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CLINICAL NORMS FOR AUDITORY BRAINSTEM RESPONSE TESTING FOR FEMALES AT THE KORLEBU TEACHING HOSPITAL, ACCRA, GHANA

Sesi Collins Akotey [1*], Geoffrey K. Amedofu[2], Samuel Anim-Sampong[3], Samuel K. Hayford[1], Yaw Nyadu Offei[1]
*[*1]University of Education, Winneba, Ghana*
[2]Korlebu Teaching Hospital, Korlebu, Accra
[3]University of Ghana, School of Biomedical Sciences and Allied Health, Legon.

Corresponding Author:-

Abstract:-

The aim of the study was to create an in-house normative data for neurodiagnostic auditory brainstem response test for the Korlebu Teaching Hospital Hearing Assessment Center, to enable the Centre to provide a comparative standard for making informed diagnostic decisions about patients' auditory function using the Intelligent Hearing System (IHSSEP). A purposive sample of 25 females aged between 18-35 years with normal hearing thresholds were selected for the study. Data was analyzed using one sample independent t-test, mean, and standard deviation with the statistical significance set to $p<0.05$ to determine how the clinical norms compared with the manufacturer's norm. Results showed that the absolute latencies generated by the study varied slightly from the IHSSEP norms. However, the variations emanated from the testing environment, the protocol used, and the software specifications of the testing equipment rather than pathological conditions from the participants. Besides, the norm data fulfilled the requirement of the upper and lower limits allowable for norm data to be considered as appropriate - thus a ±2 SD. It was concluded that the norms values were appropriate to use in testing and estimating hearing sensitivity at Korlebu Teaching Hospital Hearing Assessment Centre taking into account the clinical conditions and the varying parameters of the testing equipment.

Keywords*: Auditory brainstem response, waves, intensity, normative, & latency*

BACKGROUND:-

Auditory Brainstem Response (ABR) represent neuroelectric potentials recorded from electrodes placed on the scalp representing anatomical site of the auditory system (Atcherson, 2012; Gathe, Gandhe, Gandhe, Puttewar, Saraf & Singh, 2014; Hood, 1998). In the last three decades, auditory brainstem response (ABR) testing has assumed a prominent role as an objective method of assessing hearing sensitivity in young and/or difficult-to-test patients (Atcherson, 2012; Burkard & Secor, 2002; Gelfand, 2009). Clinically, ABR test is conducted to assess the integrity / functionality of the peripheral auditory system to the level of the lower brainstem (Arnold, 2007; Atcherson, 2012; Ness, 2009). Besides, ABR has also become useful in hearing screening and threshold estimation for early detection of hearing impairment in high-risk population and children. (Burkard & Secor, 2002; Gelfand, 2009). According to Coenraad, van Immerzeel, Hoeve and Goedegebure (2010) and Gathe, Gandhe, Gandhe, Puttewar, Saraf and Singh (2015), ABR is pivotal in the differential diagnosis of hearing loss and degree of hearing impairment. Essentially, ABR consists of eliciting and recording waveforms and then comparing the quality of the waveforms and the latencies with normative data to determine normal and abnormal responses (Don & Kwong, 2009; Gelfand, 2009; Hood, 1998; Ness, 2009). Although, there are a number of standardized normative data, literature reveals that it is important for audiology clinical facilities to develop their own set of ABR norms for each piece of test equipment (Gelfand, 2009; Hall, 1992, 2007; Ness, 2009). This is because, testing environments, software variation, test protocol and some other electroacoutic properties can significantly influence the test results and latencies. For instance, the manufacturer's protocol and software specification (a high pass filter of 3000 Hz) of the norms for the Intelligent Hearing Systems Smart EP systems (IHSSEP) compared to that of the instrument (purchased equipment) (high pass filter of 1500Hz) vary slightly. It has being argued that filtering, filter types and testing conditions can significantly affect waveform latencies and amplitude (Hall, 2007; Hood, 1998). Also, a crucial factor in accurate ABR interpretation is the consistency in the criteria used in waveform analysis during generation of a normative data base and those used in clinical analysis of the response (Hall, 1992). Authorities such as Hall (1992), Gelfand (2009), Silman and Silverman (1991) have argued that since some studies have reported slight gender and age effects (on the order of 0.2 milliseconds), gender effects must be considered when collecting normative data; also, separate norms should be obtained for subjects under 50 years of age. From the ongoing discourse, this has become the acceptable clinical practice in the world, and Ghana has no choice but to comply. Hitherto, hearing assessment at Korle-Bu Teaching (KBTH) Hearing Assessment Center was limited to pure tone audiometry, tympanometry measures and Otoacoustic emission (OAE) testing. Consequently, staff had difficulty testing children and the "difficult-to-test" population (for example, the developmentally delayed), who cannot respond behaviourally. This necessitated the procurement of the IHSSEP to facilitate ABR testing such clients. The IHSSEP is the most complete and flexible platform for the acquisition of Evoked Potentials. It is an electrophysiological equipment which provides body measurements with precision of data devoid of bias or influence of the tester. It also allows for automatic acquisition of neuro-electric potential via electrodes placed on the scalp. A straightforward Control Panel allows for fast data acquisition, while the great variety of controls allow you to perform tests the way you want them (User manual, 2012). This study was undertaken to establish a set of clinical norms for the IHSSEP that had been procured for the KBTH Hearing Assessment Centre; and as stated earlier, it is crucial for each audiology clinical facility to do so (Gelfand, 2009; Hall, 1992, 2007; Ness, 2009).

