STANDARDIZNG OF BRAINSTEM EVOKED RESPONSE AUDIOMETRY VALUES PRELIMINARY TO STARTING BERA LAB IN A HOSPITAL

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ABSTRACT: INTRODUCTION: The subjective assessment of hearing is primarily done by pure tone audiometry. It is commonly undertaken test which can tell us the hearing acuity of a person when carried under ideal conditions. However, not infrequently the otologists encounter a difficulty to do subjective audiometry or in those circumstances where the test results are not correlating with the disease in question. Hence they have to depend upon the objective tests to get a workable knowledge about the patients hearing threshold. Of the various objective tests available the most popular are Brain stem evoked response audiometry -non-invasive and more standardized parameter, Electrocochleography, auditory steady state response. Otoacoustic Emission test (OAE) Otoacoustic emission doesn't measure the hearing acuity, it gives us an idea whether there is any deafness or not. But BERA is useful in detecting and quantification of deafness in the difficult-to-test patients like infants. mentally retarded people, malingers, deeply sedated and anaesthetized patients. It determines objectively the nature of deafness (i.e., whether sensory or neural) in difficult-to-test patients. It helps to locate the site of lesion in retro-cochlear pathologies (in an area from spiral ganglion of the cochlear nerve to midbrain (inferior colliculus). Study of central auditory disorders is possible. Study of maturity of central nervous system in newborns, objective identification of brain death, assessing prognosis in comatose patients are other uses. Before starting a BERA lab in a hospital it is mandatory to standardize the normal values in a randomly selected group of persons with certain criteria like; normal ears with intact T.M and without any complaints of loss of hearing. Persons aged between 05 to 60 years are taken for this study. The study group included both males and females. The aim of this study is to assess the hearing pathway in normal hearing individuals and compare differences associated with gender, age and ear side (left and right). It was found that wave latencies differed significantly between males and females, although there were no differences regarding right or left ear sides. Comparing latency averages regarding age and gender important differences were noted. By the Same token, significant differences were also seen comparing this study with the information present in the handbook of the BERA device used and results published by Fukuda, in another study.

KEYWORDS: Audiometry, Loss of Hearing, BERA, auditory stimulus, late latency, middle latency, auditory evoked potential, V wave latency, I-III wave latency.

MATERIALS AND METHODS: This study was conducted at Department of Otorhinolaryngology and head and neck surgery, Kurnool medical college, Kurnool, Andhra Pradesh, India between February 2010 and August 2011. 60 patients aged between 5 to 60 years (mean 31.2yrs) were randomly selected from the outpatient department of Government General Hospital Kurnool. There were 25

male and 35 female subjects. Patients with otological and/or vestibular complaints were screened at the Otorhinolaryngology unit. The ears were examined with conventional Bull's eye lamp and otoscopy and patient's intact Tympanic membrane were selected and audiometry was done (pure tone audiometry, Impedance testing). Only patients with normal results were subjected to an electrophysiological assessment (Brainstem evoked auditory response potential or BERA).

INCLUSION CRITERIA: A normal otoscopy, Pure tone audiometry thresholds equal to or below 20 dB at 250 Hz, 500 Hz, 1000Hz, 2000Hz, 4000Hz and 8000Hz; Normal Impedance test (A type curve) with the presence of the ipsilateral and contralateral stapedial reflex.

EXCLUSION CRITERIA: Any of the above-mentioned tests with altered results (not within normal limits); Patients with suspected or confirmed neurological diseases, since these conditions may yield normal audiological tests and altered auditory evoked potentials.

RECORDING OF BERA: BERA was recorded using an RMS EMG EP MARK-II with three disposable electrodes one placed on frontal area (ground & positive electrode) and one on each mastoid (negative).

Click was used as the acoustic stimulus; 19 clicks per second were delivered through earphones at 80 dB NHL, totaling 2, 048 stimuli alternatively to both the ears.

DATA ANALYSIS: Data was gathered for a horizontal prospective study and patient file analysis, which characterized a cross-sectional historical cohort study. Absolute values (in milliseconds) of absolute latencies and wave I, III and V inter peak intervals were analyzed for each ear. The exam measurement means were calculated according to sex, the side (right or left side) and age of patients to analyze possible differences among absolute wave latency period values. Sex and age measures were compared with other published studies.

Student's T test for single independent samples was applied for the analysis of absolute value and latency period means. Levene's test was applied for analyzing the equality of variances. Statistically significant values were those below p < 0.05. The STASTICA software was used for these tests. This study was designed to detect a 0.05ms difference among absolute latency measures and wave inter peak intervals; the statistical power was 80% and the significance level was 5%.

