SENSITIVITY AND SPECIFICITY OF BERAPHONE® AS A SCREENING TOOL FOR NEONATAL HEARING LOSS IN A TERTIARY CARE HOSPITAL IN INDIA

A DISSERTATION SUBMITTEDIN PARTIAL FULFILMENT OF THE RULES AND REGULATIONS FOR THE **MS BRANCH IV, (OTORHINOLARYNGOLOGY)** EXAMINATION OF THE TAMIL NADU DR. M.G.R MEDICAL UNIVERSITY TO BE HELD IN APRIL 2014.

CERTIFICATE

This is to certify that the dissertation entitled '**Sensitivity and specificity of BERAphone® as a screening tool for neonatal hearing loss in a tertiary care hospital in India**' is a bonafide original work of Dr chavakula Rajkumar, submitted in partial fulfilment of the rules and regulations for the MS Branch IV, Otorhinolaryngology examination of The Tamil Nadu Dr. M.G.R Medical University to be held in April 2014.

Dr John Mathew

Professor and Head

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Christian Medical College, Vellore

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Sensitivity and specificity of MB11 BERAphone® as a screening tool for neonatal hearing loss in a tertiary care hospital in India.
Introduction:
Hearing is the special sense that enables us to recognize speech and other sounds(1). Ear is the earliest sensory organ to develop in the womb, and it gives us the capacity to hear and interpret sounds which is the basis for oral language, verbal communication, and interpersonal relationship, vocational and educational attainment. Although a child develops speech and language during the first three years of life, the ability to acquire effective spoken language is highest in the first six months after birth. (2)
Hearing disorders may cause language impairment and slower cognitive, cultural, intellectual and social development(2). Hearing impairment in early stages of childhood would lead to speech and language defects which can restrict verbal communication with others. Thus, hearing loss should be detected at the earliest so that the language and social functioning may grow as normally as possible.(3)
Various surveys indicate that prevalence rates of congenital hearing impairment is about1.2 to 5.7 per1000 live births(4). Congenital hearing impairment is seen between "1 and 3 out of every 1,000 children" (5). Of these, approximately 90% of newborns are born to parents who can hear(4)(6).
Hence the National Institutes of Health Consensus Development Conference on Early Identification of Hearing Impairment in Infants and Children' recommends 'a universal newborn screening' for early identification of hearing impairment among the newborn.(6)
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CONTENTS

Introduction:

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Hearing disorders may cause language impairment and slower cognitive, cultural, intellectual and social development(2). Hearing impairment in early stages of childhood would lead to speech and language defects which can restrict verbal communication with others. Thus, hearing loss should be detected at the earliest so that the language and social functioning may grow as normally as possible.(3)

Various surveys indicate that prevalence rates of congenital hearing impairment is about1.2 to 5.7 per1000 live births(4). Congenital hearing impairment is seen between "1 and 3 out of every 1,000 children" (5). Of these, approximately 90% of newborns are born to parents who can hear(4)(6).

Hence the 'National Institutes of Health Consensus Development Conference on Early Identification of Hearing Impairment in Infants and Children' recommends 'a universal newborn screening' for early identification of hearing impairment among the newborn.(6)

Two methods are used in 'universal newborn screening' namely (1) Otoaccoustic emissions (OAE) and (2) Auditory Brain Stem Audiometry (ABR) both methods are automated.

Among these, MB11 BERAphone®, (a type of automated Auditory Brainstem Response test) which is objective screening tool, has the added advantage of detecting hearing defects such as auditory neuropathy (AN) which is not possible with OAE testing.(7)

However the manufacturer claims that the 'BERAphone' has a test "sensitivity greater than 0.99 and specificity of 0.87 for a single test and for a two-stage test the specificity is greater than 0.96, which is possible only when the test is performed in ideal conditions (8)

Such a high sensitivity and specificity has not been the experience of the ENT department at CMC. This study was hence intended to determine the sensitivity and specificity of MB11 BERAphone®, in identifying neonates with congenital hearing loss in a post- natal ward setting.

A two stage sequential screening with MB11 BERAphone® was done first in the postnatal ward and the second screening in the audiology room for all neonates born in the hospital, who fulfilled the inclusion criteria. Children 'referred' once were subjected to a repeat screening with 'MB11 BERAphone®' and compared with a confirmatory diagnostic testing with ABR (Auditory Brainstem responses) used as the Gold standard for confirming the hearing loss in neonates and infants.

AIMS & OBJECTIVES

Objective

The main objective of this study was to determine the reliability of MB11 BERAphone® as a screening tool in the postnatal ward setting.

Aim

1. To calculate the sensitivity and specificity of MB11 BERAphone® when used as a screening tool as in identifying neonates with congenital hearing loss in comparison against the gold standard, Auditory Brain Stem response Audiometry (ABR) when performed at the bedside of the new born at the postnatal ward setting where the sound levels are over 35dB.

2. To discuss the challenges of using the MB11 BERAphone® at the bedside in a ward setting for universal neonatal hearing screening.

REVIEW OF LITERATURE

Hearing and communication

"Communication is the key to the survival of life" (10). It is through various sensory organs that communication occurs. Effective communication takes place when the sensory organs function at their optimum level.

Humans are equipped, in addition to highly specialized sensory organs like sight, hearing, taste, touch and smell, with specialized skills of reasoning, analysis, assessment and communication through speech, writing and music.(11). Among the sensory organs, the sensation of hearing for speech and music is exclusively human(12). Therefore hearing is critical for expression through speech, language and music. (12) (13)

Hearing an important sensory function

The special sense of hearing develops in the womb before birth. Ear is the earliest intrauterine sensory organ to develop , and it gives us the capacity to hear and understand sounds which is the foundation for oral language, verbal communication, and interpersonal relationship, vocational and educational attainment(2). Hearing is important for development, since it connects with the rest of world and becomes an emotional link that contributes to mental and social health(14) .

Hearing impairment in early childhood would lead to lifelong speech and language defects which can restrict verbal communication with others(15)

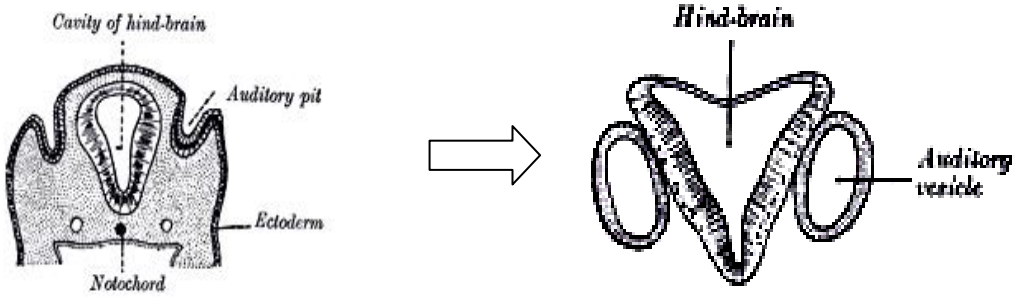
Development of the Ear

The development of the ear begins around the 22nd day of intra uterine life and is completed by 24 weeks(3).

Studies have shown that the baby is able to hear sounds with a tone of 500 Hz as early as19- 26 weeks(3). Early sonograms show that foetuses in fact turn their head in response to the noise by 20th week and that hearing becomes established by the 3rd trimester(16)(17).

Embryology of the ear

The part of the ear that develops early is the membranous portion of the inner ear. A segment of thickened ectoderm over the hind-brain becomes gradually depressed forming the auditory placode and later into the auditory pit.(18). The mouth of the pit is then closed, forming the **auditory vesicle** (Fig. 1).



Inner ear development

FIG. 1– Grace Anatomy: Section through hind-brain showing the auditory pit and auditory vesicles of an embryo(18)

The auditory vesicle gets enclosed by the mesenchyme to form into the otic capsule. Diverticula develop from the otic vesicle forming the end lymphatic duct and sac. Another extension form the otic capsule gets coiled over itself to form the cochlear duct.

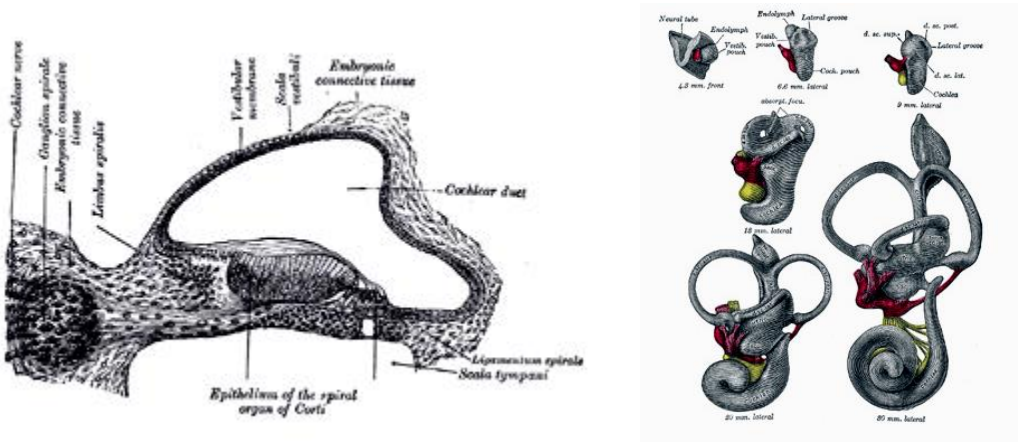


FIG. 2- Grace Anatomy – Transverse section of the cochlear duct and membranous labyrinth(18)

Three cavities within the duct which are the ‘scala vestibule’, the ‘scala tympani’ and the ‘scala media’ are formed. The scala media contains the endolymph while the ‘scala vestibule’, the scala tympani contain an extracellular fluid called as perilymph (Fig 2). The vestibular and the basilar membranes divide the cochlear duct from the scala vestibule, the scala tympani.

The cochlear duct is supported by a spiral ligament and a cartilaginous process as the modiolus which connects it to the cartilaginous structures around it. Later the sensory organ of hearing called the organ of Corti, which consists of the sensory cells and tectoral membrane is formed.

The otic vesicle then forms the statoacoustic or the spiral ganglion. (18)

A group of sensory epithelium in the inner ear called the maculae acusticae develop over the saccule and utricle.

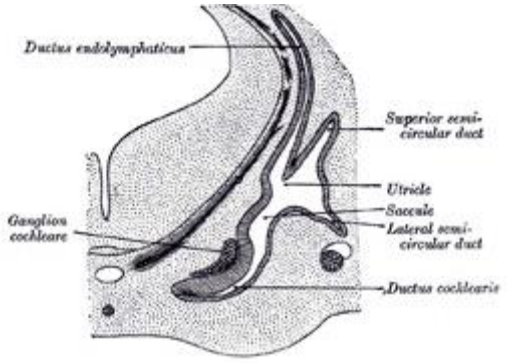


FIG. 3 Grace Anatomy – Development of Semicircular canals (18)

Three ducts later develop forming the superior, lateral and posterior semicircular canals along with their sensory epithelium (Fig.3).

The mesodermal tissue surrounding the labyrinth is converted into a cartilaginous ear-capsule which becomes ossified to form the bony labyrinth. A layer of mesodermal tissue becomes differentiated into three layers, namely the outer periosteal lining of the bony labyrinth, the inner layer in direct contact with the epithelial structures, and an intermediate gelatinous tissue. The intermediate gelatinous tissue gets absorbed to form the perilymphatic spaces. All these structures of the inner ear work together to convert the auditory signals received from the external and middle ears to electrical signals and finally convey them to the brain where they get analysed (18).

Middle ear

The middle ear and mastoid air cells develop from the endoderm of the tubotympanic recess which arises from the first and partly from the 2nd pharyngeal pouch. The Eustachian tube is the last structure of the middle ear which develops from the 1st pharyngeal pouch which connects the tympanic cavity and the nasopharynx. (18)

The ossicles malleus and Incus develop from the mesoderm of the first pharyngeal pouch while the stapes develop from the second pharyngeal pouch which gets embedded in the tympanic cavity. The foot plate of the stapes and the annular ligament are derived from the otic capsule. Finally, the tissue layer around the ossicles form a new endodermal layer of epithelial called the tympanic cavity wall. The mastoid process develops later as the tympanic cavity matures. (18)

At 18 weeks the foetus is about 5.5 inches (140 mm) long and by this time bones in the middle ear develop and the nerve connections from the brain to the ear are formed. This enables the foetus to hear the mother's heart beat and the flow of blood through the umbilical cord. (18)

Malformation of the ear occurs because the embryologic source and the development of the inner ear are independent of the timing and the development of the middle and external ear. (18)

External Ear

By the 6th week of foetal life, a series of six tubercles appear around the 1st branchial cleft which progressively coalesces to form the auricle. Tragus develops from the tubercle of the first arch, while the rest of the pinna develops from the tubercles of the second arch and achieve the adult shape by the 20th week of foetal life. (18)

The external auditory canal develops from the dorsal portion of the 1st pharyngeal arch.

The tympanic membrane along with three layers, the outer epithelial, middle fibrous and the inner mucosal layer develops from the three germinal layers namely the ectoderm, endoderm and mesoderm. (18)

Initially the external ears are placed in the lower part of the neck region. When the mandible develops they then migrate upwards to their final location in level with the eyes. Once they are fully formed, the external ear helps in capturing the sound from the outside and then conduct it through the external auditory canal and then toward the tympanic membrane. (18)

Molecular Regulation of the Inner Ear

Molecular Regulation of the Inner Ear occurs through a set of genes called the “home box gene family” such as “Pax”, “Msx” and “Otx homeobox genes”.

The maturity of the Cochlea is regulated by several genes like” Dlx5/Dlx6”, “Otx1/Otx2 and Pax2”, which are influenced by the master gene “Shh” produced by the notochord. (19)

Physiology of sound production

The Physiology of hearing

Hearing is the process where the ear converts the sound vibrations present in the surroundings into nerve impulses which are then sent to the brain, where they are understood as sounds.(20) The human ear is most sensitive to sound frequencies between 1,000 to 4,000 hertz. The range of human hearing is between 0 dB, which is just inaudible, to about 130 dB at which measurement the sound becomes painful(21)

For a sound to be conveyed to the central nervous system, the energy of the sound must pass through three stages. 1) The vibrations pass through the tympanic membrane and the ossicles of the middle ear. 2) Vibrations pass through the inner ear fluid within the cochlea. 3) These travelling waves across the basilar membrane excite the hair cells in the organ of Corti where they are changed to nerve impulses in the cochlear nerve.

They are then transmitted to the brain stem, and finally relayed to the 'primary auditory area' of the cerebral cortex, which is the centre of the brain for hearing. Only after the nerve stimulus arrive at this area, the listener becomes aware of the sound.(20)

Sound waves transmission of through the outer and middle ear

The auricle collects sound waves and funnel sound into the external auditory canal which helps to amplify the sound that reaches the tympanic membrane like a resonator adding 10-12 dB to this frequency.(22) Thus it increases the sound pressure at the drum

and helps in localizing the direction of the sound. The shape of the auricle facilitates in filtering out the unwanted frequency above 6 kHz and help in sound discrimination.(22)

At the tympanic membrane some sounds are absorbed and some are reflected. The absorbed sound waves enter the umbo, causing an inward and outward bending which gets the membrane in motion. The deflection of the membrane is greater when the sound is louder, and movement is faster when the pitch of the sound is higher. These movements are then shifted to the handle of Malleus and then to the other ossicles(20). The vibrations then cause the stapes to rock back and forth at the lower pole of its foot plate thus the sound waves are transmitted to the perilymph of the vestibule and to the scala vestibule(20).

Function of the ossicular chain

When sound is transmitted from the external to the inner ear, the vibrations of the air must be converted to vibrations in the cochlear fluids which would cause resistance to the passage of sound called as the 'impedance'(20) . Due to the 'impedance mismatch' between air and inner ear fluids, about99.9% (~30–35dB) of the acoustic energy in aerial signals would be lost or reflected. Middle ear compensates for the impedance mismatch, through impedance matching (acoustic transformer) by 1) Hydraulic action of the tympanic membrane 2) Lever action of the ossicles 3) Curved membrane effect (20).

The effective areal ratio between the tympanic membrane and the stapes foot plate is 14:1 and in the ossicular chain the handle of malleus id 1.3 times longer than the long process if incus which provides a mechanical advantage of 1.3.

Thus the product of areal ratio and lever action of ossicles is 18:1. In this way the middle ear converts sound of 'lesser amplitude but greater force' to 'greater amplitude but lesser force' which help in the transmission of sound.(20)

Function of the middle ear muscles.

Contraction of the muscle 'tensor tympani' pulls the handle of the malleus inward and thus tenses the tympanic membrane to various sounds.

Tensor tympani and stapedius muscles help to decrease a person's hearing sensitivity to his or her own speech by the contraction of the stapedius and thus reduce the intensity of sound reaching the cochlea. The stapedius muscle in addition responds reflexly to sounds of high intensity frequencies below 1000cycles per second of the same ear or the opposite ear protecting from frequencies that damage the ear, similar to the blink of the eye (20)

Thus the middle ear helps in i)impedance matching, ii) physically protects the cochlea and provides iii) a preferential path way for sound transmission (20).

Sound transmission in the inner ear

Once the sound waves by the vibrations of the stapes foot plate reach the oval window, the pressure waves are set up in the perilymph of the scala vestibuli present in the cochlea. The sound vibrations are then transmitted to the endolymph by the movement of the basilar membrane inside the cochlear duct which cause the organ or Corti move against the tectoral membrane.

The cochlea then analyzes the different frequencies of complex sounds by means of the movement of the basilar membrane, due to different amount of stiffness, or along the entire length. Inside the cochlea the vibrations are then converted into the electrical impulses which are sent to the brain stem by the cochlear nerve.(20).

Transduction of mechanical vibrations

The endolymph contains a high percentage of potassium level that causes a positive potential in the cochlear duct which surrounds the top of the hair cells. The perilymph on the contrary has a low potassium level and a negative potential in the scala vestibuli. Thus a potential difference of +80 millivolts due to the difference in potassium between the endolymph and perilymph called the endocochlear potential which is there between the endolymph and the perilymph. The inside of the hair calls has a negative intracellular potential of -60 millivolts in relation to the perilymph and -140 millivolts in comparison to the endolymph. This steep gradient which is present at the tip of the cell is known to stimulate the cell to the least sound vibration. (20).

Transduction of Mechanical Energy to Electrical Impulses

Movements of the stapes footplate are transmitted to the cochlear fluids which move the basilar membrane, setting up shearing force between the tectorial membrane and the hair cells. This distortion of hair cells, gives rise to cochlear microphonics which triggers the nerve impulse. The neurotransmitters are taken up by the nerve fibres which are located at the basal end of the hair cells, thus exciting them into sending an electrical signal across the entire length of the cochlear nerve.(22)

Greater frequency sounds are localised in the basal turn which progressively decrease towards the apex. A sound wave, reaches maximum amplitude on a 'particular place' on the basilar membrane and stimulates that segment, thus the sound wave is generated and transmitted along the cochlear nerve [travelling wave theory of von Bekesy] (20)

Cochlear nerve auditory pathways

Hair cell gets its innervation from the bipolar cells of spiral ganglion. Central axons of these cells collect together, to form the cochlear nerves which end in the ventral and dorsal cochlear nuclei. From there, both crossed and uncrossed fibres travel to the superior olivary nucleus, the lateral lemniscus, inferior colliculus, and medial geniculate body which reach the auditory cortex of the temporal lobe. (20).

Auditory nerve fibres

The vestibulocochlear nerve or the eighth nerve has two anatomically different and functionally separate parts namely a) the cochlear nerve, which is connected to the organ of hearing, and b) the vestibular nerve which in turn is connected to the organ of equilibrium. Fibres from the cochlear nerve take their origin from the cell bodies of the bipolar nerve of the spiral ganglion which is present in the modiolus of the cochlea. The central longer fibres, called as the "primary auditory fibres" form the cochlear nerve. Whereas, the shorter unmyelinated peripheral nerves go on to innervate bases of the inner and outer cells.(20).There are only 30,000 of these unmyelinated peripheral nerve fibres.

Out of these 95 percent of them innervate the inner hair cells, while the remaining pass through the tunnel of Corti to connect to the outer hair cells. The central process of the bipolar cochlear nerves called primary auditory fibres form the cochlear nerve trunk which come out from the modiolus through the internal auditory meatus and then immediately pass into the brain stem of the medulla (20).

Ascending pathways

The central auditory pathways consist of a series of nuclei that extend from the medulla to the cerebral cortex. The cochlear nerve terminates in the medulla where they reach the cochlear nucleus which is separated into dorsal and ventral cochlear nucleus(20).Fig 6. Each of the cochlear nerve fibre sends one of its branch to the dorsal and other branch to the ventral cochlear nucleus. From there, both the crossed and uncrossed fibres travel to the superior olivary nucleus and lateral lemniscus. This major tract called as the lemniscus is where most of these fibres end up in the inferior colliculus, which is the “auditory centre of the midbrain”. Some of the fibres may go around the colliculus and end at the next highest level which is the ‘medial geniculate body’. The fibres are projected to the cortex of the temporal lobe from the medial geniculate body(20).

Descending pathways

There is a descending pathway from the cortex to the cochlear nuclei which is parallel to the ascending pathway that goes from the cochlear nuclei to the cortex. In both the ascending and descending pathways some of the fibres stay on the same side, while some go along the midline towards the opposite side of the brain. In general, the

descending fibres exercise an inhibitory function by means of 'negative feedback' mechanism.

At the lower level of this pathway, the information with regard to the loudness, pitch, and localization of sounds is analyzed and proper response such as; the contraction of the middle ear muscles or the turning of the eyes and head or the body movements take place as a whole. (22)

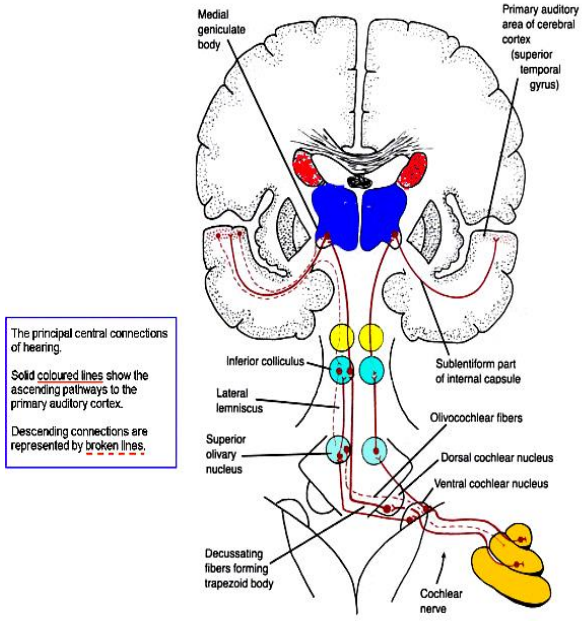


Fig-4a.Guyton- Auditory pathway(18)

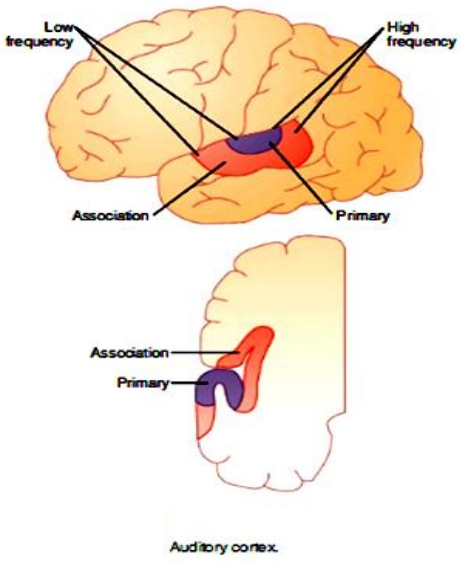


Fig-4b.Guyton- Primary and secondary auditory cortex (18)

In humans beings the 'primary auditory cortex' lie mostly on the supratemporal plane of the 'superior temporal 'gyri of Heschl' and also go into the lateral side of the temporal lobe present on the lower lobe of the deep gap between the temporal and parietal lobes along the sylvian fissure called as the 'secondary auditory cortex'(20).Fig 4b

The projections from the medial geniculate body cause direct excitation of the 'primary auditory cortex' where as the 'auditory association areas' get stimulated secondarily by the impulses from the primary auditory cortex along with some projections from the 'thalamic association areas' present next to medial geniculate body(20). Thus the central function of the auditory cortex is 'sound localization', 'lateralization through auditory discrimination', 'temporal resolution', 'masking', 'integration and ordering'. (20).

