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Aural Stimulation as Add-on to Diet for Weight Loss: A Preliminary Clinical Study

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Abstract

We investigated the efficacy of bilateral electric Aural stimulation in combination with hypocaloric or high-protein diet in 40 overweighted and obese healthy volunteer patients (4 groups of 10 individuals each) *vs.* diet alone. After 2 months of simultaneous treatment with electric stimulation and diet there was an average weight loss of 7.07 kg in the hypocaloric group and 9.48 kg in the high-protein one, whereas an average weight loss of 5.9 kg and 7.17 kg were observed with hypocaloric and high-protein diet alone, respectively. These results suggest that bilateral aural stimulation can help increase the weight loss in patients when used in combination with high-protein diet. Thus weight loss induced by nutritional strategies can safely and effectively be enhanced by neuro-reflexological aural stimulation.

Keywords: Weight loss; Aural stimulation; Diet; Hypocaloric; Protein

Introduction

Obesity is an epidemic disease affecting the population worldwide. Obesity is commonly defined as body index mass (BMI=weight (in kg) divided by height (in metres) squared) of 30 kg/m^2 or higher. On the other hand being overweight is defined by a BMI of between 25 – 29.9 kg/m^2 (World Health Organization, 2000). It has been observed that more than 80% of obesity-attributable deaths occurred in individuals with a BMI index >30 kg/m^2 [1]. Furthermore obesity is frequently associated with cancer, type 2 diabetes and cardiovascular diseases [2] as well as with mental disorders such as "binge eating" [3]. So far very-low-calorie diet is a well established method for short-term weight loss, with concomitant improvements in obesity-related medical conditions in obese patients [4].

Complementary therapies are increasingly becoming popular choices for obese people. For example acupuncture has been used effectively to support dietary restrictions. The first scientific publications dealing with auricular acupuncture for obesity management appeared between the middle 1970 and early 1980 [5-7]. These publications, even if not without criticism from a methodological point of view, indicated that aural stimulation could be advantageously used for modulating feeding behaviour, when administered through well identified auricular zones [8]. Both hunger, often expressed as compulsive behaviour [9], and satiety, usually up-regulated by neuroendocrine imbalance in the obese people [10], affect the food intake and could be modified, for instance, by electric aural stimulation. In fact feeding behaviour is the result of the close interaction among environmental, cognitive, emotional and biological factors connected in a complex neuro-psychological network.

Hypothalamic control

Food intake control is regulated by a manifold network of signals which collect information from the periphery. They are then elaborated at the hypothalamic level and eventually integrated at cortical level initiating food searching behaviour. The arcuate nucleus, between the 3rd ventricle and the median eminence plays a key role in such processes [11]. It is made of two important 1st order neural sets: Npy/AgRP [12,13], and Pomc/Cart [13,14] which are reciprocally inhibited and related to 2nd order neurons of hypothalamic paraventricular nuclei (ventromedial and lateral). Such systems receive further information and control from cortical and subcortical regions through multilevel release of cerebral amines such as noradrenaline, dopamine and serotonin. It is believed that serotonin is able to affect the food choice by stimulating the organism towards protein-rich food instead of carbohydrate-rich aliments [15-17]. During dieting, decreased food intake induces a reduction of the intracerebral serotonin causing episodes of "binge eating" or "craving" for food [18]. The hypothesis that central neuromediators such as serotonins can be modulated by other neuromediators (such as GABA) is strongly supported by the neurophysiological evidence [19]. In 1995 Shiraishi et al. detected the both inhibition of the lateral hypothalamic neuronal activity and excitation of the ventromedial hypothalamic activity. While auricular acupuncture stimulation clearly modulated feeding-related hypothalamic neuronal activity in both normal and experimental (hypothalamic and dietary) obese rats, the effects upon weight were highly related with the obesity degree. The animal experiments suggested that auricular acupuncture stimulation rather than modify eating habits was more effective on earlier satiety awareness [20].

