Original Article

The Outcomes of Cochlear Implantation in Thailand: Audiologic performance and Quality of Life

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Background: Cochlear implantation is the one of modalities for restoring hearing function. Recently, trends in cochlear implants are increase but few studies have reported on quality of life and hearing outcomes after cochlear implant placement in Thailand.

Objective: To assess the auditory performance and quality of life of patients after receiving cochlear implants.

Materials and Methods: An observational study was conducted in 11 cochlear implant centers in Thailand. The study was implemented through a secure web-based platform. Retrieved data concerning cochlear implants were classified into two periods. Prior to October 1, 2016, retrospective chart reviews were performed, whereas the prospective element of the study investigated patients who underwent cochlear implantation after October 1, 2016. Data were collected until August 31, 2017.

Results: Two hundred and twenty-six patients were registered. Unfortunately, 10 medical chart records contained insufficient data; thus, data from 216 patients were analyzed. Postoperative hearing outcomes, specifically aided thresholds, PB scores and SRT/STD scores were superior to pre-implant performance and improved at each successive post-implant assessment point (p = 0.001, p<0.001, and p<0.001, respectively). It took a median of 36 months to aurally rehabilitate patients: the criterion used was achieving a CAP score of more than 5, indicating good communication performance. Use of sign language alone as a means of pre-operative communication was a predictor of poor rehabilitation success (p = 0.013). The QOL of patients with cochlear implants was assessed with questionnaires including EQ5D5L, Pedsql, and HUI3. The outcomes were not clearly significantly better than pre-implantation; however, in the early post-operative period the trend was superior to pre-implantation performance. Complications of cochlear implantation were rare in our series.

Conclusion: Cochlear implantation in Thailand seems to be providing good audiologic parameters, communication performances and QOL. A limitation of the study is the small amount of data due to difficulty in retrieving retrospective data. Therefore, a standard system for managing case data should be instituted now to improve the evidence base concerning outcomes of cochlear implant surgery.

Keywords: Cochlear implant, Web-based registry, Sensorineural hearing loss, Quality of life

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Thailand has a population of 65 million people. In 2007, the Thai National Statistical Unit estimated that about 2.9% of these had a disability and that 21% of disabilities were due to hearing problems[1]. Hearing disabilities are second only to physical disabilities in frequency[2]. The consequences include difficulty in communication and a poor quality of life related to isolation, reduced social activity, and a feeling of being excluded, leading to increased symptoms of depression. Thus, hearing disabilities should be corrected if possible. There are numerous methods for rehabilitation of hearing. Cochlear implants are

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recommended for patients presenting with a permanent bilateral sensorineural hearing loss[3,4]. For Thais, the criteria for selecting candidates for cochlear implant include loss of hearing more than 80 dB, duration of deafness less than 10 years (if greater than 10 years, patients should be rehabilitated prior to surgery), normal mental health status, and good follow-up compliance after surgery.

There have been few studies in Thailand for assessing the outcomes of cochlear implants. Vaewvichit and Luangpitakchumpol[5] compared the benefits of a House/3M single-channel cochlear implant or a Nucleus 22-channel cochlear implant: The Nucleus users performed at a much higher level than the House/3M users. Kasemsuwan et al[6] reported that auditory ability was significantly higher in post-lingual than pre-lingual deaf patients (p<0.05). Patients capable of aural communication prior to surgery also showed higher auditory ability than those without aural communication (p<0.05). The outcomes of CAP assessments were analyzed among patients fitted with different cochlear implant devices. Users with Pulsar CI 100 Opus 2, HiRes 90K Auria, and HiRes 90K Harmony devices showed better auditory ability than those with Combi 40+ or Tempo+ devices. Mean scores of AR and of CAP were higher at each successive time of testing: three, six and 12 months (p<0.05). Kingkaew et al[7] studied the cost-effectiveness of cochlear implants in three groups including pre-lingual deaf children, pre-lingual deaf adults, and post-lingual deaf adults. They found that children with pre-lingual deafness benefitted most. However, available data for assessing outcomes in Thailand remain few and heterogeneous. Some medical record charts cannot be retrieved, requiring practitioners to rely on data from companies. The three big cochlear implant distributors in Thailand have provided around 1,100 devices over the last several years. Therefore, we have developed a standardized, electronic patient registry for the collection of a homogeneous set of data for cochlear implant recipients. The purpose of this study is to introduce the design and methodology of the Cochlear Implants Registry in Thailand [CIRT]. Furthermore, we will report analysis of the database including assessing the improvements in auditory performance with cochlear implants, changes in quality of life from using cochlear implants and success factors for cochlear implants. We will also provide statistically significant data to support patient management decisions at the clinical, regulatory, payer and policy levels.

