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Original Article

Physiotherapy Section

Comparative Effect of Vagal Stimulation on Heart Rate, Blood Pressure, and Skin Hydration at Different Anatomical Sites in Prehypertensive Individuals: A Pilot Study

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ABSTRACT

Introduction: Prehypertension is the precursor to high Blood Pressure (BP), which can lead to severe consequences such as cardiovascular disease, stroke, acute myocardial infarction, heart failure, peripheral arterial disease, and cerebrovascular complications, ultimately resulting in mortality. Vagal stimulation is frequently employed by therapists, along with various therapeutic exercises, to treat or manage Heart Rate (HR) and BP in prehypertensive individuals. The vagus nerve plays a vital role in maintaining internal physiological balance, known as homeostasis, which includes reflex pathways that regulate cardiac function. Auricular neuromodulation of the vagus nerve can be achieved through stimulation of the ear lobule, cymba concha, or tragus in the outer ear.

Aim: To compare and determine the optimal anatomical site for vagal stimulation, specifically the ear lobule, cymba concha, or tragus, to improve HR, BP, and skin hydration in prehypertensive individuals.

Materials and Methods: The present pilot study conducted a pre-post comparative analysis in the Outpatient Department (OPD) of Physiotherapy at the Institute of Applied Medicines and Research Centre, Ghaziabad, Uttar Pradesh, India. The study duration was nine months, from January 2022 to September 2022. A total of 30 subjects aged 30-55 years were divided into three groups (10 participants in each group: A, B, and C) using sealed envelopes. Group A received vagal stimulation on the ear lobule, Group B received vagal stimulation on the cymba concha, and Group C received vagal stimulation on the tragus. Baseline measurements were taken prior to treatment, including HR, BP, and skin hydration. Vagal stimulation was administered using a low-frequency Transcutaneous Electrical Nerve Stimulation (TENS) machine at 25 Hertz and a pulse width of 120 ms. The stimulus was continuously applied for 30 minutes, five days a week, for four weeks. After a 10-minute relaxation period, HR, BP, and skin hydration were measured both pre and post-intervention. The data was statistically analysed using Statistical Package for Social Sciences (SPSS) version 24.0, employing paired t-tests to compare means within groups and Analysis of Variance (ANOVA) to compare between the three groups.

Results: There were no statistical differences in the baseline among all three groups. Group C, which received vagal stimulation on the tragus, demonstrated statistically significant improvements in BP and skin hydration. The t-value and p-value for Systolic Blood Pressure (SBP) were 11.513 and $p<0.001$, for Diastolic Blood Pressure (DBP) were 10.411 and $p<0.001$, for HR were 15.231 and $p<0.001$, and for skin hydration were 9.474 and $p<0.001$, respectively. When comparing HR, BP, and skin hydration among the groups using one-way ANOVA f- value and p-value showed significant difference between the groups in all parameters.

Conclusion: The study concludes that vagal stimulation on the tragus is a superior intervention compared to vagal stimulation on the cymba concha or ear lobule for controlling HR, BP, and skin hydration in prehypertensive individuals.

Keywords: Auricular neuromodulation, Stimulation, Sympathetic parameter, Vagus nerve

INTRODUCTION

Prehypertension is the precursor to high BP, which may lead to consequences such as cardiovascular disease, stroke, acute myocardial infarction, heart failure, peripheral arterial disease, and cerebrovascular complications, resulting in mortality [1,2]. Vasan SR et al., stated that the prevalence of prehypertension progressing to high BP has increased to about 30% in the last four years. The association of prehypertension with increased stress emphasises the need for greater emphasis on prevention [3]. In its seventh summit, the Joint National Committee introduced "prehypertension" as a new BP classification [3]. Prehypertension is defined as a Systolic Blood Pressure (SBP) ranging from 120-139 mmHg and/or a Diastolic Blood Pressure (DBP) ranging from 80-89 mmHg in adults aged ≥18 years. It represents a transitional state between normal blood pressure and hypertension [4]. Prehypertension serves as a warning for physicians to initiate prevention measures to mitigate the progression to high BP and associated risks [5].

Individuals with arterial high BP exhibit elevated plasma levels of noradrenaline, approximately 25-30% higher than those of individuals with normal blood pressure of the same age. These individuals may experience increased susceptibility to heart disease and peripheral resistance, indicating autonomic imbalance. Autonomic dysfunction leads to increased sympathetic activity and decreased vagal tone [6]. Early detection, prevention, and control of BP, HR, and skin hydration are necessary in prehypertensive individuals.

