Original Article

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Efficacy of Electroacupuncture using an Insulated Needle in Adults with Abdominal Obesity: A Pilot Study

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[Abstract]

Objectives : This study evaluated the efficacy of electroacupuncture therapy using an insulated needle in adults with abdominal obesity.

Methods : This study was a randomized, double–blind, parallel–designed pilot trial. Sixteen participants eligible according to the inclusion and exclusion criteria were randomly divided into an insulated needle group and a control group. Insulated or common needles were inserted at acupoints located on the abdomen (CV12, CV6, ST25, ST27, SP15) and were electrically stimulated for 30 minutes (16 Hz, within tolerable strength). A total of 10 sessions of treatment were performed twice per week for 5 weeks. All participants were requested to maintain their usual diet and lifestyle. The outcome measures were waist circumference (WC), waist–to–hip ratio (WHR), and abdominal computed tomography (CT) of the total fat area (TFA), subcutaneous fat area (SFA), and visceral fat area (VFA).

Results : A total of 12 participants divided into the insulated needle group (n = 5) and the control group (n = 7; common needle) were treated for 10 sessions and analyzed per–protocol (PP). WC decreased significantly after 10 sessions in both groups. The WC, TFA, SFA, and VFA of abdominal CT in the insulated needle group decreased more than in the control group; however, there were no significant differences in any parameter between the insulated needle group and the control group. Patients in the insulated needle group were more strongly stimulated with electrical stimulation than patients in the control group.

Conclusion : Electroacupuncture using insulated needles in adults with abdominal obesity might be a more effective treatment than common needles. Additional studies are required to compensate for the limitations of this pilot study and to verify the results and efficacy.

Key words :
Insulated needle;
Electroacupuncture;
Abdominal obesity;
Pilot study;
Randomized controlled trial

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Ⅰ. Introduction

Obesity is a major disease of the 21st century that has a negative impact on human life and health. It is a state of caloric imbalance in which calorie intake is greater than the energy needed for physical activity. It is associated with changes in hormones, heredity, and mental and socioeconomic factors[1,2].

In Oriental medicine, obesity has been treated using various therapies such as medication[3], auricular acupuncture[4], electroacupuncture[5-7], carboxytherapy[8], and thread-embedding therapy[9]. Studies of Oriental medicine for obesity have been actively conducted since 1992; among them, electroacupuncture (EA) is one of the most commonly used methods in clinical studies[5-7].

EA dissolves fat cells by passing an electric current through a needle. When the current flows, the heat generated increases the use of triglycerides, which are hydrolyzed and removed by glycerin and fatty acids[10,11].

Insulated needles have recently been used to find nerve injury sites or stimulate a lesion locally. Part of an insulated needle is coated with an insulator. As current flow through this coating is limited, it is possible to transmit a strong local stimulation and simultaneously reduce tissue damage outside the lesion[12].

It was assumed that a stronger EA intensity would deliver a stronger stimulation to the fat layer, increase heat production, and cause greater body fat reduction. However, strong electrical stimulation cannot be performed in a clinical setting due to pain felt in the epidermis. Consequently, insulated needles were used in EA therapy to enable stronger stimulation. The coated area of the insulated needle touching the epidermis reduces pain felt by electrical stimulation and delivers more electrical current into the abdomen.

The purpose of this study was to investigate the changes in abdominal fat and obesity-related outcomes after 10 treatment sessions, and to evaluate and complement the study design to improve the efficacy, feasibility, and safety by reducing errors.

Ⅱ. Subjects and Methods

1. Study design

This study was a randomized, double-blind, parallel-designed pilot trial. A total of 10 sessions of treatment were performed twice per week for 5 weeks and all participants were requested to maintain their usual diet and lifestyle. Outcomes were measured before and after 10 treatment sessions. After every application of EA, the intensity and adverse reactions were recorded. The protocol was approved by the institutional review board of Cheonan Oriental Hospital of Dajeon University (protocol number: DJUMC-M-2016-02).

