

자율신경 활성도와 비만 여성 침치료 효과의 상관성 연구

김제인 · 양요찬 · 김고운 · 조재홍 · 김송이* · 박희준* · 송미연
경희대학교 한의과대학 한방재활의학과교실, 침구경락과학연구소*

The Correlation Analysis between Heart Rate Variability and Effect of Acupuncture on Obese Women

Je-In Kim, K.M.D., Yo-Chan Yang, K.M.D., Koh-Woon Kim, K.M.D., Ph.D., Jae-Heung Cho, K.M.D., Ph.D.,
Song-Yi Kim, K.M.D., Ph.D.*, Hi-Joon Park, K.M.D., Ph.D.*, Mi-Yeon Song, K.M.D., Ph.D.

Department of Korean Rehabilitation Medicine, Studies of Translational Acupuncture Research, Acupuncture and Meridian Science Research Center*, College of Korean Medicine, Kyung-Hee University

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CORRESPONDING TO
Mi-Yeon Song, Department of Korean Rehabilitation Medicine, Kyung Hee University Hospital at Gangdong, 149, Sangil-dong, Gangdong-gu, Seoul 05278, Korea

TEL (02) 440-7580
FAX (02) 440-6854
E-mail mysong@khu.ac.kr

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Objectives The purpose of this study was to investigate the relationship between the effects of acupuncture treatment and heart rate variability (HRV) in pre-menopausal obese women.

Methods Thirty-seven obese women who met the inclusion criteria were recruited. To estimate the effects of acupuncture, obesity indices, such as body weight (BW), waist circumference (WC), hip circumference (HC), and the waist-hip ratio (WHR), were measured before and after the treatment. The HRV test was conducted before treatment and analyzed using the frequency domain method.

Results The lnLF/HF ratio (natural logarithm of low frequency power/high frequency power ratio of the HRV value) before treatments was negatively correlated with differences in WC, HC, and WHR during treatment. The correlation coefficients between the lnLF/HF ratio and the differences in WC, HC, and WHR were $r = -0.459$ ($p < 0.01$), $r = -0.327$ ($p < 0.05$), and $r = -0.339$ ($p < 0.05$) respectively.

Conclusions As the baseline ratio of sympathetic activity to parasympathetic activity decreases, WC, HC, and WHR reduction significantly increased during treatment. Further study is needed to uncover the relationship between obesity-related variables and the autonomic nervous system to predict the effect of acupuncture. (**J Korean Med Rehabil 2016;26(4):85-96**)

Key words Obesity, Autonomic nervous system, Heart rate variability, Acupuncture, Correlation analysis

Introduction»»»»

The autonomic nervous system (ANS) consists of the sympathetic nervous system (SNS) and the parasympathetic nervous system (PNS). The ANS regulates daily energy expenditure, including resting metabolic rate, energy expenditure associated with physical activ-

ity, the thermic effect of food, cold-induced thermogenesis, and thermogenesis related to daily stimuli¹⁾. Undoubtedly, an abnormal ANS activity means a disturbance of the daily energy expenditure and storage, offering the cause and solution of the obesity. And many studies have tried to find the way using the relationship between ANS activity and obesity. For exam-

ple, the MONA LISA hypothesis, an acronym for Most Obesities kNown Are Low In Sympathetic Activity, is based on experimental evidence in rodents that exhibits low SNS activity and morbid obesity following lesions in the ventro-medial hypothalamus²⁾. And because cardiac function is extremely sensitive to autonomic influence, SNS and PNS have been estimated from sympathetic and vagal effects on heart rate variability (HRV) test.

However, it is controversial because of inconsistent results and interpretations. One of the main views is that obese people have a higher sympathetic tone, which is proved from elevated catecholamine levels and associated with impaired cardiac energetics³⁾. Another is that obese people have lower SNS activity, which is proved from lower LF^{4,5)}. And it argues the reduction of SNS activity is related to a reduced energetic cost and lowered capacity of thermogenesis and the state of obesity. On the other hand, some viewers say that obesity increases SNS activity and decreases PNS activity simultaneously⁶⁾, or even decreases both PNS and SNS activity⁷⁻¹⁰⁾.

Indeed, clinicians must prescribe the most proper way to treat obesity individually and maximize the effect by formulating a therapeutic plan quickly. However, previous reports have not researched the predictive power of ANS toward obesity-related variables, which would be more meaningful for clinicians. And we can expect the improvement of obesity state through Korean medical treatments upon previous evidences, but have not analyzed the specific relationships of alteration of obesity states with the ANS.

