3. Resarch & Methodology:

3.1 Methodology:

The aim of present study was to determine prevalence rate of auditory neuropathy spectrum disorder, its related etiologies and audiological profile. The need for this study was felt because very few studies focused on this new disorder. Moresoever its prevalence rate varies from researcher to researcher as per number of cases & lack of data related to specific disorder.

3.1.1 Resarch Design:

It is experimental type of research design.

3.1.2 Area of Study:

Auditory Neuropathy/ Dysnchrony spectrum disorder.

3.1.3 Sampling Method:

Study enrolled 730 SNHL children with in the age of 0-12yrs from different medical and pediatric setup and from neo-natal hearing screening programme. Out of 730 children (n=359) were male and (n=371) were female. Mean age of study group was 2.9 yrs and SD (standard deviation) age was 2.24yrs.

Group was dividing into 4sub-groups.

- 1) 0-3yrs
- 2) 3-6yrs
- 3) 6-9yrs
- 4) 9-12yrs

Table 2.1: Showing distribution of 730 children with SNHL separetaly for girls and boys as per age group

Age	0-3 Years	3-6 Years	6-9 Years	9-12	Total
				Years	
Girls	182	109	77	3	371
Boys	196	99	57	7	359

3.1.4 Time Period:

Study was conducted over the period of 3 yrs, from September 2012 to September 2015.

3.2 Selection Criteria:

- **3.2.1** Criteria for **inclusion** in the study group for diagnosis of ANSD were as follows:
 - 1. Testing population should be within the range of 0-12yrears.
 - 2. Permanent sensorineural hearing loss (SNHL)
 - Normal Distortion Product OAEs (normal or near normal cochlear outer hair cells function, preservation of otoacoustic emission and/or cochlear microphonics)
 - 4. Absent or elevated middle-ear muscle reflexes (MEMR)
 - 5. Severely abnormal or absent ABR waveform (absent or abnormal auditory nerve functions absent or severely abnormal auditory brainstem potential).

3.2.2 Exclusion criteria:

- 1. Testing population above 12 years of age.
- 2. Normal children or children without any significant sensori neural hearing.
- 3. Individuals with mixed or conductive hearing loss according to Otoscopic examination, pure-tone & impedance audiometry.

- 4. Absent Distortion Product OAEs (cochlear outer hair cells dysfunction with absent cochlear microphonics)
- 5. Normal or present ABR waveform (normal auditory nerve functions or normal auditory brainstem potential).

3.3 Test Instrument:

The following sequence of procedures were followed for each subject in the study:

- Client Consent
- Case History
- Otoscopy examination
- Audiometry: » Pure Tone Audiometry » Free-Field Audiometry » BOA »
 Play/Conditioning Audiometry.
- Speech Audiometry.
- Immittance Audiometery: »Tympanometry » Middle Ear Muscle Reflex
 Testing: (MEMR)
- OAE (Oto Acoustic Emissions)
- ABR (Auditory Brain Stem Responses)

3.3.1 Details of instruments:

- i. **Otoscopy:** Visual examination or ear canal and Tympanic membrane of both ears were carried out by using a Welch Allyn Otoscope.
- ii. **Audiometry:** Pure tone Audiometry » Behavioral Audiometry » Free-Field » BOA » Play Audiometry:- Audiometry was carried out in a sound treated two room set-up using Clinical Audiometer AC 40 (calibrated as per ANSI S3.6, 1996) under TDH 39 earphones with MX41-AR cushions was used to test pure tone thresholds for air conduction at octave frequencies from 250 Hz to 8000 Hz and bone conduction at octave frequencies from 250 Hz to 4000

