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ORIGINAL RESEARCH

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Acupuncture Treatment for Generalized Anxiety Disorder by Activating the Vagus Nerve and Improving Heart-Rate Variability and Heart-Rhythm Coherence, A Case-Series Study

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ABSTRACT

Objective: The goal of this case series was to observe the effectiveness of acupuncture for reducing sympathetic stress and anxiety-related symptoms in generalized anxiety disorder. The effect of acupuncture on the balance of the autonomic nervous system was also examined.

Materials and Methods: This was a case-series study with 10 participants enrolled. Each participant received acupuncture treatment 2 times per week for 4 weeks. Participants were evaluated with the Generalized Anxiety Disorder–7 (GAD-7) scale and the Body Perception Questionnaire–Short Form (BPQ-SF) before and after the treatment program. Heart-rate variability heart-rhythm coherence (HRC) was also assessed during each acupuncture session.

Results: Five participants completed the program. Both GAD-7 and BPQ mean scores showed significant reductions. The mean HRC high-coherence ratio also increased significantly after acupuncture treatment. No adverse effects occurred.

Conclusions: Acupuncture may be an effective therapy for sympathetic stress and anxiety-related symptoms. The mechanism of action may be through activating the vagus nerve and improving the HRC high coherence ratio. It is feasible to conduct larger clinical trials with random controls, longer treatment durations, and long-term follow-ups to support the results of this study.

Keywords: acupuncture, generalized anxiety disorder, Eight Extraordinary Vessels, auricular acupuncture, heart-rate variability, heart-rhythm coherence

INTRODUCTION

Generalized anxiety disorder (GAD) is increasing in frequency due to chronic stress in the modern lifestyle. Heightened cortisol over a prolonged period of time leads to an increase in anxiety symptoms and a decrease in an individual's ability to endure stress.[1] Chronic stress is implicated in numerous psychologic and physical maladies, even causing hippocampal atrophy and decreased hippocampal neurogenesis.[2,3] Common symptoms of GAD include worry in the form of repetitive thoughts, inability to focus, being overwhelmed by daily events, with a sense of doubt about one's ability to cope with these events, and emotional reactions not proportionate to a situation.[4] These subjective symptoms are often accompanied by physiologic signs of sympathetic arousal, such as sweating, trembling, dizziness, or a rapid heartbeat.[3] The number of people diagnosed with GAD has increased dramatically, and the number of people taking antianxiety and antidepressant drugs is soaring.[4]

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Acupuncture has been widely used to treat anxiety-related symptoms.[5,6] Research has shown that there is good scientific evidence for using acupuncture therapy to treat anxiety disorders as this modality yields effective outcomes, with fewer side-effects than conventional treatment.[7–9] However, the scientific bases for the mechanism of acupuncture treatment are still unknown.

The vagus nerve plays a vital role in the functioning of the human body, from regulating the digestive system to controlling heart rate and breathing. The modern lifestyle creates long-term stresses leading to an autonomic imbalance of sympathetic dominance and low vagus-nerve tone, which causes various stress-related symptoms including anxiety.[10] Vagus-nerve stimulation has been used to treat anxiety disorders.[10,11]

Acupuncture has also been shown to be an effective method for stimulating the vagus nerve, leading to a wide range of potential health benefits.[12,13] Anti-inflammatory effects of acupuncture have been linked to vagus-nerve activation via a cholinergic anti-inflammatory pathway.[12,14,15] By targeting specific acupuncture points that correspond to the vagus nerve, acupuncture can help promote relaxation, reduce inflammation, and improve overall well-being. It remains to be seen if the effect of acupuncture on anxiety disorders also works via the parasympathetic anti-inflammatory pathway.

Heart-rate variability (HRV) is the physiologic phenomenon of variation in the time interval between heartbeats. HRV describes the variation in the beat-to-beat interval at rest and has become a popular noninvasive tool for assessing the activities of the autonomic nervous system (ANS).[16] Low HRV, and an ANS imbalance with a shift toward increased sympathetic activity and decreased vagal tone, have been proven to be risk factors for adverse outcomes of many chronic illnesses.[17] Low HRV is considered a indicator of current or future health issues, as low HRV shows that the body is less resilient and struggles to handle stress situations.

