Impact of Acoustic Stimuli Used for Various Measures of VEMP on the Auditory System

by Niraj Kumar Singh

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PROJECT PROPOSAL FORMAT

Part -A

1.0 Title of the Project

Impact of Acoustic Stimuli Used for Various Measures of VEMP on the

Auditory System

Area of Research: Auditory and vestibular systems

1.1 Principal Investigator

Principal Investigator

Principal Co-Investigator(s)

Dr. Niraj Kumar Singh
Dr. Prawin Kumar

1.4 Collaborating Institution

1.5 Total Grants Required Rs 15,04,000 (Rupees fifteen lakhs

Nil

(in figures and in words) four thousands only)

1.6 Duration of the Project Three years

Project Summary

Vestibular evoked myogenic potentials (VEMPs) are elicited by loud sounds, usually 125 dB peSPL or higher in intensity. They play an important role in the test battery for vestibular assessment as they allow for evaluation of the otolith organs, which were previously not accessible to testing. But despite its proven utility in the vestibular assessment, a large contingent of scientific fraternity is increasingly showing concern regarding the effect of sound levels used for eliciting VEMP on cochlear function. Therefore the present study is aiming to investigate the effect of acoustic stimuli used for eliciting VEMP on transient evoked oto-acoustic emissions (TEAOAE), distortion product oto-acoustic emissions (DPOAE) and high frequency audiometry (HFA). The study will include 820 subjects. Of these, 720 will be randomly divided into 36 equal groups based on the type of VEMP assessment (500 Hz VEMP, frequency-amplitude ratio or frequency tuning), intensity level being used to elicit VEMP (133, 130, 125 or 120 dB peSPL) and the test used to evaluate the impact (TEOAE, DPOAE or HFA). A combination of one parameter from each of the three major aspects mentioned above (type of VEMP assessment, intensity level & the test being used) will result in formulation of each group. The assessment will include 2 baseline evaluations using TEOAE, DPOAE or HFA, depending upon the group, which will be

followed by cervical VEMP (cVEMP) recording. The post cVEMP assessment will be done using the same test as pre-cVEMP for a particular group at various times (5 minutes, 1 hour, 24 hours & 1 week after cVEMP recordings). The results of these tests will be compared between the ears at each evaluation, between the evaluations in the same ear and between cVEMP assessment types. Soon after the cVEMP recording, each participant will also be asked questions regarding his/her subjective perception of any change to their hearing or presence of any hearing-related symptoms. Upon obtaining the safe levels, the remaining 100 subjects will undergo cVEMP and oVEMP testing to arrive the normative data using the safe sound pressure levels. The outcome of the study will throw light on temporary or permanent deleterious impact of acoustic stimuli used for eliciting VEMP, if any, on the auditory system. In case a deleterious impact is found, the outcome of the study will provide the level(s) that can be safely used for eliciting VEMP without significantly altering its response rate. The study will also provide the normative data for cVEMP for the thus found safe level(s).

Introduction

Vestibular evoked myogenic potential (VEMP) reflects vestibular system's sensitivity to acoustic vibrations. It is elicited by loud sounds and detected as a change in the muscle potentials (Hall, 2007). VEMPs can be elicited from several muscles of the body. When elicited from the sternocleidomastoid muscle, these ipsilateral potentials are called cervical VEMP (Colebatch, Halmagyi, & Skuse, 1994) and when elicited from the extra-ocular muscles, specifically inferior oblique muscle, they are referred as ocular VEMP (Rosengren, Todd, & Colebatch, 2005).

Physiologically, cervical VEMP (cVEMP) are produced along a disynaptic reflex pathway (Rosengren, Welgampola, & Colebatch, 2010) whereas ocular VEMP (oVEMP) is response from a trisynaptic reflex pathway (Leigh & Zee, 2006). Usually acoustic, vibratory or galvanic stimuli of low-to-mid range of frequencies, when presented to the ears, stimulate the saccule which in turn causes an inhibition of the muscle tone within the sternocleidomastoid muscle (Halmagyi, Yavor, & Colebatch, 1995; Watson & Colebatch, 1998; Sheykholeslami, Murofushi, Kermany, & Kaga, 2000; Monobe & Murofushi, 2004; Rosengren, Welgampola, & Colebatch, 2010; Iwasaki et al., 2011). However in case of oVEMP, acoustic, vibratory or galvanic stimuli of low-to-mid range of frequencies stimulate mainly the utricle which in turn causes an excitation within the tonically contracted inferior oblique muscle (Leigh & Zee, 2006; Weber, Rosengren, Michels, Sturm, Straumann, & Landau, 2012).

