

A randomized controlled clinical trial to evaluate the efficacy of electrical vestibular stimulation, compared to a sham control for the modulation of neurotransmitters in patients with Parkinson's disease

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ABSTRACT

The existing treatments for Parkinson's disease were associated with side effects and does not offer complete cure. Hence there is a need of alternative therapy which can prevent or delay the onset of Parkinson's disease with less or no side effects. The overall objective of the present study was to assess the effectiveness of electrical vestibular nerve stimulation in the management of Parkinson's disease. Sixty cases with Parkinson's disease, including both males and females, were recruited in the study by convenient sampling after obtaining written and informed consent. They were randomly grouped with 30 participants in each group. Control group received sham stimulation and the intervention group received electrical vestibular nerve stimulation for 12 weeks. After recording the baseline biochemical parameters, post intervention assessment was performed after 6 weeks and 12 weeks of intervention and compared. Results: Demographic variables were not statistically significant among the control and intervention groups. There was a significant increase in the dopamine and GABA levels followed by the intervention. The present study results support the positive impact of non-invasive electrical vestibular nerve stimulation in modulating neurotransmitters in patients with Parkinson's disease. A further detailed translational study is required in this area with a larger sample size to generalize the results.

Keywords: Electrical vestibular nerve stimulation, Dopamine, Neurotransmitters, Parkinson's disease

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INTRODUCTION

Parkinson disease (PD), is a chronic, progressive and the second most common neurodegenerative movement disorder. It is characterized by an extensive and progressive loss of dopaminergic neurons in the substantia nigra-pars compacta that is characterized clinically by slowness of movement, rigidity, tremor, postural instability, and often cognitive impairments.¹ Parkinson disease affects approximately 1% of the population by the age of 65 years, increasing to 4% to 5% of the population by the age of 85 years.² Ageing is the single most important risk factor for Parkinson's disease, and the biochemical changes that are a consequence of aging amplify these abnormalities in Parkinson's disease brain.³⁻⁵ Mild cognitive impairment (MCI) is defined as a transitional state between normality and dementia, with subjective or objective cognitive impairment and little or no impairment in daily functioning.⁶ Studies have clearly shown that over a period of 5 years, 17% of PD patients developed Parkinson's disease dementia (PDD). Dementia is a frequent and distressing complication of Parkinson's disease with a cumulative incidence.⁷ Added to this factors like increasing age, alteration in semantic fluency and visuo-spatial function all lead to an earlier cognitive decline in PD.⁸ However, the exact underlying cause for the occurrence of dementia in PD is still not clearly known.⁹ Earlier studies reported the existence of connections between the vestibular system and basal ganglia.¹⁰ Noisy and galvanic vestibular stimulation may improve motor deficits in PD.¹¹

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interestingly, vestibular dysfunction is more prevalent in Parkinson's disease.¹²

With these points in mind, we are investigating the following aspects in our study – (a) As there is no standard treatment for Parkinson's disease without any side effects,⁴ it is essential

to find out an adjunctive therapy with minimum or no side effects to delay or prevent Parkinson's disease. This is of prime importance as Parkinson's disease burdens an increasing number of our nation's elders and their families. (b) Vestibular stimulation is known to modulate cognitive processing, enhance learning and spatial memory.¹³ So, vestibular stimulation may be considered as a neuro-physiological approach and a palliative therapy for cognitive impairment and motor dysfunctions in Parkinson's disease and this could be ideally applied to the Parkinson's patients with no side effects.¹⁴

The existing treatments for PD are associated with side effects and does not offer complete cure. Hence there is a need of alternative therapy which can prevent or delay the onset of PD with less or no side effects. Our extensive review of literature has shown no studies to be existing so far in India regarding vestibular stimulation as a treatment method for Parkinson's disease. Vestibular stimulation may be effective in enhancing cognition by reducing the neuro-degenerative, neuro-inflammatory changes and behavioral deficits observed as predictors for Mild Cognitive Impairment in Parkinson's disease dementia. In our project, we are planning to administer vestibular stimulation to PD patients which might be effective in limiting the cognitive decline and the general neuro-degeneration observed in Parkinson's disease thereby arresting or delaying the progression of this neurodegenerative disorder. This might prove to be a novel treatment with minimum or less side effects to delay or prevent Parkinson's disease. This is of prime importance as Parkinson's disease burdens an increasing number of our nation's elders and their families. The overall objective of the present study was to assess the effectiveness of electrical vestibular nerve stimulation in the management of Parkinson's disease.

