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Cochlear Implantation Status and Outcomes in Thailand from 2010 to 2020

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Cochlear Implantation Status and Outcomes in Thailand from 2010 to 2020

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Competing interests

The authors declare that they have no competing interests.

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Data sharing statement

Data are available upon request. Individual de-identified data will be available on reasonable request. Extra data is available by emailing kwayim@kku.ac.th.

Ethics approval and consent to participate

This study was approved by the Central Research Ethics Committee of Thailand (CERT004/59BRm). Written informed consent to participate in this study was provided by all patients enrolled.

Abstract

Objectives: This is the study on the status and outcomes of cochlear implantation in Thailand. This nation-wide program was supported by the Health Systems Research Institute of Thailand.

Design: Cohort study.

Setting: Tertiary care and university hospital.

Participants: Patients who underwent cochlear implant surgery in Thailand.

Methods: This project collected the data from all government and university hospitals in Thailand that able to perform cochlear implant surgery since 2010. Data were entered through a secure web-based platform.

Primary and secondary outcome measures: Patients' status, baseline characteristics, audiological outcomes, and quality of life were reported.

Results: There were 367 patients in this study, 189 of whom were male and 168 of whom were female. The average age was 38.71 years. After the operation, pure tone audiogram results significantly improved from profound hearing loss to mild hearing loss ($p < 0.05$). Scores on the categories of auditory perception scale also improved from "no awareness of environmental sounds" to at least "discrimination of some speech sounds without lip-reading" ($p < 0.05$). The general quality of life improved slightly. The complications included facial palsy, vertigo, and dislodging of the implant. Type of communication and etiology of hearing loss were the factors that statistically contributed to the surgery's success ($p < 0.05$).

Conclusions: The data indicated good audiological and acceptable quality-of-life outcomes in patients who underwent cochlear implantation in Thailand.

Keywords: cochlear implant, cochlear implantation, deafness, hearing loss, registry, report

Strengths and limitations of this study

- The cochlear implant device is a new technology that can help patients with severe to profound sensorineural hearing loss to regain their hearing.
- There have only been a few single-institution studies conducted to assess the efficacy of this new technology in Thailand.
- To our knowledge, this is the first report of cochlear implantation outcomes that was conducted with governmental support.
- This study can provide a reliable source of data for the patients, physicians, and policymakers.

Introduction

Hearing impairment is a major disability that can affect the quality of life.[1-3] According to the Department of Empowerment of Persons with Disabilities, 375,680 hearing-impaired patients were registered with the government in Thailand in 2018.[4]

The cochlear implant device is a new technology that can help patients with severe to profound sensorineural hearing loss to regain their hearing. However, there have only been a few single-institution studies conducted to assessed the efficacy of this new technology in Thailand.[5, 6]

As there was no firm evidence of the benefit of cochlear implant devices in the Thai population and the data from Western countries may not be applicable in developing countries. The Thai government needs more evidence before adding a cochlear implant device as a basic medical benefit for all Thais.

This nation-wide project was initiated to prospectively collect the data on the Thai population to give the recommendation to the government on the outcomes of cochlear implantation with the support from The Health Systems Research Institute of Thailand.[7]

To our knowledge, this is the first report of cochlear implantation outcomes that was conducted with governmental support. Providing a reliable source of data for the patients, physicians, and policymakers.

Methods

Study design and setting

All government and university hospitals in Thailand that able to perform cochlear implant surgery were involved. There were eight university hospitals (Srinagrind Hospital, King Chulalongkorn Memorial Hospital, Ramathibodi Hospital, Songklanagarind Hospital, Siriraj Hospital, Maharaj Nakorn Chiangmai Hospital, Phramongkutklao Hospital, and HRH Princess Maha Chakri Sirindhorn Medical Center) and three tertiary hospitals (King Bhumibol Adulyadej Hospital, Rajavithi Hospital, and Trang Hospital) that took part in the registry. These were the major hospitals that performed cochlear implant surgery in Thailand.

Participants

We included all patients who underwent cochlear implantation at a network hospital since 2010. There were no exclusion criteria.

Outcomes

We collected baseline, auditory performance, and quality-of-life data. Baseline data included age, sex, etiology of hearing loss, and underlying diseases.

The auditory performance was assessed based on unaided and aided pure tone audiometry, speech audiometry, and Categories of Auditory Performance (CAP) scores. The CAP scale is a functional performance evaluation that was developed as part of the Nottingham Cochlear Implant Program and as a global assessment of auditory receptive abilities. It is a nonlinear scale on which patients' developing auditory abilities can be rated in eight categories of increasing difficulty from 0-7 (0 - no awareness of environmental sounds;

1 – awareness of environmental sounds; 2 - response to speech sounds; 3 – identifies environmental sounds; 4 – discrimination of some speech sounds without lip-reading; 5 – understands common phrases without lip-reading; 6 – understands conversation without lip-reading; 7 – uses the telephone with a known speaker.[8, 9]

Quality of life was evaluated using EQ-5D-5L (for patients above 18 years of age),[10] the pediatric quality of life inventory - PedsQL (for patients between 2 and 18 years),[11] and the health utilities index mark 3 - HUI3 (for patients above 8 years of age).[12]

Ethical consideration

The research protocol was reviewed and approved by the Central Research Ethics Committee of Thailand (CERT004/59BRm). A registry assistant approached patients eligible for investigation. The patients were given a detailed explanation of the study procedures and the possible impacts of the study. Patients who agreed to participate gave written informed consent.

Patient and Public Involvement

The Health Systems Research Institute of Thailand was the public body financed by the Government of Thailand that has a role in protocol development. The representatives from the National Association of the Deaf in Thailand also giving input for this study.

Statistical Analysis

Statistical analyses were performed using SPSS version 20 and Stata version 14. Data were described as either means (for the continuous variables) or frequencies and percentages (for the categorical variables). Significant differences between groups were determined using the Student t-test or the Mann-Whitney U test for continuous variables. The chi-square test or the Fisher exact test were used to determine whether there was a significant difference

between the expected frequencies and the observed frequencies. The survival analysis was presented as a hazard ratio. The significance of association among the factors was tested using a Cox proportional hazard model. For all tests, $p < 0.05$ was considered statistically significant.

Results

There were 367 patients in this study, 189 of whom were male, and 168 of whom were female. The average age was 38.71 ± 23.32 years. Most patients were children. The cause of hearing disability was idiopathic in around half of the patients (Table 1).

Table 1. Demographic data.

	n	percent
Sex		
- Male	189	51.50
- Female	168	45.78
- No data	10	2.72
Age		
- Infants and toddlers (less than 4 years)	58	19.14
- Pre-school children (5-7 years)	42	13.86
- Early school children (8-12 years)	36	11.88
- Adolescents (13-18 years)	26	8.58
- Adults (more than 18 years)	137	45.21
Causes		
Idiopathic		
- Congenital	101	38.84
- Acquired	58	22.31
Non-idiopathic		
- Post meningitis	45	17.31
- Inner ear anomaly	11	4.23
- Genetic disorder	7	2.69
- Chronic otitis media	6	2.31
- Intrauterine infection	5	1.92
- Birth asphyxia	4	1.54
- Ototoxicity (acquired)	3	1.15
- Trauma	2	0.77
- Sepsis	2	0.77
- Other (acquired)	14	5.38
- Other (congenital)	2	0.77

Most of the patients (89%) had been trained to use hearing aids. Of the patients who were trained, 83.81% always used a hearing aid, 15.11% sometimes used one, and 1.08% percent rarely used one. Most of the patients were able to speak, while 9.77% used sign language to communicate (Table 2).

Table 2. Preoperative rehabilitation.

	n	percent
Has been trained to use a hearing aid		
- No	34	10.9
- Yes	278	89.1
Hearing aids usage		
- Always	233	83.81
- Sometimes	42	15.11
- Rarely	3	1.08
Mode of communication		
- Spoken language	175	57
- Sign language	30	9.77
- Both	102	33.22

The majority of patients (around 80%) had profound deafness. The CAP score for most patients was zero. The mean speech reception threshold was around 90 decibels for both ears. The mean phonetically balanced score was around 40% for both ears (Table 3).

Table 3. Pre-operative hearing level.

	n	percent
Audiogram		
Right ear		
- < 71 dB	3	1.46
- 71 - 90 dB	23	11.17
- > 90 dB	180	87.38
Left ear		
- < 71 dB	5	2.49
- 71 - 90 dB	26	12.94
- > 90 dB	170	82.52
CAP Score		
- 0	107	73.29
- 1	15	10.27
- 2	10	6.85
- 3	7	4.79
- 4	7	4.79
	Mean	**Standard**

		deviation
Speech reception threshold		
- Right ear	93.18	19.58
- Left ear	93.3	18.15
Phonetically balanced score		
- Right ear	42.73	29.1
- Left ear	48.13	29.1

One month after the operation, pure tone audiogram results had significantly improved from profound hearing loss to moderate hearing loss, and then they gradually improved to mild hearing loss level ($p < 0.05$). The speech reception threshold had also decreased from profound hearing loss to mild hearing loss ($p < 0.05$). Phonetically balanced word list test scores had gradually improved to around 70% at 6 months after the operation ($p < 0.05$). Categories of auditory perception scores improved to at least "discrimination of some speech sounds without lip-reading" ($p < 0.05$; Figure 1).

Quality-of-life data were collected in adult (> 18 years old) patients using the EQ-5D-5L questionnaire. This questionnaire evaluates the quality of life in 5 domains including mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. Utility scores can range from 0 to 1 (higher is better). Quality-of-life scores in the cochlear implant recipients improved slightly after the operation.