VEMP plays an important part in the test battery of clinics and medical centres worldwide offering for evaluation of otolith organs, which were previously not accessible to testing, in patients with balance and vestibular disorders (Kantner & Gurkov, 2012; Young, 2012). However, there seems increasing concern regarding the effect of sound levels used for

eliciting certain auditory and vestibular potentials like auditory brainstem responses (Mhatre et al., 2010; Soni, 2013) and VEMP (Krause et al., 2013) on cochlear function.

Need for the study

Following the findings of Mhatre et al (2010), who reported transient reduction of the distortion product oto-acoustic emissions (DPOAE) following ABR recordings in rats, Soni (2013) reported reduced DPOAE amplitudes after ABR recording in human subjects. Most often, ABR recording makes use of stimuli which are in excess of 80 dB nHL or 115-120 dB SPL. However, VEMP recordings utilize much higher levels, usually in excess of 125 dB SPL or 95 dB nHL. If levels used for ABR have been shown to reflect in reduced OAE amplitudes, it would be almost certain that intensity used for eliciting VEMP would cause a similar effect if not more. However, this aspect of VEMP recording has been rarely paid heed to.

Recently, Krause et al (2013) evaluated the impact of acoustic stimuli used for recording cVEMP on pure-tone thresholds and DPOAE amplitude in 30 young adults between 20 and 35 years of age. The tone-burst level used for recording DPOAEs was 133 dB SPL. They reported amplitude difference of DPOAEs only at 6 kHz and 8 kHz and no significant difference in pure-tone thresholds before and after the cVEMP testing. However, the tone-burst level used in this study was about 8 to 18 dB higher than most of the studies on cVEMP and oVEMP (Todd, Rosengren, Govender, & Colebatch, 2009; Murnane, Akin, Kelly, Y Byrd, 2011; Sandhu, Low, Rea, & Saunders, 2012; Singh & Barman, 2013, 2014, 2015). Therefore it is not known if these lower levels would also produce similar deleterious effect on DPAOEs. Further, Krause et al (2013) examined the effect of only single frequency recording (i.e., 500 Hz stimulus); however more recently VEMP is being used for identifying Meniere's disease (Rauch et al., 2004; Node et al., 2005; Sandhu et al., 2012) and superior

semicircular canal dehiscence (Taylor, Bradshaw, Halmagyi, & Welgampola, 2012) using its frequency tuning property. This procedure requires VEMP to be recorded for octave and midoctave frequencies from 250 Hz to 2000 Hz or to 4000 Hz. Another parameter of VEMP which is being used to identify Meniere's disease the frequency-amplitude ratio (FAR) which requires recording of oVEMP for 500 Hz and 1000 Hz (Jerin, Berman, Krause, Ertl-Wagner, & Gurkov, 2014; Singh, Sinha, Govindaswamy, Apeksha, & Barman, 2015). Since both frequency tuning and FAR require the use of multiple frequencies at high stimulus intensity, they might be potentially be producing much more deleterious impact due to their cumulative effect on the cochlear function. Nonetheless, the effect of stimulus levels used in such procedures has not been investigated yet. Therefore there is a need to not only explore the impact of VEMP evoking stimuli on cochlear function but also to do so for various types of measures using VEMP.

Aim of the study

The present study aimed at evaluating the effect of VEMP eliciting stimulus on functioning of cochlea.

Objectives of the study

- 1. To investigate the effect of 500 Hz tone-burst used for obtaining VEMP on
 - a. Amplitude of Transient-evoked oto-acoustic emissions (TEAOE)
 - b. Amplitude of DPOAE
 - c. Thresholds of high frequency audiometry (HFA)
- To investigate the effect of acoustic stimuli (500 Hz & 1000 Hz) used for obtaining FAR of VEMP on
 - a. Amplitude of TEAOE
 - b. Amplitude of DPOAE

- c. Thresholds of HFA
- To investigate the effect of acoustic stimuli (octave & mid-octave frequencies from 250
 Hz to 2000 Hz) used for obtaining frequency tuning of VEMP on
 - a. Amplitude of TEAOE
 - b. Amplitude of DPOAE
 - c. Thresholds of HFA

Method

Participants

The study will include a minimum of 820 young adults with normal audio-vestibular system in the age range of 18 to 35 years after obtaining informed written consents for their participation in the study. Out of the 820 participants, 720 will participate in phase I of the study which will be done to assess and find out the level of VEMP evoking stimuli which will not affect the auditory system. The phase II will include 100 participants who will undergo cervical and ocular VEMP recording for obtaining the normative data at the highest safe intensity level.

