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Research Article

Auricular Acupuncture with Beads Supports Sustained Weight Loss

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Abstract

Obesity causes serious long-term health problems in people worldwide. Since the effect of dietary advice is possibly limited, weight loss can be a major challenge; therefore, additional weight control techniques may be beneficial. We conducted four experiments to evaluate if auricular acupuncture point stimulation with simple metal beads (AA) rather than the popular use of intradermal needle (DA) to stimulate auricle would support weight loss. In this retrospective study, weight change in Japanese women (aged 18 to 78) was confirmed based on changes in body composition after receiving auricular acupuncture with AA for three months. Furthermore, as a prospective study, we compared three groups—AA, DA, and non-intervention groups—to evaluate if AA, which is simpler than DA, can adjust hunger and reduce food intake and snacking (n = 58). We evaluated the effect of treatment using a questionnaire that recorded changes in weight, number of snacking time, and the amount of food intake (appetite suppression monitoring study). Furthermore, to evaluate changes in post-prandial blood glucose by AA stimulation by comparing groups, we switched AA and non-intervention periods every 24 h to measure changes in blood glucose by the AA. Finally, to evaluate long-term weight loss, we conducted a follow-up study 6 months after AA intervention. The rate of weight loss in subjects who received AA intervention (n = 1362) was -11.15%, confirming a significant decrease. By comparing people who underwent AA with people who did not, we demonstrated that AA reduces snacking between meals and improves satiety. Compared to the non-intervention group (42.75 (65.23) times), the AA (6.6 (10.53) times) and DA (7.93 (4.92) times) groups saw significant decrease in the number of snacking times (p = 0.04 and p = 0.05). The rate of weight loss was -3.57%, -2.74%, and -1.38% in the AA, DA, and untreated groups, respectively; thus, presenting a significant difference (p = 0.02). Glucose decreased in the intervention group, where a significant difference was observed for the median value at 90 and 105 min (p = 0.05, p = 0.007, respectively). Interestingly, weight loss by AA was maintained for six months after the end of treatment. AA had effects equivalent to or even better than DA while being safe and simple. Thus, it can effectively support weight loss and maintain body weight.

Keywords
Acupuncture; auricular; weight loss

1. Introduction

Obesity causes long-term health problems in people with modern lifestyles. Societies are facing an unprecedented increase in obesity, leading to serious problems such as visceral fat, fatty liver, diabetes, cancer, and cardiovascular diseases [1]. Prevention and treatment of obesity-related disorders include a low-calorie diet and regular exercise, but overweight individuals have extremely low compliance with exercise; in many cases, increased appetite caused by exercise cancels any positive impact [2, 3].

To solve these problems, we can identify attractive alternative strategies against obesity through acupuncture and alternative medicine, particularly the acupoint stimulation of the auricle. Auricular acupuncture (AA) is said to have existed since the 7th century. It has been considered that people can feel satiated through AA treatment of obesity based on clinical experiences — with a small amount of food, experience less hunger, and see a reduction in food consumption. A simpler method is acupuncture stimulation with beads. In Japan, this method of obesity treatment has over 20 years of history. Previous studies on AA have shown interesting results regarding weight loss in overweight young men [4], young adults [5], obese women [6], and healthy volunteers [7]. AA has been demonstrated to be more effective on weight loss than acupuncture [8]. This method was related to a reduction in the waist circumference of overweight women [9].

Increasing satiety signals reduces food consumption between meals and prevents excess weight gain. Leptin, a peptide hormone produced by adipocytes, is linked to satiety. Its effect on hypothalamic receptors might contribute to obesity by reducing hunger and activating satiety [10].

A previous study demonstrated activation of the satiety center by acupoint stimulation of the auricle [11].

Since the effect of dietary advice is limited, the development of acupoint stimulation of the auricle is useful as an effective complementary medicine for people struggling with obesity and overweight [12]. Unlike intradermal acupuncture (DA) treatment, which requires expert acupuncturists and experts of traditional Chinese medicine, our unique method, although not validated, can provide effective dietary support through simple auricular stimulation with beads with a diameter of 1.5 mm. Since it is attached to six points on the ear, no complex expert knowledge or skills are required. In this study, we observed changes in the body composition by a diet method that used beads for stimulation, conducted a follow-up study 6 months later, and examined improvements in the diet and sustainability of weight loss. This method could a more versatile treatment option. We compared hunger, satiety, and reduction in food consumption while comparing the effects of AA and DA with non-intervention. In this manner, we evaluated if the simpler AA could provide an equivalent effect as DD on the ears. Moreover, we measured blood glucose level based on AA and discussed the impact of the auricular acupuncture point stimulation on weight loss.

In our study, we provide effective dietary support through simple auricular stimulation with beads with a diameter of 1.5 mm, although the method has not yet been validated. Since t hese beads are attached to six points on the ear, it does not require complex expert knowledge or skill. To compare if stimulation by beads is as effective as DA as a more versatile treatment method, we added an intradermal group as a control. Moreover, by comparing the reduction in food intake, we examined the sustainability of improved and reduced food intake by auricular stimulation.

2. Materials and Methods

2.1 Auricular Acupuncture (AA) and Intradermal Acupuncture (DA) Point Selection

We selected 1) ear Shen Men, 2) esophagus, 3) cardia, 4) stomach, 5) lungs, and 6) hypothalamohypophyseal axis for acupoint stimulation of the auricle using 1.5 mm metallic beads or DA. These points were selected based on the results of previous studies. Figure 1 shows the stimulation points of the auricle.

