Effect of cochlear implantation and surgery technique on cervical vestibular evoked myogenic potential

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3 PROJECT PROPOSAL FORMAT

Part -A

1.0 Title of the Project : Effect of cochlear implantation and surgery technique on cervical vestibular evoked myogenic potential

Area of Research:

- a) Hearing and vestibular system
- 1.1 Principal Investigators:

Mr. Sachchidanand Sinha

Dr. Niraj Kumar Singh

1.2 Principal Co- Investigator

Mr. Nirnay Kumar Keshree

Dr. Shenal Kothari

Dr. Prawin Kumar

1.3 Collaborating Institute

Department of Speech and Hearing

Sri Aurobindo Institute of Medical Sciences & PG Institute

Indore- Madhya Pradesh.

1.4 Total Grants Required:

Rs 5,68,000 (Five lakhs sixty eight thousands only)

1.5 Duration of the Project: 1 year

2.0 Project Summary (Max 300 Words)

Cochlear implant (CI) is an electronic device which is implanted under the skin with electrodes positioned in the cochlea to stimulate the auditory nerve. Cochlear implantation has been accepted as a safe technique to give a hearing sensation to a person with hearing impairment. Although non-auditory effects like twitching of the facial muscles due to facial nerve stimulation or pain in the ear canal or throat have been well documented. However, more recent reports on adults have shown occurrence of dizziness as a non-auditory effect, the incidence of which has been reported to vary from 2% to 47% (Kubo, Yamamoto, Iwaki, Doi, & Tamura 2001; Vibert, Hausler, Kompis & Vischer, 2001). An adult can report it properly whereas children, who easily outnumber the adult recipients of CI, may fail to explain the feeling of dizziness. Hence there is a need of studying the effect of cochlear implantation on vestibular system in children. The present study has been taken with an aim of comparing the status of pre-implanted vestibular system with the status of post-implanted vestibular system using cVEMP. The present study will comprise of 40 children in the age range of 3 to 8 years. They will be divided in two groups based on the surgery method used for electrode insertion. Vestibular system function test will be evaluated using cVEMP. Appropriate statistical analyses will be used for comparison between the groups for finding out the status of vestibular system.

Introduction(under the following heads)

3.1 Definition of the Problem

Hearing impairment is a major disability which leads to delay in the development of speech and language and later difficulties in all aspects of life. According to the recent sensus in 2011 in India, nearly 6% of the population is affected by hearing impairment. A

high percentage of them have permanent hearing loss, usually of severe to profound degree. This makes them candidates for cochlear implantation. With the central and several state governments' initiative of providing cochlear implant free of any charges to the needy who fulfill the criteria laid down by the government, there has been a spike in the number of cochlear implant recipients, especially below the age of 6 years.

Inner ear is responsible for hearing as well as maintenance of balance. The deficits in hearing are offset by the cochlear implantation and the auditory verbal learning training that follows; nonetheless, the surgery performed for inserting the electrodes into the inner ear has been reported to result in vestibular deficits in some individuals (Kubo, Yamamoto, Iwaki, Doi, & Tamura 2001; Vibert, Hausler, Kompis & Vischer, 2001). However, these studies were done using a mastoidectomy and cochleostomy approach which increases the risk of saccular damage. The more recent techniques like the 'Veria technique' has been reported to be less traumatic owing to the use of canal wall and round window electrode insertion approach (Kiratzidis, Arnold, & Iliades, 2002; Hans & Prasad, 2015). Therefore it is not known if a vestibular, more specifically saccular damage is caused by the use of this technique also.

3.2 Objectives

The aim of the current study is to assess the status of vestibular system pre- and post-CI. The specific objectives of the study are

 To compare the cVEMP parameters (response rate, latencies & amplitude) of preimplant surgery and post-implant surgery

- To compare the parameters of cVEMP between the implanted and unimplanted ears of CI
- To compare the cVEMP parameters between the implantees who received CI using mastoidectomy approach with those receiving using Veria technique.