The participants in phase I will be randomly divided in 3 groups, each group consisting of 240 subjects. Each group will correspond to a particular stimulus condition (500 Hz tone-burst evoked VEMP, frequency tuning of VEMP or FAR of VEMP). These 3 groups will be divided into further 4 sub-groups of 60 subjects each based on the stimulus levels that will be used to record VEMP (133 dB peSPL, 130 dB peSPL, 125 dB peSPL or 120 dB peSPL). Finally the group separation will be concluded by dividing each of these four subgroups into 3 sub-sub-groups each of 20 subjects each based on the test type upon which the impact of the stimuli is being studied (TEOAE, DPOAE or extended high frequency audiometry). The group division has been schematically represented in Figure 1.

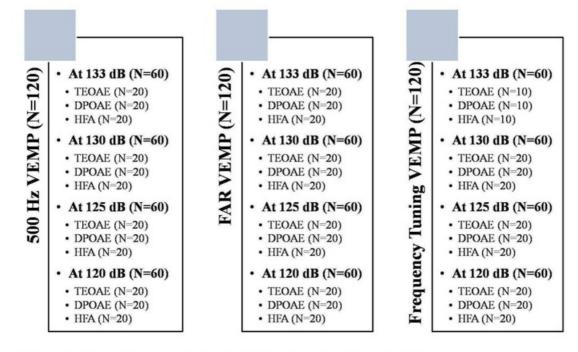


Figure 1: Schematic representation for distribution of participants to the groups

The audiological well being of the participants will be ensured through normal results on a test battery consisting of pure-tone audiometry (AC & BC thresholds \leq 15 dBHL), immittance evaluation ('A' type tympanogram with presence of ipsilateral & contralateral acoustic reflex at 100 dBHL), and oto-acoustic emissions (presence of TEOAE with a SNR of +6 dB along with response reproducibility of \geq 80%). The vestibular well being will be assured by the normal results on behavioural screening tests consisting of the Romberg test (no noticeable sway), Fukuda stepping test (deviation of \leq 45° in either direction and distance of \leq 1 meter from the starting point), Tandem gait test (heel-to-toe walking- no imbalance or stretching of arms) and Past pointing test (finger-to-nose test- no evident tremors and under/overshooting of target). Further, the participants will have no complaint or past history of vestibular and/or neurological deficits which will be assessed by a detailed structured case history.

Instrumentation

The VEMP module of the Biologic Navigator Pro version 7.2.1 with Etymotic ER-3A insert earphones will be used to record VEMPs. The TEOAE and DPOAE will be acquired using calibrated oto-acoustic emissions equipment- Mimosa. A calibrated Grasson-Stadler Incorporated 61 (GSI-61) clinical audiometer with HDA 200 high frequency circum-aural headphones will be used for high frequency audiometry.

Test environment

All the recordings will be performed in well-illuminated, air-conditioned, sound treated rooms with ambient noise levels well within the permissible limits (ANSI S3.1 1991). While high frequency audiometry will be performed in a double-room situation, the other tests (VEMP, TEAOE, & DPOAE) will be done in a single room suit.

Procedure

The study will be done in two phases. Phase I will be done to arrive at the sound pressure level that could be used for recording VEMPs without affecting the auditory system yet providing best possible response of VEMP. Phase II will be done to obtain the normative data of cervical and ocular VEMPs when using the safe levels of acoustic stimulation.

Phase I.

Following bilateral baselines (two recordings) of TEOAEs, DPOAEs or HFA, the participants will undergo cVEMP recordings (500 Hz cVEMP, FAR of cVEMP or frequency tuning of cVEMP) from one ear only. TEOAEs, DPOAEs or HFA, will be subsequently recorded bilaterally immediately after cVEMP testing (after 5 minutes). The testing will always be done first from the ear undergoing cVEMP recording in order to best obtain the effects of acoustic stimulation, after 1 hour, 24 hours and 1 week of cVEMP recording. The participants will be instructed against being subject for any other audiological evaluations or

listening to music at high volume control levels during this period. They will further asked to report about experiencing any auditory or vestibular system related complaints during this period.

