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Original Research Article

Cochlear Implant Procedure: Our Experience

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Abstract

Background: Cochlear Implant is the first bionic organ that allows a person to regain a sense and transform hearing, speech, and language in an otherwise handicapped individual. Cochlear implant is a relatively new technology where an electronic device is surgically implanted, and the electrodes are placed in the cochlea of the inner ear which stimulates the cochlear nerve. This requires a multidisciplinary approach of which surgical technique is an integral part. Several other factors influence the outcome of cochlear implant like the length of profound deafness, age at implant, etiology, use of hearing aids before implantation, family support and commitment, optimized programming and amount and quality of re/habilitation before and after implant. If carried out under optimum circumstances, the results are promising and highly beneficial.

Aim: To describe and evaluate the epidemiology, sociodemographic factors, and surgical outcome in patients with hearing impairment who have undergone cochlear implant surgery at our center and to add to the current knowledge of approach to the cochlear implant procedure.

Method: A retrospective analysis of the records of 131 pediatric patients diagnosed with bilateral severe to profound sensorineural hearing loss who underwent cochlear implant surgery at the otorhinolaryngology department of Indira Gandhi Institute of Medical Sciences between 2017 and 2022 was performed and demographic factors and surgical outcome were evaluated.

Results: A total of 131 candidates were evaluated. Mean age of 3.26 years ± 0.91 in the age group 0-5 years and 6.96 ± 1.77 years in the age group 5-15 years was found. 79 (56%) were male and 62(44%) were female. All the patients belonged to low socioeconomic status except 1 with a wide geographic distribution. The mean duration of deafness was 4.33 ± 2.08 years. Radiology of temporal bone showed abnormal findings in 13(9.9%) cases. Mostly the right ear was operated (93.1%). The postoperative complications were observed in only 5(3.8%) cases and the mean duration of postoperative hospital stay was 8.09 days ± 2.25.

Conclusion: Cochlear implant is not just a surgical management of deafness but a program that requires meticulous preoperative, intraoperative and postoperative care and evaluation. Its outcome depends on several factors. Considering the lower complication rates in our study we can say that this surgery is safe and reliable in pediatric patients when performed with utmost care.

Introduction

The cochlear implant also known as Bionic ears is a neuroprosthesis that provides electrical stimulation of the auditory nerve for the perception of sound in individuals with hearing loss where benefit from acoustic amplification alone is limited. The device is surgically implanted, and the electrodes are placed in the cochlea of the inner ear which stimulates the cochlear nerve.

According to the Center for Disease Control and Prevention 2018 Early Hearing Detection and Intervention summary data, 1.7 of every 1000 screened newborns have been diagnosed with hearing loss. Most such hearing loss is genetic in etiology, with autosomal recessive non-syndromic hearing loss accounting for 80% of these hearing loss diagnoses. However, the increasing number of cases of peri-lingual and post-lingual deafness likely suggests acquired factors, like meningitis, trauma, or ototoxicity. [1] Therefore, early diagnosis and intervention of deaf-mute individuals become crucial. Moreover, hearing loss impacts linguistic and social development, hence its evaluation is a part of mandatory health screenings at birth and early school age.

Cochlear implantation is performed under general anesthesia using the classic surgical approach involving mastoidectomy with posterior tympanotomy, which was originally described by William House in 1961. Many alternative surgical approaches have been described since then. Nonetheless, to gain optimal benefit from this surgery, not only the technique itself but proper selection of candidates is also a prerequisite. Several factors influence the outcome of cochlear implants like the length of profound deafness, age at implant, etiology, use of hearing aids before implantation, family support and commitment. In addition to this optimized programming and amount and quality of re/habilitation before and after implant also play a vital role in the success of the surgery. Intensive auditory rehabilitation is crucial in cases with delayed intervention, age over 5 years, and those with relatively poor intelligence and cognition. Each patient's need for rehabilitation is different based on the pre-operative auditory experience. For pre-lingually deaf patients, auditory and speech training are imperative for better communication abilities.

Cochlear implant is a relatively new technology that requires a multidisciplinary approach. If carried out under optimum circumstances, the promising and highly beneficial results of this life-changing surgery deem it an area of interest for many researchers. The purpose of this study is to describe and evaluate the epidemiology, sociodemographic factors, etiology, and surgical outcome in conjunction with postoperative auditory and speech rehabilitation of patients with hearing impairment who have undergone cochlear implant surgery at our center and to add to the current knowledge of approach to the cochlear implant procedure.

Objective

To describe and evaluate the epidemiology, sociodemographic factors, and surgical outcome in patients with hearing impairment who have undergone cochlear implant surgery at our center.