The current study aimed to clarify the influence of transcutaneous, bilateral aural stimulation on body weight in healthy, mildly-obese and obese volunteer patients. We used the "FoodWatcher™", a low-intensity medical device believed to act by vagus nerve inhibition to reduce the gastric secretion and motility through the hypothalamic pituitary axis. In fact The FoodWatcher™ has two conical shaped earpieces which make them easy to insert into the external auditory canal allowing the stimulation via the vagus nerve.

Materials and Methods

The present study was conducted at "Second opinion medical office" (Modena, Italy). It was approved by the Internal Review Board and it was conducted in accordance with the declaration of Helsinki.

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The overall trial required two months of follow-up but it was not registered anywhere since the methodology used is approved in the EU. Patient's compliance with the study protocol was good, no dropouts were observed.

Exclusion criteria were: subjects wearing implanted stimulators (pacemakers, prosthesis, etc.), epileptics and pregnants due to the risk of possible adverse reactions, patients affected by vertigo, headache or nausea after the first day of treatment.

Stimulation protocol

The FoodWatcher™ (http://www.themicrocurrentsite.co.uk/), a medical device, was connected to small (80 mm × 1.1 cm) auricular ear plug-like electrodes (Figure 1b). They were inserted bilaterally into both the auditory meatuses, an area innervated by the vagus nerve. The device generates a signal with amplitude of 40 V, frequency of 50 Hz and current of 40 mA through the ear plugs.

Measurements and experimental timeline

Thirty minutes before meals, all subjects that underwent aural stimulation were asked to turn on the Food-Watcher™ device for 10 minutes and two sessions a day. Glycemia was measured at the beginning and at the end of the experimental diet period by Accu-Chek Active, blood glucose monitoring system (Roche Diagnostics GmbH, Germany). Fat Free Mass (FFM) as well as basal metabolism was measured before and after treatment by bio-impedance using a Body Fat Analyzer Bt-905 (Skylark Device and System Co., Ltd., Taiwan). Test current and frequency were less than 1 mA and approximately 50 KHz, respectively. This technique entails measuring total body electrical impedance. The amount of water and FFM can be accurately estimated by measuring total body electrical impedance after placing four electrodes are over metacarpals and metatarsals and introducing a single frequency (50 KHz) signal current. The detected signal level, when corrected for subject height, is an index of total body water and FFM. Also the waist circumference was measured before and after treatment by means of a tape measure. The study lasted for 2 months when a follow-up examination was performed.

Statistical analysis

Data was analysed using Stata Software (Statistics/Data Analysis, College Station, Texas). Percentage change in FFM, BMI, weight, glycemia and waist circumference for all groups was calculated as baseline – post-treatment. Pearson chi square test was applied. A one-way ANOVA with Bonferroni post-hoc test was used. A $p<0.05$ was considered significant. All data are reported as mean ± Standard Error of the Mean (SEM).

Results

Forty healthy overweight volunteers (male 16, female 24) averaging 42.2 ± 16.2 (range: 18-76) years of age, 93.6 ± 2.8 (range: 57-131) kg of body weight, signed the informed consent and were included into this study. They were randomized to 4 groups. The first group received hypocaloric diet (50-55% of carbohydrates, 25-30% of fats e 15-20% of protein and a calorific value ranging from 1200 to 1800 Kcal, depending on the individual basal metabolism). The second group received a high-protein diet (ketogenic diet with four stages of transition with a gradual reintroduction of carbohydrates and a calorific value ranging from 1200 to 1800 Kcal depending on the individual basal metabolism). The third group received aural stimulation plus hypocaloric diet. The fourth group received aural stimulation plus high-protein diet (Figures 1a, 1c and 1d). All groups received advice on diet regimen by a qualified nutritionist once a week. An accurate record of eating habits, behaviours and fasting glycemia were collected at the first examination.

