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# BMJ Open

## 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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1  
2  
3 42 **Competing interests**  
4

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6

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15  
16

17 48 **Data sharing statement**  
18

19 49 Data are available upon request. Individual de-identified data will be available on  
20  
21 50 reasonable request. Extra data is available by emailing kwayim@kku.ac.th.  
22  
23

24 51 **Ethics approval and consent to participate**  
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26 52 This study was approved by the Central Research Ethics Committee of Thailand  
27  
28 53 (CERT004/59BRm). Written informed consent to participate in this study was provided by all  
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30 54 patients enrolled.  
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## 67 **Abstract**

68  
69 **Objectives:** This is the study on the status and outcomes of cochlear implantation in  
70 Thailand. This nation-wide program was supported by the Health Systems Research Institute  
71 of Thailand.

72 **Design:** Cohort study.

73 **Setting:** Tertiary care and university hospital.

74 **Participants:** Patients who underwent cochlear implant surgery in Thailand.

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

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

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

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

90

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

92

### 93 **Strengths and limitations of this study**

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

## 103 **Introduction**

104  
105 Hearing impairment is a major disability that can affect the quality of life.[1-3]  
106 According to the Department of Empowerment of Persons with Disabilities, 375,680 hearing-  
107 impaired patients were registered with the government in Thailand in 2018.[4]

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

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

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

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3 119 To our knowledge, this is the first report of cochlear implantation outcomes that was  
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5 120 conducted with governmental support. Providing a reliable source of data for the patients,  
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7 121 physicians, and policymakers.  
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10 122

## 123 **Methods**

124

### 125 **Study design and setting**

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

### 133 **Participants**

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

### 136 **Outcomes**

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

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



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2  
3 145 1 – awareness of environmental sounds; 2 - response to speech sounds; 3 – identifies  
4  
5 146 environmental sounds; 4 – discrimination of some speech sounds without lip-reading; 5 –  
6  
7 147 understands common phrases without lip-reading; 6 – understands conversation without lip-  
8  
9 148 reading; 7 – uses the telephone with a known speaker.[8, 9]

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11  
12 149 Quality of life was evaluated using EQ-5D-5L (for patients above 18 years of  
13  
14 150 age),[10] the pediatric quality of life inventory - PedsQL (for patients between 2 and 18  
15  
16 151 years),[11] and the health utilities index mark 3 - HUI3 (for patients above 8 years of  
17  
18 152 age).[12]

### 19 153 **Ethical consideration**

20  
21  
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23  
24 154 The research protocol was reviewed and approved by the Central Research Ethics  
25  
26 155 Committee of Thailand (CERT004/59BRm). A registry assistant approached patients eligible  
27  
28 156 for investigation. The patients were given a detailed explanation of the study procedures and  
29  
30 157 the possible impacts of the study. Patients who agreed to participate gave written informed  
31  
32  
33  
34 158 consent.

### 35 36 37 159 **Patient and Public Involvement**

38  
39 160 The Health Systems Research Institute of Thailand was the public body financed by  
40  
41 161 the Government of Thailand that has a role in protocol development. The representatives from  
42  
43 162 the National Association of the Deaf in Thailand also giving input for this study.

### 44 45 46 163 **Statistical Analysis**

47  
48 164 Statistical analyses were performed using SPSS version 20 and Stata version 14. Data  
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51 165 were described as either means (for the continuous variables) or frequencies and percentages  
52  
53 166 (for the categorical variables). Significant differences between groups were determined using  
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56 167 the Student t-test or the Mann-Whitney U test for continuous variables. The chi-square test or  
57  
58 168 the Fisher exact test were used to determine whether there was a significant difference  
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169 between the expected frequencies and the observed frequencies. The survival analysis was  
 170 presented as a hazard ratio. The significance of association among the factors was tested using  
 171 a Cox proportional hazard model. For all tests,  $p < 0.05$  was considered statistically  
 172 significant.

## 173 Results

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

177 **Table 1.** Demographic data.

	<b>n</b>	<b>percent</b>
<b>Sex</b>		
- Male	189	51.50
- Female	168	45.78
- No data	10	2.72
<b>Age</b>		
- 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
<b>Causes</b>		
<b>Idiopathic</b>		
- Congenital	101	38.84
- Acquired	58	22.31
<b>Non-idiopathic</b>		
- 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

178

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

183 **Table 2.** Preoperative rehabilitation.

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

184  
 185 The majority of patients (around 80%) had profound deafness. The CAP score for  
 186 most patients was zero. The mean speech reception threshold was around 90 decibels for both  
 187 ears. The mean phonetically balanced score was around 40% for both ears (Table 3).

188 **Table 3.** Pre-operative hearing level.

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

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

189

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

197 Quality-of-life data were collected in adult ( $> 18$  years old) patients using the EQ-5D-  
 198 5L questionnaire. This questionnaire evaluates the quality of life in 5 domains including  
 199 mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. Utility scores  
 200 can range from 0 to 1 (higher is better). Quality-of-life scores in the cochlear implant  
 201 recipients improved slightly after the operation.

202 Quality-of-life data were collected from the children using the PedsQL questionnaire.  
 203 This questionnaire consists of 23 items in physical, emotional, social, and school functioning  
 204 domains. Scores on the PedsQL can range from 0 to 100 (higher is better). The questionnaire  
 205 takes about 4 minutes to complete. It was designed for the parents of 2-4, 5-7, 8-12, and 13–  
 206 18 years old children and for self-assessment in 5-7, 8-12, and 13-18 years old children.

207 For the children aged 2-4 years old, the sole source of quality-of-life information was  
 208 the parents. Quality of life increased slightly in this age group post-operation. For the children  
 209 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
<b>Preoperative rehabilitation</b>						
• Yes	20	60	276	1	0.42 to 1.45	0.43
• No	139	58.27	2,487	0.78		
<b>Continuation of hearing aid use</b>						
• Always	109	61.47	1,943	1	0.5 to 1.67	0.76
• Seldom	28	46.43	409	0.91		
<b>Type of communication</b>						
• 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
<b>Brand of CI</b>						
• 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
<b>Etiology</b>						
• Congenital	90	46.67	1,684	1	1.23 to 2.78	<0.001
• Acquired	75	73.33	1,217	1.85		
<b>Pre-operative hearing level (dB)</b>						
• 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
<b>IQ</b>						
• Above Low Average	39	58.97	874	1	0.79 to 2.75	0.22
• Borderline or extremely low	30	70	547	1.48		
<b>Mental health</b>						
• Normal	39	58.97	874	1	0.79 to 2.75	0.22
• Abnormal	30	70	547	1.48		
<b>Electrode insertion</b>						
• Full	154	61.04	2,728	1	0.12 to 2.06	0.34
• Partial	8	25	112	0.51		
<b>Insertion Technique: insertion of electrodes via</b>						
• 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.

