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Electrical vestibular nerve stimulation (VeNS): a follow-up safety assessment of long-term usage

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Abstract

Objectives: This retrospective, open-label study was undertaken to assess the safety of repeated, long-term electrical vestibular nerve stimulation (VeNS). The primary outcome for this study was assessment of hearing function as reported by formal audiometry testing.
Methods: Assessments were conducted on n=25 long-term users of daily 1.5 mA VeNS. Skin inspection of the mastoid area, otoscope examination of the inner ear, and formal audiometry testing was conducted on n=18 users. All participants completed a survey-based assessment to determine usage of the device, adverse events, and long-term outcomes.
Results: Mean duration of use was 22 months, with approximately 80% of users reporting 1 h of daily, or 1 h of regular (2–3 times per week) VeNS usage. No adverse events were reported. There were no significant findings during examination of the mastoid areas, ear canal, or tympanic membranes. There were no significant findings reported from the formal audiogram assessments.
Conclusions: This appears to be the first study to provide formal assessment to show that repeated, long-term VeNS usage has not generated any significant side effects or adverse events. Results from this study further support previous literature that electrical vestibular stimulation is both safe and well-tolerated.

Keywords: neuromodulation; safety; vestibular.

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Introduction

The vestibular system, although best known for its role in balance, is a complex sensory unit that through extensive connectivity to the brain and brainstem can influence vital autonomic functions and contributes to a wide range of homeostatic processes [1, 2]. There are various methods available to stimulate the vestibular system; however, electric vestibular nerve stimulation has gained in popularity due to ease and safety of use [3, 4]. A key feature in electrical vestibular nerve stimulation (VeNS) is being able to control the intensity of the stimulation by adjusting the stimulation level, therefore, allowing optimal stimulation of vestibular system with the ability to reduce side effects through direct user adjustment [5]. Previous literature has provided initial suggestion that there are multiple beneficial effects of vestibular stimulation such as improving postural stability, cognition, antidiabetic effect, and stress management [6–9]. However, literature regarding the long-term use of electric vestibular stimulation and its safety is not currently available. This study was undertaken to assess the safety of repeated, long-term electrical vestibular nerve stimulation (VeNS). The primary outcome for this study was assessment of hearing function as reported by formal audiometry testing.

Materials and methods

Study design

This study was a retrospective, open-label, follow-up study conducted in July 2021.

Study participants

As a pilot study, a total of 25 participants including both male and female genders were part of the study. Follow-up assessments were conducted on n=25 long-term users of 1.5 mA electrical vestibular stimulation devices (VDM1500, Neurovalens, UK). Participants were located in Belfast, UK, and Ujjain, India (UK Neurovalens Staff (14), India public (7), UK public (4)). Willing participants who used their 1.5 mA device for a minimum of 6 months were included in the study. The average length of usage was approximately 22 months with the mean stimulation level (range 1–10) at approximately 8 (equivalent to 1.2 mA).

Methods

A survey was conducted to assess the usage of the device, adverse events, and long-term outcome as reported by the user (n=25). Bilateral application of electrical VeNS using battery-powered vestibular nerve stimulator (VDM1500, Neurovalens, UK) was practiced. The intensity of the stimulation was controlled through the Bluetooth mobile app. The electrodes are placed over each mastoid process after cleaning the area with an alcoholic wipe, and then through gentle electrical pulse the vestibular nerves get stimulated. Photographic inspection of the skin behind the ears was conducted on 18 long-term users to observe if any skin irritation had been caused at the mastoid area where the electrode pads are placed. These participants also underwent otoscope examination of the inside of both ear canals and tympanic membranes. These photographs were taken using the Awelor Wireless Smart Otoscope (Model Number: T1). Formal audiometry testing was conducted on 18 users in the UK, using the GSI AMTAS Flex device. This is an automated method for testing audiometry sensitivity and is a participant-directed evaluation tool that performs diagnostic or screening air conduction audiometry with masking presented to the non-test ear. Normal hearing was defined as air-conduction thresholds at 500, 1,000, 2,000, and 4,000 Hz less than or equal to 20 dB HL.

Ethical considerations

Appropriate ethical consideration was taken following assessment based on guidance by the Central Office for Research Ethics Committees (COREC) and amended by the National Research Ethics Service (NRES) of the Health Research Association (UK). Confidentiality of data was maintained as per the regulations.

Statistical analysis

The data was analyzed using SPSS 20.0 software. Data was presented as frequency and percentage.

Table 1: Summary of participant demographics, mean length of usage, mean stimulation level, and adverse events (n=25).

	n=25
Mean age, years	38
Male, %	15 (60)
Female, %	10 (40)
Mean length of usage, months	
All participants	22 months
UK group	28 months
Mean stimulation level	8.12 (1.22 mA)
Headaches, %	0
Nausea, %	0
Eczema, redness, or psoriasis affecting skin behind both ears, %	0

Results

Results are presented in Table 1 and Figures 1 and 2. Table 1 presents the summary of participant demographics, mean length of usage, mean stimulation level, and adverse events (n=25). The mean age of the study participants was 38 years. 60% of participants were males with 40% females. Mean length of usage for all participants for vestibular stimulation was 22 months, whereas it was 28 months for participants from the UK alone. Mean stimulation level was 8.12 (1.22 mA). None of the participants had reported symptoms such as headache, nausea, eczema, redness, or psoriasis affecting the skin behind both ears. Figure 1 presents the average duration of usage for those who had otoscope examination. 44% of UK participants who completed an otoscope examination, have used the VDM1500 device for between 3 and 4 years. Figure 2 presents the average frequency of usage for

