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Original Research Article

Factors Responsible for Poor Outcome in Pediatric Cochlear Implantation

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Abstract:

Background:

Aim of the Study: To find the prevalence and factors responsible for poor outcomes in pediatric cochlear implantation.

Materials: 85 children were grouped into four groups: Group 1: 1- 2 years, Group 2: 2-3 years, Group 3: 3-4 years and Group 4: 4-5 years. 12.9% belonged to group 1 , 35.3% belonged to group 2, 44.7% belonged to group 3 and 07.1% children belonged to group 4. The mean age was 3.08years with standard deviation 0.819.

Results: A longitudinal retrospective descriptive study of 85 children, in which 42 were implanted with Med-el sonata Ti 100 implant with Medel Opus 2 BTE external processor and 43 children were implanted with Cochlear Nucleus CI24RE (ST) implant with Cochlear CP 802 BTE external processor.

Conclusions: The mean age of cochlear implantation was 3.08 years with standard deviation 0.819 and no children underwent CI surgery prior to their first birthday. 87.1% of cochlear implantees have good auditory and speech outcomes, 11.8% have good auditory but poor speech outcome, and one with CAPD. 08.2% children had ADHD. Regular AVT and parental training has significant impact on cochlear implant outcome.

Keywords: Inner ear, Cochlea, Cochlear implant, AVT.

Introduction

The sense of hearing is a key aspect of functioning at all stages of social life and constitutes one of the primary elements of communication. The continuous learning process through perpetual communication depends upon the maintenance of integrity of both the peripheral and central part of the hearing. Diminished hearing capacity at any given point of life, if not addressed promptly affects adversely the daily functions of social and economic life. Hearing loss (HL) has become the fourth leading cause of disability globally. [1,2] HL impairs interpersonal communication, psychosocial wellbeing, academic and professional career opportunities, economic independence, and quality of life. According to the World Health Organization WHO), hearing loss is considered to be disabling for adults (15 years or older) if it is greater than 35 dB in the better hearing ear. For children (0 to 14 years), the WHO has defined a hearing loss exceeding 30 dB in the better hearing ear as disabling. However, hearing loss at lower thresholds also has a negative impact. For example, children whose hearing loss exceeds 26 dB have trouble understanding soft speech from a distance or in background noise. [3] Deafness and hearing loss are widespread and found in every region and country. Currently more than 1.5 billion people (nearly 20% of the global population) live with hearing loss. 430 million of them have disabling hearing loss. It is expected that by 2050, there could be over 700 million people with disabling hearing loss. Globally, 34 million children have deafness or hearing loss, of which 60% of cases are due to preventable causes. At the other end of the lifespan, approximately 30% of people over 60 years of age have hearing loss. [4] The maximum share is contributed by the Western Pacific Region, followed by the South-East Asia Region. [4] Wilson and co-authors noted that hearing loss was the 11th leading cause of years lived with disability (YLDs) in 2010 and the fourth leading cause in both 2013 and 2015. [5] Hearing loss make children away from mainstream of education and social life. The advent of cochlear implant was the beginning of a revolution in the treatment of bilateral severe to profound sensorineural hearing loss. Auditory rehabilitation of children with pre lingual deafness has been revolutionized by cochlear implantation. Hearing is composed of a peripheral and a central part, and the integrity of these systems is necessary as learning is connected to this factors. [6,7] The act of hearing and deciphering what is being said, the relation between the integrity of the peripheral

auditory system and the central auditory system may be observed. Therefore, in order to have effectiveness in communication, the auditory processing skills are extremely important.8 Sruthitharangam, a Kerala Government free cochlear Implantation scheme under Kerala Social Security Mission (KSSM) envisioned to provides free cochlear implantation surgery for the children in the age group of 0-5 years, who have bilateral severe to profound Sensori Neural Hearing Loss (SNHL). The early identification and intervention procedures initiated within six months of age should be the golden standard for the holistic development of a child with hearing loss. The children from poor families whose annual family income is below Rs.2 lakhs are eligible to get the benefit of this scheme.

This scheme is implemented through Government Medical colleges as well as selected empanelled private hospitals in this field. The objective of this scheme is to provide cochlear implant to children selected by state level technical committees for cochlear implantation and to provide financial support for AVT to operated children through hospital/ centers. Speech perception has improved in children with pre lingual SNHL after the Cochlear Implantation (CI) but the post CI rapidity of gain in hearing perception and speech development was varying in different groups of study and patients. Therefore studies investigating the causes for slow gain in auditory perception and speech development have become necessary. A number of patients have poor outcomes and understanding and explaining the reasons for poor outcomes following implantation is a very challenging research problem. Poor outcomes following cochlear implantation related to age at implantation, noncompliance to pre and post implantation auditory and speech habilitation, poor parental motivation, socioeconomic status, surgical complication, associated with co morbid conditions and other unknown reasons, Elizabeth Fitzpatrick et al 2007. The various factors including age at implantation in years, duration of auditory deprivation, relationship with common causes of SNHL, abnormalities of inner ear, education level of parents, speech rehabilitation and rural v/s urban population have to be looked as the causes for failure in outcomes of CI. Selection of candidates for cochlear implantation is a process that has been evolved and candidacy guidelines indicate that it is appropriate to provide cochlear implants to persons with increasing amount of residual hearing, to persons with increasing amount of preoperative open set speech perception skills, and to children as young as 12 months of age. [9]

Approach to Congenital deafness: Congenital sensorineural hearing loss (SNHL) is one of the most common congenital disorders as the prevalence is 1 to 2 per 1000 live births. [10,11] At birth the peripheral auditory organs are completely developed ,whereas the auditory cerebral cortex develops by relying on sound stimulation within 2 to 3 years after birth. After this period , the brain plasticity decreases and language development is limited regardless of hearing rehabilitation. [12] Early diagnosis and intervention is important in the acquisition of hearing, speech, and linguistic skills in children with hearing loss. [13] Therefore it is recommended that all newborns undergo newborn hearing screening (NHS)using an automated auditory brainstem response(AABR) test or otoacoustic emission test (OAE)within one month of birth in order to ensure hearing development and early diagnosis of hearing loss. [14,15,16] Those who do not pass screening should have a comprehensive audiological evaluation at no later than 3 months of age. Infants with confirmed hearing loss should receive appropriate intervention at no later than 6 months of age from health care and education professionals with expertise in hearing loss and deafness in infants and young children. Regardless of previous hearing-screening outcomes, all infants with or without risk factors should receive on-going surveillance of communicative development beginning at 2 months of age during well-child visits in the medical home. [17] These protocols must comply with coverage, process, and outcome indicators in addition to specific phase of each programme. [14] Separate protocols are recommended for NICU and well-infant nurseries. NICU infants admitted for more than 5 days are to have auditory brainstem response (ABR) included as part of their screening so that neural hearing loss will not be missed. [14] For infants who do not pass automated ABR testing in the NICU, referral should be made directly to an audiologist for rescreening and, when indicated, comprehensive evaluation including ABR. [14] Although SNHL is generally irreversible, an adequate etiological evaluation may be important for a number of reasons: prognostication of the progression of the hearing loss of the affected ear and of the unaffected ear in unilateral hearing loss, identification of associated physical conditions, identification of other family members at risk, adequate intervention if possible, and accurate counseling of the patients and their parents. [14]

Aim of the Study: To assess various factors responsible for poor outcome in pediatric cochlear implantation.