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3 240 By the way, there have also reports from cochlear implant manufacturers for which  
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5 241 data were collected from various countries, such as the Cochlear Pediatric Implanted  
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7 242 Recipient Observational Study, which collected data from Australia, China, India, Indonesia,  
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9 243 Turkey, and Vietnam.[14] But, the question for the transparency of the data from the  
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11 244 manufacturers was also raised.  
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14 245 To our knowledge, this is the first nation-wide report of the effectiveness of the  
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16 246 cochlear implant device that was implemented with government support. We prospectively  
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18 247 collected the data of the patients who underwent cochlear implant surgery in Thailand from  
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20 248 2010. Most of the recipients (55%) were children, 19% of whom were between 2-4 years old.  
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23 249 The mean pre-operative hearing level in the patients in this study was 100 dB  
24  
25 250 (profound hearing loss) with a CAP score of 0 (no awareness of environmental sounds). The  
26  
27 251 mean hearing level had significantly improved one-month post-operation and had reached the  
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29 252 level of mild hearing loss (< 40 dB) by the third month post-operation. Complications of  
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31 253 included facial palsy, vertigo, and dislodging of the implant.  
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34 254 The results of this study were comparable with those of a study from HEARRING  
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36 255 registry in Europe, the authors of which extracted data from 146 patients who underwent  
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38 256 cochlear implantation. They found that speech in quiet and speech in noise scores of patients  
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40 257 of all age groups significantly improved ( $p < 0.05$ ) post-operation. Quality of life in our study  
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42 258 also improved slightly for patients in all age groups, but not to a statistically significant  
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44 259 extent. This was consistent with the study from the HEARRING registry, although they found  
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46 260 a significant difference between the HISQUI19 scores of patients 70 years and older and those  
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48 261 younger than 56 years.[15]  
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51 262 This database is managed and hosted by the Digital Government Development  
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53 263 Agency (DGA), which is a secure government cloud server with CSA-STAR certification.  
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55 264 This study did not have adequate data to analyze the general quality of life in patients 8-12 or  
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3 265 13-18 years old. Further data collection is needed to evaluate these outcomes and related  
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5 266 factors.

## 267 **Conclusion**

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11 268 The data indicated a good audiological and acceptable quality-of-life outcomes in  
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14 269 patients who underwent cochlear implantation in Thailand.

## 270 **Author's contribution**

16  
17  
18  
19  
20 271 P.P. conceptualized, designed, and supervised the study, performed data analysis,  
21  
22 272 interpreted results, and drafted the manuscript. N.T., S.K., S.K., K.T., V.A., P.T., C.W., T.M.  
23  
24 273 and P.I. contributed to data collection. K.Y. contributed to study design, data collection and  
25  
26  
27 274 supervised the study. All authors contributed to the interpretation and discussion of the results  
28  
29 275 and read and approved the final manuscript.

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39  
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4 343 **Tables**

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6 345 **Table 1.** Demographic Data.

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8 346 **Table 2.** Preoperative rehabilitation.

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10 347 **Table 3.** Pre-operative hearing level.

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12 348 **Table 4.** The factors contributing to the success of the implantation.

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18 350 **Figures**

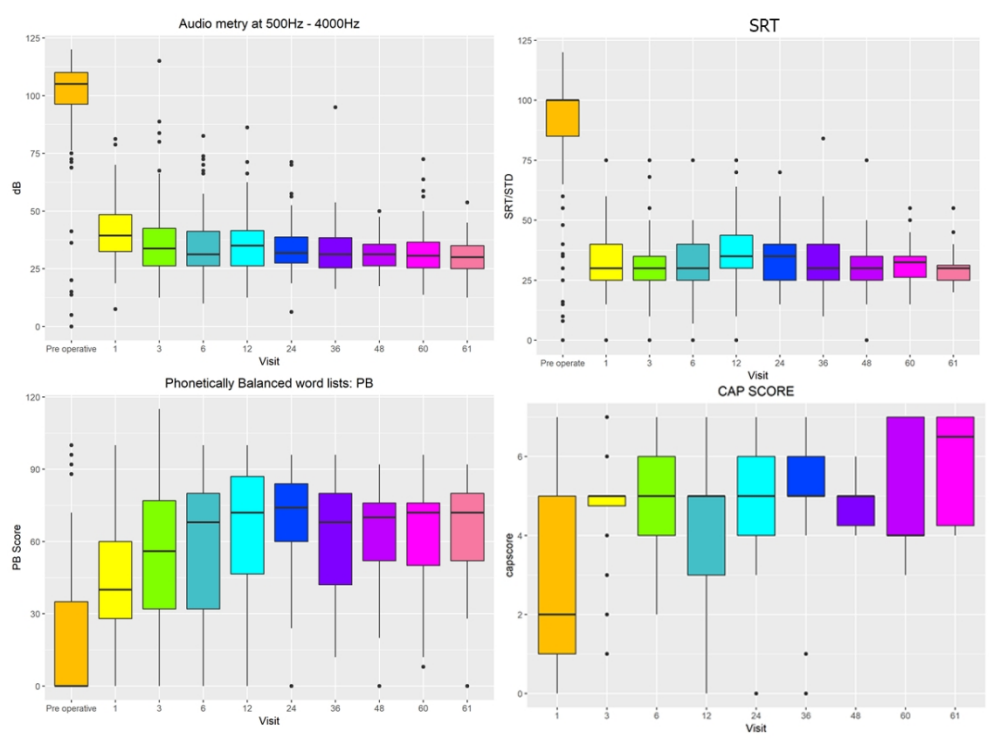
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20 352 **Figure 1.** Post-operative hearing levels.

