CHAPTER 3

METHODOLOGY

3. 0. INTRODUCTION

This chapter presents the research design and methodology of the study. The population samples, the instrument employed in this study, and procedures in data collection are discussed.

3. 1. DESCRIPTION OF THE POPULATION SAMPLE

193 infants (386ears) were included in the study, and were tested between January 1999 and July 1999 at the Audiology unit of the University hospital. Infants included in this were a small sample drawn from a larger referral group of infants and young children with risk and non-risk factors referred to the Audiology unit of the University hospital. Ages on the day of the test ranged from 2 months to 2.6 years.

3. 2. METHOD

All subjects received Otologic / ear examination at the Ear, Nose, and Throat clinic of the University Hospital before audiological evaluations were administered at the audiology unit.

The infants were brought to the testing room by their parents after registering for the tests at the Ear, Nose, and Throat clinic. The testing was carried out in sound proof rooms at the audiology unit.
The infants were first administered the Transient/Click evoked otoacoustic emissions test (TEOAE) followed by the Tympanometry test on the same day. All infants who obtained abnormal TEOAEs and abnormal tympanograms were referred back to the Ear, Nose, and Throat specialist for follow-up examination. The post-examination TEOAE test and tympanometry was scheduled for another day. All infants who obtained an abnormal TEOAE and normal tympanogram were scheduled for Auditory Brainstem response test (ABR) to obtain thresholds of hearing.

3.3. INSTRUMENTATION

3.3.1. Transient evoked otoacoustic emissions system (TEOAE)

TEOAEs were measured using the Cochlear Emission Analyser model Celesta 503, developed by Madsen Electronics. Cochlear emissions is the most recent addition to the comprehensive line of audiidiagnostic instrumentation from Madsen electronics. Celesta 503 evaluates both of the two broad classes of emissions, Spontaneous and Evoked, and two of the evoked emissions types, Transient/Click and Distortion product. Tests include amplitude and Input/Output determinations of Evoked emissions, as well as spectral averages of Spontaneous emissions.

Cochlear Emission Analyser Celesta 503 is operated by an IBM or compatible personal computer via the built in RS232C connections, and offering the following unique features:

- Madsen Electronics' superior design and attention to ergonomic detail
• Small, lightweight probe speculum which can be easily disassembled and reassembled for cleaning
• Each probe is individually calibrated for maximum probe measurement accuracy
• Mounting options for probe assembly, shoulder harness, standard sized headband or children’s headband
• Significantly reduced noise floor for threshold detection and input / output tests
• Graphic print out via built-in "screen grabbing" program.

3. 3. 2. Rating Scale for Transient Evoked Otoacoustic emissions (TEOAE)

In this study a subjective rating scale was used to document this process as illustrated in Appendix C. The subjective rating of the recorded TEOAE waveform was on a scale from 0 (absent) to 4 (very clear emissions). The rating of 2 and above was judged to be a pass, and 0 or 1 as a fail.

3. 3. 3. Tympanometry system

Tympanometry data was obtained using the Grason - Stadler GSI33 Version 2 Middle ear Analyser System. It is a microprocessor-based admittance instrument designed to be used in a clinical or research setting. It contains total capabilities for complete, automatic or manual diagnostic testing for analysis of middle ear function.
3. 3. 4. Auditory Brainstem Response test system (ABR)

Auditory Brainstem testing was carried out using the Nicolet Spirit Evoked Potential system developed by Nicolet. The Spirit Desktop consists of a stand-alone processor (computer), a monitor, keyboard and isolation transformer. The processor is an IBM compatible 80486 SXTM that runs at a 170 Mbyte hard drive, 8 MBRAM, and a 3½ inch, 1.44 Mbyte floppy drive as standard features. An optional 5¼ inch floppy drive is available. The Nicolet spirit system can analyse a wide range of evoked potential data including Auditory evoked potential, Visual and Somatosensory evoked potentials.

3. 4. TESTING PROCEDURE

3. 4. 1. Testing procedure for Transient evoked otoacoustic emission screening test.

Click/Transient evoked otoacoustic emissions from each ear were measured using the Madsen model Celesta A 503, Cochlear emissions Analyser. TEOAE evaluation begins with a visual inspection of the external ear canal to determine whether wax accumulation is significant enough to preclude signal delivery or response acquisition and to note the size, shape and tissue integrity of the canal in preparation for insertion of OAE probe tip.

