Original Article

Effect of Vagal Nerve Stimulation on Swallowing in Subjects with Post Stroke Dysphagia

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Abstract

Background: The study was developed to find the effect of auricular transcutaneous vagal nerve stimulation on difficulty in swallowing in post stroke dysphagia.

Purpose: The purpose of this research is to extensively investigate and analyse how VNS impacts swallowing in people with post-stroke dysphagia**.**

Materials and Methods: A total, 30 individuals have been selected mainly according to the criteria of both the inclusion and exclusion, from the above-mentioned study setting. The study was explained to subjects and written consent was collected from all subjects prior to the initiation of procedure. The subjects included the study was randomly allocated into 2 groups The participants in group A will receive Transcutaneous auricular vagal nerve stimulation, which is given for 20 min with the frequency of about 25 Hz, amplitude: 1 mA, pulse width: 360 μs using clip electrode being placed in Cymba Concha, along with the conventional exercises and Group B will receive Neuromuscular electrical stimulation will be given as Interrupted direct current at 30 Hz for 100ms, and the intensity was increased until perceptible visible contraction.

Results: Auricular transcutaneous vagal nerve stimulation showed a significant effect in improving swallowing functions at 4 weeks, with a p value which is < 0.001.

Conclusion: This study showed that the transcutaneous auricular vagal nerve stimulation showed a positive effect in improving swallowing functions in patients with dysphagia.

Keywords: Dysphagia, swallowing dysfunction, Transcutaneous auricular vagal nerve stimulation, Functional oral intake scale, Dysphagia outcome and severity scale.

Introduction

A stroke is a medical emergency caused by an abrupt disruption of continuous blood flow to the brain. When a blood vessel in the brain becomes blocked or restricted, or when one bursts and flows blood into the brain, a stroke occurs. A stroke, like a heart attack, requires quick medical intervention[1]. Stroke is the world's second leading cause of

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death, mainly among the elderly[2]. In 2016, 80.1 million people worldwide had a stroke (95 percent confidence interval: 74.1–86.3), with 41.1 (38.0–44.3) million women and 39.0 (36.1–42.1) million males[3]. Cerebrovascular diseases (CVD) are on the rise in India, owing to the rapid escalation of risk factors like high BP, diabetes mellitus, smoking, and obesity, which impact a large proportion of the adults. Global Burden of Disease study says that stroke caused 619,000 deaths in India, with 28.5 million Disability Adjusted Life Years lost, underscoring the fact that CVD causes significant mortality and morbidity[4]. The most commonly affected artery in acute stroke is the middle cerebral artery. It has four primary branches that branch straight from the internal carotid artery: the M1, the M2, the M3, and the M4. The lobes of the brain, and deeper structures involving the internal capsule, caudate nucleus and thalamus, receive blood from these veins. Because of its extensive supply, stroke occurring in the MCA region can present with a wide range of symptoms, occurring based on the branches and structures being injured[5]. Patients who suffer from a stroke are prone to many complications. Comorbid diseases including hypertension, diabetes, heart disease, or other illnesses are frequently present in these people, which raises the possibility of systemic medical issues during the recovery from a stroke. However, a number of difficulties may develop as a direct result of the brain injury itself, from the following impairments or immobility, or from stroke related treatments. These incidents frequently obstruct neurological rehabilitation in stroke patients and have a significant impact on their final prognosis. Following a stroke, cardiac problems, pneumonias, venous thromboembolism, fever, discomfort, dysphagia, incontinence, and depression are extremely common and mostly require for specialized therapies for their prevention and treatment. The need of this study is to look at the possible impact of Vagal Nerve Stimulation on swallowing function among individuals who have post-stroke dysphagia. We require to gain useful insights into the safety, effectiveness, and utility of this innovative treatment intervention as a rehabilitative tool for dysphagic patients by examining its effects. The goals of this study are differed. In the beginning, we want to see how Vagal Nerve Stimulation affects swallowing physiology in the short and long-term using clinical tests, imaging modalities, and patient-reported outcomes. Second, we want to understand the underlying neuronal processes by tracking changes in brain activity with functional imaging modalities like fMRI or EEG. Dysphagia is a dysfunction of the complex and interconnected sensorimotor system. Since there is an increased risk of aspiration pneumonia and its complications, neurogenic dysphagia (ND) is association with substantial morbidity, mortality, and social costs in subjects with neurological illnesses of various etiologies. Dysphagia, or difficulty in swallowing, is a commonest complication of acute stroke, with a frequency as high as 47 percent. In different neurological diseases, an irregular pattern of swallowing or flow of bolus disturbance from the mouth to the oesophagus is a major concern. One of the first barriers on the road to recovery for the wide majority around the 6.2 million post-stroke survivors in the United States is swallowing difficulties. After a stroke, dysphagia which is only increasing morbidity and mortality, which also had a major effect on quality of life. After a stroke, dysphagia may be caused by a wide range of complications. In a study, 19% patients of dysphagia developed bronchopneumonia which is compared to 8% of population those without the dysphagia; however, this difference which did not have statistical significance. Aspiration of food/saliva may result in an infection of the chest. Dehydration may also be a problem for patients. After a stroke, nutritional status declines, however it is unresolved whether this is related to problems with swallowing. Dysphagia could be an independent indication of a poor prognosis following a stroke. Although dysphagia was not taken into account as an independent variable in the research, it is known that it increases mortality in people with clinically identifiable swallowing problems[6-8]. Vagal nerve stimulation is a well-known treatment option for a wide range of neurological conditions. Because of the low danger of side effects, it's also effective in clinical trials for a variety of illnesses. Non-invasive transcutaneous vagal nerve stimulation includes transcutaneous auricular vagal nerve stimulation (taVNS) and cervical transcutaneous vagal nerve stimulation. The vagus nerve transmits afferent and efferent nerve impulses that is associated with swallowing. The locus coeruleus and the nucleus