MATERIALS AND METHODS

The present study is a randomized controlled trial (ClinicalTrials.gov Identifier: NCT04450550). Participants were assessed at 3 time points: After recording the baseline values, post-intervention values of Biochemical parameters were assessed after 6 weeks and after 12 weeks of the intervention. Assessors were blinded to subject group assignment and remained consistent for the duration of the project.

The study protocol was approved by the institutional human ethical committee of R.D. Gardi Medical College. (IEC Ref. N0- 124/2019). PD patients attending General medicine OP of R.D Gardi Medical College & Hospital. All the PD patients were diagnosed and assessed by the Neurologist of the hospital. The required sample size was calculated with Input: Tail(s) = One, Effect size $|\rho| = 0.4$, α err prob = 0.1, Power $(1 - \beta$ err prob) = 0.85 Output: Non-centrality parameter $\delta = 2.3904572$, Critical $t = 1.3125268$, $df = 28$; Total sample size = 30; Actual power = 0.8584407, hence, 30 patients per group are required. Accordingly, 60 cases with PD, including both

males and females, were recruited in the study by convenient sampling after obtaining written and informed consent.

Inclusion criteria: Participants were included if they fulfilled the Hoehn & Yahr Classification of Disability stage 1-2 who could ambulate with or without an assistive device for at least 50 feet and were able to get up and down from the floor with minimal assist or less and score 24 or above on the Folstein Mini-Mental State Examination.

Exclusion criteria: Participants were excluded if they had any of the following: decline in immune function such as pneumonia or systemic infection, progressive degenerative disease besides PD, spinal fusion or other orthopedic surgery in the past six months, mental disease/psychosis such as dementia, greater than minimal assistance required for gait and transfers, inability to make regular time commitments to the scheduled intervention sessions, or experience with regular practice of any form of vestibular stimulation within the past year.

After recruiting, the participants were randomly assigned into two groups - Control group ($n = 30$): Placebo stimulation was administered for 12 weeks and Intervention group ($n=30$): Electrical vestibular nerve stimulation was administered for 12 weeks (Figure 1).

Electrical vestibular stimulation (VeNS):

VeNS was administered for 12 weeks. Each daily session was for 1 h, with five sessions being carried out each week. Bilateral application of electrical VeNS using battery-powered vestibular nerve stimulator (ML 1000, Neurovalence, UK) was practiced. It consists of a headset, electrode pads, and skin swabs. The device was turned on by the power button. The intensity of the stimulation can be controlled manually by the subject using either the buttons on the device or through the Bluetooth mobile app. The electrodes are placed over each mastoid process after cleaning the area with swab, and then through gentle electrical pulse the vestibular nerves get stimulated.

Blood samples were collected following the international guidelines and the serum dopamine levels was assessed using General Dopamine (DA) ELISA Kit, while Gamma-Aminobutyric Acid (GABA) ELISA Kit was used to estimate GABA levels.

Statistical Analysis: The data are represented as mean \pm standard error of mean and analyzed by two-way repeated measures analysis of variance (RM ANOVA) for one-factor repetition. Factor A, was groups (between-group comparison – Control and Intervention), Factor B, was tests (within group comparison i.e., repetition factor – Baseline, 6-week and 12-week) and the group X test interaction. For post hoc multiple comparisons, Bonferroni 't' test was carried out after ANOVA, for between-group and within-group comparisons. A probability of 0.05 and less was considered as statistically significant. SigmaPlot 14.5 version (Systat Software Inc., San Jose, USA) was used for statistical analysis and graph plotting.

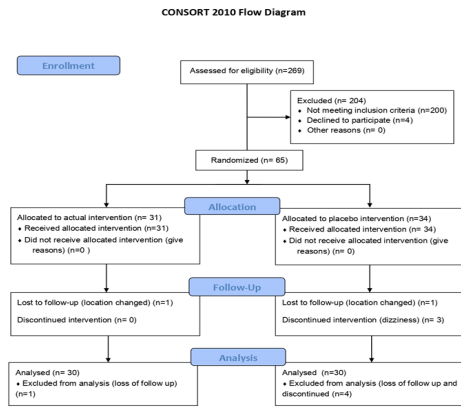


Figure 1: Consort flow diagram

RESULTS

Demographic variables were not statistically significant among the control and intervention groups (Table no 1). There was a significant increase in the dopamine and GABA levels followed by the intervention (Table no 2).

