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Effectiveness of 12 weeks of electrical vestibular nerve stimulation in the management of obesity: A pilot study

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ABSTRACT

Background: It was hypothesized that electrical vestibular nerve stimulation (VeNs) was an effective therapy in the management of obesity. **Aims and Objectives:** The present pilot study was undertaken to observe the efficacy of 12-week electrical VeNs in the management of obesity. **Materials and Methods**: As this is a pilot study, a total of ten obese male and female participants were recruited after obtaining written, informed consent. After recording the baseline values, electrical VeNs was administered as an intervention for 12 weeks. The post-interventional assessment was done after 12 weeks. **Results:** There was a significant decrease in the serum cholesterol, VLDL, and HbA1C followed by the vestibular stimulation for 12 weeks. Although the body weight was decreased, it was not statistically significant. **Conclusion:** The present pilot study results support the positive impact of electrical VeNs in the management of obesity. Further, detailed studies with higher sample size were recommended to provide adequate scientific evidence to adopt electrical VeNs as an alternative therapy for the management of obesity.

Key words: Alternative therapy; Lipid profile; Obesity; Overweight; Vestibular system

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INTRODUCTION

Obesity is a condition characterized by an increase in the size and amount of fat cells in the body. It is a chronic disorder that is officially classified as a disease by the World Health Organization (WHO), and also by several other national and international organizations.[1] It was reported that 1.9 billion adults were overweight and 650 million were obese worldwide.[2] ICMR-INDIAB study reported that the prevalence of obesity in India was 11.8–31.3% and central obesity was 16.9–36.3%.[2] Unhealthy food habits and sedentary lifestyles were reported as key contributors to obesity.[2] Interestingly, the prevalence of obesity was higher in women than men. Both rural and urban populations were obese and the burden is mushrooming throughout India.[3] Poor quality of life was reported in obese individuals and obesity is associated with several diseases such as diabetes mellitus, hypertension, and sleep apnea.[4] A considerable increase in obesity was expected in the Indian population by 2040 and the age group at risk was 20–69 years.[5] Hence, there is a strong need for translational research to introduce cost-effective obesity management methods for the benefit of the general population. Although pharmacological therapies are available, they are associated with side

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effects that limit their long-term use. There is a strong need to find an alternative therapy for the management of obesity that should be affordable and associated with minimum side effects or no side effects. Caloric vestibular stimulation was reported to decrease the triglycerides, and total cholesterol in rats supplied with a high-fat diet.[6] Vestibular dysregulation was reported to influence obesity and vestibular stimulation was reported to alter the set point of fat.[7,8] Although there are multiple methods available to stimulate the vestibular system, optimal stimulation is required to avail maximum beneficial effects. Electrical vestibular stimulation is a simple and non-invasive method and can control the strength of the stimulation offered. It was hypothesized that electrical vestibular nerve stimulation (VeNs) was an effective therapy in the management of obesity.[7] Hence, the present pilot study was undertaken to observe the efficacy of 12-week electrical VeNs in the management of obesity.

Aims and objectives

The present pilot study was undertaken to observe the efficacy of 12-week electrical VeNs in the management of obesity.

MATERIALS AND METHODS

Study setting

The present study was conducted at the Department of Physiology in collaboration with the Department of General Medicine, R. D. Gardi Medical College, Ujjain, Madhya Pradesh.

Study design

The present study was an experimental study. Participants act as self-controls. Participants were assessed twice. After recording the baseline values, electrical VeNs was administered as an intervention for 12 weeks after recording the baseline values. Post-interventional assessment was done after 12 weeks. All the participants were advised to follow a vegetarian diet during the study period.

Study participants

A total of ten obese male and female participants were recruited after obtaining written, informed consent. The following criteria were followed to recruit the participants.

Inclusion criteria

Willing participants, aged above 18 years, and with a BMI of 30–40 kg/m^2 were included in the study.

Exclusion criteria

Participants who were currently using any medications or therapy including the use of oral contraceptives or using dietary supplements known to affect the BMI, with ear problems (assessed during physical examination), and any other severe health complications were excluded from the study.

Pre-enrolment screening

All the participants underwent a thorough physical examination and detailed medical history was obtained before recruiting them.