tractus solitarii are activated when the vagus nerve is stimulated in the cavum concha, according to a systematic study. The Nucleus tractus solitarii, along with its adjacent structure of reticular origin and nucleus suspicion in the medulla oblongata that is present ventrally, is the swallowing reflex's central pattern generator and is the primary target of VNS[9]. FOSS is a scale that assesses functional outcomes. The FOIS is a statistically verified food and liquid intake scale for patients with stroke. It is often used to analyse the functional oral intake of post stroke patients with dysphagia. The swallowing results were classified into seven levels (scores 1–7). Tubes are required for levels 1–3. On a scale of 1 to 7, total oral consumption is measured. For the therapist, it is easy, clear, and effective. The Dysphagia Outcome and Severity Scale is a scale with 7 score that was established to rate the functional difficulty of dysphagia depending on objective assessment and give suggestions for independence level, diet level, and nutrition type[10].

AIM

The study is aimed to find the effect of Transcutaneous auricular vagal nerve stimulation on difficulty in swallowing in post stroke dysphagia.

Materials and Methods

Study design: Experimental study.

Subjects: Subjects were selected from Saveetha medical college and hospital.

Sampling technique: Concealed envelope method

Study Duration: The collection of data began in January 2023, and treatment sessions began in February 2023 for four weeks.

Sample size: 30

Inclusion criteria:

- Subjects of all age.
- Subjects of both genders.
- Subjects with the history of post-stroke with swallowing difficulty
- Subjects who score 3 and less than 3 in FOIS scale
- Subjects who score less than 3 in DOSS scale.

Exclusion criteria:

- Subject with swallowing difficulty caused by any other neurological disorders
- Subjects who are not interested in participating in this study
- Subjects with psychological disorders.
- Subjects with skin allergies
- Trauma that occurred recently
- Unstable vitals
- Recent surgeries involving the neck and adjacent structures.
- Symptomatic cardiovascular diseases

Outcome measure:

FOIS:

The Functional Oral Intake Scale is a statistically verified food and liquid intake scale for patients with stroke. It is often used to measure the oral intake functionally of poststroke patients having dysphagia. The swallowing results were classified into seven levels (scores 1–7). Tubes are required for levels 1–3. On a scale of 1 to 7, total oral consumption is measured. For the therapist, it is easy, clear, and effective.