Recording of cVEMP.

The participants will be seated in a comfortable chair in an upright position. The recording sites will be cleaned with a commercially available abrasive gel to obtain acceptable electrode impedances. The gold plated electrodes will be placed using adequate amount of commercially available conductive paste and secured in place with surgical tape. The inverting (negative) electrode will be placed at the sterno-clavicular junction, the noninverting (positive) electrode at the upper one third of the sternocleidomastoid muscle and the ground electrode on the forehead. Absolute impedance and the inter-electrode impedance will be maintained below 5 k Ω and 2 k Ω , respectively. The participants will be instructed to turn their heads away from the side of stimulation in order to tense the SCM muscle for ipsilateral recording of cVEMP. The tone-burst frequencies used will 500 Hz or 500 Hz and 1000 Hz or octave and mid-octave frequencies from 250 Hz to 2000 Hz, depending on the group. The stimuli will be presented at 133, 130, 125 or 120 dB peSPL, again depending on the group, at a repetition rate of 5.1 Hz. The rise/fall time and plateau time used will be 2 ms and 1 ms respectively as these ramping and plateau times were found to be best suited for cVEMP recording. Analysis window will be set to 74 ms which will include a 10 ms prestimulus (base line) recording. The responses will be averaged across 200 sweeps after being band-pass filtered between 10 Hz and 1500 Hz and multiplied by a factor of 5000. EMG normalization (pre-stimulus rectification) will be applied on the recorded responses in order to control for the effect of variable muscle tension on the cVEMP responses. cVEMP will be obtained only from one ear of each participant with half the participants undergoing recording from right ears and the other half from left ears in order to avoid ear effect, if any.

The parameters noted will the individual peak latencies and peak-to-peak amplitude from the recording of each individual and response rate (percentage of ear with presence of biphasic cVEMP waveform) from each of the groups.

We understand that some of the levels used in the present study are on the higher side. However, ethical approvals for the use of 133 or higher sound pressures levels have been granted by their respective university's ethical review boards and these studies have been published in journals of high repute that pay special attention to ethics in research. Table 1 shows a list of such publications providing specific details about the intensity and duration of the acoustic stimuli being delivered to the ear. In addition, there is no published evidence regarding any permanent damage to hearing or health caused by the use of 133 dB peSPL for durations in vicinity of 40-60 seconds. Further, care will also be taken to provide ten minutes of acoustic rest between two recordings on the same individual during the present study. Furthermore, each participant will be exposed to VEMP evoking acoustic stimuli in only one of their ears.

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Table 1: List of publications using sound pressure levels exceeding 133 dB peSPL.

S	Authors	Stimulus	Stimulus	Number of	Ethical approval	Published in (Journal)
No.		level	duration	averages		,
_;	Krasue et al (2013)	133 dB SPL	10 ms	400	IRB of Ludwig-Maximilans University & Helsinki Declaration	Otology & Neurotology
5.	Colebatch et al (1994)	145 dB SPL	0.1 ms	512		Journal of Neurology,
æ.	Kantner & Gurkov (2014)	140 dB SPL	e ms	300	IRB of University of Munich	Otology & Neurotology
4.	Nguyen et al (2010)	140 dB SPL	4 ms	200	IRB of Johns Hopkins University	Otology & Neurotology
5.	Taylor et al (2012)	135 dB SPL	4 ms	200	Helsinki Declaration	Audiology & Neurotology
9	Jerin et al (2014)	135 dB SPL	e ms	300	IRB of University of Munich	Hearing Research
7.	Chihara et al (2009)	135 dB SPL	4 ms	240	University of Tokyo Ethics Review Board	Neuroreport
∞.	Taylor et al (2012)	135 dB SPL	4 ms	400		Cephalagia
6	Seo et al (2013)	135 dB SPL	4 ms	400	IRB of Kinki University, Japan	Neuroscience Letters
10.	Iwasaki et al (2013)	135 dB SPL	4 ms	200	IRB of University of Tokya & Declaration of Helsinki	Acta-Otolaryngologica
Ξ.	Zuniga et al (2012)	140 dB SPL	4 ms	200	IRB of Johns Hopkins University	Otolaryngology- Head & Neck Surgery
12.	Xie et al (2011)	135 dB SPL	4 ms	200	IRB of University of Beijing & Declaration of Helsinki	Aviation, Space & Environmental Medicine
13.	Xie et al (2014)	135 dB SPL	4 ms	200	IRB of University of Beijing & Declaration of Helsinki	Asian Journal of Neuroscience

Note: 'IRB'- Institutional review board

Recording of TEOAE.