Objectives of the Study: To assess the prevalence of poor outcomes following pediatric cochlear implantation in Government medical college Kozhikode; to assess auditory and verbal outcomes of cochlear implantation using Aided audiogram, CAP score and ISD score; to determine the prevalence of associated issues in children who are undergoing cochlear implantation; to determine various etiologies of congenital hearing loss among

cochlear implantees; to determine the association between maternal education and cochlear implant outcomes; to determine the association between parental training and cochlear implant outcomes; to find out the relationship between the cochlear nerve thickness and length of cochlear duct with the hearing outcome; to find out the relationship between the duration of hearing aid use prior to cochlear implantation and post cochlear implant outcome.

Study Design: A longitudinal retrospective and descriptive study.

Study Setting: Department of ENT , Government Medical College, Kozhikode

Study Duration: 2 Years

Study Population: All the children who had undergone cochlear implantation under Sruthitharangam scheme at Government Medical college Kozhikode during the period of 1st January 2018 - 31st December 2019.

Sampling sample size: Sample size is calculated by the formula N= 4pq/d2;

Where p = 30%, prevalence taken from the study [59]

q=70%, d=10

Hence n=84

Inclusion criteria: All children who had undergone cochlear implantation under Sruthitharangam scheme at Government Medical College, Kozhikode from 01/01/2018 to 31/12/2019. Children who attended post implant Auditory Verbal Habilitation (AVH) for a minimum 24 months period at Government Medical College, Kozhikode. Parents of children willing to give consent for the study and come for regular follow up.

Exclusion criteria: Children who have undergone cochlear implantation from other institutes and other schemes. Those children who were not in regular follow up.

Methods of data collection: After obtaining approval from Institutional Research Committee and Institutional Ethics Committee (GMCKKD/RP 2021/IEC/237) and after getting consent from parents of implantees, study was conducted by collecting basic data through fully completed clinical records and information regarding present performance of implantees from Centre for Audiology & Speech Pathology (CASP), Department of ENT , Government Medical College Kozhikode, and Information regarding parental training, follow up and socioeconomic background data was collected using proforma. Eighty five children who had undergone cochlear implantation surgery under Sruthitharangam scheme during the period 01/01/2018 to 31/12/2019 and all of them were attending AVT at Government Medical College, Kozhikode, selected for study and followed up for 2 years retrospectively.

Outcomes were measured by using Categories of Auditory Performance (CAP) test (Archbold, 1995), Integrated Scale of Development (ISD) (Auditory habilitation from cochlear) and Aided audiogram. According to CAP test and ISD Scale poor outcome of cochlear implantation defined by following criteria:

1. CAP score ≤ 4 after 18 months of AVT.
2. ISD Score ≤ 1 year from the baseline after two years of AVT.

And factors for poor performance are assessed by considering various factors such as etiology of hearing loss, pre-operative radiological finding, intra operative surgical complications, co morbid factors such as neurological or psychological factors, audiological factors, parental factors and other factors.

Statistical Analysis: Data obtained were entered in MS Excel Spread sheet and analysed using SPSS 18 version software. Qualitative variables were expressed in percentage and frequencies. Quantitative variables were expressed as mean and standard deviation. Results were expressed by Chi Square test, ANOVA test and Paired T test were used for comparison. Level of significance of association was set at P value <0.05.

Ethics clearance: By Institutional Research Committee (IRC) and Institutional Ethics Committee (IEC) of Govt. Medical College, Kozhikode. (Ref No. GMCKKD/RP2021/IEC/237). The study was conducted after obtaining the approval and Informed consent from the parents of the implantees.

Distribution of Age of Cochlear Implantation:

Depending on the age, 85 children were grouped into four groups: Group 1: 1- 2 years, Group 2: 2-3 years, Group 3: 3-4 years and Group 4: 4-5 years. In this study, 12.9% of the cases belong to the age group 1 , 35.3%of the cases belong to the age group 2, 44.7% of cases belong to the age group 3 and only 7.1% cases were greater than 4 years of age. The average age was 3.08years with standard deviation 0.819. The minimum and maximum age was 1 and 4.9 years respectively. (Table 1)

Table: 1: Age distribution

Age group	Percentage	Frequency
1-2 Years	12.9	11
2-3 Years	35.3	30
3-4 Years	44.7	38
4-5 Years	7.1	6

Distribution of Gender: The distribution of sex was studied here. Among 85 cases included in the study, 48 (56.4%) of the cases were male and 37 (43.5%) of the cases were female. The average age of male cases was 3.13 years with standard deviation 0.885. The average age of female cases was 3.018 years with standard deviation 0.734.

Table 2: Gender Distribution

Gender	Frequency
Male	48
Female	37

Distribution of Side of Implantation: Among 85 children, 73 of them had undergone right sided cochlear implantation and 12 children had undergone left sided cochlear implantation. **(Fig 1)**

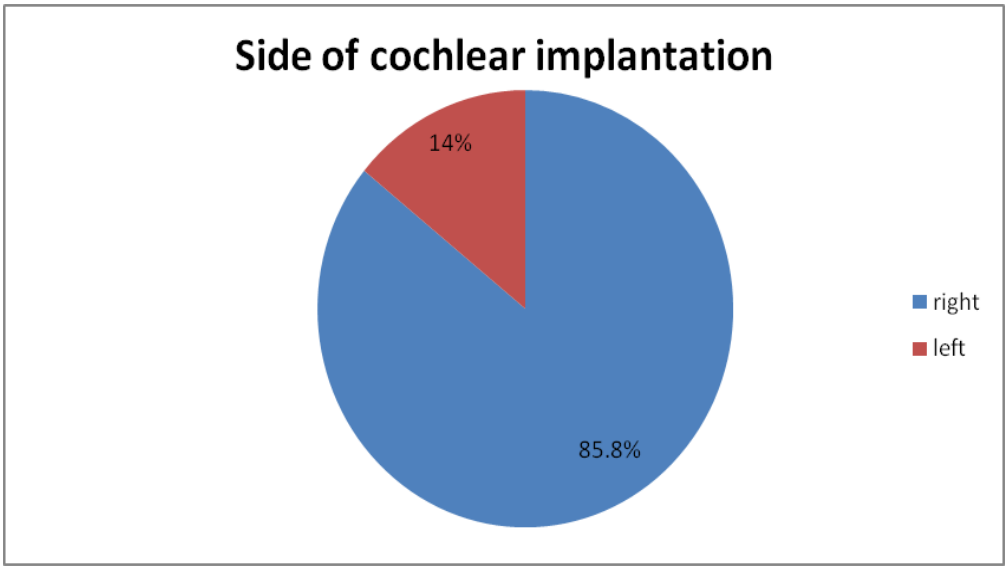

Fig 1: Determination side of cochlear implantation

Distribution of Type of Cochlear Implant Model Used: Two models of cochlear implants were used among the study population. Among 85 subjects, 42 children were implanted with Med-el sonata Ti 100 implant with Medel Opus 2 BTE external processor and 43 children were implanted with Cochlear Nucleus CI24RE (ST) implant with Cochlear CP 802 BTE external processor.

Assessment of Cochlear Implant Outcomes: Cochlear implant outcomes were assessed using free field audiometry, CAP score and ISD score for both receptive language age and expressive language age.

Average Aided Hearing Threshold: Average aided hearing threshold determined by using free field audiometry threshold of 500 Hz,1000 Hz ,2000 Hz and 4000 Hz. Pre implant average aided hearing threshold was taken with use of strong gain hearing aid and post implant average aided hearing threshold was recorded with implant system in switch on mode.