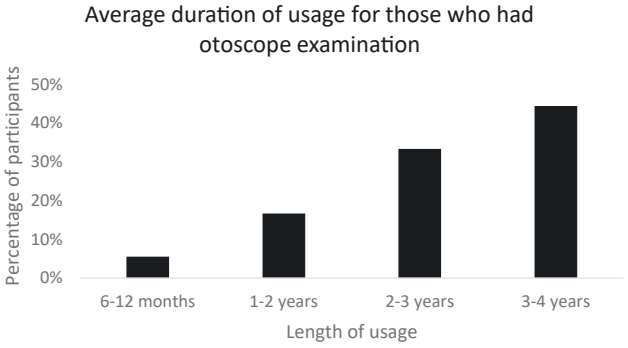

Figure 1: Percentage of UK participants who completed an otoscope examination independent of duration of usage.
Forty four percentage of UK participants who completed an otoscope examination have used the VDM1500 device for between 3 and 4 years.

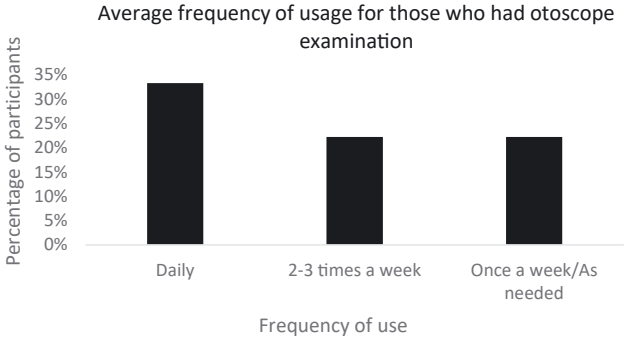

Figure 2: Percentage of UK participants who completed an otoscope examination independent of frequency of usage.
Thirty three percentage of users who completed an otoscope examination stated they used the VDM1500 device daily.

those who had otoscope examination. 33% of users who completed an otoscope examination stated they used the VDM1500 device daily.

Discussion

Several techniques exist to stimulate the vestibular system effectively including electrical, manual (such as rotational and swinging), caloric, and centrifugation. Vestibular stimulation can be divided into 2 groups: physiological and nonphysiological techniques. Electrical vestibular nerve stimulation (VeNS) is a nonphysiological approach that has gained popularity in recent years amongst researchers for the development of a system capable of artificially restoring the vestibular function. An advantage of VeNS is that the frequency of stimulation is easily adjusted therefore can be delivered across a wide range of outputs. Recent studies have seen many researchers interested in applying electrical vestibular nerve stimulation as an alternative therapy for patients with bilateral vestibulopathy [10]. Research studies in animal models suggest that vestibular stimulation appears to promote either arousal or sleep depending upon the speed of stimulation (via swinging) [11]. Electrical vestibular stimulation is also reported to show significant improvement in sleep measures and in the management of stress induced headache [12, 13]. Earlier studies have reported the benefits of electrical vestibular nerve stimulation in management of blood glucose in patients with type 2 diabetes [14].

Numerous studies support beneficial effects of vestibular stimulation, however there is limited literature to support the safety of long-term vestibular nerve stimulation, therefore, this study was undertaken to investigate the safety of repeated use of electrical vestibular nerve stimulation for a long-term basis. This study recruited participants who are using a 1.5 mA VeNS device (VDM1500) repeatedly and on a long-term basis. The mean length of usage of all participants was approximately 22 months, with 44% of UK participants (n=18) reporting regular usage of the VDM1500 device for between 3 and 4 years. The information obtained by the questionnaire revealed that all the participants were comfortable with the stimulation, and no participants reported associated adverse symptoms such as skin erythema, tinnitus, or changes to hearing. No serious adverse events were reported by any users. Photographic inspection behind the ears showed no skin irritation had been caused at the mastoid area where the electrode pads are placed. This was further testified by subjecting the participants to otoscopy examination of both ear canals and tympanic membranes. No significant findings were observed upon examination. Participants also completed formal audiometry testing with no significant findings. All audiograms were assessed, with all participant findings within the normal range. One participant had very mild reduction in 8,000 Hz hearing which is in keeping with the normal age-related changes. Overall, assessment of this group of long-term VeNS users reported no significant adverse events, with no suggestion of any changes to hearing, tinnitus, or skin irritation with repeated use.

Conclusions

These study outcomes highlight that long-term VeNS device usage appears to be a safe mechanism to provide regular stimulation to the vestibular system. These findings support previous literature that document the well-established safety profile of electrical vestibular stimulation and provide compelling evidence to suggest that long-term VeNS usage is safe and well tolerated.

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Competing interests: Erin McCulloch completed this research project as part of her university placement at Neurovalens. Dr Jason McKeown is co-founder and CEO of Neurovalens.
Informed consent: Informed consent was obtained from all individuals included in this study.
Ethical approval: This project was carried out as a post marketing follow-up study and did not require ethical committee approval as per the guidance developed by the UK Medical Research Council (MRC) Regulatory Support Centre and the UK Health Research Authority (HRA).

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