Japan. They have previously reported that repeated Waon therapy improves the vascular endothelial function, resulting in an improvement in cardiac function and clinical symptoms, in patients with heart failure (HF),²⁾ and even in patients with risk factors for atherosclerosis.³⁾ Furthermore, this therapy improved the cardiac function and exercise tolerance in patients with chronic heart failure (CHF), who suffered from chronic symptoms despite the administration of full medications in patients with high risk.^{2,4)} These effects are

attributable to the reduction in the cardiac preload and afterload.⁴⁾ Waon therapy also has been proved to have beneficial effects on peripheral arterial disease (PAD),⁵⁾ chronic fatigue syndrome,⁶⁾ chronic pain,⁷⁾ and even in patients with mild depression.⁸⁾

Waon therapy has been done in a specialized room with unique sauna system. In order to expand the use of Waon therapy, they developed a movable and sitting-position system, in which the temperature at the top and the bottom of the chamber is uniformly maintained at the same temperature of 60°C (Fig. 1).

The movable sauna system for Waon therapy was installed in our institution for the first time in Korea. It is also the first

• Received: March 5, 2009 • Revised: March 9, 2010 • Accepted: May 18, 2010

• Address for Correspondence: Il-Suk Sohn, Department of Cardiology, Kyung Hee University School of Medicine, 149 Sangil-dong, Gangdong-gu, Seoul 134-727, Korea Tel: +82-2-440-6108, Fax: +82-2-442-6638, E-mail: issohn@khu.ac.kr



Fig. 1. Movable and sitting-position sauna system for Waon therapy. The temperature at the top and bottom of the chamber is uniformly maintained at the same temperature of 60°C.

experience with movable system outside Japan. This was to assess the safety and effect of Waon therapy in Korean patients with heart failure by echocardiography.

METHODS

SUBJECTS

Ten patients with CHF were enrolled for this study between September 2006 and November 2007. The inclusion criteria were: 1) they have HF symptoms with more than New York Heart Association (NYHA) class II and with less than 45% of left ventricular ejection fraction (LVEF), 2) no medication change within previous 3 months. The patients who cannot maintain sitting position were excluded. Informed consent was obtained from all of the patients. This protocol was approved by our institutional review board.

WAON THERAPY

The patients with a light gown were placed in a sitting-position in a 60°C sauna system (Onda co., Kagoshima, Japan) for 15 minutes, and then after leaving the sauna, they underwent bed rest with a blanket to keep them warm for an additional 30 minutes. Waon therapy was performed once a day (one session), repeated 5 days a week, and recom-

mended for more than 2 weeks and for wanted sessions thereafter. We controlled and maintained the room temperature with about 28°C.

MEASUREMENTS

The body weight in two decimal places, blood pressure, heart rate, and body temperature were measured before and after the therapy in every session. Heart rate and body temperature immediately after sauna were also measured to assess the brief changes. All patients were allowed for oral hydration with tap water to compensate for weight loss due to perspiration.

ECHOCARDIOGRAPHY AND CLINICAL FOLLOW UP

During two dimensional echocardiography (2DE), we obtained standard views and measured left atrial volume (biplane method of discs), left ventricular (LV) dimensions (2D-guided M-mode), LV volumes (biplane method of discs), LV mass index (truncated ellipsoid method), and calculated LVEF according to published guideline.⁹⁾ The mitral inflow pulsed wave Doppler was performed to measure early (E) and late (A) velocities, E/A ratio, and deceleration time (DT) of E velocity. To calculate the Tei index, pulsed Doppler study from both LV outflow tract and mitral inflow was performed. Tissue Doppler study from the medial mitral annulus was taken to obtain early (E') and late (A') diastolic velocity, and E/E' ratio as useful parameters in HF patients.¹⁰⁾ Follow up echocardiography was taken after the end of 2 weeks' sessions.

All patients were monitored and followed up clinically on outpatient basis even after the discontinuation of Waon therapy. The clinical state of HF was evaluated by NYHA functional class before and after the whole sessions of Waon therapy.

