Effect of Vagal Nerve Stimulation and Jacobson Relaxation Technique on Agoraphobia among Post Neurological Ill-Patients: A Pilot Study

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Abstract

Background: This study was developed to determine the effectiveness of transcutaneous auricular vagus nerve stimulation and Jacobson relaxation technique on agoraphobia among subjects with post neurological ill-patients.

Purpose: The purpose of the study is to compare and evaluate the effectiveness of two non-pharmacological methods of treatment for Agoraphobia patients with Post neurological ill-patients.

Methods: The research project was conducted as a pilot study in a private hospital in Chennai. The experimental group (group A) received transcutaneous auricular vagus nerve stimulation for approximately 20 minutes (30 seconds ON and 5 minutes OFF) and a conventional Jacobson relaxation technique for 10 minutes. Group B got conventional cognitive behavioral therapy (20 minutes) and the Jacobson relaxation technique (10 minutes). Following the four-week treatment period, a post-test analysis was performed using the Severity measure of agoraphobia.

Results: The study found that there is a positive impact of transcutaneous auricular vagus nerve stimulation and Jacobson relaxation technique on agoraphobia in post neurological ill patients. The analysis obtained a mean value of about 18 and an SD of 26 for group A, whereas group B revealed 24.8 ± 4.40, mean ± SD, and a significant P value of <0.001.

Conclusion: When compared to group B, those in group A who received transcutaneous auricular vagus nerve stimulation improved more significantly when dealing with agoraphobia of post neurological ill patients. As a result, non-invasive transcutaneous auricular vagus nerve stimulation and Jacobson relaxation technique have been proven to be effective approaches for preventing agoraphobia.

Keywords: Anxiety, relaxation, electrical impulses, vagal nerve, transcutaneous, agoraphobia.

Introduction

An anxiety disorder is defined by a fear of situations in which the individual feels worried or panicked, such as open areas, crowded areas, and places where rescue appears difficult. Agoraphobia is a form of phobia, often known as irrational fear. The
The current weighted prevalence of Agoraphobia in India (95 percent confidence interval: 2.54-2.60) was 2.57 percent. The female gender, 40-59 age range was mostly affected. Research on women and their fear of heights has found that the percentage of female-to-male anxiety incidence ranges from 1.6 and 3.1.

Victims of psychological, physical, and child abuse are more likely to be women. In addition, a fear of height reactions in women is worse, and suffer greater impairment as a result of it than males. The various factors that induce agoraphobia are Depression, additional phobias such as claustrophobic and social phobia, as well as a different form of anxiety disorder such as generalized anxious disorder or OCD, a history of sexual or physical abuse, a problem with substance abuse, and a family history of agoraphobia are all risk factors for developing agoraphobia are all examples. Diseases of the brain, central nervous system, and autonomic nervous system are known as neurological disorders. It is critical to separate the many forms of neurological illnesses before detecting the signs and symptoms of neurological difficulties. There are a variety of neurological conditions, including Alzheimer’s disease a type of dementia (AD), Migraine headaches, Epilepsy, Parkinson’s illness, and Multiple sclerosis is a disease that affects people.

The pathophysiology of agoraphobia is people with agoraphobia are terrified of being in public places or circumstances where they cannot readily flee. They feel imprisoned, helpless, or embarrassed in these types of settings and situations, which causes them to panic or become incapacitated. After a panic episode or neurological illness, a person may acquire agoraphobia. Fear of subsequent neurological attacks, for example, may lead a person to avoid situations similar to those in which the initial attack occurred. The Severity Measure of Agoraphobia was used to diagnose agoraphobia. On a five-point scale, each item on the measure is assessed. A total score of 0 to 40 indicates the severity of agoraphobia, with higher numbers indicating more severe agoraphobia.

When someone has anxiety or severe fear in post-neurological situations, according to the Diagnostic and Statistical Manual of Mental Disorders (DSM-5) criteria, they are said to have an anxious disorder. A sort of therapy called Jacobson’s relaxation technique gradually tightens and releases particular muscle groups. Relaxation practices can provide several health benefits, a reliable source, such as anxiety reduction, a reliable source, work-related stress reduction, a reliable source, blood pressure reduction, lowering the chance of seizures, and enhancing your sleeping habits. The current treatments for agoraphobia are medications including Selective serotonin reuptake inhibitors and Benzodiazepines.

Psychotherapy and CBT are the other treatments. taVNS is used to treat disorders non-invasively by applying a current to the cutaneous receptive field produced by the auricular extension of the vagus nerve, which is located in the outer ear. In the previous twenty years, basic, medical, and transformational research have all focused on taVNS. For a number of disorders, it has been used as a replacement for pharmacological therapy. Some barriers to the advancement of this discipline have gradually come to light as a result of the rapid comprehension of how to apply taVNS to disease and health in humans. Here, we provide a thorough analysis of the field’s history and current state of study.