Quality-of-life data were collected from the children using the PedsQL questionnaire. This questionnaire consists of 23 items in physical, emotional, social, and school functioning domains. Scores on the PedsQL can range from 0 to 100 (higher is better). The questionnaire takes about 4 minutes to complete. It was designed for the parents of 2-4, 5-7, 8-12, and 13–18 years old children and for self-assessment in 5-7, 8-12, and 13-18 years old children.

For the children aged 2-4 years old, the sole source of quality-of-life information was the parents. Quality of life increased slightly in this age group post-operation. For the children aged 5-7 years, quality of life scores had dropped dramatically in the first month after the

operation and increased slightly after rehabilitation. There were too few data in the other age groups (8-12 and 13-18 years old) to distinguish any trend (Figure 2).

Health utilities indices was collected in patients above 8 years of age. These scores improved slightly post-operation similar to those on the EQ-5D-5L questionnaire.

Data regarding the factors that might have contributed to the success of cochlear implant surgery were collected including preoperative rehabilitation, a continuation of hearing aid use, type of communication, a brand of the cochlear implant, etiology, pre-operative hearing level, IQ, mental health, electrode insertion, and insertion technique. The definition of successful surgery was a CAP score greater than 5. Type of communication and etiology of hearing loss were the factors that statistically contributed to the surgery's success. The failure occurring more often in sign language users than in oral language users (HR 0.51, p = 0.040) and in congenital hearing loss more than acquired hearing loss (HR 1.85, p < 0.001) (Table 4).

Table 4. The factors contributing to the success of the implantation.

Characteristics	n	% success	Person - time (month)	HR	95% CI	p -value
Preoperative rehabilitation						
• Yes	20	60	276	1	0.42 to 1.45	0.43
• No	139	58.27	2,487	0.78		
Continuation of hearing aid use						
• Always	109	61.47	1,943	1	0.5 to 1.67	0.76
• Seldom	28	46.43	409	0.91		
Type of communication						
• Oral	85	63.53	1,340	1	0.27 to 0.98	0.04
• Sign language	24	45.83	541	0.51		
• Combined	45	64.44	966	0.67	0.42 to 1.08	0.1
Brand of CI						
• Cochlea	39	23.07	164	1	0.28 to 1.58	0.35
• Med EI	24	70.83	711	0.66		
• ABC	60	65	1,162	0.87	0.41 to 1.86	0.72
Etiology						
• Congenital	90	46.67	1,684	1	1.23 to 2.78	<0.001
• Acquired	75	73.33	1,217	1.85		
Pre-operative hearing level (dB)						
• 26 to 40	2	50	25	1	0.11 to 7.57	0.94
• 41 to 55	14	64.29	216	0.92		

• 56 to 70	15	73.33	181	1.24	0.16 to 9.70	0.84
• 70 to 90	10	50	189	0.55	0.06 to 4.78	0.59
• More than 90	2	0	30	0.00	0 to inf.	1.00
IQ						
• Above Low Average	39	58.97	874	1	0.79 to 2.75	0.22
• Borderline or extremely low	30	70	547	1.48		
Mental health						
• Normal	39	58.97	874	1	0.79 to 2.75	0.22
• Abnormal	30	70	547	1.48		
Electrode insertion						
• Full	154	61.04	2,728	1	0.12 to 2.06	0.34
• Partial	8	25	112	0.51		
Insertion Technique: insertion of electrodes via						
• cochlestomy	110	54.55	2,001	1	0.95 to 2.28	0.09
• round window	50	66	788	1.47		

Post-operation complications were uncommon (occurring in fewer than 10% of patients) and included facial palsy (1.02%), vertigo (1.02%), and dislodging of the implant (0.34%).

Discussion

The cochlear implant is a new technology that can help patients with severe or profound sensorineural hearing loss to regain their hearing. This will result in a better quality of life in adults and ultimately help in the linguistic and social developmental processes in children. However, most data on patient outcomes have been collected in individual institutions, which makes it difficult to assess the broader outcomes of cochlear implantation.

There was a need to assess the benefit of this device on a larger level. Several countries are attempting to collecting cochlear implantation data. In 2011, for example, a proposal paper from a working group in Italy was published addressing the necessity of a national cochlear implant registry in the country.[13] However, this project in Italy was halt due to the economic crisis.

By the way, there have also reports from cochlear implant manufacturers for which data were collected from various countries, such as the Cochlear Pediatric Implanted Recipient Observational Study, which collected data from Australia, China, India, Indonesia, Turkey, and Vietnam.[14] But, the question for the transparency of the data from the manufacturers was also raised.

To our knowledge, this is the first nation-wide report of the effectiveness of the cochlear implant device that was implemented with government support. We prospectively collected the data of the patients who underwent cochlear implant surgery in Thailand from 2010. Most of the recipients (55%) were children, 19% of whom were between 2-4 years old.

The mean pre-operative hearing level in the patients in this study was 100 dB (profound hearing loss) with a CAP score of 0 (no awareness of environmental sounds). The mean hearing level had significantly improved one-month post-operation and had reached the level of mild hearing loss (< 40 dB) by the third month post-operation. Complications of included facial palsy, vertigo, and dislodging of the implant.

The results of this study were comparable with those of a study from HEARRING registry in Europe, the authors of which extracted data from 146 patients who underwent cochlear implantation. They found that speech in quiet and speech in noise scores of patients of all age groups significantly improved ($p < 0.05$) post-operation. Quality of life in our study also improved slightly for patients in all age groups, but not to a statistically significant extent. This was consistent with the study from the HEARRING registry, although they found a significant difference between the HISQUI19 scores of patients 70 years and older and those younger than 56 years.[15]

This database is managed and hosted by the Digital Government Development Agency (DGA), which is a secure government cloud server with CSA-STAR certification. This study did not have adequate data to analyze the general quality of life in patients 8-12 or

13-18 years old. Further data collection is needed to evaluate these outcomes and related factors.

Conclusion

The data indicated a good audiological and acceptable quality-of-life outcomes in patients who underwent cochlear implantation in Thailand.

Author's contribution

P.P. conceptualized, designed, and supervised the study, performed data analysis, interpreted results, and drafted the manuscript. N.T., S.K., S.K., K.T., V.A., P.T., C.W., T.M. and P.I. contributed to data collection. K.Y. contributed to study design, data collection and supervised the study. All authors contributed to the interpretation and discussion of the results and read and approved the final manuscript.

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Tables

Table 1. Demographic Data.

Table 2. Preoperative rehabilitation.

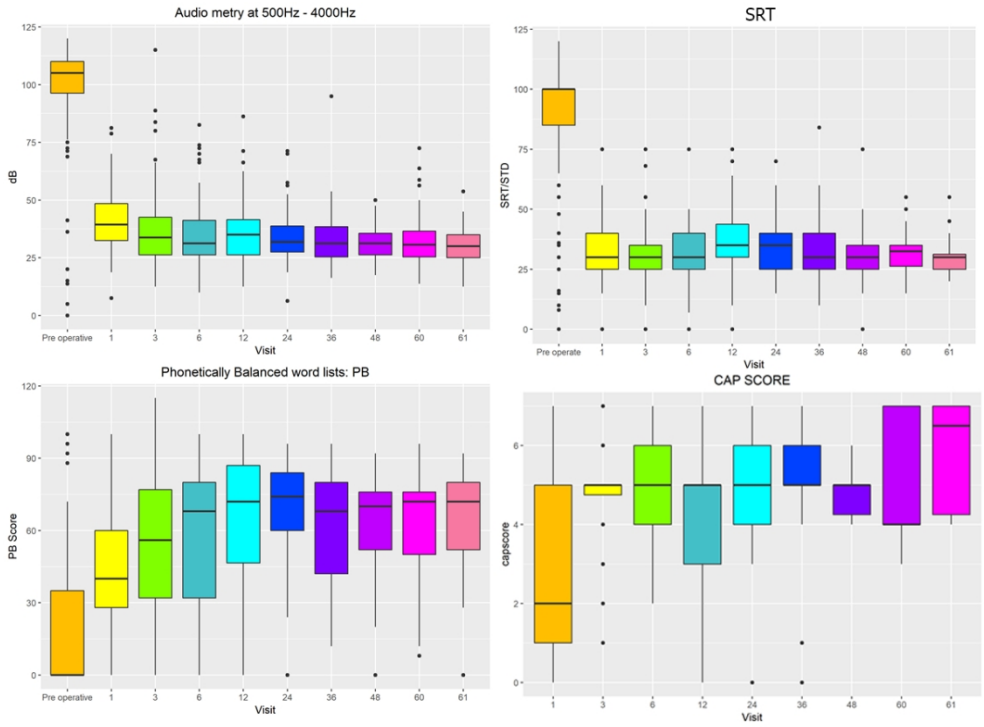
Table 3. Pre-operative hearing level.

Table 4. The factors contributing to the success of the implantation.

Figures

Figure 1. Post-operative hearing levels.

Figure 2. Quality of life.