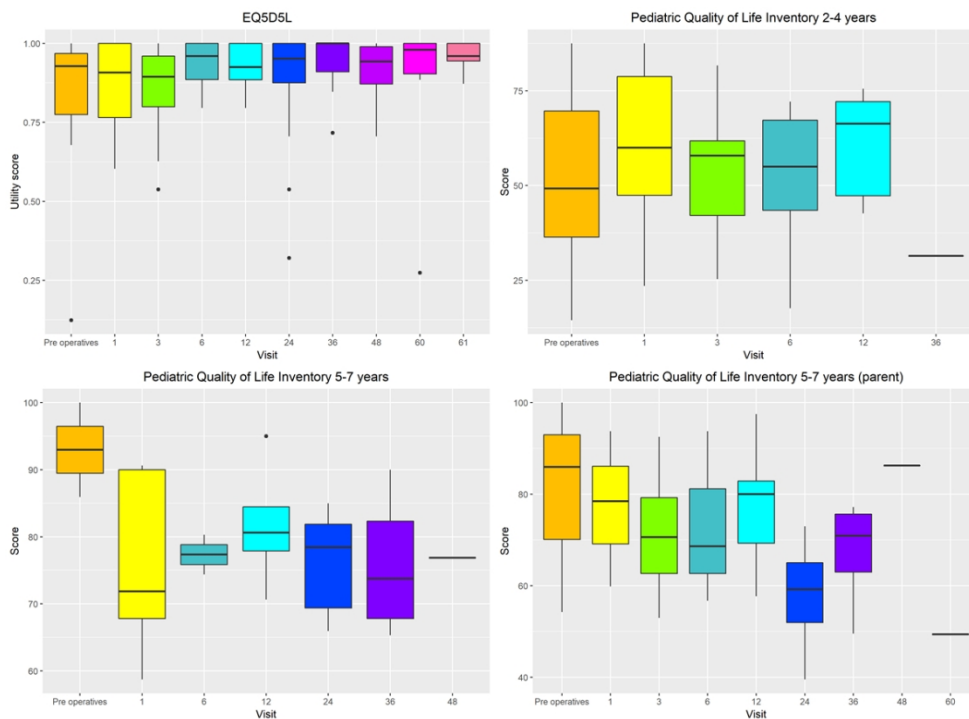
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22 353 **Figure 2.** Quality of life.

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

	Item No	Recommendation	Page No
<b>Title and abstract</b>	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
<b>Introduction</b>			
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
<b>Methods</b>			
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
<b>Results</b>			
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

1	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	7
2			(b) Report category boundaries when continuous variables were categorized	
3			(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	
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9	Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	9
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11	<b>Discussion</b>			
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13	Key results	18	Summarise key results with reference to study objectives	11
14	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
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16	Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	12
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19	Generalisability	21	Discuss the generalisability (external validity) of the study results	11
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21	<b>Other information</b>			
22	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
23				
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\*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>.

# BMJ Open

## 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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**Word count: 3,458**

## **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

## 68 **Strengths and limitations of this study**

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

## 78 **INTRODUCTION**

79  
80 Hearing impairment is a major disability that can affect the quality of life.<sup>1-3</sup>  
81 According to the Department of Empowerment of Persons with Disabilities, 375,680 hearing-  
82 impaired patients were registered with the government in Thailand in 2018.<sup>4</sup>

83 Cochlear implant devices can help patients with severe to profound sensorineural  
84 hearing loss to regain hearing. Speech perception, quality of life, and neurocognitive function  
85 improve after cochlear implantation<sup>5-8</sup>

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

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

1  
2  
3 93 countries. The Thai government needs more evidence before adding a cochlear implant device  
4  
5 94 as a basic medical benefit for all Thai people.

6  
7 95 This nationwide project with support from the Health Systems Research Institute of  
8  
9 96 Thailand was initiated to prospectively collect cochlear implantation outcomes in the Thai  
10  
11 97 population to provide recommendations to the government on cochlear implantation policy.<sup>11</sup>

12  
13  
14 98 This study aimed to evaluate the efficacy of cochlear implantation in terms of  
15  
16 99 audiological outcomes and quality of life in the Thai population.

17  
18  
19 100

## 101 **METHODS**

102

### 103 **Study design and setting**

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

### 111 **Participants**

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

### 114 **Outcomes**

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

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3 117 The baseline characteristics and operation data included the age, sex, onset of hearing  
4  
5 118 loss, type of deafness, cause of hearing loss, intelligence quotient and mental health status  
6  
7 119 evaluated by psychologists, type of hospital, electrode insertion, and insertion technique.  
8  
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10 120

11  
12 121 Auditory performance outcomes  
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14 122 Auditory performance was assessed based on pure tone audiometry, speech  
15  
16 123 recognition threshold (SRT), speech discrimination score (SDS), and categories of auditory  
17  
18 124 performance scores (CAP).  
19

20  
21 125 Pure tone audiometry was performed to determine air-conduction hearing thresholds.  
22  
23 126 Thresholds were tested separately for each ear, octave-by-octave, from 250 to 8000 Hz. A  
24  
25 127 pure tone average (PTA) refers to the average of hearing threshold levels at 500, 1,000, 2,000,  
26  
27 128 and 4,000 Hz.<sup>12</sup>  
28  
29

30  
31 129 The SRT is the minimum hearing level for speech at which an individual can  
32  
33 130 recognize 50% of the speech material. A recognition task is one in which the participant  
34  
35 131 selects the test item from a closed set of choices. The individual should repeat or, in some  
36  
37 132 other manner, indicate recognition of the speech material 50% of the time.<sup>13</sup>  
38  
39

40 133 The SDS was a score of the number of words correctly repeated from phonetically  
41  
42 134 balanced word lists, expressed as a percentage of correct.<sup>14</sup>  
43  
44

45 135 The categories of auditory performance (CAP) scale is a functional performance  
46  
47 136 evaluation that was developed as part of the Nottingham Cochlear Implant Program and as a  
48  
49 137 global assessment of auditory receptive abilities. It is a nonlinear scale on which patients'  
50  
51 138 developing auditory abilities can be rated in eight categories of increasing difficulty from 0 to  
52  
53 139 7 (0: no awareness of environmental sounds; 1: awareness of environmental sounds; 2:  
54  
55 140 response to speech sounds; 3: identification of environmental sounds; 4: discrimination of  
56  
57 141 some speech sounds without lip-reading; 5: understanding common phrases without lip-  
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3 142 reading; 6: understanding conversation without lip-reading; 7: using the telephone with a  
4  
5 143 known speaker).<sup>15 16</sup>  
6