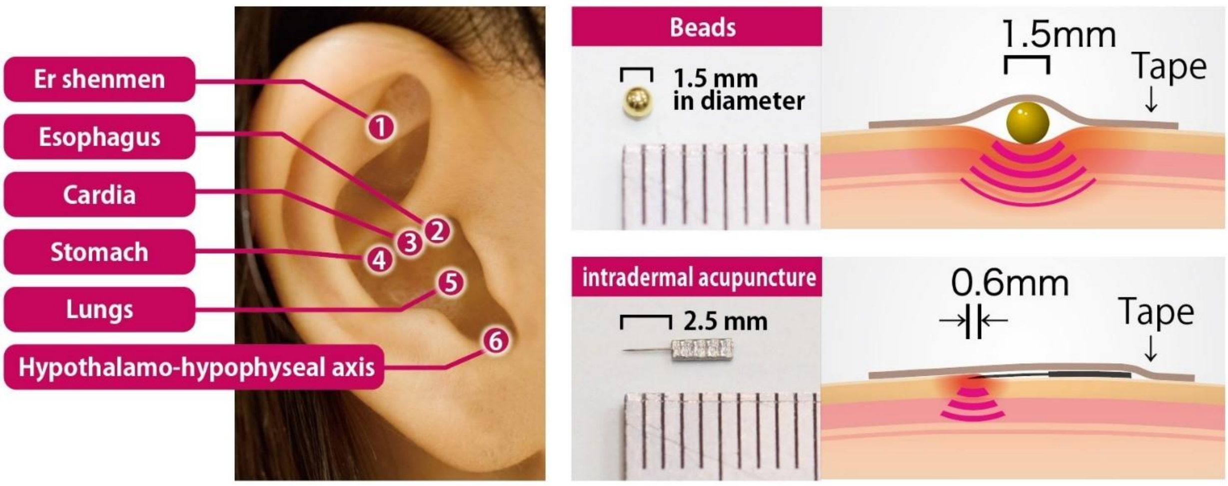

Figure 1 Locations and effects of the auricular acupuncture points.

1) Ear Shen Men [MA-TF1 Earshenmen] stimulation reduces anxieties and pain and improves mood [13]; thus, presenting the anti-anxiety effect and anti-inflammatory effect [14]. 2) Esophagus and 3) cardia [MA-IC7 Benmen] stimulation regulates appetite and reduces body weight [15] while increasing the sensitivity to salty taste [16]. 4) Esophagus [MA-IC6 Shidao] and stomach [stomach] were selected to stimulate above and below the cardia because the center point can enhance cardiac function. 5) Lung [MA-1C1 Fei] stimulation increases satiety, reduces hunger, and reduces food consumption, leading to weight loss [17] and increasing the sensitivity to salty taste [16]. 6) Hypothalamo-hypophyseal axis [MA-IC3 Neifenmi] stimulation stabilizes the entire endocrine system through the pituitary gland [13]. Codes (MA followed by numbers) are acupuncture points with WHO/WPRO numbers. The use of hunger points has been reported in a previous study on AA to treat overweight people [18]. This point is located on the outside of the ear, and we excluded it, assuming that it would interfere with the subjects' appearance in their daily lives. Anatomically, the afferent nerve is roughly divided into three types: 1) the auriculotemporal nerve [the trigeminal nerve (CN V) the mandibular nerve] dominated region; 2) the vagus nerve (X cranial nerve) auricular branch (parasympathetic nerve) dominated region, and 3) the greater occipital nerve (C3 and C4) dominated region [19]. Stimulation in this study was 1) for Ear Shen Men but 2) for other acupuncture points.

The 1.5 mm metallic beads for the treatment were attached to each acupuncture point of the auricle using a tape. During the measurement, subjects were constantly receiving the stimulus by the beads; however, we had subjects visit the hospital twice a week to replace the beads for hygienic reasons. In terms of stimulation by beads, although seeds could have been used, we used beads created by plating metallic beads for bearing because it allows uniform pressure on each point. Moreover, we could have used magnetic metallic beads; however, we avoided such beads to eliminate magnetism to make a comparison with intradermal needles. Bead replacement for auricular stimulation was performed by treatment staff who had been trained for bead replacement for at least 6 hours using a textbook showing the location of acupuncture points. We assumed that 'the innervation zone' has its impact rather than stimulating traditional 'acupuncture points'; therefore, we organized representative acupuncture points of the lungs into one. Acupuncture point stimulation through acupuncture and moxibustion requires expert knowledge and techniques. We adopted this method based on our clinical experience that a simple method of attaching 1.5-mm beads around acupuncture points suppresses hunger, and offers a wider range of stimulation than acupuncture points due to the distribution of innervation zones.

2.2 Retrospective Study on Subjects' Weight Change

This study was a retrospective analysis of data for 1362 Japanese women, between 18 and 78 years of age, who received a 3-month weight-loss program with AA. The data were collected between June 2006 and April 2017 and provided by the NPO Japan Association of Medical Body Contouring (JAMBC). The subjects under 17 years of age were excluded because the calculation method of body composition is different. The subjects had the metallic beads replaced twice a week when visiting the hospital, where they received dietary guidance. Dietary guidance provided at the hospital was different from hospital meals, and managing caloric intake and specifying items was difficult; thus, we used routine meals of each subject before the program participation as the reference. We did not reduce items but instead, we instructed subjects to eat half of each item while maintaining a balance. To prevent any nutritional deficit, the subjects were guided in using the nutritional supplement. As a management method for regulation, we had subjects to report their state during hospital visits. We analyzed the rate of weight loss in four groups divided by the degree of obesity and estimated the regression coefficient of the rate of weight loss using multivariate linear regression analysis.