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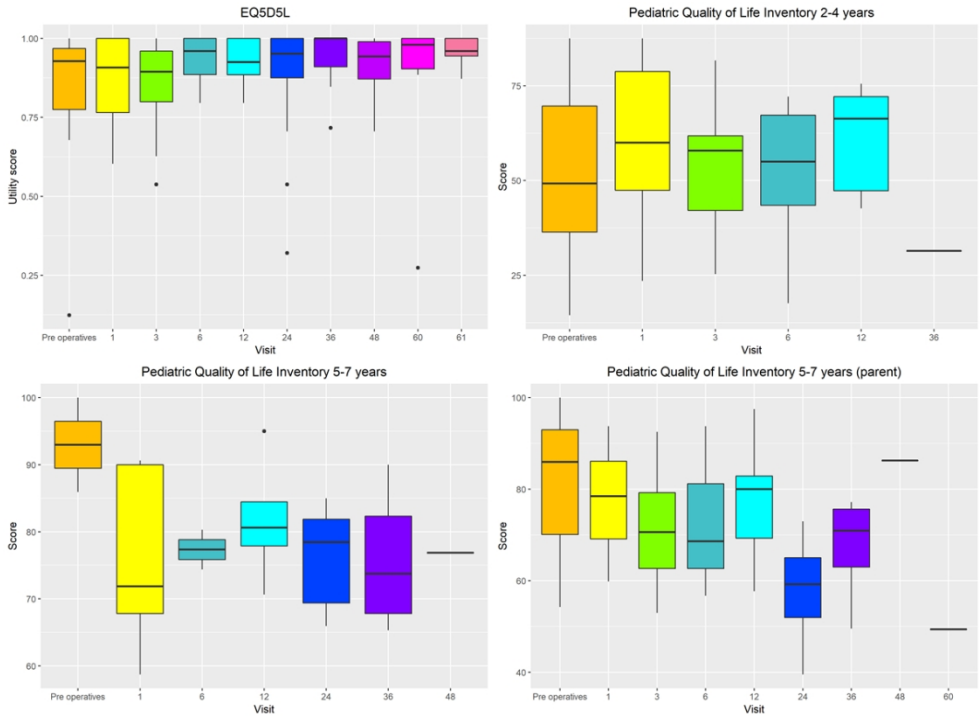

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STROBE Statement—Checklist of items that should be included in reports of ***cohort studies***

	Item No	Recommendation	Page No
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract (*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	1
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	3
Objectives	3	State specific objectives, including any prespecified hypotheses	4
Methods			
Study design	4	Present key elements of study design early in the paper	4
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	4
Participants	6	(*a*) Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up (*b*) For matched studies, give matching criteria and number of exposed and unexposed	4
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	4
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	4
Bias	9	Describe any efforts to address potential sources of bias	NA
Study size	10	Explain how the study size was arrived at	NA
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	5
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding (*b*) Describe any methods used to examine subgroups and interactions (*c*) Explain how missing data were addressed (*d*) If applicable, explain how loss to follow-up was addressed (*e*) Describe any sensitivity analyses	5
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed (b) Give reasons for non-participation at each stage (c) Consider use of a flow diagram	6
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders (b) Indicate number of participants with missing data for each variable of interest (c) Summarise follow-up time (eg, average and total amount)	6
Outcome data	15*	Report numbers of outcome events or summary measures over time	7

Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included (*b*) Report category boundaries when continuous variables were categorized (*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	7
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	9
Discussion			
Key results	18	Summarise key results with reference to study objectives	11
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	12
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	12
Generalisability	21	Discuss the generalisability (external validity) of the study results	11
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	12

*Give information separately for exposed and unexposed groups.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at http://www.strobe-statement.org.

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A multicenter cohort study of cochlear implantation outcomes in Thailand

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A multicenter cohort study of cochlear implantation outcomes in Thailand

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ABSTRACT

Objectives: To report the status and outcomes of cochlear implantation in Thailand.

Design: Cohort study.

Setting: Tertiary care and university hospitals.

Participants: Patients who underwent cochlear implant surgery in Thailand.

Interventions: This project collected data from all government and university hospitals in Thailand where cochlear implant surgery was performed between 2010 and 2020.

Primary and secondary outcome measures: Baseline characteristics, operation data, complications, audiological outcomes, and quality of life were reported.

Results: This study included 458 patients, and nearly half of the patients were children and adolescents (46.94%). At 1 year postoperatively, the mean pure tone average significantly improved from baseline (mean difference [MD] 64.23 dB HL; 95% confidence interval [CI] 59.81–68.65; $p < 0.001$). The mean speech recognition threshold also improved (MD 49.26 dB HL; 95% CI 42.28–56.24, $p<0.001$). The quality-of-life scores of the EQ-5D-5L, PedsQL, and HUI3 questionnaires at 1 year showed improved mobility (range, 0–5; MD 0.65; 95% CI 0.05–1.25; $p = 0.037$), hearing (range, 0–6; MD 0.96; 95% CI 0.30–1.61; $p = 0.006$), and speech (range, 0–5; MD 0.44; 95% CI 0.04–0.84; $p = 0.031$). Common complications included electrode dislodgement (2.18%), vertigo (1.23%), and meningitis (1.93%).

Conclusions: Excellent audiological outcomes and improvement in the quality of life in the mobility, hearing, and speech domains were observed in patients who underwent cochlear implantation in Thailand.

Keywords: cochlear implant, cochlear implantation, deafness, hearing loss, registry, report

Strengths and limitations of this study

- Few single-institution studies have assessed the efficacy of cochlear implantation in Thailand.
- This nationwide project was initiated to prospectively collect cochlear implantation outcomes in the Thai population to provide recommendations to the government on cochlear implantation policy.
- This study collected data for 10 years from 2010 to 2020.
- We did not collect data from private hospitals, and some data were missing due to the nature of the cohort study.

INTRODUCTION

Hearing impairment is a major disability that can affect the quality of life.[1-3] According to the Department of Empowerment of Persons with Disabilities, 375,680 hearing-impaired patients were registered with the government in Thailand in 2018.[4]

Cochlear implant devices can help patients with severe to profound sensorineural hearing loss to regain hearing. Speech perception, quality of life, and neurocognitive function improve after cochlear implantation[5-8]

In Thailand, cochlear implant surgery was first performed in 1986 using a 3M device from the USA. Gradually, university hospitals and major tertiary hospitals started to perform this surgery. However, the number of patients who underwent this procedure was modest owing to the price of the devices, and it was not supported by the universal health scheme.

Only a few single-institution studies have assessed the efficacy of this technology in Thailand.[9 10] No conclusive evidence of the benefits of cochlear implant devices in the Thai population is available and data from Western countries may not be applicable in developing

countries. The Thai government needs more evidence before adding a cochlear implant device as a basic medical benefit for all Thai people.

This nationwide project with support from the Health Systems Research Institute of Thailand was initiated to prospectively collect cochlear implantation outcomes in the Thai population to provide recommendations to the government on cochlear implantation policy.[11]

This study aimed to evaluate the efficacy of cochlear implantation in terms of audiological outcomes and quality of life in the Thai population.

METHODS

Study design and setting

All government and university hospitals in Thailand that were equipped to perform cochlear implant surgery were involved. A total of eight university hospitals (Srinagrind Hospital, King Chulalongkorn Memorial Hospital, Ramathibodi Hospital, Songklanagarind Hospital, Siriraj Hospital, Maharaj Nakorn Chiangmai Hospital, Phramongkutklao Hospital, and HRH Princess Maha Chakri Sirindhorn Medical Center) and three tertiary hospitals (King Bhumibol Adulyadej Hospital, Rajavithi Hospital, and Trang Hospital) participated in the registry. These were the major hospitals that performed cochlear implant surgery in Thailand.

Participants

We included all patients who underwent cochlear implantation at a network hospital between January 2010 and April 2020. There were no exclusion criteria.

Outcomes

We collected baseline characteristics, operation data, complications, auditory performance, and quality of life data.

The baseline characteristics and operation data included the age, sex, onset of hearing loss, type of deafness, cause of hearing loss, intelligence quotient and mental health status evaluated by psychologists, type of hospital, electrode insertion, and insertion technique.

Auditory performance outcomes

Auditory performance was assessed based on pure tone audiometry, speech recognition threshold (SRT), speech discrimination score (SDS), and categories of auditory performance scores (CAP).

Pure tone audiometry was performed to determine air-conduction hearing thresholds. Thresholds were tested separately for each ear, octave-by-octave, from 250 to 8000 Hz. A pure tone average (PTA) refers to the average of hearing threshold levels at 500, 1,000, 2,000, and 4,000 Hz.[12]

The SRT is the minimum hearing level for speech at which an individual can recognize 50% of the speech material. A recognition task is one in which the participant selects the test item from a closed set of choices. The individual should repeat or, in some other manner, indicate recognition of the speech material 50% of the time.[13]

The SDS was a score of the number of words correctly repeated from phonetically balanced word lists, expressed as a percentage of correct.[14]

The categories of auditory performance (CAP) scale is a functional performance evaluation that was developed as part of the Nottingham Cochlear Implant Program and as a global assessment of auditory receptive abilities. It is a nonlinear scale on which patients' developing auditory abilities can be rated in eight categories of increasing difficulty from 0 to 7 (0: no awareness of environmental sounds; 1: awareness of environmental sounds; 2: response to speech sounds; 3: identification of environmental sounds; 4: discrimination of some speech sounds without lip-reading; 5: understanding common phrases without lip-

reading; 6: understanding conversation without lip-reading; 7: using the telephone with a known speaker).[15 16]

All auditory performance outcomes were collected at baseline (preoperative) and at 3 and 12 months postoperatively.