7  
8 144 All auditory performance outcomes were collected at baseline (preoperative) and at 3  
9  
10 145 and 12 months postoperatively.  
11

12 146

13  
14  
15 147 Quality of life outcomes  
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17 148 Quality of life was evaluated using EQ-5D-5L (for patients older than 18 years of  
18  
19 149 age),<sup>17</sup> the Pediatric Quality of Life Inventory - PedsQL (for patients between 2 and 18  
20  
21 150 years),<sup>18</sup> and the health utilities index mark 3 - HUI3 (for patients older than 8 years of age).<sup>19</sup>  
22

23  
24 151 The EQ-5D-5L is a general health status questionnaire with a descriptive system and a  
25  
26 152 visual analog scale (VAS). The descriptive system comprises five dimensions: mobility, self-  
27  
28 153 care, usual activities, pain/discomfort, and anxiety/depression. Each dimension has five  
29  
30 154 levels: no problems, slight problems, moderate problems, severe problems, and extreme  
31  
32 155 problems. The patient is asked to indicate their health state by ticking the box next to the most  
33  
34 156 appropriate statement in each of the five dimensions. The VAS records the patient's self-rated  
35  
36 157 health on a vertical visual analog scale, where the endpoints are labeled "The best health you  
37  
38 158 can imagine" and "The worst health you can imagine." The VAS can be used as a quantitative  
39  
40 159 measure of health outcomes that reflect the patient's own judgment.<sup>17</sup>  
41  
42

43  
44 160 The PedsQL is a general health status questionnaire for children and adolescents. This  
45  
46 161 questionnaire evaluates the four dimensions delineated by the World Health Organization,  
47  
48 162 which are: physical, emotional, social, and school functioning. Each item has five levels:  
49  
50 163 never, almost never, sometimes, often, and almost always. The scores ranged from 0 to 100.<sup>20</sup>  
51  
52

53  
54 164 HUI3 is a generic health-related quality of life for measuring health status, health-  
55  
56 165 related quality of life, and utility scores. Health dimensions include vision, hearing, speech,  
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3 166 ambulation/mobility, pain, dexterity, self-care, emotion, and cognition. Each dimension has  
4  
5 167 five to six levels.<sup>21</sup>  
6

7  
8 168 Quality of life data were collected at 1, 3, and 12 months postoperatively.  
9

## 10 169 **Definitions**

11  
12 170 Deafness was defined as PTA (from four frequencies 0.5, 1, 2, and 4 kHz) or SRT >  
13  
14 171 80 dB HL according to the World Health Organization (WHO) classification or no response  
15  
16 172 to an auditory brainstem response at the maximum intensity of 90 dB HL.<sup>22</sup>  
17  
18

19 173 Implantation success was defined as a PTA or SRT  $\leq$  50 dB and SDS  $\geq$  50% (category  
20  
21 174 B) within 1 year post-operatively according to the American Academy of Otolaryngology-  
22  
23 175 Head and Neck Surgery classification.<sup>23</sup>  
24  
25

## 26 176 **Ethical consideration**

27  
28 177 The research protocol was reviewed and approved by the Central Research Ethics  
29  
30 178 Committee of Thailand (CERT004/59BRm). A registry assistant approached the patients  
31  
32 179 eligible for the investigation. The patients were given a detailed explanation of the study  
33  
34 180 procedures and the possible impacts of the study. Patients who agreed to participate provided  
35  
36 181 written informed consent.  
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40

## 41 182 **Patient and Public Involvement**

42  
43 183 The Health Systems Research Institute of Thailand is a public body financed by the  
44  
45 184 government of Thailand, which has a role in protocol development. Representatives from the  
46  
47 185 National Association of the Deaf in Thailand also provided input for this study.  
48  
49  
50

## 51 186 **Statistical Analysis**

52  
53 187 Statistical analyses were performed using IBM SPSS version 20 and Stata version 14.  
54  
55 188 Data were described as either means (for continuous variables) or frequencies and percentages  
56  
57 189 (for categorical variables). Significant differences between groups were determined using the  
58  
59  
60

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

194

## 195 RESULTS

### 196 Patient's demographics

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

201 **Table 1.** Demographic data.

	<b>N = 458</b>	<b>%</b>
<b>Sex</b>		
- Male	220	48.03
- Female	203	44.32
- No data	35	7.64
<b>Age</b>		
- 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
<b>The onset of hearing loss</b>		
- Pre-lingual hearing loss	41	8.95
- Post-lingual hearing loss	330	72.05
- No data	87	18.20
<b>Type of deafness</b>		
- Bilateral deafness	458	100
- Unilateral deafness	0	0
<b>Causes of hearing loss</b>		
<b>Congenital</b>	<b>N = 241</b>	
- 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
<b>Acquired</b>	<b>N = 181</b>	
- 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

202

### 203 **Audiological outcomes**

204 Preoperatively, the mean PTA, mean SRT, mean SDS, and mean CAP score was  
 205 95.53 dB HL, 86.72 dB HL, 28.82%, and 0.54 points, respectively.

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

211 At 12 months postoperatively, the mean PTA decreased to 31.87 dB HL (MD, 64.23;  
 212 95% CI, 59.81–68.65;  $p < 0.001$ ). The mean SRT also decreased to 34.45 dB HL (MD, 55.96;  
 213 95% CI, 49.50–62.42;  $p < 0.001$ ). The mean SDS increased to 62.24% (MD, -32.47; 95% CI,  
 214 -43.00 – -21.94;  $p < 0.001$ ). The mean CAP score increased to 3.97 points (MD, -3.40; 95%  
 215 CI, -3.88 – -2.92;  $p < 0.001$ ). (Table 2)

216

217 **Table 2.** Audiologic outcomes

	Pre-op	3 months	Mean difference (95% CI)	p-value <sup>a</sup>	Pre-op	12 months	Mean difference (95% CI)	p-value <sup>a</sup>
<b>Pure tone average</b>	(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*
<b>SRT</b>	(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*
<b>Speech discrimination score</b>	(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*
<b>CAP score</b>	(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*

218 a – paired t-test, \* - statistically significance

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

## 222 Quality of life outcomes

223 For EQ-5D-5L, the mean score for the mobility domain (range, 0–5; lower is better)  
224 significantly improved at 12 months compared to the postoperative first month (MD, 0.65;  
225 95% CI, 0.05–1.25; p = 0.037). However, there were no statistically significant differences in  
226 the other domains (p > 0.05).