Materials and Methods

This study was conducted after approval from the ethics committee of the institution.

Study design: Institutional retrospective clinical observational study.

Study population: 131 cochlear implant candidates

Duration of Study: September 2017 to April 2022

Inclusion Criteria:

- Twelve months-15 years of age
- Bilateral severe to profound sensorineural hearing loss
- No benefit with hearing aid use for at least 3 months
- Motivation and good family support.

Exclusion Criteria:

- complete cochlear agenesis and/or cochlear nerve aplasia
- unilateral hearing loss
- age less than 1 year or more than 15 years
- poor motivation and family support
- any medical/ psychological contraindications for surgery.

Method:

A retrospective analysis of the records of 131 pediatric patients diagnosed with bilateral severe to profound sensorineural hearing loss who underwent cochlear implant surgery at the otorhinolaryngology department of Indira Gandhi Institute of Medical Sciences between 2017 and 2022 was performed. The Assessment protocol comprised of three stages.

Stage 1 involved consultation with an ENT specialist who took detailed history followed by audiological evaluation with bilateral hearing aid trial and speech therapy for a minimum of 3 months. This included BERA (Brainstem Evoked Response Audiometry), ASSR (Auditory Steady State Responses), OAEs (Otoacoustic Emissions), and tympanometry Once the audiological reports were confirmed for severe to profound hearing loss in both the ears and no benefit was noted with hearing aid use radiological evaluation was done. High resolution Computed tomography of the temporal bone (axial, coronal) thin slice (minimum 64) was advised with 3D reconstruction and magnified view of the bony cochlea and complete delineation of the Facial Nerve. Magnetic Resonance Imaging of CP (cerebellopontine) angle (FIESTA/CISS sequence) of a minimum of 1.5 Tesla was also done with 3D reconstruction of membranous labyrinth and complete delineation of Cochlear Nerve. Any abnormality or anatomical variation was noted. The parents/guardians of all the patients were counseled at this stage and explained about cochlear implant assessments and realistic outcomes of the surgery for that patient. Dummy implants and external devices were shown, and they were explained how the implant works. The cost of the implant and the maintenance and recurring cost involved was discussed. The patient was also offered the opportunity to meet an implantee of similar age and hearing loss.

Stage 2 involved a multidisciplinary approach. Psychological evaluation for the presence of necessary cognitive and behavioral skills with IQ and DQ assessment; Speech and Language Assessment, Pediatric evaluation, and Ophthalmology evaluation for any associated pathologies such as Rubella syndrome or Usher syndrome were done. Vaccination against H. influenzas type B, pneumococcus & meningococcus was given and ensured that the last dose was more than two weeks from the date of implantation. Counseling about surgery and its risks switch-on, mapping, and rehabilitation were done at this stage.

Stage 3 involved routine blood investigations, chest X-ray and ECG followed by general anesthesia fitness for the procedure. Written informed consent in the patient's language was taken. After careful assessment, the ear to be implanted was decided, and the surgery date and time were planned. Patients belonging to low socioeconomic groups received financial aid from the state government under Mukhyamantri Shravan Shakti Yojana. A preoperative dose of antibiotics was given and part preparation was done under strict aseptic conditions.

After a thorough evaluation and consideration of the candidacy for cochlear implantation, surgery was performed under general anesthesia using the classic surgical approach but with few modifications. We performed mastoidectomy and posterior tympanotomy. However, no sutures were used to secure the receiver stimulator apparatus in its bed and we used subcutaneous suture instead of mattress for wound closure. Intraoperative Neural response telemetry was done in every individual. The patient was discharged after administering proper intravenous antibiotics for 1 week and thereafter followed at regular intervals. Device switch-on was done 3-4weeks after surgery and regular mapping and progress were evaluated. Auditory verbal therapy was conducted by a qualified speech and language therapist based on the child's stage of auditory skills development and progress monitored.

Statistical Analysis: SPSS statistics version 26 was used to analyze data. Descriptive statistics for quantitative data such as age, duration of severe to profound hearing loss, and duration of postoperative hospital stay will be presented with mean, standard deviation, median, minimum and maximum values, interquartile range, and confidence interval. The qualitative variables such as socioeconomic status and radiological findings will be tabulated for each subject with the description of relative and absolute frequencies.

Results

A total of 131 candidates were evaluated of which 93 patients were in the age group 0-5 years with a mean age of 3.26 years ± 0.91 and 38 patients were in between 5-15 years with a mean age of 6.96 ± 1.77 years. The minimum age at implantation was 1 year and the maximum 12.1 years with a standard deviation of 0.91in below 5 years of age and 1.77 in above 5 years (Table1).