DISCUSSION

Vestibular dysfunction, which is associated with risk of falling, was observed in both Parkinsonian patients and atypical Parkinson's disease.¹ Galvanic vestibular stimulation (GVS) activates the vestibular afferents, and these changes in vestibular input exert a strong influence on the subject's posture or standing balance. GVS activates extrapyramidal structures such as basal ganglia, limbic system, spinal cord, pedunculopontine nucleus through the vestibular nerves, leading to increased axial motor function and improving postural instability.² The symptoms of the Parkinson's patients includes tremor, dizziness, tinnitus, gait unbalance and falls. Alteration was observed in the peripheral vestibular system and the caloric test.³ In Parkinson's disease postural sensory integration is controlled by pedunculopontine

nucleus- thalamic innervations. Impairment of this section and their thalamic efferents causes postural instability in Parkinsonian patients.⁴ vestibular stimulation helped in improving anterior bending angle in patients with Parkinson's disease.⁵ Vestibular nuclei excitability was reduced in Parkinsonian patients which can be modulated by inducing DOPA.⁶ The processing of vestibular information was impaired in Parkinsonian patients affected by lateral trunk flexion.⁷ Frontal-basal ganglionic and frontal-parietal systems dysfunction affects visual and spatial abilities in Parkinson's disease.⁸ In advanced stage, the patients may have difficulty in performing their day to day activities. In PD, the non-availability of dopamine results in abnormal nerve firing patterns within the brain that cause impaired movement. Even though there is no cure for PD, a wide range of therapies are used to relieve the symptoms like deep brain stimulation and medicinal combinations like levodopa and carbidopa.¹⁰ Vestibular stimulation was applied through rocking chair to the patients who undergo abdominal surgery. They had shorter duration of postoperative ileus.⁹

Earlier studies suggested that, vestibular stimulation may be considered as a natural treatment for Parkinson's disease.¹¹ India has low prevalence of PD yet very good at research performance in PD and possess 16th rank in global context, in the year 2002-2011.¹² Depression, anxiety, anhedonia, psychosis, cognitive disorders, apathy, suicidal behaviour are common in Parkinson's disease.¹³ Patients with early PD performed significantly worse in the tasks involving memory, executive functions, and attention.¹⁴ PD patients were found to have delayed switching of the saccade from one target to another when compared to normal subjects. This proves that basal ganglia are not only involved in the somatomotor loop but also in the oculomotor loop of frontal sub cortical circuit.¹⁵ Increased speech impairment, restless leg syndrome (RLS),¹⁶ impulse control disorders,¹⁷ both obstructive and restrictive patterns of respiratory

Table no 1: Comparison of demographic variables in control and intervention groups for homogeneity.

S.No.	Variable	Category	Control	Intervention	Statistics
1	Gender	Male	22	18	$\chi^2 = 0.675$ P = 0.411
		Female	8	12	
2	Age	< 60 years	14	10	$\chi^2 = 0.625$ P = 0.429
		> 61 years	16	20	
3	Weight	< 60 kg	27	23	$\chi^2 = 1.080$ P = 0.299
		> 61 kg	3	7	
4	Body mass index	< 24.9 kg/m ²	30	29	$\chi^2 = 0$ P = 1.0
		> 25.0 kg/m ²	0	1	
5	Place of living	Urban	12	12	$\chi^2 = 0.0694$ P = 0.792
		Rural	18	18	
6	Disease duration	< 3 years	9	8	$\chi^2 = 0$ P = 1.0
		> 4 years	21	22	

n – Control = 30; Intervention = 30

Table 2: Comparison of Dopamine (pg/mL) (1) and GABA (pg/mL) (2) in control and intervention groups.