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

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

235 **Table 3.** Quality of life outcomes

	1 months	3 months	MD (95% CI)	p-value <sup>a</sup>	1 month	12 months	MD (95% CI)	p-value <sup>a</sup>
<b>EQ-5D-5L</b>	(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
<b>PedsQL</b>	(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
<b>HUI3</b>	(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

236 a – paired t-test, \* - statistically significance

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

238

239 **Factors contributing to the success**

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

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

Factors	N/percent success in 1 year	OR	95% CI	p-value
<b>Age</b>				
- 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
<b>Sex</b>				
- Male	103 (53.65%)	1		
- Female	89 (46.35%)	0.77	0.37 to 1.59	0.479
<b>Onset of hearing loss</b>				
- 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
<b>Type of communication</b>				
- 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
<b>Etiology</b>				
- Congenital (n=112)	98 (87.50%)	1		
- Acquired (n=115)	95 (82.61%)	0.68	0.32 to 1.42	0.304
<b>IQ</b>				
- 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
<b>Mental health</b>				
- Normal (n=81)	66 (81.49%)	1		
- Abnormal (n=6)	3 (50.00%)	0.23	0.04 to 1.24	0.087
<b>Type of hospital</b>				
- Tertiary hospital (n=18)	17 (94.44%)	1		
- University hospital (n=212)	178 (83.96%)	0.31	0.04 to 2.39	0.260
<b>Electrode insertion</b>				
- Full (n = 214)	183 (85.51%)	1		
- Partial (n=15)	11 (73.33%)	0.47	0.14 to 1.56	0.214
<b>Insertion technique</b>				
- Cochleostomy (n=158)	130 (82.28%)	1		
- Round window (n=69)	62 (89.86%)	1.91	0.79 to 4.61	0.151

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

247

## 248 Complications

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

252 **Table 5.** Complications

<b>Immediate complications</b>	<b>N = 407</b>	<b>%</b>
- 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
<b>Delayed complications</b>	<b>N = 465</b>	<b>%</b>
- Meningitis	9	1.93
- Electrodes dislodge	9	1.93
- Implant migration/extrusion	8	1.72
- Device failure	7	1.51
- Others	19	4.09

254 **DISCUSSION**

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

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

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

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3 268 1. Deafness was defined as PTA (from four frequencies 0.5, 1, 2, and 4 kHz) or SRT  
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5 269 > 80 dB HL according to the WHO classification or no response to an auditory  
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7 270 brainstem response at the maximum intensity of 90 dB HL.  
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10 271 2. No or little benefit from hearing aids and  
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12 272 3. SDS < 50% and  
13  
14 273 4. The onset of deafness should not be > 10 years.

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17 274 Our previous study collected data from 226 patients with cochlear implantation. We  
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19 275 found that the audiological outcomes, including PTA, SRT, and SDS, were significantly  
20  
21 276 improved compared to the preoperative period ( $p = 0.001$ ,  $p < 0.001$ , and  $p < 0.001$ ,  
22  
23 277 respectively). However, the quality of life data did not significantly improve.<sup>27</sup>

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25  
26 278 To the best of our knowledge, this is the first project with government support to  
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28 279 evaluate the outcomes of cochlear implantation at the national level. We prospectively  
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30 280 collected data from patients who underwent cochlear implant surgery in Thailand for 10  
31  
32 281 years.

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34  
35 282 In this study, we found that audiological outcomes, including PTA, SRT, and SDS,  
36  
37 283 were significantly improved ( $p < 0.001$ ,  $p < 0.001$ , and  $p < 0.001$ , respectively). The quality  
38  
39 284 of life, including mobility, hearing, and speech domains, was significantly improved ( $p =$   
40  
41 285  $0.037$ ,  $p = 0.006$ , and  $p = 0.031$ , respectively).

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43  
44 286 We also tried to identify factors leading to the success of cochlear implantation in our  
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46 287 setting; however, no factor significantly impacted the success ( $p > 0.05$ ).

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48  
49 288 This study had limitations owing to the nature of the cohort study. Approximately  
50  
51 289 10% of data were missing for most variables. This study was designed to follow up patients  
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53 290 for five years. However, the number of patients reporting for follow-up after 1 year declined  
54  
55 291 sharply. Therefore, we limited the analysis of outcomes to 1 year after cochlear implantation.

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3 292 The results of this study showed the excellent audiological outcomes and  
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5 293 improvement of the quality of life in mobility, hearing, and speech domains in patients who  
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7 294 underwent cochlear implantation in Thailand. Future studies should investigate the long-term  
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10 295 hearing outcomes using standardized quality of life questionnaire for patients with cochlear  
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12 296 implantation.

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## 17 298 **CONCLUSION**

20 299 Excellent audiological outcomes and improvement in the quality of life in the  
21  
22  
23 300 mobility, hearing, and speech domains were observed in patients who underwent cochlear  
24  
25 301 implantation in Thailand.

26  
27 302

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49 312

### 52 313 **Competing interests**

53  
54 314 The authors declare that they have no competing interests.

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### 58 316 **Author contributions**

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3 317 P.P. conceptualized, designed, and supervised the study; performed data analysis;  
4  
5 318 interpreted the results; and drafted the manuscript. N.T., S.K., S.K., K.T., V.A., P.T., C.W.,  
6  
7 319 T.M., and P.I. contributed to data collection. K.Y. contributed to the study design, data  
8  
9 320 collection, and supervision of the study. All authors contributed to the interpretation and  
10  
11 321 discussion of the results and read and approved the final manuscript.  
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### 16 17 323 **Data sharing statement**

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19 324 Data are available upon request. Individual de-identified data will be available on  
20  
21 325 reasonable request. Extra data is available by emailing kwayim@kku.ac.th.  
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### 25 26 327 **Ethics approval and consent to participate**

27  
28 328 This study was approved by the Central Research Ethics Committee of Thailand  
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30 329 (CERT004/59BRm). Written informed consent to participate in this study was provided by all  
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32 330 patients enrolled.  
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405

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

	Item No	Recommendation	Page No
<b>Title and abstract</b>	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
<b>Introduction</b>			
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
<b>Methods</b>			
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
<b>Results</b>			
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

1	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	7
2			(b) Report category boundaries when continuous variables were categorized	
3			(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	
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9	Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	9
10				
11	<b>Discussion</b>			
12				
13	Key results	18	Summarise key results with reference to study objectives	11
14	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
15				
16	Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	12
17				
18				
19	Generalisability	21	Discuss the generalisability (external validity) of the study results	11
20				
21	<b>Other information</b>			
22	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
23				
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25  
26 \*Give information separately for exposed and unexposed groups.