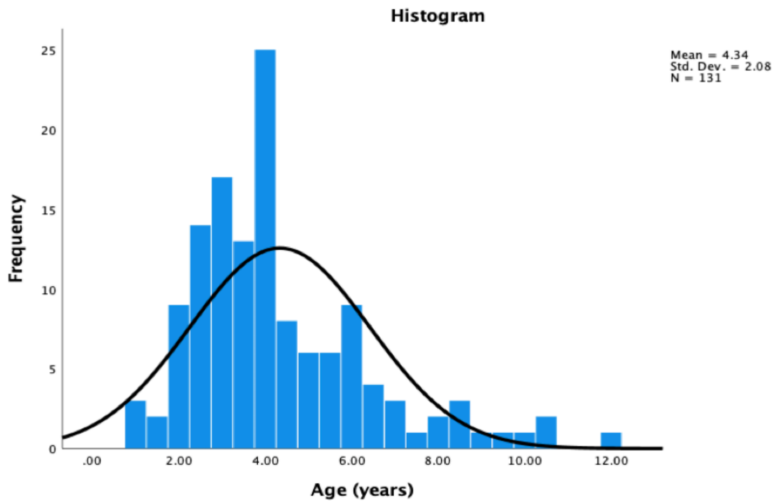
Table 1.1: Age distribution

	Frequency	Percent
0-5 years	93	71.0
5-15 years	38	29.0
Total	131	100.0

Table 1.2: statistical analysis of age distribution

Age group			Statistic	Std. Error
0-5 years	Mean		3.2624	.09470
	95% Confidence Interval for Mean	Lower Bound	3.0743	
		Upper Bound	3.4505	
	Median		3.3000	
	Std. Deviation		.91330	
	Minimum		1.00	
	Maximum		4.90	
	Interquartile Range		1.30	
	Skewness		-.455	.250
	Kurtosis		-.406	.495
5-15 years	Mean		6.9632	.28759
	95% Confidence Interval for Mean	Lower Bound	6.3804	
		Upper Bound	7.5459	

	Median	6.2500	
	Std. Deviation	1.77283	
	Minimum	5.10	
	Maximum	12.10	
	Interquartile Range	2.42	
	Skewness	1.171	.383
	Kurtosis	.710	.750



Out of 131 subjects, 79 (56%) were male and 62(44%) were female (Table 2).