The transient evoked oto-acoustic emissions (TEOAE) will be administered monaurally using 85 dB peSPL non-linear clicks train. The stimulus will be calibrated to 85 dB peSPL for each recording and stimulus stability will be maintained at minimum of 80%.

A total of 260 averages will be included per recording and a time window of 20 ms will be used. The responses will be recorded separately in two different buffers and the buffers will be compared to obtain the reproducibility. The criteria of 6 dB SPL for signal-to-noise ratio combined with a reproducibility of more than 75% will be considered for presence of TEOAEs (Starr, Picton, Sininger, Hood, & Berlin, 1996). The amplitude of TEOAEs will be noted across frequencies and also globally.

Recording of DPOAE.

standard DPOAE probe tip will be positioned in the participant's ear canal. Two frequencies (f1 & f2) will be used in such a way that the ratio between them (f2/f1) will be maintained constant at 1.22. The stimulus intensity levels for the two frequencies will be at 65 and 55 dB SPL respectively for f1 and f2. The level of the 2f1-f2 DPOAE will be depicted as a function of frequency as a DPgram at octave and mid-octave frequencies from 500 Hz to 16000 Hz.

The criteria of 6 dB SPL for signal-to-noise ratio will be considered for presence of DPOAEs.

The amplitude of DPOAE will be noted at the above mentioned frequencies.

High frequency audiometry.

Air-conduction audiometry will be carried out at octave and mid-octave frequencies from 4000 Hz to 16000 Hz using a calibrated GSI-61 clinical audiometer with HDA 200 high frequency circumaural headphones. The participant will be seated comfortably in a straight back armchair and instructed to press the response switch upon hearing the tone. The

threshold at each frequency will be obtained using modified Hughson-Westlake procedure (Carhart & Jerger, 1959). The order of frequency will be randomly changed between the subjects of the same group so as to avoid order effect.

Subjective symptoms after cVEMP recording.

Soon after the cVEMP recording, each participant will be asked questions regarding the feeling of muffled hearing, ear pressure, otalgia, and tinnitus immediately after undergoing cVEMP recording (after 5 minutes) and 1 hour, 24 hours and 1 week later. This will be done in order to find if the subjective symptoms felt by the participants correlate with the outcome of tests.

Phase II.

During phase II, a set of 100 participants will undergo cervical and ocular VEMP evaluation from both their ears. This will be done in order produce a strong normative data base for the safe level found in phase I of the study. The recording of cVEMP will be done using the same stimulus and acquisition related parameters as used in phase I of the study.

All the 100 participants will also undergo contralateral oVEMP recording using the sound pressure level that will be found safe during the phase I of the study. They will be seated comfortably in an upright position and instructed to avoid any extraneous movements of the body, limbs or neck. The electrode configuration will involve the placement of the non-inverting electrode directly beneath the eye over the inferior oblique muscle of the eye (approximately I cm below the pupil), the inverting electrode 2 cm below the non-inverting electrode over the cheek and the ground electrode on the forehead (Fz). Prior to the placement of the electrodes, the skin overlying the electrode sites will be scrubbed with a commercially available abrasive skin preparing gel in order to minimize the electrode impedance. Gold-plated cup-shaped electrodes will be placed at these sites using a commercially available conductive paste and secured in place using adhesive tape. The

absolute electrode impedance will be maintained below $5 \text{ k}\Omega$ and inter-electrode impedance below $2 \text{ k}\Omega$. The foam-type standard Etymotic ER-3A insert earphones of the Biologic Navigator Pro system will be placed in the two ear canals. During recording, the participants will be instructed to maintain eye gaze in the supero-medial direction at an elevation of 30° . The accuracy of gaze angle will be ensured by asking the participants to fix the gaze at a pointer on the wall placed at an elevation of 30° from the eyes of the participants. The stimuli used will be tone-bursts of octave and mid-octave frequencies from 500 Hz to 200 Hz which will presented at a repetition rate of 5.1 Hz. The EMG activity will be filtered using a band-pass filter of 1-1000 Hz and multiplied by a factor of 30000 in order to obtain the final oVEMP.

