The Cochlear Implant Outcome and Factors Associated of Pre-Operative among Prelingual Deafness Patients Under 3 Years and 6 Months Old in Rajavithi Hospital: A Single Center Experience

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Background: The recent government announcement that fees for cochlear implants in prelingual patients will be reimbursed means that this treatment will be more accessible in the near future. The data in the present study would form the baseline for improving the care process in Rajavithi Hospital.

Objective: To study the outcomes of cochlear implants in prelingual hearing loss patients younger than three years and six months, and to determine preoperative assessment factors that affect the outcomes.

Materials and Methods: A retrospective review was conducted of the medical records of prelingual deafness patients younger than three years and six months that underwent cochlear implants between 2013 and 2019. Forty patients were enrolled, and their demographic data, preoperative assessment, and Category Auditory Performance (CAP) score outcomes were recorded. The preoperative factors affecting the CAP score at 2 years post-operation were analyzed.

Results: A CAP score above 5 at two years after cochlear implant, considered to be good habilitation, was reported in 55% (22 cases). After further follow up, the number of patients whose CAP score reached 5 or more was 31 (77.5%). The mean age of diagnosis was 13.28±9.38 months, and the mean age at surgery was 25.73±9.74 months. The preoperative factors associated with poor CAP scores were Goldenhar syndrome, Waardenburg syndrome, Autism, small inner ear canal, and poor eye contact. The differences in preoperative factors between patients with CAP scores of 5 or more and those with scores less than 5 at two years after cochlear implant were not statistically significant.

Conclusion: The outcomes of cochlear implant operations may be improved by early age at surgery, which will be assessed by the Newborn Hearing Screening policy. Preoperative assessment factors associated with poor outcomes were identified, but they were not statistically significant in the present study.

Keywords: Cochlear implant; CAP score; Preoperative factors

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The cochlear implant operation is a complicated process that can be managed only by otolaryngology specialists in medical schools or super tertiary hospitals because of the high cost of the required

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equipment. The selection of suitable candidates has to be meticulous to ensure the safety of the patients and to achieve optimal benefits in terms of development of speech and language. Factors that affect auditory performance are assessed in the preoperative period, during the operation, and in the postoperative period. Zhou et al.⁽¹⁾ reported that cochlear implants on 34 prelingual deafness cases evaluated by the Category Auditory Performance (CAP) with a score of 5 or more at 24 months post operation yielded a success rate of 89.4% to 93.3%. Kang et al.⁽²⁾ reported a good performance rate of 64.7% three years after cochlear implant in prelingual patients and found that the factors that limited success were size of bony cochlear nerve canal of less than 1.4 mm, perinatal illness, which had a statistically significant correlation

with the progression of auditory performance but no correlation with any other disability, duration of hearing aid usage, and duration of deafness. Other studies had found the following limited factors, peripartum illness, age at diagnosis, age at start of habilitation, anomaly of inner ear, comorbidity, and family cooperation⁽²⁻⁶⁾.

Rajavithi Hospital started performing cochlear implants in 2009. Selection of suitable candidates was made by an otolaryngologist by examining preoperative assessment criteria, which were likely to lead to good outcomes. Recently, the National Health Security Office launched a program of cochlear implant reimbursement for patients with prelingual deafness who are under three years and six months, therefore, access to services for prelingual hearing loss treatment may improve in the near future. The authors' objective was to study cochlear implant outcomes in patients in this age range. The present study findings would improve the quality of the treatment and assist in predicting outcomes and making habilitation plans.

Materials and Methods

The present research was approved by the Ethics Committee of Rajavithi Hospital (No. 64284). A retrospective study was performed of the medical records of prelingual deafness patients at Rajavithi Hospital between 2013 and 2019 who underwent cochlear implants before reaching the age of three years and six months, the upper limit for cochlear implant reimbursement from the National Health Security Organization. All patients had levels of hearing above 90 decibels and underwent multidisciplinary approach of preoperative assessment by a team including an Otologist, an Audiologist, a speech therapist, a psychiatrist, and a social welfare worker. During the preoperative period, it was established that all patients had hearing aids before surgery. The cochlear implant surgery was performed by otologists who had special training for the operation. All patients underwent cochleostomy with full electrode insertion. Mapping and habilitation started the first week after the operation and was followed by a 24-month auditory verbal therapy (AVT) program with a speech therapist. Patients were excluded from the study if they were lost to follow up from the habilitation program or if their data were not complete. Information was recorded regarding the patient gender, age at diagnosis, age at start of using hearing aid, age at surgery, duration of hearing aid use before surgery, developmental assessment,