For each ear, both the right and left cerebral cortex is represented bilaterally. About half of the fibres of the auditory pathways cross the midline while the others go up on the same side of the brain. Due to this reason, even when the auditory cortical area on one side is injured by trauma or stroke binaural hearing may not be adversely affected. (20).

Maturity of auditory pathway & Plasticity

Maturity of the neurological auditory system occurs in two stages. The first phase is '*intrauterine stage*' which is completed by the sixth month of gestation. At this time the peripheral auditory pathways are established and mature. The second phase starts '*after birth'* and id completed around 18 months of life. By then the auditory pathways up to the brainstem reach maturity. (23)

The 'maturation' of the auditory pathway can be assessed, by calculating the '***pontine auditory conduction velocity***' (PACV) which is obtained by studying the auditory brainstem response (ABR) along with the magnetic resonance imaging, which is a precise indicator of the auditory function (13). To assess the brainstem function more accurately, PACV in individual patients can be used.

The results show that during the third trimester and in the first two years of life, the 'peak latencies of ABR' and 'I-V interpeak latencies' which are indicative of the delay in central transmission are gradually reduced. Marked development during the above mentioned time period is seen in the calculated 'pontine auditory conduction velocity' (PACV). By the age of two to four years, the PACV value almost equal to that of the adults. (13)

The thickness of nerve cells in the inferior colliculus and in the cochlear nucleus was found to reduce with age through a 'histomorpho-metrical' study. The study also showed that from the late fetal to the infantile period there was an increase in the myelination of the lateral lemniscus. Mostly in the infantile period, the myelin sheaths of the large diameter nerve fibre showed increase. Studying ABR in combination with the, 'quantitative histomorphometrical investigation', showed that the increase of PACV was seen to be related to the maturation of nerve cells in the upper nuclei which was corresponded to the myelination of the small and large fibres of the auditory pathway.(24)

Plasticity & auditory deprivation

"Plasticity is a property of the nervous system to modify of change itself as a result of sensory experience(25) "Neuroplasticity" or Plasticity or refers to the "alterations in the physiological and anatomical properties of neurones in the brain in association with sensory stimulation and deprivation (25)

Neuroplasticity is seen to be more marked during infancy, since the neural architecture is being established during this time. The other area where plasticity is seen is in developing sound localisation. To the differences in the sound intensities, a map of '*auditory space'* is generated and the arrival time between the two ears is represented in the superior colliculus. This map is known to be very plastic during development.(13)(23)

The present research shows that during deafness, the normal auditory development is arrested and disrupted leading to several changes in the auditory pathways which occur during the period of deafness. The extent and the type and of change that occur in the auditory pathway is dependent on the following factors such as 1) the age of deafness, 2) the stage of deafness 3) the auditory development at the onset of deafness, 4) the type and the cause of deafness, 3) and the duration of time the immature auditory pathways are left without a large auditory input or stimulus. Due to sound deprivation there is an arrest in the development of the auditory brainstem and the thalamo-cortical areas due to which other 'competitive areas' like vision can take over. (25)

The sensitive period, in the absence of normal stimulation, during which the central auditory system remains highly plastic is about 3.5 years. In some children plasticity remain until approximately 7years of age after which it is greatly reduced.(25)

Although some studies done by Shepard, Heid, & Klinke, 1997 have shown that in the absence of sound, the functional nerve connections in central auditory system is established.

In 1999, Hardie, & Shepherd proposed that the auditory deprivation causes wide-spread degeneration in the central auditory system which result in the following changes: (13)

a. Reduction in the cell density of the spiral ganglion and anteroventral and ventral part of cochlear nucleus.

b. Changes in the neural projections between brainstem nuclei.

c. Decreased cortical synaptic activity in cortico-cortical and cortico-thalamic connections.

d. Reduced number of primary dendrites in cortical pyramidal cells.

e. Takeover of auditory cortical areas by visual function". (13)

Sounds in the womb

Studies done by placing tiny microphones in the uterus near the foetus' head show that sound level in the womb is around 75 dB. Fifer and Moon et al showed that newborns prefer the sound of their mother's voice which is transmitted through the various vibrations through her body (26)

By 25 weeks the baby is able to recognize different voices. Through the use of high sonograms and high tech tools, researchers have found that the foetus live in an auditory playground, responding to voices outside the womb.(26) Studies show that foetus has a highly developed hearing mechanism which has the auditory preference to certain sounds like native language and music in the womb (27)(28).

Preterm and hearing sensitivity

Research has shown that the sensation of hearing is so delicate especially in the preterm child that the loud noise in the NICU can affect their hearing. The auditory system of the preterm is in a critical period of neurodevelopment after birth and they are no longer protected by the maternal womb to loud noises. This sudden transition from the womb exposes them to the ambient noises present in the care units which can disrupts their growth and development(16)

Studies done by Erin McMahon and et al suggest that the exposure to noise outside the womb by the preterm babies can put them at risk for hearing, language, and cognitive disabilities.(3)

Hearing evaluation of the 'small for date' new born babies showed a considerable delay in the emergence of waves III and V, and delay in waves' I-V of ABR testing, which suggests that an auditory pathway alteration within the brainstem rather than an impairment of the peripheral auditory apparatus has occurred. (29)

All the above mentioned studies show that hearing is one of the very first sensory organs to develop and that this development involves complex mechanisms that are essential to the development of speech and language outside the womb. Further, that the conditions surrounding the infant after birth can influence the speech, hearing and communication.(2)

Hearing and development of language

Hearing and speech and are strongly inter-related. Our ability to communicate through speech with others is dependent on our capability to hear. Therefore, in the development of speech and language, hearing ability has a strong part.

"**language"** by definition, is the formulation and understanding of communication using words", and **speech** is the "physical act of producing the words that convey linguistic ideas"(30). This is a special and unique capability present among humans which should be cultivated and preserved. The ability to speak various languages and sounds is developed and cultivated throughout life. It is dependent on i) hearing others speak in order to observe and register the pattern of accurate pronunciation of sounds and words, and learn to differentiate between the various type of sounds. b) the ability to hear one's own speech is called as the "*auditory feedback loop*." This special ability helps to monitor the individual's speech and allow for refining or modifying the speech production.

Articulation is also essential in order to speak properly. In order to produce the different type of voice coming from the larynx, the anatomical structures in the oral cavity are made to synchronize together into the various sounds that form the words that we speak. (31)

Because of an incomplete 'auditory feedback loop' that lead to 'imprecise articulation and substitution errors', those with hearing impairment, will not be able to perceive the sounds clearly eg: "f" for "th".

There is an overall misrepresentation of speech due to imperfect sound awareness. Problems with articulation lead to decreased "speech intelligibility," of the speaker which is understood by a listener (32)

According to the American Speech-Language-Hearing Association, children with listening difficulties would have difficulty with grammatical structures, vocabulary, multiple meaning words, plural word endings and abstract words due to hearing loss (33)

In four major ways, hearing loss affects children; it causes 1) delay in the development of “receptive and expressive communication skills like speech and language, 2) Cause learning problems and language deficit that would result in lower academic achievement. 3) Social isolation due to communication difficulties which would lead to poor self-concept and 4) Inability to learn vocational skills which would in turn impact vocational choices (34)

Hearing disorders as seen above, result in slower intellectual, cognitive, language, cultural and social development. Hearing is therefore paramount for development of the child because it provides an opportunity for individual incorporation into a society where the oral communication predominates.

Hearing impairment is truly a crippling impediment that has been expressed by persons who were affected by it. Hellen Keller who had lost both her sight and hearing at a very early age expressed that “while blindness separated her from things, her disability of speech and hearing had separated her from people and from communication (35) Such is the effect of hearing impairment on a person’s psycho-social wellbeing.

Hearing loss not only handicaps a person at a personal level, it actually isolates the individual by impeding with communication and expression.

Critical period for speech and language development

The significant phase for speech and language development is around the time from birth to about five years, the lack of early auditory stimulation during this critical language-learning years makes it difficult for the attainment of speech and language skills at a later time.(36)

Data from cohort studies indicate that the crucial time for the diagnosis and intervention is earlier than six months of age, since it provides opportunity for the improvement of language and speech in hearing-impaired children(37). Studies also have shown that those infants who have been identified and rehabilitated below six months fared better in their language, skills than the ones done after six months. (37)(2). In order for the language and social functioning to develop as normally as possible, hearing loss should be detected as early as possible.(3). Delay in the identification and rehabilitation would lead to marked delay in the language quotient (LQ) and cognitive quotient (CQ) which hinder the overall development of the child.

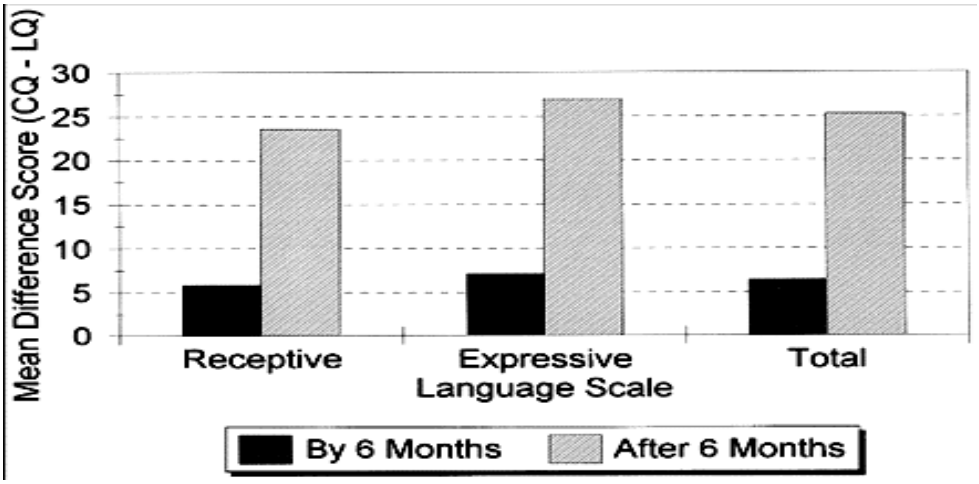


Figure 5: Discrepancy between language quotient (LQ) and cognitive quotient (CQ) of children with hearing loss before and after 6 months (Paediatrics, vol 102, p 1161–1171).

Currently detection of significant hearing loss occurs around the age of 14 months. This underscores the urgency in early identification and intervention of hearing loss by six months since it provides opportunity for better prospects in language development, academic success, social integration in the society.(37)

Hearing loss - Definition

According to Mosby's Medical Dictionary, **hearing loss** is “an inability to perceive the normal range of sounds audible to an individual with normal hearing” or any degree of impairment of the ability to apprehend sound. (38)(39)

Hearing loss is not the same for everyone and therefore the different degrees of hearing loss are divided into categories. One of the commonly used classifications is given by the “American Speech-Language-Hearing Association (ASHA). The table below shows the classification as per the degrees of hearing loss or the severity of hearing loss(40)

Degree of hearing loss	Hearing loss range (db HL)
Normal	-10 to 15
slight	16 to 25
Mild	26 to 40
Moderate	41 to 55
Moderately severe	56 to 70
severe	71 to 90
Profound	91+

Table 1 Source: Clark, J. G. (1981). Classification of hearing loss, as given by "American Speech-Language- Hearing Association (ASHA). Hearing loss range in decibels (dB HL)

Any hearing loss must be quantified on the basis of **degree** of hearing impairment, the '**type'** of hearing loss and the '**percentage'** of hearing impairment

WHO grading of the degree of hearing loss is given below

WHO grades of hearing loss	Audiometric ISO value Impairment description	(average of 500, 1000, 2000, and 4000 Hz)
0 (no impairment)	25 dBL or less (better ear)	No or very slight hearing loss
1 (slight impairment)	26 - 40 dBHL (better ear)	Able to hear whispers. Able to hear and repeat words spoken in normal voice at 1 meter.
2(Moderate impairment)	41-60 dBHL (better ear)	Able to hear using raised voice at 1 metre and repeat words
3 (severe impairment)	61-80 dBHL (better ear)	Can hear some words when shouted
4(profound impairment including deafness)	81 dBHL or greater(better ear)	Not able to hear and understand even a shouted voice.

Table-2 : WHO grading or degree of hearing loss(41)

Types of hearing loss

According to the European working group on genetics of hearing , the types of hearing impairment can be classified as follows(42)

	Types of hearing impairment
Conductive hearing impairment:	Related to disease or deformity in the outer or middle ears. Audiometrically bone conduction thresholds(< 20 dB) and an A-B gap >15 dBHL averages over 0.5,1.0 and 2 HZ
Sensorineural hearing impairment:	Disease or deformity of the inner ear or cochlear nerve with an air/bone gap < 15dB averaged over 0.5, 1 and 2 kHz.
	Sensory: sensorineural subdivision of related to a disease or deformity in the cochlear nerve **Neural::-** sensorineural subdivision of related to a disease or deformity in the cochlear nerve **Central:** sensorineural subdivision of related to a disease or deformity in the cochlear nerve
Mixed hearing impairment:	Combined involvement of the outer or middle ear and the inner or cochlear nerve. Audiometrically >20dBHL in the bone conduction threshold together with > 15 dB A-B gap averaged over 0.5, 1 and 2 kHz(42)

Table – 3 : European working group on genetics of hearing types of hearing loss (43)

Expanded criterion of hearing loss

The American academy of Paediatrics in their official joint position statement -2007 had made an addition to the classification of hearing impairment.

From congenital permanent sensory hearing loss or permanent conductive hearing loss, the definition of hearing impairment has been expanded to include ‘neural hearing loss’ which includes auditory neuropathy or dyssynchrony in infants admitted to the NICU.(39)

Hearing impairment percentage

In order to calculate the percent of hearing impairment according to the journal of American medical association, 25 dB is subtracted from pure tone average of 500 Hz, 1000 Hz, 2000 Hz, and 3000 Hz and the result obtained is multiplied by 1.5 to give an 'ear sporadic level'. The impairment is determined by weighing the better ear five times the poorer ear (44).

It may be misleading to calculate the functional impairment based on just the pure tone and may not be very useful because the conversational speech is at around 50-60 dBHL. Therefore a hearing loss of 45-dB is functionally more significant than a mere 30%. Hence a different scale of rating young children with limited hearing loss is needed, which would have a significant impact on language development(44) (8)

% Impairment	Pure Tone Average (dB)	% Residual Hearing
100%	91 dB	0%
80%	78 dB	20%
60%	65 dB	40%
30%	45 dB	70%

Table 4- pure tone average of 500 Hz, 1000 Hz, 2000 Hz, and 3000 Hz Percent Hearing Impairment for young children (44)

Once the hearing loss assessment is made the cause of congenital hearing impairment is to be found out.

It has been found that 3 in every 1000 newborns have significant hearing loss which can be caused by illness or injury which occurs after birth or inherited (congenital).(45)

Etiopathogenesis of congenital hearing loss

Maldevelopment of the inner ear occur between the third and seventh week of intrauterine life when the auditory placodes and the membranous labyrinth differentiation take place.(46).

Several morphological congenital abnormalities of the inner ear occur such as maldevelopment of the bony labyrinth, the membranous labyrinth, receptor organs and their supporting cells occur due to which severe sensory neural hearing loss occurs. (46)

Inner ear sensory hair cells are essential for hearing. Scientists believe that hearing impairment occur as a result of mutations in as many as 400 genes(47). These mutations in the cells can result in improper functioning leading to hearing loss. These gene mutations may contribute to several hereditary or non-hearing related, conditions along with deformation of the inner ear, that can result in deafness at birth or later in life.(48)

About 50% of cases on non-syndromic genetic hearing is caused by a mutation in a gene called as "**connexin 26"**(49).One third of severe-to-profound congenital deafness and half of profound autosomal recessive non-syndromic hearing loss (ARNSHL) are caused by mutations in "Connexin 26 and *GJB2"*, (a gene that encodes a 'gap junction protein)(44)

A common congenital viral infection like Cytomegalovirus (CMV) is associated with congenital hearing loss due to changes that occur in the stria vascularis, cochlear duct and saccular hydrops. (44)(46)

Prevalence of congenital hearing loss

Various surveys have reported the prevalence rates for bilateral congenital hearing impairment to be 1.2 to 5.7 per 1000 live births (2). According to the American Academy of Paediatrics task force report on newborn and infant hearing, 2 to 4 per 100 infants in the intensive care unit, and 1-3 per 1000 newborn infants in the well-baby nursery population have considerable bilateral hearing impairment.(45)(51)(50)

Several studies show that for bilateral hearing loss of more than 35 dB, the prevalence of hearing loss in the new born population vary from 0.9 in 1000 to 3.24 in 1000, and 5.95 in 1000 for unilateral and moderate hearing loss(51).

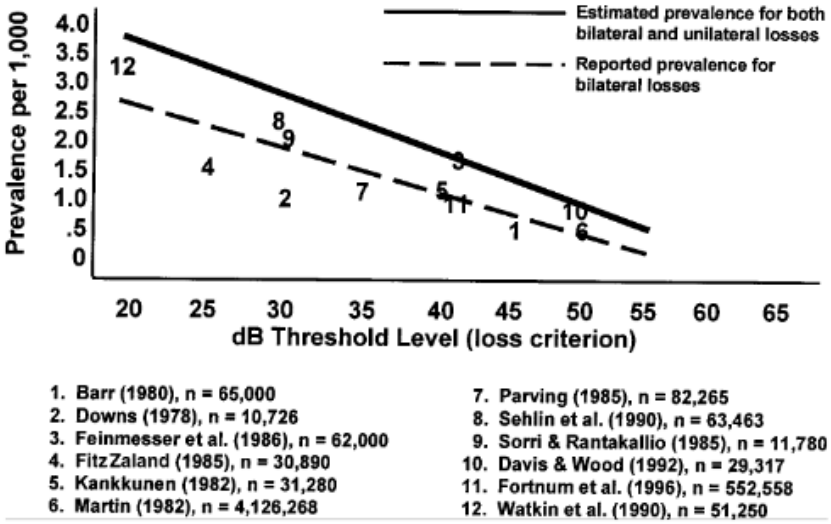


Figure 6: Prevalence rate of B/L Hearing loss (7)

The current situation in India is that 4 in 1000 children born were found with severe, to profound hearing loss(52)(53).

Prevalence rates ranging from 1% to as high as 40% were seen in studies conducted in 2004.

The Indian Council of Medical Research reported that the incidence of conductive hearing impairment in 1983 had been 48% in rural areas. In 1991, the National Sample Survey Organisation (NSSO) reports of 1986 showed 3.02 million deaf population in India and 3.24 million in the age group of 5-14 years (52)

The prevalence of hearing disability in India according to the National Sample Survey showed that 5.53 per 1000 in rural and 3.90 per 1000 in urban areas(52). According to Parmod Kalsotra et al hearing impairment affects 1.8% of the population in India (9).

In every 1000 births, about 10 new borns are estimated to be affected by a severe to profound hearing loss in developing countries. Of the 62 million deaf children younger than 15 years, two-thirds, live in developing countries worldwide(55). According to WHO estimates in 1998,two-thirds of 123 million people in the world with a hearing loss of 41dB or more live in Asia.(52)

About 0.3 million between 0-4 years of age group and 1.5 million in the age group of 5-12 years had hearing impairment, according to the Human Development report of 1999(4).

Paul et al suggests that 1 to 3 per 1000 new born infants in the nursery had congenital bilateral hearing loss.(45)

Of these, the unexpected feature is that approximately 90% of these children with deafness were born to parents not having hearing problems [5]. More than 50% of hearing loss in children is genetic and not related to anatomic, infectious, or other non-inherited causes. [6].

Causes of congenital hearing loss(56)

The causes of hearing loss can be broadly divided as i) Prenatal and ii) Post natal causes.

5-10 percent of congenital hearing loss seen at birth is due to prenatal illnesses. Of these 50% of congenital hearing loss is due to genetic causes and the other 50% is due to environmental causes.

It can be further classified as idiopathic and non-genetic types. (7)

i) Prenatal causes 5-10%

Idiopathic cause (25%): The idiopathic cause accounts for about 25% of hearing loss.

Non-genetic factors (25%): 25% of hearing loss is due to non genetic factors such as maternal infections,(rubella, cytomegalovirus, herpes simplex virus, or German measles), Toxins, drugs and alcohol during pregnancy, maternal diabetes, toxaemia during pregnancy , prematurity, low birth weight, birth injuries, Rh factor incompatibility, jaundice, cause hearing loss(9)

Genetic factors (50%): More than 50 percent of all hearing loss is caused by hereditary or **genetic factors.** These genetic defects present at birth or develop at a later period. Rare types of genetic hearing loss can be due to mitochondrial inheritance patterns or is X-linked (related to the sex chromosome). (56)

The genetic factors causing hearing loss can be further classified as a) non-syndromic congenital hearing loss b) Syndromic congenital hearing loss.

Syndromic hearing impairment occurs along with a specific group of birth defects and the non-syndromic hearing impairment can be either autosomal recessive or autosomal dominant and implies that this could be the only birth defect the baby has.

In **autosomal recessive hearing loss**, both parents even without a hearing loss, carry recessive gene and transfer it on to the child. Since they are unaware that they carry a defective gene, the parents may be surprised to see their child with a hearing loss. This type of inheritance cause 70% of all genetic hearing loss (9)

The **autosomal dominant hearing loss** is about 15% of all genetic hearing loss which is due to an abnormal gene from either of the parent, even though the matching gene of the other parents' being normal. The parent with the dominant gene may have a hearing loss along with other signs and symptoms of that genetic syndrome.

Several genetic syndromes have hearing loss as one of their symptoms like Down syndrome, Usher syndrome, Treacher Collins syndrome, Alport syndrome, and Waardenburg (9)

ii) Postnatal Causes of hearing loss (10-20%)

Postnatal causes account for 10-20% of hearing impairment which can be temporary or permanent. Permanent hearing loss can be caused by Head injury, childhood infections, like measles or chicken pox, meningitis. Temporary hearing loss is caused by medications like amino glycosides, ear infections like otitis media which can cause a permanent hearing impairment(56)

According to a study done at All India Institute of Medical Sciences (AIMS) in 2002 ,the most common cause of prenatal group of hearing loss according to Parmod Kalsotra et al, was due to maternal Rubella. Perinatal causes of hearing loss were birth anoxia and prematurity while postnatally, meningitis was most common aetiology of hearing loss.(57)

Risk factors for neonatal sensorineural hearing loss

The **"**American Academy of Paediatrics Joint Committee on Infant Hearing Year 2007 Position Statement" has outlined the risk factors associated with congenital hearing loss.(39) These are 1)Hearing, speech, language, and developmental delay, 2) Family history of permanent childhood hearing loss 3)Neonatal intensive care of more than 5 days or 4) any of the following regardless of length of stay such as assisted ventilation, exposure to ototoxic medications (gentamicin and tobramycin) or loop diuretics like furosemide(Lasix), and hyperbilirubinemia that requires exchange transfusion. In utero infections such as CMV herpes, rubella, syphilis, and toxoplasmosis. Craniofacial anomalies, including those that involve the pinna, ear canal, ear tags, ear pits and temporal bone anomalies. Physical findings such as white forelock are known to be associated with sensorineural or permanent conductive hearing loss.