Vagal stimulation, in conjunction with various exercise protocols, is commonly employed by therapists to treat or manage sympathetic diversion, such as high BP and HR, in prehypertensive individuals. Auricular Vagal stimulation is used to modulate BP and HR [6]. In the external ear, the vagus nerve possesses somatosensory afferent fibers. This auricular branch is located within the external acoustic meatus, including the tragus and upper part of the concha. As the vagus nerve provides parasympathetic supply to the heart, vagal stimulation is utilised to regulate cardiac function [7]. Due to its

innervation of the heart, vagal tone can influence cardiovascular changes. Vagus Nerve Stimulation (VNS) recruits neuronal fibers based on the electric field strength, proximity to the stimulation electrode, and inversely proportional to fiber length. A-fibers are recruited first, followed by C-fibers [8]. The vagus nerve plays a crucial role in maintaining internal physiological stability, including reflex pathways that regulate cardiac function [9].

However, the physiological response to vagal nerve stimulation depends on the anatomical site and stimulation parameters [10]. Therefore, the aim of present study was to determine the most effective anatomical site for vagal stimulation. In present study, authors compared stimulation at three anatomical sites, namely the ear lobule, cymba concha, and tragus, and observed their effects on HR, BP, and skin hydration in prehypertensive individuals. Hence, according to null hypothesis there was no statistically significant difference in BP, HR, and skin hydration among the three anatomical sites of vagal stimulation in prehypertensive individuals and according to alternative hypothesis there is a statistically significant difference in BP, HR, and skin hydration among the three anatomical sites of vagal stimulation in prehypertensive individuals.

MATERIALS AND METHODS

The study was a pre-post comparative study with a total of 30 subjects. The subjects were allocated to three groups (A, B, C) using sealed envelopes. Treatment allocations were randomly generated by the therapist and placed in equal-sized envelopes. When a subject entered the trial, an envelope was opened, and the allocated intervention was given. The study took place in the OPD of Physiotherapy at the Institute of Applied Medicine and Research Centre in Ghaziabad, Uttar Pradesh, India. Ethical clearance was obtained from the Institutional Ethical Committee (IAMR/IEC/2022-Jan/05) and (IAMR/22/1724), and written informed consent was obtained from the subjects before the intervention.

Inclusion criteria: Both males and females aged between 30-50 years with prehypertension (SBP 120-139 mmHg and DBP 80-89 mmHg) were included in the study [7].

Exclusion criteria: Subjects who had a fear of stimulation, were smokers or alcoholics, had cardiopulmonary disease, diabetes, vagal dystonia, were taking anxiolytic medications, antidepressants or beta-blockers at the time of the study, or had an inability to understand verbal commands were excluded from the study [10].

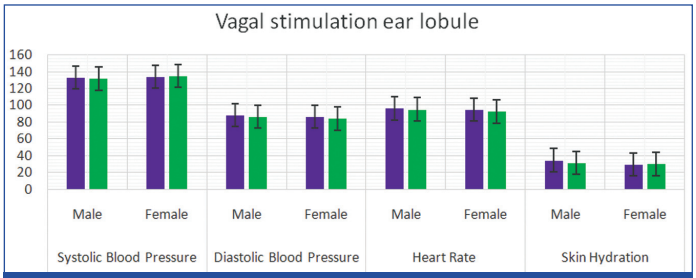
Sample size calculation: A total of 30 subjects aged between 30-50 years were included in the study. The sample size was calculated using Z-power.

Study Procedure

A total 40 subjects were screened, and 30 participated in the study based on the inclusion and exclusion criteria. The patients were assigned to the respective groups mentioned in their sealed envelopes. The study was a double-blinded. Group A consisted of 10 participants receiving vagal stimulation on the ear lobule [Table/Fig-1a,b], Group B consisted of 10 participants receiving vagal stimulation on the cymba concha [Table/Fig-2a,b], and Group C consisted of 10 participants receiving vagal stimulation on the tragus [Table/Fig-3a,b]. The electrical auricular neuromodulation of the vagus nerve was performed using a low-frequency TENS device with a pulse width of 120 ms and a pulse frequency of 25 Hz. The patients were asked to lie supine and relax for 10 minutes before and after stimulation. The auricular pavilion was initially disinfected with a cotton dab soaked in 70% alcohol. In Group A, vagal stimulation was applied to the ear lobule using the low-frequency TENS machine, with the anode placed on the ear lobule and the cathode on the lateral side of the ear above the ear lobule. In Group B, the anode was placed on the cymba concha and the cathode just above the first electrode, using the same parameters.