Methods

The project site was the Hearing Assessment Center of Korle Bu Teaching Hospital (KBTH). KBTH was established in October 9, 1923, and has grown from a 200 beds facility to 2,000. Currently, KBTH is the premiere national referral centre in Ghana. KBTH is also affiliated to the University of Ghana's medical school, which trains medical doctors, nurses as well as other paramedic professionals. It was a prospective study in which convenience and purposive sampling techniques were adopted to select participants (Cohen, Manion & Morrison, 2007; Creswell, 2005; McMillan & Schumacher, 1997). Prospective study is an analytic study designed to determine the relationship between a condition and a characteristic shared by some members of a group with the selected population, none of whom has any pathological condition. Twenty-five female participants aged 18 -25 years were drawn from students at the medical school at the KBTH. This sample was chosen because of their availability and their medical history of no auditory pathology. As an inclusion criteria, each participant should have normal hearing thresholds determined by standard audiometric clinical measurements with thresholds better than or equal to 20 dB HL at all test frequencies and no history of ear or hearing related pathology. Female participants who had histories of any ear or hearing related pathology and/or had hearing thresholds greater than 20 dB HL were excluded from the sample. Also, participants whose tympanometric results showed abnormal peak compensated static admittance and ear canal volumes were excluded since ABR results are affected by ear pathologies, hearing loss and middle ear pathologies (Atcherson, 2012; Gelfand, 2009; Hall, 2007). Participants had a thorough otoscopy examination. As stated above, only those who did not have any impacted cerumen in the ears and their eardrums were visibly-intact were included in the study. All participants had hearing sensitivity evaluation using pure tone air conduction audiometry at the standard audiometric frequencies (250, 500, 1000, 2000, 4000, 8000 Hz). The modified Hughson-Westlake (10-dB down, 5-dB) method for threshold establishment was used. A calibrated Interacoustics AC 33 clinical audiometer was used for the testing in a calibrated test booth. All the participants had pure tone behavioral thresholds ≤20 dB HL on the day of testing. Furthermore, 226-Hz tympanometry was performed to ensure the subjects had peak compensated static admittance and ear canal volumes within normal limits ruling out any middle ear pathology. All the testing equipment were within calibration to ensure consistency and reliability of the test results.