DOSS: The Dysphagia Outcome and Severity Scale is a scale with points of 7 that was established to rate the difficulty in functional component of dysphagia depending on assessment and give suggestions for independence level, diet level, and nutrition type.

Procedure

The subjects were divided into 2 groups. Both the groups received the treatment protocol for around 4 weeks. The participants in group A received Transcutaneous auricular vagal nerve stimulation for 20 min in the frequency of 25 Hz, amplitude: 1 mA, pulse width: 360 μs using clip electrode being placed in Cymba Concha, along with the conventional exercises and Group B received NMES which was given as Interrupted direct current at 30 Hz for 100ms, and the intensity was increased until perceptible visible contraction. The patient was in a supine position with a pillow beneath his head. Inactive electrodes were implanted at the nape of the neck, while active pen electrodes were put on either side of the hyoid bone in the pharyngeal muscles along with the conventional exercises.

Data analysis

Statistical analysis was done on an Intention to treat the swallowing difficulty after the stroke. Pre and post-test values for FOIS and DOSS were noted. Wilcoxon signed-rank (non-parametric) test was used for within group analysis and Mann Whitney was used for across group analysis.

Table 1: Pre and Post-test values of Group A obtained using FOIS, indicating the improvement in swallowing functions by transcutaneous vagal nerve stimulation.

TEST	MEAN	SD	W value	Z value	P value
PRE-TEST	3	1	120	3.462	<0.001
POST-TEST	6	5			

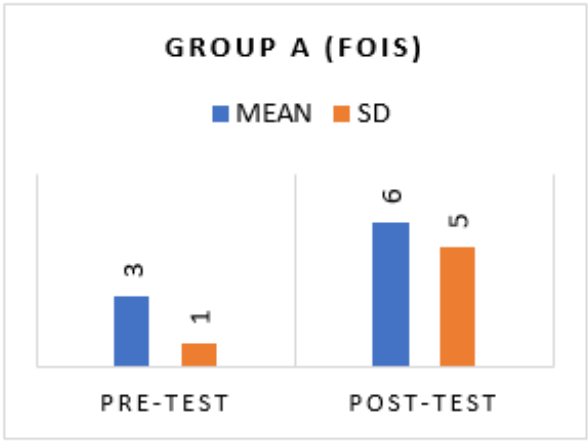

Fig 1: Pre and Post-test values of Group A obtained using FOIS, indicating the improvement in swallowing functions by transcutaneous vagal nerve stimulation.

Table 2: Pre and Post-test values of Group B obtained using FOIS, indicating the improvement in swallowing functions by transcutaneous vagal nerve stimulation.

TEST	MEAN	SD	W value	Z value	P value
PRE-TEST	3	1	120	3.542	<0.001
POST-TEST	5	4			

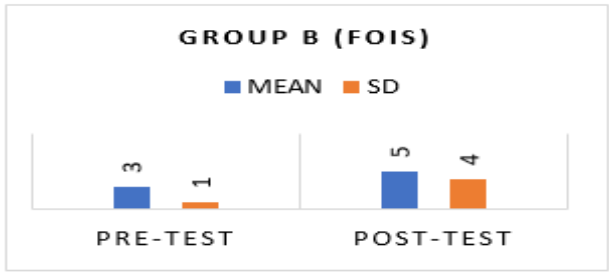

Fig 2: Pre and Post-test values of Group B obtained using FOIS, indicating the improvement in swallowing functions by transcutaneous vagal nerve stimulation.

Table 3: Post-test values of Group A and B obtained using FOIS, indicating the improvement in swallowing functions by transcutaneous vagal nerve stimulation.