The waveforms will be analyzed for individual peak latencies and peak-to-peak amplitude. The other parameters like asymmetry ratio, frequency-amplitude ratio and frequency tuning of cVEMP and oVEMP will be deduced from the peak-to-peak amplitude values. The asymmetry ratio will be calculated for only the 500 Hz response using Jonkee's formula mentioned in equation 1. The frequency producing the largest peak-to-peak amplitude will be operationally defined as frequency tuning. The FAR will be obtained as the ratio of peak-to-peak amplitude evoked by 1000 Hz and 500 Hz.

Asymmetry ratio =

Asymmetry ratio =
$$\frac{\text{(Better ear amplitude-Poorer ear amplitude)}}{\text{(Better ear amplitude+Poorer ear amplitude)}} \times 100$$
 -----Equation

Statistical analyses

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The statistical analyses will be performed using a commercially available statistical tool, namely Statistical Package for Social Sciences (SPSS) version 17.0. The within and between groups comparisons will be performed using appropriate statistical methods which will be decided (parametric or non-parametric statistics) after the results of Shapiro-Wilk's

test of normality. For reporting the normative data, mean, standard deviation, median and range will be used.

Implications

The outcome of the study will throw light on temporary or permanent deleterious impact of acoustic stimuli used for eliciting cVEMP on cochlear functions, if any. In case a deleterious impact is found, the outcome of the study will provide the level(s) that can be safely used for eliciting VEMP without significantly altering its response rate. The study will also provide the normative data of cVEMP and oVEMP for the thus found safe level(s).

Impact of Acoustic Stimuli Used for Various Measures of VEMP on the Auditory System

ORIGINALITY REPORT

1%

SIMILARITY INDEX

INTERNET SOURCES

PUBLICATIONS

STUDENT PAPERS

PRIMARY SOURCES



Submitted to All India Institute of Speech & Hearing

Student Paper

Singh, Niraj Kumar, and Animesh Barman. "Characterizing the frequency tuning properties of air-conduction ocular vestibular evoked myogenic potentials in healthy individuals", International Journal of Audiology, 2013.

2%

Publication

Singh, Niraj Kumar, Prawin Kumar, T. H. 3 Aparna, and Animesh Barman. "Rise/fall and plateau time optimization for cervical vestibular-evoked myogenic potential elicited by short tone bursts of 500 Hz", International Journal of Audiology, 2014.

1%

Publication

Singh, Niraj Kumar, and Animesh Barman. "Efficacy of Ocular Vestibular-Evoked Myogenic Potential in Identifying Posterior Semicircular Canal Benign Paroxysmal Positional Vertigo:", Ear and Hearing, 2014.

1%

Singh, Niraj Kumar, Preeti Pandey, and 1% 5 Soumya Mahesh. "Assessment of otolith function using cervical and ocular vestibular evoked myogenic potentials in individuals with motion sickness", Ergonomics, 2014. Publication Singh, Niraj Kumar, Sujeet Kumar Sinha, 1% Rajeshwari Govindaswamy, and Apeksha Kumari. "Are cervical vestibular evoked myogenic potentials sensitive to changes in the vestibular system associated with benign paroxysmal positional vertigo?", Hearing Balance and Communication, 2014. Publication "New Findings Reported from N.K. Singh and 1% Co-Authors Describe Advances in Meniere's Disease (Frequen", Health & Medicine Week, June 3 2016 Issue Publication ir.canterbury.ac.nz <1% 8 Internet Source Piker, Erin G., Gary P. Jacobson, Robert F. Burkard, Devin L. McCaslin, and Linda J. Hood. "Effects of Age on the Tuning of the cVEMP and oVEMP:", Ear and Hearing, 2013. Publication

Kamali, Behnoush; Hajiabolhassan, Fahimeh;

10	Fatahi, Jamileh; Esfahani, Ensieh Nasli; Sarrafzadeh, Javad and Faghihzadeh, Soghrat. "Effects of Diabetes Mellitus Type? with or without Neuropathy on Vestibular Evoked Myogenic Potentials", Acta Medica Iranica, 2013.	<1%
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15	www.inderscience.com Internet Source	<1%
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