Table 2: Gender distribution

	Frequency	Percent
Male	79	56.0
Female	62	44.0
Total	141	100.0

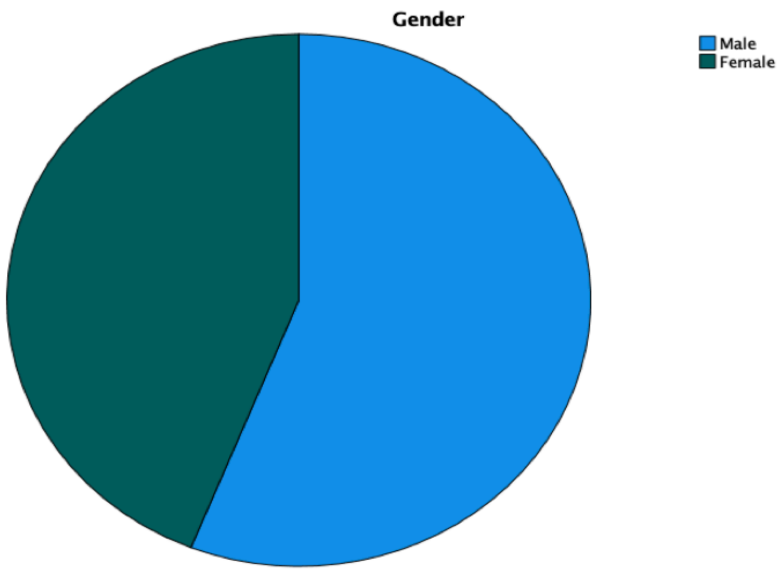


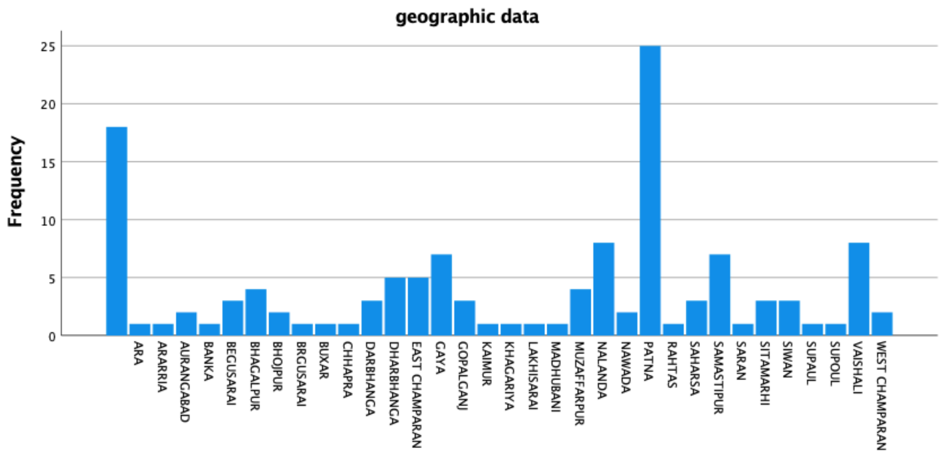
Table 3: Socio-economic profile

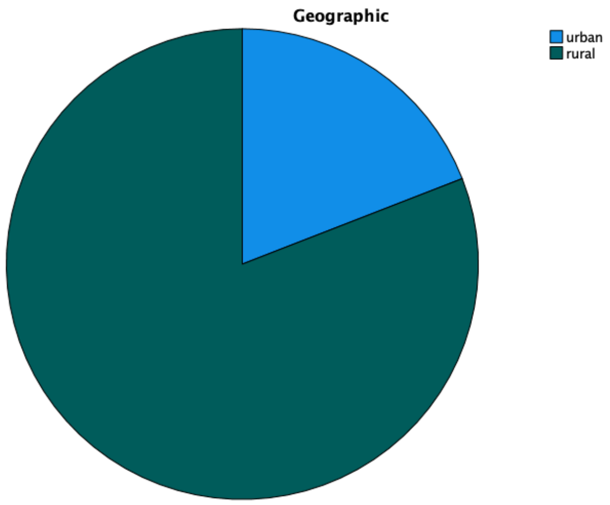
	Frequency	Percent
average	1	.8
low	130	99.2
Total	131	100.0

All the patients belonged to low socioeconomic status except 1 (Table 3) and there was wide geographic distribution of candidates as shown in the graph with 106 (80.9%) patients from rural areas (Table 4).

Table 4 Geographic distribution

	Frequency	Percent
urban	25	19.1
rural	106	80.9
Total	131	100.0





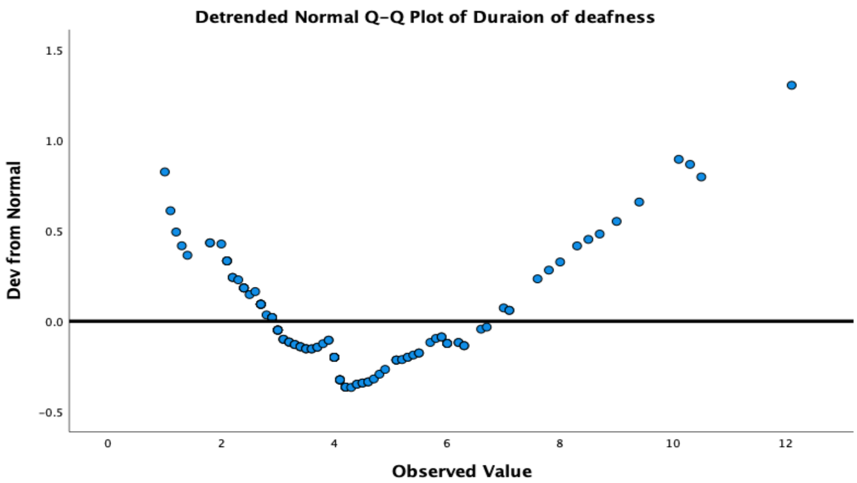
The mean duration of deafness was 4.33 ± 2.08 years, a median of 4 years, and an interquartile range of 2.4 years. The minimum duration was 1 year, and the maximum was 12.1 years (Table 5).