RESULTS: Table 1 shows the absolute latency value and the wave I, III and V inter peak interval, means with their standard deviation (SD) in 120 ears regardless of sex or side.

	Wave I	Wave III	Wave IV	Interval	Interval	Interval			
				I-III	III-V	I-V			
Mean	1.67	3.80	5.50	2.13	1.70	3.83			
Standard	± 0.13	±0.14	± 0.18	± 0.15	± 0.18	± 0.18			
Deviation					± 0.10				
Table I: Showing mean values and standard deviations in 120 ears									

Mean and standard deviation (ms) of absolute latencies (n = 120 ears).

Comparing male and female patients according to the ear (right ear - RE; left ear - LE), statistically significant differences were found only in wave V and the interval I-V in the right ear. Other mean differences were not statistically significant, CHART I shows standard deviations for these means and p values.

Results of comparing between right and left ears regardless of sex were not statistically significant. The means according to age, sex and side of the ear, separating right and left ears in male and females patients below and above age 31 years were compared.

There was only a single significant change found when comparing intervals I-V in the right ears of female patients below and above age 31 years (p = 0.000), as shown in TABLE-II

FEMALES	WAVE I	WAVE III	WAVE V	I-III	III- V	I-V
RE < 31YRS	1.72	3.80	5.53	2.08	1.73	3.80
RE> 31YRS	1.69	3.85	5.61	2.16	1.76	3.92
p Value	0.30	0.36	0.12	0.17	0.38	0.00
		Table II				

Right ear means (ms) in females and p value (n=35ears).

There were statistically significant differences (p < 0.05) between wave I, III and interval I-V means in this study and the means shown in the manual of the device, as shown in the CHART-2 Fukuda et al means vs. our means (CHART-III) The analysis revealed a significant difference between wave I in both sides, and wave III in the right ear only.

DISCUSSION: The BERA is an important test in clinical practice:

- 1. It is used to diagnose auditory threshold changes to characterize the type of hearing loss
- 2. To identify retro cochlear or central nervous System alterations
- 3. To assess central auditory system maturity in Neonates.

Its sensitivity for detecting these conditions is considered optimal, since it does not depend on information from patients:

- Because of questions raised by many authors about interferences from certain physiological factors, such as age and sex, on BERA recordings, a study is needed to assess these variables in normal individuals in a Hospital where BERA lab is set up before undertaking BERA in pathological states.
- As this test becomes more widely used in clinical practice, normalization protocols for each healthcare institution need to be discussed for comparisons with data from other institutions and other studies.
- This study presents wave I, III and V absolute latency and inter peak interval I-III, III-V and I-V means gathered from 60 male and female patients aged from 5 to 60 years for comparisons within the sample and with other studies. The analysis revealed a significant difference in the wave V latency time and the I-V inter peak interval between sexes; latencies were higher in the right ears of males. This result supports other published data, which show this wave V and inter peak interval I-V increase in males.

There were no statistically significant differences in comparisons between right and left ears regardless of sex.

Maria Carolina Braga Norte Estevez¹ knowing the great importance of BERA concluded that it is crucial that each service develops its own standards in order to enhance the accuracy of the electrophysiological diagnosis of the hearing pathway.

No latency differences between ears are expected in patients with bilaterally normal auditory thresholds. Recordings of this potential may be clinically analyzed according to a number of parameters:

- 1. Morphology
- 2. Absolute latency
- 3. Wave I III and V amplitude
- 4. I-III, I-V and III-V inter peak interval latencies
- 5. I-V latency and amplitude relation
- 6. I-V interval Inter-aural difference
- 7. Wave V absolute latency difference.

Absolute latency and inter peak interval measurements are those most widely used clinically. According to the literature, the main clinical aims of BERA lab are:

- A. To establish a minimal auditory response level
- B. To characterize the type of hearing loss
- C. To assess the maturity of the central auditory system in neonates
- D. To define the site of auditory nerve or brainstem injury
- E. To monitor surgery of the posterior fossa
- F. To monitor patients in intensive care units.

Many authors have investigated the interference caused by physiological factors on BAEP recordings. These consist of subject-related features, such as age, sex and hormonal status.

In some studies, increased wave latencies has been observed in subjects aged over 60 years, While others have demonstrated no statistically significant differences in BAEP latency with age.

Other studies have shown that latency measures (especially wave V) and inter peak intervals (especially in the I-V interval) are higher in male subjects compared with female subjects.

Thus, both age and sex are mentioned as variables that may alter BAEP recordings; their true influence, however, remains controversial, requiring additional studies of these issues.