Electrical VeNs

Bilateral electrical VeNs was administered using a battery-powered vestibular nerve stimulator (ML 1000, Neurovalance, UK). The total duration of the intervention is 12 weeks with five sessions per week. Each session duration is one hour. It consists of a headset, electrode pads, and skin swabs. The device can be turned on using the power button. The intensity of 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 a swab and then through a gentle electrical pulse, the vestibular nerves get stimulated.[9]

Outcome measures

Bodyweight, Lipid profile, HBA1C, Liver function test, and thyroid profile of the participants were assessed before and after the therapy. Omron HN 286 Ultra-Thin Automatic Personal Digital Weight Scale with Large LCD Display was used to measure the body weight. Lipid profile was estimated using vitros 5600 dry chemistry analyzer of ortho clinical diagnostics. HBA1C was estimated using bio rad detain. The liver function test was assessed using vitros 5600 dry chemistry analyzer of ortho clinical diagnostics. Thyroid profile was assessed using vitros 5600 dry chemistry analyzer of ortho clinical diagnostics. All the tests were performed at the Biochemistry Laboratory of R. D. Gardi Medical College, Ujjain, Madhya Pradesh.

Statistical analysis

The data are represented as mean ± SEM and analyzed by unpaired Student's t-test. Although the data are paired data, the unpaired "t-test" was used for better analysis, as small changes may give significance to paired "t-test." A probability of 0.05 and less was considered statistically significant. SigmaPlot 14.5 version (Systat Software Inc., San Jose, USA) was used for statistical analysis.

RESULTS

The mean body weight was decreased from 87.8 to 82.9 followed by the vestibular stimulation. However, the decrease is not statistically significant. The mean body mass index was significantly decreased from 35.6 to 33.6. However, the decrease is not statistically significant. There was no significant decrease in the ALT, AST, and serum alkaline levels followed by the vestibular stimulation (Table 1). There was no significant difference in the GGT levels before and after the intervention. HbA1C was significantly decreased followed by the intervention (P<0.001). The mean blood glucose levels decreased from 156.6 to 134.3. However, the decrease was not statistically significant. Serum cholesterol was significantly decreased followed by the intervention (P<0.0001). The mean HDL levels were increased from 44.5 to 47.7. However, the increase was not statistically significant. The mean LDL levels were decreased from 156 to 144.2. However, the decrease was not statistically significant (Table 2). There was a significant decrease in the VLDL levels followed by the intervention (P<0.01). The mean serum triglyceride levels were decreased from 200.1 to 178. However, the decrease was not statistically significant. T3, T4, and TSH levels were significantly decreased (P<0.01) but remained within the normal limits followed by the intervention (Table 3).

DISCUSSION

Obesity was labeled as a global pandemic by the WHO in the year 1998 as the prevalence was increasing globally.[10] The available methods for the management of obesity include a change in lifestyle, pharmacotherapy, and surgery. Although pharmacotherapy is effective, it cannot be practiced on a long-term basis as it is associated with side effects. It was hypothesized that electrical VeNs was simple, non-invasive, and affordable therapy with no side effects for the management of obesity. The present study was undertaken to observe the efficacy of electrical vestibular stimulation in the management of obesity. There was a significant decrease in the serum cholesterol, VLDL, and HbA1C followed by the vestibular stimulation for 12 weeks. Although the body weight was decreased, it was not statistically significant. It was reported that in the hypothalamus, there is a set point for body fat that maintain the body fat at a particular level.[11-13] The central melanocortin system in the hypothalamus that comprises arcuate nucleus and agouti-related peptide/neuropeptide Y neurons plays a pivot role in the maintenance of the set point of fat.[14,15]

Vestibular stimulation was reported to activate the arcuate nucleus of the hypothalamus.[16] Recent studies reported that vestibular stimulation influences the central melanocortin system and regulates body fat.[17] Vestibular stimulation was

Table 1: The effectiveness of 12 weeks of electrical vestibular nerve stimulation on demographic variables, ALT, AST, and serum alkaline phosphatase (n=10)

S. No.	Variable	Groups	Mean	SE	Statistics
1.	Height (cm)	Baseline	159.3	4.6	t=0
		12 weeks	159.3	4.6	P=1.0
2.	Weight (kg)	Baseline	87.8	2.3	t=1.474
		12 weeks	82.9	2.2	P=0.158
3.	Body mass index (kg/m^2)	Baseline	35.6	2.7	t=0.532
		12 weeks	33.6	2.5	P=0.601
4.	ALT (unites/L)	Baseline	63.1	3.7	t=1.312
		12 weeks	57.1	2.7	P=0.206
5.	AST (unites/L)	Baseline	28.3	1.6	t=0.581
		12 weeks	26.7	2.2	P=0.568
6.	Serum alkaline phosphatase (U/L)	Baseline	92.2	3.2	t=1.676
		12 weeks	85.4	2.4	P=0.111

Data were expressed as Mean and SEM

Table 2: The effectiveness of 12 weeks of electrical vestibular nerve stimulation on GGT, HbA1C, Mean blood glucose, serum cholesterol, HDL, and LDL (n=10)