2. Participants

The study was conducted from July to October 2016. Participants were recruited by advertisements on hospital bulletin boards. Individuals interested in participating received an explanation of the study they were able to understand. After individuals consented to participate, they signed a written consent from and were screened for eligibility.

Enrolled participants were aged 19 to 64 years, with body mass indexes (BMIs) of 25-39.9 ㎏/㎡. Men's waist circumferences (WC) were ≥ 90 ㎝; women's WC were ≥ 85 ㎝.

Patients taking medications that affected weight within 6 weeks of study onset were excluded. They also were excluded if: they had participated in a commercial obesity program within the previous month or had received calorie-restricted dietary therapy; had undergone surgery for weight loss; had anorexia nervosa or hyperactivity, non-insulin dependent diabetes mellitus, or a previous

history of those illnesses; had taken a beta-blocker or diuretic as a treatment for hypertension in the previous 3 months; were pregnant or lactating; or had a condition that the researcher deemed inappropriate for participation.

3. Randomization and blindness

Patients were randomly allocated to the IG or CG at a ratio of 1:1 according to a computer-generated assignment table created in advance; the assignment was managed by an independent statistician. To maintain double-blinding, both insulated and common needles were manufactured in the same package with the same outer shape, so that it was not possible to distinguish which group patients were allocated to unless blinding was removed.

To avoid the possibility of estimating the allocation group according to stimulation intensity during EA manipulation, the study was designed to distinguish between the Oriental doctor

who performed the acupuncture and the other Oriental doctors who performed physical examinations and manipulated EA intensity.

4. Sample size

This study was a preliminary study, and it will be the basis for the calculation of the number of subjects necessary for future clinical trials. However, as there are no previous studies of insulated needles, it was impossible to estimate the number of subjects necessary. Therefore, this preliminary study was designed to register 16 patients; a dropout rate of 20% was assumed based on previous EA studies.

5. Interventions

The treatment consisted of 10 sessions performed twice per week for 5 weeks. The trial was conducted under the same conditions, and the same practitioners treated all participants. The practitioners, licensed Doctors of Oriental Medicine with 3 additional years of clinical experience, applied the devices.

Insulated stainless steel needles 0.3 × 60 ㎜ in size (PEP30-6020, Dongbang-medical, *Korea*) were used in IG patients, and 0.3 × 60 ㎜ common stainless steel needles (4GS30-6020, Dongbang-medical, *Korea*) were used for CG patients. Needles were inserted approximately 50 mm horizontally into acupoints located on the abdomen (CV12, CV6, ST25, ST27, SP15), touching abdominal subcutaneous fat as much as possible[13]. Both groups were electrically stimulated for 30 minutes (16 Hz, within tolerable strength).

Other physical therapies and treatments were excluded. The participants were requested to maintain their usual diet and lifestyle. Medication regimens other than exclusion criteria medications (eg. appetite suppressants/accelerators, hypotensive agents, contraceptive pills, and steroids) were maintained.

6. Outcome measures

1) Physical examinations

Physical examinations were performed prior to the procedure to determine the suitability of the inclusion/exclusion criteria and to compare baseline measurements.

Height was measured to within 0.1 cm with a stadiometer while maintaining upright posture. Body weight (BW) and body mass index (BMI) were measured using Inbody 3.0 (Inbody Co., Ltd., Seoul, Korea) after patients removed metal attachments such as glasses, watches, and necklaces.

2) Waist circumference and waist-to-hip ratio

Waist circumference (WC) and waist-to-hip ratio (WHR) were recorded at baseline and after 10 sessions of treatment. Each measurement was per-

formed twice by an investigator other than the practitioner, and the average value was recorded.

WC was measured using an automatic measuring tape placed in a horizontal plane around the abdomen midway between the lowest rib and the superior border of the iliac crest, according to the measurement methods presented by the World Health Organization (WHO)[14]. Hip circumference (HC) was measured around the greater trochanter of the femur and the symphysis pubis. The waist-to-hip ratio (WHR) was calculated from WC and HC using the formula (1)

$$WHR = WC/HC$$

3) Abdominal CT

After performing abdominal CT at the L4-5 area with the patient in a supine position, abdominal fat was calculated by dividing the total fat area, subcutaneous fat area, and visceral fat area, using a program embedded in the CT. The same investigator that measured WC recorded abdominal fat.