Table 1 Baseline Characteristics of the subjects by BMI.

Factor	Normal n = 688	Overweight n = 505	Obesity I n = 147	Obesity II n = 22	P-value
Age Median [IQR]	40.00 [32.75, 49.00]	44.00 [34.00, 53.00]	44.00 [35.50, 53.50]	45.00 [30.00, 55.75]	<0.001
Weight (kg) Median [IQR]	56.60 [53.18, 60.00]	66.80 [62.90, 70.80]	78.30 [74.00, 82.60]	86.00 [84.00, 92.08]	<0.001
Body fat (%) Median [IQR]	33.40 [30.90, 35.60]	39.40 [37.40, 41.40]	45.10 [43.55, 46.35]	50.00 [48.10, 50.55]	<0.001
Fat mass (kg) Median [IQR]	18.90 [16.60, 21.20]	26.20 [23.60, 29.10]	35.00 [32.65, 37.45]	42.80 [39.60, 46.40]	<0.001
Fat-Free Mass (kg) Median [IQR]	37.70 [35.80,39.70]	40.40 [38.60, 42.30]	42.90 [40.80, 45.27]	45.20 [42.20, 47.18]	<0.001
Muscle mass (kg) Median [IQR]	35.60 [33.80, 37.40]	38.00 [36.40, 39.80]	40.30 [38.35, 42.40]	42.40 [39.70, 44.18]	<0.001
Total Body Water (kg) Median [IQR]	26.40 [24.90, 28.20]	29.70 [28.00, 31.30]	32.70 [30.60, 34.80]	33.60 [31.50, 36.00]	<0.001
Basal Metabolic Rate (kcal) Median [IQR]	1130.00 [1073.75, 1191.25]	1246.00 [1171.00, 1302.00]	1341.00 [1280.50, 1437.00]	1445.50 [1361.75, 1527.00]	<0.001
BMI Median [IQR]	23.00 [21.80, 23.92]	27.00 [25.90, 28.20]	31.60 [30.65, 32.80]	36.30 [35.52, 37.40]	<0.001

*IQR =Inter Quantile Range

2.3 Monitoring of Food Consumption

In this prospective study, we assumed that auricular stimulation suppresses appetite and helps will power. We aimed to demonstrate the impact of auricular stimulation on desire and satiety.

We recruited student volunteers from Kinki Medical College. The target number of subjects in each group was 23, and subjects were selected such that age and sex distribution would be as even as possible between the groups. In terms of sex, considering the applicability of the result and ethics of the burden put on by the study, we selected to have half the number of subjects to be male. The subjects were asked to fill out a questionnaire on food consumption, hunger, and satiety during the study period, and the changes in body composition were measured to obtain the objective measurement of the weight reduction effect.

Furthermore, we aimed to examine the difference in the frequency of snacking in the treatment groups with two types of auricular stimulation compared to the no-treatment group. The subjects were then assigned to 1) acupoint stimulation of the auricle by metallic beads (AA), 2) auricular stimulation by intradermal needle (DA), and 3) no-treatment. The caloric intake was reduced to 50% that of the pre-study level by the same method and was measured for 30 days. No other dietary restriction was imposed. Although double-blind testing is the gold standard, considering the challenges in placebo, we chose to proceed without blinding. In a previous study, multiple efforts were made to create a placebo effect by changing the current velocity and using non-acupuncture points, which did not show desirable results [19]. However, because auricular stimulation with beads is well known, it was assumed that blindness by therapy providers and subjects cannot be assured for AA or DA. With 30 days of reduced food intake, when subjects assigned in the non-intervention group found that their motivation in the study has been lost. It was thought from an ethical viewpoint that it is not appropriate for the subjects in the non-intervention group to undergo reduced food intake, as it might cause physical stress. Therefore, this study was not blinded, as subjects understood that they would be registering to treatment groups. After receiving consent, the assignee randomly assigned the subjects from the applicant list to participate in the study, considering that the ages of each group would be uniform between sexes. These subjects ate three main meals, that is, breakfast, lunch, and dinner per day. All subjects were asked to record the number of times they snacked between meals, satiety, hunger, and the amount of food consumption every 24 h during the measurement period. Both AA and DA were exchanged twice a week in the treatment group. Body composition was measured at the same timing. The no-treatment group was asked to visit the hospital at the same frequency, and their body composition was measured.

Table 2 Questionnaire on eating habits and satiety. This checklist was filled every day by subjects.

Food intake	Hunger	Satiety
Increased	Feel strongly hungry	Feel strongly full
Unchanged	Feel hungry	Feel full
Slightly reduced		Feel a little full
Less than 2/3 of the previous amount	Hardly feel	Do not feel full
Less than 1/2 of the previous amount		

2.4 Measurement of Blood Glucose Levels by Auricular Acupuncture

This prospective study aimed to measure changes in blood glucose level by acupoint stimulation of the auricle. We recruited male and female volunteers of 18–59 years of age at Kinki Medical college. The target sample number was set at 20. To observe the impact of AA stimulation, we did not provide any specific instruction on the method of dieting regardless of subjects' desire to lose weight. For the same subject, we switched 24-h measurement of intervention and no intervention (recorded at a 15-min interval) every day and took measurement three times daily for six days. No specific restriction was imposed on food consumption or any other lifestyle habits.