Table 5.1: Duration of Deafness

		Statistic	Std. Error
Mean		4.3359	.18174
95% Confidence Interval for Mean	Lower Bound	3.9763	
	Upper Bound	4.6954	
Median		4.0000	
Variance		4.327	
Std. Deviation		2.08013	
Minimum		1.00	
Maximum		12.10	
Range		11.10	
Interquartile Range		2.40	
Skewness		1.251	.212
Kurtosis		1.754	.420

Table 5.2: Tests of Normality for duration of deafness

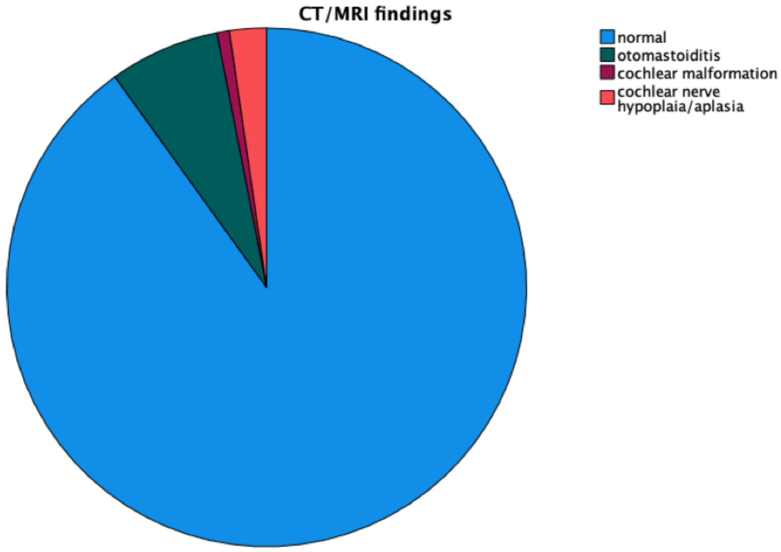
	Kolmogorov-Smirnov[a]			Shapiro-Wilk		
	Statistic	df	Sig.	Statistic	df	Sig.
Duration of deafness	.160	131	<.001	.909	131	<.001



The radiological assessment of temporal bone showed abnormal findings in 13(9.9%) cases out of 131. These included otomastoiditis in 9 (6.9%), cochlear malformation in 1(0.8%), and cochlear nerve hypoplasia in 3(2.3%) cases. So out of 13 cases, 69.2% were otomastoiditis followed by cochlear nerve hypoplasia (23.1%) and cochlear malformation (7.7%) (Table 6).

Table 6: Radiological findings

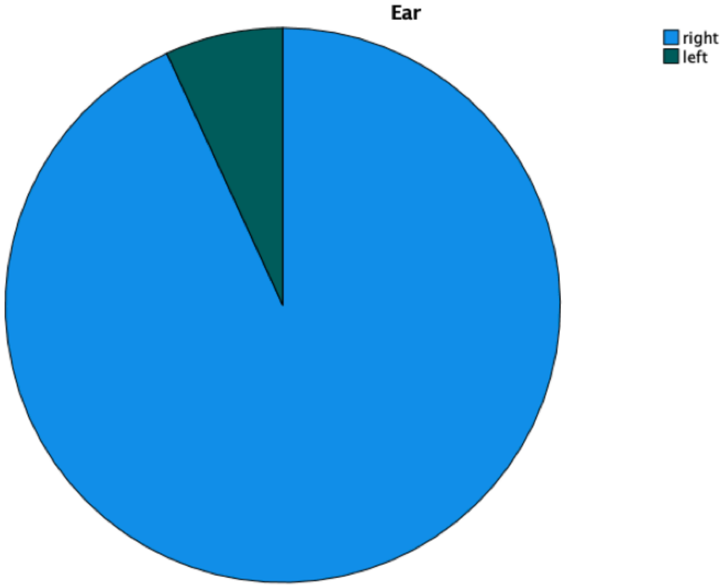
CT/MRI findings				
	Frequency	Percent	Valid Percent	Cumulative Percent
otomastoiditis	9	6.9	69.2	69.2
cochlear malformation	1	.8	7.7	76.9
cochlear nerve hypoplaia/aplasia	3	2.3	23.1	100.0
Total	13	9.9	100.0	
Normal	118	90.1		
Total	131	100.0		



Amongst all 131 subjects, the right ear was operated on in 122(93.1%) cases and the left ear in 9(6.9%) as shown in Table 7.