STATISTICAL ANALYSIS

All data are given as mean±SD. Statistical analysis was conducted using Statistical Package for Social Science (SPSS) 13.0 for Windows (SPSS Inc., Chicago, IL, USA). Comparisons of all measurements made at baseline with those made during or after Waon therapy were made using the Wilcoxon signed ranks test. Values were considered significantly different at a value of $p < 0.05$.

RESULTS

BASELINE CLINICAL CHARACTERISTICS

The baseline clinical characteristics are summarized in Table 1. Three patients (30%) were women and their ages varied from 50 to 78 years. Cause of HF was ischemic in 4 patients. Three patients had diabetes mellitus. The patients

stopped the Waon therapy with various session numbers from 1 to 112 times between a day and 255 days. Five (case 2, 3, 8, 9, 10) out of 10 patients continued with Waon therapy for more than 2 weeks as initially planned protocol. Two patients (case 1, 6) were lost from routine follow up in outpatient clinic. Two patients (case 5, 7) could not continue to have daily Waon therapy due to NYHA III class and long distance from their home to the hospital. One patient (case 4) visited our outpatient clinic again 3 months later after first session and then wanted to stop because of no change of HF symptoms.

SYMPTOMS AFTER WAON THERAPY AND DISCONTINUATION

Of 5 patients who had been treated with the Waon therapy for more than 2 weeks, 4 patients had significant improvement of HF symptoms at the end of sessions (11 to 112 times) (Table 1). No change in NYHA functional class was reported in other 5 patients after 6-9 times of Waon therapy. However, no one complained of worsening of HF symptoms.

CHANGES OF BODY WEIGHT AND VITAL SIGNS BEFORE AND AFTER WAON THERAPY

Body weight in whole session was averaged in each patient before and after Waon therapy, and it decreased significantly

after Waon therapy with a mean change -0.2 kg (61.8 ± 10.2 kg vs. 61.6 ± 10.3 kg, $p=0.008$) (Table 2). Both systolic and diastolic blood pressure decreased in each session (systolic, 119 ± 28 mmHg vs. 111 ± 27 mmHg, $p=0.005$; diastolic, 69 ± 12 mmHg vs. 63 ± 10 mmHg, $p=0.005$) (Table 2).

Body temperature measured immediately after 15 minutes' sauna was higher than before sauna ($37.0 \pm 0.9^\circ\text{C}$ vs. $35.9 \pm 0.4^\circ\text{C}$, $p=0.017$), and then decreased to almost the same level with that of before the session ($36.1 \pm 0.5^\circ\text{C}$ vs. $35.9 \pm 0.4^\circ\text{C}$, $p=0.8$). However, heart rate measured immediately after sauna and after the end of session did not change significantly (72 ± 8 beats/min vs. 71 ± 10 beats/min, $p=0.8$). No adverse events were reported during sauna.

CHANGES OF ECHOCARDIOGRAPHIC PARAMETERS AFTER WAON THERAPY

Five patients who were treated with Waon therapy for more than 2 weeks had follow up 2DE study at the end of 2 weeks, and LV volume of both end-diastolic and end-systolic periods decreased significantly after Waon therapy (Table 3, Fig. 2). There were trends in improvement of LVEF after the therapy although statistical significance was lack. Of echocardiographic parameters of LV diastolic function, mitral E/A ratio and E/E' ratio decreased but to a level of insignificance. After Waon therapy, Tei index did not change significantly.