S. No.	Variable	Groups	Mean	SE	Statistics
1.	GGT (U/L)	Baseline	58.8	3.3	t=1.623
		12 weeks	51.4	3	P=0.122
2.	HbA1C (%)	Baseline	5.6	0.3	t=3.740
		12 weeks	4.3	0.1	P=0.0015**
3.	Mean blood glucose (mg/dl)	Baseline	156.6	9.6	t=1.740
		12 weeks	134.3	8.4	P=0.098
4.	Serum cholesterol (mg/dl)	Baseline	258.1	5.9	t=6.468
		12 weeks	212.2	3.8	P=0.000004***
5.	HDL (mg/dl)	Baseline	44.5	2.4	t=1.085
		12 weeks	47.7	1.7	P=0.292
6.	LDL (mg/dl)	Baseline	156	3.6	t=2.086
		12 weeks	144.2	4.3	P=0.0515

Data were expressed as Mean and SEM. **P<0.001 was significant

Table 3: The effectiveness of 12 weeks of electrical vestibular nerve stimulation on VLDL, serum triglycerides, and thyroid profile (n=10)

S. No.	Variable	Groups	Mean	SE	Statistics
1.	VLDL (mg/dl)	Baseline	45.2	2.3	t=3.132
		12 weeks	36.6	1.3	P=0.00576**
2.	Serum triglycerides (mg/dl)	Baseline	200.1	9.7	t=1.693
		12 weeks	178	8.7	P=0.108
3.	T3 (ng/ml)	Baseline	1.4	0.07	t=3.284
		12 weeks	1.1	0.04	P=0.00412**
4.	T4 (ug/dl)	Baseline	10.4	0.3	t=3.539
		12 weeks	8.3	0.4	P=0.00234**
5.	TSH (uIU/ml)	Baseline	3.1	0.2	t=3.448
		12 weeks	1.9	0.2	P=0.00287**

Data were expressed as Mean and SEM. **P<0.001 was significant

reported to lower the set point of fat and regulate body weight. Vestibular stimulation also contributes to weight control by regulating food intake. This function is attributed to the vestibular connections with the hypothalamus, dorsal raphe nucleus, nucleus tractus solitarius, locus coeruleus, and hippocampal formation.[18] Animal studies have demonstrated a decrease in body weight followed by caloric vestibular stimulation.[6,7] Human studies also reported regulation of lipid profile followed by vestibular stimulation.[19,20] The present study results support earlier studies as there is a decrease in the body weight of the participants. Further, there is a significant decrease in total cholesterol and VLDL. The insignificant decrease in body weight may be due to the duration of the intervention. In the present study, 12 weeks was the duration of intervention and a longer duration may lead to a further decrease in body weight significantly. Long-term studies are required in this area.

Vestibular stimulation was reported to decrease blood glucose levels by stimulating the vagal nucleus, inhibiting the sympathetic nucleus, and regulating food intake. Vestibular stimulation was reported to modulate autonomic activity. Stimulation of the dorsal motor nucleus of the vagus was observed followed by the vestibular stimulation. Through stimulating the vagal nucleus, vestibular stimulation increases the release of insulin and reduces blood glucose levels. Vestibular stimulation also increases insulin secretion by inhibiting the sympathetic nucleus which is the locus ceruleus. A significant decrease in body weight, blood glucose, and glycosylated hemoglobin levels was observed in patients with type 2 diabetes followed by 90 days of electrical VeNs. Another study reported that there was a significant decrease in blood glucose and BMI in diabetic individuals who received galvanic vestibular stimulation as an adjunctive therapy. There was a decrease in blood glucose and a significant decrease in HbA1c in the present study.

A significant decrease in the TSH levels but not T3 and T4 was observed in the females with premenstrual syndrome. In contrast, another study reported that there is an increase in T3, T4, and TSH and a decrease in blood cholesterol in an individual with hypothyroidism. The vestibular system was reported to influence the hypothalamic-pituitary-thyroid pathway through its connections with the hypothalamus, especially with the paraventricular nucleus and arcuate nucleus. Interestingly, stimulation of some neurons and inhibition of other neurons of the paraventricular nucleus was observed followed by vestibular stimulation. These stimulation and inhibition patterns may be due to the type of stimulation and strength of the stimulation. There was a decrease in the T3, T4, and TSH levels followed by electrical VeNs. However, the values remained within normal limits.

Limitations of the study

The study was a pilot study and hence sample size was less. The results may not be generalized.

CONCLUSION

The present pilot study results support the positive impact of electrical VeNs in the management of obesity. Further, detailed studies with a higher sample size were recommended to provide adequate scientific evidence to adopt electrical VeNs as an alternative therapy for the management of obesity.

