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Questions and Answers about your treatment with TVNS:

The process of stimulating the Vagus Nerve with micropulses of electrical current is referred to in a number of different ways.

*Non-invasive Vagus Nerve Stimulation (**tVNS, taVNS, nVNS, LLTS**) - Refers to stimulation of the vagus nerve without penetrating the skin using an external device and surface electrode. **tVNS** stands for Transcutaneous Vagus Nerve Stimulation.*

Vagus Nerve Stimulation:

The vagus nerve provides a unique entrance to the brain via its auricular branch, where electrical stimulation allows direct modulative access to subcortical brain areas which interface with several **neurophysiological** and **neuroinflammatory** restorative pathways.

The development of vagus nerve stimulation (VNS) as therapy began with the investigations of James Corning who developed the first basic functioning VNS device. In the late 1990's, after the success of several clinical trials illustrating the beneficial use of VNS for treatment resistant epilepsy and depression, the FDA approved its use for these applications. This illustrated the safe and effective use of this treatment modality.

In the last decade however, great advances have been made in the field of vagus nerve stimulation. Through greater anatomical understanding and applied research, it is possible to stimulate the vagus nerve without the need for a surgical procedure. This is possible by utilizing the auricular branch of the nerve which runs past the tragus of the outer ear, where this method is known as transcutaneous vagus nerve stimulation (tVNS). This method has now been shown to activate vagal pathways in the same way as with the surgical (VNS) procedure, making it an accessible, **low risk** and **lower cost** route to stimulating the vagus nerve. This has fueled an already growing field bioelectric medicine, where the scope for neuromodulation via the vagus nerve is vast.

Why is stimulating the vagus nerve beneficial?

Stimulation of the vagus utilizes several modulatory actions in the **nervous, immune, autonomic, endocrine, cardiorespiratory, and gastrointestinal systems.**

The exact mechanisms of action in VNS are still being theorized however this has not hindered its ability to demonstrate safe and effective use for individuals suffering from conditions which interface vagal pathways.

Vagus nerve stimulation therapies have already been approved by regulatory bodies for applications such as **mood enhancement, pain relief, improving sleep and reducing anxiety**; with investigations underway in assessing the cardiac and inflammatory modulation properties as well as those utilizing effects of neuroplasticity.

TVNS Mechanism of Action

Autonomic Modulation

The vagus nerve is the main nerve of the parasympathetic division of the autonomic nervous system, which regulates unconscious processes in the body. The Parasympathetic Nervous System (PNS) is often referred to as the 'rest and digest' system, whereas the Sympathetic Nervous System (SNS) is thought of as the 'fight or flight' system. **Stimulation of the vagus nerve has been shown to increase PNS activity/decrease SNS activity.** Further through this regulation of metabolic homeostasis, the vagus nerve also controls heart rate, where increasing vagal activity has been associated with decreases in heart rate. This is significant as autonomic dysfunction, as characterized by an overactive SNS response, is thought to underpin several high impact chronic conditions, illustrating the value of an intervention which can modulate this.

Neurotransmitters

Neurotransmitters are chemical substances released by nerve fiber impulses to surrounding areas of this electrical activity. Examples of neurotransmitters are Serotonin, Noradrenaline/Norepinephrine and Gamma-Aminobutyric acid (GABA). Research in this area indicates stimulating the vagus nerve can influence the release of neurotransmitters in the brain. **Clinical studies indicate that TVNS likely results in changes in serotonin** (Ben-Menachem et al 1995), **norepinephrine** (Krahl et al 1998), **GABA, and glutamate** (Walker et al 1999), these are all neurotransmitters implicated in the pathogenesis of major depression. This influence on neurotransmitters, along with a number of other theorized mechanisms, are thought to explain the mood enhancing effects arising from stimulation of the vagus nerve.

Inflammatory Modulation

It is now understood that the nervous system reflexively regulates the inflammatory response in real time, in much the same way that it controls heart rate and other vital functions. This is thought to occur via the vagus nerve through a neural reflex mechanism known as the 'inflammatory reflex'. The brain receives signals from the immune system for the purposes of optimally controlling inflammation in the body, however, dysfunction in these signals can lead to excess inflammation. It was observed that without vagus nerve activity (either due to a vagotomy or neural lesions) there was an absence of the inflammatory reflex which resulted in excessive innate immune responses and cytokine toxicity (excessive inflammation). This led to clinical study and demonstration that **stimulation of the vagus nerve can lead to decreases in inflammatory cytokines**. The anti-inflammatory properties of (stimulating) the vagus nerve are thought to be through the Cholinergic Anti-inflammatory Pathway (CAP) as well as mediated through the Hypothalamic pituitary adrenal (HPA) axis. These insights have led to new opportunities in the treatment of inflammation through these selective and reversible 'hard-wired' neural systems.