Other Syndromes associated with hearing loss or progressive or late-onset hearing loss, such as Neurofibromatosis, osteopetrosis, and Usher syndrome and other frequently identified syndromes like Waardenburg, Alport, Pendred, and Jervell and Lange-Nielson.

Neurodegenerative disorders, such as Hunter syndrome, or sensory motor neuropathies, like Friedreich ataxia and Charcot-Marie-Tooth syndrome.

Culture-positive postnatal infections associated with sensorineural hearing loss, including confirmed bacterial and viral (especially herpes viruses and varicella) meningitis. Head trauma, especially basal skull/temporal bone fracture that requires hospitalization. Recurrent or persistent otitis media for at least 3 months. (39)

In order for any of the condition to be identified as congenital or hereditary the European Working Group on Genetics of Hearing Impairment had outlined the exclusion criterion which is given below(42). 'Genetic cause' on family history should be substantiated and hearing impairment should be considered as 'famillal'or'inheritance' if

a. "One or both parents or grandparents affected for two or more generations.
b. Pedigree that suggests inheritance.
c. Two or more children affected with unaffected parents.
d. Consanguinity to any degree.
e. Only child with unaffected parents but with affected cousin(s).
f. Pedigree indicating X-linked inheritance.
g. Pedigree indicating mitochondrial inheritance.
h. If there is any recognised syndrome"

Clinical audiological "hereditary" hearing impairment is a diagnosis made on probability where the clinician and the geneticist should base their assessment from the assessment made.

Early Identification of Hearing Impairment

According to U.S. Surgeon General, Dr. C. Everett Koop, M.D., ''Because it interferes with the development of language, deafness in infants is a serious concern since it sets humans apart from all other living things"(58)

In order to minimize the harmful effects according to the American Academy of Audiology, on speech, language, education, and psychological, social development, early identification, assessment and intervention for all types of hearing impairment in neonates and younger should be done (59) Lifelong defects in speech and language development, personal-social maladjustments, poor academic performance and emotional difficulties, occur when there is failure in early detection of children with congenital or acquired hearing loss. Early recognition of hearing loss, on the contrary, with appropriate involvement within the first 6 months of life have shown allay many of these adverse consequences.(60)

Primary mode of detecting hearing loss

It has been found that in almost two thirds of cases the usual primary mode of detecting hearing loss in children is by the parents themselves where the parents are the first ones to identify hearing loss, as observed from the child's inadequate or lack of response to sound. This passive detection method usually occurs at a mean age of 22 months by which time, there is considerable delay in early diagnosis and auditory rehabilitation of the child. (61). Usually the other health care providers pick up the hearing loss only in approximately 15% of cases, and paediatricians in roughly 10% of cases.(62)

The child's speech, language and cognitive development would be severely impaired, If congenital hearing loss is not detected early and managed.(63) Giving attention to the child's responses and general behaviour along with early hearing screening is therefore important for early detection and rehabilitation.

Various surveys indicate that prevalence rates of congenital hearing loss are 1.2 to 5.7 per 1000 live births. Of these, approximately 90% of children with hearing loss have parents without hearing problems. Hence the National Institutes of Health Consensus Development Conference on Early Identification of Hearing Impairment in Infants and Children recommends a universal newborn screening for early identification of hearing loss among the infants.

In a longitudinal study of 10 years, it has been reported that with immediate audiological and family centred programmes on children with hearing loss between 0-6 months, significant higher developmental function have been achieved in relation to increased expressive vocabulary and language than those with delayed identification, and rehabilitation(45)(2).

These studies underscore the importance that early identification and intervention for hearing loss by six months would provides better opportunity for language development, academic success, and social integration into the society. (45)

Evidence is shown in the Joint Committee on Infant Hearing's Year 2000 Position Statement, Principles and Guidelines for Early Hearing Detection and Intervention Programs, which was endorsed by the "American Academy of Paediatrics (AAP)(64). This confirmation is the reason which resulted in effective universal hearing screening program. (65)

Because 50 percent of congenital hearing loss is genetic, the 'genetic services' should also be a part the newborn hearing screening and Early detection and Hearing Intervention (EHDI) Programs.

If they undergo genetic tests and counselling along with the screening programmes, significant benefits for children with hearing loss and their families are seen.(8)

Although, Ewing had endorsed importance of early identification of hearing loss in addition, its usefulness was known for almost 60 years; yet implementation of the screening programme during the first few months of infants did not materialize until 1980's till the development of accurate, inexpensive, and practical screening equipment.(8). Hearing loss in infancy without appropriate tools for screening can be difficult to identify.

Newborn hearing screening tests

An **ideal screening test** is that which would correctly differentiate 100% of the time between normal and hearing impaired persons(65).

Screening or hearing test should therefore be objective, easy to administer, rapid and not time consuming, simple to use without complex cumbersome technological application, and economically suitable(66). Screening tests are useful for early diagnosis of hearing loss leading to early effective treatment and decrease morbidity due to the disease (67)

The true value of screening test is seen when it can identify mild to moderate hearing losses that can be treated which may progress to severe impairment if left undetected(65).

Therefore identification of hearing loss through a `Newborn Hearing Screening Programme within the first month of life is important(66).

History of neonatal hearing screening

The average age of picking up of congenital permanent hearing loss prior to the implementation of newborn hearing screening programmes, was around 2 years in North America, United Kingdom, and Europe, which caused a further delay of fitting of the hearing aid by another 6 months(68)

In 1970, Professor David Kemp, was able to identify the tiny sounds that a healthy ear makes in response to sounds called as the 'otoacoustic emissions' which could be analyzed in a computerised screening system by the use of a microphone in few minutes. Kemp then suggested that his discovery of the 'otoacoustic emissions' could be used as a screening hearing test. (68) In 1988 he, founded his own company in the US called "Otodynamics" where he developed the machine that could be used in newborn screening evaluations. (68)

After Kemp's discovery, Professor Adrian Davis and colleagues at the "Medical Research Company Institute of Hearing Research in Nottingham" began to work on otoacoustic idea, and proposed its capacity for highly sensitive screening programme. In 1988 Professor Davis carried out multicentre trials in eight hospitals, for a total of 7,500 babies who were at danger from hearing impairment. The conclusions were, that hearing impairment could be identified in approximately 80 % of babies screened out of the targeted neonatal hearing screening programmes (6)

As a result in 1993, the US National Institutes of Health, held a consensus conference which recommended a national newborn hearing screening by using the otoacoustic test.(6)

In 2000, a pilot study of the otoacoustic test, screening of babies in intensive care was conducted and the Newborn hearing screening programme (NHS) was introduced in 2002. In March 2006 after evaluating the initial carrying out of the programme and after a long campaign from the National Deaf Children's Society and the Royal National Institute for Deaf People, the universal test was initiated in England. (6) Thus the Newborn Hearing Screening Programme had been instrumental in reducing the average age of detecting hearing loss from 20 months to three months(6)

Universal neonatal screening

In the US, prior to the implementation of the Universal neonatal hearing screening (UNHS) profoundly deaf children were identified at 2 years and children with mild to moderate hearing impairment were not identified until school going age. With the introduction of UNHS programs, the early detection of hearing impairment in infants has changed considerably, (6)

The first recommendation for the development of a nationwide "universally applied procedures for early identification and evaluation of hearing impairment" came in 1965, from the Babbidge Report of the Advisory Committee on Education of the Deaf.

Before to the execution of universal newborn hearing screening, two important events took place which occurred in Rhode Island in 1989, Hawaii in 1990, and Colorado in 1993. The first event was the development of objective non-invasive physiological tests for hearing loss that could be conducted by non-professional personnel. The second was the exhibition of the positive educational outcome of affected infants due to the early detection of hearing loss.

In 1993, after meeting these prerequisites, the “National Institutes of Health Consensus Development Conference on Early Identification of Hearing Impairment in Infants and Children, recommended a ‘universal newborn screening programme (6).

During the next 10 years, this initiative led to the gradual increase of programs across the nation (6). ‘Neonatal hearing screening’ later became incorporated as a universal screening programme.

The Joint Committee on Infant Hearing (JCIH) issued a statement In 2000, recommending ‘universal screening’ for hearing impairment for all newborns before hospital discharge in addition to the guidelines outlined for hospital and state run programs.(64)

In 2010, after the approval by the Center for Disease Control and Prevention, the programme was similarly recommended by the American Academy of Paediatrics (69). Hence the chosen option for public health care is Universal newborn hearing screening. A third of children with permanent hearing loss without this ‘early screening’ will be left unidentified for early rehabilitation.

<u>The Joint committee on infant hearing(JCIH)the position statement is</u>

The Joint committee on infant hearing (JCIH) recommendation is he identification of children with hearing loss through the ‘universal hearing screening’ by the time children are discharged from hospital or within the first month of life. It was also recommended by the ‘Early detection and intervention of programmes’(EHDI) for newborns with hearing loss. ‘EHDI aims at taking the advantage of the “linguistic competence and literacy development” for children who are deaf or hard of hearing.

These children will lag behind their hearing peers without this early detection and appropriate opportunities to learn language, in areas like cognition, communication, reading, and social-emotional development .(39)

According to the Joint Committee of Infant Hearing (JCIH) recommendations, children should be referred to the appropriate medical expert and a speech therapist if the screening tests are positive. A 'test battery' is then undertaken to confirm the diagnosis of hearing loss which is made by the third month of life, and appropriate therapy initiated by the sixth month of life.(3)(70)

Regular performance measurements of the children is recommended by the JCIH, along with regular monitoring of these measures for comparison and continuous quality improvement.(70) It also endorses the Screening of all infants before 1 month, and a comprehensive audiological evaluation not beyond 3 months, and appropriate intervention for those not passing the screening test not beyond 6 months of age.(39)

It has been found that almost half of 95% of newborn infants that have been initially screened and referred in the United States, fail to come for the follow-up for either confirmation of the hearing loss or early initiation of appropriate intervention services(40).

Therefore a comprehensive approach for the assessment of infants is recommended by the Paediatric Hearing Assessment Task Force called as the test Battery protocol'.(59)

The Test Battery Approach

Here a variety of techniques in evaluating the hearing of the infants called as the 'test battery approach' is followed. It had been described in 1996 by Jerger and Hayes also called as 'the cross check principle'. According to the current practice of paediatric audiology, a complete evaluation protocol: behavioural, physiologic and, Electrophysiologic assessment, is followed.(59)

The following is the paediatric audiologic assessment test battery for hearing loss:(59)

a) **Behavioural observation**

b) **Visual Reinforcement Audiometry** (VRA)

c) **Conditioned Play Audiometry** (CPA)

- Frequency stimuli
- Speech Audiometry

d) **Physiologic Assessments**, including

- Acoustic Immittance, including tympanometry and acoustic reflex testing
- Otoacoustic Emission (OAE) testing

e) **Electrophysiologic Audiometry** including

- Auditory Brainstem Response (ABR)
- Auditory Steady State Response (ASSR) audiometry (59).

a) Behavioural observation

This test is the "gold standard" of hearing evaluation. The behavioural testing aim is to identify hearing thresholds of the speech frequencies for each ear, and to asses' speech awareness at a supra-threshold level, when possible, (59)

Behavioural Observation helps in the assessment of global auditory skill development. It is useful in newborns and infants below six-months of age and for those who are unable to participate in behavioural audiometry (59). The term 'Behavioural Observation Audiometry' or BOA is not appropriate, since this procedure does not determine hearing thresholds. In fact the preferred term is "Behavioural Observation". The term "audiometry" should be set aside for tests of hearing ability. These observations are carried out in a quiet room after a brief examination of the child to rule out any congenital deformities. (59)

Here the child is placed in quite state or light state of sleep, seated comfortably in car seat or on a resting pillow. If baby is placed in parent's lap, parental masking should be considered. Parents are asked not to prompt their children when the stimulus is presented. Complex acoustic stimuli such as speech, speech shaped noise is presented between 60 and 90 dBHL, for a period of 3-4 seconds. To avoid misinterpretation of random child activity, 'no sound' or 'catch trials' are given. Only about 2-3 stimulus are given prior to infant habituation(59) 'Startle reflexes' are looked for.

In this test, in response to auditory stimuli which is presented between 60 and 90 dB HL. The absence of a startle reflex should be analyzed with caution and in conjunction with other observations and test results, since the reflex can be present during hunger and fatigue. The results are recorded as "observational" and are not meant for any predictive auditory interpretation. For a final assessment of type and degree of hearing loss, the results from behavioural, physiologic and Electrophysiologic testing should be combined. (59)

b) Visual reinforcement Audiometry (VRA)

The Visual reinforcement Audiometry (VRA) is done for Infants between 5 to 24 months of developmental age and is used to evaluate frequency-and ear-specific hearing sensitivity and hearing loss using a response that is conditioned. The test is performed in a Sound-treated booth after prior otoscopic examination and the establishing of hearing thresholds based on minimum response levels levels (MRL) are used. Parents are instructed not to prompt their children when a stimulus is given. A team testing approach is used when testing children who have developmental delays.

Procedure: Earphones with ear tip or child's personal ear mould or bone conduction vibrator or sound field speakers are used to deliver sound.

Without any classical conditioning, when the presentation of the first stimulus is given, most of the children will show a definite spontaneous head turn within 2-3 seconds. Others may require certain classical conditioning, especially those with developmental delays.

A 90 degree head turn is the response preferred for a VRA task rather than a 45 degree head turn which is less confusing for an audiologist to notice. In case a response to the auditory stimulus alone could not be elicited, the transducer is changed to bone vibrator to provide tactile stimulation at a low frequency signal (e.g., 250 Hz) or speech is presented at a level that is known (e.g., 50 dB HL).(59)

c) Conditioned Play Audiometry

This test helps to determine 'ear-specific' and 'frequency-specific' hearing sensitivity in children aged two to five years which is performed in a sound-treated room. It provides a quantitative analysis of the degree, type and configuration of hearing impairment.

The child is put through a review of the play task motor response, after the otoscopic exam with adequate number of trials such that the child comprehends the instructions given. A brief initial training session, conditioning test is done to make sure that child understands the task.

In response to an speech or frequency-specific auditory stimulus, appropriate play tasks like placing a peg in a pegboard, stacking blocks, tossing a block in a box, or other game-type activities are given and analyzed.(59)

Speech Audiometry

This test is done for children above approximately 6 months developmental age to determine ability of the child to perceive speech or speech like stimuli which includes speech discrimination, and speech recognition and speech awareness. Here a clinical test booth is not required and the test can be performed in a quite room. A threshold for speech is obtained prior to obtaining thresholds to frequency specific stimuli.

Procedure: By using developmentally appropriate spondee words 'Speech reception thresholds' (SRT) are typically obtained. Response to the speech is made orally or by picture pointing with 'closed set' i.e. picture pointing tasks or 'open set' i.e. word or sentence repetition. 'Supra threshold speech perception' testing is routinely conducted.

The examiner should modify the protocol, like pointing to various body parts if in case the child is unable to point to the pictures. If procedure is still unproductive, 'speech awareness threshold' (SAT) is obtained. (59)

d) Physiologic Assessments:

- Acoustic Immittance, including tympanometry and acoustic reflex testing

- Otoacoustic Emission (OAE) testing

Paediatric Immittance Testing

1) Tympanometry 2) Acoustic Reflex Measures

Paediatric Immittance Testing is done to asses for otitis media and other middle ear anomalies and to assess auditory pathway integrity and middle ear function.

Routinely, Immittance assessment happen as a part of the hearing evaluation for Infants and young children who are at potential risk for middle ear diseases and those with known sensorineural hearing loss, or at risk for auditory neuropathy.

Below 6 months of age, a higher probe tone frequency of 1000 Hz is used for neonates,

The test is done at low frequency probe tone of 226Hz, since it is more sensitive in the detection of middle ear disease than tympanometry and acoustic reflex done (JCIH, 2007) (59)

Tympanometry is normal, if a peak is observed at or near atmospheric pressure with admittance for the patient's age.

It is considered abnormal if there is no identifiable pressure peak and "If the acoustic reflex threshold is > 95 dB HL for 500 and 4000 Hz; or > 100 dB HL for 1000 and 2000 Hz *acoustic reflexes* are abnormal.

Acoustic reflexes help in identifying auditory neuropathy along with otoacoustic emission along with other clinical findings, since this reflex is always absent or increased in established cases of auditory neuropathy. The acoustic reflex alone may not be the best indicator of middle ear effusion but a good indicator along with tympanometric gradient of less than 0.1 mmho, (B curve) and the absence of acoustic reflex for middle ear effusion (59)

Physiologic and Electrophysiologic tests

Physiologic and Electrophysiologic tests are useful in assessing the auditory function as well as in the evaluation of auditory thresholds without needing behavioural response from the child. These tests are used as a part of Neonatal hearing screening to identify congenital hearing loss among infants. (59)

<u>Neonatal screening</u>

In the first month of life, detection of hearing loss is done, through a Newborn Hearing Screening Programme(71). Over all, the test is cost effective since the child would receive early intervention for hearing loss, and it saves on costly special education later on. Neonatal hearing screening later became incorporated as a universal screening programme.

Types of screening

There are two primary types of hearing screening methods for newborns.

1) "***Otoacoustic Emission*** and 2) ***Auditory Brain Response Audiometry*** "(ABR) are the two auditory tests used in infant hearing screening programmes. For the identification of any degree of hearing loss, these electro-physiological methods are proficient, accurate and cost effective (66)

The ultimate goal is to facilitate the child to develop cognitive abilities along with language and communication skills that match up to his chronological age (72). Behavioural observation audiometry can be used for screening, in the event the instruments for screening are not present.

1) Otoacoustic Emissions Test

Otoacoustic emission (OAE) is a valid method of testing cochlear function and is quick and cost effective

It is useful for screening sensory loss in new-borns. (73)

The advantages of Otoacoustic emission (OAE) are

a) "It can be recorded in normal cochlea

b) OAE can be recorded reliably from newborns.

c) OAE can identify even mild hearing loss.

d) A non-audiologic person can perform it.

e) OAE recording requires relatively brief time.

f) OAE provides frequency specific information"

OAE

Evoked otoacoustic emissions(OAEs) are “acoustic signals produced from within the cochlea that travel in a reverse direction through the middle-ear space and tympanic membrane out to the ear canal” (59). These acoustic signals can be produced in response to an auditory stimulus like clicks or tone bursts.

OAE helps to assess cochlear or outer hair cell function and can be done quickly at any age and on the child that is asleep or awake. A very sensitive microphone probe system picks up the signals of OAE which is kept in the external ear canal.

To confirm type and degree of hearing loss, and or to detect the site of auditory disorder, OAE is used in screening neonates and children of all ages and can be utilized routinely as part of the paediatric assessment battery. Screening results can be influenced by the presence of middle-ear pathologies. Mild degrees of motion artefacts do not impede with the test.(59)

For middle-ear anomalies and for moderate or more severe degrees of hearing loss, the OAE test is a good screening tool and can help in cross-check verification of behavioural testing when indicated. OAEs can also be utilized often to screen or monitor preneural auditory function because of the ease and speed of its administration.(59)

A ‘failed’ OAE test shows that that the middle-ear condition is abnormal and the hearing loss is more than 30 to 40 dB. The automated OAE screening machine provides a ‘pass-fail’ report and therefore no special audiologist test interpretation is need. (59)

The disadvantage of OAE is that the reliability of the neural conduction of sound from the eighth nerve to the brainstem test cannot be assessed. Many will miss auditory neuropathy and other neuronal anomalies, as a result. Such children with auditory neuropathy will have normal OAE test results but abnormal auditory brainstem result (ABR).

Two types of evoked OAEs are used for clinical assessment they are a) 'transient-evoked OAE's (TEOAEs), which is produced using an acoustic click or other short transient sound, and b) distortion product OAEs (DPOAEs), can be obtained by giving two pure tones at the same time.

Procedure: For the test, continuous surrounding noise in excess of approximately 50 to 55 dB is avoided. The test is conducted in a quiet area where the ambient noise from outside sources is kept to a minimum. In the ear canal, the click stimuli are produced and the responses are evaluated by a probe assembly that is fitted to the ear disposable ear tips.

For OAE recordings, stimuli used include transient clicks for (TEOAEs) and pure tones for (DPOAEs). Level of the stimulus for TEOAEs is around 80 dB peak, equivalents SPL +/-3 dB as measured in the ear canal.

In differentiating ears those with normal hearing from the ears in the 20 to 30 dB HL range with hearing loss, DPOAE uses pairs of pure tones i.e. lower and higher frequencies tones, where f1 = the lower primary frequency tone and f2 = the higher frequency primary tone. Currently, stimulus levels of L1=65 and L2=55 typically are used within a 10 to 15 dB difference between L1 and L2 (L1>L2).(59)

The newborns and neonates must be quite or resting, sitting quietly, after eating or around their naptime to record OAE. Otoscopy is done before the test to find the status of the external auditory canal and to determine the probe tip size to be used for testing.

If a response is seen with signal-to-noise ratios (SNR) > 3 to 6 dB in the majority of frequency bands analysed, **TEOAEs** are considered to be present and normal. If a response is not seen with a SNR of ≥3 to 6 dB in more than one frequency band TEOAEs are considered to be 'absent'

If the distortion products are observed at a signal-to-noise ratios (SNR) > 3 to 6 dB at the majority of frequency bands, **DPOAEs** are considered to be present and normal

DPOAEs are considered absent if a response is not noticed with a ≥3 to 6 dB SNR for more than one f2 frequency; the results are analyzed within the context of a test battery for diagnostic purposes. When OAEs are present at normal amplitudes throughout most of frequency bands evaluated results are reported as reliable with the functional integrity of the outer hair cell system (59)

Auditory Brainstem Response Test

History of ABR

In 1967, the first to publish **Auditory Brainstem Response** (ABRs) recorded with surface electrodes in humans beings *were Sohmer* and *Feinmesser*

They demonstrated that cochlear potentials could be elicited with a non-invasive method. In 1971, *Jewett* and *Williston* described the human ABR waves and as arriving from the brainstem.