27  
28 **Note:** An Explanation and Elaboration article discusses each checklist item and gives methodological background and  
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31 <http://www.annals.org/>, and Epidemiology at <http://www.epidem.com/>). Information on the STROBE Initiative is  
32 available at <http://www.strobe-statement.org>.  
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# BMJ Open

## 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  $2.96 \pm 5.83$  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



## 68 **Strengths and limitations of this study**

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

74

## 75 **INTRODUCTION**

76

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

80 Cochlear implant devices can help patients with severe to profound sensorineural  
81 hearing loss to regain hearing. Speech perception, quality of life, and neurocognitive function  
82 improve after cochlear implantation.<sup>5-7</sup>

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

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

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2  
3 92 This nationwide project with support from the Health Systems Research Institute of  
4  
5 93 Thailand was initiated to prospectively collect cochlear implantation outcomes in the Thai  
6  
7 94 population to provide recommendations to the government on cochlear implantation policy.<sup>10</sup>  
8  
9

10 95 This study aimed to evaluate the efficacy of cochlear implantation in terms of  
11  
12 96 audiological outcomes and quality of life in the Thai population.  
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## 17 98 **METHODS**

### 19 99 **Study design and setting**

20 100  
21  
22 101 All government and university hospitals in Thailand that were equipped to perform  
23  
24 102 cochlear implant surgery were involved. A total of eight university hospitals (Srinagrind  
25  
26 103 Hospital, King Chulalongkorn Memorial Hospital, Ramathibodi Hospital, Songklanagarind  
27  
28 104 Hospital, Siriraj Hospital, Maharaj Nakorn Chiangmai Hospital, Phramongkutklao Hospital,  
29  
30 105 and HRH Princess Maha Chakri Sirindhorn Medical Center) and three tertiary hospitals (King  
31  
32 106 Bhumibol Adulyadej Hospital, Rajavithi Hospital, and Trang Hospital) participated in this  
33  
34 107 study. These were the major hospitals that performed cochlear implant surgery in Thailand.  
35  
36  
37

### 38 108 **Participants**

39  
40 109 We included all patients who underwent cochlear implantation at a network hospital  
41  
42 110 between July 2016 and April 2020. There were no exclusion criteria.  
43  
44

### 45 111 **Outcomes**

46  
47 112 We collected baseline characteristics, operation data, complications, auditory  
48  
49 113 performance, and quality of life data.  
50

51  
52 114 The baseline characteristics and operation data included the age, sex, onset of hearing  
53  
54 115 loss, type of deafness, cause of hearing loss, intelligence quotient using Wechsler Intelligence  
55  
56 116 Scales<sup>11</sup> and mental health status evaluated by psychologists (normal or abnormal), type of  
57  
58 117 hospital, electrode insertion depth, and insertion technique.  
59  
60

118

119 Auditory performance outcomes

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

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

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

133 The SDS was a score of the number of words correctly repeated from phonetically  
134 balanced word lists, expressed as a percentage of correct.<sup>15</sup>

135 The categories of auditory performance (CAP) scale is a functional performance  
136 evaluation that was developed as part of the Nottingham Cochlear Implant Program and as a  
137 global assessment of auditory receptive abilities. It is a nonlinear scale on which patients'  
138 developing auditory abilities can be rated in eight categories of increasing difficulty from 0 to  
139 7 (0: no awareness of environmental sounds; 1: awareness of environmental sounds; 2:  
140 response to speech sounds; 3: identification of environmental sounds; 4: discrimination of  
141 some speech sounds without lip-reading; 5: understanding common phrases without lip-

1  
2  
3 142 reading; 6: understanding conversation without lip-reading; 7: using the telephone with a  
4  
5 143 known speaker).<sup>16 17</sup>  
6

7  
8 144 All auditory performance outcomes were collected at baseline (preoperative) and at 3  
9  
10 145 and 12 months postoperatively. The preoperative auditory performance was unaided  
11  
12 146 assessment (without hearing aids) while postoperative evaluation was aided assessment  
13  
14 147 (cochlear implant device turn on).  
15  
16

17 148

### 19 149 Quality of life outcomes

20  
21 150 Quality of life was evaluated using EQ-5D-5L (for patients older than 18 years of  
22  
23 151 age),<sup>18</sup> the Pediatric Quality of Life Inventory - PedsQL (for patients between 2 and 18  
24  
25 152 years),<sup>19</sup> and the health utilities index mark 3 - HUI3 (for patients older than 8 years of age).<sup>20</sup>  
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27

28 153 The EQ-5D-5L is a general health status questionnaire with a descriptive system and a  
29  
30 154 visual analog scale (VAS). The descriptive system comprises five dimensions: mobility, self-  
31  
32 155 care, usual activities, pain/discomfort, and anxiety/depression. Each dimension has five  
33  
34 156 levels: no problems, slight problems, moderate problems, severe problems, and extreme  
35  
36 157 problems. The patient is asked to indicate their health state by ticking the box next to the most  
37  
38 158 appropriate statement in each of the five dimensions. The VAS records the patient's self-rated  
39  
40 159 health on a vertical visual analog scale, where the endpoints are labeled "The best health you  
41  
42 160 can imagine" and "The worst health you can imagine." The VAS can be used as a quantitative  
43  
44 161 measure of health outcomes that reflect the patient's own judgment.<sup>18</sup>  
45  
46  
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48

49 162 The PedsQL is a general health status questionnaire for children and adolescents. This  
50  
51 163 questionnaire evaluates the four dimensions delineated by the World Health Organization,  
52  
53 164 which are: physical, emotional, social, and school functioning. Each item has five levels:  
54  
55 165 never, almost never, sometimes, often, and almost always. The scores ranged from 0 to 100.<sup>21</sup>  
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3 166 HUI3 is a generic health-related quality of life for measuring health status, health-  
4  
5 167 related quality of life, and utility scores. Health dimensions include vision, hearing, speech,  
6  
7 168 ambulation/mobility, pain, dexterity, self-care, emotion, and cognition. Each dimension has  
8  
9 169 five to six levels.<sup>22</sup>

10  
11  
12 170 Quality of life data were collected at 1, 3, and 12 months postoperatively. In children  
13  
14 171 aged less than 5-year-old, the input on the quality of life was derived from their parents or  
15  
16 172 caregivers.