Table 1. Clinical characteristics and changes after Waon therapy in the subjects

Case No.	Age (years)	Sex	Cause of HF	Co-morbidity	BP (mmHg)		Smoking	Session days (No.)	NYHA class	
					Before	After			Before	After
1	50	Woman	Non-ischemic	HTN	156/83	138/78	Current	9 (7)	II	II
2	67	Woman	Ischemic	Old MI, DM, HTN	113/70	105/62	Never	22 (11)	II	I
3	60	Man	Non-ischemic	HCM, DM	103/58	96/55	Never	239 (112)	II	I
4	71	Man	Ischemic	Old MI, HTN	175/90	171/70	Ex	1 (1)	III	III
5	52	Man	Non-ischemic	DCM	100/63	99/61	Current	8 (6)	III	III
6	78	Man	Ischemic	Old MI, HTN, Stroke	120/64	108/60	Current	8 (7)	II	II
7	68	Man	Non-ischemic	DCM	89/50	87/47	Current	2 (2)	III	III
8	52	Man	Ischemic	Old MI, COLD	95/62	86/58	Current	255 (80)	II	I
9	60	Man	Non-ischemic	DM, CKD	136/79	124/75	Never	24 (12)	II	II
10	65	Woman	Non-ischemic	DCM, AF	103/66	97/64	Never	35 (20)	II	I

HF: heart failure, BP: blood pressure, NYHA: New York Heart Association functional classification, HTN: essential hypertension, MI: myocardial infarction, DM: diabetes mellitus, HCM: hypertrophic cardiomyopathy, DCM: dilated cardiomyopathy, COLD: chronic obstructive lung disease, CKD: chronic kidney disease, AF: atrial fibrillation

Table 2. Changes of body weight and vital signs before and after Waon therapy

	Before	After	p value
Body weight (kg)	61.8 ± 10.2	61.6 ± 10.3	0.008
Systolic blood pressure (mmHg)	119 ± 28	111 ± 27	0.005
Diastolic blood pressure (mmHg)	69 ± 12	63 ± 10	0.005
Heart rate (beats/min)	71 ± 10	71 ± 8	0.8
Body temperature ($^\circ\text{C}$)	35.9 ± 0.4	36.1 ± 0.5	0.73

Mean \pm S.D.

Table 3. Changes in echocardiographic parameters after 2 weeks of Waon therapy in the 5 subjects

	Before	After	p value
LV end-diastolic volume (mL)	189.1±136.9	156.1±125.9	0.04
LV end-systolic volume (mL)	140.2±116.5	107.6±112.5	0.04
LV ejection fraction (%)	28.6±7.5	39.5±13.8	0.08
LV end-diastolic dimension (mm)	64.5±17.5	57.5±23.3	0.14
LV end-systolic dimension (mm)	54.8±20.2	46.8±26.3	0.14
Left atrial volume index (mL/m ²)	58.0±16.6	54.8±31.1	0.50
Mitral E/A ratio	2.2±1.2	0.9±0.3	0.07
Deceleration time of E velocity (ms)	132.0±29.5	215.8±59.4	0.14
Mitral annular E' velocity (cm/sec)	3.5±1.2	4.2±2.2	0.27
E/E'	26.0±10.3	19.4±9.3	0.07
Tei index	0.69±0.06	0.64±0.09	0.14

Mean±S.D. LV: left ventricular, E/A: ratio of mitral inflow early (E) to late (A) velocity, E': early diastolic velocity from tissue Doppler of septal annulus