- Hz using the modified Hughson and Westlake method recommended by ASHA 1978. The ambient noise levels in the test room were maintained within the limits specified by ANSI S3.1 1999.
- iii. **Speech Audiometery:** SpeechAudiometry was carried out in a sound treated two-room set-up using Clinical Audiometer AC 40. Speech stimuli was "monitored live voice" (MLV) presented through a transducer (speaker). Speech stimuli were standard. The accepted measures for speech audiometery were Speech detection thresholds (SDT), speech reception thresholds (SRT) & speech discrimination score (SDS). Material Used spondees (two syllable words). Monosyllabic words (phonetically balanced words), open & close set words.
- iv. Tympanometry » Middle Ear Muscle Reflex Testing: Interacoustics AT235 middle ear analyzer was used for tympanometry& MEMR using a 226 Hz probe tone.
- v. **Oto Acoustic Emission (OAE) measurements:** MAICO, Version 100.02 ME 100128 ME 2001213.
- vi. **Auditory Brain Stem Responses (ABR) measurement:** The Biologic System Corp. (Navigator Pro), Version 580-NVBOX1014.



Photo 2.1-a: Showing Clinical Audiometer AC-40 used for data collection for Pure Tone audimetery, Free field audiomatery, Play audiometery and Speech audiometry.



Photo 2.3:-c: Showing MAICO, OAE Analyser used for DPOAE.



Photo 2.2-b: AT235 middle ear analyzer was used for tympanometry& MEMR using a 226 Hz probe tone.

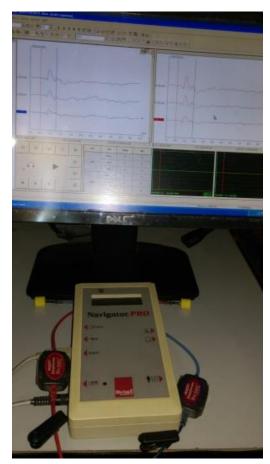


Photo 2.4-d: Biologic Navigator pro instrument and set up used for data collection and for testing ABR

Photo 2.1-a, 2.2-b, 2.3-c, and 2.4-d: Showing instruments & set up used for data collection.



Photo 2.5-e: Photo Showing electrode placement & montage for testing ABR

3.3.2 Audiological testing and test protocol:

- Standard pure tone audiometry test was performed with frequencies 250Hz,
 1 kHz, 2 kHz, 4 kHz, and 8 kHz. Behavior observation audiometry
 (BOA), play audiometry and free field audiometry (FFA) were performed for those children who were not cooperative for standard pure tone audiometrt
- Speech audiometry, speech reception thresholds (SRT) & speech
 discrimination score (SDS) were performed. Material Used spondees (two
 syllable words). Monosyllabic words (phonetically balanced words), open &
 close set words.
- 3. Tymapnogram and Middle ear muscle reflex (MEMRs) had obtained for all the children using a 226 Hz probe tone.
- 4. Distortion product otoacoustic emissions (DPOAEs) was performed above the background noise level of 3dB in the octave band frequency.
- 5. Auditory brainstem evoked potentials were recorded in two channel setup with four electrode configuration, optimize detection of wave V. Band pass from 30 or 100 Hz to 4000 Hz was used to detect principle ABR waves. Click stimuli (rare fraction) was presented monaurally on repetition at rate 11.1 to 33.3/s and at intensities from 55dBnHL to 85 dBnHL and in most cases, 95dBnHL.

3.4 Scheme of Data Analysis:

Variables.

3.4.1 Independent variables:

- 1. Disorder type (ANSD and SNHL)
- 2. Age
- 3. Sex

3.4.2 Dependent variables:

Results obtained from the following tests were considered as dependent variables -

- 1. PTA
- 2. Impedance Audiometry
- 3. OAE
- 4. BERA

3.5 Statistics:

Descriptive statistics were calculated for testing the initial objectives and hypotheses.

Pearson product moment correlation and t-test was employed to test the hypotheses

3.6 Ethical Considerations:

mentioned in objective no. three.

In the present study, all the testing procedures done were using non-invasive technique and all the procedure were explained to the patient and their family members before testing and informed consent was taken from all the patients and their family members for participating in the study. The study followed the principal of Declaration of Helsinki