### 17 173 **Definitions**

18  
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20  
21 174 Deafness was defined as PTA (from four frequencies 0.5, 1, 2, and 4 kHz) or SRT >  
22  
23 175 80 dB HL according to the World Health Organization (WHO) classification or no response  
24  
25 176 to an auditory brainstem response at the maximum intensity of 90 dB HL.<sup>23</sup>

26  
27  
28 177 Implantation success was defined as a PTA or SRT  $\leq$  50 dB and SDS  $\geq$  50% (category  
29  
30 178 B) within 1 year post-operatively according to the American Academy of Otolaryngology-  
31  
32 179 Head and Neck Surgery classification.<sup>24</sup>

### 33 180 **Ethical consideration**

34  
35  
36  
37 181 The research protocol was reviewed and approved by the Central Research Ethics  
38  
39 182 Committee of Thailand (CERT004/59BRm). A registry assistant approached the patients  
40  
41 183 eligible for the investigation. The patients were given a detailed explanation of the study  
42  
43 184 procedures and the possible impacts of the study. Patients who agreed to participate provided  
44  
45 185 written informed consent.

### 46 186 **Patient and Public Involvement**

47  
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50  
51 187 The Health Systems Research Institute of Thailand is a public body financed by the  
52  
53 188 government of Thailand, which has a role in protocol development. Representatives from the  
54  
55 189 National Association of the Deaf in Thailand also provided input for this study.

### 56 190 **Statistical Analysis**

1  
2  
3 191 Statistical analyses were performed using IBM SPSS version 20 and Stata version 14.  
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5  
6 192 Data were described as either means (for continuous variables) or frequencies and percentages  
7  
8 193 (for categorical variables). Significant differences between groups were determined using the  
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10  
11 194 Student's t-test, paired sample t-test, or Mann–Whitney U test for continuous variables. The  
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13  
14 195 chi-square test or Fisher's exact test was used to determine whether there was a significant  
15  
16  
17 196 difference between the expected and observed frequencies. The factor of success is presented  
18  
19  
20 197 as an odds ratio. For all tests, statistical significance was set at  $p < 0.05$ .  
21  
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23 198

## 25 199 **RESULTS**

### 28 200 **Patient's demographics**

30 201 There were 458 patients in this study, of whom, 220 were male and 203 were female.  
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32  
33 202 Nearly half of the patients were children and adolescents (46.94%). The common causes of  
34  
35 203 congenital and acquired hearing disabilities were idiopathic (51.87% and 34.02%,  
36  
37  
38 204 respectively). (Table 1)

39  
40 205 **Table 1.** Demographic data.

	<b>N = 458</b>	<b>%</b>
<b>Sex</b>		
- Male	220	48.03
- Female	203	44.32
- No data	35	7.64
<b>Age</b>		
- 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
<b>The onset of hearing loss</b>		
- Pre-lingual hearing loss	41	8.95
- Post-lingual hearing loss	330	72.05

- No data	87	18.20
<b>Type of deafness</b>		
- Bilateral deafness	458	100
- Unilateral deafness	0	0
<b>Causes of hearing loss</b>		
<b>Congenital</b>		
<b>N = 241</b>		
- 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
<b>Acquired</b>		
<b>N = 181</b>		
- 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

206

### 207 **Audiological outcomes**

208 Preoperatively, the mean PTA, mean SRT, mean SDS, and mean CAP score was  
 209 95.53 dB HL, 86.72 dB HL, 28.82%, and 0.54 points, respectively. At three months  
 210 postoperatively, the mean PTA, mean SRT, mean SDS, and mean CAP score was 34.14 dB  
 211 HL, 37.47 dB HL, 47.33% and 2.62 points respectively. At 12 months postoperatively, the  
 212 mean PTA, mean SRT, mean SDS, and mean CAP score was 31.87 dB HL, 34.45 dB HL,  
 213 62.24% and 3.97 points respectively.

214 All audiological outcomes were significantly improved from baseline at 3 months ( $p <$   
 215  $0.001$ ) and 12 months post operation ( $p < 0.001$ ). (Table 2)

216

217

218 **Table 2.** Audiological outcomes

	Pre-op	3 months	Mean difference (95% CI)	p-value <sup>a</sup>	Pre-op	12 months	Mean difference (95% CI)	p-value <sup>a</sup>
<b>Pure tone average</b>	(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*
<b>SRT</b>	(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*
<b>Speech discrimination score</b>	(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*
<b>CAP score</b>	(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*

219 a – paired t-test, \* - statistically significance

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

### 223 Quality of life outcomes

224 For EQ-5D-5L, the mean score for the mobility domain (range, 0–5; lower is better)  
225 significantly improved at 12 months compared to the postoperative first month (MD, 0.65;  
226 95% CI, 0.05–1.25; p = 0.037). However, there were no statistically significant differences in  
227 the other domains (p > 0.05).

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

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



236 **Table 3.** Quality of life outcomes

	1 months	3 months	MD (95% CI)	p-value <sup>a</sup>	1 month	12 months	MD (95% CI)	p-value <sup>a</sup>
<b>EQ-5D-5L</b>	(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
<b>PedsQL</b>	(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
<b>HUI3</b>	(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

237 a – paired t-test, \* - statistically significance

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

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240 **Factors contributing to the success**