S.No.	Groups	Tests	1	2
1	Control	Baseline	742.387±116.356	115.555±12.125
	Control	6-week	747.027±116.126	121.109±13.388
	Control	12-week	755.480±114.774	132.071±13.686
	Intervention	Baseline	767.308±134.867	110.739±10.537
	Intervention	6-week	1176.660±135.822	196.616±35.419
	Intervention	12-week	1620.036±117.187	276.692±61.688
2	Significance among Groups		F = 7.475 P = 0.008	F = 4.320 P = 0.043
	Significance among Tests		F = 29.742 P = <0.001	F = 12.477 P = <0.001
	Significance among Groups X Tests Interaction		F = 27.964 P = <0.001	F = 8.384 P = <0.001
	Significance within control Baseline and 6-week		t = 0.0613 P = 1.000	t = 0.226 P = 1.000
3	Significance within control Baseline and 12-week		t = 0.173 P = 1.000	t = 0.671 P = 1.000
	Significance within control 6-week and 12-week		t = 0.112 P = 1.000	t = 0.445 P = 1.000
	Significance within intervention Baseline and 6-week		t = 4.936 P = <0.001	t = 3.183 P = 0.006
	Significance within intervention Baseline and 12-week		t = 10.282 P = <0.001	t = 6.152 P = <0.001
	Significance within intervention 6-week and 12-week		t = 5.346 P = <0.001	t = 2.968 P = 0.011
	Significance between baseline Control and intervention		t = 0.144 P = 0.886	t = 0.119 P = 0.906
4	Significance between 6-week Control and intervention		t = 2.478 P = 0.016	t = 1.866 P = 0.065
	Significance between 12-week Control and intervention		t = 4.986 P = <0.001	t = 3.574 P = <0.001

n – Control = 30 and Intervention = 30

dysfunction were very common in PD.¹⁸ Decreased response of heart rate and blood pressure to autonomic stimulation revealed the presence of cardiac autonomic dysfunction in PD patients.¹⁹ It was reported that the combined effect of reduction in muscle strength, decreased proprioception, visual sense, and narrow base of support leads to the imbalance in PD.²⁰ Ayurvedic treatment like cleansing or eliminating therapy (panchakarma) followed by mixture of cow's milk, Mucunapuriens, Hyoscyamusreticulatus seeds, Withaniasomnifera, and Sidacordifolia roots were useful to improve the activities of daily living in PD patients.²¹ It was reported that a systematic program of exercises improves the UPDRS scores, activities of daily living, and gait in PD patients.²² Wireless vibratory feedback system called PD shoe and partial weight supported treadmill gait training (PWSTT) like physical therapies were effective in treating difficult symptoms of PD like freezing and gait disturbances.²³

Vestibular System plays a vital role in everyday life, contributing to a surprising range of functions from reflexes

to the highest levels of perception and consciousness. One of the newest and most popular therapies for developmentally delayed children is vestibular stimulation. Our extensive preliminary studies have shown that the application of controlled vestibular stimulation by swing not only serves as an intervention for learning disability but also to relieve stress, cancer pain, to promote sleep to improve immunity and also to treat endocrine disorders.²⁴ Cold water vestibular stimulation suppresses the stress induced changes in immunological parameters in Wistar albino rats.²⁵ Hot and cold vestibular stimulations are beneficial in maintaining lipid profile of Wistar albino rats.^{26,27} Cold water vestibular stimulation significantly decreased blood glucose levels in alloxan-induced diabetes rats.¹⁸ It was also reported that caloric vestibular stimulation suppressed the stress induced changes in thyroid function of cold water swimming stress induced Wistar albino rats.¹⁹ Sahayarani et al, reported that Vestibular stimulation through electric rocking chair was found to be beneficial in improving the postural stability

in elderly population.²⁸ As there is no standard treatment for Parkinson's disease without any side effects, the present study introduces an adjunctive therapy with minimum or no side effects to manage the Parkinson's disease. This is of prime importance as Parkinson's disease burdens an increasing number of our nation's elders and their families. Vestibular stimulation may be considered as a neuro-physiological approach and a palliative therapy for cognitive impairment and motor dysfunctions in Parkinson's disease and this could be ideally applied to Parkinson's patients with no side effects.

CONCLUSION

The present study results support the positive impact of non-invasive electrical vestibular nerve stimulation in modulating neurotransmitters in patients with Parkinson's disease. A further detailed translational study is required in this area with a larger sample size to generalize the results.

Conflicts of interest: None declared

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