Accordingly, we explored whether the ANS could be used to predict the efficacy of acupuncture treatment for treating obesity in pre-menopausal women using HRV variables.

Materials and Methods>>>>

1. Subjects

This study was conducted from 14 April to 20 August 2014 at Kyung-Hee University Korean Medicine Hospital (Gang-dong, Seoul, South Korea). Subjects were recruited through announcements on the hospital's notice board and newspaper advertisements using the following criteria.

1) Inclusion criteria

- a. Pre-menopausal with regular menstruation 18~55 years old women; and
- b. Body-mass index (BMI) >25 kg/m², according to the obesity criteria (Asian-Pacific standards).

2) Exclusion criteria

- a. Gynecological diseases, including hysterectomy and/or oophorectomy;
- b. Heart disease (e.g., cardiac arrhythmia or implanted cardiac pacemaker);
- c. Endocrine disease (e.g., thyroid disorder or pituitary disorder);
- d. History of taking medications, including female hormones, thyroid hormones, oral steroids or an antihypertensive agent in the 3 months preceding the study;
- e. Underwent weight control management within the past 3 months; and
- f. Pregnant or lactating.

Forth-five subjects who met the inclusion criteria were recruited, and informed consent was obtained from all subjects. All subjects were free to withdraw from the study at any time and agreed to announce any adverse effects during and after the study. All procedures were approved by the Institutional Review Board of Kyung-Hee University Korean Medicine Hospital at Gang-dong (KHNMCOH 2013-01-020-004).

2. Material and methods

1) Interventions

Manual acupuncture and electroacupuncture (EA) were given to all subjects. All acupuncture points were based on traditional acupuncture theory for treating obesity and needle depth was based on the particular tissue level and the unit of measurement (Table I). Ten acupuncture needles (Dong-bang Acupuncture Inc., 0.25×40 mm) were inserted vertically in CV12 and CV6 on the middle of the body, and in LI4, LI11, ST36, and SP6 bilaterally for manual acupuncture. Simultaneously, four longer acupuncture needles (Dong-bang Acupuncture, 0.25×75 mm) were inserted horizontally and bilaterally in ST25 and ST28 for EA. Electrical stimulation was applied to these four acupuncture points intensity using a LipoDR low-frequency electroacupuncture device (Dow Meditec Corp., Seoul, Korea). The manual acupuncture treatment and electrical stimulation were conducted for 30 minutes twice, each comprised of 25 minutes of 25 Hz electrical stimulation for the lipolytic phase, and 5 minutes of 60 Hz for the elasticity maintenance phase at a maximal tolerable. All subjects underwent stimulation twice per week for 6 weeks (Fig. 1).

Other interventions, such as diet and exercise, were directed through brochures and a Korean medicine doctor's management in the obesity clinic of Kyung-Hee University Korean Medicine Hospital at Gang-dong. No additional treatment or intervention was allowed.

2) Data measurements

A skilled assistant measured all variables using a designated ruler¹¹⁻¹³. All data were collected between 9:00 and 13:00 to minimize the effects of circadian rhythms. All subjects were restricted from food for 1 hour and from smoking and drinking for 8 hours before assessments.

(1) Anthropometry

The assessments were performed before and after treatment in 12 sessions during 6 weeks. Body weight (BW), height, and BMI were measured with a body fat analyzer (Inbody 720, Biospace, Seoul, South Korea). Waist circumference (WC) was measured midway between the lateral lower rib margin and the iliac crest according to the WHO standard. Hip circumference (HC) was measured at the level of the major trochanter through the pubic symphysis. All of these assessments were measured to the nearest 0.1 cm or 0.1 kg. The waist-hip ratio (WHR) was calculated as WC/HC.