Post implant average aided hearing threshold was taken during post switch on after 1 week, 1 year and 2 years. Pre implant average aided hearing threshold with strong gain hearing aid was 56-70dBHL in 32.9% cases and average aided hearing threshold was 71-90dBHL in 65.8% cases. After 1 week of post-switch on, 52.9% cases showed average aided hearing threshold 26-40dBHL and in 36.4% cases, average aided hearing threshold was 41-55 dBHL.

Only 9.35% cases had an average aided hearing threshold poorer than 56 dBHL. After 2 years of post-switch on 82.3% cases had an average aided threshold between 26-40 dBHL and 15.2% cases had an average aided hearing threshold between 41-55 dBHL. Only 1 case had an average aided hearing threshold poorer than 90 dBHL.

Table 3: Average aided hearing threshold

Average aided hearing threshold (dB HL)	Pre Implant	Post switch on		
		After 1 week	After 1 year	After 2 years
15-25	0 (0%)	1 (1.18%)	0 (0%)	1 (1.18%)
26-40	0 (0%)	45 (52.9%)	70 (82.3%)	70 (82.3%)
41-55	0 (0%)	31(36.4%)	13 (15.2%)	13 (15.2%)
56-70	28 (32.9%)	5 (5.8%)	1 (1.18%)	0 (0%)
71-90	56 (65.8%)	1 (1.18%)	0 (0%)	0 (0%)
>90	1 (1.18%)	2 (2.35%)	1 (1.18%)	1 (1.18%)

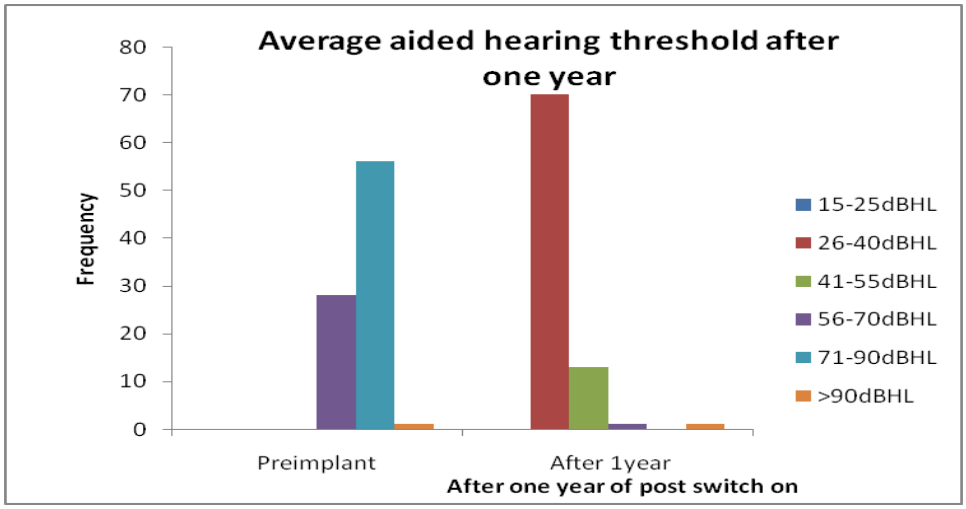

Fig 1: Average aided hearing threshold after 1 year of post switch on

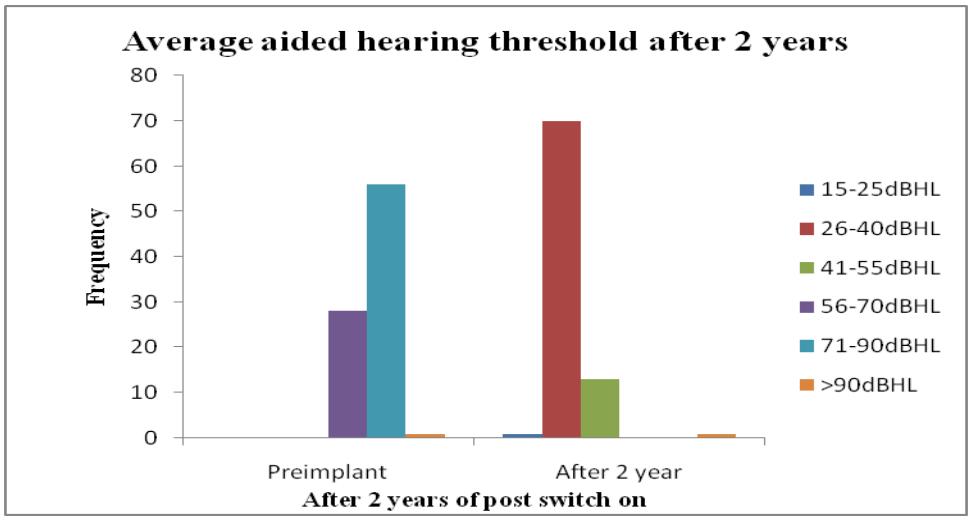

Fig: 2. Average aided hearing threshold after2 years of post-switch on

Relationship between Average Aided Hearing Threshold and Age of Cochlear Implantation:

Here the relationship between age of cochlear implantation and average aided hearing threshold were studied.

The mean average aided hearing threshold at 1 week, 1 year and 2 years of post-cochlear implant switch on and different age groups were studied. Depending on the age, 85 children were grouped into four groups: Group 1: 1- 2 years, Group 2: 2-3 years, Group 3: 3-4 years and . Group 4: 4-5 years.

Group 1: Mean average aided hearing threshold after 1week of switch on was 41.7dBHL, after 1 year of switch on, average aided hearing threshold was 35.7 dBHL and after 2 years of switch on average aided hearing threshold was 32 dBHL.

Group 2: Mean average aided hearing threshold after 1week post switch on was 45.8dBHL, average aided hearing threshold after 1 year post switch on and after 2 years of post-switch on was 38.3 dBHL.

Group 3: Mean average aided hearing threshold after 1 week of post switch on was 42.2 dBHL, after 1

year of post switch on was 36.1 dBHL and after 2 years of post-switch on was 34.5 dBHL.

Group 4: Mean average aided hearing threshold after1week of post switch on was 35.8 dBHL, after 1year post switch on was 35.6 dBHL and after 2 years of post-switch on was 35.4 dBHL. Statistically significant (P value < 0.05) improvement in average aided hearing threshold was seen after 1 week, 1 year and 2 years of post-cochlear implant switch on irrespective of the age of cochlear implantation.

Table 4: Average aided hearing threshold and age of implantation

Age (Years)	Mean (dBHL)	Standard deviation	P value
At 1 week			
1-2	41.7	8.7	0.339
2-3	45.8	16.4	
3-4	42.2	11.9	
4-5	35.8	3.4	
At 1 year			
1-2	35.7	5.03	0.674
2-3	38.3	12.2	
3-4	36.1	5.4	
4-5	35.6	4.4	
At 2 year			
1-2	32	4.8	0.161
2-3	38.3	12.5	
3-4	34.5	5.6	
4-5	35.4	4.7	

Using a one way ANOVA test, P value obtained is greater than the level of significance (>0.05) .Hence the relationship between average aided hearing threshold and age at cochlear implantation is not statistically significant (Table 7.6). However statistically significant improvement in average aided hearing threshold was seen after 1 week, 1 year and 2 years of post-switch irrespective of the age of cochlear implantation.