For evaluation, in addition to comparing overall measurements, we compared measured values 2 h after the meal. Since we did not place restrictions, such as standardization of food, it was assumed that there is a notable difference in food consumption, time, and alcohol consumption between breakfast and dinner; thus, we compared the glucose level after lunch, when the dietary habit was relatively stable. In order to compare glucose level when not eating, we compared the data measured when not eating, excluding three main meals and 2 h after these three meals between AA and no intervention. Since it was a comparison of the same person, and the subject was aware of intervention based on the presence of beads, the comparison could not be blinded. Rather, AA and no intervention were switched every day, and evaluation was made based on repetitive data. For measurement, a flash glucose monitoring system (FreeStyle Libre, Abbott: flash glucose monitoring measurement range of 40–500 mg/dL, the accuracy of ±15 mg/dL (±0.83 mmol/L), and ±20% of the reference value) was used.

2.5 Analysis of Weight and Body Composition

To examine changes in weight after the acupuncture point stimulation, we recruited volunteers from the retrospective study on subjects' weight change (subjects who had the treatment less than six months or longer than six months were excluded). In order to measure body weight and composition, we used dual-frequency body composition analyzer DC-430-A (TANITA Corporation).

The measurement method was the dual-frequency BIA method where the weak high-frequency alternating current was applied, and body composition was calculated based on the electric resistance. Measurement frequencies were 6.25 kHz/50 kHz, and the current was 90 µA or below.

2.6 Statistical Analysis

The R software version 3.6.0 was used for data analysis. In the retrospective study on subjects' weight change under Section 2.2, repeated-measures ANOVA was performed. Then, Paired t-test and multivariate linear regression analysis were performed.

For the three-group trial described in Section 2.3, we performed the Kruskal–Wallis rank-sum test and then used the Welch two-sample t-test to avoid problems associated with multiple tests for body composition measurements. For the questionnaire data analysis, we used chi-square test.

In the blood glucose tests under Section 2.4, we performed the Friedman rank-sum test and then used the Wilcoxon signed-rank test for intergroup comparison.

A paired t-test was used for the rebound test described in Section 2.5. Significance level was $P < 0.05$.

This study only used existing anonymized data that cannot be linked.

3. Results

3.1 Changes in Body Composition by AA

The data collected from the weight loss program by auricular acupuncture (n = 1362) had an overall rate of weight loss of -11.15% (5.73). Moreover, we performed an analysis in groups separated by the obesity level based on BMI and reported that the normal group (n = 688), overweight group (n = 505), obese I group (n = 147), and obese II group (n = 22) had a rate of weight loss of -10.10% (5.65), -12.04% (5.59), -13.01% (5.61), and -10.95% (5.64), respectively. The regression coefficient of the rate of weight loss demonstrated that each time BMI increased by 1, a -0.2% weight loss occurred with a significant difference.

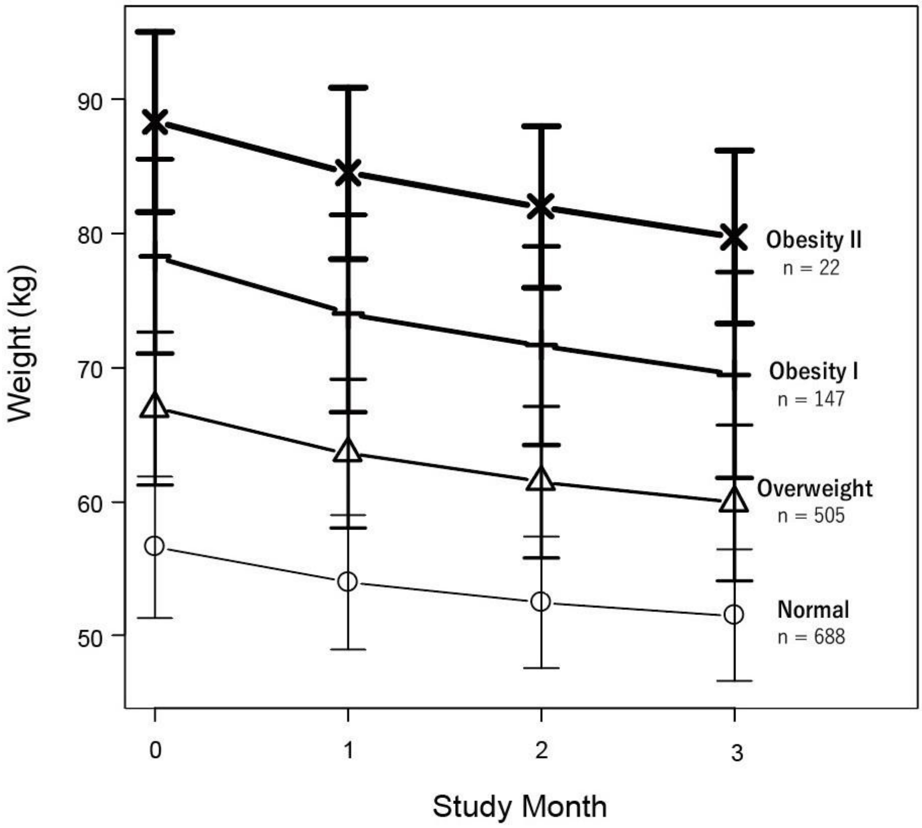

Figure 2 Changes in body weight in groups separated by the degree of obesity based on BMI over three months.