Heart-rhythm coherence (HRC; also termed *psychophysiologic coherence*) describes a distinct mode of physiologic functioning—with a smooth, sine wave–like pattern derived from HRV parameters—that reflects increased synchronization between sympathetic and parasympathetic activities; a shift in the ANS balance toward increased vagal tone; and increased heart–brain synchronization (the brain's rhythms become more synchronized with the heartbeat). This physiologic mode results in a highly efficient state in which the body, brain, and nervous system function with increased synchronization and harmony.[18] Higher rates of coherence have been linked with reductions of anxiety, depression, and other stress-related symptoms.[19]

Although positive outcomes of acupuncture for treating anxiety and anxiety disorders have been reported,[20] the mechanism of action has not been thoroughly examined. The effect of acupuncture on HRV has also been studied.[21,22] However, acupuncture's effect on HRC has never been reported. This case series study examined the effectiveness of acupuncture on GAD and proposes a hypothesis that acupuncture may treat anxiety symptoms through vagus-nerve activation and improving HRC.

According to Chinese Medicine, anxiety always involves the Heart organ, as it contains the *Shen*, which embodies consciousness, emotions, and thought. *Shen* is disturbed easily by Heat and Deficiency of Yin and Blood.

The Heart and Kidney organs are fundamentally connected. The Kidney hosts the *Jing* (also termed the *Essence*) as the original ''information of life.'' The *Jing* and *Shen* rely upon each other for clear expression of mental consciousness. The *Chong* channel (also termed the *Penetrating Vessel* or *Sea of Blood*), one of the Eight Extraordinary Vessels (EEV), contains *Jing* and links the Heart and Kidney. The *Chong* channel brings the *Yuan* Qi (innate or prenatal Qi), in the forms of Yin and Yang, to the *Ren* (also termed the *Conception Vessel* or *Sea of Yin*) and *Du* (also termed the *Governing Vessel* or *Sea of Yang*) channels, respectively, to support postnatal Qi and Blood. The *Ren* channel provides material Yin for the *Du* channel, which animates the *Shen*.[23] Needling the *Chong*, *Ren*, and *Du* channels from the EEV allows a patient to access the original information of life and to come closer to embodying his or her true nature.

The Use acupoints from the EEV to treat GAD were reported in a previous study.[5] Studies have shown that auricular acupuncture plays a role in regulating the vagal activity of autonomic functions of various systems through an auriculovagal afferent pathway.[24] In this case series, a combination of acupoints from the EEV, to balance Yin and Yang with auricular and related body points to activate vagal activity, was used to treat GAD. It remains to be seen if this integrated protocol shows any synergetic effect on anxiety symptoms.

MATERIALS AND METHODS

The study design and treatment protocol were reviewed and approved by the Atlantic Institute of Oriental Medicine (Fort Lauderdale, FL) institutional review board. The study was conducted by a licensed acupuncturist, Meira do Valle, DAOM, at a single private acupuncture practice. Harry Hong, PhD, participated in study design and data analysis. Participants were recruited from the clinic's patients and staff members. Participation in the program was free of charge. All prospective participants were interviewed and assessed at the clinic. Details about the study were discussed and all risk factors were disclosed. All participants were asked to sign the Protection of Human Subjects Consent Form. Inclusion, exclusion, and dropout criteria are shown in Table 1.

Treatment Procedure

The treatment procedure was as follows:

Table 1. Inclusion, Exclusion, and Dropout Criteria

Criteria	*Description*
Inclusion	Age between 18 & 70
	Score of >10 on GAD-7
	Signed informed consent & release of liability forms
Exclusion	Score of <4 on GAD-7
	Pacemaker or preexisting cardiac diagnosis
	Pregnancy
	Outside of age range
	Receiving other acupuncture therapy
	Having infectious diseases (i.e., COVID-19)
Dropout	Missing more than 1 consecutive treatment session

GAD-7, Generalized Anxiety Disorder–7 scale.

1. Patient intake for ~5–10 minutes to discuss any changes noticed since the previous treatment, including digestive, sleep, perceived level of anxiety, and ability to manage anxiety. Assessments were conducted during this time frame (see details below).
2. Each participant was asked to lie on the treatment table in a supine position.
3. Practitioner administered acupuncture, using 0.22mm x 30 mm-gauge DBC^{tm} brand needles in the following order: SP-4; PC-6; DU-20; *Yin Tang*; left ear *Shen Men*, Sympathetic, Heart, and *San Jiao*; SJ-17; ST-9; *Ren*-14; and SP-21. The acupuncture points and their needling sequence are summarized in Table 2.
4. For body acupuncture points, needles were inserted and manipulated until the De Qi sensation was reached. Needles were retained for 22 minutes and then removed.
5. Treatments were repeated 2 times per week for 4 weeks at similar times of day, for a total of 8 treatments.