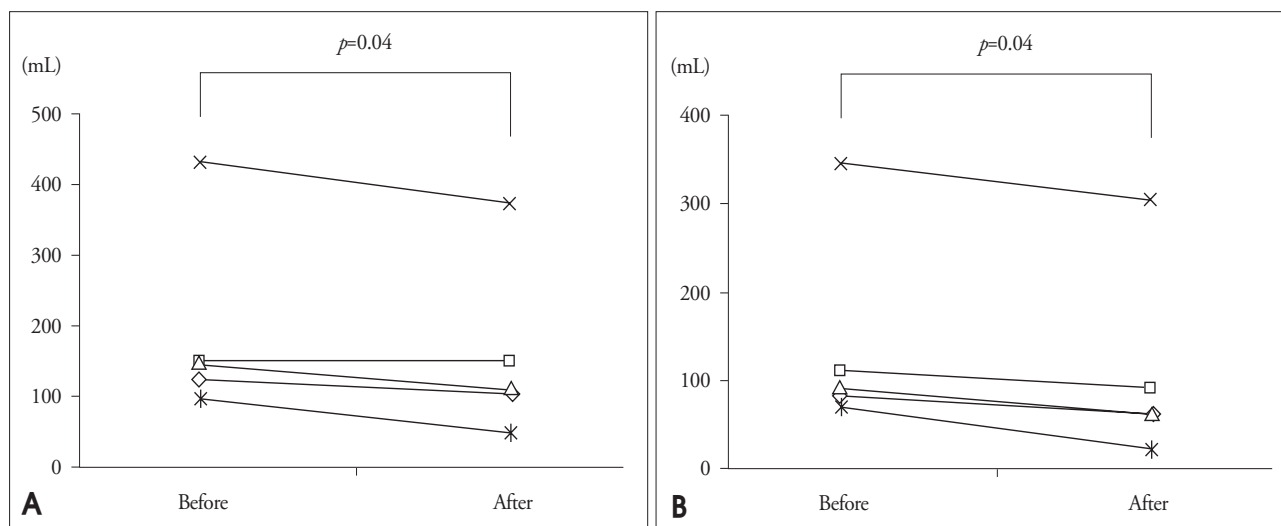


Fig. 2. Changes of left ventricular end-diastolic (A) and end-systolic (B) volumes before and after Waon therapy.

DISCUSSION

This is the first report to present experiences with Waon therapy in Korea. The present study indicates that Waon therapy was found to be safe and improve symptoms in some patients with CHF. No adverse events were recorded during the entire sessions.

Waon therapy uses far infrared-ray dry sauna which has not hydrostatic pressure and so more comfortable than hot bath. Tei et al.⁴⁾ developed this unique form of thermal therapy and have been investigating the various effects and its mechanisms on several diseases.²⁾⁵⁾⁷⁾¹¹⁾¹²⁾ Thermal therapy in cardiovascular diseases consists of systemic soothing warmth that comfortably refreshes the mind and body. Therefore, Tei¹⁾ changed the name from thermal to “Waon” therapy, since “Waon” in Japanese means soothing warmth. 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”.¹⁾

HEMODYNAMIC EFFECTS OF WAON THERAPY

Regarding the acute effect of Waon therapy, it has been reported that 60°C sauna therapy for 15 minutes improved acute hemodynamics in patients with CHF, including cardiac index, mean pulmonary wedge pressure, systemic and pulmonary resistance, and cardiac function.⁴⁾

In the present study we used movable and sitting-position sauna system which was developed in order to expand the use of Waon therapy (Fig. 1). In each session body weight (-0.2 kg), systolic blood pressure (-8 mmHg), and diastolic blood pressure (-6 mmHg) were decreased significantly (Table 2). Body temperature immediately after 15 minutes’ sauna was about 1.0°C higher than before sauna, and then decreased to almost the same level with that of before the session after Waon therapy. Heart rate did not change signi-

fically and no adverse hemodynamic events occurred.

EFFECT OF WAON THERAPY ON HEART FAILURE

It has been reported that Waon therapy improves hemodynamics and ameliorates symptoms, suppresses ventricular arrhythmias, and improves vascular function in CHF patients.^{2,4,13,14} Although changes in N-terminal pro-B-type natriuretic peptide (NT-proBNP), which has important roles in CHF but was not included in this study,¹⁵⁻¹⁷ and 2DE were not performed in all patients, we noted symptomatic improvement in 4 of 5 patients with CHF with the use of movable and sitting position-sauna system.

Vascular endothelial function significantly improved after two-week Waon therapy in the brachial artery in patients with CHF, and systemic vascular resistance significantly decreased after two-week sauna therapy, suggesting an improvement of endothelial function in resistance vessels.² Improved endothelial function leads to dilation of vessels by an increase in nitric oxide (NO) production. The fact that two weeks of Waon therapy significantly decreased blood pressure in the present study may reflect the improvement in endothelial function. This results in decreased afterload and, thus, increased cardiac output as previously reported.⁴ These changes improve peripheral circulation, which is probably responsible for the improvement in clinical symptoms.