3.3 Review of status of research and development in the subject

CI facilitates remarkable improvement in hearing ability but it can also lead to complications. Some of the complications reported include symptoms like dixzziness, vertigo or imbalance. In literature, it has been reported that 0.33% to 75% patient develops vertigo after cochlear implantation (Buchnan et al., 2004). Todt, Basta & Ernst (2008) reported that 50% of cases that were implanted using cochleostomy and 13% of patient who were implanted using round window approach were having hypo functional post-operative VEMP. Tsukuda et al (2013) reported that post operative VEMP responses were normal in all patients except 1 patient. In contrast, Psillas et al (2014) evaluated vestibular system using VEMP on 10 children and reported that 60% children had abnormal cVEMP responses on both ears and later in post operative sessions no child showed any cVEMP response on the implanted side. Hence they concluded that saccule of children can be extensively damaged following cochlear implantations. Similar to this Xu, Zhang, Zhang, Hu, Chen & Xu (2014) have also reported decrease in response rate of cVEMP post implantation. They have also shown increase in cVEMP thresholds and decrease in amplitude of cVEMP.

3.4 International and national status

The above literature reports are suggestive of mixed results regarding vestibular deficits caused by cochlear implantation. While most of the studies demonstrated agreement over the finding of reduced vestibular function after CI in 13-60% recipients (Todst et al., 2008; Psillas et al., 2014; Xu et al., 2014), Tsukuda et al (2013) observed no abnormality of VEMPs in 9 of their 10 cases of CI. There is no Indian study, to the best of our knowledge, in this regard.

3.5 Importance of the proposed project in the context of current status

The above review of literature has shown that there could be likelihood of vestibular disturbance induced by cochlear implantation. If the results of the present study are on similar lines, this will strengthen this viewpoint. Further, it will highlight the need for a vestibular rehabilitation program to be inculcated in their rehabilitation regime along with the auditory verbal learning. Furthermore, if the results of the present study show that vestibular damage is less often encountered due to one technique of surgery than the other, it will provide evidence to support the use of that technique over the other for cochlear implantation.

4.0 Work Plan

4.1 Method

Participants.

Forty participants in the age range of 3 to 8 years who fulfill the criteria for cochlear implant candidacy will serve as the participants in the present study. The complete CI candidacy evaluation will include ENT evaluation, paediatric evaluation, detailed

audiological evaluation, speech and language evaluation, IQ assessment and radiological evaluation. The participants will be divided in two groups based on surgical technique used.

Procedure.

cVEMP will be obtained from both ears of all participants, 1 week prior to the cochlear implantation surgery, on the day of the switch-on and 4 month after the switch-on. For cVEMP acquisition, the participants will be seated in an upright position on a straight back chair. The non-inverting electrode will be placed at two-thirds the way up the sternocleidomastoid muscle, inverting at the sterno-clavicular junction and ground on the forehead, similar to the one used previously (Murofushi, Shimizu, Takegoshi, & Cheng, 2001; Rauch et al, 2004). In order to achieve a constant level of muscle activity, the participants will be instructed to turn their head in opposite direction to the ear of acoustic stimulation. Tone-bursts of 500 Hz will be presented at the rate of 5.1 Hz at an intensity of 125 dB peSPL. The responses will be band-pass filtered from 10 to 1500 Hz and amplified by a factor of 5000. The artifact rejection mode will be switched off throughout the recording in order to avoid rejection of cVEMP responses owing to its considerably larger amplitude compared to some of the other auditory evoked potentials. The response window will be set to 60 ms. Total of 150 presentations of the tone-burst will be used to obtain an averaged recording and two recordings will acquired per ear. An inter-recording rest period of 2 minutes will be given to avoid the responses getting contaminated by fatigue. All the cVEMP recording and acquisition parameters will be kept constant across the individuals, ears and recordings. cVEMP will be recorded and analyzed separately for both the ears (unimplanted and implanted ear) of individuals. The

parameter considered and noted will be response rate, latencies of individual peaks, peakto-peak amplitude and asymmetry ratio.

Statistical analyses

Shapiro-Wilk's test of normality will be performed to assess the normality of distribution of the data. Depending upon the outcome of this, appropriate parametric or nonparametric statistical analysis will be used for within and between groups comparisons.

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