In classical vagus nerve stimulation, a surgically implanted device under the chest stimulates the implanted vagus nerve, which is connected to the left vagus nerve. When you switch on the device, it delivers electrical signals to your brain stem, which then sends messages to certain parts of your brain. Non-invasive transcutaneous auricular vagal nerve stimulation devices, which do not require surgical implantation and are applied using external appliances such as clip electrodes, have become popular in recent years. The clip electrode is attached to the outside of the ear. In a non-invasive procedure called transcutaneous auricular vagal nerve stimulation (taVNS), the vagus nerve’s auricular branch, which innervates the ear’s Cymba Concha, is electrically stimulated in order to trigger the inflammatory reflex. Recent studies have shown that patients who have recovered from neurologic illness can treat their agoraphobia with transcutaneous auricular vagal nerve stimulation.
Initial stimulation of the vagus nerve enhances memory and quality of life by boosting slow-wave sleep and decreasing anxiety\textsuperscript{11,12}.

Despite its effectiveness, the surgical strategy of vagal nerve stimulation has significant technical challenges and, as a result, a limited spectrum of usage. As a result, non-invasive vagus nerve stimulation was developed. The two non-invasive treatments employed were stimulating the ear and applying superficially to the cervical nerve\textsuperscript{13}. The aim of this study is to determine the effectiveness of transcutaneous auricular vagal nerve stimulation and Jacobson relaxation technique on agoraphobia in post neurological ill patients.

**AIM**

To determine the effectiveness of transcutaneous auricular vagal nerve stimulation and Jacobson relaxation technique on agoraphobia among subjects with post neurological ill patients.

**Material and Methods**

The research project was conducted as a pilot study in a private hospital in Chennai to investigate the efficacy of transcutaneous auricular vagal nerve stimulation and Jacobson relaxation technique in improving agoraphobia in patients with post neurological ill patients. A private college’s Scientific Study Board approved a human population study in line with all applicable laws and regulations (01/027/2022/ISRB/PGSR/SCPT). Following a thorough description of the procedure, individuals were selected from the private hospital with their signed consent. There was blinding of both the participant and the evaluated participant involved in this study during the period of June 2022 and September 2022. Participants were clearly explained about the study procedure and informed consent was obtained.

**Selection criteria:** Eight participants were selected, representing both genders, based on the following eligibility criteria: Participants with post neurological ill patients, as well as those with a pre-test Severity measure of agoraphobia score of less than 40, were eligible to participate. Participants who had a history of various neurological diseases, recent injuries, mental instability, or a lack of interest in participating in the study were excluded.

**Outcome measure:** A fast screening assessment tool, the Severity measures of agoraphobia, was developed to identify Agoraphobia in Post neurological ill patients. On a five-point scale, each item on the measure is assessed (0=Never; 1=Occasionally; 2=Half of the time; 3=Most of the time, and 4=All of the time). A total score of 0 to 40 indicates the severity of agoraphobia, with higher numbers indicating more severe agoraphobia. The severity measure of agoraphobia includes a variety of factors, including the stability of the person’s symptoms and the state of their therapy; the measure may be completed at regular intervals as clinically required to monitor changes in the severity of the person’s agoraphobia over time. High scores on a given domain over time may point to important and troublesome areas for a person who could require additional evaluation, care, and monitoring. Your choice should be based on your clinical expertise.

**Procedure**

The participants were separated into two groups, A and B, using the closed envelope method. Both groups received 30-minute therapy sessions three days a week for four weeks. The experimental group (group A) received transcutaneous auricular vagal nerve stimulation for approximately 20 minutes (30 seconds ON and 5 minutes OFF), with clip electrodes placed on the Cymba concha of the left ear at a frequency of 25 Hz, amplitude: 0.1-10 mA, pulse width: 250 µs, and conventional Jacobson relaxation therapy for 10 minutes. Group B got conventional cognitive behavioral therapy (20 minutes) and Jacobson relaxation technique (10 minutes). Following the four-week treatment period, a post-test analysis was performed using the Severity measure of agoraphobia.

**Data analysis**

Statistical analysis was done with the intention of treating agoraphobia after the stroke (post neurological ill-patients). Pre- and post-test values for SMA were noted. A paired t-test was used for within-group analysis, and a Mann-Whitney U test was used for between-group analysis.
Table 1: Baseline characteristics of population included.