Variables	Gender	Vagal stimulation ear lobule			
		Pre	Post	t-value	p-value
Systolic Blood Pressure (SBP) (mmHg)	Male	133.33±2.8	131.66±3.5	-0.484	0.64
	Female	134±3.8	135±3.2		
Diastolic Blood Pressure (DBP) (mmHg)	Male	88.66±0.33	86.66±1.1	6.678	<0.001
	Female	86.71±1.7	84.57±1.2		
Heart Rate (HR) (beats per minute)	Male	96.33±4.04	95.33±5.03	1.667	0.13
	Female	94.85±3.3	92.57±3.3		
Skin hydration (%)	Male	34.83±2.3	31.73±3.72	-2.927	0.017
	Female	30.08±7.9	30.41±5.88		

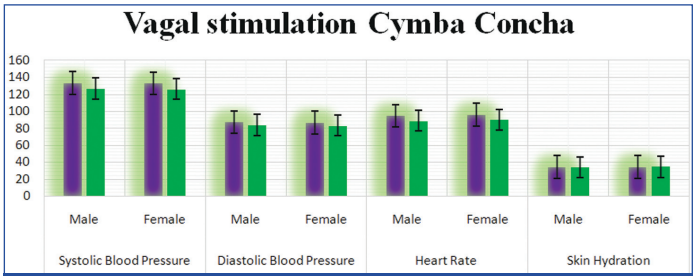
[Table/Fig-1a]: Descriptive statistical scores of the variable in ear lobule.



[Table/Fig-1b]: Graphical representation of the variables scores of the variable in vagal stimulation ear lobule.

Variables	Gender	Vagal stimulation cymba concha			
		Pre	Post	t-value	p-value
Systolic Blood Pressure (SBP) (mmHg)	Male	133.2±4.4	126.6±1.3	4.736	0.001
	Female	133±4.1	126.2±3.4		
Diastolic Blood Pressure (DBP) (mmHg)	Male	87.2±1.6	83.8±2.2	4.295	0.002
	Female	86.6±1.5	83.2±2.1		
Heart Rate (HR) (beats/minute)	Male	94.6±2.5	88.8±3.1	5.687	<0.001
	Female	95.8±2.7	90±3.1		
Skin hydration (%)	Male	34.12±7.25	33.94±6.68	6.019	<0.001
	Female	34.24±7.90	34.38±7.70		

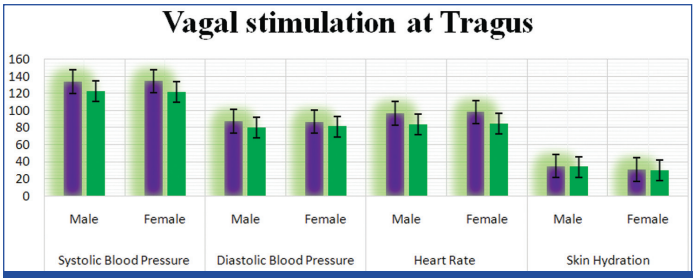
[Table/Fig-2a]: Descriptive statistical scores of the variable in vagal stimulation cymba concha.



[Table/Fig-2b]: Graphical representation of the variables scores of the variable in vagal stimulation cymba concha.

Variables	Gender	Vagal stimulation tragus			
		Pre	Post	t-value	p-value
Systolic Blood Pressure (SBP) (mmHg)	Male	134±3.6	122.6±2.0	11.513	<0.001
	Female	134.5±2.9	121.6±1.7		
Diastolic Blood Pressure (DBP) (mmHg)	Male	87.6±1.1	80±0.0	10.411	<0.001
	Female	87±1.6	81.5±0.78		
Heart Rate (HR) (beats/minute)	Male	97±1.7	84±1.7	15.231	<0.001
	Female	98.42±1.7	85.1±2.4		
Skin hydration (%)	Male	35.13±0.55	34.13±1.48	9.474	<0.001
	Female	30.87±6.55	30.02±5.72		

[Table/Fig-3a]: Descriptive statistical scores of the variable in vagal stimulation at tragus.



[Table/Fig-3b]: Graphical representation of the variables scores of the variable in vagal stimulation at tragus.

