5. METHODOLOGY

Institutional Ethical committee clearance (REF: IEC-NI/13/APR/33/21) was obtained for this study. Written informed consent was obtained from the parents.

5.1 Study Design

We prospectively evaluated whether preoperative HRCT temporal bone measurements were helpful in predicting the visualization of round window through facial recess during cochlear implant surgery.

Sample size

Seventy pediatric cochlear implant candidates referred for temporal bone evaluation to the Radiology department were taken up for the study; two cases with congenital malformations of inner ear were excluded.

Inclusion criteria

- Children aged 1-6 years with history of bilateral sensorineural hearing loss who underwent cochlear implantation surgery.

Exclusion criteria

- Children who had congenital malformations of the inner ear.
5.2 Data Acquisition and Measurement Protocol

High Resolution CT imaging was performed using 16- slice CT scanner (Brilliance CT; Philips Medical systems, Cleveland, OH, USA) [Figure 5.1]. The images of temporal bone were obtained with a slice thickness of 0.7 mm. The CT scan data were acquired at 120 kVp, 250 mA, and imaging matrix of 512x512. The axial images were obtained parallel to orbito-meatal base line.

HRCT images of cochlear implant candidates aged between 1-6 years (mean age- 3.6 years), who were referred for HRCT temporal bone during period of 2012-2015 were studied prospectively. These included 70 children (48 in the right ear, 22 in the left ear); two cases with congenital malformations of inner ear were excluded. The cochlear implant surgery was performed by an ENT surgeon who had experience of more than 5 years in cochlear implant surgeries. The pediatric subjects were given pedicloryl syrup in the following doses depending on the age for 1 year- 25-30 mg/kg, 1-5 years- 25-50mg/kg, 6 years- 50-100 mg/kg. The radiation dose to the temporal bone incurred in our study was 0.8-1.7 mSv.

Fig. 5.1: Philips Brilliance 16- slice CT scanner
5.3 Pre-operative HRCT Temporal Bone Measurements

1. Distance between Short process of incus and Round window membrane is defined as distance between the tip of the short process of incus and midpoint of round window membrane (Figure 5.2).

The oblique axial reconstructed image showing the incus and malleus head was chosen (Figure 5.3 A). Oblique coronal reformation (Figure 5.3 C) was done by a plane passing through the body of incus (Figure 5.3 A) and through the center of the round window (Figure 5.3 B) on the oblique axial image. The tip of short process of incus was identified on the oblique coronal reformatted images and localized using two lines drawn manually (Figure 5.3 D). These lines were extrapolated on to the oblique coronal image showing the round window membrane (Figure 5.3 E). Then the measurement was obtained between the tip of the short process of incus and midpoint of round window membrane (Figure 5.3 F).

![Fig. 5.2: Schematic diagram of distance between the tip of short process of incus (SPI) and round window membrane (RWM).]
Fig. 5.3 (A) Axial HRCT image of the right ear showing the incus and malleus head. (B) A plane (black line) passing through the body of incus and round window was used to obtain oblique coronal reformation (C) showing oval window (white arrow) and round window membrane (white arrow head). (D) On oblique coronal reformations the tip of short process of incus was localized using vertical and horizontal planes (black lines). (E) These lines were transposed on to the image showing oval window and round window membrane. (F) The distance between the tip of short process of incus and mid-point of round window membrane (black dotted line).
2. Distance between Oval window and Round window membrane (Cranio-Caudal) is defined as the distance between midpoint of oval window and mid-point of round window membrane. (Figure 5.4)

The oblique axial image showing the incus and malleus head was chosen (Figure 5.5 A). Oblique coronal image (Figure 5.5 C) was obtained by plane passing through the body of incus and midpoint of round window (Figure 5.5 B) on oblique axial image. Then the distance between midpoint of the oval window and mid-point of round window membrane was measured on the oblique coronal reformatted images (Figure 5.5 C).

Fig. 5.4: Schematic diagram of distance between oval window (OW) and round window membrane (RWM)
3. Anterior angle of Basal turn of Cochlea (with respect to mid sagittal plane)

The anterior angle of the basal turn of the cochlea was measured in axial sections with respect to the mid-sagittal plane. Axial image showing basal turn of cochlea was chosen (Figure 5.6A). A line was drawn passing through the nasal septum and internal occipital protuberance to obtain the midsagittal line (Figure 5.6B). Another line was drawn for a distance of 4mm from the centre of the round window membrane through the middle of the basal turn of the cochlea (Figure 5.6 C). This line was extended to meet the mid-sagittal line.