Quality of life outcomes

Quality of life was evaluated using EQ-5D-5L (for patients older than 18 years of age),[17] the Pediatric Quality of Life Inventory - PedsQL (for patients between 2 and 18 years),[18] and the health utilities index mark 3 - HUI3 (for patients older than 8 years of age).[19]

The EQ-5D-5L is a general health status questionnaire with a descriptive system and a visual analog scale (VAS). The descriptive system comprises five dimensions: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. Each dimension has five levels: no problems, slight problems, moderate problems, severe problems, and extreme problems. The patient is asked to indicate their health state by ticking the box next to the most appropriate statement in each of the five dimensions. The VAS records the patient's self-rated health on a vertical visual analog scale, where the endpoints are labeled "The best health you can imagine" and "The worst health you can imagine." The VAS can be used as a quantitative measure of health outcomes that reflect the patient's own judgment.[17]

The PedsQL is a general health status questionnaire for children and adolescents. This questionnaire evaluates the four dimensions delineated by the World Health Organization, which are: physical, emotional, social, and school functioning. Each item has five levels: never, almost never, sometimes, often, and almost always. The scores ranged from 0 to 100.[20]

HUI3 is a generic health-related quality of life for measuring health status, health-related quality of life, and utility scores. Health dimensions include vision, hearing, speech,

ambulation/mobility, pain, dexterity, self-care, emotion, and cognition. Each dimension has five to six levels.[21]

Quality of life data were collected at 1, 3, and 12 months postoperatively.

Definitions

Deafness was defined as PTA (from four frequencies 0.5, 1, 2, and 4 kHz) or SRT > 80 dB HL according to the World Health Organization (WHO) classification or no response to an auditory brainstem response at the maximum intensity of 90 dB HL.[22]

Implantation success was defined as a PTA or SRT ≤ 50 dB and SDS ≥ 50% (category B) within 1 year post-operatively according to the American Academy of Otolaryngology-Head and Neck Surgery classification.[23]

Ethical consideration

The research protocol was reviewed and approved by the Central Research Ethics Committee of Thailand (CERT004/59BRm). A registry assistant approached the patients eligible for the investigation. The patients were given a detailed explanation of the study procedures and the possible impacts of the study. Patients who agreed to participate provided written informed consent.

Patient and Public Involvement

The Health Systems Research Institute of Thailand is a public body financed by the government of Thailand, which has a role in protocol development. Representatives from the National Association of the Deaf in Thailand also provided input for this study.

Statistical Analysis

Statistical analyses were performed using IBM SPSS version 20 and Stata version 14. Data were described as either means (for continuous variables) or frequencies and percentages (for categorical variables). Significant differences between groups were determined using the

Student's t-test, paired sample t-test, or Mann–Whitney U test for continuous variables. The chi-square test or Fisher's exact test was used to determine whether there was a significant difference between the expected and observed frequencies. The factor of success is presented as an odds ratio. For all tests, statistical significance was set at $p < 0.05$.

RESULTS

Patient's demographics

There were 458 patients in this study, of whom, 220 were men and 203 were women. Nearly half of the patients were children and adolescents (46.94%). The common causes of congenital and acquired hearing disabilities were idiopathic (51.87% and 34.02%, respectively). (Table 1)

Table 1. Demographic data.

	N = 458	**%**
Sex		
- Male	220	48.03
- Female	203	44.32
- No data	35	7.64
Age		
- Infants and toddlers (<4 years)	44	9.61
- Pre-school children (4–7 years)	79	17.25
- Early school children (8–12 years)	52	11.35
- Adolescents (13–18 years)	40	8.73
- Adults (> 18 years)	211	46.07
- No data	32	6.99
The onset of hearing loss		
- Pre-lingual hearing loss	41	8.95
- Post-lingual hearing loss	330	72.05
- No data	87	18.20
Type of deafness		
- Bilateral deafness	458	100
- Unilateral deafness	0	0
Causes of hearing loss		
Congenital	**N = 241**	
- Idiopathic	125	51.87

- Inner ear anomalies	12	4.98
- Genetic disorder	7	2.90
- Intrauterine infection	5	2.07
- Birth asphyxia	4	1.66
- Ototoxicity	1	0.41
- Others	5	2.07
- No data	82	34.02
Acquired	**N = 181**	
- Idiopathic	67	37.02
- Post meningitis	63	34.81
- Chronic otitis media or cholesteatoma	10	5.52
- Sepsis	4	2.21
- Ototoxicity	3	1.66
- Trauma	3	1.66
- Head injury	3	1.66
- Noise-induced or noise trauma	2	1.10
- Autoimmune hearing loss	1	0.55
- Others	19	10.50
- No data	6	3.31

Audiological outcomes

Preoperatively, the mean PTA, mean SRT, mean SDS, and mean CAP score was 95.53 dB HL, 86.72 dB HL, 28.82%, and 0.54 points, respectively.

At three months postoperatively, the mean PTA decreased to 34.14 dB HL (mean difference [MD], 61.39; 95% confidence interval [CI], 57.39–65.40; $p < 0.001$). The mean SRT also decreased to 37.47 dB HL (MD, 49.26; 95% CI, 42.28–56.24; $p < 0.001$). The mean SDS increased to 47.33% (MD, -18.5; 95% CI, -27.13 to -9.90; $p < 0.001$). The mean CAP score increased to 2.62 points (MD, -2.08; 95% CI, -2.45 – -1.71; $p < 0.001$).

At 12 months postoperatively, the mean PTA decreased to 31.87 dB HL (MD, 64.23; 95% CI, 59.81–68.65; $p < 0.001$). The mean SRT also decreased to 34.45 dB HL (MD, 55.96; 95% CI, 49.50–62.42; $p < 0.001$). The mean SDS increased to 62.24% (MD, -32.47; 95% CI, -43.00 – -21.94; $p < 0.001$). The mean CAP score increased to 3.97 points (MD, -3.40; 95% CI, -3.88 – -2.92; $p < 0.001$). (Table 2)

Table 2. Audiologic outcomes

	Pre-op	3 months	Mean difference (95% CI)	p-value[a]	Pre-op	12 months	Mean difference (95% CI)	p-value[a]
Pure tone average	(n = 144)	(n = 144)			(n = 101)	(n = 101)		
- Better ear	95.53 ± 20.68	34.14 ± 13.93	61.39 (57.39 to 65.40)	<0.001*	96.10 ± 22.05	31.87 ± 12.71	64.23 (59.81 to 68.65)	<0.001*
SRT	(n = 58)	(n = 58)			(n = 53)	(n = 53)		
- Better ear	86.72 ± 24.11	37.47 ± 17.00	49.26 (42.28 to 56.24)	<0.001*	90.42 ± 21.47	34.45 ± 11.54	55.96 (49.50 to 62.42)	<0.001*
Speech discrimination score	(n = 39)	(n = 39)			(n = 34)	(n = 34)		
- Better ear	28.82 ± 34.83	47.33 ± 32.92	-18.51 (-27.13 to -9.90)	<0.001*	29.76 ± 35.39	62.24 ± 28.51	-32.47 (-43.00 to -21.94)	<0.001*
CAP score	(n = 147)	(n = 147)			(n = 118)	(n = 118)		
	0.54 ± 1.03	2.62 ± 2.32	-2.08 (-2.45 to -1.71)	<0.001*	0.57 ± 1.09	3.97 ± 2.57	-3.40 (-3.88 to -2.92)	<0.001*

a – paired t-test, * - statistically significance

CI, confidence interval; CAP, categories of auditory performance; SRT. Speech recognition threshold

Quality of life outcomes

For EQ-5D-5L, the mean score for the mobility domain (range, 0–5; lower is better) significantly improved at 12 months compared to the postoperative first month (MD, 0.65; 95% CI, 0.05–1.25; p = 0.037). However, there were no statistically significant differences in the other domains (p > 0.05).

For PedsQL (range, 0–100; higher is better), there was no statistically significant difference in physical, emotional, social, and school functioning domains at 3 and 12 months compared to the postoperative first month (p > 0.05).

For HUI3, the mean score for hearing (range, 0–6; lower is better) and speech domain (range, 0–5; lower is better) significantly improved at 12 months compared to the postoperative first month (MD for hearing score, 0.96 points; 95% CI, 0.30–1.61; p = 0.006; MD for speech score, 0.44 points; 95% CI, 0.04– 0.84; p = 0.031). However, there were no statistically significant differences in the other domains (p > 0.05). (Table 3)