A small acoustic probe fitted with rubber tip was introduced into the ear canal to obtain an air tight seal in the subject's external ear canal. The position of the probe in the subject's ear canal is tested in the probe fit mode, which allows to optimize the position of the probe for accurate and replicable
measuring. The probe fit mode starts automatically and presents bursts of 10 clicks in the ear canal. The response is measured and then shown on screen. The probe in the ear canal is adjusted until the curve in the stimulus response window is as flat as possible (Appendix D). After obtaining a good probe fit in the canal, the test function key to measure the TEOAE is selected.

The TEOAEs were averaged in response to a series of acoustic clicks presented to the test ear and the sound pressure level measured in the external ear canal following stimulation. The stimulus level was set to 70 dBSPL in non-linear mode of acquisition with condensation polarity. The TEOAEs were averaged in response to 1000 clicks at 70dBSPL for the purpose of noise reduction. Both the ears of the infants are tested. The test was repeated twice for each ear.

The results of the screening test (Appendix E) is displayed on 3 traces labelled A and B representing a superimposition of the response stored in each of 2 memory buffers (A and B). This trace can be used to determine the reproducibility of the response, the better the match between the traces in each memory buffer, the higher the reliability of the measure. The middle trace labelled A+ B represents the addition of response divided by 2 from each of the memory buffers. It is an indication of overall amplitude level of the response. The bottom trace labelled A - B represents the subtraction of responses from both memory buffers and is an indication of amplitude and frequency characteristics of the noise floor during the measure.
3.4.2. Testing procedure for Tympanometry test

Tympanometry data was obtained using GSI 33 Version 2 Middle ear analyser (pressure change from +200 dapa to -400 dapa), in order to determine the tympanometrically revealed middle ear abnormality. Whenever possible the testing was carried out after a feed or when the infants are very settled or asleep. An air tight seal is obtained with a small probe which is inserted into the external auditory canal of the patient. The probe has 3 small holes. From one hole a 220 Hz probe tone is emitted; a second hole is an outlet for an air pressure system which is capable of creating positive, negative or atmospheric air pressure in the cavity between the probe tip and the tympanic membrane; the third hole leads to a pick-up microphone which measures the sound pressure level of the 220Hz probe tone in the canal cavity.

Once the air tight seal is obtained in the ear canal, the test is started and the pressure sweep starts from +200 dapa and continues to the end of the pressure range at 400dapa. Upon completion of the pressure sweep, numeric values for compliance peak (ml), pressure peak (dapa) and the tympanogram graph related to the middle ear conditions appear along with the summary data for interpretation.

3.4.3. Testing procedure for Auditory Brainstem Response test (ABR)

The ABR test was performed in a quiet, but not sound proof room using the Nicolet Spirit evoked potential system. Relevant history from the parents about the baby's hearing were documented. The test procedure was
explained to the parents and the infant was made comfortable either in the parents arms or on a couch. Whenever necessary the uncooperative infants were given chloral hydrate before administering the test. Most of them needed the sedative due to their age group.

3. 4. 3. 1. **Electrode placement**

The forehead, vertex and earlobes were cleaned using skin preparation paste 'Omni – prep' or acetone. With gentle thorough cleaning, impedances of below 6 Kilo ohms were typically obtained. The vertex site was chosen as the 'active' (positive CZ), the forehead as the (common FPZ), and the medial side of the earlobes as the negative (A1 for left and A2 for right). Electrode gel was applied to silver/ silver chloride disc electrodes. Collodium paste was used to fix the vertex electrode. Click stimulus of alternating and rarefaction polarity of 100 us duration were delivered through TDH 49 earphones at a rate of 11.1

For each infant who failed the OAE screening, the aim was to find the ABR threshold for each ear at as many different click intensities as possible with a minimum of 2click intensity. Testing was started at 80dBnHL, and if a clear ABR was recorded, click intensities was dropped to 30dBnHL and increased to 10dB steps if there was no wave V detectable. This procedure was then repeated on the other ear to obtain thresholds.

If no repeatable ABR was detected at 30dBnHL, the ear was deemed to be in need of further follow - up for behavioral audiometry and hearing aid evaluation.