radiological inner ear image, perinatal illness, other disability, family support, such as caregiver, living place, family income, and education. The outcome of habilitation was recorded by CAP score at 6, 12, and 24 months after cochlear implant, and patients whose CAP score was less than 5 were further followed up for at least one year or until the CAP score exceeded 5. The CAP Score is used for measurement of auditory performance on a scale of 0 to 7 with 0 for no awareness of environmental sounds, 1 for awareness of environmental sounds, 2 for response to speech sounds, 3 for identification of environmental sounds, 4 for discrimination of some speech sounds without lip reading, 5 for understanding common phrases without lip reading, 6 for understanding conversation without lip reading, and 7 for using the telephone with a known speaker. Statistical analyses were performed using IBM SPSS Statistics, version 22.0 (IBM Corp., Armonk, NY, USA). Categorical data were presented as number and percentage, while continuous data were reported as mean and standard deviation. Comparisons between categorical data were made using chi-square test or Fisher's exact test, and either Student t-test or Mann-Whitney U test was used to compare continuous data. A p-value of less than 0.05 was considered statistically significant.

Results

There were 45 patients aged under three years and six months on the day of surgery. But five patients were excluded because of loss to attend the habilitation after surgery. Demographic data revealed that 25 were males (62.5%), the mean age of diagnosis was 13.28±9.38 months, the mean age of starting to use a hearing aid was 18.30±9.60 months, the duration of hearing aid use before surgery was 7.48±5.22 months, and the mean age at surgery was 25.73±9.74 months. Thirty patients (75.0%) had history of regular hearing aid usage, and 22 (55%) had preoperative assessment of good eye contact. Most of the cases had no perinatal illness and had normal cochlear assessed by radiographic image. Family and caregiver information revealed that 35 patients were taken care of by their parents, and 26 (65%) lived in Bangkok or nearby (Table 1).

The outcomes of the cochlear implants in the present study were measured by the CAP Score, which was assessed every six months during the habilitation program. The intensive program lasted for 24 months, subsequent to surgery, after which it was adjusted in accordance with the last CAP Score. After the first six months, 21 cases reported having

Table 1. Demographic data (n=40)

Characteristic data				
Sex; n (%)				
Male	25 (62.5)			
Female	15 (37.5)			
Access to system; n (%)				
Newborn hearing screening	24 (60.0)			
By symptom of delayed development	16 (40.0)			
Age at diagnosis (months); median (IQR)	12.00 (5.00, 22.00)			
Age on cochlear implant surgery day (months); median (IQR)	28.00 (18.25, 33.00)			
Age started using hearing aid (months); median (IQR) $% \left(IQR\right) =0$	18.50 (9.00, 26.75)			
Duration of hearing aid use before cochlear implant (months); median (IQR)	6.00 (4.00, 10.00)			
History of hearing aid use; n (%)				
Regular	30 (75.0)			
Not regular/uncertain	7 (17.5)			
No data	3 (7.5)			
Eye contact assessment; n (%)				
Good	22 (55.0)			
No eye contact/unsure	7 (17.5)			
No data	11 (27.5)			
Perinatal illness; n (%)				
No	35 (87.5)			
Yes	4 (10.0)			
No data	1 (2.5)			
Pre-operative syndrome comorbidity; n (%)				
No	37 (92.5)			
Yes	3 (7.5)			
• Goldenhar syndrome	1			
Waardenburg syndrome	1			
• Cleft lip	1			
Radiological cochlear and internal auditory canal image; n (%)				
Normal	37 (92.5)			
Abnormal	3 (7.5)			

IQR=interquartile range

discrimination of some speech sounds without lip reading, but only three of these reported being able to understand common phrases without lip reading. Twenty-two cases had CAP score of 5 or more, two years post-operation, while after follow up, another nine cases reported further progress to CAP scores of 5 or more, making a total of 31 who reported reaching this level, as shown in Table 2.