Table 3. Quality of life outcomes

	1 months	3 months	MD (95% CI)	p-value[a]	1 month	12 months	MD (95% CI)	p-value[a]
EQ-5D-5L	(n=20)	(n=20)			(n=17)	(n=17)		
- Mobility	1.8 ± 0.95	1.65 ± 0.95	0.15 (-0.23 to 0.53)	0.419	1.94 ± 1.09	1.29 ± 0.59	0.65 (0.05 to 1.25)	0.037*
- Self-care	1.2 ± 0.70	1.15 ± 0.67	0.05 (-0.05 to 0.15)	0.330	1.47 ± 1.01	1.12 ± 0.33	0.24 (-0.16 to 0.87)	0.164
- Usual activities	1.55 ± 0.89	1.45 ±0.83	0.1 (-0.20 to 0.40)	0.494	1.59 ± 0.71	1.47 ± 0.72	0.12 (-0.05 to 0.29)	0.164
- Pain/discomfort	1.55 ± 0.69	1.55 ± 0.60	0 (-0.34 to 0.34)	0.999	1.71 ± 1.35	1.47 ± 0.51	0.24 (-0.05 to 0.52)	0.104
- Anxiety/depression	1.6 ± 0.88	1.65 ± 0.99	-0.05 (-0.37 to 0.27)	0.748	1.53 ± 0.62	1.18 ± 0.39	0.35 (-0.01 to 0.71)	0.055
- VAS (0–100)	84.44 ± 14.44	84.78 ± 12.24	-0.33 (-3.80 to 3.13)	0.841	85.67 ± 14.74	89.33 ± 8.21	-3.67 (-9.44 to 2.11)	0.195
PedsQL	(n=23)	(n=23)			(n=8)	(n=8)		
- Physical functioning	74.59 ± 23.67	77.58 ± 19.32	-2.99 (-14.53 to 8.55)	0.597	78.91 ± 23.49	87.11 ± 14.70	-8.20 (-26.41 to 10.00)	0.322
- Emotional functioning	56.96 ± 18.63	52.83 ± 18.76	4.13 (-6.23 to 14.49)	0.417	55.63 ± 28.09	56.88 ± 29.39	-1.25 (-21.58 to 19.08)	0.889
- Social functioning	50.22 ± 22.94	51.09 ± 19.07	-0.87 (-10.62 to 8.88)	0.855	56.25 ± 25.88	63.13 ± 25.20	-6.88 (-20.64 to 6.89)	0.276
- School functioning	50.94 ± 32.08	57.46 ±34.13	-6.52 (-18.78 to 5.74)	0.282	65 ± 32.74	51.67 ± 24.93	13.33 (-5.35 to 32.01)	0.135
HUI3	(n=26)	(n=26)			(n=25)	(n=25)		
- Vision	1.20 ± 0.77	1.06 ± 0.26	0.13 (-0.15 to 0.42)	0.334	1.36 ± 1.04	1.12 ± 0.44	0.18 (-0.12 to 0.60)	0.185
- Hearing	4.20 ± 1.77	3.92 ± 1.67	0.29 (-0.51 to 1.09)	0.460	3.52 ± 2.06	2.56 ± 1.20	0.96 (0.30 to 1.61)	0.006*
- Speech	1.35 ± 0.89	1.35 ± 0.98	0 (-0.40 to 0.40)	1.000	1.44 ± 0.96	1 ± 0.00	0.44 (0.04 to 0.84)	0.031*
- Ambulation/mobility	3.17 ± 1.47	4.33 ± 1.03	0.60 (-2.71 to 0.37)	0.110	3.00 ± 0.00	3.00 ± 0.00	0	1.00
- Dexterity	1.00 ± 0.00	1.00 ± 0.00	0	1.00	1.00 ± 0.00	1.00 ± 0.00	0	1.00
- Emotion	1.5 ± 0.52	1.33 ± 0.49	0.17 (-0.08 to 0.41)	0.166	1.17 ± 0.39	1.08 ± 0.29	0.08 (-0.24 to 0.41)	0.586
- Cognition	2.24 ± 1.41	2.05 ± 1.28	0.19 (-0.55 to 0.93)	0.599	2.15 ± 1.38	2.11 ± 1.20	0.05 (-0.82 to 0.92)	0.901
- Pain	2.12 ± 1.23	1.88 ± 1.37	0.24 (-0.16 to 0.63)	0.233	1.73 ± 1.05	1.97 ± 1.30	-0.23 (-0.62 to 0.16)	0.229

a – paired t-test, * - statistically significance

VAS, visual analog scale; MD, mean difference; CI, confidence interval

Factors contributing to the success

The effect of factors including the age, sex, onset of hearing loss, type of communication, etiology, intelligence quotient, mental health status, type of hospital, electrode insertion, and insertion technique on the success of cochlear implantation was evaluated. However, there were no significant differences in the odds ratios (ORs) for all factors ($p > 0.05$). (Table 4)

Table 4. The factors contributing to the success of the implantation.

Factors	N/percent success in 1 year	OR	95% CI	p-value
Age				
- Infants and toddlers (<4 years) (n=9)	8 (88.89%)	1		
- Pre-school children (4–7 years) (n=28)	25 (89.29%)	1.04	0.09 to 11.47	0.973
- Early school children (8–12 years) (n=27)	23 (85.19%)	0.72	0.07 to 7.42	0.782
- Adolescents (13–18 years) (n=23)	22 (95.65%)	2.75	0.15 to 49.36	0.492
- Adults (>18 years) (n=138)	114 (82.61%)	0.59	0.07 to 4.97	0.631
Sex				
- Male	103 (53.65%)	1		
- Female	89 (46.35%)	0.77	0.37 to 1.59	0.479
Onset of hearing loss				
- Pre-lingual hearing loss (n=21)	18 (85.71%)	1		
- Post-lingual hearing loss (n=199)	169 (84.92%)	0.94	0.26 to 3.39	0.923
Type of communication				
- Oral (n=122)	108 (88.52%)	1		
- Sign language (n=21)	18 (85.71%)	0.78	0.20 to 2.98	0.714
- Combined (n=77)	61 (79.22%)	0.49	0.23 to 1.08	0.078
Etiology				
- Congenital (n=112)	98 (87.50%)	1		
- Acquired (n=115)	95 (82.61%)	0.68	0.32 to 1.42	0.304
IQ				
- Above low Average (n=62)	51 (82.26%)	1		
- Borderline or extremely low (n=36)	33 (91.67%)	2.37	0.62 to 9.15	0.210
Mental health				
- Normal (n=81)	66 (81.49%)	1		
- Abnormal (n=6)	3 (50.00%)	0.23	0.04 to 1.24	0.087
Type of hospital				
- Tertiary hospital (n=18)	17 (94.44%)	1		
- University hospital (n=212)	178 (83.96%)	0.31	0.04 to 2.39	0.260
Electrode insertion				
- Full (n = 214)	183 (85.51%)	1		
- Partial (n=15)	11 (73.33%)	0.47	0.14 to 1.56	0.214
Insertion technique				
- Cochleostomy (n=158)	130 (82.28%)	1		
- Round window (n=69)	62 (89.86%)	1.91	0.79 to 4.61	0.151

OR, odds ratio; CI, confidence interval; IQ, intelligence quotient

Complications

The common immediate postoperative complications were vertigo, facial weakness, and electrode dislodgement. Common delayed complications included meningitis, electrode dislodgement, and cochlear implant migration/extrusion. (Table 5)

Table 5. Complications

Immediate complications	**N = 407**	**%**
- Vertigo	5	1.23
- Facial weakness	3	0.74
- Electrodes dislodge	1	0.25
- Tinnitus	0	0
- Wound infection	0	0
- Bleeding	0	0
- Others	12	2.95
Delayed complications	**N = 465**	**%**
- Meningitis	9	1.93
- Electrodes dislodge	9	1.93
- Implant migration/extrusion	8	1.72
- Device failure	7	1.51
- Others	19	4.09

DISCUSSION

Cochlear implants can help patients with severe or profound sensorineural hearing loss to regain hearing. This results in a better quality of life in adults and ultimately helps in the linguistic and social developmental processes in children.[24] However, most data on patient outcomes have been collected in individual institutions, which makes it less generalizable.

Several studies have found that speech perception and disease-specific quality of life scores were significantly improved in adults.[6 25] A recent systematic review of 18 articles, including a total of 1,093 records of older adults who underwent cochlear implantation, found that an improvement in disease-specific quality of life was generally reported. However, the generic quality of life questionnaires assessing general health status were ambiguous. The author concluded that there is a need for a standardized quality of life assessment tool for patients with cochlear implantation.[26]

There are no standard cochlear implantation criteria in Thailand. The common criteria used in most institutes were:

1. Deafness was defined as PTA (from four frequencies 0.5, 1, 2, and 4 kHz) or SRT > 80 dB HL according to the WHO classification or no response to an auditory brainstem response at the maximum intensity of 90 dB HL.
2. No or little benefit from hearing aids and
3. SDS < 50% and
4. The onset of deafness should not be > 10 years.

Our previous study collected data from 226 patients with cochlear implantation. We found that the audiological outcomes, including PTA, SRT, and SDS, were significantly improved compared to the preoperative period ($p = 0.001$, $p < 0.001$, and $p < 0.001$, respectively). However, the quality of life data did not significantly improve.[27]

To the best of our knowledge, this is the first project with government support to evaluate the outcomes of cochlear implantation at the national level. We prospectively collected data from patients who underwent cochlear implant surgery in Thailand for 10 years.

In this study, we found that audiological outcomes, including PTA, SRT, and SDS, were significantly improved ($p < 0.001$, $p < 0.001$, and $p < 0.001$, respectively). The quality of life, including mobility, hearing, and speech domains, was significantly improved ($p = 0.037$, $p = 0.006$, and $p = 0.031$, respectively).

We also tried to identify factors leading to the success of cochlear implantation in our setting; however, no factor significantly impacted the success ($p > 0.05$).

This study had limitations owing to the nature of the cohort study. Approximately 10% of data were missing for most variables. This study was designed to follow up patients for five years. However, the number of patients reporting for follow-up after 1 year declined sharply. Therefore, we limited the analysis of outcomes to 1 year after cochlear implantation.

The results of this study showed the excellent audiological outcomes and improvement of the quality of life in mobility, hearing, and speech domains in patients who underwent cochlear implantation in Thailand. Future studies should investigate the long-term hearing outcomes using standardized quality of life questionnaire for patients with cochlear implantation.

CONCLUSION

Excellent audiological outcomes and improvement in the quality of life in the mobility, hearing, and speech domains were observed in patients who underwent cochlear implantation in Thailand.

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Competing interests

The authors declare that they have no competing interests.

Author contributions

P.P. conceptualized, designed, and supervised the study; performed data analysis; interpreted the results; and drafted the manuscript. N.T., S.K., S.K., K.T., V.A., P.T., C.W., T.M., and P.I. contributed to data collection. K.Y. contributed to the study design, data collection, and supervision of the study. All authors contributed to the interpretation and discussion of the results and read and approved the final manuscript.