The precise mechanisms by which long-term Waon therapy improves endothelial function in patients with CHF has not been clarified. However, Tei et al.⁴ have previously demonstrated that thermal therapy increases cardiac output in patients with CHF. This results in increased peripheral blood flow, which increases shear stress in the vessels, which, in turn, probably leads to an increase in NO production by the vessels. Repeated Waon therapy upregulates the endothelial NO synthase (eNOS) protein in the arterial endothelium, including the aorta and carotid, femoral and coronary arteries, of hamsters.^{11,18} Therefore, it is likely that the improvement in endothelial function after long-term, repeated Waon therapy is due to improved NO production by eNOS upregulation in patients with CHF.

Recently Tei et al. conducted a prospective multicenter case-control study to confirm the clinical efficacy and safety of Waon therapy on CHF at 10 hospitals in Japan.¹⁹ And they demonstrated that Waon therapy improved clinical symptoms and cardiac function evaluated by 2DE and BNP concentrations, and decreased cardiac size on chest radiography and 2DE after once a day, 2 weeks of Waon therapy in patients with CHF using the movable and sitting-position sauna system.¹⁹

STUDY LIMITATION

We have several limitations in this study. First and most

critical limitation is that it has been conducted in a single center, and limited small numbers of patients were enrolled. Only half of the study patients continued the Waon therapy for more than 2 weeks. Second, although Waon therapy is safe, non-invasive, and may be an important part of non-pharmacological therapy in some diseases including CHF, it should be performed in a specialized sauna system with careful attention of physician or nurses, because most CHF patients might experience unexpected collapse. Last, more objective tests such as bio-markers or other clinical functional assessment and long-term follow-up in larger cohort of Korean HF patients will be needed to ensure the clinical and prognostic benefits of Waon therapy.

In conclusion, for the first time in Korea, we have experienced 10 CHF patients with Waon therapy which is safe and has some beneficial effects. Large scale randomized study is needed to expand the use of Waon therapy as a promising, safe and effective therapy in Korean HF patients.

• Acknowledgements

This work was supported by a grant from the Kyung Hee University in 2006 (KHU-20060443). All authors in this study have no conflict of interest.

REFERENCES

1. Tei C. *Waon therapy: soothing warmth therapy*. *J Cardiol* 2007;49:301-4.
2. Kihara T, Biro S, Imamura M, Yoshifuku S, Takasaki K, Ikeda Y, Otsuji Y, Minagoe S, Toyama Y, Tei C. *Repeated sauna treatment improves vascular endothelial and cardiac function in patients with chronic heart failure*. *J Am Coll Cardiol* 2002;39:754-9.
3. Imamura M, Biro S, Kihara T, Yoshifuku S, Takasaki K, Otsuji Y, Minagoe S, Toyama Y, Tei C. *Repeated thermal therapy improves impaired vascular endothelial function in patients with coronary risk factors*. *J Am Coll Cardiol* 2001;38:1083-8.
4. Tei C, Horikiri Y, Park JC, Jeong JW, Chang KS, Toyama Y, Tanaka N. *Acute hemodynamic improvement by thermal vasodilation in congestive heart failure*. *Circulation* 1995;91:2582-90.
5. Tei C, Shinsato T, Miyata M, Kihara T, Hamasaki S. *Waon therapy improves peripheral arterial disease*. *J Am Coll Cardiol* 2007;50:2169-71.
6. Masuda A, Kihara T, Fukudome T, Shinsato T, Minagoe S, Tei C. *The effects of repeated thermal therapy for two patients with chronic fatigue syndrome*. *J Psychosom Res* 2005;58:383-7.
7. Masuda A, Koga Y, Hattamaru M, Minagoe S, Tei C. *The effects of repeated thermal therapy for patients with chronic pain*. *Psychother Psychosom* 2005;74:288-94.
8. Masuda A, Nakazato M, Kihara T, Minagoe S, Tei C. *Repeated thermal therapy diminishes appetite loss and subjective complaints in mildly depressed patients*. *Psychosom Med* 2005;67:643-7.
9. Lang RM, Bierig M, Devereux RB, Flachskampf FA, Foster E, Pellikka PA, Picard MH, Roman MJ, Seward J, Shanewise JS, Solomon SD, Spencer KT, Sutton MS, Stewart WJ; Chamber Quantification Writing Group; American Society of Echocardiography's Guidelines and Standards Committee; European Association of Echocardiography. *Recommendations for chamber quantification: a report from the American Society of Echocardiography's Guidelines and Standards Committee and the Chamber Quantification Writing Group, developed in conjunction with the European Association of Echocardiography, a branch of the European Society of Cardiology*. *J Am Soc Echocardiogr* 2005;18:1440-63.
10. Bae JW, Kang HJ, Kim KI, Kim YJ, Sohn DW, Oh BH, Lee MM, Park YB, Choi YS. *Usefulness of mitral inflow velocity and mitral annulus velocity for predicting long-term prognosis in heart failure with restrictive filling pattern*. *J Kor Soc Echocardiogr* 2003;11:81-6.

