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Multicentre cohort study of cochlear implantation outcomes in Thailand

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BMJ Open Multicentre cohort study of cochlear implantation outcomes in Thailand

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ABSTRACT

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

Design Cohort study.

Setting Tertiary care and university hospitals.

Participants Patients who underwent cochlear implant surgery in Thailand.

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

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

Results This study included 458 patients, and nearly half of the patients were children and adolescents (46.94%). The mean age of the patients was 2.96±5.83 years. At 1 year postoperatively, the mean pure tone average of the hearing threshold in the implanted ear significantly improved from unaided preoperative baseline (mean difference (MD) 64.23 dB HL; 95% CI 59.81 to 68.65; p<0.001). The mean speech recognition threshold also improved (MD 55.96 dB HL; 95% CI 49.50 to 62.42, 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 to 1.25; p=0.037), hearing (range, 0–6; MD 0.96; 95% CI 0.30 to 1.61; p=0.006) and speech (range, 0–5; MD 0.44; 95% CI 0.04 to 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.

INTRODUCTION

Hearing impairment is a major disability that can affect the quality of life.^{1–3} According to the Department of Empowerment of Persons with Disabilities, 375 680 hearing-impaired patients were registered with the government in Thailand in 2018.⁴

Cochlear implant devices can help patients with severe to profound sensorineural hearing loss to regain hearing. Speech perception,

Strengths and limitations of this study

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

quality of life and neurocognitive function improve after cochlear implantation.^{5–7}

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

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

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

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



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Table 1 Demographic data

	N=458	%
Sex		
Male	220	48.03
Female	203	44.32
No data	35	7.64
Age		
Infants and toddlers (<4 years)	44	9.61
Preschool children (4–7 years)	79	17.25
Early school children (8–12 years)	52	11.35
Adolescents (13–18 years)	40	8.73
Adults (>18 years)	211	46.07
No data	32	6.99
The onset of hearing loss		
Prelingual hearing loss	210	45.85
Postlingual hearing loss	152	33.19
No data	96	20.96
Type of deafness		
Bilateral deafness	458	100
Unilateral deafness	0	0
Causes of hearing loss		
Congenital N=241		
Idiopathic	125	51.87
Inner ear anomalies	12	4.98
Genetic disorder	7	2.90
Intrauterine infection	5	2.07
Birth asphyxia	4	1.66
Ototoxicity	1	0.41
Others	5	2.07
No data	82	34.02
Acquired N=181		
Idiopathic	67	37.02
Post meningitis	63	34.81
Chronic otitis media or cholesteatoma	10	5.52
Sepsis	4	2.21
Ototoxicity	3	1.66
Trauma	3	1.66
Head injury	3	1.66
Noise-induced or noise trauma	2	1.10
Autoimmune hearing loss	1	0.55
Others	19	10.50
No data	6	3.31

METHODS

Study design and setting

All government and university hospitals in Thailand that were equipped to perform cochlear implant surgery were involved. A total of eight university hospitals (Srinagrind

Hospital, King Chulalongkorn Memorial Hospital, Ramathibodi Hospital, Songklanagarind Hospital, Siriraj Hospital, Maharaj Nakorn Chiangmai Hospital, Phramongkutklao Hospital and HRH Princess Maha Chakri Sirindhorn Medical Center) and three tertiary hospitals (King Bhumibol Adulyadej Hospital, Rajavithi Hospital and Trang Hospital) participated in this study. These were the major hospitals that performed cochlear implant surgery in Thailand.

Participants

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

Outcomes

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

The baseline characteristics and operation data included the age, sex, onset of hearing loss, type of deafness, cause of hearing loss, IQ using Wechsler Intelligence Scales¹¹ and mental health status evaluated by psychologists (normal or abnormal), type of hospital, electrode insertion depth and insertion technique.

Auditory performance outcomes

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

Pure tone audiometry was performed to determine air-conduction hearing thresholds. Thresholds were tested separately for each ear, octave-by-octave, from 250 to 8000 Hz. A pure tone average (PTA) refers to the average of hearing threshold levels at 500, 1000, 2000 and 4000 Hz.¹²

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

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

The CAP scale is a functional performance evaluation that was developed as part of the Nottingham Cochlear Implant Programme and as a global assessment of auditory receptive abilities. It is a nonlinear scale on which patients' developing auditory abilities can be rated in eight categories of increasing difficulty from 0 to 7 (0: no awareness of environmental sounds; (1) awareness of environmental sounds; (2) response to speech sounds; (3) identification of environmental sounds; (4) discrimination of some