In Group C, the anode was placed on the tragus and the cathode on the ear lobule, again with the same parameters [Table/Fig-3a,b]. The intensity was adjusted to a comfortable range [10]. The stimulus was continuously applied for 30 minutes per day for four weeks, five days a week [11]. After 10 minutes of relaxation, HR, BP, and skin hydration were measured before and after the intervention. No adverse effects were reported, except for normal itching that subsided over time.

Outcome measures:

- **Blood Pressure (BP):** SBP/DBP measured in mmHg using a sphygmomanometer.
- **Heart Rate (HR):** Measured in beats per minute using a pulse oximeter.
- **Skin hydration:** Measured as a percentage using a skin hydration meter at the forehead [Table/Fig-4].

ANOVA- one-way factor									
Parameters	Gender	Ear lobule		Cymba concha		Tragus		F-value	p-value
		Pre	Post	Pre	Post	Pre	Post		
Systolic Blood Pressure (SBP) (mmHg)	Male	133.33±2.8	131.66±3.5	133.2±4.4	126.6±1.3	134±3.6	122.6±2.0	52.79	<0.01
	Female	134±3.8	135±3.2	133±4.1	126.2±3.4	134.5±2.9	121.6±1.7		
Diastolic Blood Pressure (DBP) (mmHg)	Male	88.66±0.33	86.66±1.1	87.2±1.6	83.8±2.2	87.6±1.1	80±0.0	46.73	<0.02
	Female	86.71±1.7	84.57±1.2	86.6±1.5	83.2±2.1	87±1.6	81.5±0.78		
Heart Rate (HR) (Beats/minute)	Male	96.33±4.04	95.33±5.03	94.6±2.5	88.8±3.1	97±1.7	84±1.7	19.21	<0.04
	Female	94.85±3.3	92.57±3.3	95.8±2.7	90±3.1	98.42±1.7	85.1±2.4		
Skin hydration (%)	Male	34.83±2.3	31.73±3.72	34.12±7.25	33.94±6.68	35.13±0.55	34.13±1.48	20.17	<0.04
	Female	30.08±7.9	30.41±5.88	34.24±7.90	34.38±7.70	30.87±6.55	30.02±5.72		

[Table/Fig-4]: Showing the descriptive comparison between vagal stimulation at ear lobule, cymba concha and tragus through one-way ANOVA.

STATISTICAL ANALYSIS

The data were statistically analysed using Microsoft Excel (MS) and the Statistical Package for the Social Sciences (SPSS) version 24.0. The paired t-test was used to compare the means of measurements within the groups. ANOVA was used to compare the differences between the three groups. The Confidence Interval (CI) was set at 99%, and a p-value greater than 0.05 was considered the threshold level for significance. [Table/Fig-4] shows the results.

RESULTS

In the present study, 40 eligible subjects initially participated, but 30 participants were eventually included. Group A consisted of 10 subjects receiving vagal stimulation on the ear lobule, Group B had 10 participants receiving stimulation on the cymba concha, and Group C included 10 participants receiving stimulation on the tragus. There were no statistically significant differences in baseline measurements among the three groups. In Group C, receiving stimulation at the tragus, the t-value and p-value for SBP were 11.513 and <0.001, for DBP it was 10.411 and <0.001, for HR it was 15.231 and <0.001, and for skin hydration it was 9.474 and <0.001 [Table/Fig-3a,b]. In Group A, the t-value and p-value for SBP were -0.484 and 0.64, for DBP it was 6.678 and <0.001, for HR it was 1.667 and 0.13, and for skin hydration it was -2.927 and 0.017 [Table/Fig-1a,b]. In Group B, the t-value and p-value for SBP were 4.736 and 0.001, for DBP it was 4.295 and 0.002, for HR it was 5.687 and <0.001, and for skin hydration it was 6.019 and <0.001 [Table/Fig-2a,b].

When comparing HR, BP, and skin hydration among the groups using one-way ANOVA, it was found that there was significant difference between the groups in each parameter. The systolic BP showed F-values and p-values of 52.79<0.01respectively, Diastolic BP 46.73 <0.02 , the heart rate showed F-values and p-values of 19.21 <0.04 and according to skin hydration the values were 20.17 <0.04 among the three groups [Table/Fig-4].