Testing procedure
The following protocol described in Table 1 was used for testing and data collation.

Table 1: Testing Protocol

Stimulus	0.1 milliseconds click
Rate	21.1/sec
Polarity	Rarefaction
Transducer	Insert Earphones
Filters	30-1500 Hz
Intensity	80 dB HL down to 10 dB HL
Amplification	100x
Runs	2
Analysis time window	12.8 milliseconds
Sweeps	2048
Electrode montage	Ipsilateral

Data for the study was collected by setting every subject up for a one-channel differential recording. The non-inverting/positive (+) electrode was placed on the high forehead while the inverting (-) reference electrode was placed on one ear lobe (C7 vertebra) and the ground placed on the other ear lobe. The surface of the skin for the electrode montage was prepared in the conventional manner using a prep-pad in order to reduce the impedance between electrodes. All impedances were required to be <3 kOhm (the resolution of the measuring equipment) and the testing conducted in a sound-attenuated room with the participants lying (mainly supine) on a bed and instructed to relax and sleep (if possible) to reduce myogenic interference. Insert headphones (Etymotic Research ER-3) were used for stimulus presentation (Hall, 2007; Sokolov, 2005). Double waveform collection was made at each intensity to ensure repeatability of the waveforms for the validity and reliability of the data generated, most especially in the identification and labeling of the waveform peaks at each intensity. The various latency values were also automatically generated by the equipment once the waveform peaks are identified and labeled. According to Vanderstoep and Johnson (2009), physiological measures provide bodily measures with precision of data of the instruments.

Data Analysis
Descriptive statistics was used to analyze the data collected for the study. For every participant, the absolute latencies of the waveforms were measured from the onset of the stimulus to the most prominent peaks of waves I, III and V and recorded at intensities of 80 dB to 30 dB with a 10 dB decrease. The mean and standard deviations were calculated for the latency values of waves; composite data was also computed for the determination of waves I, III and V as a function of stimulus intensity. All the data were computed and analyzed using the one simple independent ttest (Z-score or standard score) with the statistical significance set to p <0.05. The mean latencies and standard deviations for clinical data have been presented in Table 2 below.

Results
Table 2 highlights mean latencies and standard deviations for participants in the study.

Intensity (dB HL)	Wave I (ms)		Wave III (ms)		Wave V (ms)		Inter-wave I-V (ms)		Inter-wave I-III (ms)		Inter-wave III-V (ms)	
	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD
80	1.75	0.20	3.82	0.27	5.75	0.22	4.00	0.30	2.07	0.29	1.93	0.26
70	1.98	0.15	4.03	0.27	5.93	0.28	3.95	0.29	2.05	0.25	1.90	0.25
60	2.29	0.24	4.27	0.31	6.17	0.29	3.90	0.31	1.99	0.23	1.90	0.25
50	2.62	0.33	4.65	0.37	6.48	0.26	3.89	0.33	2.03	0.24	1.84	0.27
40	3.00	0.45	5.01	0.41	6.92	0.28	3.92	0.42	2.02	0.18	1.87	0.31
30	3.51	0.45	5.55	0.31	7.35	0.32	3.95	0.41	2.07	0.37	1.86	0.22

Source: Field data from participants.

Table 2 above represents the average absolute latencies, inter-wave latencies and their respective standard deviations from participants across the various intensity levels. The results shown in Table 2 establish an inverse relationship between the

latency values and the intensities [for instance at Wave I latency: 80 dBnHL (1.75ms), 70 dBnHL (1.98ms), 60 dBnHL (2.29ms), 50 dBnHL (2.62.98ms), 40 dBnHL (3.00ms), 30 dBnHL (3.51ms), and 70 dBnHL (1.98ms)]. This finding is consistent with other studies; for example, Atcherson (2012), Don and Kwong (2009) and Gelfand (2009) observed that as the generating intensity decreases the absolute latency increases considerably.