Outcome Measurements

The Generalized Anxiety Disorder–7-item (GAD-7) scale is a standardized, self-rated scale that is used as a screening tool and a severity indicator for GAD.[25] The scale consists of 7 questions with 4 possible levels of anxiety for each question based on how often the participant has experienced each symptom in a 2-week time frame (0 points for ''not at all''; 1 point for ''several days''; 2 points for ''over half of the days''; and 3 points for ''nearly every day''). The 7 questions include: (1) Feeling nervous, anxiety, or on edge; (2) Not being able to stop or control worrying; (3) Worrying too much about different things; (4) Trouble relaxing; (5) Being so restless that [it is] so difficult to sit still; (6) Being easily annoyed or irritable; and (7) Feeling afraid as if something awful might happen. A total score of 0–4 indicates minimal anxiety, 5–9 indicates mild anxiety, 10–14 indicates moderate anxiety, and 15–21 indicates severe anxiety.

The GAD-7 survey was chosen not only because it is well-accepted as a measurement of anxiety, but also for its ease of administration. The GAD-7 was given in the initial patient intake as a screening tool to determine inclusion/exclusion in the study and during the last visit as a measure of the change in GAD symptoms over treatment time.

The Body Perception Questionnaire–Short Form (BPQ-SF) is a self-report measure of body awareness and autonomic reactivity.[26] This measure consists of 46 questions to assess body awareness, stress response, ANS reactivity, stress style, and health history. Items were chosen based on their relationship with the ANS. This questionnaire was used in the study to assess sympathetic nervous system–activation changes from the onset of treatment to the completion of the series. The scores were calculated on a scale of 0–4. An answer of ''Never'' corresponded to a score of 0 points per question, ''Occasionally'' scores 1 point, ''Sometimes'' scores 2 points, ''Usually'' scores 3 points, and ''Always'' scores 4 points. After scoring each question individually, the points were added to comprise the overall BPQ-SF Score. The higher the BPQ-SF score, the higher the sympathetic stresses the body shows. The BPQ-SF was given to each participant before and after the program. The before-and-after scores were analyzed and compared.

HRC was measured during the patient-intake time for each visit. Each participant was asked to sit with the HRV ear sensor attached to the left ear while the testing ran for 5 minutes. The HRC was measured and analyzed with the Emwave2® Pro software from the Institute of HeartMath. HRC high-coherence ratio was analyzed in the study.

All assessment data were recorded and analyzed with Microsoft® Excel.® The mean and standard deviation were calculated, and the graphs were generated using the same program. A *P*-value was calculated with an Excel® *t*-test that had a paired 2-sample for means function.

Table 2. Acupuncture Points Used for the Cases

Needling sequence	*Point name*	*Side of body*
1	SP-4	Bilateral
2	PC-6	Bilateral
3	DU-20	Center
4	*Yin Tang* (Ex-HN-3)	Center
5	Ear *Shen Men*	Unilateral, left
6	Ear Sympathetic	Unilateral, left
7	Ear Heart	Unilateral, left
8	Ear *San Jiao*	Unilateral, left
9	SJ-17	Bilateral
10	ST-9	Bilateral
11	*Ren*-14	Center
12	SP-21	Bilateral

RESULTS

Ten participants were enrolled using the criteria shown in Table 1. This case-series study took place during the COVID-

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Table 3. Patients' Demographics

Patient #[a]	*Age*	*Gender*	*Race*	*Weight (lbs)*	*Disorder duration (yrs)*
1	55	F	White	258	20+
4	21	F	White	115	5
7	34	F	White	213	6
9	43	M	White	125	15+
10	39	F	Latinx	145	15+

[a]Original patient number in the original group of 10 patients.
lbs; pounds; yrs, years; F, female; M, male.

19 pandemic. Three participants were unable to complete the series (a minimum of 7 continuous sessions) due to COVID-19 diagnoses, which caused them to quarantine and miss more than 1 week of treatment. The reasons for the other 2 dropout participants was unknown. Five participants completed the study, with 4 participants finishing all 8 sessions and 1 participant (No. 7) finishing 7 sessions due to a hurricane passing through the area. Demographic and clinical characteristics of the 5 participants, 1 male and 4 female, ages 21–to 55, are summarized in Table 3.