4) Intensity of EA

The EA intensity for every treatment (CV12-CV6, bilateral ST25, ST27, and SP15) was recorded at four sites by the same person who controlled the electrical stimulation. The measured values of IG and CG were compared.

7. Statistical analysis

The per-protocol (PP) analysis was used as a method of analyzing participants who completed the clinical trial according to the protocol; the missing case was analyzed by last observation carried forward (LOCF).

All data were summarized as mean, standard deviation, median, maximum, and minimum values. When comparing the differences in baseline values between groups, a Student's *t*-test was used for continuous variables.

When performing comparisons of WC, WHR, abdominal CT of TFA, SFA, and VFA, and the change in EA intensity between the groups, the Student's t-test was used according to the assumption of normalized data; the Mann-Whitney U test was used to analyze non-normal data. When comparing the values of each group before and after treatment, the paired t-test was used according to the assumption of normalized data, and the Wilcoxon signed rank test was performed if the normality assumption was not satisfied. A p-value < 0.05 was considered significant.

Statistical analyses were performed using SPSS Statistics for Windows Version 20.0 (IBM Corp., Armonk, NY, USA); graphs and tables were created using SPSS Version 20.0 or Microsoft Excel (Microsoft Corp., Redmond, WA, USA).

Ⅲ. Results

A total of 17 individuals were recruited. One was excluded during screening, and 16 individuals were enrolled and treated in this study. Among the enrolled individuals, 3 IG patients and 1 CG patient withdrew; 12 individuals completed the study (Fig. 1).

Among those 12 participants, 11 (91.7%) were female and 1 (8.3%) was male. The mean age of the IG patients was 42.6 ± 8.6 years, mean height was 160.5 ± 7.6 ㎝, mean weight was 78.7 ± 7.8 ㎏, and mean BMI was 30.6 ± 1.7 ㎏/㎡. The mean age of CG patients was 47.4 ± 9.5 years, mean height was 158.4 ± 6.7 ㎝, mean weight was 3.5 ± 5.0 ㎏, and mean BMI was 29.4 ± 2.9 ㎏/㎡. There was no significant difference in baseline demographics, WC, WHR, or abdomen CT (TFA, SFA, VFA) between the two groups (Table 1).

1. WC and WHR

WC and WHR were observed at the baseline and endpoint of the study (10 treatments) (Table 2).