Comparison of absolute latency of study to IHSSEP norm

The data from all participants for absolute wave latencies for waves I, III and V were compared with the published normative data provided by the IHSSEP manufacturer for each intensity respectively. Table 3 provides data on normative values for IHSSEP system as provided by the manufacturer.

Table 3: Normative data for IHSSEP system

Intensity (dB HL)	Wave I (ms)		Wave III (ms)		Wave V (ms)	
	Mean	SD	Mean	SD	Mean	SD
80	1.60	0.26	4.10	0.31	6.27	0.44
70	1.79	0.32	4.26	0.34	6.50	0.33
60	1.93	0.31	4.46	0.40	6.34	0.27
50	2.28	0.41	4.75	0.37	6.68	0.41
40	2.49	0.48	4.93	0.37	6.86	0.33
30	2.86	0.61	5.08	0.50	7.20	0.44

Source: IHSSEP users' manual (2011)

Table 4 to 9 show results of comparing the mean latencies of normative data generated by the study to that of the IHSSEP published normative data at an intensity level of 80 to 30 dBnHL. The absolute wave I, wave III and wave V compared to that of the IHSSEP normative data at the various intensities. Generally, there was significant differences between the clinically established normative data and the IHSSEP normative data at the $p<0.05$ level [at 80 dBnHL Wave I (1.75ms), wave III (3.82ms), wave V (5.75ms)]. In effect, the clinical normative latencies were delayed compared with those of the manufacturer.

Table 4: Compared mean latencies for wave I, III and V at 80 dBnHL

Waves/Parameters	N	Df	Mean	SD	SEM	T	*p*-value
Wave I	25	24	1.7480	.19698	.03940	3.757	.001
Wave III	25	24	3.8224	.27472	.05494	-5.052	.000
Wave V	25	24	5.7496	.21830	.04366	-11.919	.000

Source: Field data from participants.

Statistics from Table 4 on the comparison of the established norms to that of the IHSSEP normative data showed that there was a difference between the latencies at 80 dBnHL. In effect the data's absolute latencies were slightly delay compared to that of the IHSSEP.

Table 5: Compared mean latencies for wave I, III and V at 70 dBnHL

Waves/Parameters	N	Df	Mean	SD	SEM	T	*p*-value
Wave I	25	24	1.9784	.15386	.03077	6.123	.000
Wave III	25	24	4.0320	.27375	.05475	-4.164	.000
Wave V	25	24	5.9264	.28148	.05630	-10.189	.000

Source: Field data from participants.

Results from Table 5 revealed that there was a difference between the latencies at 70 dBnHL statistically with the p-values less than 0.05 [wave I (1.98ms), wave III (4.03ms), wave V (5.92ms); p = 0.000]. This implies that, the study's absolute latencies were slightly delayed as compared to that of the IHSSEP.

Table 6: Compared mean latencies for wave I, III and V at 60 dBnHL

Waves/Parameters	N	Df	Mean	SD	SEM	T	*p*-value
Wave I	25	24	2.2908	.23850	.04770	7.564	.000
Wave III	25	24	4.2736	.30632	.06126	-3.043	.006
Wave V	25	24	6.1732	.28834	.05767	-2.892	.008

Source: Field data from participants.

From Table 6, the results showed that there was a difference between the latencies at 60 dBnHL [wave I (2.29ms), wave III (4.27ms), wave V (6.17ms)] with $p<0.05$ for waves III and V. This also implies that, the data's absolute latencies were slightly delayed as compared to that of the IHSSEP.

Table 7: Compared mean latencies for wave I, III and V at 50 dBnHL

Waves/Parameters	N	Df	Mean	SD	SEM	T	*p*-value
Wave I	25	24	2.6240	.33174	.06635	5.185	.000
Wave III	25	24	4.6512	.36563	.07313	-1.351	.189
Wave V	25	24	6.4840	.25833	.05167	-3.794	.001

Source: Field data from participants.