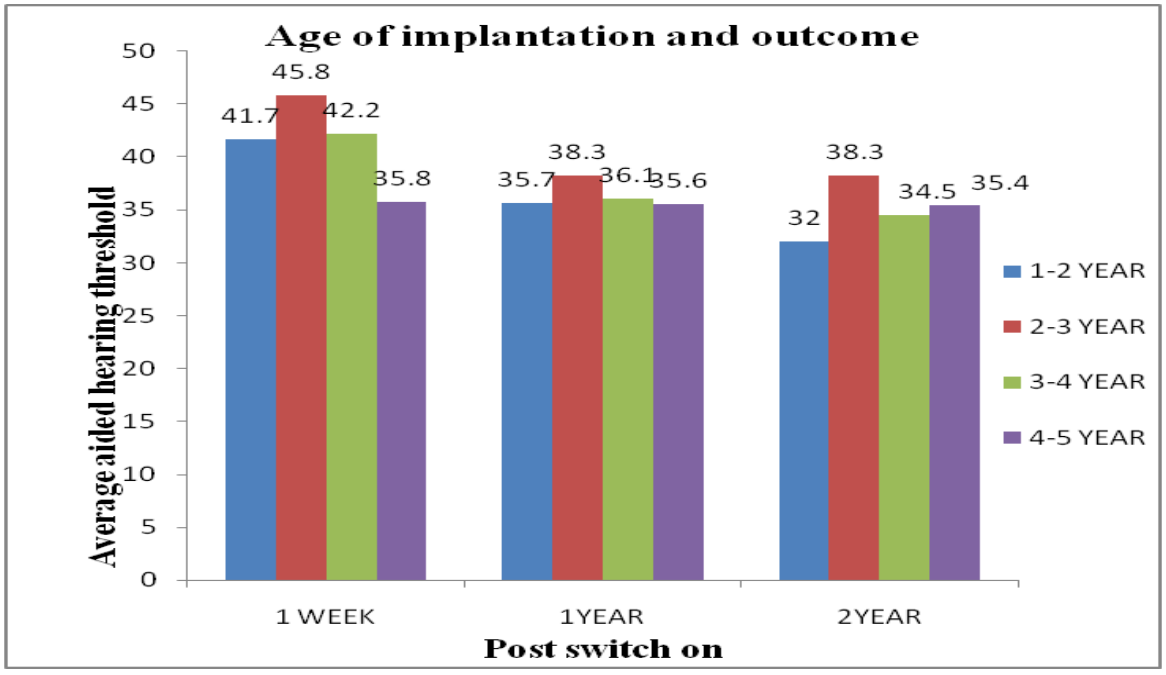

Fig 3: Post switch on average aided hearing threshold and age groups

Relationship between Age of Cochlear Implantation and Cap Score: Here the relationship between age of cochlear implantation and CAP score were studied.

Categories of Auditory Performance (CAP score) is a global outcome measure of auditory receptive abilities which comprises a nonlinear, hierarchical scale on which developing auditory abilities of children are rated according to twelve categories of increasing difficulty. Baseline CAP score was assessed after 1 week of switch on of cochlear implant and CAP was repeated at 1 year,1.6 years, and 2 years.

In our study one of the criteria for poor outcome is based on CAP score .If CAP score is ≤ 4 after 18 months (1.6 years) of AVT indicates poor outcome. Based on the age of implantation,85 children were grouped into four groups ,Group 1: 1- 2 years, Group 2: 2-3 years Group 3: 3-4 years, Group 4: 4-5 years and CAP score is given in the below table.

Table 5: CAP score of different age groups

Age of cochlear implantation	CAP score (post switch on)			
	At 1 week	At 1 year	At 1.6 year	At 2 year
1-2 YEARS	0.73	6.09	7.73	8.9
2 -3 YEARS	0.83	5.4	7.07	8.17
3-4 YEARS	1.03	6.24	7.24	8.16
4-5 YEARS	1.17	8.5	9.33	10.33

Table 6: Analysis of statistical difference in CAP score and age of cochlear implantation

Post switch on	Chronological Age of cochlear implantation	Mean CAP score	Standard deviation	Minimum value	Maximum value	Sig.
At 1 week	1-2 Years	0.73	0.47	0	1	0.698
	2-3 Years	0.83	0.78	0	4	
	3-4 Years	1.03	1.28	0	7	
	4-5 Years	1.17	0.41	1	2	
At 1 year	1-2 Years	6.09	1.75	4	9	0.003
	2-3 Years	5.40	1.83	0	9	
	3-4 Years	6.24	1.77	4	10	
	4-5 Years	8.50	2.07	7	12	
At 1.6 year	1-2 Years	7.73	2.33	4	10	0.124
	2-3 Years	7.07	2.10	0	10	
	3-4 Years	7.24	2.14	4	11	
	4-5 Years	9.33	2.50	5	12	
At 2year	1-2 Years	8.91	2.88	4	12	0.240
	2-3 Years	8.17	2.51	0	11	
	3-4 Years	8.16	2.63	4	12	
	4-5 Years	10.33	2.42	6	12	

Using a one way ANOVA test, age of cochlear implantation and CAP score has no significant relationship as P value greater than 0.05. After 1 year of post implant switch on age of cochlear implantation and CAP score has statistically significant association (P value <0.05).

After 2 years of implant age there is no significant relationship between age of cochlear implantation and mean CAP score. However there was statistically significant improvement of CAP score observed after 1 year,1.6 year and 2 years of post-cochlear switch irrespective of age of cochlear implantation. Percentage of children having CAP score ≤ 4 after 1 week, 1 year, 6 years and 2 years post CI switch on was analysed.

98.8% of children had CAP score ≤ 4 after 1 week of post switch on and 14.1% children had CAP score ≤ 4 after attending 1.6years of AVT .Only 10.5 % children had CAP score ≤ 4 after attending 2 year of post implant AVT.

Table 7: Assessment of CAP score

Assessment	CAP Score ≤ 4	CAP Score > 4
Baseline at 1week	84 (98.8%)	1(1.2%)
At 1 year	22(25.9%)	63(74.1%)
At 1.6 year	12(14.1%)	73(85.9%)
At 2 year	9(10.5%)	76(89.5%)

Assessment of ISD RLA & ELA Score: Integrated scale of development (ISD) used to assess speech and language skills. It is expressed in receptive language age (RLA) and expressive language age (ELA) Score.

ISD RLA and ELA score assessed and mean value given in the table 7.21. At baseline ISD RLA score is 1.78 that is between 0-3 months to 4-6 months and for ELA it is 1.59 almost in the same range. At 1 year ISD RLA and ELA improved to 25-30 months and 19-24 months respectively. Further improvement noted after 2 years of AVT, mean ISD RLA and ELA score was 37-42 months and 31-36 months respectively.

After 1week, 1 year and 2 years of AVT, ISD score for both RLA and ELA showed statistically significant improvement irrespective of age of cochlear implantation. Significance in the difference of ISD score assessed by Paired t test and Sig. (2-tailed) was 0.001.

Table 8: ISD score

ISD score (RLA & ELA)	
0-3 Months	1
4-6 Months	2
7-9 Months	3
10-12 Months	4
13-15 Months	5
16-18 Months	6
19-24 Months	7
25-30 Months	8
31-36 Months	9
37-42 Months	10
43-48 Months	11
>49 Months	12

Table 9: Assessment of ISD score

Assessment (Post switch on)	ISD-RLA Mean	ISD-ELA Mean
Baseline At 1week	1.78	1.59
After 1 year	7.20	6.73
After 2 years	9.08	8.84

Determination of Outcomes of Cochlear Implantation:

Outcomes of cochlear implantation are classified into 3 types according to CAP score, Aided Audiogram, Integrated Scale of Development-Expressive Language Age (ISD ELA) & Integrated Scale of Development Receptive Language Age (ISD RLA) score.