After treatment, the patients' mean GAD-7 score was reduced from 16.4 (before) to 9.6 (after), which was a 41.46% reduction. This reduction of the GAD-7 score was statistically significant ($P = 0.025581$). The patients' mean BPQ-SF score was also reduced from 84.2 (before) to 47.2 (after), with a 43.94% reduction. This reduction was also statistically significant ($P = 0.008516$). An analysis of the GAD-7 and BPQ-SF scores is shown in Table 4 and in Figure 1.

The HRC high-coherence ratios from visit 1 through 7 were analyzed; the results are shown in Table 5 and Figure 2. The raw data included the coherence ratio of low, medium, and high levels. Only the high-coherence ratio was included in the analysis, because the high-coherence ratio is associated with reduction of anxiety and stress-related

Table 4. Comparison of GAD-7 and BPQ Before and After Treatment

	GAD-7		*BPQ-SF*	
Patient #[a]	*Before*	*After*	*Before*	*After*
1	21	9	80	23
4	15	7	85	46
7	11	5	23	11
9	21	21	186	121
10	14	6	65	35
Mean (SD)	16.40 (3.98)	9.60 (5.85)	84.20 (47.23)	47.20 (38.71)
Percentage reduction	41.46%		43.94%	
P-value	0.025581		0.008516	

[a]Original patient number in the original group of 10 patients.
GAD-7, Generalized Anxiety Disorder–7 scale; BPQ-SF, Body Perception Questionnaire–Short Form; SD, standard deviation.

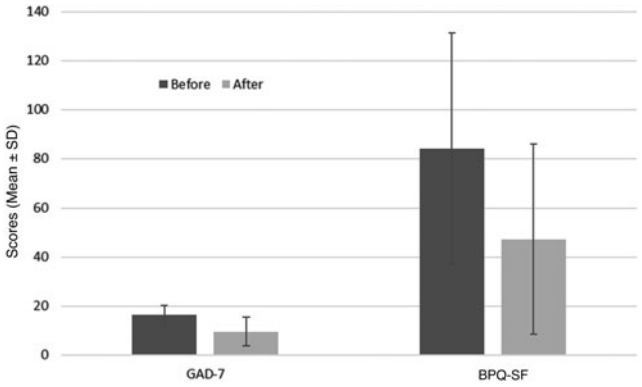

FIG. 1. Comparison of Generalized Anxiety Disorder–7 (GAD-7) scale and Body Perception Questionnaire–Short Form BPQ-SF before and after treatment. SD, standard deviation.

symptoms. The mean high-coherence ratio increased gradually from visit 1 through 7. The mean ratio increases between visit 1 and visit 7 was 122.14% and was statistically significant ($P = 0.020836$).

There were no side-effects reported from the participants in this study, based on clinical findings. One participant who received acupuncture for the first time reported dislike of PC-6 being needled. No participant reported any other adverse effects. No follow-up interviews were conducted.

DISCUSSION

In this case series, the GAD-7 mean score showed significant reduction after treatment, suggesting that the acupuncture protocol successfully helped the participants reduce their anxiety symptoms. The BPQ-SF mean score also showed significant reduction after treatment assessment. This suggests that sympathetic activation was decreased and that low vagus-nerve tone was improved after treatment. This finding was also supported by the improvement of the HRC high coherence ratio, which showed a significant increase after the treatment program. This finding supports the current authors' hypothesis that acupuncture treatment may help anxiety symptoms through activating vagus-nerve tone and improving HRC. The findings also suggest that this treatment protocol—a combination of EEV and vagus-nerve auricular stimulation—may have a synergistic effect to help reduce anxiety-related symptoms.

Among the 5 participants, only 1 participant (No. 9) had an unchanged GAD-7 score after treatment. All of other 4 participants showed decreased GAD-7 scores. Yet, all 5 participants showed decreases in BPQ-SF scores, including the participant No. 9, who showed a BPQ-SF score decreased from 186 to 121 after treatment, a nearly 35% reduction. This participant also showed an increase in HRV coherence ratio, from 43% on visit 1 to 70% on visit 7, a 62.8% increase. This indicates that, after the 4-week treatment, this participant had

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Table 5. Change of Heart-Rhythm Coherence High-Coherence Ratio with Acupuncture Treatment