Significant difference in repeated measures ANOVA (P < 0.001).

Table 3 Age, baseline body weight, and estimated rate of weight loss adjusted to BMI.

Variable	Estimate (95% CI)	P-value
Age	0.02 (0 – 0.05)	0.079

BMI	-0.24 (-0.42 – -0.05)	0.012
Weight (kg)	-0.05 (-0.11 – 0.02)	0.19

3.2 Comparison of AA and DA on Body Weight Loss

After the recruitment, 58 men and women of 21–60 years of age participated in the study (23 in the AA group, 17 in the DA group, and 18 in the no-treatment group).

Table 4 Patients' Baseline Characteristics in three-group comparison trial for the AA group, DD group, and no-treatment group.

Factor	Group	AA n = 23	DA n = 17	No treatment n = 18	P-value
Sex (%) No.(%)	Female Male	11 (47.8) 12 (52.2)	9 (52.9) 8 (47.1)	9 (50.0) 9 (50.0)	0.95
Age Median [IQR]		39.00 [34.00, 47.00]	36.00 [26.00, 42.00]	41.00 [35.25, 46.50]	0.108
BMI Median [IQR]		27.20 [24.75, 31.50]	26.70 [25.20, 29.00]	23.25 [20.88, 24.98]	0.001
Body weight (kg) Median [IQR]		71.60 [64.20, 92.75]	76.10 [56.10, 80.00]	64.80 [58.52, 67.83]	0.049

*IQR = Inter Quantile Range

We conducted the Kruskal–Wallis rank-sum test on the AA group, DA group, and non-intervention group and reported a significant difference in the rate of weight loss (P = 0.02). Thus, we compared the baseline and the final weight of each group through the paired t-test. The result demonstrated that the weight decrease for AA, DA, and no-treatment groups was 78.81 kg (18.08) → 76.10 kg (17.18), 71.36 kg (14.95) → 70.91 kg (14.58), and 64.7 kg (0.12) → 62.59 kg (11.48), respectively; thus, presenting significant difference in each group (P < 0.001, P < 0.001, and P = 0.05, respectively).

When we compared to the AA group and non-intervention group, a significant decrease in body weight was observed in the AA group with -3.39% (2.26) and the non-intervention group with –1.52% (1.71) (P = 0.004). The difference between the DA group and non-intervention group was -2.34% (1.79), which was not statistically significant (P＝0.18). There was no significant difference between the AA group and the DA group (P = 0.11).

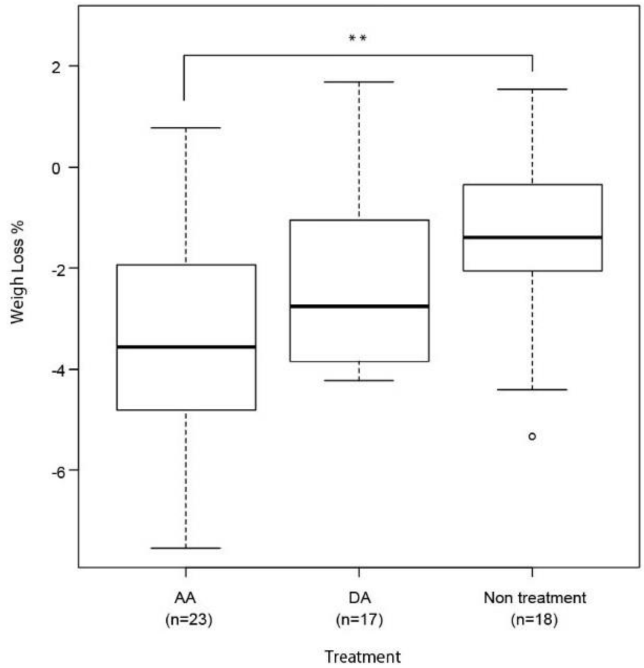

Figure 3 Median of weight loss in each treatment group after 30 days, expressed in percentage of the initial weight. ** = P < 0.01, ° = outliers.

In order to compare the number of snacking during food consumption reduction over 30 days, certain subjects did not respond to necessary questions on the questionnaire. Therefore, a comparison was made between 23 subjects in the AA group, 14 subjects in the DA group, and 16 subjects in the no-treatment group.

Since the Kruskal–Wallis rank-sum test confirmed a significant difference (P = 0.001), we compared with the non-intervention group 42.75 (65.23 times) and reported that it was 6.64 (10.54 times) (P = 0.04) and 7.93 (4.92 times) (P = 0.05) for the AA and DA groups, respectively.

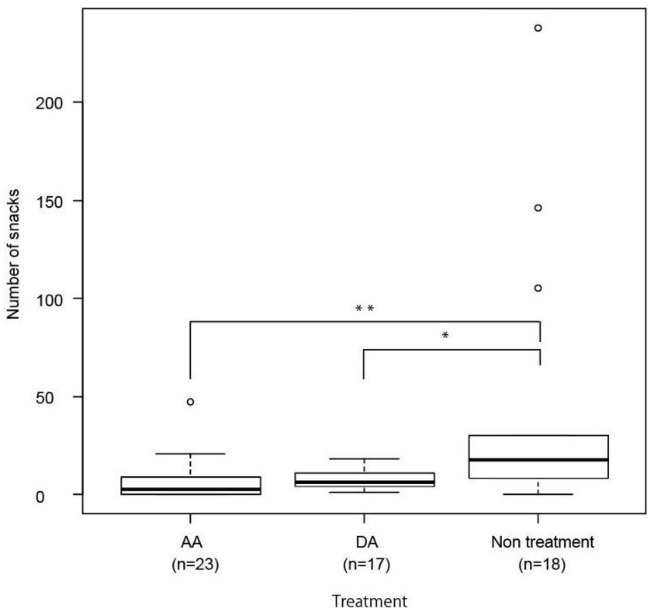

Figure 4 Intergroup comparison of the number of snacks. *=P<0.05, **=P<0.01, ° = outliers.