Poor outcome defined by

1. ISD score ≤ 1 year from the baseline after two years of AVT
2. Average aided hearing threshold >45dBHL
3. CAP score ≤ 4 after 18 months of AVT.

Depending on above mentioned criteria overall outcome of CI classified as follows;

1. Good auditory and speech outcomes
2. Good auditory and poor speech outcome
3. Poor auditory and speech outcome

Table 10: Outcome assessment

Outcome	Percentage	Frequency
Good auditory & speech outcome	87.1	74
Good auditory & poor speech outcome	11.8	10
Poor auditory and speech outcome	1.2	1

Here 87.1 % (74) cases have good auditory and speech outcome, 11.8 %(10) cases have good auditory and poor outcome and only1.2%(1) case have poor auditory as well as speech outcome.

Difference in The Average Aided Hearing Threshold after Surgery: The difference in the average aided hearing threshold after surgery is significant which is assessed by Paired t test. There is a significant difference in aided hearing threshold after surgery.

The table reveals that average aided hearing threshold is significantly better after 1 week (43.03 ± 13.17) , further better after 1 year (36.85 ± 8.39) and after 2 year (35.5±8.7) of post switch on, compared to the average aided hearing threshold before surgery (83.06 ± 9.31).

Table 11: Difference in average aided hearing threshold after surgery

Aided Audiogram	Mean	Standard deviation	Sig (2 tailed)
Pre Implant	83.06	9.31	
1 week	43.03	13.17	0.001
1 year	36.85	8.39	0.001
2 year	35.5	8.7	0.001

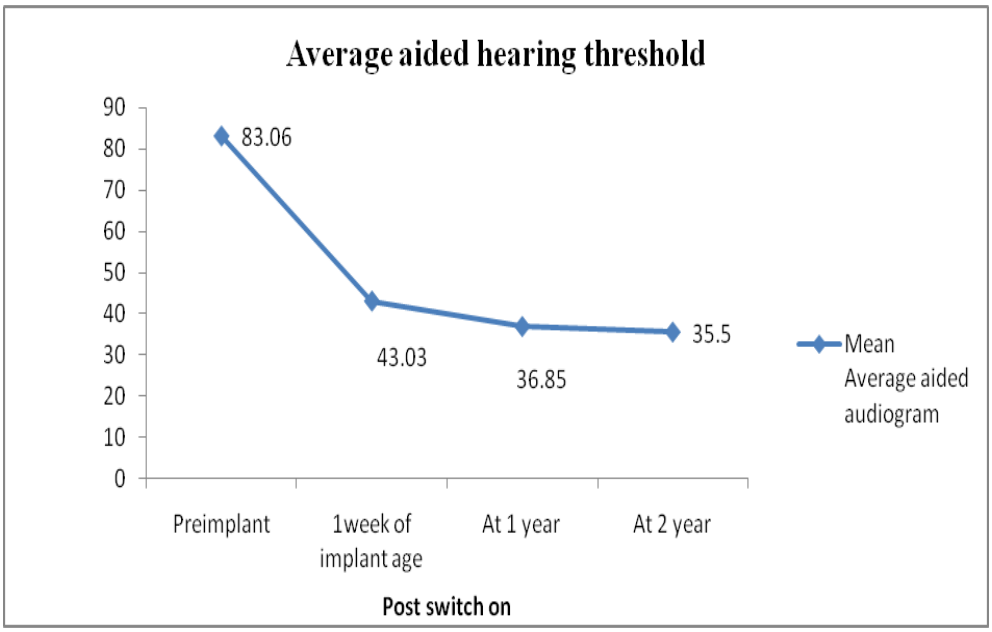

Fig 6: Difference in average aided hearing threshold after surgery

Difference in Cap Score after Surgery: The difference in CAP score after surgery is significant. There is a significant difference in CAP score after surgery and AVT which is assessed by Paired t test. The table 7.18 reveals that CAP score is significantly improved after 1 year (43.03 ± 13.17) and further improved after 2year (36.85 ± 8.39) of post switch on when compared to the baseline CAP score after 1 week of post switch on.

Table 12: Difference in CAP score after CI

Post switch on	Mean CAP score	Standard deviation	Sig (2 tailed)
Baseline at 1week	0.93	0.985	
12 Months	6.8	1.941	0.001
18 months	7.39	2.210	0.001
24 months	8.41	2.62	0.001

DETERMINE AGE ADEQUACY AFTER 2 YEARS OF AVT: Age adequacy of post cochlear implant children following 2 years of AVT were analysed by using ISD scores. 50.5% of cases are age adequate and 49.4% of cases are age inadequate with nearly 1-1.6 years of age gap with chronological age was observed.

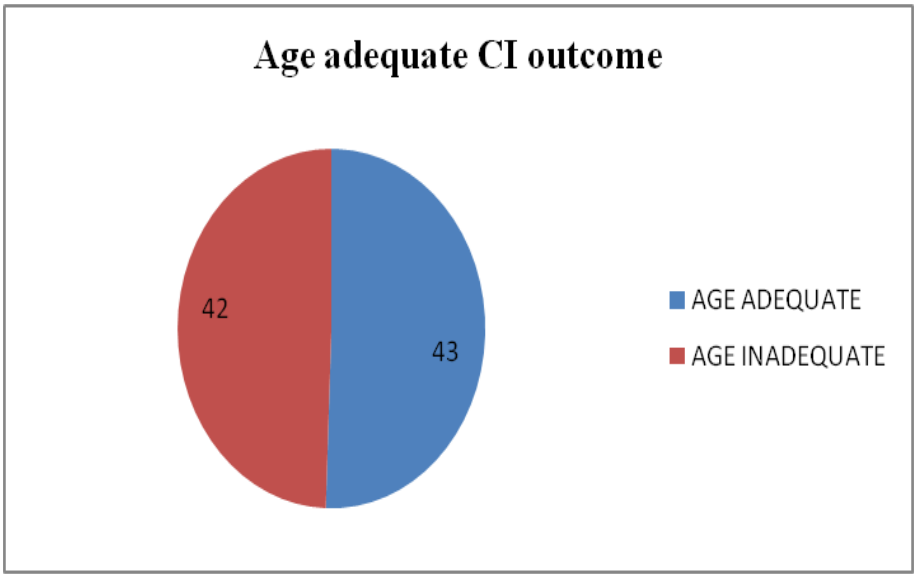

Fig 7: Age adequate CI outcome

Relationship between Various Factors and Cochlear Implant Outcomes:

Relationship between Duration of Hearing Aid Use and Cochlear Implantation Outcome:

Duration of Hearing Aid (HA) use prior to cochlear implantation and outcomes of cochlear implant (CI) was analysed using Chi Square test. P value obtained was >0.05 and hence there is no statistically significant relationship between duration of pre implant hearing aid use and CI outcomes. Among 85 cases, only one had a history of HA use for 3 years and had a good auditory & speech outcome. Twenty out of 85 cases had a history of HA use for 5 months and 85% of them had good auditory and speech outcomes. This implies that there was no significant association of duration of pre implant HA use and CI outcomes.

Table 13: Analysis of duration of pre implants HA use and outcomes.

Outcome	Mean duration of HA use (Year)	Standard deviation	P Value
Good auditory and speech outcome	1.09	0.528	
Good auditory and poor speech	1.3	0.586	
Poor outcome	0.5	0.536	0.280

Mean duration of pre implant HA use in children with good auditory and speech outcome was 1.09 ± 0.528 years. Mean duration of HA use in children with poor outcome was 0.5months. But no statistically significant association between duration of hearing aid use and post CI outcome as P value is 0.280, it may be due to other variables which influence the poor outcome such as quality and gain of hearing aid used, pre implant therapy, parental factors and associated issues.