Materials and Methods

Study design

An observational study was conducted in multiple cochlear-implant centers in Thailand. The study was implemented through a secure, web-based, registry platform. Data collection was classified into two periods. Data on cochlear implants before October 1, 2016 were retrieved retrospectively from chart reviews. The prospective study investigated patients who underwent cochlear implantation after October 1, 2016. The study was also listed on the ClinicalTrials.gov website (NCT02830659).

Population

The study enrolled all patients who underwent cochlear implants at 11 hospitals (Srinagrind Hospital, King Chulalongkorn Memorial Hospital, King Bhumibol Adulyadej Hospital, Rajavithi Hospital, Ramathibodi Hospital, Songklanagarind Hospital, Siriraj Hospital, Trang Hospital, Maharaj Nakorn Chiangmai Hospital, Phramongkutklao Hospital, and HRH Princess Maha Chakri Sirindhorn Medical Center) representing most of the cochlear implantation procedures done in Thailand. Before being interviewed, all participants provided written informed consent. The study was approved by the Central Research Ethics Committee (CERT004/59BRm).

Data collection

Prior to surgery, we recorded data including etiology of hearing loss, auditory performance, quality of life, CT, and MRI. Surgical technique used, brand of cochlear implant device, cost of surgery, cost of devices, and cost of hospital stay were also recorded. For follow-up, we observed the changes in auditory performance, quality of life [QoL] at one month, 3 months, 6 months, and then annually for up to five years after surgery. Regarding QoL, we used EQ5D5L (for patients above 18 years of age), Pedsql (for patients between 2 and 18 years) and HUI3 (for patients above 8 years of age). For patients who had received cochlear implants more than 5 years previously, QoL was assessed only once.

Data management

The CIRT was managed by an experienced, third-party database service provider (Data Management and Statistical Analysis Center

[DAMASAK]; Faculty of Public Health, Khon Kaen University, Thailand). The data were stored centrally in an externally hosted and standard electronic data platform.

Data privacy

All hospitals would have ownership rights for their site's data and operate under their own local processes or regulations around data collection, privacy and maintenance of patient records.

Electronic case record form [eCRF]

The CIRT consists of a series of evaluation tools in the form of eCRFs that must be completed through data entry via the electronic platform according to the study's evaluation schedule.

Data entry

The CIRT may complement management of patients at clinics including their routine, clinical follow-up. A clinician or another approved person at the clinic can enter the data into the CIRT platform. Investigators participating in the registry would have access to real-time patient data updates as well as automated summary reports using their confidential, system-allocated password.

Data output

The CIRT web interface facilitates automated summary reports. Here, we reported data for each hospital and overall.

Data analysis

Demographic data was reported as descriptive data. Hearing performance and quality of life were analyzed with paired t-tests to compare pre- and postoperative data. Success of rehabilitation was evaluated with Cox regression. These preliminary outcomes were calculated on August 31, 2017.

Results

The CIRT web-based system was set up on October 1, 2016. Investigators at each site were then able to fill in eCRFs. Two hundred and twenty-six patients were registered. Unfortunately, 10 medical chart records contained insufficient data; thus, data for only 216 patients were analyzed (Table 1). Data for 159 patients who underwent implantation before October 1, 2016 were retrieved retrospectively from medical records. Another 39 patients were registered as prospective sources of data. Data for a further 18 patients did not include date of surgery; thus, these data were omitted from analysis. Idiopathic hearing loss was the most common cause of sensorineural hearing loss (57.32%). Most patients (85.71%) had used hearing aids for rehabilitation before surgery. 85.12% patients continued using hearing aids and 88.38% patients still communicated with oral language. Pre-operative audiogram information (including hearing threshold, speech discrimination score or speech reception threshold [SRT], phonetically balanced word score [PB score], and categories of auditory performance score [CAP score]) was demonstrated in Table 2.

Regarding postoperative hearing outcomes, aided thresholds were superior to pre-implant performance (baseline). Furthermore, aided thresholds showed incremental improvement at each successive post-implant assessment point (at first month, 3 months, 6 months, and annually for up to five years) during the study (p-value = 0.001) (Figure 1).

Most patients receiving an implant achieved better PB scores and SRT/STD scores than pre-implant (baseline) and there was improvement at each successive post-implant follow-up point (at first month, 3 months, 6 months, and annually for up to five years) (p<0.001). We accepted CAP scores of 5 or more as indicating good communication performance. The median time to reach this score was 36 months (Figure 1).