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

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247

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

Factors	N/percent success in 1 year	OR	95% CI	p-value
<b>Age</b>				
- 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
<b>Sex</b>				
- Male	103 (53.65%)	1		
- Female	89 (46.35%)	0.77	0.37 to 1.59	0.479
<b>Onset of hearing loss</b>				
- 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
<b>Type of communication</b>				
- 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
<b>Etiology</b>				
- Congenital (n=112)	98 (87.50%)	1		
- Acquired (n=115)	95 (82.61%)	0.68	0.32 to 1.42	0.304
<b>IQ</b>				
- 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
<b>Mental health</b>				
- Normal (n=81)	66 (81.49%)	1		
- Abnormal (n=6)	3 (50.00%)	0.23	0.04 to 1.24	0.087
<b>Type of hospital</b>				
- Tertiary hospital (n=18)	17 (94.44%)	1		
- University hospital (n=212)	178 (83.96%)	0.31	0.04 to 2.39	0.260
<b>Electrode insertion</b>				
- Full (n = 214)	183 (85.51%)	1		
- Partial (n=15)	11 (73.33%)	0.47	0.14 to 1.56	0.214
<b>Insertion technique</b>				
- Cochleostomy (n=158)	130 (82.28%)	1		
- Round window (n=69)	62 (89.86%)	1.91	0.79 to 4.61	0.151

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

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## 253 **Complications**

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

257 **Table 5.** Complications

<b>Immediate complications</b>	<b>N = 407</b>	<b>%</b>
- 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
<b>Delayed complications</b>	<b>N = 465</b>	<b>%</b>
- Meningitis	9	1.93
- Electrodes dislodge	9	1.93
- Implant migration/extrusion	8	1.72
- Device failure	7	1.51
- Others	19	4.09

## 259 **DISCUSSION**

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

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

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2  
3 269 author concluded that there is a need for a standardized quality of life assessment tool for  
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5 270 patients with cochlear implantation.<sup>27</sup>

7 271 There are no standard cochlear implantation criteria in Thailand. The common criteria  
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10 272 used in most institutes were:

- 12 273 1. Deafness was defined as PTA (from four frequencies 0.5, 1, 2, and 4 kHz) or SRT  
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14 274 > 80 dB HL according to the WHO classification or no response to an auditory  
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17 275 brainstem response at the maximum intensity of 90 dB HL.
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19 276 2. No or little benefit from hearing aids and
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21 277 3. SDS < 50% and
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24 278 4. The onset of deafness should not be > 10 years.

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26 279 Our previous study collected data from 226 patients with cochlear implantation. We  
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28 280 found that the audiological outcomes, including PTA, SRT, and SDS, were significantly  
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30 281 improved compared to the preoperative period ( $p = 0.001$ ,  $p < 0.001$ , and  $p < 0.001$ ,  
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32 282 respectively). However, the quality of life data did not significantly improve.<sup>28</sup>

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35 283 To the best of our knowledge, this is the first project with government support to  
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37 284 evaluate the outcomes of cochlear implantation at the national level. We prospectively  
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39 285 collected data from patients who underwent cochlear implant surgery in Thailand.

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42 286 In this study, we found that audiological outcomes, including PTA, SRT, and SDS,  
43  
44 287 were significantly improved ( $p < 0.001$ ,  $p < 0.001$ , and  $p < 0.001$ , respectively). The quality  
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46 288 of life, including mobility, hearing, and speech domains, was significantly improved ( $p =$   
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48 289  $0.037$ ,  $p = 0.006$ , and  $p = 0.031$ , respectively).

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51 290 We also tried to identify factors leading to the success of cochlear implantation in our  
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53 291 setting; however, no factor significantly impacted the success ( $p > 0.05$ ).

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56 292 This study had limitations owing to the nature of the cohort study. Approximately  
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58 293 10% of data were missing for most variables. This study was designed to follow up patients  
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3 294 for five years. However, the number of patients reporting for follow-up after 1 year declined  
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5 295 sharply. Therefore, we limited the analysis of outcomes to 1 year after cochlear implantation.  
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8 296 The results of this study showed the excellent audiological outcomes and  
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10 297 improvement of the quality of life in mobility, hearing, and speech domains in patients who  
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12 298 underwent cochlear implantation in Thailand. Future studies should investigate the long-term  
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14 299 hearing outcomes using standardized quality of life questionnaire for patients with cochlear  
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16 300 implantation.  
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## 20 21 22 302 **CONCLUSION**

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25 303 Excellent audiological outcomes and improvement in the quality of life in the  
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27 304 mobility, hearing, and speech domains were observed in patients who underwent cochlear  
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29 305 implantation in Thailand.  
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32 306

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35  
36  
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40  
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44 311

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### 56 57 317 **Competing interests**

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3 318 The authors declare that they have no competing interests.  
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8 320 **Author contributions**

9  
10 321 P.P. conceptualized, designed, and supervised the study; performed data analysis;  
11  
12 322 interpreted the results; and drafted the manuscript. N.T., S.K., S.K., K.T., V.A., P.T., C.W.,  
13  
14 323 T.M., and P.I. contributed to data collection. K.Y. contributed to the study design, data  
15  
16 324 collection, and supervision of the study. All authors contributed to the interpretation and  
17  
18 325 discussion of the results and read and approved the final manuscript.  
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24 327 **Data sharing statement**

25  
26 328 Data are available upon request. Individual de-identified data will be available on  
27  
28 329 reasonable request. Extra data is available by emailing [kwayim@kku.ac.th](mailto:kwayim@kku.ac.th).  
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32  
33 331 **Ethics approval and consent to participate**

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35 332 This study was approved by the Central Research Ethics Committee of Thailand  
36  
37 333 (CERT004/59BRm). Written informed consent to participate in this study was provided by all  
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39 334 patients enrolled.  
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For peer review only



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

	Item No	Recommendation	Page No
<b>Title and abstract</b>	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
<b>Introduction</b>			
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
<b>Methods</b>			
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
<b>Results</b>			
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

1	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	7
2			(b) Report category boundaries when continuous variables were categorized	
3			(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	
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9	Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	9
10				
11	<b>Discussion</b>			
12				
13	Key results	18	Summarise key results with reference to study objectives	11
14	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
15				
16	Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	12
17				
18				
19	Generalisability	21	Discuss the generalisability (external validity) of the study results	11
20				
21	<b>Other information</b>			
22	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
23				
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26 \*Give information separately for exposed and unexposed groups.

27  
28 **Note:** An Explanation and Elaboration article discusses each checklist item and gives methodological background and  
29 published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely  
30 available on the Web sites of PLoS Medicine at <http://www.plosmedicine.org/>, Annals of Internal Medicine at  
31 <http://www.annals.org/>, and Epidemiology at <http://www.epidem.com/>). Information on the STROBE Initiative is  
32 available at <http://www.strobe-statement.org>.  
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