Table 14: Duration of Hearing Aid (HA) use and cochlear implant outcome

Duration of HA use	Good auditory and speech outcome	Good auditory and poor speech outcome	Poor auditory and speech outcome
5 months	17	2	1
1 year	39	3	0
1.5 years	7	2	0
2 years	9	3	0
2.5 years	1	0	0
3years	1	0	0

Relationship between Parental Training and Outcome of Cochlear Implantation: Here the relationship between parental training of children and outcomes of cochlear implantation was studied. Chi Square Test showed significant relation between parental training and outcome as P value is 0.001 which is less than level of significance (0.05). Better outcomes were observed in children with good parental training compared to those with poor parental training. Good parental training was observed in 72 out of 85 children.

93.1% of children with good parental training have good auditory and speech outcomes.

Table 15: Parental training and CI outcome

Parental training	Good auditory and speech outcome	Good auditory and poor speech	Poor auditory and speech outcome
GOOD	67	4	1
POOR	7	6	0

Relationship between Regular AVT and CI Outcomes: Here relation between regular AVT (Audio Verbal Therapy) and outcomes of cochlear implantation was studied. Using Chi Square test regular AVT has significant impact on outcomes of pediatric cochlear implantation (P value <0.05). Overall 73 children had regular AVT and among them 68 children had good auditory & speech outcomes.

Table 16: Association between regular AVT and CI outcome

Regular AVT	Good auditory & speech outcome	Good auditory & poor speech	Poor auditory and speech outcome
YES	68	4	1
NO	6	6	0

Relationship between Maternal Education and CI Outcome: Here the relationship between maternal education and outcomes of cochlear implantation was studied. P value obtained as 0.631 which is greater than level of significance hence there is no statistically significant relation between outcome and maternal education.

Table 17: Relation between education of parent and CI outcomes

Parent Education	Good auditory & speech outcome	Good auditory & poor speech	Poor auditory and speech outcome	Total
Post Graduate	10	0	0	10
Graduate	45	8	1	54
Plus Two	19	2	0	21

Relationship between Length of Cochlear Duct and Cochlear Nerve Thickness with Hearing Outcome: Relationship between length of cochlear duct and hearing outcomes of cochlear implantation was studied. P value obtained was more than 0.05; hence there was no significant association. Association between thickness of cochlear nerve and outcomes of cochlear implantation also studied, but not statistically significant.

Table 18: Association between length of cochlear duct and Average aided hearing threshold

Variables	Mean	SD	P value
Length of Cochlear Duct	28.44	0.915	
Aided Audiogram – 1 week	43.03	13.17	0.897
Aided Audiogram – 1 year	36.89	8.39	0.647

Table 19: Association between thickness of cochlear nerve and Average aided hearing threshold

Variables	Mean	SD	P value
Cochlear Nerve Thickness	0.652	0.053	
Aided Audiogram – 1 week	43.03	13.17	0.277
Aided Audiogram – 1 year	36.89	8.39	0.542

Determination of Associated Issues among The Study Subjects and Relationship with CI Outcome: Here associated issues among the study population were evaluated. Among 85 children, 18 (20%) children had associated issues. 78.8% of children had no associated diseases. 8.2% children had ADHD and 4.7% children had Autism and Global developmental delay. One had Sticklers syndrome and one child had been diagnosed with central auditory processing disorder (CAPD). Children with associated issues had poor outcomes following cochlear implantation. Chi square test was used to determine the association between presence of associated issues and post CI outcomes. Statistically significant relation exists with CI outcome and children with complex needs (P value = 0.001).

Table 20: Prevalence of associated issues

Associated Diseases	Frequency
ADHD	7
AUTISM	3
CAPD	1
Stickler Syndrome	1
CHD	1
Global Developmental Delay	4
Others	1
No Associated Issues	67

Determination of Factors for Poor Outcomes:

Here factors for poor outcomes following pediatric cochlear implantation were analysed. 11.8% (10) of children have good auditory and poor speech outcomes. But one has poor auditory as well as speech outcome.

Presence of associated issues, parental training and regular AVT has a statistically significant impact on post CI outcomes. Presence of associated issues (60.5%) in children accounts a major factor for poor outcome following cochlear implantation. Parental training (19.5%) and regular AVT (19.5%) are other two factors responsible for poor outcomes. In 1% of cases the reason for poor outcome is unknown or genetics factors.

Determine Various Etiologies Of Congenital Hearing Loss Among Cochlear Implantees:

1. Determination of Frequency of Consanguineous Marriage and Family History of Hearing Loss: Here frequency of consanguineous marriage and family history of hearing loss among the study population were studied. Three parents among 85 cases had consanguineous marriage and 8 cases had family history of hearing loss.

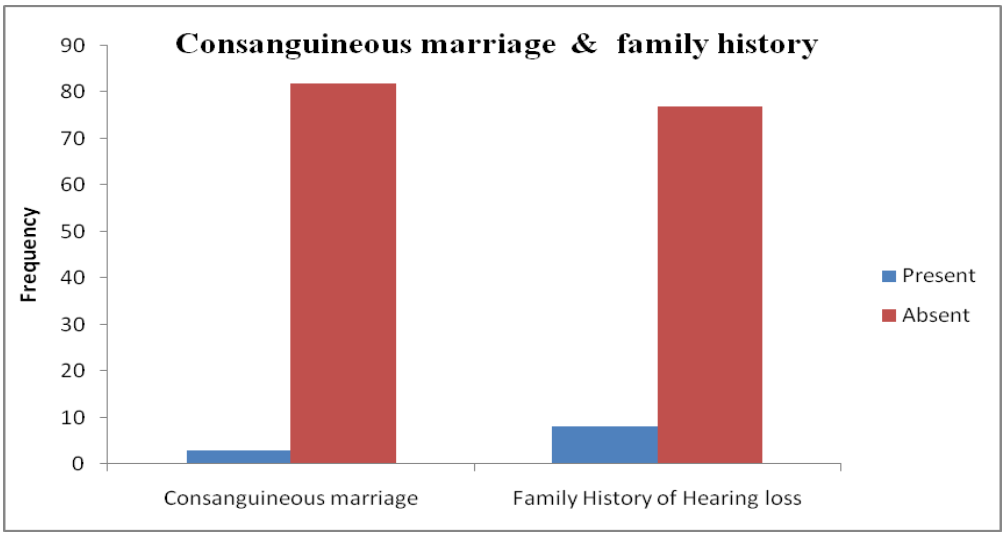

Fig 8: Consanguineous marriage and family history of hearing loss

2. Prevalence of Congenital / Neonatal Infection: Frequency of congenital /neonatal infections among study samples was evaluated. 5.8% of cases had congenital rubella syndrome and 1.2% of cases had congenital toxo-plasmosis. Neonatal meningitis observed in 4.7% of cases, Neonatal sepsis seen in one case, history of NICU admission for respiratory distress and Neonatal hyperbilirubinemia seen in 4.7% of cases.