Data sharing statement

Data are available upon request. Individual de-identified data will be available on reasonable request. Extra data is available by emailing kwayim@kku.ac.th.

Ethics approval and consent to participate

This study was approved by the Central Research Ethics Committee of Thailand (CERT004/59BRm). Written informed consent to participate in this study was provided by all patients enrolled.

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STROBE Statement—Checklist of items that should be included in reports of ***cohort studies***

	Item No	Recommendation	Page No
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract (*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	1
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	3
Objectives	3	State specific objectives, including any prespecified hypotheses	4
Methods			
Study design	4	Present key elements of study design early in the paper	4
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	4
Participants	6	(*a*) Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up (*b*) For matched studies, give matching criteria and number of exposed and unexposed	4
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	4
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	4
Bias	9	Describe any efforts to address potential sources of bias	NA
Study size	10	Explain how the study size was arrived at	NA
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	5
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding (*b*) Describe any methods used to examine subgroups and interactions (*c*) Explain how missing data were addressed (*d*) If applicable, explain how loss to follow-up was addressed (*e*) Describe any sensitivity analyses	5
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed (b) Give reasons for non-participation at each stage (c) Consider use of a flow diagram	6
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders (b) Indicate number of participants with missing data for each variable of interest (c) Summarise follow-up time (eg, average and total amount)	6
Outcome data	15*	Report numbers of outcome events or summary measures over time	7

Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included (*b*) Report category boundaries when continuous variables were categorized (*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	7
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	9
Discussion			
Key results	18	Summarise key results with reference to study objectives	11
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	12
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	12
Generalisability	21	Discuss the generalisability (external validity) of the study results	11
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	12

*Give information separately for exposed and unexposed groups.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at http://www.strobe-statement.org.

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A multicenter cohort study of cochlear implantation outcomes in Thailand

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A multicenter cohort study of cochlear implantation outcomes in Thailand

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ABSTRACT

Objectives: To report the status and outcomes of cochlear implantation in Thailand.

Design: Cohort study.

Setting: Tertiary care and university hospitals.

Participants: Patients who underwent cochlear implant surgery in Thailand.

Interventions: This project collected data from all government and university hospitals in Thailand where cochlear implant surgery was performed between 2016 and 2020.

Primary and secondary outcome measures: Baseline characteristics, operation data, complications, audiological outcomes, and quality of life were reported.

Results: This study included 458 patients, and nearly half of the patients were children and adolescents (46.94%). The mean age of the patients was 2.96 ± 5.83 years. At 1 year postoperatively, the mean pure tone average of the hearing threshold in the implanted ear significantly improved from unaided preoperative baseline (mean difference [MD] 64.23 dB HL; 95% confidence interval [CI] 59.81–68.65; $p < 0.001$). The mean speech recognition threshold also improved (MD 49.26 dB HL; 95% CI 42.28–56.24, $p < 0.001$). The quality-of-life scores of the EQ-5D-5L, PedsQL, and HUI3 questionnaires at 1 year showed improved mobility (range, 0–5; MD 0.65; 95% CI 0.05–1.25; $p = 0.037$), hearing (range, 0–6; MD 0.96; 95% CI 0.30–1.61; $p = 0.006$), and speech (range, 0–5; MD 0.44; 95% CI 0.04–0.84; $p = 0.031$). Common complications included electrode dislodgement (2.18%), vertigo (1.23%), and meningitis (1.93%).

Conclusions: Excellent audiological outcomes and improvement in the quality of life in the mobility, hearing, and speech domains were observed in patients who underwent cochlear implantation in Thailand.

Keywords: cochlear implant, cochlear implantation, deafness, hearing loss, registry, report

Strengths and limitations of this study

- This is a multicenter prospective cohort study to collect the cochlear implantation outcomes conducted in Thailand.
- This study collected data from 2016 to 2020.
- We did not collect data from private hospitals, and some data were missing due to the nature of the cohort study.

INTRODUCTION

Hearing impairment is a major disability that can affect the quality of life.[1-3] According to the Department of Empowerment of Persons with Disabilities, 375,680 hearing-impaired patients were registered with the government in Thailand in 2018.[4]

Cochlear implant devices can help patients with severe to profound sensorineural hearing loss to regain hearing. Speech perception, quality of life, and neurocognitive function improve after cochlear implantation.[5-7]

In Thailand, cochlear implant surgery was first performed in 1986 using a 3M device from the USA. Gradually, university hospitals and major tertiary hospitals started to perform this surgery. However, the number of patients who underwent this procedure was modest owing to the price of the devices, and it was not supported by the universal health scheme.

Only a few single-institution studies have assessed the efficacy of this technology in Thailand.[8 9] No conclusive evidence of the benefits of cochlear implant devices in the Thai population is available and data from Western countries may not be applicable in developing countries. The Thai government needs more local evidence to establish a cochlear implant device as a basic medical benefit for all Thai people.

This nationwide project with support from the Health Systems Research Institute of Thailand was initiated to prospectively collect cochlear implantation outcomes in the Thai population to provide recommendations to the government on cochlear implantation policy.[10]

This study aimed to evaluate the efficacy of cochlear implantation in terms of audiological outcomes and quality of life in the Thai population.

METHODS

Study design and setting

All government and university hospitals in Thailand that were equipped to perform cochlear implant surgery were involved. A total of eight university hospitals (Srinagrind Hospital, King Chulalongkorn Memorial Hospital, Ramathibodi Hospital, Songklanagarind Hospital, Siriraj Hospital, Maharaj Nakorn Chiangmai Hospital, Phramongkutklao Hospital, and HRH Princess Maha Chakri Sirindhorn Medical Center) and three tertiary hospitals (King Bhumibol Adulyadej Hospital, Rajavithi Hospital, and Trang Hospital) participated in this study. These were the major hospitals that performed cochlear implant surgery in Thailand.

Participants

We included all patients who underwent cochlear implantation at a network hospital between July 2016 and April 2020. There were no exclusion criteria.

Outcomes

We collected baseline characteristics, operation data, complications, auditory performance, and quality of life data.

The baseline characteristics and operation data included the age, sex, onset of hearing loss, type of deafness, cause of hearing loss, intelligence quotient using Wechsler Intelligence Scales[11] and mental health status evaluated by psychologists (normal or abnormal), type of hospital, electrode insertion depth, and insertion technique.

Auditory performance outcomes

Auditory performance was assessed based on pure tone audiometry, speech recognition threshold (SRT), speech discrimination score (SDS), and categories of auditory performance scores (CAP).

Pure tone audiometry was performed to determine air-conduction hearing thresholds. Thresholds were tested separately for each ear, octave-by-octave, from 250 to 8000 Hz. A pure tone average (PTA) refers to the average of hearing threshold levels at 500, 1,000, 2,000, and 4,000 Hz.[12]

The SRT is the minimum hearing level for speech at which an individual can recognize 50% of the speech material. A recognition task is one in which the participant selects the test item from a closed set of choices. The individual should repeat or, in some other manner, indicate recognition of the speech material 50% of the time.[13] In this study, the original Thai monosyllabic word lists (RAMA.SD-1) containing five lists of 25 monosyllabic words were used.[14]

The SDS was a score of the number of words correctly repeated from phonetically balanced word lists, expressed as a percentage of correct.[15]

The categories of auditory performance (CAP) scale is a functional performance evaluation that was developed as part of the Nottingham Cochlear Implant Program and as a global assessment of auditory receptive abilities. It is a nonlinear scale on which patients' developing auditory abilities can be rated in eight categories of increasing difficulty from 0 to 7 (0: no awareness of environmental sounds; 1: awareness of environmental sounds; 2: response to speech sounds; 3: identification of environmental sounds; 4: discrimination of some speech sounds without lip-reading; 5: understanding common phrases without lip-

reading; 6: understanding conversation without lip-reading; 7: using the telephone with a known speaker).[16 17]

All auditory performance outcomes were collected at baseline (preoperative) and at 3 and 12 months postoperatively. The preoperative auditory performance was unaided assessment (without hearing aids) while postoperative evaluation was aided assessment (cochlear implant device turn on).

Quality of life outcomes

Quality of life was evaluated using EQ-5D-5L (for patients older than 18 years of age),[18] the Pediatric Quality of Life Inventory - PedsQL (for patients between 2 and 18 years),[19] and the health utilities index mark 3 - HUI3 (for patients older than 8 years of age).[20]

The EQ-5D-5L is a general health status questionnaire with a descriptive system and a visual analog scale (VAS). The descriptive system comprises five dimensions: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. Each dimension has five levels: no problems, slight problems, moderate problems, severe problems, and extreme problems. The patient is asked to indicate their health state by ticking the box next to the most appropriate statement in each of the five dimensions. The VAS records the patient's self-rated health on a vertical visual analog scale, where the endpoints are labeled "The best health you can imagine" and "The worst health you can imagine." The VAS can be used as a quantitative measure of health outcomes that reflect the patient's own judgment.[18]

The PedsQL is a general health status questionnaire for children and adolescents. This questionnaire evaluates the four dimensions delineated by the World Health Organization, which are: physical, emotional, social, and school functioning. Each item has five levels: never, almost never, sometimes, often, and almost always. The scores ranged from 0 to 100.[21]

HUI3 is a generic health-related quality of life for measuring health status, health-related quality of life, and utility scores. Health dimensions include vision, hearing, speech, ambulation/mobility, pain, dexterity, self-care, emotion, and cognition. Each dimension has five to six levels.[22]

Quality of life data were collected at 1, 3, and 12 months postoperatively. In children aged less than 5-year-old, the input on the quality of life was derived from their parents or caregivers.