3.3 Effects of AA, DA, and no Treatment on Satiety

It was observed in the questionnaire that one person missed answers in both DA and no-treatment groups. Therefore, the analysis was performed with 23 subjects in the AA group, 16 subjects in the DA group, and 17 subjects in the no-treatment group. After 30 days of treatment, those who answered with 'able to reduce in half": 'unchanged' + 'increased' regarding the amount of food consumed during the measurement period were 51%:7% for the AA group, 33.1%:16% for the DA group, and 18.4%:29% for the no-treatment group. In terms of hunger, those who answered 'hardly felt hungry': 'strongly felt hunger' were 45.6%:7% for the AA group, 36.5%:8.5% for the DA group, and 20.7%:26.5% for the no-treatment group. For satiety, those who answered 'did not feel full': 'felt strong fullness' were 5.5%:11.7% for the AA group and 16.6%:7.7% for the DA group, which does not confirm independence in any item (P < 0.001).

Table 5 Questionnaire response regarding food amount.

Group	Less than 1/2 of the previous amount	Less than 2/3 of the previous amount	Slightly reduced	Unchanged	Increased
AA Frequencyr (%) dij	342 (51.5) 14.3 **	146 (22) –2.1 *	130 (19.6) –6.4 **	37 (5.6) –18.2 **	9 (1.4) –22.4 **
DA Frequencyr (%) dij	155 (33.1) –2.2 *	152 (32.5) 9.9 **	86 (18.4) –6.2 **	57 (12.2) 0.1	18 (3.8) –1.4
No treatment Frequencyr (%) dij	91 (18.4) –13.1 **	83 (16.8) –7.6 **	177 (35.8) 12.9 **	104 (21.1) 19.5 **	39 (7.9) 25.2 **

dij = Adjusted residual, * P < 0.05, ** P < 0.01.

Table 6 Questionnaire responses on the sensation of hunger.

Group	Hardly feel	Feel hungry	Feel strongly
AA frequencyr (%) dij	308 (45.6) 9.6 **	321 (47.5) –2.5 *	47 (7) –16.2 **
DA frequencyr (%) dij	171 (36.5) 0.7	258 (55) 1.9	40 (8.5) –9.1 **
No treatment frequencyr (%) dij	100 (20.7) –11 **	255 (52.8) 0.9	128 (26.5) 26.4 **

dij = Adjusted residual, * P < 0.05, ** P < 0.01.

Table 7 Questionnaire responses on the sensation of satiety.

Group	Do not feel full	Feel a little full	Feel full	Feel strongly full
AA frequencyr (%) dij	37 (5.5) –20.6 **	263 (39.3) 1.9	291 (43.5) 2.5 *	78 (11.7) 15.2 **
DA frequencyr (%) dij	75 (16.6) 4.5 **	172 (38) 0.5	171 (37.7) –1.8	35 (7.7) –1.1
No treatment frequencyr (%) dij	113 (23.5) 17.8 **	163 (34) –2.4 *	188 (39.2) –1	16 (3.3) –15.4 **

dij = Adjusted residual, * $P < 0.05$, ** $P < 0.01$.

3.4 Effects of AA on post-prandial glucose levels

In total, 13 men and women who were 19–52 years old participated in the study. Among subjects, two showed abnormalities in the measurement device; thus, the analysis was performed with 13 subjects.

Table 8 Patients Baseline Characteristics in a follow-up survey six months after the end of the treatment.

Factor	Overall n = 13
Sex No. (%)	Female 3 (23.1) Male 10 (76.9)
Age Median [IOR]	27.00 [24.00, 36.00]
BMI Median [IOR]	22.60 [20.60, 25.30]
Weight (kg) Median [IQR]	60.00 [59.30, 77.10]

Median [IQR], *IQR = Inter Quantile Range

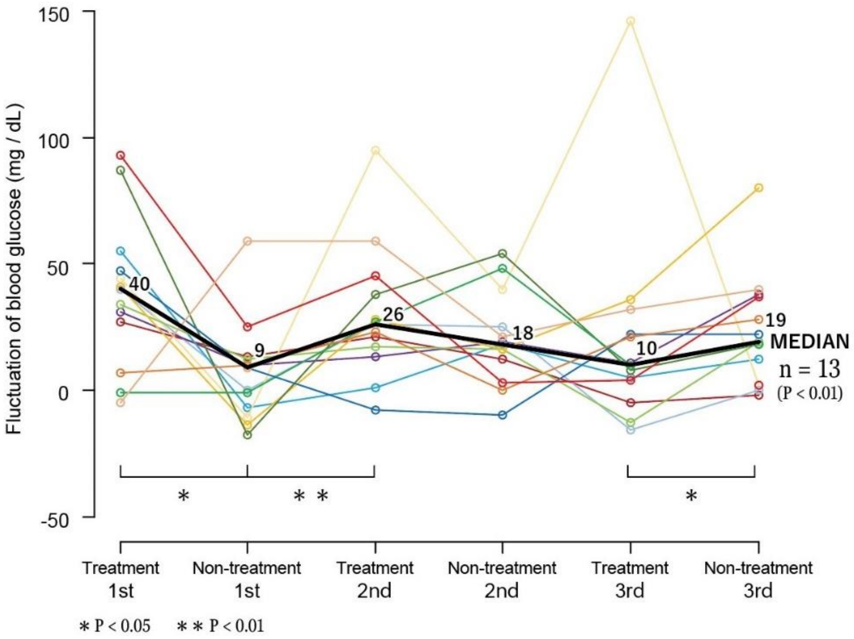

Figure 5 Changes in post-prandial blood glucose by the bead treatment (after 105 min).