Table 7 shows that there was a difference between the latencies at 50 dBnHL with $p<0.05$ for the waves I and V absolute latencies [wave I (2.62ms), wave V (6.48ms) with p-values 0f 0.000 and 0.001 respectively]. However, there was no difference in the latency of the wave III compared to that of the IHSSEP's norms [wave III (4.65ms) with p-value of 0.189]. In effect, while wave I and V absolute latencies were slightly delayed, wave III showed no difference as compared to that of the IHSSEP.

Table 8: Compared mean latencies for wave I, III and V at 40 dBnHL

	N	Df	Mean	SD	SEM	T	*p*-value
Wave I	20	19	3.0020	.44749	.10006	5.117	.000
Wave III	24	23	5.0100	.41316	.08434	.949	.353
Wave V	25	24	6.9168	.27681	.05536	1.026	.315

Source: Field data from participants.

Table 8 reveals that there was a difference between the latencies at 40 dBnHL with $p<0.05$ for the waves I [3.00ms and p-value of 0.000] absolute latency. However, there was no difference in the latency of the wave III and V [wave III (5.01ms), wave V (6.92ms) with p-values of 0.353 and 0.315 respectively] as compared to that of the IHSSEP's norms. In effect absolute latency of wave I was slightly delayed but that of wave III and V showed no difference compared to that of the IHSSEP.

Table 9: Compared mean latencies for wave I, III and V at 30 dBnHL

Waves/Parameters	N	Df	Mean	SD	SEM	T	*p*-value
Wave I	9	8	3.5111	.44616	.14872	4.378	.002
Wave III	19	18	5.5505	.31265	.07173	6.560	.000
Wave V	23	22	7.6209	.43476	.09065	4.643	.000

Source: Field data from participants.

Statistics from Table 9 on the comparison of the established norms to that of the IHSSEP normative data showed that there was a difference between the latencies at 30 dBnHL with $p<0.05$ [wave I (3.52ms), wave III (5.56ms), wave V (7.62ms) and p-values of 0.002, 0.000 and 0.000 respectively]. In effect the data's absolute latencies were slightly delayed as compared to that of the IHSSEP.

Discussion

Results of the clinical normative data generated by this research from the 25 females participants for the waves I, III and V latencies across the intensities range of 80 dBnHL to 30 dBnHL suggest that the normative data compared with those of the IHSSEP system were delayed on the whole except for wave III at 50 dB and waves III and V at 40 dB. As Hood (1998), Sininger and Hyde (2009) and Baiduc, Poling, Hong and Dhar (2013) explained, the manipulations of test stimuli

affect both the latency and the amplitude of early-evoked potentials. Filter type and filtering affect ABR results since changes in frequency band through which the ABR is filtered affect waveform latency and amplitude, that is, increasing the high-pass filter cutoff frequency from 30 Hz to 100 Hz or 150 Hz results in decrease in amplitude and latency of response (Hood, 1998, Sininger & Hyde, 2009). Silman and Silverman (1991) observed that as the low pass filter is increased from 300 to 3000 Hz, the latencies of all the waves decrease and there is improvement in the resolution of waves I and V. Therefore, due to the variability of filter change between the clinical data of the study (30 to 1500 Hz) and that used by the manufacturer (30 to 3000 Hz), there is the likelihood of significant differences between the latencies of the two norms. According to Hall (1992), interpretation of auditory evoked responses using specific normative data base may be invalid after filter settings have been significantly altered. Due to the variability of testing environment and its acoustic characteristics, there is the tendency that wave latencies would also exhibit significant differences. These, in effect will explain the variation in the latencies of the clinically norms compared to those of the IHSSEP. However, in the determination of the significance of absolute latency value for a normative data or otherwise for clinical use, Atcherson (2012) and Hood (1998) suggested that the absolute latency of wave I should occur at approximately 1.6 milliseconds (ms) after stimulation onset, wave III at about 3.7 ms, and wave V at about 5.6 ms for clicks presented at an intensity of approximately 75 dB above normal threshold. They further noted that the normal latency limit range should be within either two or three standard deviations from the mean values. This means that wave I would be 1.6 ms ± 0.2 ms, wave III, 3.7 ms ± 0.2 ms and wave V, 5.6 ms ± 0.2 ms. Ness (2009) citing Hall (1997, 2006) reported that the absolute latencies for normal hearing adults, wave I was 1.65 ms (2 SD of 0.28 ms), 3.80 ms (2 SD of 0.36 ms) for waveform III, and 5.64 ms (2 SD of 0.46 ms) for waveform V. With these reference points, and the IHSSEP norms as reference points, all the clinically established norms for the absolute latencies fell favorably within the ±0.2 ms standard deviation allowance. In effect, the clinical norm are appropriate for consideration and use at Korlebu Teaching Hospital.