Definitions

Deafness was defined as PTA (from four frequencies 0.5, 1, 2, and 4 kHz) or SRT > 80 dB HL according to the World Health Organization (WHO) classification or no response to an auditory brainstem response at the maximum intensity of 90 dB HL.[23]

Implantation success was defined as a PTA or SRT ≤ 50 dB and SDS ≥ 50% (category B) within 1 year post-operatively according to the American Academy of Otolaryngology-Head and Neck Surgery classification.[24]

Ethical consideration

The research protocol was reviewed and approved by the Central Research Ethics Committee of Thailand (CERT004/59BRm). A registry assistant approached the patients eligible for the investigation. The patients were given a detailed explanation of the study procedures and the possible impacts of the study. Patients who agreed to participate provided written informed consent.

Patient and Public Involvement

The Health Systems Research Institute of Thailand is a public body financed by the government of Thailand, which has a role in protocol development. Representatives from the National Association of the Deaf in Thailand also provided input for this study.

Statistical Analysis

Statistical analyses were performed using IBM SPSS version 20 and Stata version 14. Data were described as either means (for continuous variables) or frequencies and percentages (for categorical variables). Significant differences between groups were determined using the Student's t-test, paired sample t-test, or Mann–Whitney U test for continuous variables. The chi-square test or Fisher's exact test was used to determine whether there was a significant difference between the expected and observed frequencies. The factor of success is presented as an odds ratio. For all tests, statistical significance was set at $p < 0.05$.

RESULTS

Patient's demographics

There were 458 patients in this study, of whom, 220 were male and 203 were female. Nearly half of the patients were children and adolescents (46.94%). The common causes of congenital and acquired hearing disabilities were idiopathic (51.87% and 34.02%, respectively). (Table 1)

Table 1. Demographic data.

	N = 458	**%**
Sex		
- Male	220	48.03
- Female	203	44.32
- No data	35	7.64
Age		
- Infants and toddlers (<4 years)	44	9.61
- Pre-school children (4–7 years)	79	17.25
- Early school children (8–12 years)	52	11.35
- Adolescents (13–18 years)	40	8.73
- Adults (> 18 years)	211	46.07
- No data	32	6.99
The onset of hearing loss		
- Pre-lingual hearing loss	41	8.95
- Post-lingual hearing loss	330	72.05

- No data	87	18.20
Type of deafness		
- Bilateral deafness	458	100
- Unilateral deafness	0	0
Causes of hearing loss		
Congenital	**N = 241**	
- Idiopathic	125	51.87
- Inner ear anomalies	12	4.98
- Genetic disorder	7	2.90
- Intrauterine infection	5	2.07
- Birth asphyxia	4	1.66
- Ototoxicity	1	0.41
- Others	5	2.07
- No data	82	34.02
Acquired	**N = 181**	
- Idiopathic	67	37.02
- Post meningitis	63	34.81
- Chronic otitis media or cholesteatoma	10	5.52
- Sepsis	4	2.21
- Ototoxicity	3	1.66
- Trauma	3	1.66
- Head injury	3	1.66
- Noise-induced or noise trauma	2	1.10
- Autoimmune hearing loss	1	0.55
- Others	19	10.50
- No data	6	3.31

Audiological outcomes

Preoperatively, the mean PTA, mean SRT, mean SDS, and mean CAP score was 95.53 dB HL, 86.72 dB HL, 28.82%, and 0.54 points, respectively. At three months postoperatively, the mean PTA, mean SRT, mean SDS, and mean CAP score was 34.14 dB HL, 37.47 dB HL, 47.33% and 2.62 points respectively. At 12 months postoperatively, the mean PTA, mean SRT, mean SDS, and mean CAP score was 31.87 dB HL, 34.45 dB HL, 62.24% and 3.97 points respectively.

All audiological outcomes were significantly improved from baseline at 3 months ($p < 0.001$) and 12 months post operation ($p < 0.001$). (Table 2)

Table 2. Audiological outcomes

	Pre-op	3 months	Mean difference (95% CI)	p-value[a]	Pre-op	12 months	Mean difference (95% CI)	p-value[a]
Pure tone average	(n = 144)	(n = 144)			(n = 101)	(n = 101)		
- Better ear	95.53 ± 20.68	34.14 ± 13.93	61.39 (57.39 to 65.40)	<0.001*	96.10 ± 22.05	31.87 ± 12.71	64.23 (59.81 to 68.65)	<0.001*
SRT	(n = 58)	(n = 58)			(n = 53)	(n = 53)		
- Better ear	86.72 ± 24.11	37.47 ± 17.00	49.26 (42.28 to 56.24)	<0.001*	90.42 ± 21.47	34.45 ± 11.54	55.96 (49.50 to 62.42)	<0.001*
Speech discrimination score	(n = 39)	(n = 39)			(n = 34)	(n = 34)		
- Better ear	28.82 ± 34.83	47.33 ± 32.92	-18.51 (-27.13 to -9.90)	<0.001*	29.76 ± 35.39	62.24 ± 28.51	-32.47 (-43.00 to -21.94)	<0.001*
CAP score	(n = 147)	(n = 147)			(n = 118)	(n = 118)		
	0.54 ± 1.03	2.62 ± 2.32	-2.08 (-2.45 to -1.71)	<0.001*	0.57 ± 1.09	3.97 ± 2.57	-3.40 (-3.88 to -2.92)	<0.001*

a – paired t-test, * - statistically significance
CI, confidence interval; CAP, categories of auditory performance; SRT. Speech recognition threshold

Quality of life outcomes

For EQ-5D-5L, the mean score for the mobility domain (range, 0–5; lower is better) significantly improved at 12 months compared to the postoperative first month (MD, 0.65; 95% CI, 0.05–1.25; p = 0.037). However, there were no statistically significant differences in the other domains (p > 0.05).

For PedsQL (range, 0–100; higher is better), there was no statistically significant difference in physical, emotional, social, and school functioning domains at 3 and 12 months compared to the postoperative first month (p > 0.05).

For HUI3, the mean score for hearing (range, 0–6; lower is better) and speech domain (range, 0–5; lower is better) significantly improved at 12 months compared to the postoperative first month (MD for hearing score, 0.96 points; 95% CI, 0.30–1.61; p = 0.006; MD for speech score, 0.44 points; 95% CI, 0.04– 0.84; p = 0.031). However, there were no statistically significant differences in the other domains (p > 0.05). (Table 3)

Table 3. Quality of life outcomes

	1 months	3 months	MD (95% CI)	p-value[a]	1 month	12 months	MD (95% CI)	p-value[a]
EQ-5D-5L	(n=20)	(n=20)			(n=17)	(n=17)		
- Mobility	1.8 ± 0.95	1.65 ± 0.95	0.15 (-0.23 to 0.53)	0.419	1.94 ± 1.09	1.29 ± 0.59	0.65 (0.05 to 1.25)	0.037*
- Self-care	1.2 ± 0.70	1.15 ± 0.67	0.05 (-0.05 to 0.15)	0.330	1.47 ± 1.01	1.12 ± 0.33	0.24 (-0.16 to 0.87)	0.164
- Usual activities	1.55 ± 0.89	1.45 ±0.83	0.1 (-0.20 to 0.40)	0.494	1.59 ± 0.71	1.47 ± 0.72	0.12 (-0.05 to 0.29)	0.164
- Pain/discomfort	1.55 ± 0.69	1.55 ± 0.60	0 (-0.34 to 0.34)	0.999	1.71 ± 1.35	1.47 ± 0.51	0.24 (-0.05 to 0.52)	0.104
- Anxiety/depression	1.6 ± 0.88	1.65 ± 0.99	-0.05 (-0.37 to 0.27)	0.748	1.53 ± 0.62	1.18 ± 0.39	0.35 (-0.01 to 0.71)	0.055
- VAS (0–100)	84.44 ± 14.44	84.78 ± 12.24	-0.33 (-3.80 to 3.13)	0.841	85.67 ± 14.74	89.33 ± 8.21	-3.67 (-9.44 to 2.11)	0.195
PedsQL	(n=23)	(n=23)			(n=8)	(n=8)		
- Physical functioning	74.59 ± 23.67	77.58 ± 19.32	-2.99 (-14.53 to 8.55)	0.597	78.91 ± 23.49	87.11 ± 14.70	-8.20 (-26.41 to 10.00)	0.322
- Emotional functioning	56.96 ± 18.63	52.83 ± 18.76	4.13 (-6.23 to 14.49)	0.417	55.63 ± 28.09	56.88 ± 29.39	-1.25 (-21.58 to 19.08)	0.889
- Social functioning	50.22 ± 22.94	51.09 ± 19.07	-0.87 (-10.62 to 8.88)	0.855	56.25 ± 25.88	63.13 ± 25.20	-6.88 (-20.64 to 6.89)	0.276
- School functioning	50.94 ± 32.08	57.46 ±34.13	-6.52 (-18.78 to 5.74)	0.282	65 ± 32.74	51.67 ± 24.93	13.33 (-5.35 to 32.01)	0.135
HUI3	(n=26)	(n=26)			(n=25)	(n=25)		
- Vision	1.20 ± 0.77	1.06 ± 0.26	0.13 (-0.15 to 0.42)	0.334	1.36 ± 1.04	1.12 ± 0.44	0.18 (-0.12 to 0.60)	0.185
- Hearing	4.20 ± 1.77	3.92 ± 1.67	0.29 (-0.51 to 1.09)	0.460	3.52 ± 2.06	2.56 ± 1.20	0.96 (0.30 to 1.61)	0.006*
- Speech	1.35 ± 0.89	1.35 ± 0.98	0 (-0.40 to 0.40)	1.000	1.44 ± 0.96	1 ± 0.00	0.44 (0.04 to 0.84)	0.031*
- Ambulation/mobility	3.17 ± 1.47	4.33 ± 1.03	0.60 (-2.71 to 0.37)	0.110	3.00 ± 0.00	3.00 ± 0.00	0	1.00
- Dexterity	1.00 ± 0.00	1.00 ± 0.00	0	1.00	1.00 ± 0.00	1.00 ± 0.00	0	1.00
- Emotion	1.5 ± 0.52	1.33 ± 0.49	0.17 (-0.08 to 0.41)	0.166	1.17 ± 0.39	1.08 ± 0.29	0.08 (-0.24 to 0.41)	0.586
- Cognition	2.24 ± 1.41	2.05 ± 1.28	0.19 (-0.55 to 0.93)	0.599	2.15 ± 1.38	2.11 ± 1.20	0.05 (-0.82 to 0.92)	0.901
- Pain	2.12 ± 1.23	1.88 ± 1.37	0.24 (-0.16 to 0.63)	0.233	1.73 ± 1.05	1.97 ± 1.30	-0.23 (-0.62 to 0.16)	0.229