Later In 1974, *Hecox* and *Galambos* described in adults and infants that the ABR was suitable for threshold assessment. Starr and Achor in 1975 were the first to report the effects on the ABR of CNS pathology in the brainstem.(67)

The **Auditory Brainstem Response Test** (ABR) is an effective and non invasive electrophysiological measurement for assessing the brain stem auditory sensory pathway and the functional status of the auditory nerve. The condition of the inner ear and or auditory nerve can be obtain through ABR and **is an objective way of recording brain stem potentials in response to click stimuli.**(67) **By electrodes placed over the scalp of the person, these waves are picked up.** This test gives information on the degree, the type, and composition of a hearing loss. Because it is fairly an accurate and reliable indicator of hearing loss, it is considered as an important procedure in the initial test battery, in infants who are very young to respond to behavioural testing.(67)

The ABR is used for various assessments like the newborn hearing screening, auditory threshold evaluation, auditory nerve brainstem lesion detection, determining hearing loss type and degree, and intra-operative monitoring. The ABR test is done, after the otoscopic exam, in a sound treated booth or a quiet room. The standard electrode is a 'non inverting' electrode which is placed on the vertex, and another 'inverting electrode' is fixed over the ear lobe or mastoid prominence. (Fig 7 b-c)

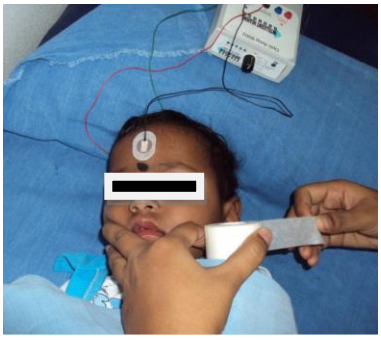
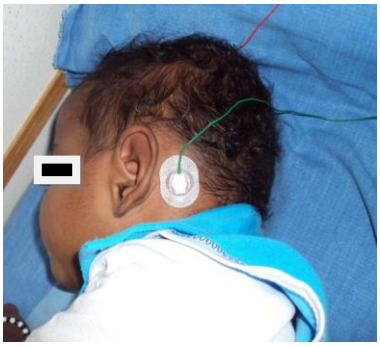
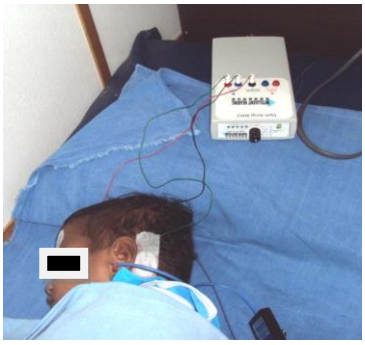




Fig 7a Vertex Electrode for ABR Fig 7b: Mastoid electrode for ABR Fig 7c: electrodes +Transducer fixed

One more 'earthing electrode' is fixed over the forehead of the infant (Fig 7a). For proper functioning of the preamplifier this earthing electrode is important**(67)**

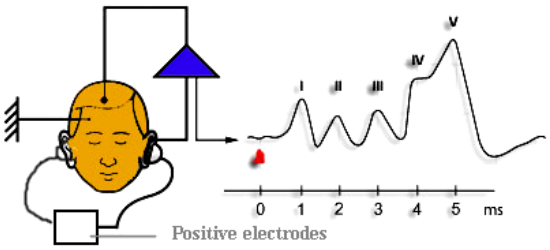


Figure showing placement of BERA electrodes

Fig 8 Placement of Electrodes for ABR(67)

The stimulus in the form of 'click' or 'tone pip' is sent to the ear via a transducer placed in the head phone or insert ear phone (fig 9). The impulses from the brain stem in the wave forms are picked up by electrodes placed over the scalp.

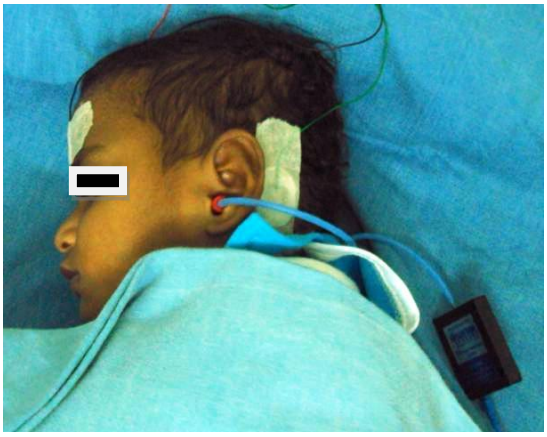


Fig 9: Transducer placed in the ear

Signal to noise ratio (Sound signal given to the ear against the background noise) in ABR is improved by filtering, repeated stimulation and by polarity alteration.

In auditory brain stem evoked response audiometry, the areas of the response that are neural and those that are cochlear such as the cochlear microphonics, are differentiated by alternating the polarity of the tone bursts. (75)

6 ms or less tones or tone bursts or pips which consists of at least 3 cycles of the specified frequencies which are of short duration are used along with stimuli of nominal octave frequencies from 250 or 500 to 4000 Hz(59). The amplitude in micro voltage of the signal is averaged and recorded against the time in milliseconds.

The waves in the form of positive peaks and negative troughs by the impulses generated by the brain stem are recorded. After a click stimulus is given, these waveforms are seen usually within a 10-millisecond time period, at high intensities of 70-90 dB normal hearing level. The positive peaks (vortex positive) are indicated by the Roman numerals I – VII (Fig 8, 10).(75)

These peaks are considered to originate from the following anatomical sites:

Cochlear nerves - waves I and II

Cochlear nucleus - wave III

Superior olivary complex - wave IV

Nuclei of lateral lemniscus - wave V

Inferior colliculus - waves VI and VII”

These peaks occur over a period of 1 - 10 milliseconds, in response to a click stimuli after the stimulus is given in normal hearing. Its threshold as elicited by conventional audiometry has been found to be within 10dB. **(67)**

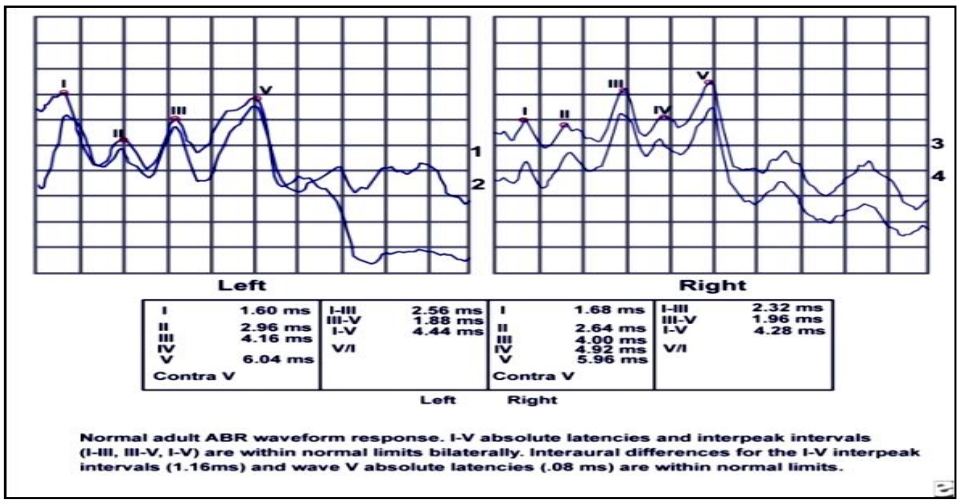


Fig 10- Normal adult brainstem response (ABR)(75)

Interpretation of results

The results of ABR can be interpreted by looking at the a) ***amplitude*** (the number of neurons firing), b) ***latency*** (the speed of transmission), c) ***interpeak latency*** (the time between peaks), and d) ***interaural latency*** (the difference in wave V latency between ears)

The activity of the neuron that begins at the base of the cochlea and moves toward the apex over a 4ms period of time is sown by ABR. Beginning from the most basal regions on the cochlea the peaks usually show activity. Initially, any disturbance affects the basal end and a significant amount of phase cancellation occurs by the time it gets to the apex,.(75)

Auditory Brainstem Response Test (ABR) can be done without sedation and does not require the child's participation in infants less than 5 months of age. It is considered the method of choice for hearing screening. The specificity and sensitivity rate reported by Hall et al have been more than 96% for ABR screening in the new-borns(75)

The advantages of ABR are(67)

1. It is objective measurement of auditory system.
2. It provides ear specific information.
3. It is independent of subject's state (sleeping, awake).
4. It does not require sound booth for evaluation.
5. ABR is independent of cerebral status.
6. Helps in detecting auditory neuropathy(67)

Auditory Steady State Responses (ASSR)

ASSR, is another electrophysiologic measurement of infant's hearing. It provides more "frequency-specific threshold information" regarding the neonates who have severe to profound hearing losses. To have more accurate information to go ahead with hearing aid fittings or to determine the cochlear implant for the candidate this test is useful. Sedation may be needed for infants over 6 months of age for ASSR testing.

At the present time, the recommendation of this procedure as the only measure of auditory status in newborn and neonatal populations has not been given by the Joint Committee on Infant Hearing (JCIH) 2007 Position Statement.(70)

ASSR vs ABR (78)

Similarities:

a) “Both record bioelectric activity from electrodes arranged in similar recording arrays.

b) Both are auditory evoked potentials.

c) Both use acoustic stimuli delivered through inserts (preferably).

d) Both can be used to estimate threshold for patients who cannot or will not participate in traditional behavioral measures”. (76)

Differences:

a. “ASSR can be used binaurally while evaluating broad bands or four frequencies (500, 1k, 2k, & 4k) simultaneously, but ABR typically uses click or tone-burst stimuli in one ear at a time.

b. The ABR estimates thresholds from 1-4k in typical mild to moderately-severe hearing losses where as ASSR can also estimate thresholds in the same range, but offers more frequency specific information more quickly and also can estimate hearing in the severe-to-profound hearing loss ranges.

c. ABR depends highly upon a subjective analysis of the amplitude/latency function. A statistical analysis of the probability of a response (usually at a 95% confidence interval) is used by ASSR.

d. ABR is measured in micro volts (millionths of a volt) and the ASSR is evaluated in nanovolts (billionths of a volt).

e. The ASSR is an evoked response which uses sound which is given at a high repetition rate rather than a onetime sudden sound at a low repetition rate”. (76)

Automated Auditory Brainstem Response (aABR) test

The ABR is one physiologic objective method of hearing screening. Information about the outer ear, middle ear and cochlea is provided by the automated auditory brainstem response (aABR) screener and also gives information regarding the auditory pathway up to the brainstem. The brain activity in response to sounds is recorded by the aABR screening test. The sound waves travel through the outer ear as vibrations where it is changed into an electrical signal when it reaches the cochlea. To reach the brain, these electrical signals now travel along the eighth nerve where it is processed into recognizable sounds. The instrument measures the cochlear response to the broadband click stimulus in the 1- to 4-kHz range in each ear.

The aABR test uses a series of clicking sounds at 35 dB near hearing level, which are played through the headphones that are placed over the baby's ears. Three small sensors are kept on the baby's head which are attached to the computer equipment. The computer will report strong responses as 'pass' if the hearing system normal. The computer will report a 'referral' when there is no strong response to the stimulus. (57). Usually 3 out of 100 babies will be referred for a full diagnostic assessment of hearing.

Advantages

a) Automated ABR screener (aABR) is time and cost effective which has a 'high sensitivity and a 'low failure rate(67)

b) It can be used on the ward where no operator assessment is needed. It can also be used without interference from ambient noise during oxygen therapy.

c) The time needed for screening is from 4 to 15 min(66). With the same results, aABR can be used in a home setting,

d) Further test interpretation by an audiologist is not needed, since the automated screener gives a 'pass-fail' report. A 'fail' report given by an aABR show that the hearing level is worse than 40 dB.

e) Can test each ear individually .The aABR can be performed on children of any age

f) The test can be repeated when motion artefacts interfere with test results (7)

g) For universal hearing screening, the AABR has acceptably low 'refer' rate.

h) Can be used after birth within the first 24 hours in the nursery, by various personnel.

i) The low rate of screening failures decreases any potential of false-positives during screening, minimizing the costs associated with later follow-up assessments.(75)

j) Even in the nursery, It can identify mild, moderate, and severe bilateral, persistent hearing loss which helps to provide amplification before 6 months of age and thus facilitates speech and language development.(75)

Several ABR screening instruments incorporate built-in artefact rejection for myogenic, electrical, and environmental noise interference, which ensures that data collection is halted if testing conditions are unfavourable.

Neonatal hearing screening programs have been initiated in many countries across the world. In India the universal hearing screening had been initiated in few areas like cochin since January 2003.(77).

<u>aABR Versus OAE screening</u>

For hearing screening, two methods are used. One is dependent on the measurement of otoacoustic emissions (OAE) and the other is dependent on the Auditory Brainstem Response (ABR).

The sensitivity of ABR is superior to that of OAE, among the screening tests, because, the OAE is not able to distinguish retrocochlear hearing impairments, such as 'auditory neuropathy' which has a prevalence of 5–10% among the newborns.

The MB11 BERAphone gives an automatic ABR at the speed and cost of OAE measurement along with very high sensitivity and specificity. (75)

Several machines are available in the market for neonatal screening that provide aABR and OAE screening. (76)

Manufacturer	Equipment Name	Technology Type		
		AABR[1]	DPOAE[2]	TOAE[3]
Grason-Stadler Inc (GSI)	GSI 70	...	X	...
	Audioscreener	X	X	X
Intelligent Hearing Systems	SmartScreener-Plus 2	X	X	X
	Smart Screener	X	...	...
	Smart OAE	...	X	...
	SmartTrOAE	...	...	X
Interacoustics	OtoRead	...	X	X
Otometrics	Accuscreen	X	X	X
Maico	Ero*Scan	...	X	X
	MB 11	X	...	...
Natus Medical Inc	ALGO 5	X	...	...
	ALGO 3i	X	...	...
	Echo-Screen®	X	X	X
	ABaer®	X	X	X
	AuDX® I, AuDX® Pro, AuDX® Pro II, AuDX® Pro Plus	...	X	X

Table 5. Machines available in the market for Neonatal screening.(78)

Since the aim of neonatal hearing screening program is to detect all types of permanent hearing loss along with those that are due to dys-synchrony and auditory neuropathy, an ABR-based method is chosen.

ABR screening by **MB11 BERAphone**, can be performed without the use of disposable and adhesive electrodes, and the additional operational costs associated with traditional ABR screening devices is also low.(75)

MB11 BERAphone® screening device

Traditional click stimulus' or 'time step stimulus' was used in the first type of the BERAphone® machine to obtain the ABR.

A series of six successive clicks in diminishing intensities of 10 dB steps are given at intensities ranging from 60 to 10 dB HL. ABR thresholds analysis of the screened newborns was done visually and interpreted by an experienced clinician.

In 2002,a new algorithm based on statistical analysis for ABR data was introduced, to replace the visual analysis time step ABR, making the screening fully automatic.(75)

For evoking higher ABR amplitudes, a new, device with optimized 'chirp stimulus' was incorporated in the screening machine in 2006. Due to this, vast improvement was seen in the screening quality and detection rate. Regularly, since then the MB11 BERAphone® has been used for neonatal hearing screening with the optimized chirp stimulus.

For newborn hearing screening, White et al had done another comparative study with MB11 BERAphone® using a chirp stimulus and the ABaer -aABR. MB11 showed a considerable advantage for the testing time of 2.3 min compared to the ABaer which had taken longer time of 6.9 min. (75)

Melagrana et al also in their study concluded that screening of babies in an intensive care environment with MB11 screening test was appropriate.(75)

The MB11 BERAphone® device (7)

The Maico MB11 BERAphone® is a dependable machine for auditory brainstem response newborn hearing screening; in addition it gives results quickly.

Owing to the automatic detection of ABR, the instrument does not need the assistance of an experienced examiner, therefore can be used by any trained technicians (75)

An earlier study done at CMC found BERAphone to be a very suitable tool for neonatal screening in the ward by the bedside.

The device, MB11 BERAphone® is fitted with a handheld 'headphone unit' that has all the ingredients needed for ABR recording such as the loudspeaker, a preamplifier and a set of three integrated, reusable electrodes.

Test preparation time for an ABR screening is short, since additional materials like disposable electrodes or ear couplers need not be attached to the skin for the screening.

Features:

- Fast and automatic ABR-screening, reliable results within seconds
- Unique BERAphone® with integrated electrodes saves costs for disposables
- CE-Chirp-Stimulus ensures fast results
- Automatic Impedance Check indicates impedance conditions
- Export function of test data for quality ensuring tracking
- Stimulation level at 35 dBHL
- USB connection for power supply and data transfer"

Sensitivity >99.9%

Specificity > 96.7%

Beraphone Screening tests the entire auditory pathway up to the brainstem with auditory brainstem response. In addition, it also detects conditions like the auditory neuropathy and other neural defects which cannot be made with OAE testing.(79)

The hand held unit has of two electrodes that can be used to trace the ABR recordings from the vertex and from the mastoid, and a third electrode functions as the ground reference. An adjustable 'vertex electrode' is present for its proper placement on different sizes of heads. (75)

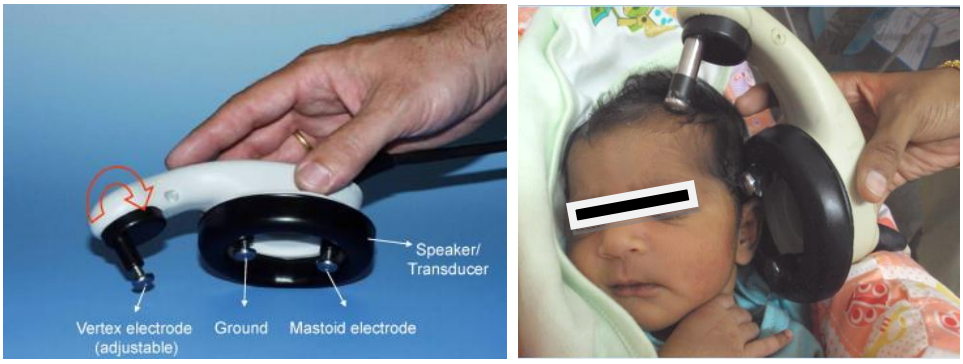


Fig 11:. MB11 BERAphone® device with the three electrodes

Since 2006, MB11 BERAphone® CE-Chirp™, had incorporated an optimized 'chirp stimulus' for the

hearing screening. The waveform of the chirp stimulus is seen in Fig 12.

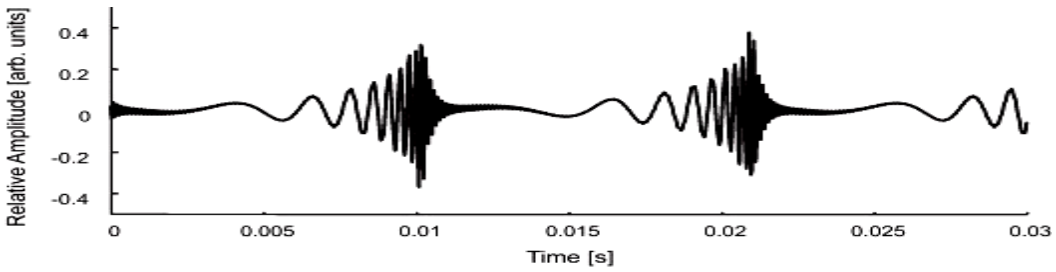


Fig 12: The 'temporal waveform' of chirp stimulus used in the MB11 BERAphone®.

In comparison to typical 'click stimuli', the MB11 generates high chirp stimulation at the rate of 92 stimuli per second which is designed to decrease the delay in time for the production of a threshold response. In contrast the MB11 click stimuli, attempts to enhance the temporal synchrony among the neural responses from various regions on the basilar membrane. (75)

To identify the presence of an ABR response automatically, the device takes a maximum test time of 180 seconds and which is based on an implemented statistical test algorithm (modified q-sample uniform scores test) as given by Cebulla et al. This implemented test algorithm attempts to detect a response from the auditory system. The screening test generates a "PASS" result when a response is detected. The screening test generates a 'REFER' result if there is no response within 180 s (75).

The device is set to the screening stimulus level of 35 dB HL for a "Pass. This acoustic calibration is made by the manufacturer and yearly recalibration of the machine is done by the medical service team of the manufacturer.

Two stage protocol

The screening protocol included two stages. The first stage includes an initial screenings by Beraphone which is recorded at the bed side of the nursery within 48 h of delivery. Both ears of the infant are tested. The result shows 'PASS' when the response to the stimulus is below 35 dB HL and "Refer" when either of the ears shows no response to all the frequencies presented.

The second stage screening is done in the Department of Audiology where the audiological diagnostic tests are done in an acoustically shielded room.

The newborns that generated a ‘Refer’ were re-tested after a week, as per the second stage of the hearing screening protocol, in the department of audiology.

Two step screening protocol is followed because screening immediately after birth often results in high false positives due to vernix plugs in the baby’s ear canals therefore a more effective way of minimizing over-referral due to false positives is to implement a two-stage screening protocol with aABR first, followed by a diagnostic test such as ABR. (66)(75)

This protocol also improves the specificity where it is able to correctly identify those who do not have the disease. Also the two step screening is a standard practice in western countries for the universal screening programme (75)

The manufacturer reports that the ‘BERAphone’ has a sensitivity more than 0.99 and test specificity of 0.87 for a one time test and as a two-stage test, the specificity is greater than 0.96.(7)

Van Straaten et al, in his study of using automated ABR, reported a 92% ‘pass’ in the first screening and 98% ‘pass’ after the second screening (66)

Such high values of sensitivity and specificity are only possible when testing is done under ideal conditions. Where as in a tertiary care centres like CMCH where the annual delivery rate is more than 13,000 the above mentioned testing in ‘ideal’ conditions is not possible to get a universal neonatal screening. This has made it necessary to test babies at the bedside to accomplish such high coverage.

Fig 13 Bed side neonatal screening

This study is therefore intended to calculate the sensitivity and specificity of this neonatal hearing screening tool 'MB11 BERAphone® when used at the bedside of an infant in a ward setting in less than ideal conditions against the gold standard diagnostic test ABR done in ideal conditions. The ideal conditions include an air conditioned sound proof room where the sound levels are less than 35dB.

MATERIALS AND METHODS

The main objective of this study was to determine the sensitivity and specificity of MB11 BERAphone® as a screening tool in identifying neonates with congenital hearing loss in comparison against the gold standard, 'Auditory Brain Stem response Audiometry'(ABR) when performed at the bedside of the new born at the postnatal ward setting where the sound levels are over 35dB.

This is an observational study performed between October 2012 to October 2013 at the Christian Medical College, Vellore (CMCH), after institutional review board and ethical committee clearance. Neonates born in CMCH that have been referred once on sequential screening with MB11 BERAphone® were recruited after obtaining informed consent from the parents.

The sample size for the study was obtained as follows:

No of ear

$$n = \frac{Z^2 * P(1-P)}{\Delta^2}$$

		Disease +	Disease -	
Test	+	a	b	
	-	c	d	
		(a+c)	(b+d)	N

△

n = (a+c)

N= (a+c) / prevalence

Δ = precision

N = Total sample size, Z = Constant – (1.96), P = Expected Sensitivity – 0.95

$$(a+c) = \frac{(1.96)^2 \times 0.95\{1-0.95\}}{(0.07)^2} = \frac{3.84 \times 0.0475}{0.0049} = 37$$

$$Sample\ size\ N = \frac{(a+c)}{prevalence} = \frac{37}{0.5} = 74$$

For an expected sensitivity and specificity of 95% each and prevalence (in the second screen positives) of 0.5 and a precision of ± 0.07 %, a sample size of 74 will be required for the estimation of both sensitivity and specificity of the screening tool MB11 BERAphone®.

37 consecutive healthy neonates (which would make up to 74 ears) born in CMCH during the study period of one year, and who have been 'REFERRED' once on sequential first screening with MB11 BERAphone® fulfilling inclusion and exclusion criteria were recruited for the study which was performed in the postnatal ward setting, and in the Audio vestibular unit after obtaining informed consent from the parents.

Inclusion criteria:

a. Infants born in CMCH.
b. 37 Neonates who were 'REFERRED' after the First MB11 BERAphone® test.

Exclusion criteria:

a. Upper respiratory tract infection
b. Discharging ears
c. Very sick new born.
d. New born with obvious anomalies.
e. Parental refusals.

The screening protocol included two stages (two step protocol) (Fig14).