Table I. Acupuncture Point Locations and Depths

Acupuncture points		Who standard locations	Depths
Manual acupuncture	(LI4)	On the dorsum of the hand, radial to the midpoint of the second metacarpal bone.	vertical insertion/10 mm
	Hegu		
	(LI11)	On the lateral aspect of the elbow, at the midpoint of the line connecting LU5 with the lateral epicondyle of the humerus.	vertical insertion/15 mm
	Quchi		
	(ST36)	On the anterior aspect of the leg, on the tibialis anterior muscle.	vertical insertion/30 mm
	Zusanli		
	(SP6)	On the tibial aspect of the leg, posterior to the medial border of the tibia, 3 B-cun superior to the prominence of the medial malleolus.	vertical insertion/10 mm
Electro-acupuncture	Sanyinjiao		
	(CV12)	On the upper abdomen, 4 B-cun superior to the centre of the umbilicus, on the anterior median line.	vertical insertion/24 mm
	Zhongwan		
	(CV6)	On the lower abdomen, 1.5 B-cun inferior to the centre of the umbilicus, on the anterior median line.	vertical insertion/36 mm
	Qihai		
	(ST25)	On the upper abdomen, 2 B-cun lateral to the centre of the umbilicus.	horizontal insertion/24 mm
	Tianshu		
(ST28)	On the lower abdomen, 3 B-cun inferior to the centre of the umbilicus, 2 B-cun lateral to the anterior median line.	horizontal insertion/75 mm	
Shuidao			

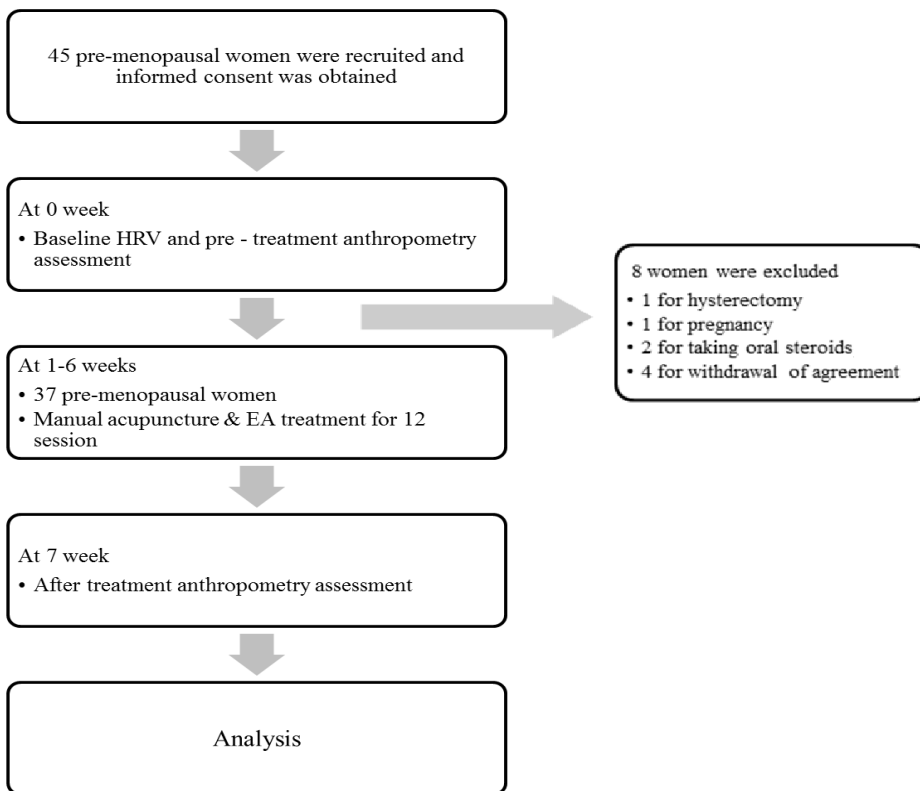


Fig. 1. Study flow chart. HRV: heart rate variability, EA: electroacupuncture.

(2) Heart Rate Variability (HRV)

Baseline HRV measurements were taken after 5 minutes of rest in the supine position and lasted 5 minutes using the Heart Rhythm Scanner (Version 2.0, Biocom Technologies, Washington, DC, USA). The HRV leads were attached 4 cm above the right nipple, 4 cm below the left nipple, and the lateral left side.

3. Analysis

1) Anthropometric data

Pre- and post-treatment measurements were calculated to estimate the change due to treatment. The differences (Δ BW, WC, HC, and WHR) were obtained by subtracting post-treatment values from pre-treatment values.