The type of communication used before surgery was a very important predictor of rehabilitation success after cochlear implantation. We found that use of sign language alone prior to surgery is associated with failure of rehabilitation (p-value = 0.013) (Table 3).

The QoL of patients with cochlear implants was assessed with questionnaires including EQ5D5L (Figure 2), Pedsql (Figure 3) and HUI3 (Figure 4). The outcomes were not clearly significantly better than pre-implantation; however, the trend of these outcomes was superior to pre-implant performance (baseline) in the early post-operative period.

Complications of cochlear implantation were rare in our series. However, there were a few delayed complications requiring reoperation (Table 4).

Discussion

The CIRT is designed to collect data via a multi-center web-based registry. Two hundred and twenty-six patients were registered. This is far below the number of devices sold in Thailand according to the cochlear implant distributers. Furthermore, it represents less than 10% of reimbursement reports to

Table 1. Demographic data

Characteristics	Percentage	95% CI
Gender		
Male	52.31	45.67 to 58.88
Female	47.69	41.12 to 54.33
Age at enrollment (years)		
2 to 4	10.28	6.89 to 15.07
5 to 7	10.28	6.89 to 15.07
8 to 12	14.95	10.80 to 20.35
13 to 18	13.55	9.60 to 18.78
19 or older	50.93	44.28 to 57.56
Etiology		
Idiopathic	57.32	45.46 to 60.30
Post meningitis	17.19	11.15 to 22.12
Sepsis	5.73	2.81 to 9.75
Genetic disorder	5.10	2.40 to 9.01
Inner ear anomalies	4.46	2.01 to 8.25
Trauma	2.54	0.92 to 5.89
Ototoxicty	1.91	0.60 to 5.06
Middle ear infection	1.91	0.60 to 5.06
Intrauterine infection	1.91	0.60 to 5.06
Birth asphyxia	1.27	0.32 to 4.19
Other	9.93	4.97 to 13.35
Beginning rehabilitation (HA)		
No	14.29	10.07 to 19.87
Yes	85.71	80.13 to 89.93
Continuing of hearing aids use		
Always	69.74	62.97 to 75.76
Seldom	15.38	10.99 to 21.11
Never	14.87	10.56 to 20.54
Type of communication		
Oral language	55.05	48.09 to 61.82
Sign language	11.62	7.87 to 16.83
Combined	33.33	27.14 to 40.16

Table 2. Preoperative audiogram information

	Percentage	95% CI
Hearing threshold at 500 to 4,000 Hz		
71 to 90 dB	9.03	5.35 to 14.83
>90 dB	90.97	85.17 to 94.15
SDR/SRT score: Mean (SD): 92.30 (23.40)		
PB score: Mean (SD): 10.5 (17.9)		
CAP score		
0	77.27	69.14 to 83.59
1	9.09	5.28 to 15.22
2	3.79	1.63 to 8.56
3	4.55	2.10 to 9.56
4	5.30	2.59 to 10.54

Table 3. Factors associated with failure rehabilitation

Characteristics	Number (month)	Person-time per 100	Rate HR	Crude HR	Adjusted	95% CI	*p*-value
Beginning HA rehabilitation							
No	19	344	1.45	1	1		
Yes	97	1,764	2.78	2.03	1.94	0.39 to 9.56	0.416
Continuing of HA use							
always	77	1,460	2.53	1	1		
seldom	24	399	3.26	1.23	1.48	0.71 to 3.08	0.297
never	14	297	1.35	0.54	0.59	0.12 to 2.94	0.520
Type of communication							
Oral language	60	834	3.60	1	1		
Sign language	20	520	1.73	0.57	0.32	0.12 to 0.78	0.013
Combine language	37	765	2.09	0.68	0.60	0.31 to 1.17	0.133
Brand of CI							
Cochlea	33	292	1.37	1	1		
Med EI	26	743	1.35	1.38	0.84	0.23 to 3.12	0.798
ABC	71	1,292	3.41	3.04	2.51	0.76 to 8.28	0.131

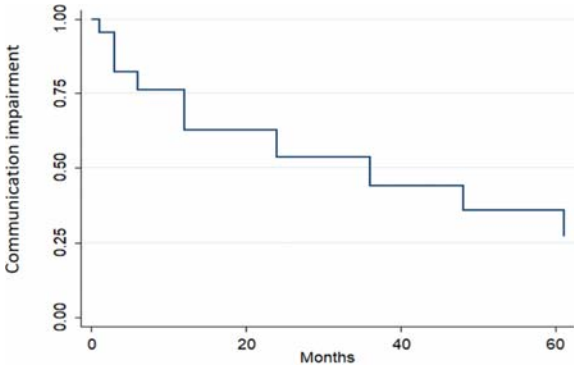

Figure 1. The median time to reach a CAP score ≥5 after surgery was 36 months.