Table 7: Side operated

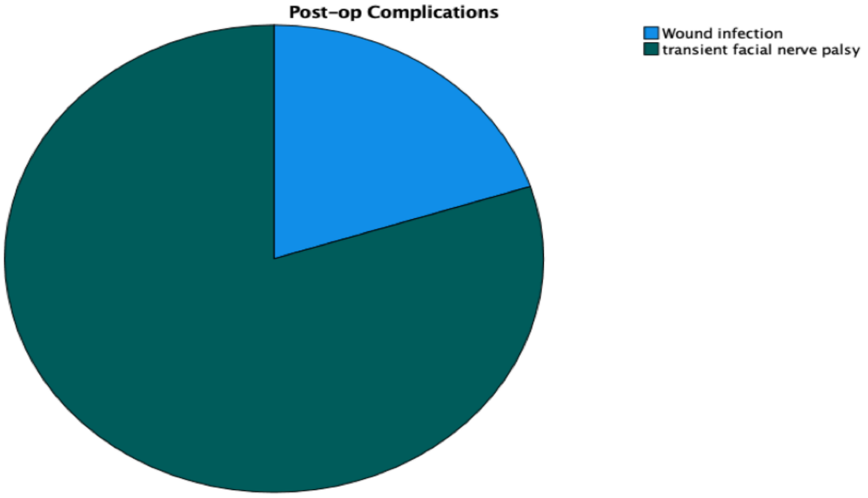
	Frequency	Percent
right	122	93.1
left	9	6.9
Total	131	100.0



The postoperative complications as shown in Table 8 were observed in total 5(3.8%) subjects out of 131.

Table 8: Post-op Complications

		Frequency	Percent	Valid Percent	Cumulative Percent
Major					
	Device failure	0	0	0	0
	Electrode extrusion	0	0	0	0
	Device migration	0	0	0	0
	Total Facial Nerve Palsy	0	0	0	0
	CSF leak	0	0	0	0
	CSOM	0	0	0	0
	Total	0			
Minor					
	Chorda tympani injury	0	0	0	0
	Vertigo/Vomiting/seizures	0	0	0	0
	Injury to EAC	0	0	0	0
	Wound infection	1	.8	20.0	20.0
	Seroma/Hematoma	0	0	0	20.0
	transient facial nerve palsy	4	3.1	80.0	100.0
	Total	5	3.8	100.0	
	No complications	126	96.2		
	Total	131	100.0		



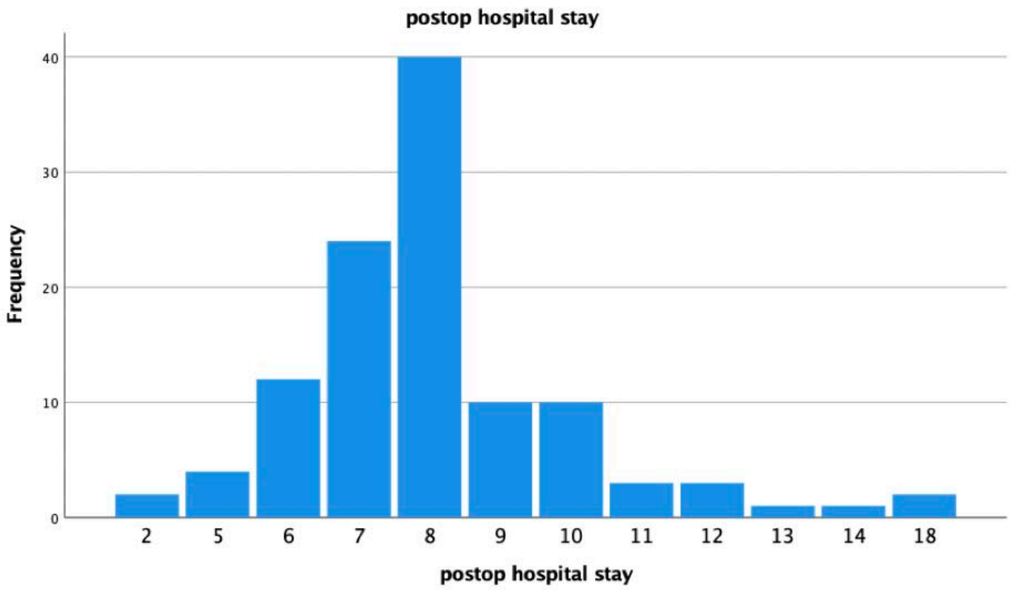
These included wound infection (magnet induced boil) in 1(0.8%) and transient facial nerve palsy in 4(3.1%) cases. There were no cases of device failure, electrode extrusion, device migration, total facial nerve paralysis, CSF leak, CSOM, chords tympani nerve injury, injury to EAC, vertigo, seizures or hematoma formation. The mean duration of postoperative hospital stay was 8.09 days ± 2.25. The minimum duration was 2 and a maximum of 18 days with skewness of 1.51 and kurtosis of 6.28 (Table 9).