2) HRV analysis

5-minute electrocardiographic recordings were analyzed using the HRV frequency domain method to assess ANS activity. HRV data were using the Fourier

transform algorithm at a frequency resolution of 0.01 Hz, which separates very low frequency power (VLF; ≤ 0.04 Hz), low frequency power (LF; 0.04~0.15 Hz), and high frequency power (HF; 0.15~0.4 Hz). Total power (TP), which was the total of VLF, LF, and HF, and the LF/HF ratio were also calculated¹⁴. VLF was not analyzed because it is an ambiguous measurement with low confidence^{15,16}. The TP, LF, HF, and LF/HF ratio data were positively skewed and were natural log transformed to satisfy the normal distribution criteria (\ln TP, \ln LF, \ln HF, and \ln LF/HF).

3) Statistical analysis

All outcomes were analyzed with SPSS ver. 18.0 software for Windows (SPSS Inc., Chicago, IL, USA). Two-tailed p-values < 0.05 were considered significant. The paired t-test was used to examine differences between baseline and after treatments of 12 sessions. Pearson's correlation coefficient analysis was conducted to assess associations.

Results>>>>

1. General subject characteristics and baseline HRV data

Of the 45 women who agreed to participate, eight

Table II. General Characteristics and 5-minute Heart Rate Variability Values of the Subjects

Variables	Values	Range
Age	38.16±8.53*	21~54
BMI (kg/m ²)	26.74 (25.79, 29.22) [†]	25.09~38.41
WC (cm)	87.09±7.30*	74.4~108.2
HC (cm)	98.75±0.90*	90.2~113.9
WHR (cm)	0.88±0.01*	0.77~0.96
BW (kg)	74.16±9.77*	57.8~106.8
TP (msec ²)	378.78 (270.25, 816.40) [†]	97.38~2839.86
LF (msec ²)	128.29 (58.45, 185.50) [†]	5.56~819.66
HF (msec ²)	89.09 (27.77, 162.78) [†]	2.11~697.65
LF/HF ratio	1.87 (0.59, 3.56) [†]	0.14~9.33
lnTP (msec ²)	6.04±0.837*	4.58~7.95
lnLF (msec ²)	4.60±0.98*	1.72~6.71
lnHF (msec ²)	3.98±1.17*	0.75~6.55
lnLF/HF (msec ²)	0.58±0.84*	-1.94~2.23

*Values are mean±standard deviation, [†]Values are median (interquartile range).

BMI: body mass index, WC: waist circumference before treatment, HC: hip circumference before treatment, WHR: the ratio of WC to HC, BW: body weight before treatment, TP: total power, LF: power in the low frequency range, HF: power in the high frequency range, Ln: natural logarithm (the spectral power data were log transformed).

Table III. Pearson's Correlation Coefficients between 5-minute Heart Rate Variability Values and Differences in the Obesity Index during Treatment

Variables	ΔWC (cm)	ΔHC (cm)	ΔWHR (cm)	ΔBW (kg)	lnTP	lnLF	lnHF	lnLF/HF
ΔWC (cm)	1.00	.565 [†]	.827 [†]	.267	-.140	-.212	.150	-.459 [†]
ΔHC (cm)		1.00	.007	.252	-.215	-.218	.046	-.327*
ΔWHR (cm)			1.00	.145	-.001	-.079	.179	-.339*
ΔBW (kg)				1.00	-.218	-.167	.006	-.211
lnTP					1.00	-.830 [†]	-.605 [†]	-.168
lnLF						1.00	-.705 [†]	-.234
lnHF							1.00	.525 [†]
lnLF/HF								1.00

*Correlation coefficients are significant at p<0.05, [†]Correlation coefficients are significant at p<0.01.

ΔWC: difference in waist circumference during treatment, ΔHC: difference in hip circumference during treatment, ΔWHR: difference in the waist-hip ratio during treatment, ΔBW: difference in body weight during treatment, TP: total power, LF: power in the low frequency range, HF: power in the high frequency range, Ln: natural logarithm (the spectral power data were log transformed).

were excluded (one for hysterectomy, one for pregnancy, two for taking oral steroids, and four for withdrawal of agreement), resulting in 37 subjects. No side effects were reported. Thirty-one of the 37 women (83.8%) had WC >80 cm, which is the female limit for abdominal obesity.

The baseline BMI and HRV data were positively skewed and are summarized as median and interquartile range. Other variables, general characteristics and natural log 5-minute HRV values satisfied a normal distribution and are summarized as means±standard deviations (Table II).