Table 2 Audiological outcomes

	Preoperative			Mean difference (95% CI)		Postoperative			Mean difference (95% CI)		P value†
	(n)	Mean	SD	3 months (n)	12 months (n)	Preoperative (n)	Mean	SD	12 months (n)	P value†	
Pure tone average	(n=144)	95.53±20.68		(n=144)	(n=101)	(n=101)	64.23	59.81	(n=101)	64.23 (59.81 to 68.65)	<0.001*
Better ear	(n=58)	86.72±24.11		(n=58)	(n=53)	(n=53)	55.96	49.50	(n=53)	55.96 (49.50 to 62.42)	<0.001*
SRT	(n=39)	28.82±34.83		(n=39)	(n=34)	(n=34)	-32.47	-43.00	(n=34)	-32.47 (-43.00 to -21.94)	<0.001*
Speech discrimination score	(n=147)	0.54±1.03		(n=147)	(n=118)	(n=118)	-3.40	-3.88	(n=118)	-3.40 (-3.88 to -2.92)	<0.001*
Better ear	(n=147)	28.82±34.83		(n=147)	(n=118)	(n=118)	-3.40	-3.88	(n=118)	-3.40 (-3.88 to -2.92)	<0.001*
CAP score	(n=147)	0.54±1.03		(n=147)	(n=118)	(n=118)	-3.40	-3.88	(n=118)	-3.40 (-3.88 to -2.92)	<0.001*

*Statistically significance.

†paired t-test.

CAP, categories of auditory performance; ; SRT, speech recognition threshold.

speech sounds without lip-reading; (5) understanding common phrases without lip-reading; (6) understanding conversation without lip-reading and (7) using the telephone with a known speaker).^{16 17}

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

Quality of life outcomes

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

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

The PedsQL (Pediatric Quality of Life Inventory™) is a general health status questionnaire for children and adolescents. This questionnaire evaluates the four dimensions delineated by WHO, which are: physical, emotional, social and school functioning. Each item has five levels: never, almost never, sometimes, often and almost always. The scores ranged from 0 to 100.²¹

HUI3 (Health Utility Index Mark 3) is a generic health-related quality of life for measuring health status, health-related quality of life and utility scores. Health dimensions include vision, hearing, speech, ambulation/mobility, pain, dexterity, self-care, emotion and cognition. Each dimension has 5–6 levels.²²

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

Definitions

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

Implantation success was defined as a PTA or SRT ≤50 dB and SDS ≥50% (category B) within 1 year postoperatively

Table 3 Quality of life outcomes

	1 month (n=20)	3 months (n=20)	MD (95% CI)	P value†	1 month (n=17)	12 months (n=17)	MD (95% CI)	P value†
EQ-5D-5L								
Mobility	1.8±0.95	1.65±0.95	0.15 (-0.23 to 0.53)	0.419	1.94±1.09	1.29±0.59	0.65 (0.05 to 1.25)	0.037*
Self-care	1.2±0.70	1.15±0.67	0.05 (-0.05 to 0.15)	0.330	1.47±1.01	1.12±0.33	0.24 (-0.16 to 0.87)	0.164
Usual activities	1.55±0.89	1.45±0.83	0.1 (-0.20 to 0.40)	0.494	1.59±0.71	1.47±0.72	0.12 (-0.05 to 0.29)	0.164
Pain/discomfort	1.55±0.69	1.55±0.60	0 (-0.34 to 0.34)	0.999	1.71±1.35	1.47±0.51	0.24 (-0.05 to 0.52)	0.104
Anxiety/depression	1.6±0.88	1.65±0.99	-0.05 (-0.37 to 0.27)	0.748	1.53±0.62	1.18±0.39	0.35 (-0.01 to 0.71)	0.055
VAS (0–100)	84.44±14.44	84.78±12.24	-0.33 (-3.80 to 3.13)	0.841	85.67±14.74	89.33±8.21	-3.67 (-9.44 to 2.11)	0.195
PedsQL								
Physical functioning	74.59±23.67	77.58±19.32	-2.99 (-14.53 to 8.55)	0.597	78.91±23.49	87.11±14.70	-8.20 (-26.41 to 10.00)	0.322
Emotional functioning	56.96±18.63	52.83±18.76	4.13 (-6.23 to 14.49)	0.417	55.63±28.09	56.88±29.39	-1.25 (-21.58 to 19.08)	0.889
Social functioning	50.22±22.94	51.09±19.07	-0.87 (-10.62 to 8.88)	0.855	56.25±25.88	63.13±25.20	-6.88 (-20.64 to 6.89)	0.276
School functioning	50.94±32.08	57.46±34.13	-6.52 (-18.78 to 5.74)	0.282	65±32.74	51.67±24.93	13.33 (-5.35 to 32.01)	0.135
HUI3								
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

*Statistically significance.

†paired t-test.

EQ-5D-5L, the EuroQol Research Foundation 5-level EQ-5D version; HUI3, Health Utility Index Mark 3; MD, mean difference; PedsQL, Pediatric Quality of Life Inventory; VAS, Visual Analogue Scale.

