METHOD

Research Design

Retrospective case control study.

Sample

The total sample size was 420 with 210 infants each in the study group and control group. Age range of sample was 6 months to 2 years. Samples were collected between 2008 and 2012.

Sample Size Calculation

Sample size was calculated based on 80% power from the results of prevalence of risk factors among infants with hearing impairment by Cone-Wesson et al. (2000). As per the alpha error of 5%, the sample size required in each of the study group and control group was 182, which was met in the present study.

Sampling Population

The control group was selected from the Department of Pediatrics of Sri Ramachandra Hospital, Chennai. Infants with hearing impairment were also selected from the same hospital and three other hospitals & two schools for hearing impairment in Chennai, Tamilnadu, India.
Exclusion criteria

Infants with history of ear discharge were excluded from the study in order to rule out transient conductive pathology. Subjects without any medical records were also excluded.

4.1 METHOD IN FLOW CHART

CONTROL GROUP

Pediatric Unit of Sri Ramachandra Hospital

ABR Screening

STUDY GROUP

Four hospitals and two schools in Chennai

Diagnostic ABR

Elimination as per the exclusion criteria

Parent interview and review of medical history for collecting information on risk factors
Study Group

This comprised of Infants in the age range of 6 months to 2 years in the study period with a permanent hearing impairment (PHI). Hearing impairment was either sensorineural or mixed. Conductive hearing impairment due to congenital atresia was also included in this group as those hearing impairment are permanent. Sample was collected from Sri Ramachandra Hospital, Rajiv Gandhi Government Hospital, KKR ENT Hospital, MERF ENT Hospital, Little flower convent for the deaf and Bala vidyalaya, a school for the young children with hearing impairment. Hearing impairment in this group was confirmed by the Audiologist in the above mentioned hospitals using ABR testing. Children from schools of hearing impairment also got their hearing testing done in the above said hospitals.

Control Group

Age matched infants who attended the pediatric unit of a tertiary hospital with normal hearing. They were selected using alternative sampling method. Hearing status was confirmed using ABR screener (Maico MB 11 BERA phon).

Variables in the Study

Individual and combined risk factors were the independent variables while hearing impairment was dependent variable.
Data collection procedure

Information was collected regarding the following risk factors:

1) Family history of hearing impairment
   A history of hearing impairment in child’s parents or in their relatives. This should be from childhood without ear discharge.

2) Consanguinity
   Mother of the child having one of the following family relationships with father:
   a. Second degree- Maternal/Paternal uncle
   b. Third degree- Maternal/Paternal Uncle’s Son

3) Congenital anomalies
   -Cleft lip and Palate, Ear canal atresia, microtia, Pre auricular tag etc.

4) Hyperbilirubinemia
   -The total bilirubin level > 20 mg/dL in the medical record or the history of neonatal jaundice requiring exchange transfusion.

5) Prematurity (< 37 weeks),

6) Low Apgar score (< 8 at 5 min),

7) Low birth Weight (< 2500 g),

8) Post natal infection
   Meningitis, chicken pox, TORCH-S, mumps and measles.

9) Intra uterine infection
   TORCH-S

10) Seizures (at least one episode)
11) Ototoxic drugs

Kanamycin, Amikacin, Furosemide etc.

12) NICU admission (> 5 days).

The above mentioned risk factors were taken from JCIH (2000, 2007) recommendation. Consanguinity was taken as an additional factor since this is an important risk factor in India (Anitha, 2002; Bittles, 2009). Parental interview was done to collect the information on consanguinity, family history and seizures. Information regarding the other risk factors was collected based on the referring physician's diagnosis (Intrauterine and post natal infection) or from the medical history and observation (Prematurity, low birth weight, low Apgar score, hyperbilirubinemia, ototoxic drugs, NICU, craniofacial anomaly).

**Ethical Permission**

Permission was obtained from the Institutional Ethics Committee of Sri Ramachandra University, Chennai. (IEC-NI/08/Mar/03/11) for the conduct of study (Appendix I).

**Permission from relevant HOD**

Due permission was taken from the authorities of sources for sample collection.
**Written informed consent**

A consent form was signed by parent/caregiver for their willingness to participate in the study. (Appendix II)

**Data tabulation and Statistics used for the study**

1) A 2x2 matrix table was made to calculate Odds ratio,

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<th>Risk Factor + ve</th>
<th>Risk Factor –ve</th>
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<tbody>
<tr>
<td>HI +ve</td>
<td>A</td>
<td>B</td>
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<tr>
<td>HI -ve</td>
<td>C</td>
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Odds ratio = AD/BC

The presence and absence of risk factors was coded as 1 and 0 respectively for all the samples in an excel sheet to calculate the Chi-square value, 95% confidence interval and logistic regression analysis.