2. Correlations between baseline HRV and differences in the obesity index

The baseline lnLF/HF and ΔWC (r=-0.459, r²=0.211, p<0.01), ΔHC (r=-0.327, r²=0.107, p<0.05), and ΔWHR were correlated (r=-0.339, r²=0.115, p<0.05). The lnLF/HF and ΔBW tended to be negatively correlated, but insignificantly (p>0.05). lnTP, lnLF and lnHF were not associated with any variables (Table III, Fig. 2~4).

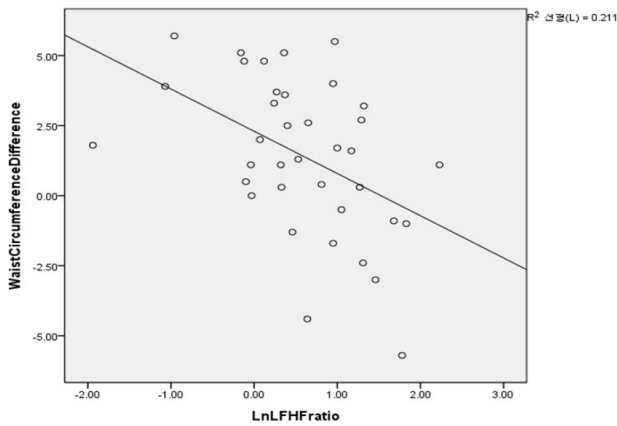


Fig. 2. Scatter plots for the correlations between the difference in waist circumference (WC) and lnLF/HF. The difference in WC during treatment was negatively correlated with the lnLF/HF before treatment ($r = -0.459$, $p < 0.01$).

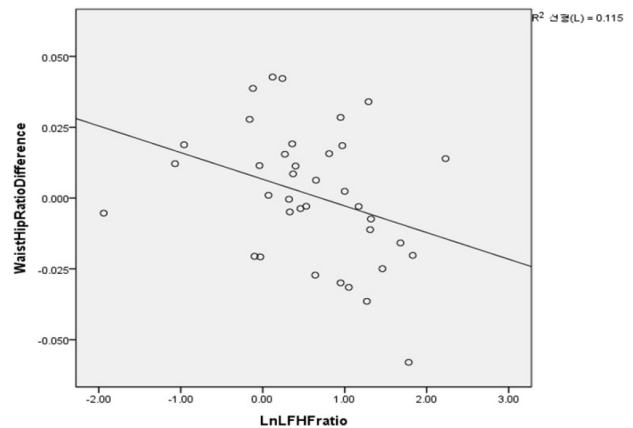


Fig. 4. Scatter plots for the correlations between the difference in the waist-hip ratio (WHR) and lnLF/HF. The difference in WHR during treatment was negatively correlated with the lnLF/HF before treatment ($r = -0.339$, $p < 0.05$).

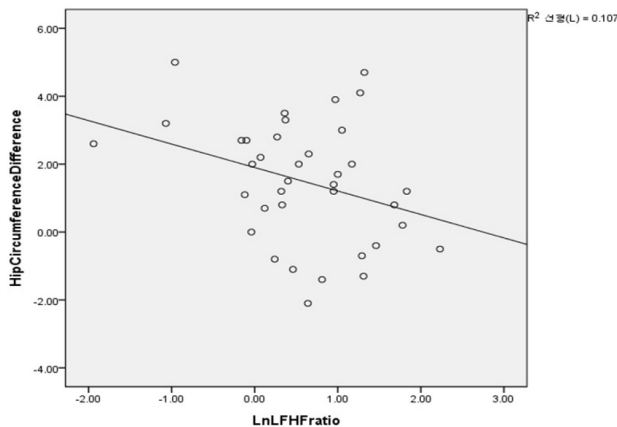


Fig. 3. Scatter plots for the correlations between the difference in hip circumference (HC) and lnLF/HF. The difference in HC during treatment was negatively correlated with the lnLF/HF before treatment ($r = -0.327$, $p < 0.05$).

Discussion»»»»

The effect of changes in ANS activity on metabolism has been implicated in the development and maintenance of obesity, and the ANS is a potential therapeutic target for treating obesity¹⁷⁾. Thus HRV, which represents ANS activity, has been proposed as useful to understand obesity. This is supported by various studies on HRV and obesity indices (BMI, %BG, and WHR) in Korean pre-menopausal women^{18,19)}. Moreover, multiple regression analysis was used to predict

the concentration of obesity~related metabolites via the HRV in pre-menopausal obese Korean women²⁰⁾ and a linear regression analysis was conducted between HRV and changes in BW²¹⁾.

