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Effects of auricular stimulation in the cavum conchae on glucometabolism in patients with type 2 diabetes mellitus

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Summary
Objective: To investigate the effect of auricular stimulation in cavum conchae on the glycemic control for patients with type 2 diabetes mellitus.
Methods: Seventy-one cases were treated with auricular electrical stimulator in the cavum choncha for 30 min, once daily for consecutive 3 months. The changes on the fasting plasma glucose (FBG), 2-h postprandial blood glucose after a 75 g oral glucose load (P_2BG), glycated hemoglobin (HbA1c), blood urea nitrogen (BUN), serum creatinine (SCr), total cholesterol (TC) and aspartate transaminase (AST) were compared before and after the treatment.
Results: The level of the HbA1c was significantly decreased ($P < 0.05$), and there were also statistically significant decreases in BUN, SCr, TC and AST after the treatment ($P < 0.05$). A few patients ($n = 7$) reduced the dose of the hypoglycemic agents in response to repeated hypoglycemia during the treatment.
Conclusion: The stimulation in the cavum conchae of patients with types 2 diabetes mellitus may help decrease HbA1c, BUN, SCr, TC and AST, and may be an effective treatment for type 2 diabetes mellitus.

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Introduction

Diabetes mellitus is one of the most common chronic diseases throughout the world. Its global prevalence was predicted as 285 million by 2010, and type 2 diabetes (T2D) accounted for 90% of the cases.[1,2] Hyperglycemia is the hallmark of diabetes and can increase the risk of cardiovascular, neuropathic, renal and retinopathic complications.[3–6] Normally, blood glucose homeostasis is regulated by both glucagon and insulin. Insulin functions to decrease blood glucose level by promoting cellular uptake and usage of circulating glucose. However, in T2D, the insulin production is somehow impaired and the peripheral insulin resistance develops, resulting in failure in blood glucose absorption. High blood glucose can potentially disturb cellular metabolism to induce acute ketoacidosis or chronic inflammatory damages to vascular wall, glomerular membrane, retina and neurons.[3–6] Therefore, it is one of main treatment purposes to maintain proper blood glucose level.

The widely used methods to manage diabetes include the oral hypoglycemic agents (OHAs) (including insulin secretagogues, insulin sensitizers, alpha-glucosidase inhibitor and gluconeogenesis inhibitors) and the subcutaneous injection of insulin. However, they may increase the risk of gastrointestinal discomfort,[7,8] impaired hematological function,[9] and rarely but yet critically impaired renal function[10] and cancer.[11]

Auriculotherapy has been used in China as an independent or auxiliary method to treat diseases for millennia. It uses needles or other devices to stimulate certain points on the ear pavilion. Auriculotherapy has gained increasing global notice since the past half century for its 'easy manipulation, broad indication, and few side effects, while being economical and providing good results'.[12] According to the theory of Chinese medicine, ear pavilion is a convergent area of the meridians correlating with internal organs and the whole body. Thus, stimulating the auricular points can help regulate the function of internal organs. This bioholographic model has been confirmed by recent findings that the innervation of the auricle possesses the auricular branch of the vagus nerve and many sympathetic nerve fibers, which may play important roles in the regulation of viscera.[13] In some clinical studies, it has been demonstrated that auricular stimulation could help patients with impaired glucose tolerance (IGT) improve fasting blood glucose (FBG) and 2-h postprandial blood glucose after a 75 g oral glucose load (P2BG) after 3-month treatment,[14] and ear pallet acupressure could help T2D patients reduce dosage of oral hypoglycemic agent.[15] However, few previous clinical studies had ever investigated the influence of auriculotherapy on blood glucose as well as other metabolic indices in diabetes patients.

This study aimed to investigate changes in blood glucose as well as other metabolic indices during auriculotherapy in T2D patients. The results would be used to generate a hypothesis, which will be tested further in controlled clinical trial study.

Figure 1 Ear vagus nerve stimulator (Huatuo).

Method

Patients

From May 2009 to October 2010, totally 84 patients at the age of 29 to 73 in the outpatient clinic of Pecking University Shenzhen Medical Hospital were recruited into the study. All the patients met the following inclusion criteria: (1) clinically diagnosed with type 2 diabetes: FBG $\geq$ 7.0 mmol/L, or P2BG $\geq$ 11.1 mmol/L, or a random blood glucose $\geq$ 11.1 mmol/L. Borderline result must be reconfirmed by a repeated test on another day; (2) for patients on oral hypo-glycemic agents (OHA) or subcutaneous insulin, glycated hemoglobin (HbA1c) during consecutive 6 months > 6.5%, while for patients not on medication, HbA1c > 6.0%; (3) voluntary to accept auricular acupuncture therapy. Patients presenting with evidence of the following events were excluded from the study: (1) pregnant and lactating women; (2) loss of self-care ability, or with psychiatric disorder; (3) acute metabolic disorders within recent 1 month such as diabetic ketoacidosis; (4) anemia; (5) severe heart, brain, liver, kidney disease; or (6) malignancies, systemic infection diseases or immune system diseases. The institutional Review Board of Pecking University Shenzhen Medical Hospital approved the study and each included patient provided written informed consent before enrollment.

Treatment

The auricular electrical stimulator (ear vagus nerve stimulator produced by Huatuo, Figure 1) was used to stimulate cavum conchae of both ears. After sterilization of the auricular cavity by 75% alcohol cylindrical swab, one electrode was placed in the external ear canal, and the other electrode was placed on the cavum conchae (Figure 2). The intensity of electric stimulation from the electrodes to the patient was defined as the maximum tolerance without pain (practically 4—10 Hz). A treatment session of 30-min stimulation on both ears was conducted every day, and continued for 3 months. Patients were required to use the self-check blood glucose devices to monitor the daily glycemic level. The patients received training before the study to ensure that they could