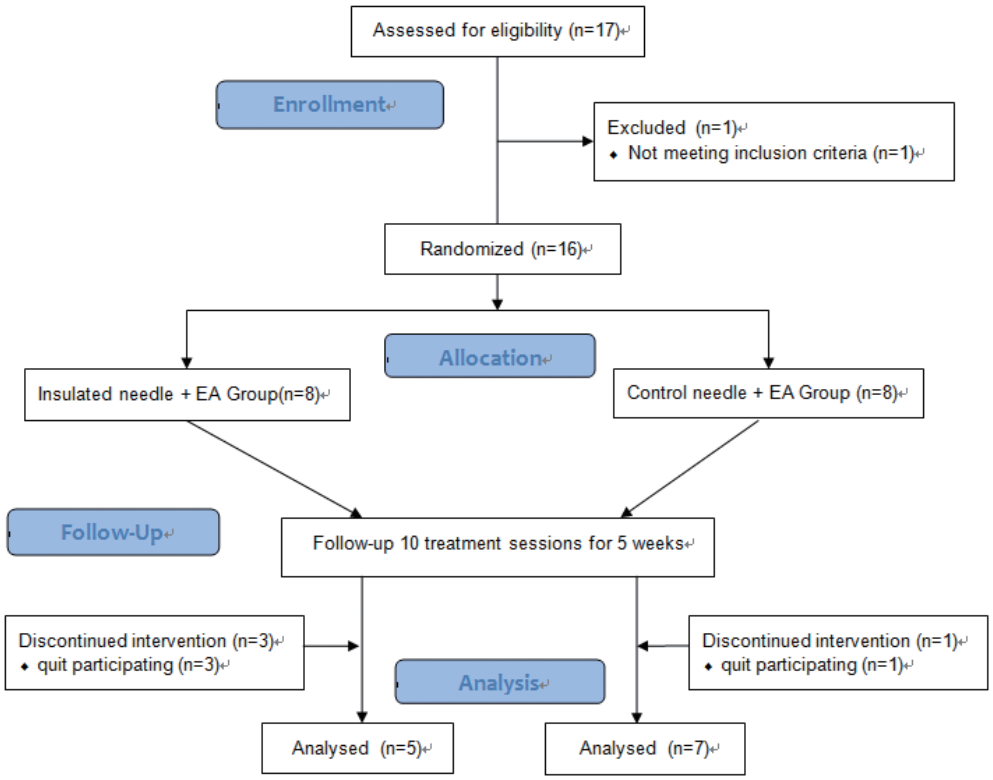

Fig. 1. Flow chart of the steps of the randomized clinical trial

Abbreviations: EA = electrical acupuncture.

Table 1. Baseline demographics and WC, WHR, and abdomen CT (TFA, SFA, VFA) by group

		Insulated needle (n = 5)	Control (n = 7)	Total	*p*-value*
Sex	Male	–	1 (14.3%)	1 (8.3%)	
	Female	5 (100.0%)	6 (85.7%)	11 (91.7%)	
Age		42.6±8.6	47.4±9.5	45.4±9.5	0.29
Height (㎝)		160.5±7.3	158.4±6.7	159.3±7.0	0.97
Body weight (㎏)		78.7±7.8	73.5±5.0	159.3±7.0	0.23
Body mass index (㎏/㎡)		30.6±1.7	29.4±2.9	159.3±7.0	0.50
WC (㎝)		98.40±5.71	97.59±6.54	97.93±6.22	0.84
WHR		0.93±0.04	0.96±0.08	0.95±0.07	0.47
TFA (㎠)		428.99±114.95	388.21±83.72	405.20±99.99	0.53
SFA (㎠)		278.21±78.41	277.13±73.84	277.58±75.78	0.98
VFA (㎠)		150.78±44.03	125.36±36.45	135.95±41.71	0.34

Values are expressed as mean±SD.
Note: Insulated needle = insulated needle + EA; Control = common needle + EA
Abbreviations: EA = electrical acupuncture; n = number; SD = standard deviation; WC = waist circumference; WHR = waist-to-hip ratio; TFA = total fat area; SFA = subcutaneous fat area; VFA = visceral fat area

* : *p*-value according to the Student's *t*-test

Table 2. Changes in waist circumference and waist-to-hip ratio between visit 1 and visit 11

	Visit 1 (baseline)	Visit 11 (10 Tx.)	Changes§	*p*-value†	Changes‖	*p*-value‡
WC (㎝)						
Insulated needle	98.40±5.71	93.10±5.61	5.30±2.55	0.01**	1.71	0.33
Control	97.59±6.54	94.00±6.05	3.59±2.64	0.02*		
WHR						
Insulated needle	0.93±0.04	0.92±0.05	0.01±0.04	0.66	0.60	0.59
Control	0.96±0.08	0.94±0.07	0.02±0.02	0.06		

Values are expressed as mean±SD.
Note: Insulated needle (n = 5); Control (n = 7)
Abbreviations: n = number; Tx. = Treatment; WC = waist circumference; WHR = waist-to-hip ratio

*: *p*-value 〈 0.05; **: *p*-value 〈 0.01,
†: *p*-value by paired *t*-test; ‡: *p*-value by Student's *t*-test
§: Changes = (visit 1 - visit 11); ‖: Changes = (insulated needle changes - control changes)

1) WC

WC decreased from 98.40 ± 5.71 ㎝ to 93.10 ± 5.61 ㎝ (5.30 ± 2.55 ㎝) in the IG, and from 97.59 ± 6.54 to 94.00 ± 6.05 ㎝ (3.59 ± 2.64 ㎝) in the CG. The WC of the IG decreased by approximately 1.71 cm compared to the CG, but there was no significant difference.