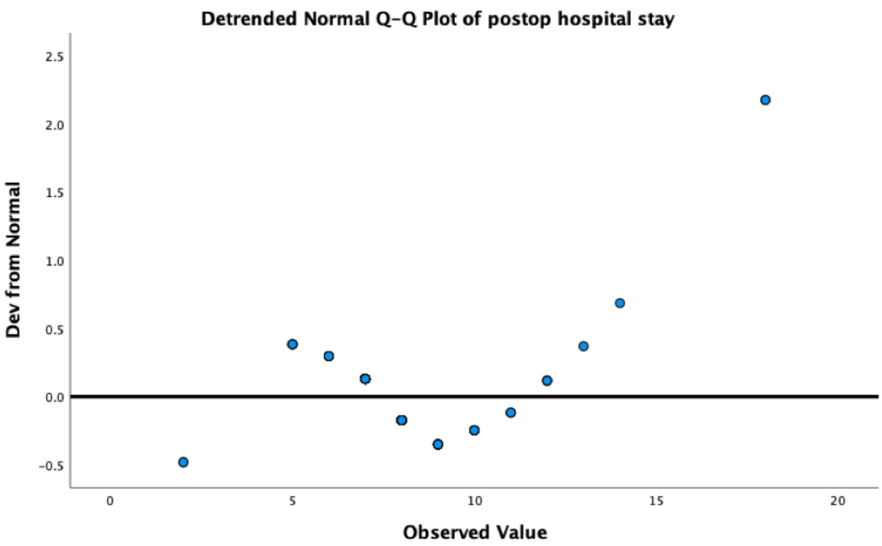
Table 9.1: Postoperative hospital stay

		Statistic	Std. Error
Mean		8.09	.213
95% Confidence Interval for Mean	Lower Bound	7.67	
	Upper Bound	8.51	
Median		8.00	
Variance		5.091	
Std. Deviation		2.256	
Minimum		2	
Maximum		18	
Range		16	
Interquartile Range		2	
Skewness		1.511	.228
Kurtosis		6.284	.453

Table 9.2: Tests of Normality for post operative hospital stay

	Kolmogorov-Smirnov[a]			Shapiro-Wilk		
	Statistic	df	Sig.	Statistic	df	Sig.
postop hospital stays	.248	112	<.001	.841	112	<.001





Discussion

The cochlear implant was started at Indira Gandhi Institute of Medical Sciences, Bihar, India in September 2017 and to date, 131 patients under 15 years of age and few adults have received the implant. The present study is focused on pediatric age group who were diagnosed with severe to profound hearing loss in both the ears.

Several factors account for the success of this surgery from candidacy for implant up to postoperative auditory and speech rehabilitation. At our center, patients are assessed diligently at several stages before proceeding for surgery. This involves a multidisciplinary approach comprising psychological, pediatric, ophthalmic, radiological, and speech and language evaluation. We have assessed various parameters crucial to a favorable outcome of this surgery in the cases operated at our institute.

Age at implantation is a key factor when considering a candidacy for the implant. At birth, the cochlea is fully formed but the auditory pathway is not. The auditory pathway is dependent on stimulation for its maturation and this stimulation is vital to the acquisition of speech and language skills. We can achieve optimal results when the patient is between 1 to 5years. From 5 to 7 years the results may vary and those who are 7yrs and above require good hearing aid use and re/habilitation. Our study showed that in children under 15 years of age the mean age at implantation was 4.3 years with a standard deviation of 2.08, a median of 4 years, and an interquartile range of 2.4 years. In a study conducted by Zohdi et al., similar descriptive statistics revealed that the average age at implantation for the 62 prelingual subjects was 4.70 years, with a standard deviation of 2.19 years, a median of 4.25 years, and an interquartile range of 1.93 years. [2] Several other studies have reported similar results. [3-5] This relative delay in implantation can be attributed to the delayed presentation which implies a deficiency in our health care system. We found a slight male preponderance with 56% cases male. These findings were consistent with those of Barbosa MH et al. [6] However most studies have reported slight female predominance in pediatric patients. [3,4,7-9] Almost all the patients presenting at our center belonged to low socioeconomic status. The increase in the prevalence of deaf mutism in this group is suggestive of a higher risk of infections and poor antenatal and perinatal care. However, the greater number of cases from this class could also be accounted to the fact that these patients receive financial aid from the government at our center.

Furthermore, the geographic data also correlates to the low socioeconomic data as 80.9% of patients came from rural areas of the state.