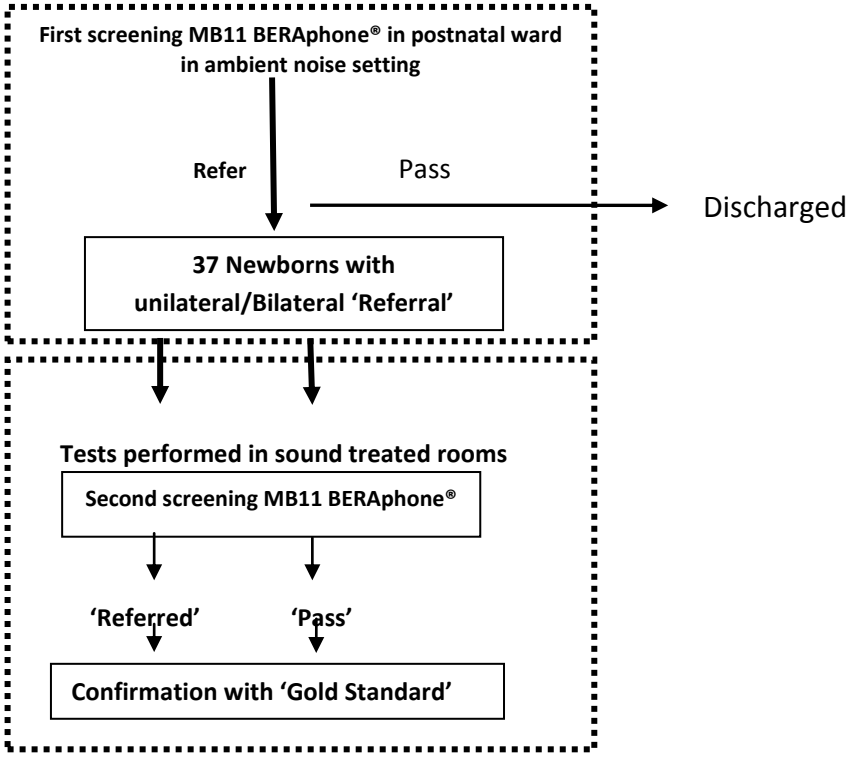


Fig 14: Two stage protocol for Neonatal screening

In the first stage, the initial screening was done in the postnatal ward prior to hospital discharge within 48 hours of delivery at normal ambient sound levels which were above 35dB.

The neonatal screenings both the first and second were done by **MAICO MB11 BERAphone® (MAICO** Diagnostic GmbH, Berlin / Germany). **The MB11 BERAphone®** is a screening device that is fitted with a handheld 'headphone unit' that incorporates all the ingredients required for ABR recording like the loudspeaker, a preamplifier and a set of three integrated reusable electrodes. The time required to prepare for an ABR screening test using this equipment is brief because it is not necessary to adhere disposable electrodes or ear couplers to the skin.

Two electrodes are used to record the ABR from the vertex and mastoid, while a third electrode is used as a ground reference. The position of the vertex electrode is adjustable to enable its optimal placement on different head sizes.

Fig 15a: BERAphone unit

Fig 15b: BERAphone headphone unit

From start of the study for a period of one year the mothers or carers were counselled about the test (Appendix *item no* - ***1***) and consent taken (Consent form *Appendix item no-**2**)*

A complete case history with important developmental and medical history that includes prenatal and perinatal history was obtained from parent or primary care taker of the infant (Appendix (Performa) item no-**3**).

History pertaining to various risk factors for hearing loss (TORCH infections, diabetes, hypothyroidism, ototoxic drug intake and other illnesses) was recorded. Family history with regard to deafness, blindness and other systemic diseases were noted. Complete physical and ENT exam was done. The external ear was examined for any malformations in and around the pinna, position of the pinna and any lesions or cysts on the pinna.

Detailed otoscopic exam was done to determine the size and direction of the ear canal for the placement of probes or inserts used during testing.

The screening process was organized and supervised by the Audio vestibular unit of the department of ENT. The measurement with the MB11 BERAphone® was performed by support staff recruited from the department of audiology. The screeners had received prior training on the use of the device.

The mother was asked to feed the child and when asleep or quiet, the special hand-held headphone unit of MB11 BERAphone® which emits a series of soft clicks was positioned over the newborn's ears after application of electrode gel. The electrodes which are present within the unit were positioned on the infant's forehead and neck. Two electrodes record the ABR from the vertex and mastoid, while a third electrode is a ground reference.

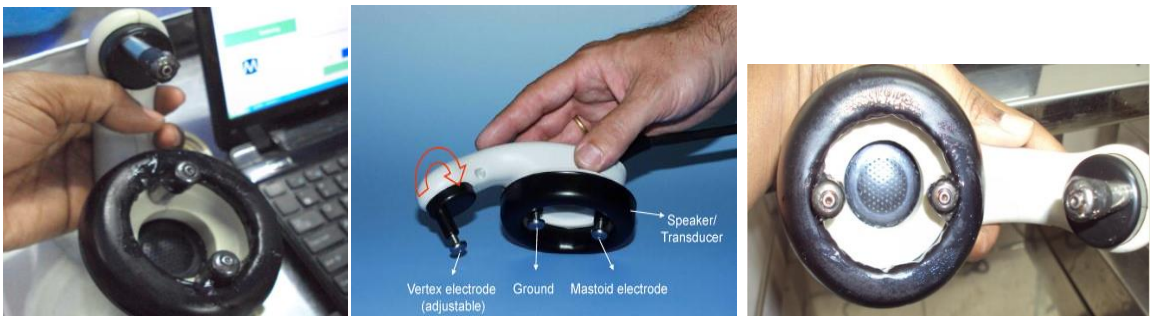


Fig 16: MB11 BERAphone® hand held device with three integrated electrodes and transducer

The vertex electrode is adjustable to ensure its proper placement on various head sizes. These electrodes measure the brain wave activity in response to the clicks or chirp stimulus. The tests are non-invasive, painless and quick.

The test takes 1.5 minutes per ear when the response is good, and about 4.5 minutes per ear when there is no clear response from the ear.

Comparison of the brain wave activity with normal response templates is done by the software in the laptop which is connected to the MB11 BERAphone® and provides a 'PASS' or 'REFER' result. If a response is detected and verified at 35 dBHL, the test result is 'PASS'. The machine indicates a 'REFER 'when there is no response at 35 dBHL at all frequencies.

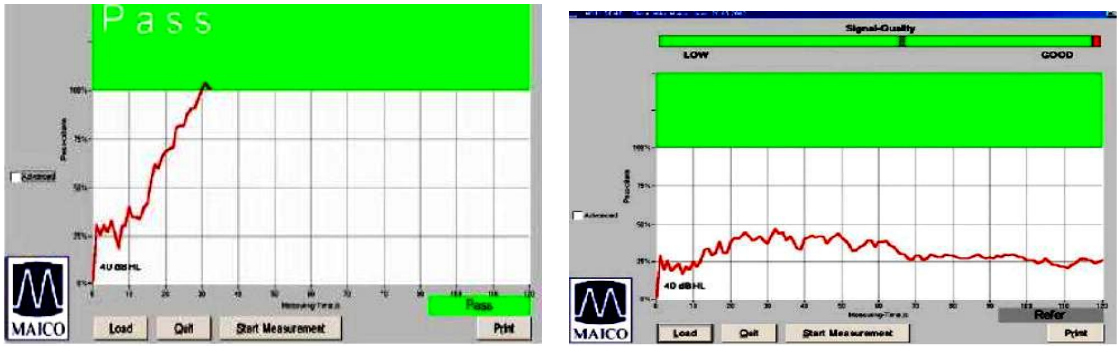


Fig 17: BERAphone screening test results 'PASS' and 'REFER'

The second stage screening along with all audiological diagnostic tests were performed in an electrically and acoustically shielded room in the department of audiology where the noise is relatively low. The mothers/carers, after counselling were asked to report to the department of Audiology in the out-patient department after a period of one week for the second screening and for the confirmatory test.

This was done to overcome the possibility of vernix in the ear of the neonate interfering in the first screening soon after birth. Similar to the first screening the mother was asked to feed the child and when asleep or quiet the second screening was done with MB11 BERAphone® in a sound treated audiology room.

All the 37 infants who had been 'REFERRED' or 'PASSED' in the second screening with 'MB11 BERAphone® were subjected to a confirmatory diagnostic testing with ABR (Auditory Brainstem response) which was used as the Gold standard for confirming the hearing loss in neonates recruited for the study.

The second screening with the MB11 BERAphone® was done at the same sitting prior to the ABR test.

The subset of children who were 'Referred' in the first screening and have 'Passed' in the second screening (where the tool says no hearing loss) were also subject to the confirmatory ABR testing to provide the second arm of the 2x2 table for calculation of sensitivity and specificity.

Fig 18: ABR Testing

Following the second screening, the neonates underwent the confirmatory test Auditory Brain stem Response audiogram (ABR) using **Intelligent Hearing Systems ABR Machine ISO 13485**, Miami, Florida.

The ABR test was done in a sound proof room by an experienced audiologist who was blinded to the results of the first and second screening by MB11 BERAphone® under standard conditions.

The procedure of the test was explained to the mothers/carers and once the neonate was comfortable, dry, breast fed and naturally sleeping the infant was placed in a secure area for testing. The skin for electrode application was prepared by carefully cleaning and mildly abrading the skin. The positive 'non-inverting' electrode was placed on the vertex at the midline and the negative 'inverting' electrode was placed on the mastoid. The ground electrode was placed on the opposite ear. It was ensured that the electrode impedance was kept to a minimum (< 5 kOhms).

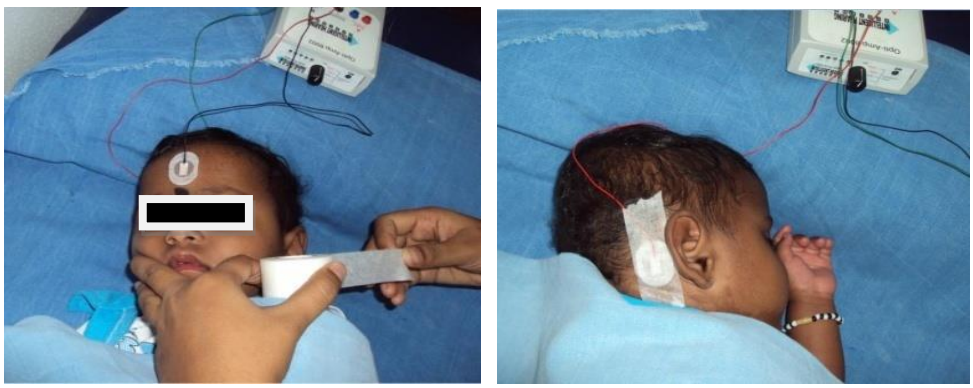


Fig 19: Confirmatory testing by ABR

The signal was delivered through insert earphones. The stimulus used was a click signal which was presented at various intensities to obtain the air conduction threshold of the ear. The threshold of hearing is taken as the lowest intensity at which repeatable wave V becomes visible on ABR tracing.

The ambient sound level was tested in the ward the Audiology room and the ABR room with sound level meter CENTER 322 - Sound Level Meter (Data logger) Center Technology Corp, Victoria, Australia..

Fig 20 Sound Level Meter (Data logger)

The data presented in the first screening was collected in the prenatal ward as part of the newborn hearing screening program. This protocol till now is the normal standard of practice offered to the patients.The results of the history and examination were recorded and evaluated at the end of the study. The analysis of the second screening was maintained separately in the department of audiology and a separate register maintained for the ABR confirmatory tests. At the end of the study period, the results were finally compared and the analysis was done by the study physician.

Statistical analysis:

The data of all the patients was collected systematically using the software EPIDATA version 3.1. All statistical analysis was performed using statistical software STATA (version 10.0), STATA corporation, Texas, USA. The sensitivity, specificity, positive and negative predictive values were calculated using this software.

RESULTS

Of the 37 newborns screened during the 13 month period 23(62.2%) were males and 14(37.8%)were

females

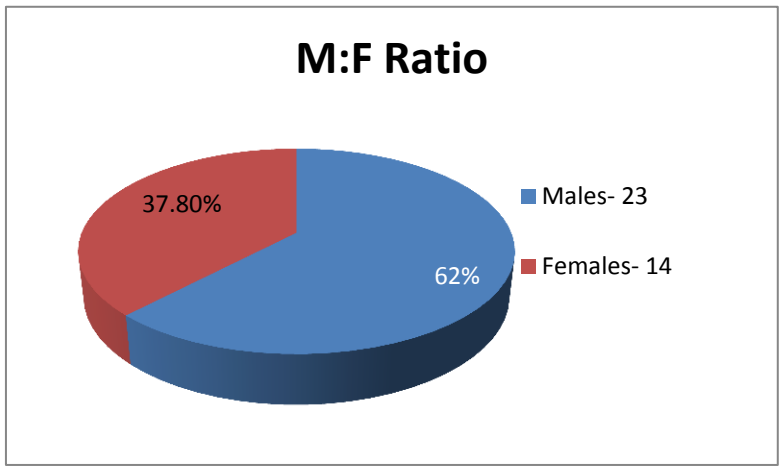


Fig 21: Male and female ratio of the study population

Prenatal variables

a) Consanguinity

Among the total of 37 neonates (100%), 8 neonates (21.6%) were born of consanguineous marriage and 29(78.3%) of non-consanguineous marriage. Among the 8 neonates of consanguineous marriage, 5 (23.3%) neonates were bilaterally referred, and 3(19.4%) showed bilateral pass in the second BERAphone screening. Among them only one neonate was a confirmed case of bilateral hearing loss. There was no difference in the proportion of 'PASS' and 'REFER' among the consanguineous group of neonates.

From the 29 neonates born out of non consanguineous marriage, 23 (79.3%) were 'Referred' and 7(24.1%) from them showed confirmed hearing loss.

b) Parity

Out of the 37(100%) neonates in the study, 17 mothers were primigravida and 20 were multigravida. 8 neonates of primigravida mothers showed 'REFERRAL' and 3 of them were confirmed to have hearing loss. Among the neonates of multiparous mothers 19 were "REFERRED', 3 of them were confirmed to have hearing loss.

c) Gestational age

Gestational ages at birth of all the newborns recruited in this study were above 36 weeks of gestation and hence all the study newborns were within the accepted normal gestational period and were not born preterm.

Prenatal Risk factors

Two mothers had associated maternal risk factors.(Table 6)

Risk factors	Present	%	Absent	%	Total
Maternal Diabetes	2	5.4%	35	94.6%	37
Hypothyroidism	1	2.7%	36	97.3%	37
TORCH	0	0	37	100%	37
Ototoxic drugs	0	0	37	100%	37
Others	0	0	37	100%	37
Total ears					74 ears

Table 6: **Prenatal risk factors and the screening outcome.**

One mother had maternal diabetes and hypothyroidism and underwent delivery by Caesarean section. The neonate of this mother showed bilateral 'referral' in the second screening and hearing loss was confirmed in the left ear by ABR. Another mother had maternal diabetes. The second screening for this neonate showed bilateral 'referral' and bilateral hearing loss was confirmed by ABR.

Perinatal variables

Table 7 shows the list of various perinatal risk factors. Of the 37 neonates in the study 3 neonates had birth weight <2.5kg, all 3 showed confirmed hearing loss. There were12 neonates born by LSCS of these 9 neonates were 'referred' of these 4 neonates had confirmed hearing loss and rest of the 8 showed normal hearing. Among the other risk factors two had neonatal jaundice, one had seizure and one infant had bacterial infection. From these, 3 were 'REFERRED', but only one had confirmed hearing loss.

	Frequency no	Ref %	Second Screening 'Refer	ABR HL
Apgar <7	0	0		
BT Wt- <2.5kg	3	7 %	3	3
Instrumental delivery	12	32.4%	9	4
Bacterial Infection	1	2.7%	0	0
Jaundice	2	5.4%	2	1
Seizures	1	2.7%	1	0
Aspiration	0	0	0	0
Meconium aspiration	0	0	0	0
Meningitis	0	0	0	0
Ototoxic drugs	0	0	0	0
NICU	0	0	0	0
Total	**19**		**16**	**8**

Table 7: Perinatal risk factors and confirmed hearing loss

Among the total of 19 neonates with perinatal risk factors, eight of them had hearing loss.

First and second screening results

The first screening consisted of all 37 neonates that were 'Referred' and recruited in the study which make up a total of 74 ears. Of these 13 (35.10%) infants had bilateral 'REFERAL' and 24(64.80%) neonates had unilateral 'referral'. All of them were subjected to the second BERAphone screening.

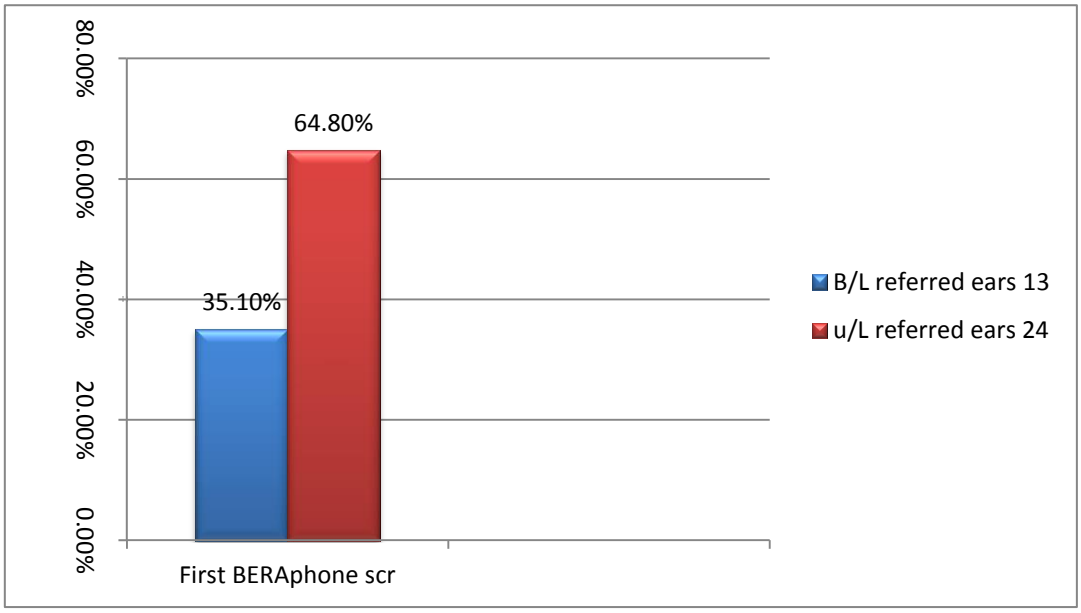


Fig: 22. Results of ears tested in first screening

The 37 newborns who participated in the second stage of the screening process provided 74 ears for comparative testing against the ABR. Of the 74 ears of newborns referred for the second stage screening, 31(41.9%) ears passed and 43 (58.1%) ears were referred again. Therefore the pass rate for the second screening was 41.9 % and the referral rate was 58.1 % (Fig 24).

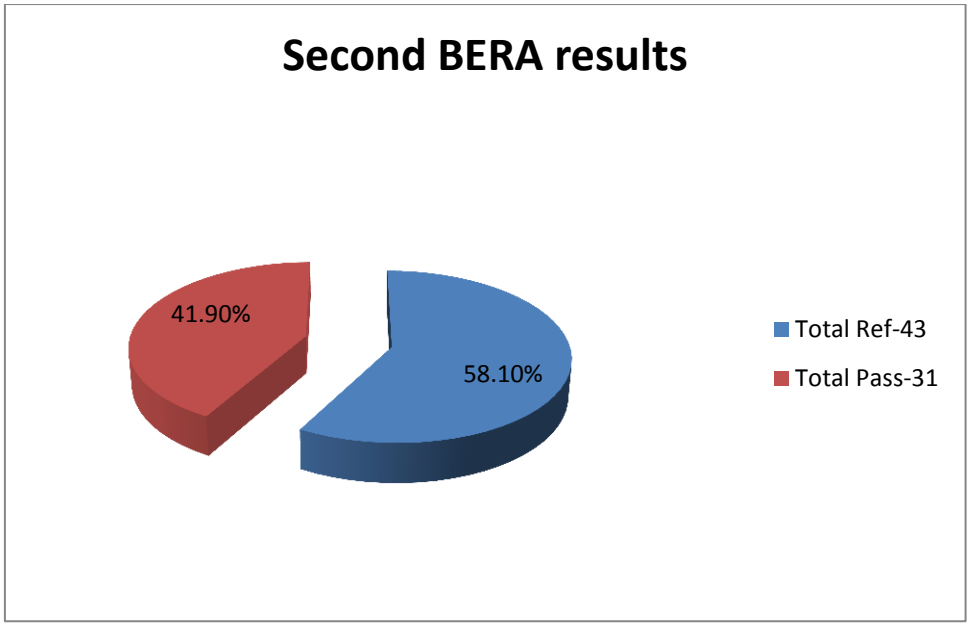


Fig 23: Second BERAphone screening results

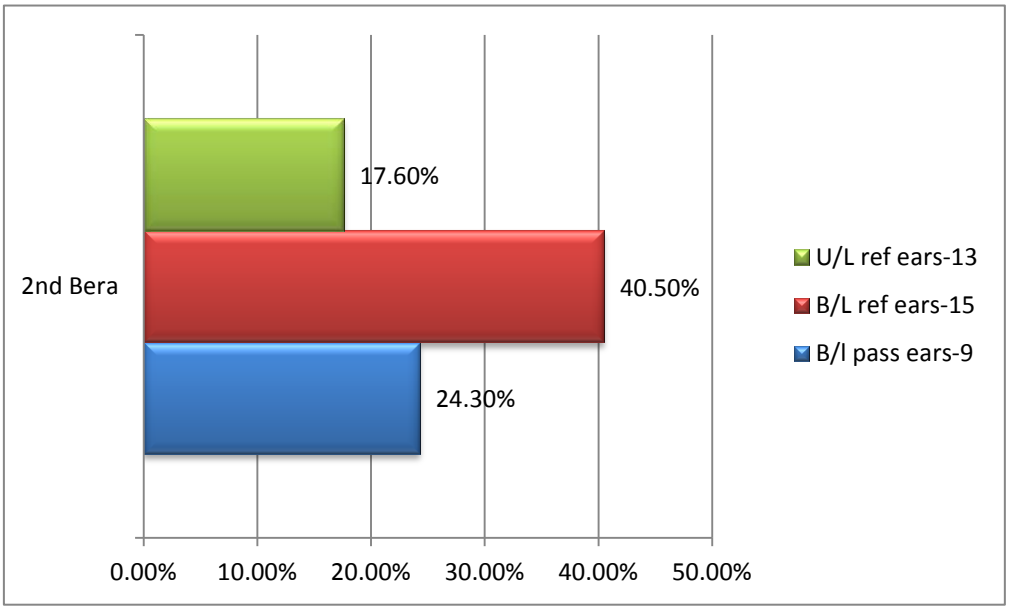


Figure 24: Number and percentage of ears that were bilaterally and unilaterally referred at second referral.