<table>
<thead>
<tr>
<th>CHARACTERISTICS</th>
<th>GROUP A (mean ± SD)</th>
<th>GROUP B (mean ± SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>AGE</td>
<td>43.25 ± 2.38</td>
<td>44.5 ± 2.29</td>
</tr>
<tr>
<td>DURATION</td>
<td>7.75 ± 1.47</td>
<td>7.82 ± 1.11</td>
</tr>
<tr>
<td>MoCA</td>
<td>18.25 ± 20.18</td>
<td>24 ± 26.47</td>
</tr>
</tbody>
</table>

Table 2: Pre and Post-test comparison of Group A (taVNS + Jacobson relaxation technique).

<table>
<thead>
<tr>
<th>GROUP A</th>
<th>MEAN ± SD</th>
<th>t value</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-test</td>
<td>25 ± 18.25</td>
<td>-210</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Post-test</td>
<td>18 ± 26</td>
<td></td>
<td></td>
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</table>

Table 3: Pre and post-test comparison of Group B (conventional Jacobson relaxation technique).

<table>
<thead>
<tr>
<th>GROUP A</th>
<th>MEAN ± SD</th>
<th>t value</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-test</td>
<td>26.5 ± 4.38</td>
<td>10.925</td>
<td>&lt;0.001</td>
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<tr>
<td>Post-test</td>
<td>24.8 ± 4.40</td>
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Table 4: post-test comparison of both Group A and B (taVNS + Jacobson relaxation technique and Conventional Jacobson relaxation technique).

<table>
<thead>
<tr>
<th>PARAMETRICS</th>
<th>MEAN ± SD</th>
<th>t value</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group A</td>
<td>18 ± 3.08</td>
<td>-5.6</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Group B</td>
<td>24.8 ± 4.4</td>
<td></td>
<td></td>
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</table>

Results

Both groups were allocated with 4 members. Because it was intended to treat both groups, the intervention group (group A) received transcutaneous auricular vagus nerve stimulation and Jacobson relaxation technique while the control group (group B) received conventional Jacobson relaxation technique. Nobody in either group left before the research had ended. The collection of data began in January 2023, and treatment sessions began in February 2023 for four weeks. Following the treatment phase, the post-test analysis was carried out using the Severity measure of agoraphobia.

The statistical analysis of the study revealed a significant p-value of less than 0.001 (Table 4) for those who underwent transcutaneous auricular vagal nerve stimulation in addition to the conventional Jacobson relaxation technique. Both groups had the same baseline characteristics in the pre-test (Table 1).

SMA testing was done on Group A before the therapy started. They underwent the conventional Jacobson relaxation technique for 10 minutes each week for four weeks while also receiving transcutaneous auricular vagal nerve stimulation for 20 minutes. The patient’s post-test analysis then made use of the same outcome. The data collected before and after the treatment was recorded, and the paired t-test was used to look into the difference. The statistical analysis shows that P < 0.001 is significant (Table 2).

Before and after the treatment period, Group B underwent the same examination. Group B received the standard Jacobson relaxation technique. The paired t-test was used to examine the differences between the data acquired before and after the test. With a p-value of <0.001, it also showed statistical significance (Table 3).

On comparing the effect of transcutaneous auricular vagus nerve stimulation along with the Jacobson relaxation technique and conventional Jacobson relaxation technique the post-test values obtained in both group A and B was analyzed using the Mann-Whitney U test and it revealed a statistically significant p value of <0.001 (Table 4).

Discussion

This study describes the non-invasive method for the stimulation of the vagus nerve auricularly in reducing fear among patients with post-neurological conditions. Following a diagnosis of a post-neuro condition, fear and panic attacks are common symptoms that have an effect on the daily life of participants. Post-neurological conditions include a year after stroke, TIA, TBI, dementia, parkinsonism, and other neurological disorders. All the post-neurological patients have been developing fear, panic, and feelings of being trapped, helpless, or embarrassed. This study has decided to examine the current therapy choices for agoraphobia following these conditions because there is not much literature available identifying the optimal treatment approach to reduce agoraphobia.

In Xiao X, Hou X, et.al suggested that Vagal nerve stimulation has been demonstrated to have a
positive impact on reducing agoraphobia, according to research that has established its impact on agoraphobia. It lessens fear, a psychological element that is extremely unique among individuals with post-neurological conditions, by stimulating the vagus nerve auricularly.\textsuperscript{15,16}