Fig. 5.5 (A) Axial HRCT image of right ear shows the incus and malleus head. A plane (black line) passing through the body of incus and round window (B) is used to obtain oblique coronal reformation. (C) The distance between the midpoint of oval window and mid-point of round window membrane measured on the oblique reformatted image (black dotted line).
The anterior angle was measured where the two lines meet each other (Figure 5.6 D)

Fig. 5.6 (A) Axial HRCT image showing basal turn of the cochlea. (B) A line was drawn passing through the nasal septum and internal occipital protuberance (C) Another line was drawn for a distance of 4 mm (black arrow) from midpoint of round window membrane through middle of basal turn of the cochlea (D) This line was extended to meet the midsagittal line, the anterior angle was measured where the two lines meet each other.

5.4 Intra and Inter Observer Variability for HRCT Measurements

Intra observer variability

HRCT measurements were performed by two readers. Reader A (Ph.D. Research scholar) who is expert in reading temporal bone scans, performed all the measurements. All the measurements were taken by the reader A at two different sessions. Paired Student’s t-test was done to assess intra observer variability.
**Inter observer variability**

The measurements were read again by reader B (radiologist) who has experience of more than 10 years in interpretation of temporal bone scans. *Kappa (K)* was calculated to assess inter observer variability

**5.5 Classification of Visibility of Round Window**

The visibility of the round window was assessed after performing optimal posterior tympanotomy and maximum possible dissection of round window niche. We classified the visibility of round window based on surgical view (i.e. through facial recess) during surgery into three types (Figure 5.7 A-C):

(a) Type 1- Fully visible

(b) Type 2- Partially visible

(c) Type 3- Difficult to visualize

![Fig. 5.7: Types of visualization (A) Fully visible (B) Partially visible (C) Difficult to visualize.](image)

The preoperative HRCT temporal bone measurements were used to predict the type of visualization of round window before the surgery and correlated during surgery.
5.6 Blinding

The surgeon was blinded about the preoperative HRCT temporal bone measurements and the type of visualization of round window before the surgery.

5.7 Sensitivity, Specificity, Positive Predictive Value (PPV), Negative Predictive Value (NPV) and Receiver Operator Characteristic Curve (ROC):

For calculating the sensitivity and specificity we have grouped the types 1 and 2 (not difficult to visualize) as one group and type 3 (difficult to visualize) as another group and then calculated the sensitivity and specificity, positive predictive value, Negative predictive value and cut off values for pre-operative HRCT measurements (distance between the tip of short process of incus and round window membrane; distance between oval window and round window membrane) in predicting the visualization of round window.

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<th>HRCT</th>
<th>Surgical</th>
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<tr>
<td></td>
<td>Not difficult to visualize</td>
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<tr>
<td>Not difficult to visualize</td>
<td>TP</td>
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<td>(Types 1 and 2)</td>
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<td>Difficult to visualize</td>
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<td>(Type 3)</td>
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5.8 Correlation of Measurement done on HRCT and Surgery

The cochlear implantation surgery was done using Carl Zeiss microscope. A total magnification of 125x (magnification of objective lens is 12.5x and magnification of ocular lens is 10 times) was used to obtain the surgical view showing fossa incudis, stapedial tendon inserting in to head of stapes and round window membrane.

The photos were taken from the monitor without changing the magnification using Sony camera of RX series. The photographs were imported to a computer to measure the parameter using DinoLite Digital microscope software. The magnification value used was entered for calibration of the software and then distance was measured.

**Distance between Short process of incus and Round window membrane**

We did not measure distance between the tip short process of incus and round window membrane surgically because the tip of the short process of incus is placed much higher at the level of facial nerve, where as Round window membrane is deep inside on the medial wall of the middle ear. As they are not at same height the measurement done between them will not be accurate.
Distance between Oval window and Round window membrane

As the oval window cannot be visualized during surgery we have approximately taken the distance between mid-point of the head of stapes covering oval window and mid-point of round window membrane (Figure: 5.8).

Fig. 5.8: Intra operative photograph of the right ear showing the distance between the head of stapes and midpoint of round window membrane
5.9 Statistical Analysis

The data were analyzed with SPSS (Statistical Package for the Social Sciences) version 16.0 (Chicago IL, USA). p-value of <0.01 was considered significant.

1. One way analysis of variance and Tukey’s post hoc test for finding the significant difference between the means of the pre-operative HRCT measurements for three types of visualization.

2. Sensitivity, Specificity, Positive predictive value and Negative predictive value for determining the accuracy of pre-operative HRCT measurements (Distance between the tip of short process of incus and round window membrane; Distance between oval window and round window membrane) in predicting the visualization of round window.

3. Pearson’s correlation for comparing the pre-operative HRCT measurement (Distance between oval window and round window membrane) and surgical measurement.

4. Pearson’s correlation for determining the correlation of pre-operative HRCT temporal bone measurements with age.

5. Inter (Kappa) and intra-observer (student’s t-test) variability was calculated for pre-operative HRCT measurements.