The glucose level for non-intervention and intervention groups was 100.62 mg/dL; however, it was 98.48 mg/dL for the intervention group. We compared the post-prandial changes for every 15 min till 2 h after lunch based on the treatment and confirmed a significant difference for 90 min and 105 min (P = 0.05 and P = 0.007, respectively). Then, we examined the changes at 105 min and reported that it was +40 → +9 mg/dL after the first treatment, +9 → +26 mg/dL after the second non-treatment, and +10 → +19 mg/dL after the third non-treatment; thus, confirming significant differences (P = 0.03, 0.01, and 0.04, respectively). Moreover, in a comparison that excluded data from 2 h from the start breakfast, lunch, and dinner, i.e., non-meal times, blood glucose was 96.55 mg/dL for the non-intervention group and 94.75 mg/dL for the intervention group where the latter had a significantly lower value (P < 0.001).

3.5 Weight and Body Composition Six Months Post Treatment

Among the 1,362 subjects of the retrospective study on subjects' weight change, we were able to obtain measurement data from 57 subjects after six months.

Table 9 Baseline Characteristics of the Patients.

Factor	Overall n = 57
Sex (%)	57 (100.0)
Age Median [IOR]	48.00 [39.75, 53.75]
BMI Median [IOR]	24.60 [23.40, 26.70]

Weight (kg) Median [IQR]	62.20 [57.10, 67.50]

Median [IQR], *IQR = Inter Quantile Range.

The result demonstrated that no significant difference was present in body fat percentage, basal metabolic rate, muscle mass, and fat mass between the end of the study and six months after the treatment where the weight loss effect was maintained six months later, and reduction in both weight (-0.8) and BMI (-0.3) was significant. The change in the body weight six months after the treatment was -1.3 ±4.2 kg (P < 0.01); however, the rate of weight change between the baseline and six months after the end of the treatment was -11.1% ±8.8% (P < 0.01).

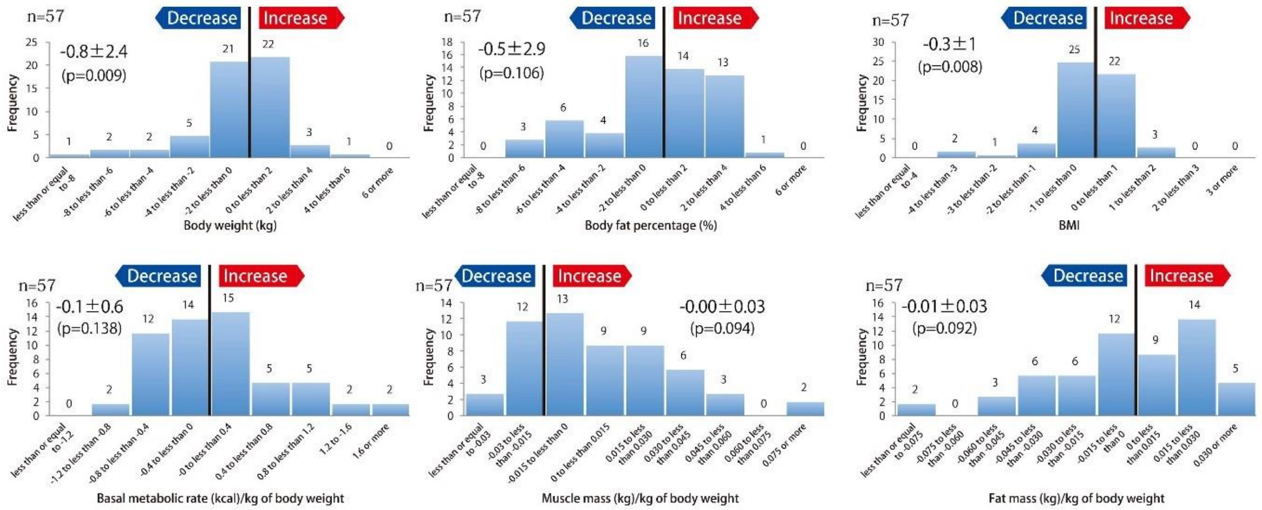

Figure 6 Frequency distribution of changes in body weight and body compositions six months after the treatment.

Figure 6 shows the change in the body composition of subjects (n = 57) from the end of the treatment to six months after the end of the treatment as frequency distribution. The boundary between reduction and increase is shown with a solid line. Each measured item was analyzed with the paired t-test.

4. Discussion

Interestingly, in the retrospective study of weight change, the subjects were mainly women. This can be explained as it is an observational study and most subjects who preferred to diet were women.

The goal for weight loss programs is usually -10% (average -8%) of the body weight in six months [20]. In a study that summarized acupuncture to manage obesity [21], compared to sham needling, there was a weight loss of -1.54 kg; moreover, compared to diet and exercise, there was a weight loss of -3.27 kg. However, the data of the weight loss program by AA that we collected (n = 1362) showed an overall weight loss of -11.15% (5.73) in three months. For the obesity I group, a weight loss of -13.01% (5.61) occurred, which was notably higher than the average.