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REFERENCES

1. Venkatrao M, Nagarathna R, Majumdar V, Patil SS, Rathi S and Nagendra H. Prevalence of obesity in India and its neurological implications: A multifactor analysis of a nationwide cross-

sectional study. Ann Neurosci. 2020;27(3-4):153-161.
https://doi.org10.1177/0972753120987465.

2. Ahirwar R and Mondal PR. Prevalence of obesity in India: A systematic review. Diabetes Metab Syndr. 2019;13(1):318-321.
https://doi.org/10.1016/j.dsx.2018.08.032
3. Rai R, Kumar C, Singh L, Singh P, Acharya S, and Singh S. Rising burden of overweight and obesity among Indian adults: Empirical insights for public health preparedness. JBiosoc Sci. 2021;53(5):709-723.
https://doi.org/10.1017/S0021932020000486
4. Khaodhiar L, McCowen KC and Blackburn GL. Obesity and its comorbid conditions. Clin Cornerstone. 1999;2(3):17-31.
https://doi.org/10.1016/s1098-3597(99)90002-9
5. Luhar S, Timæus IM, Jones R, Cunningham S, Patel SA, Kinra S, et al. Forecasting the prevalence of overweight and obesity in India to 2040. PLoS One. 2020;15(2):e0229438.
https://doi.org/10.1371/journal.pone.0229438
6. Sadanandan NN, Rajagopalan A, Goothy SS, Mukkadan JK and Antony NJ. Antihyperlipidemic effect of vestibular stimulation in wistar albino rats. Int J Res Ayurveda and Pharmacy. 2015;6(4):509-512.
https://doi.org/10.7897/2277-4343.06496
7. Kawao N, Takafuji Y, Ishida M, Okumoto K, Morita H, Muratani M, et al. Roles of the vestibular system in obesity and impaired glucose metabolism in high-fat diet-fed mice. PLoS One. 2020;15(2):e0228685.
https://doi.org/10.1371/journal.pone.0228685
8. McGeoch PD. Can vestibular stimulation be used to treat obesity? Bioessays. 2019;41(2);1800197.
https://doi.org/10.1002/bies.201800197
9. Goothy SS and McKeown J. Modulation of sleep using electrical vestibular nerve stimulation prior to sleep onset: A pilot study. J Basic Clin Physiol Pharmacol. 2020;32(2):19-23.
https://doi.org/10.1515/jbcpp-2020-0019
10. Suastika K. Update in the management of obesity. Acta Med Indones. 2006;38(4):231-237.
11. Harris R. Role of set-point theory in regulation of body weight. FASEB J. 1990;4(15):3310-3318.
https://doi.org/10.1096/fasebj.4.15.2253845
12. Yon M, Mauger S and Pickavance L. Relationship between dietary macronutrients and adult neurogenesis in the regulation of energy metabolism. Br J Nutr. 2011;109(9):1573-1589.
https://doi.org/10.1017/S000711451200579X
13. Horvath TL. The hardship of obesity: A soft-wired hypothalamus. Nat Neurosci. 2005;8(5):561-565.
https://doi.org/10.1038/nn1453
14. Varela L and Horvath T. Leptin and insulin pathways in POMC and AgRP neurons that modulate energy balance and glucose homeostasis. EMBO Rep. 2012;13:1079-1086.
https://doi.org/10.1038/embor.2012.174
15. Belgardt BF, Okamura T, Bruening JC. Hormone and glucose signalling in POMC and AgRP neurons. J Physiol. 2009; 587(Pt 22):5305-5314.
https://doi.org/10.1113/jphysiol.2009.179192
16. .Fuller PM, Jones TA, Jones SM and Fuller CA. Evidence for macular gravity receptor modulation of hypothalamic, limbic and autonomic nuclei. Neuroscience. 2004;129(2):461-471.
https://doi.org/10.1016/j.neuroscience.2004.05.059
17. Shang D, Xiong J, Xiang HB, Hao Y and Liu JH. Melanocortinergic circuits from medial vestibular nuclei to the kidney defined by transneuronal transport of pseudorabies virus. Int J Clin Pathol. 2015;8(2):1996-2000.
18. Goothy SS. Vestibular balance of food intake. Int J Pharm Bio Sci. 2014;5(3):B1069-B1073.
19. Saritha S, Sailesh KS and Mukkadan JK. Impact of linear vestibular stimulation on lipid profile in underweight females: A pilot study. J Med Sci Health. 2017;3(3):43-46.
https://doi.org/10.46347/jmsh.2017.v03i03.009
20. Baby S, Sailesh KS, Johny M and Mukkadan JK. Beneficial effects of vestibular stimulation in limiting thyroid modulation in females with Premenstrual syndrome. J Chem Pharm Sci. 2017;10(1):258-260.

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