At the second screening 15 infants showed bilateral 'REFER', 13 infants showed unilateral 'REFER' and 9 infants have shown bilateral 'PASS'

ABR Confirmation of hearing loss

On confirmatory testing by ABR, of the 74 ears tested, 14 ears (18.9%) had confirmed hearing loss and 60 ears (81.1%) were normal which represents a percentage of confirmed hearing loss of 18.9% and a pass level of 81.1%. (Fig 24)

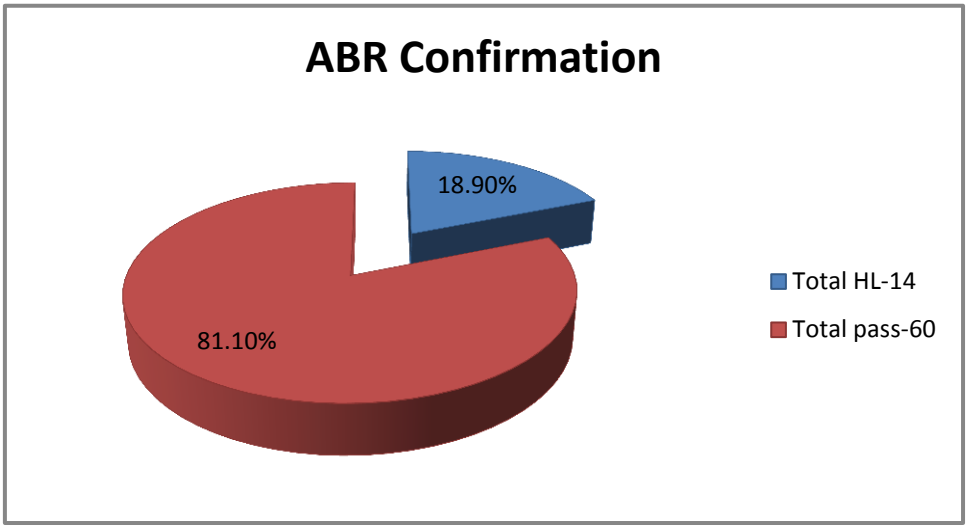


Fig 25:ABR confirmation of total Hearing loss

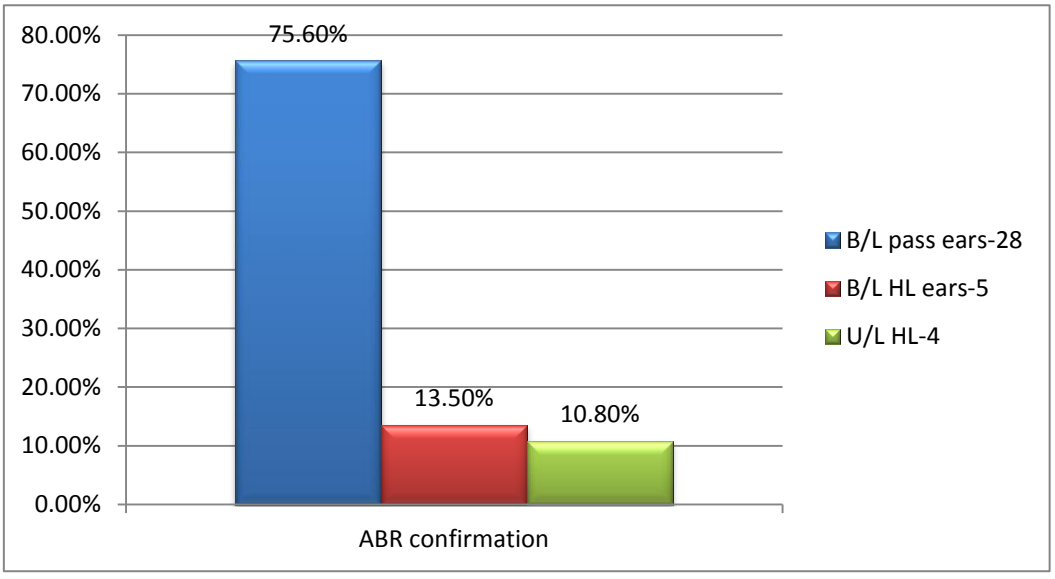


Fig 26: ABR confirmation of unilateral and bilateral hearing loss

ABR confirmation showed that of the 9 neonates with hearing loss, 5 neonates had bilateral impairment and 4 neonates had a unilateral impairment.

Sensitivity, Specificity, PPV NPV for BERA2 with ABR

	ABR Hearing loss	ABR Pass	Total
BERAphone 'Refer'	13 **92.9%**	30 50.0%	43 58.1%
BERAphone 'Pass'	1 7.1%	30 **50.0%**	31 41.9%
	14	60	74 100%

Table 8: BERAphone second screening with ABR confirmation

The purpose of the study was to calculate the specificity and sensitivity of the neonatal screening tool MB11 BERAphone® (Maico diagnostic, Germany) when used in the ward setting. The table 8 shows the results of second BERAphone when confirmed with ABR.

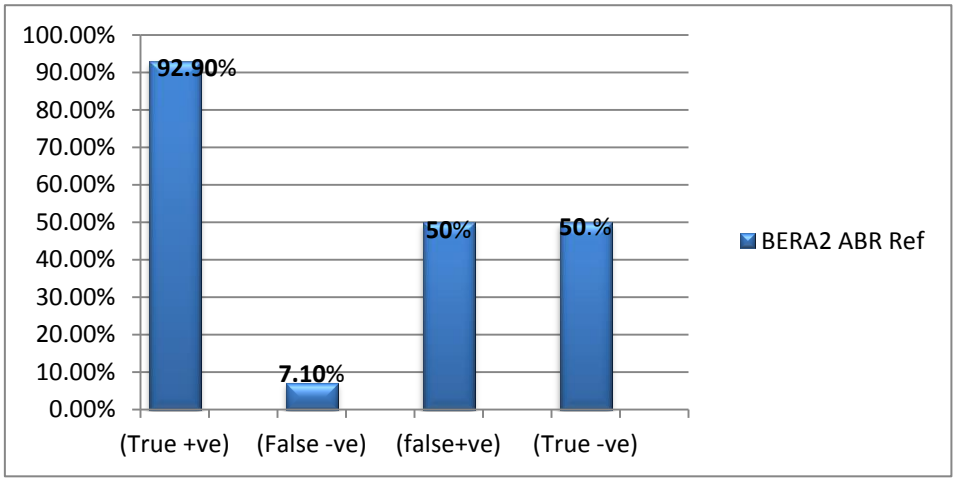


Fig 27: Showing true and false positive and negative test results

The test results show 93% were true positives and 50% were true negatives. 50% showed false positive results with the second screening and 7% showed false negative result.

	ABR Referred	ABR Pass	Total
BERA Referred	13 (a)	30 (b)	43
BERA Pass	1 (c)	30 (d)	31
Total	14	60	74
Sensitivity	93%		
Specificity	50%		
Positive predictive value	30%		
Negative predictive value	97%		
Prevalence	18%		

Table 9: Sensitivity, Specificity, Positive and n-Negative predictive values.

Sensitivity means “the ability of the test to identify correctly those who have the disease” and specificity indicates “the ability of the test to identify correctly those who do not have the disease”

The sensitivity and specificity were calculated by using the formulae sensitivity=a/a+c(true positives/disease) and specificity=d/b+d(true negatives).

1. **Sensitivity of BERAphone** in detecting congenital hearing loss in infants in the ward setting

Sensitivity = $\frac{13}{14} \times 100 \ = 92.6\%$

Sensitivity of BERAphone 93% (95% CI: **66.06 %** to **98.81 %)**

2. **Specificity of BERAphone** in the infants in the ward setting

Specificity = $\frac{30}{60} \times 100 \ = 50\%$

Specificity of BERA 50 %(95% CI: **36.81 %** to **63.19 %)**

The sensitivity of a 2 stage screening with BERAphone was 93% while its specificity was 50%.

3. Positive predictive value of BERAphone (PPV)

PPV = $\frac{13}{43} \times 100 = 30.23\%$

PPV = **30.23**% (95% CI: 17.20 % to 46.13 %)

The positive predictive value of the 2 stage BERAphone screening was 30%

4. Negative predictive value of BERAphone (NPV)

NPV = $\frac{30}{31} \times 100 = 96.77\%$

NPV = 96.77% (95% CI: **83.24 %** to **99.46 %)**

Negative predictive value was 97%, compared to the ABR (Table 9).

The prevalence of hearing loss in this study group was 14/74, = **18.9%.(19%)**

The diagnostic results in Table 9 shows that of the 28 neonates (43 ears) who failed the 2nd stage screening, 9 neonates were confirmed with ABR as having a hearing impairment which required intervention. Of these 5 neonates had a bilateral impairment and 4 neonates had a unilateral impairment.

The remaining 28 neonates were found to have bilaterally normal hearing after confirmation.

The MB11 BERAphone screening yielded 1 false negative (7.1%) and 30 false positives (50%). Efficacy of MB11 showed a sensitivity of 92.9% and a specificity of 50%. The positive predictive value (PPV) was **30.23**% (95% CI: 17.20 % to 46.13 %) and negative predictive value (NPV) was **96.77**% (95% CI: **83.24 %** to **99.46 %)** for the diagnosis of hearing loss.

Hearing loss

The observed prevalence of confirmed hearing impairment was 18.9%. The rate of unilateral impairment was 10.8% and the rate of bilateral impairment was 13.5%

Discussion

Several estimates have shown that the prevalence of hearing loss in the newborn population varies from 0.9 in 1000 to 3.24 in 1000 (51). More than 10 infants in every 1000 births in the developing countries are estimated to be affected by severe to profound hearing loss.(40)

In India 4 out of every 1000 children born were found to have severe to profound hearing loss(53)(80). The National Sample Survey shows that the prevalence of hearing disability per 1000 population in India was 5.53 in rural and 3.90 in urban areas(80). Other studies have shown various prevalence rates from 1%, to as high as 40%.(80) According to Parmod Kalsotra et al congenital hearing impairment affects 1.8% of the population of India(57).

Even with such high prevalence rates of hearing loss in India there is no dedicated national screening programme in India(57) (45). Although 'a universal newborn screening' for early identification of hearing loss among infants had been recommended by the 'National Institutes of Health Consensus Development Conference'(52), it is yet to be established in India.

Nikam and Dharamraj et al(52) attempted an infant hearing screening programme in 1971 and Basvaraj et al. in 1984, carried out the screening for hearing impairment in Bangalore. (52)

Paul AK has initiated the screening programme in cochin in 2011.(77)

Ideally, ABR is the method of choice for hearing screening of infants less than 5 months of age.

Hall et al. have reported in his study a specificity and sensitivity rate in excess of 96% for ABR screening in newborns.(73) However, due to certain drawbacks like high cost, difficult transportation of instrument, long execution time, and the need for qualified personnel to interpret the result, ABR implementation is impractical. As per the Joint Committee of Infant Hearing (JCIH) recommendations the hearing assessment for the newborn is undertaken by screening programmes using Otoaccoustic emissions (OAE) and Auditory Brainstem Response audiometry (ABR) where both methods are automated. (73)

Cebulla M et al, have shown that Maico MB11 BERAphone® is a reliable device for auditory brainstem response screening for the newborn and in addition it provides the results within a very short time.(75) It also has a high sensitivity and a low failure rate, and has the advantage of detecting hearing defects such as auditory neuropathy (AN).(7) The test is relatively quick, non-invasive and does not require sedation which makes the test tolerable for the babies and agreeable to parents. It has also been recommended by the "American Speech –Language Hearing Association Guidelines for Audiologic Assessments of Children as the method of choice for hearing screening in infants less than 5 months of age.(2) Therefore screening with Maico MB11 BERAphone (®) had been the method of choice in this study

The average number of live babies born per month in Christian Medical College Hospital (CMCH) during the period of study from October2012 had been 1107. Considering the large numbers, implementation of the 'universal screening programme' in the ideal setting (sound treated room) was not possible; hence the screening was undertaken in the neonatal ward setting where the average ambient noise levels is around 62.1 dB.

Studies by Van Straaten HL et al also showed that the screening test can be used in the ward setting without disturbance from ambient noise and during oxygen therapy (66)

A two stage sequential screening with BERAphone as recommended by the Joint committee report and which is a standard protocol of screening in CMCH was performed since October 2012, to overcome the false positive results that would occur due to vernix and fluid present in the ears.

The first screening was performed by well trained technicians, in the post natal ward where the noise conditions are typically higher than in an acoustically shielded room(Fig 15). The results showed that out of the 37 neonates screened 23 of them were males and 14 were females. Statistical significance was not found between the sex ratio in relation to hearing loss in accordance with the study by Bener et al.(81)

Consanguinity: Eight neonates (21.6%) under the study were born of consanguineous marriage and 29(78.3%) of non-consanguineous marriage. Among the 8 neonates of consanguineous marriage, 5 (23.3%) neonates were bilateral refer, and 3 (19.4%) showed bilateral pass in the second BERAphone screening. Among them only one infant was a confirmed case of bilateral hearing loss. There was no significant difference in the proportion of 'PASS' and 'REFER' among the consanguineous group of infants. From the 29 neonates born out of non consanguineous marriage, 23 neonates (79.3%) were 'Referred' and 7(24.1%) of them showed confirmed hearing loss.

According to the study by Bener et al done in Qatar, hearing loss was more common among parents with first or second degree consanguinity (81). This association was not seen in our study probably due to the small number of infants of consanguineous marriage who underwent the screening.

With regard to parity, out of the 37(100%) neonates in the study, 17 mothers were primigravida and 20 were multigravida. 8 neonates of primigravida mothers showed 'Refer' and 3 (17.6%) of them were confirmed with hearing loss. Among the neonates of multiparous mothers 19 were 'Referred' and 3 (15%) of them were confirmed with hearing loss. The association between parity and hearing loss was not significant.

The study showed that gestational age at birth of the infants was above 36 weeks and hence all the neonates under the study were not preterm newborns.

Two mothers had associated maternal risk factors. One had maternal diabetes and hypothyroidism and underwent delivery by Caesarean section. Another mother had maternal diabetes. Neonates of both the mothers with risk factors showed confirmed hearing loss.

A study by Ohl C, et al on newborn hearing screening showed that association of several risk factors could be a significant additional risk factor for hearing impairment.(82)

Our study show 100% association with the maternal risk factor diabetes , however our sample size is too small (i.e. 2 mothers only) to consider the association significant.

Table 7 shows various perinatal variables assessed in the study. Of the 3 neonates with birth weight <2.5kg, all 3 showed confirmed hearing loss. Ohl C, et al in their study also showed that birth weight less than 1500g and premature birth before the 34^{th} week of pregnancy did not show a statistically significant association with sensorineural hearing loss. (82) There were 12 neonates born of LSCS. Of these 9 neonates were 'referred'; among them 4 neonates had confirmed hearing loss and rest of the 8 showed normal hearing.

Bener et al (81)showed in his study that family history of hearing loss and other risk factors like, prenatal smoking, prenatal high blood pressure and caesarean section did not show any significant association with neonatal hearing loss. (81)

Among the other risk factors two had neonatal jaundice, one had seizure and one infant had bacterial infection. From these, 3 were 'Referred', but only one had confirmed hearing loss.

Sanders et al showed that 2 to 4% of neonates with one or more risk factors such as birth asphyxia, hyperbilirubinemia, prolonged NICU stay, low birth weight, in-utero TORCH infections etc. exhibit a moderate to profound hearing loss. (83)(84)

A Study by Hille ET et a(85)revealed that severe birth asphyxia was the only independent risk factors for hearing loss seen in their study.(85)

Many authors suggest that 'hereditary' causes approximately one half of sensorineural hearing loss in children (86)(44). Similarly, one study showed that more than 50 percent of hearing impairment in children is genetic in origin and was unrelated to non-inherited causes, infections and anatomic abnormality [6].

In our study only normal infants were recruited (infants with congenital anomalies were excluded). While craniofacial anomalies (mostly cleft palate and ear aplasia) were a significant factor for conductive hearing loss(82), such infants were not included in our study.

In our study we followed a two step protocol for screening. The first screening sample included a total of 37 infants who have been referred once which made up to a sample size of 74 ears**.** All the infants were subjected to the second BERAphone screening.

Clemens et al. (75) had published the results of a survey investigating this issue where all the infants were subjected to the second screening. (75) The main goal is to decrease the false-positive results of the first screening so that stress caused by a referral for further testing to the parents is minimized. This in turn will reduce the costs incurred by the second stage screening and further diagnostic tests.

Mario Cebulla et al (75) showed in their study that the pass rate in the first stage of the hearing screening performed at the well-baby nursery was 96.2%(75).

A two step protocol had been followed which was similar to many studies. Benito-Orejas JI, et al(87), followed a two step screening protocol where the first screening was undertaken during the first 48 hours of life, before discharge from the hospital and the infants referred from the first screening underwent a second screening after discharge, before one month .

They showed that aABR gave 2.6% failed results in the first screening and in the second screening step, 0.32% of those screened with aABR were referred.(87)

Another study by Lin HC et al (88)showed a significant reduction in referral rate using a two step protocol. The referral rate of 5.8% in the first screening came down to 1.8% in the second screening. The rate of congenital hearing loss in the 1 step protocol was 0.45% and 0.3% in the 2 step protocol (88)

Another study by Iley KL et al (89)concluded that the adoption of aABR as an initial screening is less expensive ,more practical, and acceptable to the parents.(89)

The second screening of infants who have been 'referred' in the first screening was done after a period of one week in a sound treated room in the department of Audiology with an ambient sound level of 44 dB. We have adopted this approach of performing the

second screening after a week since an earlier study shows a large number of drop outs when there was a delay in the second screening.

Mathur et al (90)suggests that screening all neonates within the first 48 hours of life is impractical and that it should be delayed upto three months of age(90). However in our study the second screening could be completed as per the protocol.

Of the 74 ears of newborns referred for the second stage screening, 31(41.9%) ears passed and 43 (58.1%) ears were referred again. Therefore the pass rate for the second screening was 41.9 % and the referral rate was 58.1 % (Fig 23). According to study by Mario Cebulla et al second stage hearing screening in the Department of Audiology showed that 27.4% passed and 72.6% referred again. (75)

Our study showed one neonate with a false negative result (7.1%) and 15 neonates had false positive results (50%) which is high compared to various studies. Stewart DL (91)showed that the refer rate using universal hearing screening with the aABR was acceptably low < 2% and the false-positive rate was between 0.3% to 2.5% although it was performed by various personnel and the total incidence of confirmed SNHL was 2.7 per thousand newborns.(91)

Another study done by Lin HC et al(92) showed that screening with BERAphone reduced the number of false positives where the rate of congenital hearing loss was 0.42% in aABR protocol(92). Thus using screening tools like BERAphone helped in the reduction of false positives. Our study showed 50% of false positives.

All the infants who underwent the second screening were subjected to the confirmation test by ABR which enabled the assessment of the sensitivity (True positive) and specificity (True negative) of the test.

ABR Confirmation

On confirmatory testing by ABR, of the 74 ears tested, 14 ears (18.9%) had confirmed hearing loss and 60 ears (81.1%) were normal which represents a percentage of confirmed hearing loss of 18.9% and a pass level of 81.1%. (Fig 25).

ABR confirmation showed that of the 9 neonates with hearing loss, 5 neonates had bilateral impairment and 4 neonates had a unilateral impairment. The remaining 28 newborns were found to have bilaterally normal hearing.

The MB11 test yielded 1 false negative(7.1%) and 30 false positives(50%). As per the study the Efficacy of MB11 showed

Sensitivity of - **92.9%** (95% CI: **66.06 %** to **98.81 %**)

Specificity of - **50%** (95% CI: **36.81 %** to **63.19 %**)

The positive predictive value was **30.23 %** %(95% CI: **17.20 %** to **46.13 %**) and negative predictive value was **96.77%** (95% CI: **83.24 %** to **99.46 %)** for the diagnosis of hearing loss.

Confirmed Hearing loss

From our study the observed prevalence of confirmed hearing impairment was 18.9%. The rate of unilateral impairment was 10.8% and the rate of bilateral impairment was 13.5%. All the 9 infants with confirmed hearing loss have been put on regular follow up.

Our study confirms the manufacturer's claim that the test has a sensitivity greater than 0.96.(7) but does not correspond to the claimed specificity of greater than 0.99.

Several studies have been reported with the use of BERAphone® as a screening devise. Van Straaten et al. reported a 92% pass and 98% pass after the after the first and second screening using automated ABR (66)

A study of comparison of currently available newborn hearing screening devices in 2004 by Meier S et al(76) showed that pass rates were highest (98%) for aABR recordings using the Algo 3 and lowest (92%) for aABR recordings using the Beraphone MB11, although there was no statistically significance in the differences among them.(76) A study by Melagrana A et al (79)of newborns who were evaluated after the second month of life showed that the MB11 test had no false negatives but had yielded 10 false positives .

The MB11 test showed a good specificity of 96.8% (95% CI 94.8-98.7%) and a sensitivity of 100% (95% CI 93.9-100%). The positive predictive value was 88.2% (95% CI 79-93.9%) and a negative predictive value was 100% (95% CI 98.4-100%) for diagnosis of hearing loss.(79)

However our results showed a sensitivity of - **92.9%** (95% CI: **66.06 %** to **98.81 %**), specificity of - **50%** (95% CI: **36.81 %** to **63.19 %),** positive predictive value of **30.23 %** (95% CI: **17.20 %** to **46.13 %**) and negative predictive value of **96.77 %** (95% CI: **83.24 %** to **99.46 %)** for the diagnosis of hearing loss using the MB11 BERAphone in the postnatal ward setting.

Although studies have been done using different screening protocols under quiet conditions, few studies have been reported from developing countries where the screening tool is used in the ward setting due to high volume of deliveries. This makes

our study unique because this testing was performed in the ward in the presence of ambient noise.

One study by Richmond et al(93) has indicated that ambient noise levels can cause alteration in the screening results of the infants.(93) Therefore this study would provide an index for future screening in such environment.

Our study shows a higher prevalence of hearing loss than that reported in the literature. This value is seen after the confirmation with the gold standard screening with ABR. The reason for the high prevalence can be attributed to the fact that only newborns who were 'referred' on the first screening were recruited for the study.

Bansal et al (94) in his study suggested a delayed hearing screening at 3 months of age which would bring down the number of false positive cases and that the implementation of the universal neonatal hearing screening within 48h of life was impractical for developing countries. He also suggested in the study that the screening be combined with 3rd dose of universal immunization program which can be incorporated into national deafness programs in the developing countries.(94) Olusanya et al in their study also suggests that in developing countries hearing screening programs are practical if integrated into childhood immunization programs.(95) While screening the infants along with the immunization programme in a novel approach in developing countries, delay of the screening to 3 months would miss out on early identification and rehabilitation.

Good screening tests have high sensitivity and the two stage screening with BERAphone has shown high sensitivity. Those tests with very high sensitivity are useful "to rule out" diseases or characteristics if they come back negative. On the other hand good

confirmatory tests have high specificity and two stage screening with BERAphone has shown a low specificity. High specificity is useful “to rule in” diseases or characteristics if they come back positive. Both sensitivity and specificity are intrinsic properties of a given test which do not depend on the given population. Positive and negative predictive values however are dependent on the prevalence rate of the characteristic in a given population. The rarer the characteristic, the lower the positive predictive value and the higher the negative predictive value. The two stage screening protocol with BERAphone has a low positive predictive value and a high negative predictive value. The prevalence of hearing loss in the study group (13/74) was 18.9%. The BERAphone would have had a higher positive predictive value had the prevalence been higher i.e in a situation with a higher prevalence (eg NICU). In such situations BERAphone would be a useful screening tool. A third round of screening with BERAphone may have improved the predictive value of this instrument and this would have to be the subject of a future study.

Summary

Hearing loss is a silent crippling sensory disorder of childhood. If left undiagnosed it can result in speech, hearing and communication problems. Early detection through screening as recommended in the universal screening protocol is mandatory.

The present study was done to evaluate the effectiveness of the screening tool BERAphone when it is used to screen high volumes of babies in the natural ward setting with background noise. Our study had used the updated version of the MB 11 device which is known to increase the amplitude of the ABR response using a chirp stimulus. These studies were carried out on healthy newborns who did not present with any particular audiologic risk factors within the first days of life.

The present report shows the data analysis from 37 newborns screened using the MB11 BERAphone® as a screening tool. The first stage of the two staged hearing screening was performed in the postnatal ward and the second stage in the audiology lab. After the two stage screening the pass rate was 41.9% and the referral rate was 58.1%. The screening tool BERAphone showed a sensitivity of 92.86%, a specificity of 50%, positive predictive value of 30.23 % and negative predictive value 96.77% for the diagnosis of hearing loss.

The results that were obtained show that MB11 is a good screening tool among infants and can be used as a first level diagnostic tool for suspected hearing loss but must be verified with Auditory Brainstem Response (ABR) which is the “gold standard” test essential to a correct neonatal screening programme.

Conclusion

From our experience, the MB11 BERAphone® is a reliable device for use in a two stage newborn hearing screening based on auditory brainstem response. It gives good results within a very short time with minimal cost of materials since no disposables are necessary to be used compared to other ABR screening devices. Due to the implemented automated detection algorithm for ABR, the device is suitable for use by trained technicians in a post natal environment.

The machine shows good specificity as predicted where it is able to identify those who do not have the disease but it has a low sensitivity than expected when used in the ward setting with surrounding high ambient noise. Thus it must be used along with a confirmatory test like ABR to establish hearing loss.