GROUP	MEAN	SD	T value	p value
GROUP-A	6	5	294	<0.008
GROUP-B	5	4		

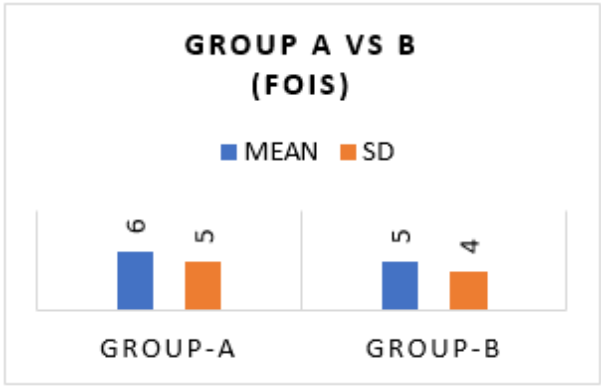

Fig 3: Post-test values of Group A and B obtained using FOIS, indicating the improvement in swallowing functions by transcutaneous vagal nerve stimulation.

Table 4: Pre and Post-test values of Group A and B obtained using DOSS, indicating the improvement in swallowing functions by transcutaneous vagal nerve stimulation

TEST	MEAN	SD	W value	Z value	P value
PRE-TEST	2	1	120	3.460	<0.001
POST-TEST	6	5			

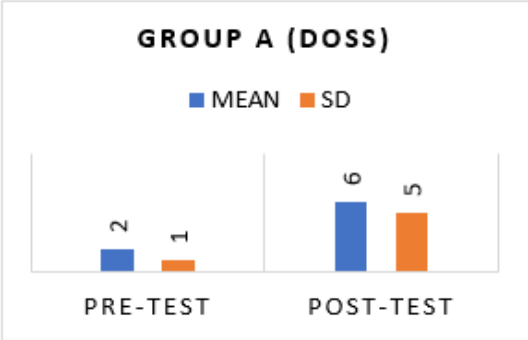

Fig 4: Pre and Post-test values of Group A and B obtained using DOSS, indicating the improvement in swallowing functions by transcutaneous vagal nerve stimulation.

Table 5: Pre and Post-test values of Group B obtained using DOSS, indicating the improvement in swallowing functions by transcutaneous vagal nerve stimulation.

GROUP	MEAN	SD	T value	p value
GROUP-A	6	5	308.5	<0.001
GROUP-B	5	4		

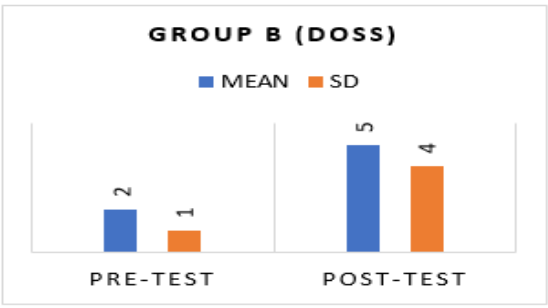

Fig 5: Pre and Post-test values of Group B obtained using DOSS, indicating the improvement in swallowing functions by transcutaneous vagal nerve stimulation.

Table 6: Post-test values of Group A and B obtained using DOSS, indicating the improvement in swallowing functions by transcutaneous vagal nerve stimulation.

TEST	MEAN	SD	W value	Z value	P value
PRE-TEST	2	1	120	3.473	<0.001
POST-TEST	5	4			

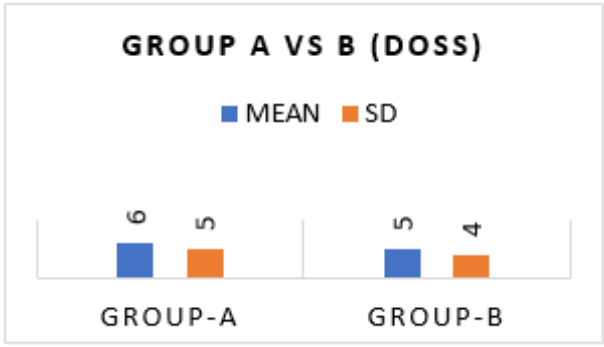

Fig 6: Post-test values of Group A and B obtained using DOSS, indicating the improvement in swallowing functions by transcutaneous vagal nerve stimulation.