Table 4 The factors contributing to the success of the implantation

Factors	N/per cent success in 1 year	OR	95% CI	P value
Age				
Infants and toddlers (<4 years) (n=9)	8 (88.89)	1		
Pre-school children (4–7 years) (n=28)	25 (89.29)	1.04	0.09 to 11.47	0.973
Early school children (8–12 years) (n=27)	23 (85.19)	0.72	0.07 to 7.42	0.782
Adolescents (13–18 years) (n=23)	22 (95.65)	2.75	0.15 to 49.36	0.492
Adults (>18 years) (n=138)	114 (82.61)	0.59	0.07 to 4.97	0.631
Sex				
Male (n=119)	103 (86.55)	1		
Female (n=107)	89 (83.18)	0.77	0.37 to 1.59	0.479
Onset of hearing loss				
Prelingual hearing loss (n=112)	98 (87.50)	1		
Postlingual hearing loss (n=118)	97 (82.20)	0.66	0.32 to 1.37	0.266
Type of communication				
Oral (n=122)	108 (88.52)	1		
Sign language (n=21)	18 (85.71)	0.78	0.20 to 2.98	0.714
Combined (n=77)	61 (79.22)	0.49	0.23 to 1.08	0.078
Aetiology				
Congenital (n=112)	98 (87.50)	1		
Acquired (n=115)	95 (82.61)	0.68	0.32 to 1.42	0.304
IQ				
Above low Average (n=62)	51 (82.26)	1		
Borderline or extremely low (n=36)	33 (91.67)	2.37	0.62 to 9.15	0.210
Mental health				
Normal (n=81)	66 (81.49)	1		
Abnormal (n=6)	3 (50.00)	0.23	0.04 to 1.24	0.087
Type of hospital				
Tertiary hospital (n=18)	17 (94.44)	1		
University hospital (n=212)	178 (83.96)	0.31	0.04 to 2.39	0.260
Electrode insertion				
Full (n=214)	183 (85.51)	1		
Partial (n=15)	11 (73.33)	0.47	0.14 to 1.56	0.214
Insertion technique				
Cochleostomy (n=158)	130 (82.28)	1		
Round window (n=69)	62 (89.86)	1.91	0.79 to 4.61	0.151

according to the American Academy of Otolaryngology-Head and Neck Surgery classification.²⁴

Patient and public involvement

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

Statistical analysis

Statistical analyses were performed using IBM SPSS V.20 and Stata V.14. Data were described as either means

(for continuous variables) or frequencies and percentages (for categorical variables). Significant differences between groups were determined using the Student's t-test, paired sample t-test, or Mann-Whitney U test for continuous variables. The χ^2 test or Fisher's exact test was used to determine whether there was a significant difference between the expected and observed frequencies. The factor of success is presented as an OR. For all tests, statistical significance was set at $p < 0.05$.

**Table 5** Complications

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

RESULTS

Patient's demographics

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

Audiological outcomes

Preoperatively, the mean PTA, mean SRT, mean SDS and mean CAP score was 95.53 dB HL, 86.72 dB HL, 28.82% and 0.54 points, respectively. At 3 months postoperatively, the mean PTA, mean SRT, mean SDS and mean CAP score was 34.14 dB HL, 37.47 dB HL, 47.33% and 2.62 points, respectively. At 12 months postoperatively, the mean PTA, mean SRT, mean SDS and mean CAP score was 31.87 dB HL, 34.45 dB HL, 62.24% and 3.97 points, respectively.

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

Quality of life outcomes

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

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

For HUI3, the mean score for hearing (range, 0–6; lower is better) and speech domain (range, 0–5; lower is better) significantly improved at 12 months compared with the postoperative first month (MD for hearing score, 0.96 points; 95% CI 0.30 to 1.61; $p=0.006$; MD for

speech score, 0.44 points; 95% CI 0.04 to 0.84; $p=0.031$). However, there were no statistically significant differences in the other domains ($p>0.05$) (table 3).

Factors contributing to the success

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

Complications

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

DISCUSSION

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

Several studies have found that speech perception and disease-specific quality of life scores were significantly improved in adults.^{6 26} A recent systematic review of 18 articles, including a total of 1093 records of older adults who underwent cochlear implantation, found that an improvement in disease-specific quality of life was generally reported. However, the generic quality of life questionnaires assessing general health status were ambiguous. The author concluded that there is a need for a standardised quality of life assessment tool for patients with cochlear implantation.²⁷

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

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

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

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

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

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

This study had limitations owing to the nature of the cohort study. Approximately 10% of data were missing for most variables. This study was designed to follow up patients for 5 years. However, the number of patients reporting for follow-up after 1 year declined sharply. Therefore, we limited the analysis of outcomes to 1 year after cochlear implantation.

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

CONCLUSION

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

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Contributors PP conceptualised, designed and supervised the study, performed data analysis, interpreted the results, drafted the manuscript, and responsible for the overall content as guarantor. NT, SKI, SKa, KT, VA, PT, CW, TM and PI contributed

to data collection. KY contributed to the study design, data collection, supervision of the study, and responsible for the overall content as guarantor. All authors contributed to the interpretation and discussion of the results and read and approved the final manuscript.

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