The reasons for some patients' failure to progress after two years of habilitation were explored. Preoperative assessment factors that limited outcome success included Goldenhar syndrome and Waardenburg syndrome. Preoperative assessment of small internal acoustic canal (IAC) was found in one case, and poor eye contact was reported in one case. The Autism was diagnosed later after habilitation

 Table 2. The number of patients at each CAP score at 6 months,

 1 year, and 2 years after cochlear implant

CAP score	Pre-operative	6 months	1 years	2 years	\geq 2 years
0	21	0	0	0	0
1	14	1	1	1	1
2	4	15	5	2	1
3	0	3	2	0	1
4	1	18	16	15	6
≥5	0	3	16	22	31

CAP=Category Auditory Performance

in one case. The CAP score of No. 9 patient was 4, two years after regularly attended the program of habilitation but due to illness of caregiver, the patient was loss to follow up and there was no habilitation done at home. The other three cases showed no preoperative limiting factors, as shown in Table 3.

Preoperative assessment of these patients revealed that factors affecting the cochlear implant (CI) outcomes were age at diagnosis, age at surgery, and age at starting to use a hearing aid, but these factors were not significantly different among the patients with CAP score of 5 or more and those with lower scores after two years. As shown in Table 4, the differences between the following factors were not statistically significant in the two groups, perinatal illness, other disabilities, inner ear radiologic image, patient cooperation, family support including father and mother versus others caregivers, distance of living place to hospital, and level of education of caregiver.

Discussion

Reports of the success of CI surgery in prelingual patients are varied. One of the measurements used is the CAP score, which assesses the progression of auditory performance at specific points in time. Ganesh et al.⁽⁷⁾ reported that 30 of 40 patients or 75.0% who had no other comorbidity reached a CAP score of 5 or more, one year after surgery, compared with just 12/40 (30.0%) of their counterparts with multiple disabilities. Zhou et al.⁽¹⁾ reported CAP score of 5 or more, two years after surgery in 89.4% to 93.3% of cases of prelingual deafness patients under 18 months of age. In a study by Lyu et al.⁽⁸⁾ of 278 cases with 5 years' follow up after cochlear implant, it was discovered that auditory improvement measured by CAP was the fastest within the first six months after CI, showing a significant growth. After this, growth slowed and reached a plateau at the 24th month. The team at Rajavithi Hospital measured

Table 3. Follow up data of patients with CAP score <5 after 2 years habilitation

Case No.	Age at surgery (months)	CAP score at 2 years	Last CAP score	Data that limit outcome
1	16	1	1 at 4 years after CI	Goldenhar syndrome
2	29	2	2 at 3 years 6 months after CI	Small IAC
3	28	2	3 at 5 years after CI	Diagnosis of Autism later because of poor progression after habilitation
4	28	4	4 at 2 years 10 months after CI	Eye contact: uncertain
5	8	4	4 at 2 years 10 months after CI	-
6	22	4	4 at 3 years 3 months after CI	
7	32	4	4 at 5 years after CI	Waardenburg syndrome
8	30	4	4 at 4 years after CI	
9	29	4	4 at 2 years after CI	Loss to follow up after 2 years habilitation

CAP=Category Auditory Performance; CI=cochlear implant; IAC=internal acoustic canal

Table 4. Preoperative factors and CAP score ≥5 at 2 years vs. CAP score <5 at 2 years

Factors	CAP score \geq 5 at 2 years post CI	CAP score <5 at 2 years post CI	p-value
Age at diagnosis (months); median (IQR)	12.00 (3.75, 24.00)	9.00 (5.00, 19.75)	0.565
Age at starting to use hearing aid (months); median (IQR)	18.50 (13.00, 27.50)	18.50 (7.00, 25.50)	0.796
Age at surgery (months); median (IQR)	27.00 (18.75, 34.75)	28.50 (17.50, 30.50)	0.967
Duration of hearing aid use before surgery (months); median (IQR)	6.00 (3.75, 10.00)	6.50 (3.75, 10.25)	0.774
Appointment attended before surgery (%); median (IQR)	83.33 (65.00, 94.64)	81.18 (65.79, 100.00)	0.858
Age at diagnosis; n (%)			0.243
≤6 months	7 (43.8)	9 (56.3)	
>6 months	15 (62.5)	9 (37.5)	
Age at starting to use hearing aid; n (%)			1.000
≤6 months	4 (57.1)	3 (42.9)	
>6 months	18 (54.5)	15 (45.5)	
Age at surgery; n (%)			0.731
≤18 months	5 (50.0)	5 (50.0)	
>18 months	17 (56.7)	13 (43.3)	
Perinatal illness history; n (%)			0.609
No	18 (51.4)	17 (48.6)	
Yes	3 (75.0)	1 (25.0)	
Other disability; n (%)			0.579
No	21 (56.8)	16 (43.2)	
Yes	1 (33.3)	2 (66.7)	
Eye contact assessment; n (%)			1.000
Good	12 (54.5)	10 (45.5)	
Uncertain or poor	4 (57.1)	3 (42.9)	
Inner ear radiology; n (%)			1.000
Normal	20 (54.1)	17 (45.9)	
Abnormal	2 (66.7)	1 (33.3)	
Caregiver; n (%)			0.642
Father-mother	20 (57.1)	15 (42.9)	
Others	2 (40.0)	3 (60.0)	
Level of education of caregiver; n (%)			0.356
Bachelor degree	13 (61.9)	8 (38.1)	
Others	9 (47.4)	10 (52.6)	
Living place; n (%)			0.385
Bangkok or surroundings	14 (60.9)	9 (39.1)	
Others	8 (47.1)	9 (52.9)	
Appointment attended before surgery; n (%)			0.822
≥80%	13 (56.5)	8 (47.1)	
<80%	9 (52.9)	10 (43.5)	