DISCUSSION

The present study demonstrated that auricular electrical neuromodulation of the vagus nerve at the tragus induced a significant reduction in BP and improvement in HR and skin hydration in prehypertensive individuals. The ear has direct innervation from the cranial nerve, specifically the vagus nerve, which regulates the autonomic nervous system and cardiovascular system [7]. The vagus nerve is a mixed nerve that consists of 80% afferent and 20% efferent fibers. The efferent fibers originate in the dorsal motor nucleus and the nucleus ambiguous located in the brainstem, providing innervation to various internal organs such as the heart, lungs, larynx, pharynx, stomach, spleen, and others [8]. Due to its connection with the heart, the vagal tone can also result in cardiovascular changes. Sensory information from sensory organs indirectly reaches the brain through cranial nerves, leading to higher perception and cognition. The cranial nerves influence the functional activities of the brain, consequently improving an individual's clinical, cognitive, and behavioural aspects [3]. The vagus nerve plays a key role in maintaining internal physiological stability, known as homeostasis, through reflex pathways that modify sympathetic parameters. The physiological response to vagal nerve stimulation depends on the site and parameters of stimulation [10].

The present study utilised three anatomical sites for stimulation: the ear lobule, cymba concha, and tragus. Stimulation at the tragus proved to be an excellent site for auricular stimulation. This finding is consistent with a previous study by da Silva PS et al., where they confirmed the acute effects of non invasive electric stimulation of the vagus nerve on BP and HR variability in hypertensive individuals. They observed a remarkable improvement in BP and HR variability and demonstrated that vagal stimulation can be used to manipulate BP and HR [11].

Previous research on vagal nerve stimulation has shown that salt-sensitive rats induced with high BP through a high-salt diet consumption for six weeks exhibited significant increases in arterial pressure, pulse rate, and episodes of arrhythmia. After four weeks, there was a further increase in mean arterial pressure and the number of arrhythmic episodes in rats. These enhancements were attributed to changes in the physiology of the heart, including a reduction in action potential during rapid pacing, increased dispersion of action

potential, and an increase in conduction velocity [12-14]. These changes may have occurred due to the electrical impulses transferred to the tragus, which stimulated the auricular branch of the vagus nerve. This, in turn, stimulated the medulla oblongata in the brainstem, which further stimulated the vagal efferent fibers to regulate HR and BP [15]. The increased vagal activity produced positive outcomes on the cardiovascular system, as the mechanoreceptors in the aorta decreased BP through vagal nerve fibers to the brainstem and activated the baroreflex, resulting in lower BP [16].

Plachta DT et al., support our research findings, which demonstrated the positive effects of cardiac cycle-synchronised vagal stimulation on BP and HR in rats [17]. Stimulation of the Auricular Branch of the Vagus Nerve (ABVN) through transcutaneous auricular vagus stimulation may also affect afferent vagal networks [18]. Vagal stimulation has the potential to shift from sympathetic to parasympathetic activation in older adults, thereby improving cardiovascular parameters. This is an important feature for BP and HR regulation [19]. The normal activation of the sympathetic system and myogenic reflex regulate the heart and muscle vasculature to maintain normal BP during exercise [20,21]. The effects may be due to the balance between myocardial oxygen supply and demand, which is achieved through the reduction in HR [22]. Therefore, vagal stimulation is often used by therapists in conjunction with various therapeutic interventions to treat or manage HR, BP, and skin hydration in prehypertensive individuals. Due to its innervation of the vagus nerve, it is recognised as a potential and emerging non invasive therapy for cardiovascular disorders and complications. The conduction in the ventricles receives innervation from postganglionic vagal fibers. The authors compared groups receiving vagal stimulation at the ear lobule, cymba concha, and tragus, and found that vagal stimulation at the tragus (Group C) showed the most significant and remarkable improvement, followed by vagal stimulation at the cymba concha and ear lobule.

Limitation(s)

The change in seasons may affect various parameters, especially skin hydration, in individuals. The nature of the skin may vary among different individuals, and their physical activities may also differ. Additionally, the present study did not include a longer follow-up period to examine the sustained effects of the interventions.

CONCLUSION(S)

Prehypertension is an alarming stage for individuals and medical professionals, as it indicates the need to start preventive measures to halt its progression to hypertension and its associated cardiovascular complications. Vagal stimulation via the tragus which is a non invasive therapy that helps maintain homeostasis in the autonomic nervous system. It also has the ability to modulate skin hydration, making it potentially useful in the management of various skin conditions.

The conclusion of the study is that vagal stimulation at the tragus is a more effective intervention than vagal stimulation at the cymba concha or ear lobule for controlling HR, BP, and skin hydration in prehypertensive individuals thus, rejecting Null hypothesis. Future research can be conducted in the dermatological field to further explore the effects of vagal stimulation on skin conditions and hydration. Additionally, investigating the impact of vagal stimulation on psychological parameters would be an interesting area for further study.

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