Table 21: Prevalence of Congenital / Neonatal infection

Congenital / Neonatal Infection	Frequency
Congenital Toxoplasmosis	1(1.2%)
Congenital Rubella syndrome	5(5.8%)
Neonatal Meningitis	4(4.7%)
Neonatal Sepsis	1(1.2%)
Respiratory Distress	4(4.7%)
Neonatal Hyperbilirubinemia	4(4.7%)
No Infections	66(77.6%)

Discussion:

Early detection of pediatric hearing loss and early intervention can drastically improve their auditory and language skills. Best practices in Early Hearing Detection and Intervention (EHDI) specifies timeline for Universal New-born Hearing Screening, diagnosis, and intervention as the 1:2:3 rule that is every new-born is screened for hearing loss at 1 month of age, diagnosis is confirmed by 2 months of age, and intervention is initiated by 3 months of age. [18] Development of such standardized programs has ensured that every child born with a permanent hearing loss is identified before 2 months of age and appropriate intervention services provided timely by 3 months of age. The purpose of the study is to determine the various factors responsible for poor outcome in pediatric cochlear implantation and as well as to determine the prevalence of poor outcome of pediatric cochlear implantation. In the present study 85 children were included; they had undergone cochlear implantation during January 2018- December 2019. Outcomes of cochlear implantation evaluated using Aided audiogram, CAP score and ISD score at 1 week of post switch on, after 1 year and 2 year of post implant AVT (auditory verbal Therapy). Detailed analysis was done based on socio-demographic characteristics, associated issues, congenital or neonatal infections, parental motivation and training, education of parents, preoperative radiological investigations, intra operative and postoperative complications and attendance of AVT.

Socio demographic data: Age and sex distribution: In the present study the mean age of cochlear implantation was 3.08 years with standard deviation 0.819. The minimum and maximum age was 1 and 4.9 years respectively. No children underwent CI surgery prior to their first birthday. Children born with congenital hearing loss who meet FDA criteria may receive cochlear implant by target age of 12 months. However many children are being implanted at older age. [19] In contrast, the mean age of CI was 16.1 months with SD 4.9months which was earlier than the present study. Mean age of diagnosis of hearing loss was 1.5 years (1.5±0.740). Minimum age of diagnosis in this study was 2 months. Among the study subjects 12.9% of the cases belong to the age group 1-2 years , 35.3%of the cases belong to the group 2 -3 years, 44.7% of

cases belong to the age group of 3-4 years and only 7.1% cases were greater than 4 years of age. Similar study was conducted by Rohit Mehrotra, Anubhaw, Pankaj Srivastav et al [20] in UP, India grouped children into 5 groups, 5 children belongs to age group less than 1 year, 21 in age group 1-2 years, 46 in 2-3 year age group, 103 in 3-4 year age group and 125 in age group 4-5 years of age. Total 300 children among them 162 were males and 138 were females. In this study the percentage of children implanted at less than 2 years of age was 8.6%. But in the present study 12.9% of children were in the age group of less than 2 years. Another study conducted by Jane Black, Louise Hickson , Bruce Black et al [21] at the Royal Children's Hospital and the Here and Say Centre, Brisbane. Mean age was 4.5 years which was more than the mean age of the present study. Gender distribution was similar to that of the present study. Mean age of diagnosis was 16.9 months but it was 17 months in present study with minimum age of diagnosis was at 2 months. In both studies Early Hearing Detection and Intervention (EHDI) criteria were not met. In the present study out of 85 children 48(56.4%) were male and 37(43.55) were female. In India another similar study was conducted by Parth Patni, Deepak Dalmia, Udayanila Tet al**,** [22] they evaluated 51 patients with the ratio of male to female of 1.4:1. Around 10% of the study population was implanted at age less than 2 years, 58% at 2-5 years and around 25% at age more than 5 years in this study. The present study included children with age less than 5 years. Multivariate analysis done by Devendra Gupta et al [23] in this study out of 30 children, 14 children were less than 30 months of age and 16 above 30 months at the time of implantation. The youngest child was 11 months of age and oldest was 56 months. The mean age at implantation was 35.1 months that was more than that of present study; here mean age was 17 months. Gender distribution was almost comparable with present study.

Side of cochlear implantation and Model of CI used: Right sided cochlear implantation was done in 85.8% of total subjects and left sided implantation in 14.2%. Two models of cochlear implants were used; these are Medel sonata Ti 100 with Opus 2 BTE external processor and Cochlear Nucleus CI RE (ST) with CP 802 BTE external processor. 42 cases were implanted with Med-el sonata Ti 100 and 43 cases with Cochlear Nucleus CI 24 SE (ST). Statistically there was no relationship between the model of cochlear implant used and post cochlear implantation outcomes. Similarly in a study conducted by Rohit Mehrotra, Anubhaw, Pankaj Srivastav et al, [20] 260(86.6%) children were operated in right side and 40(13.3%) in left side. This was similar to the present study. Jane Black, Louise Hickson, Bruce Black et al [21], seventy-six (44%) children were implanted in the left ear and 98 (56%) were implanted in the right ear. Cochlear implant used were 137(44.9%) digisonic, 163(55.1%) freedom device in Rohit et al and nucleus device used in Jane Black et al [21] in their study.

Outcomes of cochlear implantation: In the present study auditory outcome of cochlear implantation assessed using Aided audiogram, CAP score and speech & language assessed using ISD score for receptive language age and expressive language age. Present study 65.8% of children had an aided hearing threshold of 71-90 dBHL prior to cochlear implantation with high gain hearing aid. After 1 week of post switch on 52.9% of children had average aided hearing threshold of 26-40dBHL and 36.4% had an average aided hearing threshold of 41-55 dBHL. 5.8% of children had an average aided hearing threshold of 56-70 dBHL and 2 of them had average aided hearing threshold poorer than 90 dBHL. After 1 year of AVT 82.3% of children had average aided threshold within 26-40 dBHL and 15.2% had 41-55 dBHL; only one had >90 dBHL. After 2year one had average aided hearing threshold 15-25 dBHL, 82.3% of children had 26-40 dBHL and 15.2% had 41-55 dBHL of average aided hearing threshold. After cochlear implantation, statistically significant improvement noted in Aided audiogram (P value<0.05). But no significant association noted between age of cochlear implantation and average aided audiogram as P value greater than the level of significance. In this present study, CAP score was assessed after 1 week, 1 year, 1.6 year and 2 years of post-cochlear switch on. There was statistically significant improvement of CAP score observed after surgery and from baseline during AVT. After 1 week, 67.1% of children have CAP score 1 which was improved after 1 year. At 18 months 14% had CAP score≤ 4. 89.4% (76) had attained CAP score more than 04 and 10.55% (9) had CAP ≤ 4 at the end of 2 years of AVT. Age of implantation is not significantly associated with improvement of CAP score. This finding was supported by Parth Patni , Deepak Dalmia, Udayanila Tet al. [23] Dong Hoon Kang et al, CAP score assessed at 3 years of post-CI, the poor performance group (poor performance group, CAP scores≤4, n=41) and the good performance group (good performance group, CAP scores≥5, n=85). Number of poor performers was more than that of present study. Rohit Mehrotra, Anubhaw, Pankaj Srivastav et al in UP, India,20 in their study 80% of children in age less than 3 had attained higher level of CAP (level 7,8,9,10) whereas in the age group of 3-5 years only 09% had attained highest level of 9, 8 and 7) highlighting the need for early age implantation. No such finding noted in present study as CAP score was significantly improved from baseline irrespective of age of implantation. It might be due to the mean age of CI being 3.05 years in present study and 48.2% of cochlear implantees younger than 3 years. Present study showed