IQR=interquartile range; CAP=Category Auditory Performance; CI=cochlear implant; IAC=internal acoustic canal

CAP score two years after surgery and reported that 55.0% (22/40 cases) reached 5 or more. After follow up in the cases of CAP score of less than 5, nine cases improved after continuing the habilitation program and the final overall proportion with CAP score of 5 or more was 77.5%. Recently, CAP score at 12 months after cochlear implant reported from a multicenter cohort study of cochlear implantation in Thailand was $3.97\pm2.57^{(9)}$, which the present study was in that range, with a mean CAP score of 4.02.

A study by Kang et al.⁽²⁾ of factors that adversely affected outcomes significantly were perinatal problems such as low birth weight, meningitis, and hyperbilirubinemia (p<0.01), inner ear anomaly (p<0.003), and narrow bony cochlear nerve canal with a width of less than 1.4 mm. Panda et al.⁽⁴⁾ reported that age at surgery, socioeconomic status, concentration of patient, family cooperation in habilitation, and education of caregiver were the factors that had an impact on postoperative outcomes. In the present study, the mean age of diagnosis was 13.28±9.38 months, and mean age at surgery was 25.73±9.74 months. These exceeded the recommendations of the Joint Committee on Infant Hearing (JCIH), which state that the age at diagnosis should be under three months and that habilitation should be started before the age of six months to achieve good results. Other factors that adversely affected the outcomes in the present study were comorbidities such as Goldenhar syndrome, Waardenburg syndrome, Autism, and small IAC. There was one case of poor eye contact in the preoperative period, which may support the finding of Nikolopoulos et al.⁽³⁾ that the most constant predictor of the outcomes was children's learning style. However, there were few cases of these comorbidities syndrome and other factors such as small IAC in this study.

In three cases of the present study that did not achieve good progress, no preoperative limiting factors were discovered. The postoperative period may be the most crucial time, and the effects of family structure and habilitation were not examined in the present study. Therefore, these need to be explored.

The limitation of the present study was the possibility of selection bias as the small number of the abnormal radiology and the poor eye contact were not exclusion criteria for cochlear implant, which would affect the analysis of pre-operative factors for the outcome. As all cases underwent cochleostomy with full insertion of electrodes, intraoperative factors probably did not affect the outcomes. A newborn hearing screening policy was not provided in every case, so the delay in diagnosis and habilitation could have affected the results. A universal newborn hearing screening policy will be launched in the near future, resulting in earlier diagnosis and intervention. That policy, together with postoperative intensive habilitation program for prelingual deafness, will provide an opportunity to improve postoperative CI outcomes.

Conclusion

The overall proportion of cases that reached the CAP score of 5 or more two years after habilitation for prelingual deafness age under the age of three years and six months was 77.5%. Preoperative assessment factors were not statistically different between the good and the poor performance groups in the present retrospective study of the authors' center. The postoperative factors of family cooperation and habilitation program should be explored to determine whether they have any impact on outcomes.

What is already known in this topic?

Cochlear implant success is measured by the CAP Score and preoperative factors that affect the outcomes.

What this study adds?

The outcomes of these cochlear implants performed at a maximum age of three years and six months in Rajavithi Hospital can provide baseline data for quality improvement and comparison with other institutes.

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Conflicts of interest

The authors declare no conflict of interest.

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