The frequency of food consumption was assessed by a multiple response grid in which patients were asked to estimate how often a particular food or beverage was consumed. We arranged the food items, based on their similarities in nutrient content, into six major food groups as previously reported [21]. The food groups were: 1) Bread, cereal and starches (different types of bread, rice, pasta, porridge and bakery products); 2) Meat, eggs and fish; 3) Dairy products; 4) Vegetables (fresh and cooked vegetables excluding potatoes), and fruits (fresh and canned); 5) Beverages (fruit juice, alcoholic and non-alcoholic drinks, coffee and tea); 6) Sweets and salads (nuts, candy and cake). In order to estimate the average frequency of intake of foods during the previous year we used close-ended responses consisting of 9 categories: Never or less than once/month, 1–3/month, 1/week, 2–4/week, 5–6/week, 1/day, 2–3/day, 4–5/day, >6/day.

When comparing the percentage change in BMI from baseline in the 4 treatment groups, the therapy with high-protein diet plus FoodWatcher™ resulted to be significantly more effective *vs* hypocaloric diet and hypocaloric diet plus Food-Watcher™ ($p<0.05$; (Figure 2); 3.28% increased improvement in BMI *vs.* group hypocaloric diet group; 2.02% increased improvement in BMI *vs.* hypocaloric diet plus FoodWatcher™ group; 1.59% increased improvement in BMI *vs.* high-protein diet group). Referring to the percentage change

Figure 1: (a-c) patients wearing the FoodWatcher device; b) FoodWatcher device.

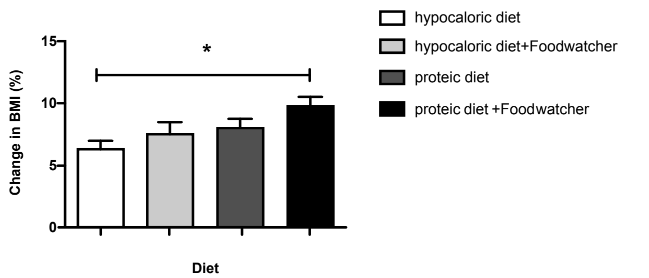
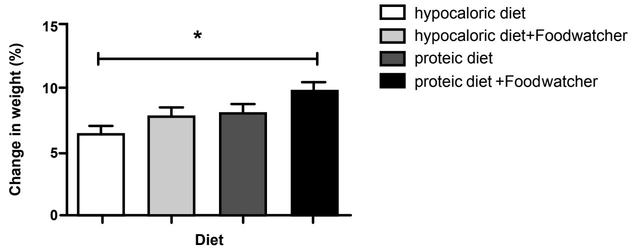
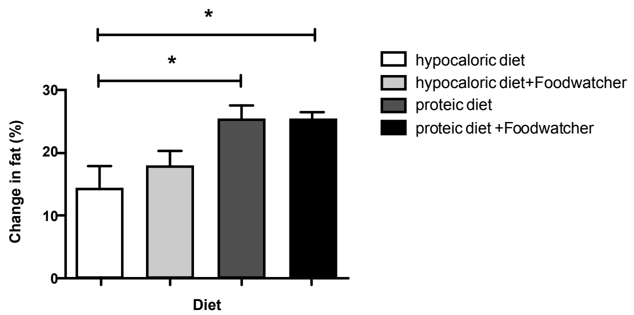


Figure 2: BMI change after 2 months treatment with different diet approaches *p<0.05 Protein diet + Foodwatcher versus hypocaloric diet.



*p<0.05 Proteic diet + Foodwatcher versus hypocaloric diet

Figure 3: Weight change after 2 months treatment with different diet approaches.