2) WHR

The WHR decreased from 0.93 ± 0.04 to 0.92 ± 0.05 (0.01 ± 0.04) in the IG, and from 0.96 ± 0.08 to 0.94 ± 0.06 ㎝ (0.02 ± 0.02) in the CG. The WHR of IG patients increased by approximately 0.01 compared to that of CG patients, but there was no significant difference.

2. Abdominal CT

The abdominal CTs of TFA, SFA, and VFA were recorded at the baseline and endpoint of the study (Table 3, Fig. 2).

Table 3. Changes in abdominal CT between visit 1 and visit 11

	Visit 1 (baseline)	Visit 11 (10 Tx.)	Changes§	*p*-value†	Changes‖	*p*-value‡
TFA (㎠)						
Insulated needle	428.99±114.95	421.28±122.62	7.71±26.00	0.59	29.22	0.93
Control	388.21±83.72	397.50±122.13	-9.29±75.86	1.0		
SFA (㎠)						
Insulated needle	278.21±78.41	272.64±88.10	5.57±24.87	0.68	0.85	0.99
Control	277.13±73.84	272.41±102.55	4.72±8.73	0.90		
VFA (㎠)						
Insulated needle	150.78±44.03	148.64±56.33	2.15±23.60	0.87	1.88	0.89
Control	125.36±36.45	125.09±35.20	0.27±7.49	1.0		

Values are expressed as mean ± SD.
Note: insulated needle (n = 5); control (n = 7)
Abbreviations: n = number; Tx. = treatment; TFA = total fat area; SFA = subcutaneous fat area; VFA = visceral fat area.
†: *p*-value by paired *t*-test or Wilcoxon signed rank test; ‡: *p*-value by Student's *t*-test or Mann Whitney U test,
§: Changes = (visit 1 - visit 11); ‖: Changes = (insulated needle changes - control changes).

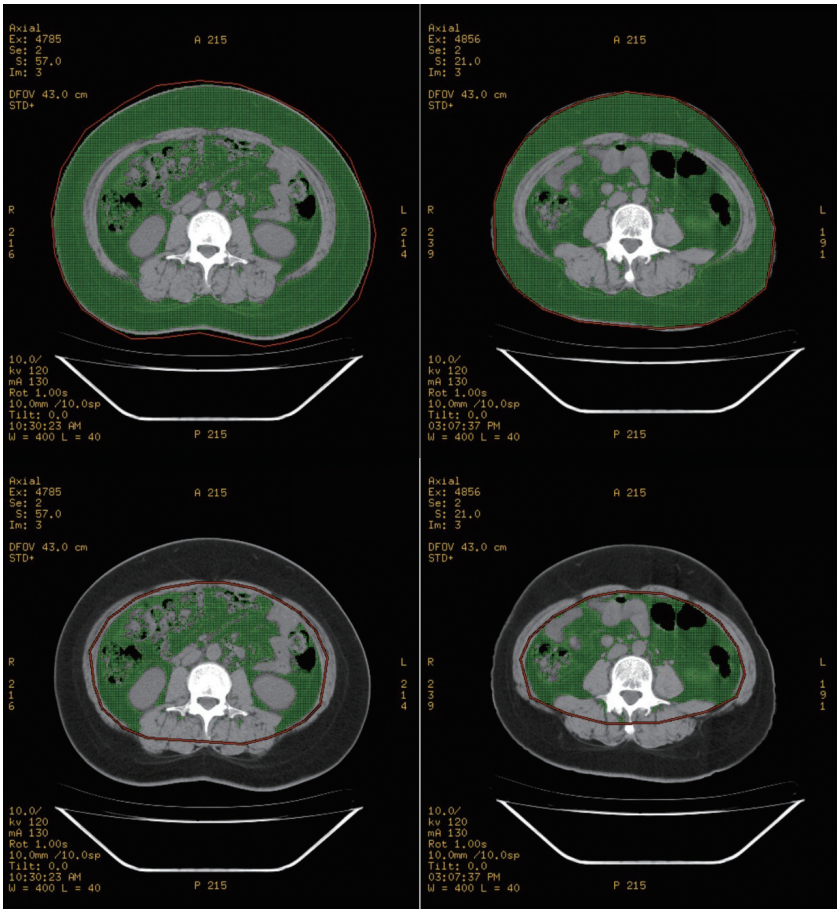

Fig. 2. Abdominal CT images before and after EA treatment

1_{st} line: Total fat area with red line and green shading (Left: before Tx., Right: after Tx.)
2_{nd} line: Visceral fat area with red line and green shading (Left: before Tx., Right: after Tx.)