On the inter-wave latencies, according to Atcherson (2012) and Hood (1998), the inter-wave latencies used in clinical interpretation of ABR waveforms pertain to waves I to III, waves III to V and waves I to V. That is to say, you estimate the difference between the latencies of Wave III minus that of wave I, then that of wave V minus that of wave III and finally wave V minus the latency of wave I at the respective intensities. Atcherson (2012) and Hood (1998) opined that the inter-wave intervals for wave's I-III and III-V should be approximate 2.0 milliseconds (ms) and the wave I-V interval, about 4.0 ms taking into account a standard deviation of ± 0.4 ms for the normal limits of the I-V interval. In a related study, Ness (2009) reported mean inter-wave latency values of 2.15 ms with a 2 SD of 0.28 for wave I-III, 1.84 ms with a 2SD of 0.28 ms for waves III-V, and 3.99 ms with a 2 SD of 0.40 ms for wave's I-V. However, it is observed that the inter-wave latency is usually considered abnormal if it is greater than 2 or 2.5 standard deviations above the mean. In effect, the inter-wave latencies of the clinical normative values must not be greater than 2 or 2.5 SD above their respective mean in order to be considered normal. Based on these findings, the inter-wave normative data generated by this research project are consistent with the conditions mentioned above. In light of the above discussions, the results of the current study are consistent with studies on normative data. This means that the data generated by this study are appropriate and can be used as a reference point at Korlebu Teaching Hospital's Hearing Assessment Centre (KBTH HAC) for assessing the auditory system's sensitivity and for the possible estimation of the presence of hearing difficulties and retrocochlear pathologies during neurodiagnostic ABR testing and evaluation. This is particularly relevant for the KBTH HAC taking into account testing protocol, the testing environment and its acoustic properties as well as the specifications of the equipment. Pathological disorders prolong ABR latencies. Hence, without considering the uniqueness of the testing environment, protocol and equipment software specification in addition to the norm values generated by the study there would have been the possibility of wrong diagnosis based on the delays in the clinical values compared with the IHSSEP values. Accordingly, Ness (2009) noted that the upper latency limit is determined by applying +2 or +2.5 SD to the mean values. On the lower limits of the applied standard deviation range, Ness (2009) stated that it is not used to delineate between a normal auditory system and an auditory system with retro cochlear pathology.

Conclusions

The established norm data fulfilled the requirement of the upper and lower limits allowable of a ±2 SD. The absolute latencies (waves I, III and V) and the inter-wave latencies (wave I-III, III-V and I-V) varied slightly compared with the IHSSEP norms. However, these variations were related to the testing environment, the protocol used as well as the software specifications of the testing equipment rather than pathological conditions. These findings is significant because clinically, any delays in latencies is suggestive of a pathological condition in the auditory system. In effect, using the original norms provided for the IHSSEP would lead to misdiagnosis due to the slight delays in the latencies. It is therefore concluded that these norms values are appropriate to used clinical to facilitate effective diagnosis taking into account the clinical conditions and the varying parameters of the testing equipment.

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