Therefore, the purpose of this study was to analyze absolute wave I, III and V latencies and I-III, III-V and I-V inter peak intervals in audiological normal subjects of both sexes.

COMPARISON WITH OTHER STUDIES: J Jerger, J Hall² examined amplitude and latency of the auditory brainstem response (ABR) waveform as functions of chronological age in 182 male and 137 female subjects and found that hearing sensitivity was within normal limits in 98 subjects. The remaining 221 subjects had varying degrees of sensori-neural hearing loss. Age had a slight effect on both latency and amplitude of wave V. In subjects with normal hearing, latency increased about 0.2 ms over the age range from 25 to 55 years. In the same group, wave V amplitude decreased about 10%. Sex also affected the ABR. In both normal and hearing-impaired subjects, female subjects

showed consistently shorter latency and larger amplitude at all age levels. Wave V latency was about 0.2 ms shorter and wave V amplitude was about 25% larger in female subjects.

B Mokotoff, C Schulmann - Galambos, R Galambos³ presented evaluation of the peripheral auditory system attempted in 81 infants and children using an electrophysiological response, the brain stem auditory evoked response (BERA). These measurements, which were successfully made in all cases, were supplemented with impedance measures in some subjects. Results were compared with previous and follow-up audiograms whenever possible. The BERA test proved to be a highly reliable diagnostic tool when used in assessing "difficult-to-test" patients. It also identified new patients with peripheral auditory abnormality who subsequently received confirming conventional audiological tests.

Burkard RF, Sims D⁴ studied about the human auditory brainstem response to high click rates: aging effects. Many papers have demonstrated that BAEP recordings change in elderly subjects. In 2002Burkard and Sims and Boettcher assessed individuals with presbycusis and found that absolute wave latencies in BAEP were increased and that inter peak latencies were unaltered.

In a study by V Rupa⁵ Department of ENT, Speech and Hearing, Christian Medical College Hospital, Vellore, India, where the records of 94 consecutive developmentally retarded children with speech retardation and suspected hearing loss who underwent auditory assessment by both conventional behavioral observation audiometry (BOA) and brain stem evoked response audiometry (BERA) were analyzed. In 54 children (57.4 per cent) there was good agreement between the results of both techniques leading to a clear-cut diagnosis. In 22 children a diagnosis was possible only by the results of BERA as the results of BOA were inconclusive.

According to Anias et al⁶, controversies in the literature about the relation between BAEP and age in adults may be due to varying selection criteria, especially those related with the health status, auditory selection criteria, sex and the stimulus unit. Only one statistically significant change was found in our study: the interval I-V was higher in the right ears of female subjects aged over 31 years compared to female subjects aged below 31 years, which supports published results.

A comparative analysis of our means with those in Fukuda et al⁷ [1988] study, Maria Carolina Braga Norte Estevez [2009] study, revealed a significant difference between wave I (both sides) and wave III (right ear), once again showing that different devices and examiners may yield distinct results; thus, each institution should have its own parameters. These differences may also be explained by the fact that this study was designed to detect a 0.05 ms difference among means. Statistically significant differences were equal to or higher than 0.05ms. For this reason they concluded that comparisons between young and elderly patients with presbycusis are not recommended

Beagley and Sheldrake⁸ and Anias et al. studied normal-hearing subjects and found no age related effect, this may be explained by the inclusion criteria of that study, which took into account only normal-hearing ears.

CONCLUSION: A statistical analysis of results revealed a significant difference between wave I and III absolute latency times and the inter peak interval I-V values found in this study and values suggested by the equipment manual. The analysis revealed a significant difference in the wave V latency time and the I-V inter peak interval between sexes; latencies were higher in the right ears of males. This result supports other published data, which show this wave V and inter peak interval I-V increase in

males. There were no statistically significant differences in comparisons between right and left ears regardless of sex.

Such data demonstrate the need for each institution to standardize its own wave absolute latency and inter peak interval values for each device, regardless of values suggested in the literature, to avoid incorrect diagnosis. As this test becomes more widely used in clinical practice, normalization protocols for each healthcare institution need to be discussed for comparisons with data from other institutions and other studies. Considering that the differences found in this study does not yield different medical interpretations, since examinations are within normal limits and will therefore not alter subsequent approaches.

This study aimed mainly to highlight the importance of each institution to set its own parameters - as shown in the analysis to avoid controversies in results when compared with other institutions. BERA is an important and widely applicable test, it is essential for each institution to conduct their own parameter-setting study to increase the accuracy of the electrophysiological assessment of auditory pathways.

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