statistically significant improvement (p value <0.05) in speech and language development both for receptive language age and expressive language age after cochlear implantation evaluated by ISD score. The receptive and expressive speech evaluation was conducted by using ISD at 1week of post AVT on, after 1 year and 2 years of switch on. Baseline ISD –RLA mean was 0-3 months which was found to improve to 25-30 months at 1 year and 37-42 months at 2 years of post AVT, similarly ISD-ELA improved from mean score of 0-3 months to 19-24 months at 1 year and 31-36 months at 2 years. Parth Patni, Deepak Dalmia, Udayanila Tet al, [22] SIR (Speech Intelligibility Rating) was used for speech outcome and SIR score improved significantly at 6, 12 and 24 months postoperatively but rate of improvement depend on duration of auditory deprivation contrary to present study. At the end of 1 year 16% have got SIR score of 5, 34% have score of 4, 30% score of 3, 19 % score of 2 and 01% score of 1 in Rohit Mehrotra, Anubhaw, Pankaj Srivastav et al.20 80% children had shown significant improvement in speech at the end of 1 year after implantation which was comparable to present study with ISD score. Duration of pre implant hearing aid use and cochlear implant outcome (CAPscore and ISD score) was analysed. Outcomes are not statistically significant with duration of hearing aid use (p value >0.05). Rohit Mehrotra, Anubhaw, Pankaj Srivastav et al, [20] 70% of children in age group less than 3 attaining CAP level of 7-10 were prior hearing aid users. High CAP score seen in hearing aid users prior to CI in the present study also. However the overall improvement in the CAP score following CI is not statistically significant with hearing aid use. There was no statistically significant association between duration of hearing aid use and post CI outcome as P value is 0.280, it may be due to other variables which influence the poor outcome such as quality and gain of hearing aid used, pre implant therapy, parental factors and associated issues. In the present study no intraoperative complications were observed. Only one case had postoperative complication as flap necrosis. Rohit Mehrotra, Anubhaw, Pankaj Srivastav et al, [20] complications present among their study subjects ,7 patients had facial paresis which recovered in 4-6 weeks, 12 had hematoma which recovered in 2 weeks, 2 had discharge which recovered in 1 week. Vergenia S. Ahmed Elkayala, Mona I. Mourad et al, [24] concluded that there was no statistically significant difference (P= 0.755) between age of implantation and postoperative grade of benefit from cochlear implant in phoniatric evaluation. In the present study also concluded the same finding. Devendra Gupta et al, [23] multivariate study conducted on outcome of CI the P-value was found to be significant for age at implantation, duration of auditory deprivation and residual hearing. However it was found that the CAP, aided hearing threshold, ISD and age of implantation is not statistically significant (P value > 0.05) in the present study. In the present study overall 3.5% cases had a history of consanguineous marriage and 8 children have family history of hearing loss. Parth Patni, Deepak Dalmia, Udayanila Tet al, [22] 17% of study population had family history of Consanguineous marriage and comparison of the CAP, SIR, MAIS score at periodic intervals between the two groups showed that the CAP, SIR and MAIS score is higher in no group and is statistically not significant. Similarly family history of consanguineous marriage and hearing loss has no significant relation with CI outcome in the present study also. Prevalent etiological factors of congenital hearing loss among implantees were determined in the present study are,5.8% of the study subjects have congenital rubella syndrome,4.7% have neonatal meningitis, 4.7% have respiratory distress, 4.7% have neonatal hyperbilirubinemia,1.2% have congenital toxoplasmosis and one had neonatal sepsis in present study. ParthPatni , Deepak Dalmia, Udayanila Tet al, [22] 11% had prenatal Infection, 10% had low birth weight,17% of study population had Hyperbilirubinemia one patient had meningitis, and 17% had TORCH infections were possible etiological factors, these finding are similar to the present study. In the present study, 87.1% of cochlear implantees have good auditory and speech outcomes, 11.8% have good auditory but poor speech outcome and only one had both auditory and speech outcome poor which is diagnosed as CAPD (central auditory processing disorder). 43 of children were age adequate in terms of communication skills as per ISD score, and 42 were age inadequate that is an age gap of 1-1.6 years compared to chronological age. Jane Black 2014 et al 21 based on outcome measures: receptive, expressive ,and total language, vocabulary and categories of auditory performance at 18 -24 months post implant,26% children had poor outcomes CAPI score<4. But in present study 12.8% children have poor outcome. Regular AVT and parental training have statistically significant impact on cochlear implant outcome. Education of parents does not significantly produce a difference in the cochlear implant outcome according to present study, which is supported by Rohit Mehrotra, Anubhaw, Pankaj Srivastav et al. [20] In present study 85.2% children were regular follow up and 14.8% irregular follow up. 80% of children had shown significant improvement in speech at the end of 1 year after implantation. The trend showed extensive rehabilitation with regular follow up with good compliance lead to improvement in outcome not only in hearing but also in speech. COVID 19 pandemic may also influence AVT which can also lead poor outcome. Parental training of children had a statistically significant impact on post CI outcomes supported by another study conducted by Ivette

Cejas et al [25], children of parents with higher maternal sensitivity had only a 1.3-year language delay 4 years post-CI compared with a 2.7-year delay in children of parents with low maternal sensitivity. Maternal sensitivity plays a strong role in the development of oral language. The present study showed there is no significant difference in outcomes in relation with maternal education as minimum maternal education was plus two. Similarly Parth Patni, Deepak Dalmia, Udayanila Tet al, [22] there is no significant difference in outcome and education of parents was observed. According to Parth Patni et al [22] two most important factors that affect the outcome of a pre lingual deaf child who undergoes Cochlear Implantation are - the Age at implantation and the duration of auditory deprivation. Cochlear duct length and thickness of cochlear nerve assessed by MRI and association with outcomes of cochlear implant was analysed in this study, no significant relation obtained. No inner ear anomaly observed among the present study population. However Jane Black, Louise Hickson, Bruce Black et al, [21] 13% of implantees had inner ear malformations. Dong Hoon Kang et al [26], assessed perinatal problems, inner ear anomalies, narrow bony cochlear nerve canal (BCNC), and intra operative problems and found significantly higher in the poor performance group than the good performance group (P=0.010, P=0.003, P=0.001, and P=0.045, respectively) Among 85 children, 18 (20%) children had associated issues. 78.8% of children had no associated issues. 8.2% children had ADHD and 4.7% children had Autism and 4.7% children had Global developmental delay. One had Sticklers syndrome and one child had been diagnosed with central auditory processing disorder (CAPD). Children with associated issues have poor outcomes following cochlear implantation, was statistically significant.

Cochlear implantees with associated issues significantly result in poor outcome compared to those without any associated problems. This is supported by Ivette Cejas et al, [25] Comparisons of outcomes across these disabilities indicate that children with little to no cognitive impairment (Attention Deficit Hyperactivity Disorder) had better outcomes than those with greater deficits in intellectual functioning (Autism). It is critical to evaluate these children's developmental milestones to provide early implantation and intervention, counsel families regarding realistic expectations for the implant and facilitate family adaptation.

Conclusion:

The mean age of cochlear implantation was 3.08 years with standard deviation 0.819 and no children underwent CI surgery prior to their first birthday. 87.1% of cochlear implantees have good auditory and speech outcomes, 11.8% have good auditory but poor speech outcome, and one with CAPD. 08.2% children had ADHD. Regular AVT and parental training has significant impact on cochlear implant outcome. 14% of children had irregular AVT. Congenital rubella syndrome was the most common etiology of congenital HL. Age of cochlear implantation and duration of pre implant hearing aid use were not statistically significant with CI outcome.

Limitations: Study sample size is not large enough to generalize the conclusions and this study did not include those cases with inner ear anomalies and age more than 5 years. Experience and efficiency of AV therapist and quality of the hearing aid used prior to the cochlear implantation was not considered in this study. Influence of COVID 19 pandemic on AVT and post CI outcome not studied in the study.

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