Complementary Therapies in Clinical Practice 21 (2015) 193-200

Contents lists available at ScienceDirect



Complementary Therapies in Clinical Practice

journal homepage: www.elsevier.com/locate/ctcp



Acupuncture-induced changes of vagal function in patients with depression: A preliminary sham-controlled study with press needles



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ARTICLE INFO

Article history: Received 21 May 2015 Accepted 3 July 2015

Keywords: Autonomic function Blood pressure Medication-resistant depression Holter electrocardiogram Press needle acupuncture Vagal function

ABSTRACT

To study the biological effects of acupuncture on depression, we hypothesized that acupuncture will exert its antidepressant effect through a bottom-up neuromodulation of the autonomic dysfunction in depression. The participants received press needle (PN) acupuncture for 72 h continuously in a shamcontrolled design. Psychological assessments and Holter electrocardiography were performed before and after PN acupuncture. We evaluated their autonomic functions through the heart rate variability (HRV). As a result, following PN acupuncture participants showed significant improvement in the Beck's Depression Inventory scores (P = 0.031), systolic/diastolic blood pressures (P = 0.002/P = 0.011), and coefficient of variation of the R–R interval (P < 0.0001), compared to sham PN. The present findings showed PN acupuncture induced alterations in vagal function, blood pressure, and Beck's Depression Inventory scores. It was suggested that vagal stabilization effect by acupuncture may be associated with the therapeutic mechanism in depression.

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1. Introduction

Affective disorder is a highly prevalent condition associated with large socioeconomic loss [1]. In October 2012, the World Health Organization (WHO) estimated that more than 350 million patients are suffering from depression worldwide. Antidepressants and psychotherapy are typically administered for depression and are effective in many patients. However, approximately 10–40% of patients remain significantly treatment-resistant [2].

1.1. Acupuncture and depression

The therapeutic effect of acupuncture on depression is well known empirically, however, evidence from randomized controlled trials (RCTs) is relatively limited [3–7]. Further, acupuncture reportedly affects the autonomic nervous system, but the

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therapeutic mechanism underlying this effect remains unknown [8] because of the variable results such as the effects on heat rate variability (HRV) from several sham-controlled RCTs [9]. Nevertheless, there are convincing prior studies demonstrating that patients with major depression exhibited diminished parasympathetic reactivity and, presumably, increased sympathetic reactivity [10,11]. Moreover, Wang et al. has reported that the severity of depression was associated with the severity of autonomic dysfunction [11].

1.2. Press needle acupuncture

Press needle (PN) is a special acupuncture needle, which has been developed in Japan by improving the conventional intradermal needles (see Fig. 1). PN can stimulate the targeted acupoints continuously for a few days in a non-invasive and safe way [12], and further it enable us to apply acupuncture in a double-blind, placebo-controlled design by using sham PN. Indeed, there are several clinical studies using PN for various diseases. For example, Anders et al. applied active PN to PC6 (*nèiguān*) to alleviate the symptom of acute vomiting in children with gastroenteritis and pneumonia,

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Abbreviations		HRV ICD-10	Heart rate variability International Classification of Disease, 10th edition
ANOVA	Analysis of variance	JIS	Japanese Industrial Standard
BDI-II	Beck's depression inventory, 2nd edition	ĹF	Low frequencies
BP	Blood pressure	LF/HF	Ratio of low- to high-frequency power
CSI	Cardiac sympathetic index	PN	Press needle
CVI	Cardiac vagal index	RCT	Randomized controlled trial
CVRR	Coefficient of variation of the R-R interval	SBP	Systolic blood pressure
DBP	Diastolic blood pressure	STAI	State-Trait Anxiety Inventory
ECG	Electrocardiogram	TMI	Toho Medical Index
ECT	Electroconvulsive therapy	VLF	Very low frequency
HC	Healthy control	VNS	Vagal nerve stimulation
HF	High frequencies	WHO	World Health Organization
HR	Heart rate		



Pyonex PN

Active PN

Sham PN

Fig. 1. The left figure shows the appearance of the PN (Pyonex; Seirin Co., Ltd.). The middle figure shows the appearance of an active PN with an acupuncture needle while the right figure shows a sham PN without an acupuncture needle.

which resulted in clinical improvement with feasibility and high acceptance for these children [13]. In other case series study, they stimulated at LI11 ($Q\bar{u}ch\hat{i}$) with active PN for treatment of hospital-induced constipation in children and observed a remarkable effect in all children within 2 h after active PN intervention [14]. Further, a randomized, double-blind, placebo-controlled trial using active or sham (i.e., placebo) PN to BL23 (*shènshū*) for patients with lower back pain has shown a significant effect for pain relief and also active and sham PNs were indistinguishable for the subjects [15].

1.3. Objectives of the present study

With this background, we intended to verify the therapeutic effects of acupuncture on depression and investigate its therapeutic mechanism for depression by employing PN approach in the shamcontrolled design described below. In this study, we hypothesized the following therapeutic mechanism of PN acupuncture for depression: PN acupuncture stimulates the somatosensory nerves through multimodal receptors in the skin; thereby this somatosensory afferent input indirectly neuromodulates the autonomic nervous system [16-18]; thus the neuromodulated autonomic function (primarily through a vagal nervous function) indirectly provides an antidepressant effect [19,20].

2. Material and methods

2.1. Study participants

Twelve healthy participants and 30 inpatients with medication-resistant depression, who were recruited from

Kanagawa Psychiatric Center (Yokohama, Japan), have participated in this sham-controlled study. Diagnosis was determined by certified psychiatrists based on the International Classification of Disease, 10th edition (ICD-10). In this study, we defined medication-resistant depression as the lack of response to more than 2 antidepressants over 3 months and a persistent depressive state. Of the 30 patients (16 men and 14 women; mean ± standard deviation, 50 ± 11 years old), 20 had monopolar depression, 2 had bipolar I depression, 4 had bipolar II depression, and 4 had dysthymia in the diagnosis. For patients group, the inclusion criteria were i) patients who have diagnosis of depression, ii) score over 11 (this is a cutoff value for autonomic dysfunction) in the Toho Medical Index (TMI) [21] for either autonomic nerve symptoms (factor A) or psychiatric symptoms (factor P), and iii) enough consent capacity for this study. The exclusion criteria were other psychiatric comorbidities; a history of seizure, epilepsy, severe or acute medical illnesses, neurological disorders, alcohol or other drug dependence; or electroconvulsive therapy (ECT) within 6 months of the study. All patients received antidepressants throughout the study period but the type and dose of medication remained constant. The mean imipramine equivalent dose of the antidepressant [22] in the patients group was 96.1 \pm 25.8 mg. The healthy control (HC) group comprised 12 healthy participants (5 men and 7 women; 36 ± 8 years) with no history of depression or any of the exclusion criteria. There were no dropouts in this study. The study design was reviewed by the local ethics committee of Kanagawa Psychiatric Center and the committee approved this study. The study was carried out in accordance with the latest version of the Declaration of Helsinki, and informed consent of the participants was obtained after the nature of the procedures had

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