Considering the relationship between the ANS and anthropometric changes after obesity treatment, Joo²²⁾ reported that a short-term intervention for obese subjects decreases SNS activity and Ito²³⁾ found that the combination of exercise and mild caloric restriction led to improved modulation of the PNS. Kim²⁴⁾ argued that both the SNS and PNS are negatively correlated with fat mass, percentage fat content, and WHR at rest in obese subjects. In addition Karason²⁵⁾ suggested that obese subjects show increased SNS activity and lower vagal activity and that autonomic disturbances improve after gastropasty. However, these studies evaluated ANS activity differently and the cause and effect between obesity and ANS activity was confusing.

Additionally, some trials to assess the relationship between baseline SNS activity of obese subjects and weight loss outcomes have been conducted. Astrup²⁶⁾ and Kempen²⁷⁾ used a 36 week hypoenergetic diet or an 8 week very-low-energy diet, and maximum weight loss was positively associated with baseline levels of plasma noradrenaline (NA) and adrenaline. In addition,

Hellström²⁸⁾ also found that plasma NA and α_2 -adrenergic receptor sensitivity are associated with weight loss during 4 weeks on diet restriction. These three studies suggest that plasma NA can be used as a prognostic marker for treating obesity. These findings show that constitutional differences in ANS activity may explain the variability in weight loss observed by obese subjects¹⁷⁾. Nevertheless, it is insufficient to show that the ANS can predict the propensity to lose weight in obese individuals, and all interventions in those studies²⁶⁻²⁸⁾ were dietary restriction.

Most studies have simply compared HRV between obese and non-obese subjects³⁻¹⁰⁾ or conducted a cross-sectional study with a short follow-up without treatment^{3-10,18-21)}. The relationships between ANS activity and therapeutic changes based on dietary restriction^{21-24,26-28)} or gastroplasty²⁵⁾ have been studied but have not included traditional Korean medical treatment, such as acupuncture or herbal medicine. Therefore, we aimed to uncover the effect of acupuncture on the ANS of pre-menopausal Korean obese women through an HRV analysis. In addition, we discussed whether HRV could predict the therapeutic effect of acupuncture on obesity.

As a result, the baseline lnLF/HF was negatively correlated with Δ WC, Δ HC, and Δ WHR during treatments. As the lnLF/HF varies with SNS activity, it is assumed that loss of WHR, WC, and HC after treatment will be maximized as the SNS is activated. This result corresponds to the argument that low frequency stimulation by EA into subcutaneous adipose tissue activates lipolysis, leading to hormonal modulation and elevated catecholamine levels²⁹⁻³¹⁾. However, this is inconsistent with the findings that the elevated RMSSD (Root Means Square of Standard Deviation) and decreased LF/HF ratio have been reported, indicating that the increase of the baseline PNS activity may be negatively correlated with BW, BMI, and fat mass after an obesity treatments²¹⁾. However, we didn't use dietary restrictions or exercise but used acupuncture.

One of limitations of this study was that the reli-

ability and validity of HRV measurements are not well known. It is necessary to collect data over 24 hours using the HRV time-domain method to further generalize our results. Moreover, additional study with a larger sample size and performed in a well-controlled environment will reveal various predictive models for Korean medical treatments of obesity.

In conclusion, the efficacy of acupuncture treatment on abdominal obesity was maximized as the baseline lnLF/HF decreased, suggesting that baseline lnLF/HF could be considered to predict the effectiveness of abdominal obesity treatment.

Conclusion>>>>

We investigated the hypothesis that HRV can be used to predict the effect of acupuncture on obesity in pre-menopausal women.

1. The lnLF/HF before treatment was negatively correlated with differences in WC, HC, and WHR during treatment.
2. None of the HRV values was associated with the difference in BW during treatment.

In conclusion, as the baseline parasympathetic activity over the sympathetic activity increases, WC, HC and WHR reductions significantly increased, meaning high effects of acupuncture on obesity treatment. Further study is needed to uncover the relationship between obesity-related variables and autonomic nervous system to predict the effect of acupuncture.

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Appendix 1. 임상연구 참가자 모집공고

자율신경 활성도와 폐경 전 비만 여성의 침치료 효과의 상관성 연구

1. 임상연구 목적

자율신경계 활성도에 따른 비만환자의 침 치료 효과의 상관성을 알아보기 위해 실시하는 연구입니다.