11. Ikeda Y, Biro S, Kamogawa Y, Yoshifuku S, Eto H, Orihara K, Yu B, Kihara T, Miyata M, Hamasaki S, Otsuji Y, Minagoe S, Tei C. *Repeated sauna therapy increases arterial endothelial nitric oxide synthase expression and nitric oxide production in cardiomyopathic hamsters.* *Circ J* 2005;69:722-9.
12. Tei C, Shinsato T, Kihara T, Miyata M. *Successful thermal therapy for end-stage peripheral artery disease.* *J Cardiol* 2006;47:163-4.
13. Tei C, Tanaka N. *Thermal vasodilation as a treatment of congestive heart failure: a novel approach.* *J Cardiol* 1996;27:29-30.
14. Kihara T, Biro S, Ikeda Y, Fukudome T, Shinsato T, Masuda A, Miyata M, Hamasaki S, Otsuji Y, Minagoe S, Akiba S, Tei C. *Effects of repeated sauna treatment on ventricular arrhythmias in patients with chronic heart failure.* *Circ J* 2004;68:1146-51.
15. Ahn MS, Yoo BS. *Serial monitoring of B-type natriuretic peptide in heart failure patients.* *Korean Circ J* 2007;37:393-8.
16. Horio T, Kawano Y. *Bio-molecular markers for cardiovascular disease: significance of natriuretic peptides and adrenomedullin.* *Korean Circ J* 2008;38:507-13.
17. Hunt SA, Abraham WT, Chin MH, Feldman AM, Francis GS, Ganiats TG, Jessup M, Konstam MA, Mancini DM, Michl K, Oates JA, Rahko PS, Silver MA, Stevenson LW, Yancy CW, Antman EM, Smith SC Jr, Adams CD, Anderson JL, Faxon DP, Fuster V, Halperin JL, Hiratzka LF, Jacobs AK, Nishimura R, Ornato JP, Page RL, Riegel B; American College of Cardiology; American Heart Association Task Force on Practice Guidelines; American College of Chest Physicians; International Society for Heart and Lung Transplantation; Heart Rhythm Society. *ACC/AHA 2005 Guideline Update for the Diagnosis and Management of Chronic Heart Failure in the Adult: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Writing Committee to Update the 2001 Guidelines for the Evaluation and Management of Heart Failure): developed in collaboration with the American College of Chest Physicians and the International Society for Heart and Lung Transplantation: endorsed by the Heart Rhythm Society.* *Circulation* 2005;112:e154-235.
18. Ikeda Y, Biro S, Kamogawa Y, Yoshifuku S, Eto H, Orihara K, Kihara T, Tei C. *Repeated thermal therapy upregulates arterial endothelial nitric oxide synthase expression in Syrian golden hamsters.* *Jpn Circ J* 2001;65:434-8.
19. Miyata M, Kihara T, Kubozono T, Ikeda Y, Shinsato T, Izumi T, Matsuzaki M, Yamaguchi T, Kasanuki H, Daida H, Nagayama M, Nishigami K, Hirata K, Kihara K, Tei C. *Beneficial effects of Waon therapy on patients with chronic heart failure: Results of a prospective multicenter study.* *J Cardiol* 2008;52:79-85.