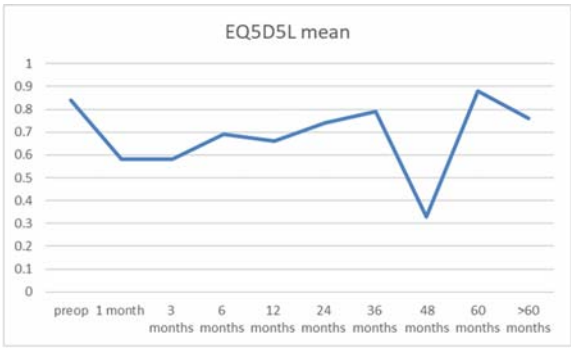

Figure 2. The quality of life of patients was evaluated using EQ5D5L.

government. This indicates poor data management: the Thai healthcare system should improve database management systems concerning the expensive procedure of cochlear implantation.

Data were insufficient for 10 patients; thus, data from 216 patients were investigated. Thirty-nine patients who received surgery after October 1, 2016 provided prospective data. Data were only analyzed from 159 patients who received surgery before October 1, 2016 due to the difficulties of collecting retrospective data and incomplete medical records. Moreover, data from 18 patients did not include date of surgery in the eCRF; thus, these data cannot be assigned to retrospective or prospective groups.

Although this study is not large scale, it is the first report of the overall situation of cochlear implantation in Thailand and allows some important conclusions to be reached. The most common etiology of profound hearing loss in our series is idiopathic (57.32%) and the second most common etiology is post meningitis hearing loss (17.19%). Petersen et al[8] similarly reported that the most common etiological category was 'unknown' 40.3% (95% CI 32.8 to 48.0), which we take to mean idiopathic. His study was a systematic review from four cochlear implantation databases. All pre-operative hearing thresholds of our patients at speech frequencies (500 to 4,000 Hz) indicated severe to profound sensorineural hearing

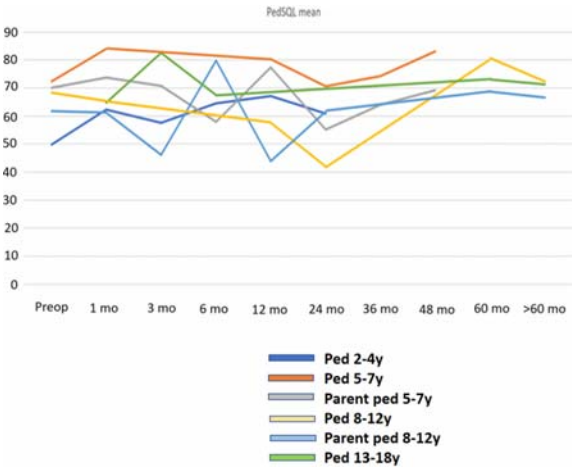

Figure 3. The quality of life of patients was evaluate with Pedsql.

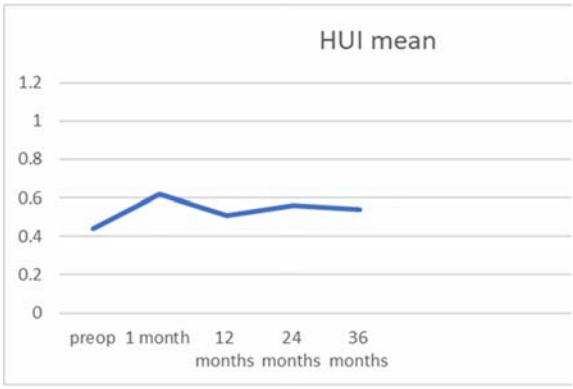

Figure 4. The quality of life of patients was evaluate with HUI3.

loss, indicating that hearing aids would be of limited use for achieving optimized communication function. Although hearing aids allow some benefits in this group, aural training with hearing aids prior to implantation may provide stimulation of residual hearing and underpin aural training with the device. Some studies have mentioned that the use of a hearing aid before implantation influences subsequent auditory performance[9,10]. Use of hearing aids may slow the central and peripheral modifications induced by auditory deprivation. Lazard et al[10] reported that reduction in speech performance after cochlear implantation was 0.83% per year for patients who had used no hearing aids during the period of hearing loss, while it was 0.45% per year for patients who had