1) TFA

TFA decreased by 7.71 ± 26.00 ㎠ in IG patients and increased by 9.29 ± 75.86 ㎠ in CG patients. The TFA of the IG decreased by approximately 17.00 ㎠ compared to that of the CG, but the difference was not significant.

2) SFA

The SFA decreased by 5.57 ± 24.87 ㎠ in the IG and decreased by 4.72 ± 8.73 ㎠ in the CG. TFA of the IG decreased by approximately 0.85 ㎠ compared to that of the CG, but the difference was not significant.

3) VFA

VFA decreased by 2.15 ± 23.60 ㎠ in the IG and increased by 0.27 ± 7.49 ㎠ in CG. TFA of the IG decreased by approximately 1.88 ㎠ compared to that of the CG, but the difference was not significant.

3. EA intensity

EA intensities between the IG and CG were compared. Means and standard deviations of EA intensity in the IG and CG were calculated for all 10 treatments. The mean value of EA intensity in the IG was 6.27 ± 0.41 Vp, and mean intensity in the CG was 4.92 ± 0.46 Vp. EA intensity in the IG was 1.35 Vp higher than that in the CG, and the difference was significant (Table 4).

Table 4. EA intensity between the insulated needle and control groups over 10 treatment sessions

	Insulated needle (n = 5)			Control (n = 7)			Differences in the groups§ (mean)
	Mean±SD	Min	Max	Mean±SD	Min	Max	
EA intensity (Vp)	6.27±0.41	4.75	10.00	4.92±0.46	3.13	6.88	1.35
p-value†							0.001***

Values are expressed as mean±SD.
Note: Insulated needle = insulated needle + EA; Control = common needle + EA
Abbreviations: EA = electrical acupuncture; n = number; SD = standard deviation; Min = minimum; Max = maximum

***: *p*-value 〈 0.001; †: *p*-value according to Student's *t*-test; §: Differences between insulated needle and control (Insulated needle - Control).

4. Adverse events

None of the participants experienced any adverse reaction during the study period, including adverse events or unexpected adverse events.

Ⅳ. Discussion

The number of obese patients is increasing globally, and the distribution of body fat and the total body fat mass increase in obese patients is considered clinically important. The prevalence of the disease varies according to the distribution or type of fat even if the obesity level is the same[15]. In particular, abdominal obesity is closely related to the risk of stroke, cardiovascular disease, and diabetes. Among these, the risk of complications and metabolic syndrome is increased in cases of visceral obesity, and a risk of insulin sensitivity in subcutaneous obesity has been reported[16,17]. Unlike in the West, in Korea, the prevalence of abdominal obesity is high even if the BMI is considered normal or overweight; thus, the clinical significance is more important[18].

In Oriental medicine, obesity has been treated using various modalities; EA is one of the most commonly used treatment methods, as reported in papers and clinical studies[5-7].

When an electric current flows through an acupuncture needle, it generates heat in accordance with Joule's law and consumes calories by allowing the fat cells to actively metabolize. The enhancement of microcirculation through vasodilation stimulates local fat decomposition, and the low frequency transmitted to the fat layer excites sympathetic nerves and secretes catecholamine. The lipolytic enzymes of adipocytes are strongly stimulated and decompose into glycerol and free fatty acids, and current stimulation affects the potential difference at the cell membrane level, promoting metabolism and lipolysis[12,19].

This was a preliminary study to prepare for further clinical trials; it investigated the efficacy and safety of symptom improvement by performing EA therapy with an insulated needle.