Disclaimer:

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Appendix

PARENTS INFORMED CONSENT FORM TO PARTICIPATE IN A RESEARCH STUDY

Study Title: **SENSITIVITY AND SPECIFICITY OF BERAPHONE® AS A SCREENING TOOL FOR NEONATAL HEARING LOSS IN A TERTIARY CARE HOSPITAL IN INDIA**

Study Number:8052

Hospital No:

Subject's Name: _____ Mother's name_____

Date of Birth / Age:_____

I the mother /close relative confirm that I have read and understood the information sheet dated _____ for the above study and have had the opportunity to ask questions. [ ]

(ii)I have been informed that the Neonatal Hearing Screening is done for all the babies born in CMCH. Hence the current research involves testing the babies for hearing problems from the time of birth. I am aware that my baby may be enrolled in the 2 step hearing screening.

(iii) I understand that my participation in the study is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected. [ ]

(iv) I understand that the Sponsor of the clinical trial, others working on the Sponsor's behalf, the Ethics Committee and the regulatory authorities will not need my permission to look at my health records both in respect of the current study and any further research that may be conducted in relation to it, even if I withdraw from the trial. I agree to this access. However, I understand that my baby's identity will not be revealed in any information released to third parties or published. [ ]

(v) I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific purpose(s) [ ]

(vi) I agree to take part in the above study. [ ]

Signature (or Thumb impression) of the Subject/Legally Acceptable Representative:_____

Date: _____/_____/_____

Signature of the Investigator: _____

Date: _____/_____/_____

Study Investigator's Name: _____

Signature of the Witness: _____

Date:_____/_____/_____

Name of the Witness: _____

PATIENT INFORMATION SHEET

Hearing is a special ability that develops in the womb before the child is born. After birth the child develops speech and language in the first 3 years of life which is very important for the development of communication, and educational skills.

It is estimated that 4 out of every 1000 children born in India have hearing loss in spite of the parents having no hearing problems. Unless the hearing loss is detected early and appropriately treated by the age of one year, the child may develop speech and language defects which in turn can limit communication and learning.

Screening of newborn babies for hearing impairment is done routinely at an early age in many parts of the world in order to detect hearing loss and initiate appropriate rehabilitation.

In CMCH hearing screening is being carried out for all babies born in the hospital for the past two years. The test is done using an instrument called 'BERAphone'.

The first test is done within 1-2 days after the delivery. During the test, the earphones of the machine are placed over your child's ear at the bed side. The instrument produces a series of soft click sounds and records the response to these sounds from the brain. After analysing these responses the machine produce a **'pass'** result if the hearing is normal or a '**refer**' result if there is a suspicion of hearing loss.

For babies who obtain a 'refer' result on the first screening test, a second screening will be done after one week in the audiology lab and those babies will be examined by an ENT specialist' on the same day. Following this certain specialized tests called 'Tympanometry' (to find out about the condition of the middle ear) and a reliable standard hearing test called ABR is done to confirm the results of the previous screening tests. If hearing loss is present after the second testing the babies are booked in the 'Audiovestibular clinic' where evaluation and appropriate methods for rehabilitation will be suggested.

These tests done on your baby will not cause any pain, reaction or harm. The test will have the best results when the child is sleeping after feeds

During the course of this routine testing a special study is being done to find out the accuracy of the machine (BERAphone) which is used for screening new born babies.

There are no risks involved in this study. You will not have to bear any additional costs as a result of enrolling in the study apart from the cost of routine tests. .

Your participation in this study is purely voluntary and you can withdraw from this study at any time you feel so. This will not compromise your treatment at ENT department. Your participation in the study will remain confidential and the results of the tests conducted on your baby will not be disclosed to others. For any queries you can contact:

Dr Chavakula Rajkumar

PG Registrar

Dept. of ENT,

CMC Vellore, Mob: 08344041008

Proforma for Neonatal Hearing Screening

Mother's Name_____ Mo.Hosp.No _____

Baby's Hosp No._____

FAMILY HISTORY

Consanguinity: Yes No

S. No	Age	Sex	About child	Educational level	Present occupation	Special needs	Illnesses

H /o Speech delay, Hearing insufficiency, Visual insufficiency, poor scholastic performance in :

i. Father ii. Paternal grandparents iii. Siblings

iv. Mother v. Maternal grandparents vi. Others Yes No Dk

Neurofibromatosis Yes No Dk

White forelock Yes No Dk

Blindness Yes No Dk

Cardiac diseases Yes No Dk

Specify:

Renal disease Yes No Dk

Short neck Yes No Dk

Other disease Yes No Dk

Specify:

ANTENATAL HISTORY

TORCHES/HIV Infection at

_____ months of pregnancy

Yes No

1-3 4-7 8-10 (encircle)

(fever with rash + joint pains + lymphnode enlargement)

H/o Diabetes Yes No

H/o Hypothyroidism Yes No

H/o ototoxic drug (aminoglycosides, frusemide)

usage by mother for > 3 days during pregnancy Yes No Dk

H/o Other illness Yes No Dk

Specify:

PERINATAL HISTORY

Date of Birth ___/___/_____ Date of Examination___/___/_____

Birth Weight _____ gm Gest Age: _____ weeks

Sex: Male / Female

APGAR: 1'_____ 5'_____10'_____

(1) Labour > 24 hours Yes No

(2) Neonatal Asph yxia Yes No

Respiratory distress Yes No

Meconium aspiration Yes No

(5) Neonatal bacterial infections Yes No

(6) Meningitis Yes No

(7) Hyperbilirubinemia Yes No

(8) Seizures Yes No

(9) SGA/?Suspected TORCH Yes No

(Check for IgM test on the patient order sheet)

(10) Ventilatory support > 48 hours Yes No

(11) Ototoxic medication (gentamycin, frusamide) Yes No

(12) Exchange transfusion Yes No

Dysmorphic features (please describe if any)

Face

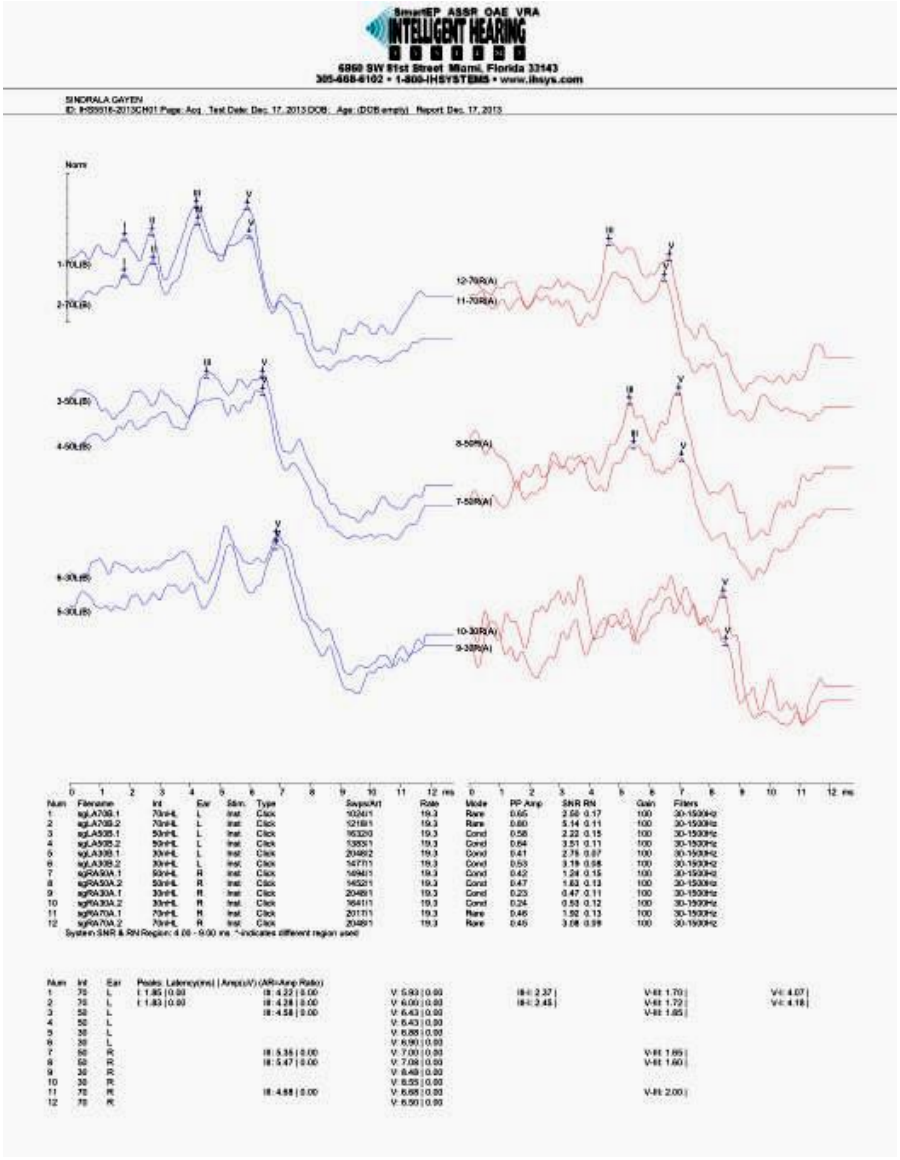
Trunk

Limbs

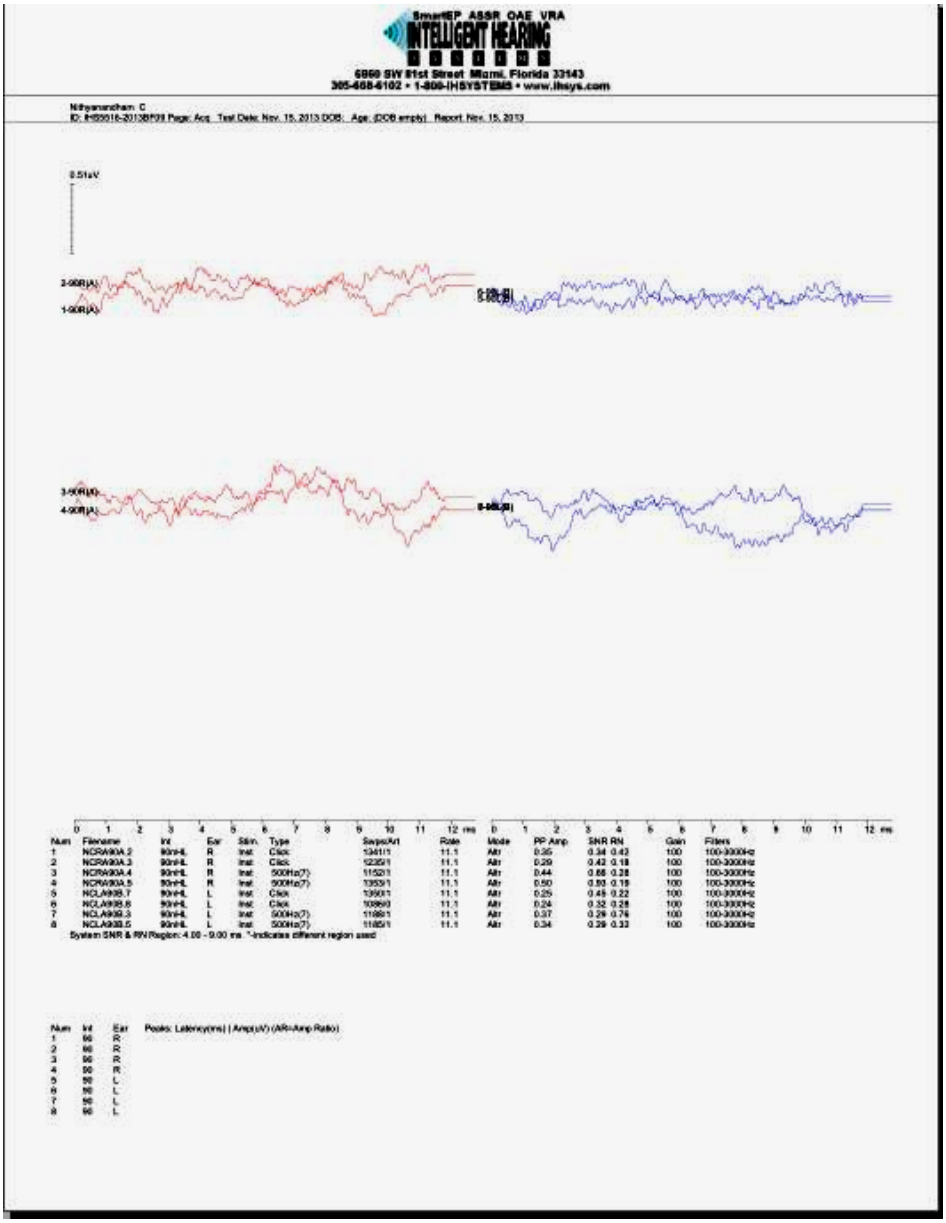
Genitalia

Skin Other

COLOUR PLATES



Colour plate1: ABR report with normal hearing



Colour plate 2:: ABR report with Bilateral hearing los

Colour plate 3: BERAphone unit

Colour plate 4right ear ‘Pass’ result with BERAphone

Colour plate 6: Right ear 'Refer result' with BERAphone

Colour plate8: Left Ear 'Pass' Result with BERAphone

Colour plate 8: Left ear ‘Refer’ result with BERAphone

DATA SHEET - 1

srno	place	con	cage	csex	cdob	cbwight	cascore1	cascore5	dbp1	rdbp1	ldbp1	dbp2	rdbp2	ldbp2
1	Vellore	1	new born	2	10/7/2012	2.53	9	10	10/8/2012	ref-25%	ref	10/16/2012	ref-25%	ref
2	vellore	0	new born	1	10/12/2012	3.48	9	10	11/13/2012	ref	ref	11/7/2012	ref	ref
3	Vellore	1	new born	1	10/9/2012	2.1	9	10	10/10/2012	ref	pass	11/5/2012	pass	pass
4	Chittor	0	new born	2	10/4/2012	3.52	9	10	12/5/2012	pass	ref	11/7/2012	ref	ref
5	Chennai	0	new born	2	2/13/2013	2.54	9	10	2/14/2013	pass	ref	3/6/2013	ref	pass
6	Vellore	0	new born	1	1/10/2013	2.64	9	10	1/11/2013	ref	pass	1/31/2013	pass	pass
7	Vellore	0	new born	1	2/14/2013	3.19	9	10	2/15/2013	ref	ref	3/14/2013	ref	pass
8	Vellore	0	new born	2	3/1/2013	3.4	7	9	3/3/2013	pass	ref	3/20/2013	ref	ref
9	Meghalaya	0	new born	1	1/9/2013	2.9	9	9	1/10/2013	ref	pass	1/23/2013	pass	pass
10	Vellore	0	new born	2	3/31/2013	2.87	9	9	4/1/2013	ref	ref	4/4/2013	ref	ref
11	Arni	0	new born	1	4/1/2013	3.09	9	9	4/2/2013	ref	pass	4/8/2013	pass	pass
12	Thrichurap	0	new born	1	4/1/2013	2.86	9	9	4/2/2013	ref	ref	4/10/2013	ref	ref
13	Vellore	0	new born	1	4/3/2013	2.76	9	9	4/4/2013	pass	ref	4/16/2013	ref	pass
14	Thiruvanam	1	new born	1	4/7/2013	3.4	9	10	4/11/2013	ref	ref	4/16/2013	ref	ref
15	velore	0	new born	2	4/8/2013	2.78	9	10	4/9/2013	pass	ref	4/19/2013	ref	pass
16	Velore	0	new born	1	4/8/2013	3.3	9	10	4/9/2013	pass	ref	4/22/2013	ref	pass
17	Vellore	0	new born	1	4/11/2013	2.77	7	9	4/12/2013	ref	ref	4/25/2013	ref	pass
18	Tiruvamlai	0	New born	2	4/10/2013	3.05	9	9	4/11/2013	ref	pass	4/26/2013	pass	pass
19	Chitoor	1	new born	2	4/9/2013	2.79	9	10	4/11/2013	ref	pass	4/30/2013	pass	pass
20	Vellore	0	new born	2	1/8/2003	3.4	9	9	4/9/2013	pass	ref	5/1/2013	ref	ref
21	Vellore	0	new born	2	4/24/2013	2.82	9	9	4/25/2013	pass	ref	5/2/2013	ref	pass
22	Vellore	1	new born	2	4/4/2013	3.28	9	10	4/11/2013	ref	pass	4/25/2013	pass	pass
23	Vellore	0	new bor	1	5/8/2013	3.02	9	10	5/9/2013	pass	ref	5/20/2013	ref	pass
24	vellore	0	new born	2	5/8/2013	3.06	6	10	5/9/2013	ref	ref	5/22/2013	ref	ref
25	polur	0	new born	1	5/26/2013	2.84	9	10	5/27/2013	ref	pass	6/3/2013	pass	pass
26	Thiruvalam	0	new born	1	5/15/2013	2.8	9	9	5/17/2013	ref	pass	6/3/2013	pass	pass
27	Thiruvamal	0	new born	1	6/2/2013	2.92	9	10	6/3/2013	pass	ref	6/7/2013	ref	pass
28	vellore	1	new bor	1	6/8/2013	2.08	9	9	6/10/2013	ref	ref	6/19/2013	ref	ref
29	chittor	0	new born	1	7/3/2013	3.18	9	9	7/4/2013	pass	ref	7/11/2013	ref	ref
30	Thiruvamal	0	new born	1	8/29/2013	3.14	9	9	8/31/2013	ref	ref	9/6/2013	ref	ref
31	velore	1	new born	1	9/1/2013	2.57	5	9	9/3/2013	ref	ref	9/13/2013	ref	ref
32	vellore	1	new born	1	9/11/2013	2.66	9	10	9/12/2013	ref	pass	9/16/2013	ref	ref
33	vellore	0	new born	1	9/3/2013	2.03	2	9	9/6/2013	ref	pass	9/13/2013	ref	pass
34	vellore	0	new born	1	9/17/2013	2.88	9	10	9/19/2013	pass	ref	10/2/2013	pass	referred
35	Bangalore	0	new born	2	10/17/2013	2.86	9	10	10/19/2013	ref	pass	10/21/2013	ref	pass
36	vellore	0	new born	2	6/26/2013	2.67	9	10	6/27/2013	ref	ref	10/3/2013	ref	ref
37	Vellore	0	new born	1	10/19/2013	3.58	9	10	10/22/2013	ref	ref	11/1/2013	pass	ref

DATA SHEET - 2

sno	dabr	rabr	labr	clabor	cna	crd	cbi	cm	cj	cs	ct	cv	com	cet	ceexam	cnexam	ctexam	cgexam	cgexam1	sno
1	11/1/2012	pass	pass	0	0	0	0	0	1	0	0	1	0	0	normal	normal	normal	normal	normal	1
2	11/7/2012	ref	ref	0	0	0	0	0	0	0	0	0	0	0	normal	normal	normal	normal	normal	2
3	11/5/2012	pass	pass	0	0	0	0	0	0	0	0	0	0	0	normal	normal	normal	normal	normal	3
4	11/7/2012	pass	Ref	0	0	0	0	0	0	0	0	0	0	0	normal	normal	normal	normal	normal	4
5	3/6/2013	pass	pass	0	0	0	0	0	0	0	0	0	0	0	normal	normal	normal	normal	normal	5
6	1/31/2013	pass	pass	0	0	0	0	0	0	0	0	0	0	0	normal	normal	normal	normal	normal	6
7	3/14/2013	pass	pass	0	0	0	0	0	0	0	0	0	0	0	normal	normal	normal	norma	normal	7
8	3/20/2013	pass	pass	0	0	0	0	0	0	1	0	0	0	0	normal	normal	normal	normal	normal	8
9	1/23/2013	pass	pass	0	0	0	1	0	0	0	0	0	0	0	normal	normal	normal	normal	normal	9
10	4/4/2013	pass	ref	0	0	0	0	0	0	0	0	0	0	0	normal	normal	normal	normal	normal	10
11	4/8/2013	pass	pass	0	0	0	0	0	0	0	0	0	0	0	normal	normal	normal	normal	normal	11
12	4/10/2013	pass	pass	0	0	0	0	0	0	0	0	0	0	0	normal	normal	normal	normal	normal	12
13	4/16/2013	pass	pass	0	0	0	0	0	0	0	0	0	0	0	normal	normal	normal	normal	normal	13
14	4/16/2013	pass	pass	0	0	0	0	0	0	0	0	0	0	0	normal	normal	normal	normal	normal	14
15	4/19/2013	pass	pass	0	0	0	0	0	0	0	0	0	0	0	normal	normal	normal	normal	normal	15
16	4/22/2013	pass	pas	0	0	0	0	0	0	0	0	0	0	0	normal	normalnorm	al	normal	normal	16
17	4/25/2013	pass	pass	0	0	0	0	0	0	0	0	0	0	0	normal	normal	normal	normal	normal	17
18	4/26/2013	pas	pass	0	0	0	0	0	0	0	0	0	0	0	normal	normal	normal	normal	normal	18
19	4/30/2013	pass	pass	0	0	0	0	0	0	0	0	0	0	0	normal	normal	normal	normal	normal	19
20	5/1/2013	pas	pass	0	0	0	0	0	0	0	0	0	0	0	Normal	normal	normal	normal	normal	20
21	5/2/2013	pass	pass	0	0	0	0	0	0	0	0	0	0	0	normal	normal	normal	normal	normal	21
22	4/25/2013	pass	pass	0	0	0	0	0	0	0	0	0	0	0	normal	normal	normal	normal	normal	22
23	5/20/2013	pass	pass	0	0	0	0	0	0	0	0	0	0	0	Normal	noral	normal	normal	normal	23
24	5/22/2013	pass	pass	0	0	0	0	0	0	0	0	0	0	0	noral	normal	normal	normal	normal	24
25	6/3/2013	pass	pass	0	0	0	0	0	0	0	0	0	0	0	normal	normal	normal	normal	normal	25
26	6/3/2013	pas	pass	0	0	0	0	0	0	0	0	0	0	0	normal	normal	normal	normal	normal	26
27	6/7/2013	pass	pass	0	0	0	0	0	0	0	0	0	0	0	normal	normal	normal	normal	normal	27
28	6/19/2013	pas	pass	0	0	0	0	0	0	0	0	0	0	0	normal	normalnorm	al	normal	normal	28
29	7/18/2013	normal	normal	0	0	0	0	0	0	0	0	0	0	0	normal	normal	normal	normal	normal	29
30	9/16/2013	ref	ref	0	0	0	0	0	0	0	0	0	0	0	normal	normal	normal	noral	normal	30
31	10/16/2013	pass	pass	0	0	0	0	0	0	0	0	0	0	0	normal	normal	normal	normal	normal	31
32	9/20/2013	ref	ref	0	0	0	0	0	0	0	0	0	0	0	normal	normal	normal	normal	normal	32
33	9/13/2013	ref	ref	0	0	0	0	0	1	0	0	0	0	0	normal	normal	normal	normal	normal	33
34	10/2/2013	pass	pass	0	0	0	0	0	0	0	0	0	0	0	normal	normal	normal	normal	normal	34
35	10/21/2013	pass	pass	0	0	0	0	0	0	0	0	0	0	0	normal	normal	normal	normal	normal	35
36	10/3/2013	ref	ref	0	0	0	0	0	0	0	0	0	0	0	normal	normal	normal	normal	normal	36
37	11/1/2013	pass	refer	0	0	0	0	0	0	0	0	0	0	0	normal	normal	normal	normal	normal	37