Results

In this study, we analysed the effect of transcutaneous auricular vagal nerve stimulation on swallowing difficulty in post-stroke dysphagia patients. Transcutaneous auricular vagal nerve stimulation showed a significant effect in improving swallowing functions at 4 weeks, with a p value which is < 0.001. There was an improvement in swallowing functions in both the groups, after receiving the treatment for 4 weeks. The improvement of swallowing functions in Group A (experimental group) and Group B (control group) has been analysed using Wilcoxon signed rank test, both of which showed a significance in improving swallowing functions (TABLE 1 and TABLE 4).

Group B (control group), also showed a considerable improvement in improving the swallowing functions in subjects with dysphagia, was analysed using FOIS and DOSS and level of significance were calculated and tabulated (TABLE 2 and 5).

Post-test values of both the group which was obtained using FOIS and DOSS were analysed using Mann Whitney U test and were tabulated, it showed that transcutaneous auricular vagal nerve stimulation was more effective than the conventional therapy in improving the swallowing functions in patients with Dysphagia (TABLE 3 and 6).

Discussion

The goal of the study was to determine the effect of transcutaneous auricular vagal nerve stimulation on

swallowing dysfunction in patients with dysphagia. Dysphagia has a considerable negative impact on QOL in addition to increasing morbidity and mortality following a stroke. Aspiration pneumonia is the second-most feared complication of dysphagia after stroke. The frequency of lung infection increased by 17% when dysphagia was discovered on bedside clinical examination[11]. Although most patients with post-stroke dysphagia recover on their own, it persists in certain patients, which has an impact on their QOL. Thus, there are certain treatment techniques used to overcome the post stroke dysphagia. Both compensatory and rehabilitative strategies are used in dysphagia treatment. While compensatory measures are adapted to bring down dysphagia symptoms without changing the function, rehabilitative methods are framed to improve the physiology of swallowing, increase swallow risk, and increase tolerance for the less restrictive diet[12].

Subjects with cerebral infarction and swallowing difficulty received NMES treatment, a day for 20minute with intervals of 3 seconds for the period of 12 days with a intensity of 28 mA and pulse width of 800 ms, with a a two-day break and then other 12-day treatment, according to Yanfang Zenga's investigation[13]. F Marrosu in 2007 carried out the investigation with multiple sclerosis patients and found that improvement is believed to be VNS related since the NTS, the primary brainstem, visceral component of the vagus, is involved in modifying CPGs associated to the swallowing and olive complex pathway. The data collected point to another therapeutic use for VNS and could signify a unique approach to treating patients with advanced MS[14].

While there are certain studies suggesting about the adverse effects of the invasive method of vagal nerve stimulation, Hoarseness, voice changes, dyspnea, cough, throat discomfort, neck pain and tingling and twitching in the neck muscles, headache, dysphagia and chest pain are common AE along with VNS activation. Most of VNS adverse effects were observed during the stimulations on phase and appear to be dose-dependent, making it possible to lessen them by carefully adjusting the VNS parameters[15]. Thus, we made a try to overcome all this drawback by choosing a non-invasive method of stimulation of vagus nerve by transcutaneous auricular method with TENS 7000.

In 2018, A. Kumaresan conducted a quasi-experimental study in which A total of 30 post-stroke dysphagic subjects were chosen for a EMG examination of the masseter, submental, and infrahyoid muscles. For four weeks, neuromuscular electrical stimulation was applied to the Pharyngeal muscles. The values were collated and statistically examined at the last day of the fourth week after the test. He concluded that in terms of amplitude, neuromuscular electrical stimulation has a more positive effect on swallowing muscle activation in post-stroke dysphagia[18].

Conclusion

To conclude, the Vagus nerve plays a significant role in post-stroke patients with Dysphagia by providing a significant improvement on application of transcutaneous auricular vagal nerve stimulation for 4 weeks.

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, institutional regulations. (Application Number 01/024/2022/ISRB/PGSR/SCPT).

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Conflict of interest: The authors report no conflict of interest.

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