Patient #[a]	*Visit 1 (%)*	*Visit 2 (%)*	*Visit 3 (%)*	*Visit 4 (%)*	*Visit 5 (%)*	*Visit 6 (%)*	*Visit 7 (%)*
1	0	40	56	63	62	58	55
4	2	55	24	47	29	15	35
7	48	52	43	39	58	40	51
9	43	3	47	75	67	69	70
10	38	22	20	67	52	62	80
Mean (SD)	26.2 (20.83)	34.4 (19.52)	38 (13.78)	58.2 (13.24)	53.6 (13.25)	48.8 (19.43)	58.2 (15.59)
Percentage increase (visit 1 vs visit 7)				122.14%			
P-value (visit 1 vs visit 7)				0.020836			

[a]Original patient number in the original group of 10 patients.
SD, standard deviation.

a decrease in sympathetic stress and an improvement of ANS balance, but this patient's anxiety symptoms remained. This result for participant No. 9 suggests that acupuncture treatment may help relieve stress-related symptoms before relieving anxiety symptoms and that anxiety symptoms may need longer treatment to achieve optimal results. This finding also supports the current authors' hypothesis that acupuncture treats anxiety symptoms probably through vagus-nerve activation and ANS balancing. After the ANS is rebalanced, anxiety symptoms may be reduced gradually.

The treatment protocol started with opening the *Chong* channel with SP-4 and PC-6, then balancing the Yang channels with DU-20. *Yin Tang* (Ex-HN-3)—which has been reported to reduce anxiety symptoms,[27]—was used for Calming the Mind and reducing stress. Auricular points *Shen Men*, Sympathetic, Heart, and *San Jiao*, were used to activate vagal activity. SJ-17 and ST-9 were used due to their direct connection to the vagus nerve anatomically. Additionally, *Ren*-14 was used to balance the Heart and *Shen*, and SP-21 was used to regulate Qi and Blood production and embrace all the *Luo* channels of the entire body.

This protocol was designed to balance Yin, Yang, Qi, Blood, and *Shen* of the EEV and to activate vagal activity of the ANS. In this study, no further pattern differentiation was conducted for each participant. Improvement occurred in most of the remaining participants, suggesting that the protocol may work for most patients who have GAD. However, detailed pattern differentiation for each patient and individualized modification of the protocol may help to improve efficacy of this protocol even more in everyday clinical practice.

Limitations of this case-series study included the small sample size with similar demographics, the short treatment time frame, and lack of a control group and long-term follow-up. However, this protocol was well-tolerated among the participants and no adverse effects were reported. It can be used as a safe and effective treatment protocol to manage anxiety symptoms. Meanwhile, it is feasible to conduct clinical trials with larger sample sizes, longer treatment time frames, randomized control groups, and post-treatment follow-ups to support the results.

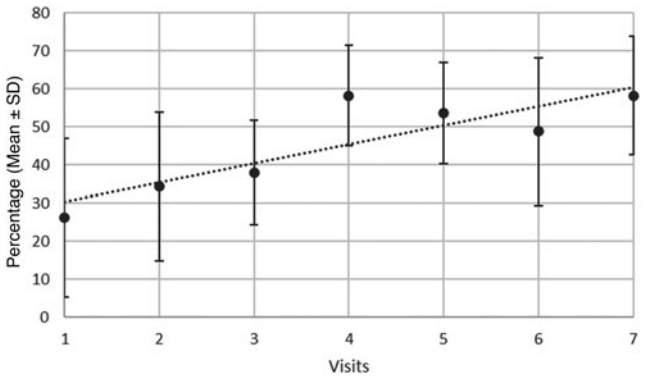

FIG. 2. Change of heart-rhythm coherence (HRC) high-coherence ratio with acupuncture treatment. SD, standard deviation.

CONCLUSIONS

Although conducted with only 5 cases and 4 weeks of treatment, this case series showed that, after acupuncture treatment using the acupoints of the EEV and auricular vagal stimulation, the patients' mean GAD-7 and BPQ-SF scores were reduced significantly. The mean HRC high-coherence ratio was also significantly increased. These findings support the concept that this acupuncture protocol may be an effective therapy for relieving sympathetic stress and GAD. The findings also suggest that the mechanism of action may be through vagus-nerve activation and improving the HRC high-coherence ratio. It is feasible to conduct larger clinical trials with longer treatment durations, randomized controls, and long-term follow-ups to support the results.

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AUTHOR DISCLOSURE STATEMENT

No competing financial interests exist.

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