DATA SHEET - 3

cgexam2	cgexam3	cgexam4	cgexam5	fshsd	fhd	fhb	nf	wf	hd	kd	sn	od	fsex	fage	fed	fo	msex	mage
normal	normal	normal	clubfoot	0	0	0	0	0	0	0	0	nil	1				2	25
normal	normal	normal	nil	0	0	0	0	0	0	0	0	nil	1				2	
normal	normal	normal	nil	0	0	0	0	0	0	0	0	nil	1	23	9th std	coolie	2	21
normal	normal	normal	nil	0	0	0	0	0	0	0	0	nil	1	28	12th std	business	2	26
normal	normal	normal	nil	0	0	0	0	0	0	0	0	nil	1	33	MBA	Accounts	2	31
normal	normal	normal	nil	0	0	0	0	0	0	0	0	nil	1	27	B.E	officer	2	25
normal	normal	normal	nil	0	0	0	0	0	0	0	0	nil	1	32	12th std	coolie	2	31
normal	normal	normal	nil	0	0	0	0	0	0	0	0	nil	1	28	BA	company	2	27
normal	normal	normal	nil	0	0	0	0	0	0	0	0	nil	1	27	10th std	labourer	2	23
normal	normal	normal	nil	0	0	0	0	0	0	0	0	nil	1	29	12th std	police	2	20
normal	normal	normal	nil	0	0	0	0	0	0	0	0	nil	1		8th sd	textile	2	18
normal	normal	normal	nil	0	0	0	0	0	0	0	0	nil	1				2	20
normal	normal	normal	nil	0	0	0	0	0	0	0	0	nil	1				2	29
normal	normal	normal	nil	0	0	0	0	0	0	0	0	nil	1	34	Mcm	Student	2	31
normal	normal	normal	nil	0	0	0	0	0	0	0	0	nil	1				2	25
normal	normal	normal	nil	0	0	0	0	0	0	0	0	nil	1	30	10th std	farmer	2	25
normal	normal	normal	nil	0	0	0	0	0	0	0	0	nil	1	25	BBA	Business	2	24
normal	normal	normal	nil	0	0	0	0	0	0	0	0	nil	1	29	Polytech	college	2	27
normal	normal	nomal	nil	0	0	0	0	0	0	0	0	nil	1	32	MBA	Software	2	25
normal	nrmal	normal	nil	0	0	0	0	0	0	0	0	nil	1		10thbu std	business	2	23
normal	normal	normal	nil	0	0	0	0	0	0	0	0	nl	1	36	12th std	electrical	2	34
normal	normal	normal	il	0	0	0	0	0	0	0	0	nil	1	45	10th std	vet	2	33
normal	ormal	normal	nil	0	0	0	0	0	0	0	0	nil	1	36	MBA	Business	2	31
normal	normal	normal	nil	0	0	0	0	0	0	0	0	nil	1				2	23
normal	normal	normal	normal	0	0	0	0	0	0	0	0	nil	1				2	31
normal	normal	norml	nil	0	0	0	0	0	0	0	0	nil	1	41	ITI	Superisor	2	39
normal	normal	normal	nil	0	0	0	0	0	0	0	0	nil	1				2	24
normal	normal	normal	nil	0	0	0	0	0	0	0	0	nil	1	30	5th std	shop	2	27
normal	normal	normal	noral	0	0	0	0	0	0	0	0	no	1				2	28
normal	normal	normal	normal	0	0	0	0	0	0	0	0	nil	1				2	29
normal	normal	normal	normal	0	0	0	0	0	0	0	0	nil	1				2	
normal	normal	normal	normal	0	0	0	0	0	0	0	0	nil	1				2	23
normal	normal	normal	normal	0	0	0	0	0	0	0	0	nil	1				2	21
normal	normal	normal	normal	0	0	0	0	0	0	0	0	nil	1				2	
normal	naemal	normal	normal	0	0	0	0	0	0	0	0	nil	1				2	26
normal	normal	normal	normal	0	0	0	0	0	0	0	0	nil	1				2	
ormal	normal	normal	normal	0	0	0	0	0	0	0	0	nill	1				2	27

DATA SHEET - 4

sno	med	mo	gage	para	del	mt	md	mt1	mod	moi
1		house wife	40.3	G-2, A-1	LSCS	0	0	0	0	0
2		house wife	39.2	primi	NVD	0	0	0	0	0
3	7th std	House Wife	37.2	primi	NVD	0	0	0	0	0
4	12th std	housewife	41.4w	primi	LSCS	0	1	1	0	0
5	PECE	house wife	40.5w	primi	NVD	0	0	0	0	0
6	B.Tech	Infosys	37.6	primi	LSCS	0	0	0	0	0
7	12th std	house wife	39.3	P2,L2,A2	NVD	0	0	0	0	0
8	BSc Nurse	Nurse	39.6	primi	NVD	0	0	0	0	0
9	ANM	Aux nurse	37.5	pimi	LSCS	0	0	0	0	0
10	12th std	house wife	39.3	primi	vaccum cup	0	0	0	0	0
11	10th std	house wife	39.4	primi	NVD	0	0	0	0	0
12		house wife	39.6	primi	NVD	0	0	0	0	0
13		house wife	36.5	p-1,L-1	NVD	0	0	0	0	0
14	MSc	Student	39.3	G2,A1	NVD	0	0	0	0	0
15		house wife	39	G2,A1	NVD	0	0	0	0	0
16	DTA	Teacher	38.5w	G2,P1,L1	NVD	0	0	0	0	0
17	BCom	House wif	39.2	Primi	NVD	0	0	0	0	0
18	BCom	Bank	39.6	primi	Suction cup	0	0	0	0	0
19	MCA	House wife	38.6	primi	NVD	0	0	0	0	0
20	10th std	house wife	40.4	G5,P2,L2A2	NVD	0	0	0	0	0
21	12th std	house wife	36.2	G5P2,l2,a2	LSCS	0	0	0	0	0
22	12th std	house wife	39.6	G2,P1,L1	NVD	0	0	0	0	0
23	MABEd	Teacher	37.6	G2,p0,loA1	NVD	0	0	0	0	0
24		Housewife	38.3	G4,P3,L1A2	LSCS	0	0	0	0	0
25		House wife	39w	G2,P1,L1	NVD	0	0	0	0	0
26	BSc	House wife	38.3	G2,P1,L1	LSCS	0	0	0	0	0
27		house wife	38.5	G2,A1	NVD	0	0	0	0	0
28	10th std	house wife	36.2	G2P1L1	LSCS	0	0	0	0	0
29		house wife	38.6	G2P1L1	LSCS	0	0	0	0	0
30		house wife	36.6	G2P1L1	LSCS	0	0	0	0	0
31			40.6	G2p1A1	suction cup	0	0	0	0	0
32			38	G1p1	NVD	0	1	0	0	0
33		house wife	36.2	primi	LSCS	0	0	0	0	0
34			38.6	p2l2	NVD	0	0	0	0	0
35			40	p2l2	NVD	0	0	0	0	0
36			39.5	G2p1L1	NVD	0	0	0	0	0
37			37.4	G2,P-1,L-1	LSCS	0	0	0	0	0

sno	place	con	cage	csex	cdob	cbwight	cascore1	cascore5	dbp1	rdbp1	ldbp1	dbp2	rdbp2	ldbp2
1	Vellore	1	new born	2	10/7/2012	2.53	9	10	10/8/2012	ref-25%	ref	10/16/2012	ref-25%	ref
2	vellore	0	new born	1	10/12/2012	3.48	9	10	11/13/2012	ref	ref	11/7/2012	ref	ref
3	Vellore	1	new born	1	10/9/2012	2.1	9	10	10/10/2012	ref	pass	11/5/2012	pass	pass
4	Chittor	0	new born	2	10/4/2012	3.52	9	10	12/5/2012	pass	ref	11/7/2012	ref	ref
5	Chennai	0	new born	2	2/13/2013	2.54	9	10	2/14/2013	pass	ref	3/6/2013	ref	pass
6	Vellore	0	new born	1	1/10/2013	2.64	9	10	1/11/2013	ref	pass	1/31/2013	pass	pass
7	Vellore	0	new born	1	2/14/2013	3.19	9	10	2/15/2013	ref	ref	3/14/2013	ref	pass
8	Vellore	0	new born	2	3/1/2013	3.4	7	9	3/3/2013	pass	ref	3/20/2013	ref	ref
9	Meghalaya	0	new born	1	1/9/2013	2.9	9	9	1/10/2013	ref	pass	1/23/2013	pass	pass
10	Vellore	0	new born	2	3/31/2013	2.87	9	9	4/1/2013	ref	ref	4/4/2013	ref	ref
11	Arni	0	new born	1	4/1/2013	3.09	9	9	4/2/2013	ref	pass	4/8/2013	pass	pass
12	Thrichurap	0	new born	1	4/1/2013	2.86	9	9	4/2/2013	ref	ref	4/10/2013	ref	ref
13	Vellore	0	new born	1	4/3/2013	2.76	9	9	4/4/2013	pass	ref	4/16/2013	ref	pass
14	Thiruvanam	1	new born	1	4/7/2013	3.4	9	10	4/11/2013	ref	ref	4/16/2013	ref	ref
15	velore	0	new born	2	4/8/2013	2.78	9	10	4/9/2013	pass	ref	4/19/2013	ref	pass
16	Velore	0	new born	1	4/8/2013	3.3	9	10	4/9/2013	pass	ref	4/22/2013	ref	pass
17	Vellore	0	new born	1	4/11/2013	2.77	7	9	4/12/2013	ref	ref	4/25/2013	ref	pass
18	Tiruvamlai	0	New born	2	4/10/2013	3.05	9	9	4/11/2013	ref	pass	4/26/2013	pass	pass
19	Chitoor	1	new born	2	4/9/2013	2.79	9	10	4/11/2013	ref	pass	4/30/2013	pass	pass
20	Vellore	0	new born	2	1/8/2003	3.4	9	9	4/9/2013	pass	ref	5/1/2013	ref	ref
21	Vellore	0	new born	2	4/24/2013	2.82	9	9	4/25/2013	pass	ref	5/2/2013	ref	pass
22	Vellore	1	new born	2	4/4/2013	3.28	9	10	4/11/2013	ref	pass	4/25/2013	pass	pass
23	Vellore	0	new bor	1	5/8/2013	3.02	9	10	5/9/2013	pass	ref	5/20/2013	ref	pass
24	vellore	0	new born	2	5/8/2013	3.06	6	10	5/9/2013	ref	ref	5/22/2013	ref	ref
25	polur	0	new born	1	5/26/2013	2.84	9	10	5/27/2013	ref	pass	6/3/2013	pass	pass
26	Thiruvalam	0	new born	1	5/15/2013	2.8	9	9	5/17/2013	ref	pass	6/3/2013	pass	pass
27	Thiruvamal	0	new born	1	6/2/2013	2.92	9	10	6/3/2013	pass	ref	6/7/2013	ref	pass
28	vellore	1	new bor	1	6/8/2013	2.08	9	9	6/10/2013	ref	ref	6/19/2013	ref	ref
29	chittor	0	new born	1	7/3/2013	3.18	9	9	7/4/2013	pass	ref	7/11/2013	ref	ref
30	Thiruvamal	0	new born	1	8/29/2013	3.14	9	9	8/31/2013	ref	ref	9/6/2013	ref	ref
31	velore	1	new born	1	9/1/2013	2.57	5	9	9/3/2013	ref	ref	9/13/2013	ref	ref
32	vellore	1	new born	1	9/11/2013	2.66	9	10	9/12/2013	ref	pass	9/16/2013	ref	ref
33	vellore	0	new born	1	9/3/2013	2.03	2	9	9/6/2013	ref	pass	9/13/2013	ref	pass
34	vellore	0	new born	1	9/17/2013	2.88	9	10	9/19/2013	pass	ref	10/2/2013	pass	referred
35	Bangalore	0	new born	2	10/17/2013	2.86	9	10	10/19/2013	ref	pass	10/21/2013	ref	pass
36	vellore	0	new born	2	6/26/2013	2.67	9	10	6/27/2013	ref	ref	10/3/2013	ref	ref
37	Vellore	0	new born	1	10/19/2013	3.58	9	10	10/22/2013	ref	ref	11/1/2013	pass	ref

sno	dabr	rabr	labr	clabor	cna	crd	cbi	cm	cj	cs	ct	cv	com	cet	ceexam	cnexam	ctexam	cgexam	cgexam1	sno
1	11/1/2012	pass	pass	0	0	0	0	0	1	0	0	1	0	0	normal	normal	normal	normal	normal	1
2	11/7/2012	ref	ref	0	0	0	0	0	0	0	0	0	0	0	normal	normal	normal	normal	normal	2
3	11/5/2012	pass	pass	0	0	0	0	0	0	0	0	0	0	0	normal	normal	normal	normal	normal	3
4	11/7/2012	pass	Ref	0	0	0	0	0	0	0	0	0	0	0	normal	normal	normal	normal	normal	4
5	3/6/2013	pass	pass	0	0	0	0	0	0	0	0	0	0	0	normal	normal	normal	normal	normal	5
6	1/31/2013	pass	pass	0	0	0	0	0	0	0	0	0	0	0	normal	normal	normal	normal	normal	6
7	3/14/2013	pass	pass	0	0	0	0	0	0	0	0	0	0	0	normal	normal	normal	norma	normal	7
8	3/20/2013	pass	pass	0	0	0	0	0	0	1	0	0	0	0	normal	normal	normal	normal	normal	8
9	1/23/2013	pass	pass	0	0	0	1	0	0	0	0	0	0	0	normal	normal	normal	normal	normal	9
10	4/4/2013	pass	ref	0	0	0	0	0	0	0	0	0	0	0	normal	normal	normal	normal	normal	10
11	4/8/2013	pass	pass	0	0	0	0	0	0	0	0	0	0	0	normal	normal	normal	normal	normal	11
12	4/10/2013	pass	pass	0	0	0	0	0	0	0	0	0	0	0	normal	normal	normal	normal	normal	12
13	4/16/2013	pass	pass	0	0	0	0	0	0	0	0	0	0	0	normal	normal	normal	normal	normal	13
14	4/16/2013	pass	pass	0	0	0	0	0	0	0	0	0	0	0	normal	normal	normal	normal	normal	14
15	4/19/2013	pass	pass	0	0	0	0	0	0	0	0	0	0	0	normal	normal	normal	normal	normal	15
16	4/22/2013	pass	pas	0	0	0	0	0	0	0	0	0	0	0	normal	normalnorm	al	normal	normal	16
17	4/25/2013	pass	pass	0	0	0	0	0	0	0	0	0	0	0	normal	normal	normal	normal	normal	17
18	4/26/2013	pas	pass	0	0	0	0	0	0	0	0	0	0	0	normal	normal	normal	normal	normal	18
19	4/30/2013	pass	pass	0	0	0	0	0	0	0	0	0	0	0	normal	normal	normal	normal	normal	19
20	5/1/2013	pas	pass	0	0	0	0	0	0	0	0	0	0	0	Normal	normal	normal	normal	normal	20
21	5/2/2013	pass	pass	0	0	0	0	0	0	0	0	0	0	0	normal	normal	normal	normal	normal	21
22	4/25/2013	pass	pass	0	0	0	0	0	0	0	0	0	0	0	normal	normal	normal	normal	normal	22
23	5/20/2013	pass	pass	0	0	0	0	0	0	0	0	0	0	0	Normal	noral	normal	normal	normal	23
24	5/22/2013	pass	pass	0	0	0	0	0	0	0	0	0	0	0	noral	normal	normal	normal	normal	24
25	6/3/2013	pass	pass	0	0	0	0	0	0	0	0	0	0	0	normal	normal	normal	normal	normal	25
26	6/3/2013	pas	pass	0	0	0	0	0	0	0	0	0	0	0	normal	normal	normal	normal	normal	26
27	6/7/2013	pass	pass	0	0	0	0	0	0	0	0	0	0	0	normal	normal	normal	normal	normal	27
28	6/19/2013	pas	pass	0	0	0	0	0	0	0	0	0	0	0	normal	normalnorm	al	normal	normal	28
29	7/18/2013	normal	normal	0	0	0	0	0	0	0	0	0	0	0	normal	normal	normal	normal	normal	29
30	9/16/2013	ref	ref	0	0	0	0	0	0	0	0	0	0	0	normal	normal	normal	noral	normal	30
31	10/16/2013	pass	pass	0	0	0	0	0	0	0	0	0	0	0	normal	normal	normal	normal	normal	31
32	9/20/2013	ref	ref	0	0	0	0	0	0	0	0	0	0	0	normal	normal	normal	normal	normal	32
33	9/13/2013	ref	ref	0	0	0	0	0	1	0	0	0	0	0	normal	normal	normal	normal	normal	33
34	10/2/2013	pass	pass	0	0	0	0	0	0	0	0	0	0	0	normal	normal	normal	normal	normal	34
35	10/21/2013	pass	pass	0	0	0	0	0	0	0	0	0	0	0	normal	normal	normal	normal	normal	35
36	10/3/2013	ref	ref	0	0	0	0	0	0	0	0	0	0	0	normal	normal	normal	normal	normal	36
37	11/1/2013	pass	refer	0	0	0	0	0	0	0	0	0	0	0	normal	normal	normal	normal	normal	37

cgexam2	cgexam3	cgexam4	cgexam5	fshsd	fhd	fhb	nf	wf	hd	kd	sn	od	fsex	fage	fed	fo	msex	mage
normal	normal	normal	clubfoot	0	0	0	0	0	0	0	0	nil	1				2	25
normal	normal	normal	nil	0	0	0	0	0	0	0	0	nil	1				2	
normal	normal	normal	nil	0	0	0	0	0	0	0	0	nil	1	23	9th std	coolie	2	21
normal	normal	normal	nil	0	0	0	0	0	0	0	0	nil	1	28	12th std	business	2	26
normal	normal	normal	nil	0	0	0	0	0	0	0	0	nil	1	33	MBA	Accounts	2	31
normal	normal	normal	nil	0	0	0	0	0	0	0	0	nil	1	27	B.E	officer	2	25
normal	normal	normal	nil	0	0	0	0	0	0	0	0	nil	1	32	12th std	coolie	2	31
normal	normal	normal	nil	0	0	0	0	0	0	0	0	nil	1	28	BA	company	2	27
normal	normal	normal	nil	0	0	0	0	0	0	0	0	nil	1	27	10th std	labourer	2	23
normal	normal	normal	nil	0	0	0	0	0	0	0	0	nil	1	29	12th std	police	2	20
normal	normal	normal	nil	0	0	0	0	0	0	0	0	nil	1		8th sd	textile	2	18
normal	normal	normal	nil	0	0	0	0	0	0	0	0	nil	1				2	20
normal	normal	normal	nil	0	0	0	0	0	0	0	0	nil	1				2	29
normal	normal	normal	nil	0	0	0	0	0	0	0	0	nil	1	34	Mcm	Student	2	31
normal	normal	normal	nil	0	0	0	0	0	0	0	0	nil	1				2	25
normal	normal	normal	nil	0	0	0	0	0	0	0	0	nil	1	30	10th std	farmer	2	25
normal	normal	normal	nil	0	0	0	0	0	0	0	0	nil	1	25	BBA	Business	2	24
normal	normal	normal	nil	0	0	0	0	0	0	0	0	nil	1	29	Polytech	college	2	27
normal	normal	nomal	nil	0	0	0	0	0	0	0	0	nil	1	32	MBA	Software	2	25
normal	nrmal	normal	nil	0	0	0	0	0	0	0	0	nil	1		10thbu std	business	2	23
normal	normal	normal	nil	0	0	0	0	0	0	0	0	nl	1	36	12th std	electrical	2	34
normal	normal	normal	il	0	0	0	0	0	0	0	0	nil	1	45	10th std	vet	2	33
normal	ormal	normal	nil	0	0	0	0	0	0	0	0	nil	1	36	MBA	Business	2	31
normal	normal	normal	nil	0	0	0	0	0	0	0	0	nil	1				2	23
normal	normal	normal	normal	0	0	0	0	0	0	0	0	nil	1				2	31
normal	normal	norml	nil	0	0	0	0	0	0	0	0	nil	1	41	ITI	Superisor	2	39
normal	normal	normal	nil	0	0	0	0	0	0	0	0	nil	1				2	24
normal	normal	normal	nil	0	0	0	0	0	0	0	0	nil	1	30	5th std	shop	2	27
normal	normal	normal	noral	0	0	0	0	0	0	0	0	no	1				2	28
normal	normal	normal	normal	0	0	0	0	0	0	0	0	nil	1				2	29
normal	normal	normal	normal	0	0	0	0	0	0	0	0	nil	1				2	
normal	normal	normal	normal	0	0	0	0	0	0	0	0	nil	1				2	23
normal	normal	normal	normal	0	0	0	0	0	0	0	0	nil	1				2	21
normal	normal	normal	normal	0	0	0	0	0	0	0	0	nil	1				2	
normal	noemal	normal	normal	0	0	0	0	0	0	0	0	nil	1				2	26
normal	normal	normal	normal	0	0	0	0	0	0	0	0	nil	1				2	
ormal	normal	normal	normal	0	0	0	0	0	0	0	0	nill	1				2	27

sno	med	mo	gage	para	del	mt	md	mt1	mod	moi
1		house wife	40.3	G-2, A-1	LSCS	0	0	0	0	0
2		house wife	39.2	primi	NVD	0	0	0	0	0
3	7th std	House Wife	37.2	primi	NVD	0	0	0	0	0
4	12th std	housewife	41.4w	primi	LSCS	0	1	1	0	0
5	PECE	house wife	40.5w	primi	NVD	0	0	0	0	0
6	B.Tech	Infosys	37.6	primi	LSCS	0	0	0	0	0
7	12th std	house wife	39.3	P2,L2,A2	NVD	0	0	0	0	0
8	BSc Nurse	Nurse	39.6	primi	NVD	0	0	0	0	0
9	ANM	Aux nurse	37.5	pimi	LSCS	0	0	0	0	0
10	12th std	house wife	39.3	primi	vaccum cup	0	0	0	0	0
11	10th std	house wife	39.4	primi	NVD	0	0	0	0	0
12		house wife	39.6	primi	NVD	0	0	0	0	0
13		house wife	36.5	p-1,L-1	NVD	0	0	0	0	0
14	MSc	Student	39.3	G2,A1	NVD	0	0	0	0	0
15		house wife	39	G2,A1	NVD	0	0	0	0	0
16	DTA	Teacher	38.5w	G2,P1,L1	NVD	0	0	0	0	0
17	BCom	House wif	39.2	Primi	NVD	0	0	0	0	0
18	BCom	Bank	39.6	primi	Suction cup	0	0	0	0	0
19	MCA	House wife	38.6	primi	NVD	0	0	0	0	0
20	10th std	house wife	40.4	G5,P2,L2A2	NVD	0	0	0	0	0
21	12th std	house wife	36.2	G5P2,l2,a2	LSCS	0	0	0	0	0
22	12th std	house wife	39.6	G2,P1,L1	NVD	0	0	0	0	0
23	MABEd	Teacher	37.6	G2,p0,loA1	NVD	0	0	0	0	0
24		Housewife	38.3	G4,P1,L1A2	LSCS	0	0	0	0	0
25		House wife	39w	G2,P1,L1	NVD	0	0	0	0	0
26	BSc	House wife	38.3	G2,P1,L1	LSCS	0	0	0	0	0
27		house wife	38.5	G2,A1	NVD	0	0	0	0	0
28	10th std	house wife	36.2	G2P1L1	LSCS	0	0	0	0	0
29		house wife	38.6	G2P1L1	LSCS	0	0	0	0	0
30		house wife	36.6	G2P1L1	LSCS	0	0	0	0	0
31			40.6	G2p1A1	suction cup	0	0	0	0	0
32			38	G1p1	NVD	0	1	0	0	0
33		house wife	36.2	primi	LSCS	0	0	0	0	0
34			38.6	p2l2	NVD	0	0	0	0	0
35			40	p2l2	NVD	0	0	0	0	0
36			39.5	G2p1L1	NVD	0	0	0	0	0
37			37.4	G2,P-1,L-1	LSCS	0	0	0	0	0