The importance of early diagnosis and intervention cannot be highlighted enough when it comes to cochlear implant surgery. The duration of deafness roughly corresponds to the age at implantation in our study. The mean duration was 4.33 ± 2.08 years, with a median of 4 years, and an interquartile range of 2.4 years. Our study revealed that most of the patients had deafness since birth but had delayed presentation. The cause for this delayed presentation can be attributed to unawareness and illiteracy in the families, especially mothers. This is another area of concern to be addressed with regards to early referral in implant patients.

When we evaluated the radiological findings, it was revealed that most of the patients with severe to profound hearing loss had a normal inner ear and only 4 out of 131 cases had inner ear deformity. 1 patient had complete labyrinthine agenesis (Michel's aplasia) in the left ear, hence right ear was implanted which appeared normal on CT and MRI. However, there was no neural response on intraoperative telemetry despite complete electrode insertion. Bilateral Cochlear nerve hypoplasia was seen in 3 cases that underwent cochlear implant surgery with a guarded prognosis resulting in device failure in 2 cases with no device complication but transient seizures in 1 case. Unilateral Otomastoiditis was found in 9 cases in which the opposite healthy ear was implanted with no postoperative complications. In the remaining 122 cases, the right ear was implanted considering hand preference to facilitate device manipulation. Agenesis of the cochlea and/or cochlear nerve are absolute contraindications for this surgery. Radiology of temporal bone is not just essential to detect any pathology but is also a road map for surgery. Any surgical challenges like contracted mastoid, low lying tegmen, anteriorly placed sigmoid sinus, high jugular bulb, or anomalous course of the facial nerve can be identified before surgery and the approach can be modified accordingly. This fact was also emphasized in a study conducted by Tiwari et al. and Widmann et al. [10,11]

The complications of this procedure are classified into major and minor. The major complications are those which require surgical intervention or cause permanent disability, while minor complications were defined as those with spontaneous resolution or requiring medical management alone. The minor and major complication rates reported in the literature range from 3.71% to 20.67% and 2.3% to 16.1% respectively. [4,8,9,12,13] Ajalloueyan et al. reported an overall complication rate of 18.7%. [3]. Our study revealed no major complications and very few minor complications (3.8%). These include wound infection in 1 case (magnet-induced boil), and transient facial nerve palsy in 4 cases. All the cases were managed conservatively. The magnet was removed in the former case and appropriate course of antibiotic was given. After complete healing, the size of the size of the magnet was reduced from 2 to 1. Facial palsy was thought to be due to retrograde inflammation. An intravenous course of corticosteroids led to complete recovery on the 4^{th} to $5`^{th}$ postoperative days respectively. The mean duration of postoperative hospital stay was 8.09 days with a standard deviation of 2.25. Appropriate surgical technique plays pivotal role in reducing postoperative complications. The use of sutures for securing receiver-stimulator in its bed can act as foreign body and cause inflammation and granulation tissue formation. [14] This may lead to device migration or extrusion. Furthermore, drilling holes for suture placement poses risk of dural injury and CSF leak particularly in pediatric patients who have thin skull. So, in order to properly secure the implant, we made an adequately deep implant bed, tight subperiosteal pocket and firm suturing of musculo-periosteal flaps.[15] Subcutaneous suture also had an advantage of no need for suture removal which is again difficult in children who are given mattress or simple sutures. These modifications in technique also reduced the operating time to some degree. The imperative postoperative care under strict supervision in the hospital is likely another reason for reduced complication rates at our center. Apart from stringent patient selection and robust preoperative assessment protocol, meticulous postoperative care includes adequate intravenous antibiotics, proper patient hygiene in wards dedicated to the implant, and educating guardians regarding patient care as well as implant care and maintenance before discharge.

Conclusion

Cochlear Implantation is a surgery that can reduce the disability burden to a great degree and transform hearing, speech, and language in an otherwise handicapped individual. To achieve maximum benefit from this surgery optimum age at implantation is the key. This needs to be achieved by early detection of hearing loss by screening newborns for congenital as well as early school age for acquired hearing loss followed by timely referral. Public awareness about identifying signs of hearing impairment at an early age by means of health care programs will also prove helpful. We also conclude from our study that a robust preoperative assessment protocol, good surgical technique and stringent postoperative care can significantly reduce the complication rates. This includes a detailed radiological study of the patient which is valuable in not just deciding the candidacy for the implant, but also in detecting the degree of surgical difficulty, and determining the ear to be implanted. No use of sutures to secure implant and subcutaneous suturing of post aural incision not only prevents certain complications but also reduces operating time. Prolonged hospital stay for ample postoperative intravenous antibiotics and care under strict supervision can curb the infection rate in children. Considering the lower complication rates in our study we can say that this surgery is safe and reliable in pediatric patients when performed with utmost care.

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