*p<0.05 hypocaloric diet vs. Protein diet +Foodwatcher

*p<0.05 hypocaloric diet vs.protein diet

Figure 4: FFM percentage change after 2 months treatment with different diet approaches.

in weight from baseline, a comparison among the 4 groups showed a significant improvement in the high-protein diet plus FoodWatcher™ *vs.* hypocaloric diet and hypocaloric diet plus FoodWatcher™ (p<0.05; (Figure 3); 3.25% increased improvement in weight *vs* hypocaloric diet group I; 2.78% increased improvement in weight *vs.* hypocaloric diet plus FoodWatcher™ group; 1.49% increased improvement in weight *vs.* high-protein diet group). When comparing the percentage change in FFM from baseline in the 4 treatment groups, the therapy with high-protein diet alone or plus FoodWatcher™ resulted to be both significantly more effective *vs.* hypocaloric diet and hypocaloric diet plus FoodWatcher™ groups (p<0.01; (Figure 4);10.21% increased improvement in fat in high-protein diet group *vs.* hypocaloric diet; 4.99% increased improvement in fat in high-protein diet group *vs.* hypocaloric diet plus FoodWatcher™ group; 12.59% increased improvement in fat group 4 *vs.* group 1; 7.37% increased improvement in fat in high-protein plus FoodWatcher™ group *vs.* hypocaloric diet plus FoodWatcher™ group). Regarding waist circumference and glycemia, no significant difference was observed between groups. Glycemia, BMI, weight, waist circumference and FFM variation from baseline, before and after each diet approach, are summarized in table 1.

Conclusions

The present study evaluated the effect of hypocaloric or high-protein diet alone or in combination with FoodWatcher™ device on weight, FFM, BMI, waist circumference and glycemia. Our results support the concept that, after a 2-month therapy, auricular stimulation can produce dramatic body weight reduction in obese patients [5,6,22-26]. As to the action mechanism, a reflex activation of fat metabolism through the auditory meatus via a Yin-yang acupuncture energy balance has been supposed; nevertheless the classic neural pathway originally described by Shiraishi et al., supports the auricular stimulation effects on feeding-related lateral hypothalamic and ventromedial hypothalamic neuronal activity in normal and experimental (hypothalamic and dietary) obese rats [20].

Parameter	Baseline	After Hypocaloric Diet	After Hypo-caloric Diet + Food-watcher	After High Protein Diet	After High Protein Diet + Foodwatcher
Weight (kg)	93.57 ± 2.85	87.22 ± 4.48	86.47 ± 4.08	86.09 ± 4.10	83.99 ± 3.78
FFM (%)	37.32 ± 1.02	32.75 ± 1.51	30.33 ± 2.18	28.46 ± 1.04	27.52 ± .93
Waist Circumference (cm)	107.45 ± 2.11	99.06 ± 3.67	100.2 ± 2.69	101.04 ± 2.58	99.38 ± 2.59
Glycemia (mg/dl)	98.1 ± 2.20	90.4 ± 3.06	91.3 ± 2.86	87 ± .47	90.1 ± 2.72
BMI	32.82 ± .86	30.73 ± 1.22	30.38 ± 1.25	30.47 ± .92	29.44 ± 1.46

Table 1: Summary of values from patients at the baseline and after 2 months treatment with diets.
Values are Mean ± SEM (n=40).

The patients participating in this study reached satiety during aural stimulation if compared to patients treated without electrical stimulation. In addition a significant average body weight loss, FFM and BMI reduction during bilateral aural stimulation in high protein plus FoodWatcher™ diet group were achieved. In conclusion our study supports the synergistic use of the FoodWatcher™ medical device in combination with high-protein diet. No adverse side effects (such as vertigo, headache, and nausea) or negative rebounds consisting in increase in hunger and compulsive food intake were observed. In conclusion the present study supports the use of the FoodWatcher™ as add-on therapy to high protein diet program although further studies in larger cohorts of patients are required.

Statement of Authorship

The authors hereby certify that all work contained in this article is original work. The authors claim full responsibility for the contents of the article.

Conflict of Interest Statement

The authors certify that there is no conflict of interest with any financial organization regarding the material discussed in the manuscript.

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