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The effects of auricular electroacupuncture on obesity in female patients — A prospective randomized placebo-controlled pilot study

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KEYWORDS
Auricular acupuncture;
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Summary
Background: Obesity is a chronic condition related to serious morbidity and mortality of increasing incidence and prevalence. Several studies show a significantly higher weight loss with acupuncture treatment. This is the first prospective, randomized, double-blinded study, testing the effects of auricular electroacupuncture on weight loss in obese female patients.
Methods: 56 female obese patients (age > 18, Body Mass Index, BMI > 25) were randomized to receive either auricular acupuncture with electrical stimulation with a P-Stim® device (verum group, $n = 28$) or placebo treatment with a P-Stim® dummy ($n = 28$) for four days. Three auricular acupuncture points were chosen (hunger 18, stomach 87 and colon 91). The treatment was performed once a week for a period of six weeks. A follow-up visit was performed after 4 weeks. At each visit body weight, BMI (Body Mass Index) and body fat were measured.
Results: Relative reduction of body weight was significantly greater in the verum group (−3.73%; CI = −4.70 to −2.76) than in the placebo group (−0.70%; CI = −1.57 to +0.16; $p < 0.001$) In addition we also observed a significant reduction of BMI ($p < 0.001$) in the verum group (−3.62%; CI = −4.39 to −2.84) compared to placebo (−0.82%; CI = −1.55 to −0.10; $p < 0.001$). No patient reported side effects related to acupuncture.
Conclusion: In conclusion electrical auricular acupuncture could be a safe, additive, non-pharmacological treatment in obese patients.

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Introduction

Obesity is a chronic condition that is related to serious morbidity and mortality of increasing incidence and prevalence. Excess bodyweight is associated with elevated health risks, such as cardiovascular and cerebrovascular diseases as well as diabetes.[1] The Body Mass Index (BMI) is generally accepted as classification of obesity. According to WHO (World Health Organization) guidelines, a BMI of >25.00 kg/m^2 is considered as overweight, 25—29.99 kg m^{-2} as preobese and over 30.00 kg^{-2} as obese. As the incidence of obesity increases new therapies to improve weight management are looked for.

Especially the effects of complementary medicine on obesity are under closer investigation. Recent studies showed a positive effect of acupuncture on appetite, metabolism, intestinal motility and emotional factors such as stress. In addition, it can increase neural activity in the ventromedial nuclei of hypothalamus, the tone of the smooth muscle of the stomach and levels of encephalin and serotonin in the plasma and brain tissue.[2,3] The clinical effects of acupuncture on obesity have been summarized by several meta-analyses in[4,5] suggesting a positive effect of acupuncture on weight loss in obese patients. The authors however criticized a lack of randomized placebo-controlled trials on this topic.

The aim of this study was to investigate if auricular electroacupuncture combined with moderate diet recommendations based on Traditional Chinese Medicine (TCM) can result in bodyweight reduction in obese female patients when compared to a placebo acupuncture treatment. It is the first study that uses a P-Stim® auricular electroacupuncture device in the indication of weight loss.

Materials and methods

Study design and patient selection criteria

This prospective randomized placebo-controlled clinical trial was conducted at the Department of Special Anesthesia and Pain Management at the Medical University of Vienna (AKH Vienna). The study was approved by the local ethics committee according to the declaration of Helsinki. All participants were healthy, obese women (age > 18, BMI > 25) who had no prior experience with acupuncture or auricular acupuncture. Further exclusion criteria were pregnancy, allergy against material (metal of needles or patch), bleeding disorders, anticoagulation, implanted pacemaker or implantable cardioverter defibrillators.

Fifty six patients were randomized in two groups by a computer-generated randomization table. Randomization of patients was stratified with respect to age (<50 or ≥50 years) and BMI (<30 or ≥30 kg/m^2). Patients in the verum group (n = 28) received auricular acupuncture with electrical stimulation using a P-Stim®-electroacupuncture device (Biegler GmbH. Allhangstrasse 18a, 3001 Mauerbach, Austria) at the auricular acupuncture points hunger 18, stomach 87 and colon 91. The P-Stim®-device consists of a battery-powered stimulator worn behind the ear, which was connected to sterile, single use permanent needles (titanium, 27 gauge, length 3 mm). Electrical stimulation consisted of biphasic constant current (2 mA) pulses of 1 Hz every 3 s (3 h of stimulation followed by a pause of 3 h to avoid development of tolerance).

In the placebo group (n = 28) a P-Stim® dummy was used. The dummy-device had no power supply and had been grinded to leave only metal plates.

An electrical conductance device meter (multipoint selection pen™, Biegler GmbH, Mauerbach, Austria) which measures skin resistance, was used to identify acupuncture points in both groups.

Patients received auricular electro acupuncture or placebo for 4 days (24 h) per week during a period of 6 weeks. All patients received their acupuncture needles between 07:00 and 11:00 a.m. A follow-up was performed 4 weeks after the last treatment.

At each visit, body weight, BMI and body fat were measured. The Body Impedance Analysis (BIA formulas) from Schindler and Ludvik[6] were used for the calculation of the FFM (fat free mass) and BCM (body cell mass).

Diet according to TCM guidelines

At the first visit all patients received a dietary consultation following guidelines according to Traditional Chinese Medicine (TCM). Patients should eat regularly (e.g. 3 times a day), avoid cold and raw food, white sugar and fast food and should reduce intake of dairy products.

Statistical analysis

The study was planned to detect a group difference of 4 percent points with respect to relative weight change between start and end of treatment. Since the variability of relative weight change was unknown an a priori sample size of 60 patients was targeted, a number seen in previous studies. After the data of 40 patients were available the standard deviation was estimated (without performing an interim analysis of the group comparison) in order to obtain a more reliable sample size estimate (''half-sampling''). Based on this new sample size further patients were finally recruited for the study.

In the planning phase of the study the relative reduction of body weight between baseline and end of treatment was selected as the primary outcome variable. Relative reduction of body weight between baseline or end of treatment and follow-up as well as relative reduction in BMI and body fat were defined as secondary outcome variables.

Due to asymmetric distribution of some of the variables, continuous baseline variables are presented as group specific medians and quartiles and compared between groups using Wilcoxon's rank-sum test. Relative weight changes are calculated such that negative signs represent reduction (e.g., of weight). Missing values are imputed using multiple imputation (''proc MI'' of SAS with ''monotone reg'' statement and 200 imputations). Boxplots of relative weight changes use the full data set, i.e. available and averaged imputed values. Models with imputed values are analyzed using Rubin's rules as implemented in proc mianalyze of SAS. ANOVA models are used to compare relative changes between groups, age and baseline BMI are used as co-variables for group adjustment. Results of univariate