However, data used in this study are taken from an observation of a single group, and reduction in food intake was a direct result of being asked to reduce food consumption by half; thus, there was no quantitative observation of food intake reduction by will power. Performing repeat analysis, such as crossover test, incorporating a research design that evaluates changes between individuals, and observing long-term changes would be effective in solving this problem.

In the appetite suppression monitoring study, AA demonstrated the most weight loss rate and the least frequency snacking between meals. Beads have a wider range of stimulation than intradermal needles. Unlike leaving intradermal needles in situ, when those in the AA group felt stress from hunger, additional stimulation was applied, such as application of pressure at the treatment sites. Thus, these additional stimulations and psychological peace might amplify the amount of stimulation. However, with an intradermal needle, no additional stimulation is caused, as ears have few voluntary muscles, unlike joints. The stimulation effect might decrease as the subject becomes accustomed to stimulation. Even without acupuncture and moxibustion stimulation that requires a special technique, AA can sufficiently reduce hunger, among other changes. By comparing the snacking tendency and hunger when the food consumption was reduced to half in this study, we confirmed that there is a conscious reduction in food consumption. The use of false acupoints with the innervation zone in the control group would be questionable because it may cause adverse effects. Moreover, in this trial, we concluded that there would be a reduction effect on hunger; however, because psychological elements of subjects who strongly wish for weight loss have a notable impact on the result, for non-blind trial or when blindness is broken, weight reduction effect might drastically decrease, and reduced motivation might have a notable impact on the result. Since the study was not blind, the challenge is removing the bias by making the acupuncture treatments such as AA and DA blind and knowing the difference in the methods.

The result of the study to measure changes in blood glucose by AA confirmed that AA suppresses an increase in blood glucose. This suppression effect was most prominent between 90 and 105 min after the start of a meal. The suppression effect on blood glucose was clear at the non-meal time as well, indicating that AA delays increase in blood glucose and potentially suppresses insulin secretion.

Since it is well known that the satiety center is located in the ventromedial hypothalamus and the feeding center is located outside the hypothalamus, we assumed that AA reduces appetite through the medial hypothalamus [17]. A previous study on obese rats showed that electric stimulation of the low resistance region of the ear reached the hypothalamus through the auricular branch of the vagus nerve, stimulating neurons associated with feeding adjustment. Rats that are not very obese experienced the promotion of leptin production in peripheral white adipose tissue, and binding with leptin receptors (Ob-R) in the peripheral and central nervous system regulates feeding [22]. In this study, we proposed that the stimulation of the auricular acupoints with beads leads to the expression of leptins from adipocytes to the vagus nerve. We attempted to make repetitive measurements using the crossover test method because of the difficulty of blinding AA; however, by having a longer duration of measurement for each method, mode detailed data can be obtained.

The retrospective study on subjects' weight change confirmed the result of a previous study on the impact of acupuncture on the ear on body weight [23]. Furthermore, using the follow-up study, six months after the AA intervention, we clearly showed a statistically significant difference in subjects whose weight continued to drop even after the treatment had ended. This may be caused by improved body type because of change in diet and resetting of the point comprising leptin sensitivity at the satiety center as a result of AA. However (though this is true for all studies), subjects are all Japanese women, and a study on multiple races would be desired.

In conclusion, AA might offer a method of weight reduction, in addition to diet and exercise. We demonstrated that even a simple method of adhering beads to the auricle can offer an effect equivalent or better than intradermal needles that require a high level of knowledge and technique. AA has been demonstrated to reduce hunger caused by dietary restrictions to lose weight and help consciously control food consumption.

From the perspective of weight loss maintenance upon the end of the program, AA might improve lifestyle-related diseases.

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Author Contributions

Takahiro Fujimoto conceived and planned the experiments. Hidetake Kobayashi and Takeshi Hataoka planned and supervised all the experiments. Takeshi Hataoka also produced formats for all the experiments and was responsible for their distribution, collection, data input for tabulation, and preparation of figures and tables. Takahiro Fujimoto and Takeshi Hataoka were responsible for statistical analysis. Takahiro Fujimoto took the lead in writing the manuscript. Hidetake Kobayashi, Kazuo Taniguchi, and Keisuke Miura contributed to the interpretation of the results. All authors provided critical feedback and helped shape the research, analysis, and manuscript.

Competing Interests

The authors have declared that no competing interests exist.

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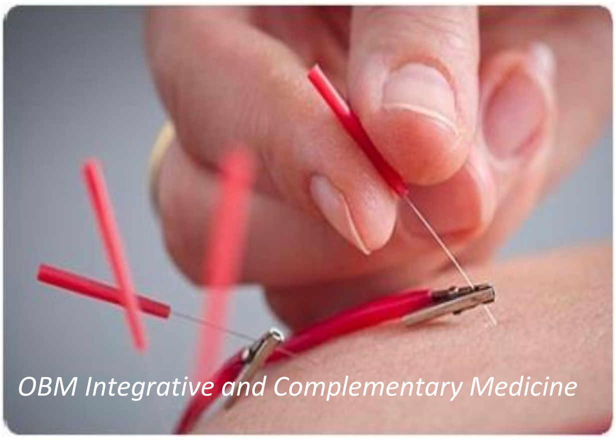
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