a – paired t-test, * - statistically significance

VAS, visual analog scale; MD, mean difference; CI, confidence interval

Factors contributing to the success

The effect of factors including the age, sex, onset of hearing loss, type of communication, etiology, intelligence quotient, mental health status, type of hospital, electrode insertion, and insertion technique on the success of cochlear implantation was evaluated. However, there were no significant differences in the odds of success between factors ($p > 0.05$). (Table 4)

Table 4. The factors contributing to the success of the implantation.

Factors	N/percent success in 1 year	OR	95% CI	p-value
Age				
- Infants and toddlers (<4 years) (n=9)	8 (88.89%)	1		
- Pre-school children (4–7 years) (n=28)	25 (89.29%)	1.04	0.09 to 11.47	0.973
- Early school children (8–12 years) (n=27)	23 (85.19%)	0.72	0.07 to 7.42	0.782
- Adolescents (13–18 years) (n=23)	22 (95.65%)	2.75	0.15 to 49.36	0.492
- Adults (>18 years) (n=138)	114 (82.61%)	0.59	0.07 to 4.97	0.631
Sex				
- Male	103 (53.65%)	1		
- Female	89 (46.35%)	0.77	0.37 to 1.59	0.479
Onset of hearing loss				
- Pre-lingual hearing loss (n=21)	18 (85.71%)	1		
- Post-lingual hearing loss (n=199)	169 (84.92%)	0.94	0.26 to 3.39	0.923
Type of communication				
- Oral (n=122)	108 (88.52%)	1		
- Sign language (n=21)	18 (85.71%)	0.78	0.20 to 2.98	0.714
- Combined (n=77)	61 (79.22%)	0.49	0.23 to 1.08	0.078
Etiology				
- Congenital (n=112)	98 (87.50%)	1		
- Acquired (n=115)	95 (82.61%)	0.68	0.32 to 1.42	0.304
IQ				
- Above low Average (n=62)	51 (82.26%)	1		
- Borderline or extremely low (n=36)	33 (91.67%)	2.37	0.62 to 9.15	0.210
Mental health				
- Normal (n=81)	66 (81.49%)	1		
- Abnormal (n=6)	3 (50.00%)	0.23	0.04 to 1.24	0.087
Type of hospital				
- Tertiary hospital (n=18)	17 (94.44%)	1		
- University hospital (n=212)	178 (83.96%)	0.31	0.04 to 2.39	0.260
Electrode insertion				
- Full (n = 214)	183 (85.51%)	1		
- Partial (n=15)	11 (73.33%)	0.47	0.14 to 1.56	0.214
Insertion technique				
- Cochleostomy (n=158)	130 (82.28%)	1		
- Round window (n=69)	62 (89.86%)	1.91	0.79 to 4.61	0.151

OR, odds ratio; CI, confidence interval; IQ, intelligence quotient

Complications

The most common immediate postoperative complications were vertigo, facial weakness, and electrode dislodgement. Most common delayed complications included meningitis, electrode dislodgement, and cochlear implant migration/extrusion. (Table 5)

Table 5. Complications

Immediate complications	**N = 407**	**%**
- Vertigo	5	1.23
- Facial weakness	3	0.74
- Electrodes dislodge	1	0.25
- Tinnitus	0	0
- Wound infection	0	0
- Bleeding	0	0
- Others	12	2.95
Delayed complications	**N = 465**	**%**
- Meningitis	9	1.93
- Electrodes dislodge	9	1.93
- Implant migration/extrusion	8	1.72
- Device failure	7	1.51
- Others	19	4.09

DISCUSSION

Cochlear implants can help patients with severe or profound sensorineural hearing loss to regain hearing. This results in a better quality of life in adults and ultimately helps in the linguistic and social developmental processes in children.[25] However, most data on patient outcomes have been collected in individual institutions, which makes it less generalizable.

Several studies have found that speech perception and disease-specific quality of life scores were significantly improved in adults.[6 26] A recent systematic review of 18 articles, including a total of 1,093 records of older adults who underwent cochlear implantation, found that an improvement in disease-specific quality of life was generally reported. However, the generic quality of life questionnaires assessing general health status were ambiguous. The

author concluded that there is a need for a standardized quality of life assessment tool for patients with cochlear implantation.[27]

There are no standard cochlear implantation criteria in Thailand. The common criteria used in most institutes were:

1. Deafness was defined as PTA (from four frequencies 0.5, 1, 2, and 4 kHz) or SRT > 80 dB HL according to the WHO classification or no response to an auditory brainstem response at the maximum intensity of 90 dB HL.
2. No or little benefit from hearing aids and
3. SDS < 50% and
4. The onset of deafness should not be > 10 years.

Our previous study collected data from 226 patients with cochlear implantation. We found that the audiological outcomes, including PTA, SRT, and SDS, were significantly improved compared to the preoperative period ($p = 0.001$, $p < 0.001$, and $p < 0.001$, respectively). However, the quality of life data did not significantly improve.[28]

To the best of our knowledge, this is the first project with government support to evaluate the outcomes of cochlear implantation at the national level. We prospectively collected data from patients who underwent cochlear implant surgery in Thailand.

In this study, we found that audiological outcomes, including PTA, SRT, and SDS, were significantly improved ($p < 0.001$, $p < 0.001$, and $p < 0.001$, respectively). The quality of life, including mobility, hearing, and speech domains, was significantly improved ($p = 0.037$, $p = 0.006$, and $p = 0.031$, respectively).

We also tried to identify factors leading to the success of cochlear implantation in our setting; however, no factor significantly impacted the success ($p > 0.05$).

This study had limitations owing to the nature of the cohort study. Approximately 10% of data were missing for most variables. This study was designed to follow up patients

for five years. However, the number of patients reporting for follow-up after 1 year declined sharply. Therefore, we limited the analysis of outcomes to 1 year after cochlear implantation.

The results of this study showed the excellent audiological outcomes and improvement of the quality of life in mobility, hearing, and speech domains in patients who underwent cochlear implantation in Thailand. Future studies should investigate the long-term hearing outcomes using standardized quality of life questionnaire for patients with cochlear implantation.

CONCLUSION

Excellent audiological outcomes and improvement in the quality of life in the mobility, hearing, and speech domains were observed in patients who underwent cochlear implantation in Thailand.

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Competing interests

The authors declare that they have no competing interests.

Author contributions

P.P. conceptualized, designed, and supervised the study; performed data analysis; interpreted the results; and drafted the manuscript. N.T., S.K., S.K., K.T., V.A., P.T., C.W., T.M., and P.I. contributed to data collection. K.Y. contributed to the study design, data collection, and supervision of the study. All authors contributed to the interpretation and discussion of the results and read and approved the final manuscript.

Data sharing statement

Data are available upon request. Individual de-identified data will be available on reasonable request. Extra data is available by emailing kwayim@kku.ac.th.

Ethics approval and consent to participate

This study was approved by the Central Research Ethics Committee of Thailand (CERT004/59BRm). Written informed consent to participate in this study was provided by all patients enrolled.

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STROBE Statement—Checklist of items that should be included in reports of ***cohort studies***

	Item No	Recommendation	Page No
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract (*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	1
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	3
Objectives	3	State specific objectives, including any prespecified hypotheses	4
Methods			
Study design	4	Present key elements of study design early in the paper	4
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	4
Participants	6	(*a*) Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up (*b*) For matched studies, give matching criteria and number of exposed and unexposed	4
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	4
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	4
Bias	9	Describe any efforts to address potential sources of bias	NA
Study size	10	Explain how the study size was arrived at	NA
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	5
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding (*b*) Describe any methods used to examine subgroups and interactions (*c*) Explain how missing data were addressed (*d*) If applicable, explain how loss to follow-up was addressed (*e*) Describe any sensitivity analyses	5
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed (b) Give reasons for non-participation at each stage (c) Consider use of a flow diagram	6
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders (b) Indicate number of participants with missing data for each variable of interest (c) Summarise follow-up time (eg, average and total amount)	6
Outcome data	15*	Report numbers of outcome events or summary measures over time	7

Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included (*b*) Report category boundaries when continuous variables were categorized (*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	7
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	9
Discussion			
Key results	18	Summarise key results with reference to study objectives	11
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	12
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	12
Generalisability	21	Discuss the generalisability (external validity) of the study results	11
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	12

*Give information separately for exposed and unexposed groups.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at http://www.strobe-statement.org.