Table 4. Complications of cochlear implantation

Complication	Percentage	95% CI
Immediate complication		
NO	91.71	87.12 to 94.76
Facial weakness	0.49	0.09 to 2.71
Vertigo	1.46	0.50 to 4.21
Wound infection	0.49	0.09 to 2.71
Other	3.90	1.99 to 7.51
Delay complications		
Device failure	0.96	0.17 to 5.25
Electrode dislodge	0.56	0.16 to 2.04
Implant migration	0.53	0.09 to 2.94

used hearing aids during that period. These results confirm that inputs from a hearing aid may slow down the pathological reorganization of auditory pathways induced by hearing loss[11,12]. Most of our patients (85.71%) were trained with hearing aids prior to implantation. However, we cannot delay implantation to allow training in post-meningitis cases because labyrinthine ossificans may develop in the cochlea. Such ossifications make it very difficult to insert electrodes through the cochlea; thus, early implantation will provide more benefits.

We found that hearing parameters post-implantation (including aided thresholds, PB scores and SRT/STD scores) were significantly better than pre-implantation (p-value = 0.001, p-value <0.001 and p-value <0.001, respectively) (Figure 1 to 3). In addition, audiological and speech tests found incremental improvement at each successive post-implant assessment point; one month, 3 months, 6 months, and annually for up to five years. Furthermore, aural training after implantation is very significant for achievement of good communication performance. The CAP score is a common tool to assess this performance. We defined a CAP score of more than 5 as indicating a successful implantation: patients could understand common phrases without lip reading. Half of our patients had post-lingual deafness: they took a median time of 36 months of aural rehabilitation to improve their CAP score to more than 5. We found that communication using sign language alone before surgery was predictive of poor rehabilitation outcomes (p-value = 0.013); whereas other factors (prior and continuing use of hearing aids, and brand of device fitted) did not reach statistical significance (Table 3). Our findings differ from those of Lazard et al[10] who

studied 2,251 patients with cochlear implants in 15 international centers. They found that the significant factors were the pure tone average threshold of the better ear, the brand of device, the percentage of active electrodes, the use of hearing aids during hearing loss, and duration of hearing loss. Although our study used a small database, the use of sign language alone before surgery predicted poor rehabilitation outcomes. Thus, surgeons must be aware of this point.

The measures used to assess QoL in cochlear implant studies have varied greatly, making it difficult to compare outcomes. We found that QoL values increased in the first month of the postoperative period (Figure 4 to 6). Similarly, Ramos-Macias et al[13] reported that QoL values increased very rapidly straight after implantation regardless of age of patient. However, the trend of QoL in our study after the first month fluctuated (especially after 36 months) likely due to our small sample and problems in obtaining retrospective data. The Pedsql questionnaire was used to investigate quality of life of children between 2 and 18 years of age. However, the sample is too small to permit sub age-group analysis and the trend of Pedsql values varied widely. Long-term follow-ups are required to indicate trends of QoL of patients receiving cochlear implants in Thailand.

Farinetti et al[14] reported that the global cochlear implant complication rate was 19.9%, comprising 5% of major complications (requiring surgical revision) and 14.9% of minor complications needing conservative management. The complication rate was significantly higher in the adult population (p = 0.004). In our study, we found few immediate complications (including 1.49% vertigo, 0.49% wound infection, and 3.49% others) that resolved with conservative management. Only 0.49% of patients developed facial weakness after surgery. However, we found major complications including 0.96% device failure, 0.56% electrode dislodgement, and 0.53% implant migration. These few complications needed reoperation.

A limitation of our study is the small database available due to the difficulty of retrieving retrospective data. An effective systematic database management system should be developed for this high-cost, and increasingly common, procedure. More than half of the patients who underwent cochlear implantation surgery were civil servants or insured through government-sponsored schemes. More complete medical data will enhance the evidence base to demonstrate the effectiveness of cochlear implantation in Thailand and provide an informed basis for policy-making.

Conclusion

Cochlear implantation in Thailand seems to lead to good audiologic parameters and communication performances. These outcomes influence the QoL of patients, especially in the early postoperative period. However, the study is limited by the small database available because of the difficulty of accessing retrospective data. Therefore, systematic management of data should be urgently implemented to improve the evidence base concerning cochlear implant outcomes.

What is already known on this topic?

Cochlear implants are the recommended devices for patients presenting with a permanent bilateral sensorineural hearing loss. It allows improved hearing for achieving optimized communication function. In our study show that hearing outcomes and CAP score were improved from preimplantation. Moreover, the patients' quality of life was also better than preimplantation.

What this study adds?

We found that communication using sign language alone before surgery was predictive of poor hearing rehabilitation after cochlear implantation (p-value = 0.013).

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Appendix

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Potential conflicts of interest

The authors declare no conflicts of interest.

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