Daruj Aniwattanapong, Justine J List et al., titled Effect of Vagus Nerve Stimulation on Attention and Working Memory in Neuropsychiatric Disorders: A Systematic Review suggested that there is not enough excellent proof that VNS is an efficient treatment for enhancing working memory and attention in individuals with neuropsychiatric illnesses, despite the fact that we found some encouraging outcomes from trials that were eligible. Additional research is required to determine the effectiveness of this intervention. Memory function after VNS was shown to significantly improve from a within-subject design of experiments. Three nonrandomized controlled experiments indicated that following VNS, the attentional ability was greatly enhanced. Cohort studies that compared VNS and surgery discovered improvements in attention in both groups. In nine out of twelve pre-post investigations, attention or working memory had improved following VNS. Although one trial for mood disorders revealed an important boost in attention after VNS, the other did not.\textsuperscript{17,18}

Most of the studies were conducted through invasive vagal nerve stimulation, whereas Bashar W. Badran, and Christopher W. Austelle discussed the safety and utility of taVNS, which is that the potential of taVNS as a secure at-home wearable therapy for a range of neurologic illnesses is enormous. According to the study’s findings, psychological adjustments like reducing fear, panic attacks, functional capacity, and social interaction all showed mild to moderate increases, as did overall well-being and quality of life.\textsuperscript{19,20}

Looking into the available therapeutic methods or preventive measures, we studied certain studies that discussed the management of agoraphobia. The pharmaceutical intervention included the administration of Selective Serotonin reuptake inhibitors. A vital part of treating agoraphobia involves medication. The advantages of medication, however, may differ based on the underlying cause and the unique patient response.

Kyriakoula Merakou, Konstantinos Tsoukas et al., entitled The Effect of Progressive Muscle Relaxation on Emotional Competence: Depression-Anxiety-Stress, Sense of Coherence, Health-Daily Life and Well-Being of Jobless Greeks: An Intervention Study suggested that in the study, 50 long-term jobless individuals with anxiety problems took part. Those who participated were segregated into two groups: the intervention group (30 people) got counseling services in addition to an 8-week training program in the gradual relaxation of muscles, and the control group (20 people) received simple counseling services. Among the two groups, there were significant differences in the studied variables, with the intervention group experiencing better results. The intervention group demonstrated improvements in well-being. The control group showed no discernible change over the course of the period of follow-up.\textsuperscript{21}

Tejal C. Nalawade, Dr. Nitin S. Nikhade et al. suggests that Jacobson’s PMR technique may be beneficial in decreasing fear, anxiety, and depression symptoms in older persons, as well as enhancing Quality-of-Life Enjoyment and Satisfaction. Progressive Muscle Relaxation can help negate some of the consequences of stress reaction by releasing tension in the body when practiced and incorporated into an individual’s lifestyle.\textsuperscript{22}

Jonathon A. Nye, Bradley D. Pearce et al. suggested that the taVNS was demonstrated to increase vagal tone in PTSD patients and suppress long-term fear reactions during extinction training in healthy human participants, according to the researchers. Noninvasive VNS technology would be a valuable addition, allowing for more research into the circuit of PTSD and treatment-resistant depression, as well as a novel and very acceptable therapeutic choice for patients suffering from serious and recurrent depression and PTSD.\textsuperscript{23,24}

Gagandeep Singh, Vasudev Singh, et al. suggested that the development of fear and anxiety disorders after TBI was proven to be an excellent indicator of social, intimate, and occupational dysfunction, as was seen in our patient, according to the case study The condition of a with Panic Attacks The act of
manifestation after Trauma Brain Injury. However, there was a correlation between compensation claims and the prevalence of psychiatric disorders. According to the case study, some people with TBI may have psychological issues that linger for decades. It further highlights the significance of all patients receiving psychiatric continuation after TBI. The study was limited by the small sample size and the use of one outcome measure to rule out agoraphobia. Furthermore, large sample size research with additional outcome measures was required.

Since this study is self-funded, we haven’t performed any quantitative analysis, like biological markers. The study is unique since it addressed the population’s post-stroke cognitive loss and vascular dementia by providing a special non-invasive, efficient, and safer treatment approach. This research helps in the prevention of dementia in people with cognitive impairment.

Conclusion

According to the results of the current study, non-invasive vagal nerve stimulation performed trans-auricularly and the conventional Jacobson relaxation technique resulted in a greater improvement in agoraphobia than the conventional Jacobson relaxation technique, with a significant value of \( p = 0.001 \). Participants who underwent the conventional Jacobson relaxation technique also showed improvement. But when comparing the two groups, those in group A who received transcutaneous auricular vagal nerve stimulation and Jacobson relaxation technique showed a more significant improvement in treating the agoraphobia of post neurological ill-patients.

Ethical clearance: The ISRB committee of a private hospital and institution in Chennai has provided its clearance for the conduct of human research that complies with all applicable national laws, and institutional regulations. (Application Number 01/027/2022/ISRB/PGSR/SCPT).

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Conflict of interest: The authors state that there is no conflict of interest

References