2. 모집 대상자

- ① 폐경 전이며 월경주기가 일정한 연령 만 18~55세의 여성
- ② 체질량지수(BMI) 25 kg/m²이상인 비만 환자

3. 제외 기준

- ① 부인과 질환자 및 질환력이 있는 자 (자궁적출술 그리고/혹은 난소절제술 포함)
- ② 심질환력이 있는 자 (부정맥 혹은 심장박동조절장치(pacemaker) 의존 환자)
- ③ 내분비 질환, 인슐린 비의존성 당뇨병 등의 질환자와 기왕력자
- ④ 최근 3개월 이내에 여성호르몬제, 갑상선 호르몬, 경구용 스테로이드 및 고혈압 치료제(β -blocker 또는 이뇨제), 암페타민, 싸이프로헵타딘, 페노디아진 또는 흡수, 대사, 배설에 영향을 주는 약물 등과 같이 체중과 체내 대사물질 농도에 영향을 미칠 수 있는 약물을 복용한 경험이 있는 환자
- ⑤ 최근 3개월 이내에 체중 감량을 위한 다른 치료 및 노력을 하고 있는 자
- ⑥ 수유부, 임신부, 임신계획이 있는 자

4. 지원자 혜택

5. 임상연구 모집 기간 및 임상연구 소요시간

- ① 모집기간 :
- ② 임상연구 소요시간 : 6주간 1주일에 두 번 치료 위한 방문. 총 13회 방문 (침치료 총 12회, 최초 방문시 심박변이도 검사 실시), 침치료 및 검사, 상담에 소요되는 시간은 1회 40분 내외

Appendix 2. 피험자 설명문 및 동의서

연구과제명	자율신경 활성도와 폐경 전 비만 여성 침치료 효과의 상관성 연구			
	소 속 과	직 급	성 명	연락처
책임연구자				
공동연구자				
연구담당자				

귀하는 체질량지수(BMI) 25 kg/m²이상의 비만환자로, 강동 경희대학교 한방병원에서 진행되는 임상 연구에 참여하실 것을 권유 받으셨습니다. 45명의 대상자가 이 연구에 참여할 것이며, 이 연구에 참여하는 것은 전적으로 참가자 본인의 지원에 의한 것입니다. 참가자는 이 연구에 대한 참여여부를 결정하기 전에 아래의 사항을 읽으셔야 하며 이해가 되지 않는 사항에 대해서는 질문해 주시기 바랍니다.

1. 임상시험의 목적, 방법, 예측 효능 및 효과

본 임상시험은 비만 치료에 사용되는 복부 및 팔다리의 주요 혈자리에 침치료(일반침 및 전기침)를 주 2회씩 총 6주간 시행했을 때, 치료전 자율신경 활성도와 치료 효과의 상관성을 알아보고자 수행됩니다.

2. 본 연구에 참여하게 됨으로써 피험자가 받게되는 검사 및 절차

만약 귀하께서 동의하신다면, 참가자는 6주간의 치료 기간 동안 1주일에 두 번 강동 경희대학교 한방병원에서 침치료를 받게 될 것입니다. 본 연구에 참여를 동의하시면 치료 시작 전 병력, 혈압과 키, 체중 검사, 체성분 검사, 심박변이도 검사를 하게 됩니다. 또한 마지막 치료가 시행된 후에 다시 키, 체중 검사, 체성분 검사를 시행하게 됩니다.

3. 본 연구를 위해서 피험자가 준수해야 하는 사항

본 임상시험기간 동안 일상생활의 엄격한 제한은 없으나, 가급적 교육해드린 식이와 운동에 대해 유념하시어 체중 감량에 방해될 수 있는 과도한 음식 섭취는 피하시고, 정해진 일정에 내원하시어 시험책임자의 지시에 적극 협조하셔야합니다.

4. 본 임상시험의 검증되지 않은 실험적인 측면

본 연구에서 시행하는 침치료가 비만 환자의 체중 감량, 허리둘레 감소 등의 치료 효과를 나타낸다는 것을 입증한 임상 연구가 다수 진행되었으며, 지방분해를 위한 전기침 기술의 안전성 및 안정성이 검증되었으나, 침치료 효과와 비만 환자의 치료전 자율신경 활성도 간의 관계에 대한 연구는 진행되지 않았습니다.