Neuroplasticity

Research towards the end of the 20th century has shown that many aspects of the brain can be altered, or are 'plastic', even through adulthood. **Neuroplasticity is the brain's ability to restructure itself by generating new neural connections**. It allows the neurons or nerve cells in the brain to compensate for injury or disease and amend their processes in response to new situations or environmental changes. The promotion of neuroplastic effects from tVNS/VNS through alterations in central nervous system neurotransmitter levels and/or processing have led to greater focus on the use of tVNS as therapy for tinnitus and stroke rehabilitation. It is now theorized that a significant number of Tinnitus cases arise or are disproportionality contributed by maladaptive plasticity of the auditory cortex. These applications utilize the mechanisms of 'targeted plasticity', by stimulating the vagus to promote neuroplasticity and pair this with a specific stimulus, eg. sound therapy (for tinnitus) or rehabilitative exercise (for stroke recovery), which targets this effect of plasticity in the specific region of the brain associated with each condition. **This has led to outcomes such as accelerated and improved recovery from stroke and reductions in the symptoms of tinnitus**.

Pioneering a new field:

We at Alpha Allied, find a tremendous amount of evidence that electroceuticals will and is currently a vital part of treatment in mental health.

What are the New Discoveries?

The researchers investigated the effects of transcutaneous (non-invasive) vagus nerve stimulation (tVNS) in volunteers who were more than 55-year old - the population that was most vulnerable to age-related complications.

They found that a single tVNS treatment session could significantly increase heart rate variability (HRV) compared to control treatment[2]. This shows the ability for tVNS to increase parasympathetic tone as measured by HRV, which is significant as low HRV has been associated with an increased risk of cardiovascular events[6,7].

Also, the use of tVNS for just **15 minutes daily over two weeks** showed similar **benefits to autonomic function** in addition to **improvements in depression score, sleep quality, and other aspects in the quality-of-life measurement.**

More importantly, volunteers who had a greater sympathetic tone at the beginning of the study showed a better response over the two week period. This demonstrated that people who were at a higher risk would benefit most from tVNS.

Benefits to the Ageing Society

Healthy ageing is now a priority in our society. Instead of combating diseases after they have manifested, it is always a better choice to expand the period where healthy ageing can occur.

The capacity of tVNS to reduce the shift towards sympathetic prevalence and improve vagal tone is a promising discovery to reduce the impact of many chronic illnesses.

Studies have demonstrated that patients with coronary artery disease who received tVNS treatment had better exercise tolerance and required less medication[8].

Some other studies also described the beneficial effects of tVNS in reducing inflammation - the hallmark of ageing - and its associated problems.

Excessive inflammation was associated with many illnesses such as depression and chronic fatigue syndrome, all of which have shown to benefit from tVNS treatment.

Summary:

tVNS can be effective in inducing functional changes in the brain as well as enhancing mood without using pharmaceutical drugs. fMRI scans of 22 healthy subjects who underwent stimulation of the tragus showed a reduction in signals from the limbic areas (amygdala, hippocampus, Para hippocampal gyrus and the middle and superior temporal gyrus). In contrast, heightened signals were found in the insula, precentral gyrus and the thalamus. **Psychometric assessment (Adjective Mood Scale) showed significant improvement in well-being after treatment when compared to placebo therapy.**

A deficit in the amygdala-frontal functional connectivity had been implicated in major depressive disorder (MDD). **A four-week tVNS treatment** on patients with MDD found a **significant reduction** in the **Hamilton Depression Rating Scale** as well as an increase in the resting state functional connectivity (rsFC) between the right amygdala and left dorsolateral prefrontal cortex, thus shedding light on a possible mechanism of action of tVNS to treat MDD.

Is this treatment covered by my insurance?

*As of January 2020, this type of procedure does have a procedure code. Each payor rate will be different. We make every effort to not increase your payment responsibility past your co-pay. We will discuss if we know certain insurance do not cover well.

How many Treatments should I have? How many do I have to have?

The treatments are cumulative. This means, each treatment lasts longer than the first. One treatment could last as long as twenty-four hours. We recommend you do a minimum of two treatments a week for four weeks. Remember, this treatment is not electric shock. Optimal treatment regimen is: three days a week for four weeks. At the end of the treatment, we re-evaluate if the patient is getting better and what is the recommended next steps. We calibrate each person's "Alpha-Wave" and then they are set to enjoy each treatment.

How much does it cost out of pocket? How much by Insurance? Check with insurance \$500.00/month.