The insulated needles used in this study were coated with an insulator for approximately 1 cm. The epidermis, which most acutely feels pain, contacts the insulated coating, which reduces epidermal pain. Therefore, the needle can stimulate the fat layer more strongly than a common needle by applying a stronger current[13].

Studies of abdominal obesity suggest several views regarding appropriate outcome measures; most include WC or WHR, obesity index of Inbody composition, and abdominal CT. In this study, the outcome measures selected were WC, WHR, and

abdominal CT.

WC or WHR better reflect the distribution of abdominal fat, and WC is superior to WHR and BMI as a predictable, simple obesity index for abdominal visceral fat or metabolic abnormalities associated with obesity. It is also known that WC is highly associated with independent risk factors for cardiovascular disease[20,21]. There have been many studies comparing BMI, BFR, and other obesity indexes of Inbody composition. However, in the case of Inbody composition, the reproducibility of the measurement is somewhat low, body fat and fat-free mass are not equally reflected, and it is also an insufficient indicator of metabolic risk factors[7]. It can be seen that the above-mentioned obesity index reflects abdominal visceral fat and subcutaneous fat, but there is a limit to the ability of the index to reflect the degree of obesity and the state of the body. Therefore, it has been reported that it is necessary to observe changes through abdominal CT when studying treatments of abdominal obesity, especially visceral obesity[22]. Considering these reports, it was determined that the importance of WC and abdominal CT was more important than the Inbody composition analyzer to confirm the efficacy of treatment for abdominal obesity.

Observing the changes before and after 10 treatments, we determined that all outcome measures decreased in both groups. The WC of the IG decreased by 1.71 ㎝ and the WHR increased by 0.01 compared to the CG. Additionally, the TFA of abdominal CT decreased by 17.00 ㎠, SFA decreased by 0.85 ㎠, and VFA decreased by 1.88 ㎠ compared to the CG. Overall, there was no significant difference between the two groups.

Based on WC outcome, it was found that a sample size of 38 patients per group was required to satisfy the conditions of 5% significance and 80% power.

In all outcome measures except WHR, the reduction rate of IG was larger than that of CG. In this study, we believe that the strong electrical stimulation on eight abdominal acupoints was effective in terms of intensive treatment and local improvement of the abdomen.

EA intensity in the IG was approximately 1.35 Vp stronger than that in the CG. If the pain felt in the epidermis was equal, the insulated needle could provide a stronger electrical stimulus to the abdomen than a common needle. EA therapy with the insulated needle reduced the pain felt in the epidermis, provided strong stimulation to the abdomen, and generated more heat. It suggests that the effect of this study on abdominal obesity may be more satisfactory than that of conventional EA therapy.

No adverse events were observed. As this study was conducted on the assumption that a stronger electrical stimulation would generate more heat and provide additional reduction of the fat layer, there was concern about adverse reactions such as burns; fortunately, no adverse events occurred.

This trial had some limitations. As it was a pilot study, the small sample size limited the ability to detect significant differences between the two groups, and a small bias has a large effect on the results. As the small sample size significantly reduced the power, it was not possible to conclude that a statistically insignificant result indicated that the treatment was ineffective. Second, we think that the lack of time for treatment is another limitation. Obesity lowers the quality of life, causes various adult diseases and chronic diseases[23], and is chronic and difficult to treat. Considering that obesity is a chronic disease, it is necessary to extend the treatment period or increase the number of treatments.

As a result, the following points are the merits of this pilot study, and indicate the need for further clinical trials. First, it was confirmed that insulated needles can provide a stronger stimulus than a common needle, and the IG showed a higher tendency of fat reduction compared to CG. Second, no adverse events were observed in any of the patients during the entire study period, including those patients in which EA intensity was increased to a maximum. Third, we managed to maintain

blinding by using separate practitioners to perform acupuncture, record physical measurements, and control EA, and by making it impossible to distinguish between the packages of needles. Fourth, use of abdominal CT provided relatively objective evaluation criteria.

Based on this study, further clinical trials are necessary to demonstrate the safety and efficacy of improving symptoms of abdominal obesity in adults using insulated needles.

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