5. 임상시험에 참여함으로써 예견되는 위험(부작용)이나 불편사항

침치료로 인한 이상반응은 드물다고 보고되어 있으나 본 임상시험 중 일반적으로 알려진 침치료의 부작용, 즉 가슴이 뛰거나, 어지럽거나, 속이 메스꺼리거나 구토 등이 발생할 수 있으며 피하출혈이나 알러지 반응, 발적의 부작용 이외의 예상되는 위험성은 없습니다.

6. 본 임상시험에 참여함으로써 기대되는 이익

귀하께서는 치료비, 심박변이도 검사비 및 설문지 검사비를 연구비에서 지원받게 되며, 본 임상 시험을 통해 잠재적으로 체중 감량 및 허리둘레 감소가 예상되지만 일부 참가자의 경우 어떤 치료 효과도 경험하지 못할 수도 있습니다. 본 연구가 완료된 후에는 체중 측정 결과, 심박변이도 검사 결과를 의료진에게 들으실 수 있습니다.

7. 본 질환으로 선택할 수 있는 다른 치료방법 및 이러한 치료의 잠재적 위험과 이익

비만 치료에 대한 일반적인 한방 치료법으로는 침, 한약, 전기침, 부항, 뜸 요법 등이 있습니다. 각각의 치료법 모두 장단점이 있으며, 한약 요법의 경우 전문의의 정확한 진료를 통하여 환자의 체질에 맞는 약을 처방받을 경우 비만 치료에 좋은 효과를 나타낼 수 있으나 체질에 맞지 않는 약을 처방받을 경우 부작용을 경험하게 될 수 있습니다.

8. 예상 참여기간 및 본 시험에 참여하는 대략의 전체 피험자수

귀하께서는 앞으로 6주 동안 1주일에 두 번 병원에 오셔서 침치료를 받으시고 체중이 얼마나 감소했는지, 부작용은 없는지 알아보는 여러 질문에 솔직히 답해 주시면 됩니다. 매번 치료 및 상담 시간은 약 40분 정도가 걸리며, 연구에 참여하는 피험자의 수는 총 45명입니다.

9. 임상시험과 관련된 손상이 발생하였을 경우 피험자에게 주어질 보상과 치료방법

10. 임상시험에 참여함으로써 받게 되는 금전적 보상의 여부 및 참여 정도에 따른 조정 정도 또는 임상시험에 참여함으로써 피험자에게 추가적으로 발생이 예상되는 비용

11. 자유의사에 의한 시험참여 동의 및 철회

12. 연구책임자가 필요하다고 판단될 경우, 본인의 동의 없이도 본 연구참여에서 제한될 수 있음을 알고 있습니다. 또한, 이 경우 연구책임자 또는 동의서 상에 명시된 연구자에게 통보함으로써 본 연구에서 불참할 수 있습니다.

13. 신분의 비밀보장

14. 임상시험 도중 피험자의 임상시험 참여가 중지되는 경우 및 해당사유

연구담당자는 정당한 사유가 발생한 경우 참가자를 연구에서 탈락시킬 수 있습니다. 만약 연구도중에 특정한 질병이 발생 되면 참가자가 연구를 지속하고자 하여도 탈락되게 됩니다. 연구담당자는 참가자가 연구 참여를 지속하지 못하게 될 상황이 발생하면 참가자에게 설명하고 탈락여부를 결정하게 됩니다. 탈락 결정은 참가자의 건강과 안전을 보호하기 위해 이루어질 수도 있고, '특정한 사정이 발생한 사람들은 이 연구를 지속할 수 없다' 고 하는 연구 계획의 일부분 때문에 결정되기도 합니다.

15. 임상시험과 피험자의 권익에 관해 추가적인 정보를 얻고자 하거나 임상시험과 관련이 있는 손상이 발생한 경우에 접촉해야 하는 사람

본 임상시험은 피험자의 권리, 안전 복지를 보호할 책임이 있는 임상시험심사위원회에 의해 승인되었으며 본 연구의 참가자로서 귀하의 권리에 대해 질문이 있으시면 본원 임상시험심사위원회 담당자(Tel. 〇〇〇-〇〇〇〇)에게 문의하실 수 있습니다. 또한, 임상시험과 관련이 있는 손상이 발생한 경우에는 위의 연구자에게 연락할 수 있습니다.